

The negative impacts of Covid vaccine mandates in the United States

I have published, as the lead author, two widely read academic papers on Covid vaccine mandates, and have several more in the analysis phase. The 2 published papers are submitted as part of my testimony today, and I urge members to read them.

1. The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good, published in *BMJ Global Health*. (See: https://gh.bmj.com/content/7/5/e008684?fbclid=IwAR2VI1IPUozvc_bEAiR1uAtGDR0L_3JVeQB9-LIgMX0kpe4TsuulnAuP48).
2. COVID-19 vaccine boosters for young adults: a risk benefit assessment and ethical analysis of mandate policies at universities. *Journal of medical ethics*. (See: <https://jme.bmj.com/content/early/2022/12/05/jme-2022-108449.abstract>).

In the first paper, written in late 2021, I and a group of scholars from Johns Hopkins, Oxford, Harvard and elsewhere outlined a set of 12 reasons why the coercive approach to Covid vaccination policy would ultimately be both counterproductive and damaging to public health and society. We based these ideas on the existing literature at the time, with nearly 150 citations.

We divided these 12 reasons into 4 categories:

1. **Behavioural psychology:** reactance and entrenchment; cognitive dissonance; stigma and scapegoating; distrust and conspiracy theories.
2. **Politics and law:** erosion of civil liberties; social polarization, global governance.
3. **Socio-economics:** disparities and inequalities; reduced health system capacity; exclusion from work and social life.
4. **The integrity of science and public health:** erosion of key principles of public health ethics; and the erosion of trust in regulatory vaccine oversight.

I would like to quote directly from our abstract:

“Our analysis strongly suggests that mandatory COVID-19 vaccine policies have had damaging effects on public trust, vaccine confidence, political polarization, human rights, inequities and social wellbeing. We question the effectiveness and consequences of coercive vaccination policy in pandemic response and urge the public health community and policymakers to return to non-discriminatory, trust-based public health approaches.”

We started the result section of this paper with the following statement:

“Although studies suggest that current policies are likely to increase population-level vaccination rates to some degree, gains were largest in those under 30 years old (a very low-risk group) and in countries with below average uptake.”

The totality of actual data on increases in vaccination uptake from mandates and passports does not suggest an overwhelming positive impact. For example, a recent study found that indoor vaccine passports had no significant impact on COVID-19 vaccine uptake, cases, or deaths across all nine US cities that implemented the policy (See: <https://www.mercatus.org/research/working-papers/indoor-vaccine-mandates-and-covid-19>).

The second paper focused on booster mandates at American universities. Let me digress for a moment. We received a lot of emails from people after this first paper, including concerned students and parents. At first, I was reluctant to write this second paper on boosters (this work was conducted voluntarily; it was all free time) and was skeptical of our findings, based on publically available data from CDC and Pfizer. I thought, “Surely the CDC and other professional bodies have crunched the numbers. The adults are in the room.” But we have seen the stifling of debate in our institutions of higher education, a lack of transparency and a worrying groupthink in the liberal class. This has been alarming to witness first-hand.

It was surprising to see just how widespread vaccine mandates were at universities in North America. This was not the case in Europe, where the vast majority did not have mandates.


In our paper, we combined empirical risk-benefit assessment and ethical analysis.

- We estimated that to prevent one COVID-19 hospitalisation over a 6-month period, between 31,000–42,000 young adults aged 18–29 years would have to receive a third mRNA vaccine.
- But this would mean that for each hospitalization prevented with these booster mandates, at least 18.5 serious adverse events from mRNA vaccines would occur, including 1-5 booster-associated myopericarditis cases in males (typically requiring hospitalisation).
- Our ethical analysis argued that university booster mandates are unethical because:
 1. Are not based on an updated (Omicron era) stratified risk-benefit assessment for this age group;
 2. May result in a net harm to healthy young adults;
 3. Are not proportionate: expected harms do not outweigh their public health benefits given modest and transient effectiveness of vaccines against transmission;
 4. Violate the reciprocity principle because serious vaccine-related harms are not reliably compensated due to gaps in vaccine injury schemes; and
 5. May result in wider social harms, such as losing educational opportunities for those who do not comply.

Let me finish with my own personal opinion.

May I remind everyone here about the higher law, inspired by God, on which this country defines liberty. We consider a deprivation of bodily autonomy to be fundamentally humiliating and associated with a form of mental and physical enslavement. Inherent to human nature is the desire to have self-determination over ones own body and mind. Notice that many American chose to suffer the deprivations of losing their material income rather than be subject to the humiliations of forced medical treatments that would have denied their own medical privacy, physical agency and psychological freedom. The shock and dismay citizens of this country have expressed over these coercive mandate measures makes the situation clear for anyone willing to pay attention- that they are an affront to the God given order of freedom on which American liberty is founded. Never mind that they are scientifically inconsistent and illogical- the mandates are an insult to our American foundation of freedom and I hope we never are reduced to such humiliations again in the future- or we risk demoralizing an already demoralized people further. Thank you.

The unintended consequences of COVID-19 vaccine policy: why mandates, passports and restrictions may cause more harm than good

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ABSTRACT

Vaccination policies have shifted dramatically during COVID-19 with the rapid emergence of population-wide vaccine mandates, domestic vaccine passports and differential restrictions based on vaccination status. While these policies have prompted ethical, scientific, practical, legal and political debate, there has been limited evaluation of their potential unintended consequences. Here, we outline a comprehensive set of hypotheses for why these policies may ultimately be counterproductive and harmful. Our framework considers four domains: (1) behavioural psychology, (2) politics and law, (3) socioeconomics, and (4) the integrity of science and public health. While current vaccines appear to have had a significant impact on decreasing COVID-19-related morbidity and mortality burdens, we argue that current mandatory vaccine policies are scientifically questionable and are likely to cause more societal harm than good. Restricting people's access to work, education, public transport and social life based on COVID-19 vaccination status impinges on human rights, promotes stigma and social polarisation, and adversely affects health and well-being. Current policies may lead to a widening of health and economic inequalities, detrimental long-term impacts on trust in government and scientific institutions, and reduce the uptake of future public health measures, including COVID-19 vaccines as well as routine immunisations. Mandating vaccination is one of the most powerful interventions in public health and should be used sparingly and carefully to uphold ethical norms and trust in institutions. We argue that current COVID-19 vaccine policies should be re-evaluated in light of the negative consequences that we outline. Leveraging empowering strategies based on trust and public consultation, and improving healthcare services and infrastructure, represent a more sustainable approach to optimising COVID-19 vaccination programmes and, more broadly, the health and well-being of the public.

INTRODUCTION

Since 2021, mandatory proof-of-vaccination policies have been implemented and justified by governments and the scientific community

SUMMARY BOX

- ⇒ Mandatory COVID-19 vaccine policies have been used around the world during the COVID-19 pandemic to increase vaccination rates. But these policies have provoked considerable social and political resistance, suggesting that they have unintended harmful consequences and may not be ethical, scientifically justified, and effective.
- ⇒ We outline a comprehensive set of hypotheses for why current COVID-19 vaccine policies may prove to be both counterproductive and damaging to public health. Our framework synthesizes insights from behavioural psychology (reactance, cognitive dissonance, stigma, and distrust), politics and law (effects on civil liberties, polarization, and global governance), socio-economics (effects on inequality, health system capacity and social wellbeing) and the integrity of science and public health (the erosion of public health ethics and regulatory oversight).
- ⇒ Our analysis strongly suggests that mandatory COVID-19 vaccine policies have had damaging effects on public trust, vaccine confidence, political polarization, human rights, inequities and social wellbeing. We question the effectiveness and consequences of coercive vaccination policy in pandemic response and urge the public health community and policymakers to return to non-discriminatory, trust-based public health approaches.

to control COVID-19. These policies, initiated across the political spectrum, including in most liberal democracies, have spread globally and have involved: workplace mandates (eg, a 'no jab, no job' US federal mandate); green passes/vaccine passports that limit access to social activities and travel (eg, Israel, Australia, Canada, New Zealand and most European countries); school-based mandates (eg, most North American universities); differential lockdowns for the unvaccinated (eg, Austria and Australia); the use of vaccine



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Table 1 The global turn towards mandatory COVID-19 proof-of-vaccination policies*

Policy/intervention	Countries
'No jab, no job' mandates (eg, government employees, key workers, public and private sector)	Australia, Canada, China, Costa Rica, Croatia, Czech Republic, Denmark, Egypt, Fiji, France, Ghana, Hungary, Italy, Kazakhstan, Latvia, Lebanon, New Zealand, Oman, Poland, Philippines, Russia, Saudi Arabia, Tunisia, Turkey, Ukraine, USA
Healthcare worker mandates	Australia, Britain, Canada, Croatia, Czech Republic, England, Finland, France, Germany, Greece, Hungary, Lebanon, New Zealand, Poland, USA (some states)
Internal vaccine passports to attend social events, restaurants, bars, nightclubs, fitness facilities, entertainment venues and for bus/train/airport travel	Australia, Austria, Britain, Bulgaria, Canada, Czech Republic, Denmark, Egypt, France, Germany, Italy, Israel, Kenya, Lebanon, Morocco, Netherlands, Romania, Serbia, Singapore, Switzerland, South Korea, Ukraine, USA (some states)
School-based mandates	Canada (several provinces), Costa Rica, Lithuania and USA (some states)
Full country mandatory vaccination	Austria, Ecuador, Germany, Indonesia, Micronesia, Turkmenistan, Tajikistan
Full population mandate for the elderly	Czech Republic, Greece, Malaysia, Russia

*This is not a comprehensive list of policies, which are rapidly changing in early 2022. This list excludes the use of segregated lockdowns of the unvaccinated (eg, Austria, Germany, Australia), entry requirements for international travel, fines and penalties (including restricted access to social services and medical care, business capacity restrictions and threats of imprisonment) and the use of vaccine metrics to inform other restrictions. There is a significant variation in how countries recognise infection-derived immunity, allow religious, philosophical and/or medical exemptions and incorporate testing as an alternative to vaccination. In addition, some countries have implemented a combination of policies and interventions, so each is not mutually exclusive. As of March 2022, some countries also shifted course and decided to not implement these policies due to changing epidemiological circumstances and sociopolitical resistance. Adapted from Reuters.¹³⁶

metrics in lifting lockdowns and other restrictions (eg, Australia, Canada and New Zealand); differential access to medical insurance and healthcare (eg, Singapore); and mandatory population-wide vaccination with taxes, fines, and imprisonment for the unvaccinated (eg, the Philippines, Austria, Greece) (see [table 1](#)).

The publicly communicated rationale for implementing such policies has shifted over time. Early messaging around COVID-19 vaccination as a public health response measure focused on protecting the most vulnerable. This quickly shifted to vaccination thresholds to reach herd immunity and 'end the pandemic' and 'get back to normal' once sufficient vaccine supply was available.^{1 2} In late summer of 2021, this pivoted again to a universal vaccination recommendation to reduce hospital/intensive care unit (ICU) burden in Europe and North America, to address the 'pandemic of the unvaccinated'.

COVID-19 vaccines have represented a critical intervention during the pandemic given consistent data of vaccine effectiveness averting COVID-19-related morbidity and mortality.³⁻⁶ However, the scientific rationale for blanket mandatory vaccine policies has been increasingly challenged due to waning sterilising immunity and emerging variants of concern.⁷ A growing body of evidence shows significant waning effectiveness against infection (and transmission) at 12-16 weeks, with both Delta and Omicron variants,⁸⁻¹³ including with third-dose shots.^{14 15} Since early reports of post-vaccination transmission in mid-2021, it has become clear that vaccinated and unvaccinated individuals, once infected, transmit to

others at similar rates.¹⁶ Vaccine effectiveness may also be lower in younger age groups.¹⁷ While higher rates of hospitalisation and COVID-19-associated morbidity and mortality can indeed be observed among the unvaccinated across all age groups,³⁻⁶ broad-stroke passport and mandate policies do not seem to recognise the extreme risk differential across populations (benefits are greatest in older adults), are often justified on the basis of reducing transmission and, in many countries, ignore the protective role of prior infection.^{18 19}

Mandate and passport policies have provoked community and political resistance including energetic mass street protests.^{20 21} Much of the media and civil debates in liberal democracies have framed this as a consequence of 'anti-science' and 'right-wing' forces, repeating simplistic narratives about complex public perceptions and responses. While vaccine mandates for other diseases exist in some settings (eg, schools, travel (eg, yellow fever) and, in some instances, for healthcare workers (HCWs)),²² population-wide adult mandates, passports, and segregated restrictions are unprecedented and have never before been implemented on this scale. These vaccine policies have largely been framed as offering 'benefits' (freedoms) for those with a full COVID-19 vaccination series,^{23 24} but a sizeable proportion of people view conditioning access to health, work, travel and social activities on COVID-19 vaccination status as inherently punitive, discriminatory and coercive.^{20 21 25-28} There are also worrying signs that current vaccine policies, rather than being science-based, are being driven by sociopolitical attitudes that reinforce segregation, stigmatisation

Potential Unintended Consequences of COVID-19 vaccine policies

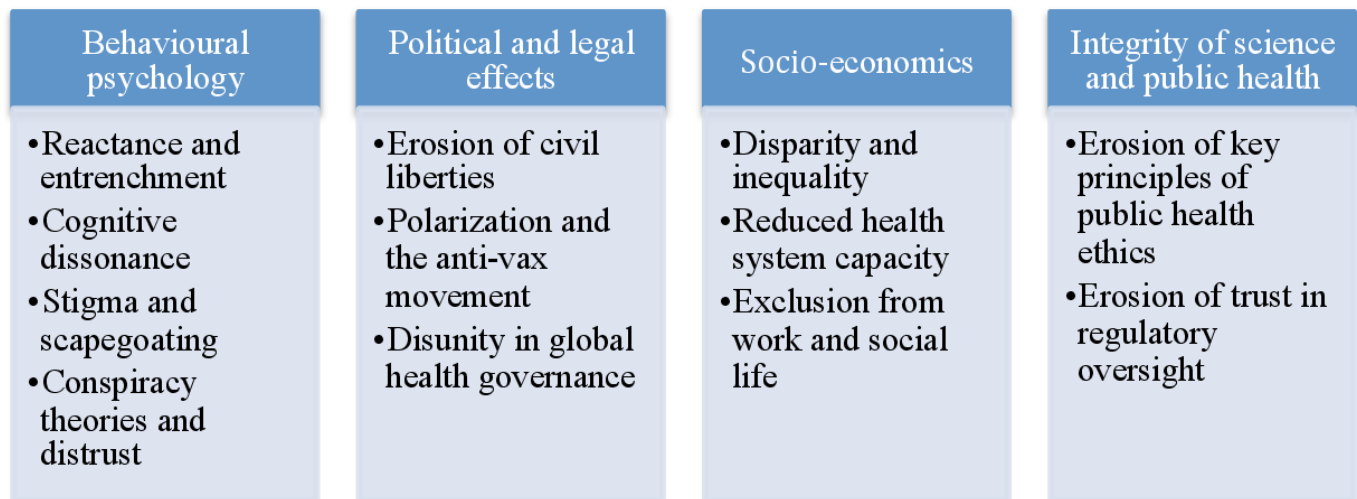


Figure 1 Conceptual framework. We consider a broad conceptual framework spanning core aspects of behavioral psychology, politics and the law, the socio-demographic drivers of health inequality and the integrity of science and public health.

and polarisation, further eroding the social contract in many countries. Evaluating the potential societal harms of COVID-19 pandemic restrictions is essential to ensuring that public health and pandemic policy is effective, proportionate, equitable and legally justified.^{29 30} The complexity of public responses to these new vaccine policies, implemented within the unique sociopolitical context of the pandemic, demands assessment.

In this paper, we reflect on current COVID-19 vaccine policies and outline a comprehensive set of hypotheses for why they may have far-reaching unintended consequences that prove to be both counterproductive and damaging to public health, especially within some sociodemographic groups. Our framework considers four domains: (1) behavioural psychology, (2) politics and law, (3) socioeconomic, and (4) the integrity of science and public health (see [figure 1](#)). Our aim is not to provide a comprehensive overview or to fully recapitulate the broad ethical and legal arguments against (or for) COVID-19 vaccine mandates and passports. These have been comprehensively discussed by others.^{31–33} A full review of the contribution of mandates and passports to COVID-19 morbidity and mortality reductions is not yet possible, although some existing studies on vaccine uptake are cited below. Rather, our aim is to add to these existing arguments by outlining an interdisciplinary social science framework for how researchers, policy-makers, civil society groups and public health authorities can approach the issue of unintended social harm from these policies, including on public trust, vaccine confidence, political polarisation, human rights, inequities and social well-being. We believe this perspective is urgently needed to inform current and future pandemic policies. Mandatory population-wide vaccine policies have become a normative part of pandemic governance

and biosecurity response in many countries. We question whether this has come at the expense of local community and risk group adaptations based on deliberative democratic engagement and non-discriminatory, trust-based public health approaches.

WHAT CAN WE LEARN FROM THE BEHAVIOURAL SCIENCES?

Reactance, entrenchment and vaccine uptake

Apart from mandatory vaccination of the elderly (planned in Czech Republic, Greece, Malaysia and Russia), most policies do not specify individuals at higher risk of severe COVID-19 outcomes—among whom COVID-19 vaccine uptake rates, and vaccine confidence, are very high.^{34 35}

Although studies suggest that current policies are likely to increase population-level vaccination rates to some degree,^{36–39} gains were largest in those under 30 years old (a very low-risk group) and in countries with below average uptake.³⁶ Moreover, insights from behavioural psychology suggest that these policies are likely to entrench distrust and provoke *reactance*—a motivation to counter an unreasonable threat to one’s freedom. Literature reviewed by Drury *et al*,⁴⁰ including a survey by Porat *et al*⁴¹ in the UK and Israel, found that compulsory COVID-19 vaccination would likely increase levels of anger, especially in those who are already mistrustful of authorities, and do little to persuade the already reluctant. Two experiments in Germany and the USA found that a new COVID-19 vaccine mandate would likely energise anti-vaccination activism, reduce compliance with other public health measures, and decrease acceptance to future voluntary influenza or varicella (chickenpox) vaccines.^{42 43} A third experiment found that selective mandates increased reactance when herd immunity targets were not clearly explained⁴⁴—which

most governments failed to communicate adequately and convincingly as they shifted their rationale from herd immunity to hospital/ICU admission metrics. De Figueiredo *et al*⁴⁵ found that vaccine passports in the UK would induce a net *decrease* in inclination to get vaccinated among those who had not received a full vaccination dose, while Bell *et al*⁴⁶ found that UK HCWs who felt pressured to get vaccinated were more likely to have declined the COVID-19 vaccine. Jørgensen *et al*⁴⁷ found that the reintroduction of vaccine passports in late 2021 in Denmark increased distrust among the unvaccinated. Finally, recent evidence from France suggests that the *passé sanitaire* was associated with increased vaccination but that it did so to a lower extent among the most vulnerable, may have contributed to increased nocebo effects and did not reduce vaccine hesitancy itself; the authors concluded: “Mandatory vaccination for COVID-19 runs the risk of politicising vaccination further and reinforcing distrust of vaccines.”⁴⁸

Cognitive dissonance

The public interpretation of these policies has occurred within the context of the rapidly changing pandemic. Oftentimes, public announcements and media coverage have oversimplified, struggled to communicate potential adverse events (including a potentially higher risk in the convalescent)⁴⁹ and overstated vaccine efficacy on transmission. Significant public concerns about safety signals and pharmacovigilance have been furthered by the lack of full transparency in COVID-19 clinical trial data^{50 51} as well as shifting data on adverse effects, such as blood-clotting events,⁵² myocarditis⁵³ and altered menstrual periods.⁵⁴ These changes have been associated with changes to vaccination guidelines in terms of eligibility for different vaccines in some countries. Mandates, passports and segregated restrictions create an environment where reactance effects are enhanced because people with low vaccine confidence see contradictory information as validating their suspicions and concerns. The pressure to vaccinate and the consequences of refusal heighten people’s scrutiny of information and demand for clarity and transparency. Current policies have likely facilitated various layers of *cognitive dissonance*—a psychological stress precipitated by the perception of contradictory information.

Citing the potential for backlash and resistance, in December 2020, the director of the WHO’s immunisation department stated: “I don’t think we envision any countries creating a mandate for [COVID-19] vaccination.”⁵⁵ Many governments originally followed with similar public statements, only to shift positions, often suddenly, in mid or late 2021 during the Delta or Omicron surge, including in Austria (the first country to announce a full population-wide mandate).^{56 57} Cognitive dissonance may have been compounded by the changing rationale provided for vaccine mandate policies, which originally focused on achieving herd immunity to stop viral transmission and included public messaging that vaccinated

people could not get or spread COVID-19. Policies often lacked clear communication, justification and transparency, contributing to persistent ambiguities and public concerns about their rationale and proportionality.⁵⁸ In late 2021, however, the re-introduction of onerous non-pharmaceutical interventions in countries with mandates and passports perpetuated cognitive dissonance, since governments had made promises that vaccination would ensure a ‘return to normal’ and many people (especially younger people) had vaccinated based on these announcements.^{36 48}

When mandate rules are perceived to lack a strong scientific basis, the likelihood for public scrutiny and long-term damage to trust in scientific institutions and regulatory bodies is much higher. A good example is the lack of recognition of infection-derived immunity in employer-based vaccine mandates and passports in North America, including most universities and colleges.⁵⁹ Despite clear evidence that infection-derived immunity provides significant protection from severe disease on par with vaccination,^{18 31} prior infection status has consistently been underplayed. Many individuals with post-infection immunity have been suspended or fired from their jobs (or pushed to leave) or been unable to travel or participate in society^{31 56–59} while transmission continued among vaccinated individuals in the workplace. This inconsistency was widely covered in American conservative and libertarian-leaning media in ways that reinforced distrust not only about the scientific basis of vaccine policies but also the entire public health establishment, including the US Centers for Disease Control and Prevention (CDC).

Stigma as a public health strategy

Since 2021, public and political discourse has normalised stigma against people who remain unvaccinated, often woven into the tone and framing of media articles.⁶⁰ Political leaders singled out the unvaccinated, blaming them for: the continuation of the pandemic; stress on hospital capacity; the emergence of new variants; driving transmission to vaccinated individuals; and the necessity of ongoing lockdowns, masks, school closures and other restrictive measures (see [table 2](#)). Political rhetoric descended into moralising, scapegoating, and blaming using pejorative terms and actively promoting stigma and discrimination as tools to increase vaccination. This became socially acceptable among pro-vaccine groups, the media and the public at large, who viewed full vaccination as a moral obligation and part of the social contract.⁶¹ The effect, however, has been to further polarise society—physically and psychologically—with limited discussion of specific strategies to increase uptake especially in communities where there would be disproportionately larger individual and societal benefits. There is rarely a discussion of *who* and *why* people remain unvaccinated. Vaccine policy appears to have driven social attitudes towards an us/them dynamic rather than adaptive strategies for different communities and risk groups.

Table 2 Political rhetoric regarding the unvaccinated

Country leader	Statement
Emmanuel Macron, PM of France	"[It is] only a very small minority who are resisting. How do we reduce that minority? We reduce it by pissing them off even more...When my freedoms threaten those of others, I become someone irresponsible. Someone irresponsible is not a citizen." ¹¹⁷
Justin Trudeau, PM of Canada	"When people are seeing cancer treatments and elective surgeries put off because beds are filled with people who chose not to get vaccinated, they're frustrated...When people see that we are in lockdowns or serious public health restrictions right now because of the risk posed to all of us by unvaccinated people, people get angry." "They are extremists who don't believe in science, they're often misogynists, also often racists...It's a small group that muscles in, and we have to make a choice, as a leader and as a country: Do we tolerate these people?" ¹³⁷
Joe Biden, President of the USA	"This is a pandemic of the unvaccinated. And it's caused by the fact that despite America having an unprecedented and successful vaccination program, despite the fact that for almost five months free vaccines have been available in 80 000 different locations, we still have nearly 80 million Americans who have failed to get the shot." ¹³⁸ "For the unvaccinated, you're looking at a winter of severe illness and death for yourselves, your families, and the hospitals you may soon overwhelm." ¹³⁹
Naftali Bennett, PM of Israel	"Dear citizens, those who refuse vaccines are endangering their health, those around them and the freedom of every Israeli citizen. They are endangering our freedom to work, the freedom of our children to learn and the freedom to hold celebrations with the family. Those who refuse vaccines hurt us all because if all of us were vaccinated, we would all be able to maintain daily life. But if one million Israelis continue to not get vaccinated, this will oblige the eight million others to shut themselves in their homes." ¹⁴⁰
Michael Gunner, Northern Territories Chief Minister, Australia	"If you are anti-mandate, you are absolutely anti-vax, I don't care what your personal vaccination status is. If you support, champion, give a green light, give comfort to [or] support anybody who argues against the vaccine, you are an anti-vaxxer, absolutely. Your personal vaccination status is not relevant. If you campaign against the mandate...If you say 'pro-persuasion', stuff it, shove it. You are anti-vax." ¹⁴¹
Jacinda Ardern, PM of New Zealand,	"If you are still unvaccinated, not only will you be more at risk of catching COVID-19, but many of the freedoms others enjoy will be out of reach.... we have managed very high vaccination rates, generally, without the use of certificates but what has become clear to me is that they are not only a tool to drive up vaccines; they are a tool for confidence. People who are vaccinated will want to know that they are around other vaccinated people...it is a tool for business." ¹⁴²
Tony Blair, former UK PM	"We need to target the unvaccinated. Frankly if you are unvaccinated at the moment and you're eligible and have no health reason for being unvaccinated, you're not only irresponsible but you're an idiot. I am sorry but truthfully you are. With this Omicron variant...you will get it and this will put a lot of strain on the health service." ¹⁴³
Rodrigo Duterte, President of the Philippines	"I'm now giving orders to village leaders to look for those persons who are not vaccinated and request them to stay put [in their house]...If they refuse to vaccinate, or continue to leave their home, the village leaders are empowered to arrest them...." ¹⁴⁴
PM, Prime Minister.	

Leveraging stigma as a public health strategy, regardless of whether or not individuals are opposed to vaccines, is likely to be ineffective at promoting vaccine uptake.⁶² Unvaccinated or partially vaccinated individuals often have concerns that are based in some form of evidence (eg, prior COVID-19 infection, data on age-based risk, historical/current trust issues with public health and governments, including structural racism), personal experiences (eg, direct or indirect experience of adverse drug reactions or iatrogenic injuries, unrelated trauma, issues with access to care to address adverse events, etc) and concerns about the democratic process (eg, belief that governments have abused their power by invoking a constant state of emergency, eschewing public consultation and over-relying

on pharmaceutical company-produced data) that may prevent or delay vaccination.^{45 46 63-66} Inflammatory rhetoric runs against the pre-pandemic societal consensus that health behaviours (including those linked to known risk factors for severe COVID-19, for example, smoking and obesity) do not impact the way medical, cultural or legal institutions treat individuals seeking care. Some governments discussed or imposed medical insurance fines or premiums on the unvaccinated, while hospital administrators considered using vaccination status as a triage protocol criterion. The American Medical Association released a statement decrying the refusal to treat unvaccinated patients⁶⁷ but this has not prevented the ongoing narrative of shaming and scapegoating people choosing not to get vaccinated.

Trust, power and conspiracy theories

Trust is one of the most important predictors of vaccine acceptance globally,^{68 69} including confidence in COVID-19 vaccines.^{63 70 71} Data show that being transparent about negative vaccine information increases trust and Petersen *et al*⁷² found that when health authorities are not transparent, it can increase receptivity to alternate explanations.

COVID-19 vaccine policies have the potential to erode vaccine confidence, trust and the social contract in the particular context of the pandemic, which has exacerbated social anxieties, frustrations, anger and uncertainty. By the time COVID-19 vaccine mandates were introduced, many communities had struggled under lockdowns and other severe public health restrictions, undergone a succession of pandemic waves with changing rules that stretched public confidence in government, had their economic security and livelihoods negatively impacted and been exposed to a media-induced culture of fear perpetuated by an abundance of conflicting and confusing information. All of this occurred within the broader global trend of increasing inequities between North and South, rich and poor, as well as the erosion of trust in institutions and experts.

It is likely that many of the alternative explanations of the pandemic, often called conspiracy theories, were further entrenched when vaccine policies were forcefully implemented in 2021, creating a strong confirmation bias that governments and corporate powers were acting in an authoritarian manner. Those who resist vaccine mandates and passports are more likely to have low trust in government and scientific institutions,^{25–28 63 64} and these beliefs and distrust have likely grown due to the propensity of policies to justify social segregation, creating new forms of activism. Furthermore, multiple social perceptions and logics about science, technology and corporate and government power have been grafted onto the public discussion about COVID-19 vaccines, specifically related to authoritarian biosurveillance capabilities.⁷³ These include concerns about the adoption of implantable tracking devices (including microchips), digital IDs, the rise of social credit systems and the censorship of online information by technology companies and state security agencies. The COVID-19 pandemic happens to coincide with far-reaching technological advances that do provide the capability for new forms of mass state surveillance.^{74 75} For example, emerging biocompatible intradermal devices can be used to hold vaccine records,⁷⁶ while multifunction implantable microchips (that can regulate building access and financial payments, much like cellphones) are now available on the market.⁷⁷ Aspects of vaccine passport policies (dependent on QR codes) combined with these innovations—as well as censorship by social media companies of vaccine clinical trial and safety issues from reputable sources like the BMJ⁷⁸—have likely reinforced and exacerbated suspicion and distrust about the impartiality of public health guidance and vaccines.⁷⁹ It is highly likely

that reactance effects generated by current vaccine policies have increased the view that public health is influenced by powerful sociopolitical forces acting in the private interest, which may damage future social trust in pandemic response.

THE POLITICAL AND LEGAL EFFECTS OF VACCINE MANDATES, PASSPORTS AND RESTRICTIONS

The erosion of civil liberties

The COVID-19 vaccine policies that we have outlined represent a broad interference with the rights of unvaccinated people. While some governments introduced mandates and passports through the democratic process (eg, Switzerland, Austria, France), many policies were imposed as *regulations, decrees, orders* or *directions* under states of emergency and implemented in ways that allowed ad hoc juridical decisions and irregular and over-permissive private sector rules, with limited accountability or legal recourse to address rights violations.⁵⁸

Vaccine passports risk enshrining discrimination based on *perceived* health status into law, undermining many rights of healthy individuals: indeed, unvaccinated but previously infected people may generally be at *less* risk of infection (and severe outcomes) than doubly vaccinated but infection-naïve individuals.⁸⁰ A weekly negative SARS-CoV-2 test is often seen as a compromise in lieu of full vaccination status, but this places additional burdens (including financial) on the unvaccinated while also risking reputational damage. Employer-imposed mandates that do not provide reasonable accommodation (eg, testing, relocation or reassignment of duties) or that require people to be vaccinated following prior infection even where employees can work remotely, arguably constitute a disproportionate imposition of a health intervention without workplace-related justification.⁸¹ Many countries have also tightened the ability to seek religious, medical or philosophical exemptions, open to unclear decision-making and political interference.⁸² Perhaps the most high-profile case to date involves the deportation of the top-ranked men's tennis player, Novak Djokovic, at the Australian Open 2022, despite having been granted a medical exemption on the basis of documented prior infection.⁸³ While media outlets were quick at hinting about problems in his official submission, the Minister of Immigration accepted that he had a valid test result and that he posed only a 'very low' risk to the health of Australians.⁸⁴ Yet, the court ruled that it was reasonable for the Minister to conclude that Mr Djokovic's presence could 'foster anti-vaccination sentiment' and thus have a negative impact on vaccination and boosters.⁸⁴ It endorsed Mr Djokovic characterisation as a threat to Australian 'civil order and public health'.^{83 84} The case underlines concerns of vaccine mandates and passports as a tool for disproportionate policy that circumvents normative civil liberties and process.

There are also significant privacy issues with passports, which involve sharing medical information with strangers.

Having set these population-wide passport precedents, it is conceivable that they could be expanded in the near future to include other personal health data including genetic tests and mental health records, which would create additional rights violations and discrimination based on biological status for employers, law enforcement, insurance companies, governments and tech companies. COVID-19 vaccine passports have normalised the use of QR codes as a regulated entry requirement into social life; in France and Israel, double-vaccinated citizens lost their ‘status’ when passports required a booster dose in 2021/2022.^{85 86} Technology companies interested in biosurveillance using artificial intelligence and facial recognition technology have obtained large contracts to implement vaccine passports and now have a financial interest in maintaining and expanding them.⁸⁷

Political polarisation

COVID-19 vaccine policies have generated intense political debate, mass street protests and energised new populist movements with varied political views.^{20 21 25–28 56} Studies show that while many support these policies, others view them as inherently coercive, discriminatory, disproportionate and counter to liberal values of bodily autonomy, freedom of choice and informed consent.^{25–28} It is clear that current policies are divisive and unpopular with many, even vaccinated people, and that they have become a source for collective rage and anger, notably for those who have been fired from their jobs or isolated and barred from social life.

COVID-19 vaccine policies may influence upcoming elections. For instance, right-wing and populist parties in Germany (the Alternative for Germany), Canada (People’s Party) and Austria (Freedom Party) have come out strongly against medical segregation. After implementing the world’s first population-wide mandatory vaccine policy in February 2022, Austria suspended it 6 days before police would impose fines (max €3600), partially due to legal concerns, mass street protests and the fact that the rate of vaccination had not significantly improved (20% of adults remain unvaccinated).^{56 88} In 2022, the US Supreme Court struck down the Biden administration’s federal vaccine mandate as unconstitutional,⁸⁹ just as it came into effect for 80 million workers (although upholding the mandate for HCWs); republicans had long criticised the mandates.^{90 91} In Martinique and Guadelupe, vaccine passports have led to months of political unrest and violent protests that threaten the stability of the French government.⁴⁸ Pottinger⁹² argued that mandates and passports could trigger insurrection and civil war in South Africa.

Just as the smallpox vaccination mandates in 1850s Britain created the first ‘anti-vax’ movement,⁹³ the backlash against COVID-19 policies is energising a global network connected by modern communication technology against these measures. These backlashes may contribute to increased distrust of other vaccines and foster new forms of radicalisation and protest. While

mainstream news outlets have voiced concern about the rising ‘anti-vaccination fervour’ among the far-right, and potential for violence,⁹⁴ centre and left politicians have also used this rhetoric for their own agenda. In Canada, Prime Minister Trudeau used majority support for mandatory vaccination and passports to divide the conservative opposition in the 2021 federal election. The end to exemptions for unvaccinated truckers crossing the US–Canadian border precipitated the trucker ‘freedom convoy’ protests in early 2022 in Canada, which led to weeks of protesters occupying streets outside parliament. The protest ended with the unprecedented invoking of the Emergencies Act, equivalent to martial law, which was heavily criticised by civil liberty organisations and included the freezing of protester bank accounts.^{95 96} In the USA, California and New York (Democrat-controlled states) have implemented COVID-19 vaccine passports for children while Florida, Georgia and Texas (Republican-controlled) are introducing legislation to remove childhood school vaccine mandates in general. Some medical freedom and anti-vaccination groups have made increasingly false and inflammatory claims, and business owners and employees requiring QR codes for entry have been targeted for abuse, in some cases. In turn, pro-vaccine advocates have equated anti-mandate social groups as ‘anti-vaxxers’ and even domestic terrorists, calling for government agencies and social media companies to strengthen censorship laws. Echo chambers have skewed the reasonableness of risk assessment of some pro-mandate individuals, who now fear that unvaccinated people are ‘unsafe’—physically but also culturally—despite the scientific evidence. Political polarisation and radicalisation—both anti-mandate and pro-mandate—will increase if punitive vaccine policies continue.

Disunity in global health governance

Current vaccine policies risk furthering disunity in global health governance. Despite the WHO stating in early 2022 that boosters would prolong the pandemic by contributing to vaccine hoarding and low supply,⁹⁷ universities (including some global health departments) in wealthy countries have mandated boosters for low-risk healthy students and faculty,⁵⁹ when vaccination rates remained low in many low/middle-income countries (LMICs).⁹⁸ Efforts to pressure pharmaceutical companies (who developed vaccines with the support of publicly funded research money) to remove patent protections have proven unsuccessful.^{99 100} Pharmaceutical companies have ensured that the costs of adverse effects are borne by governments¹⁰¹; in turn, the world’s tens of millions of migrants and asylum-seekers may be denied COVID-19 vaccines because of legal liability issues.¹⁰² Simultaneously, some scientists are calling the unvaccinated (as a homogeneous group) the source of future variants (‘variant factories’) fuelling inflammatory rhetoric¹⁰³ that may have contributed to the heavily criticised reaction to close international borders to southern Africa during the spread of Omicron in late 2021. International

travellers, especially from the global south, have been barred from travelling to high-income countries based on the type of received vaccine.

The rollout of vaccine passports and mandates is financially costly and diverts resources and focus away from other interventions. In Canada, \$1 billion was pledged by the Trudeau government for vaccine passports¹⁰⁴ and in New York State, the Excelsior Pass App-system developed by IBM will cost more than \$27 million.⁸⁷ Importantly, focus on ‘the unvaccinated’ as the cause of health system collapse diverts public attention away from global equity failures and deep structural challenges facing public health capacity in many countries. It absolves governments of attending to other strategies for opening schools and keeping public spaces safe, including improved ventilation and paid sick leave. The indiscriminate global adoption of current COVID-19 vaccine policies may also compromise national sovereignty by skewing health priorities in LMICs, taking budgets away from other important health priorities and disregarding public opinion—a new form of vaccine colonialism. Perhaps more significantly, it is possible that vaccination metrics become tied to international financial agreements and development loans and that pharmaceutical and technology companies influence the global adoption of passport systems and mandate policies for the current but also future pandemics.

SOCIOECONOMIC IMPACTS

Increasing disparity and inequality

Historically, marginalised groups—those facing economic challenges and racial and minority groups—tend to have less confidence in vaccination programmes and are more likely to be distrustful.^{63–66 68–71} This raises the possibility that current vaccine policies may fuel existing inequity.¹⁰⁵ A rapid policy briefing by the Nuffield Council on Bioethics¹⁰⁶ emphasised that immunity passports could ‘create coercive and stigmatising work environments’ and are ‘more likely to compound than redress...structural disadvantages and...social stigmatisation’.¹⁰⁶ It is highly likely that mandates and passports have been implemented in ways that discriminate against disadvantaged groups including immigrants, the homeless, isolated elderly people, those with mental illness, specific cultural and religious groups, those in precarious living circumstances, and people with certain political views and values. Moreover, communities who have historically been subject to state surveillance, segregation, structural racism, trauma or violence may be more likely to resist medical mandates. In Israel, reports suggest that Bedouin and Palestinian communities in the Occupied Palestinian Territory have faced major barriers to vaccine access, with more distrust of vaccination and bureaucratic barriers to accessing and using green passes even when vaccinated.⁵⁸ Similar challenges have been raised among Europe’s Roma and in black communities in the UK and USA.^{45 66 107} Altogether, rather than enhancing human

agency and strengthening communities and social cohesion, many current vaccine policies—including monthly fines for non-compliance (eg, Greece and Austria)—may work to disempower individuals and contribute to long-term psychosocial stress and disharmony.

Reduced health system capacity

The pandemic has created immense strain on health systems, contributing to disruptions in global immunisation programmes¹⁰⁸ and burnout in healthcare and social care workers that risk worsening clinical outcomes for all patients. These trends may be exaggerated by the current policy push towards mandatory COVID-19 vaccination of healthcare/social care workers and firing of unvaccinated staff. The ethical arguments against these policies have been outlined by others.^{31 33 109}

Despite these considerations, many countries may lose frontline staff due to mandates. By December 2021, despite the forthcoming imposition of a (later rescinded) vaccine mandate for patient-facing National Health Service (NHS) workers, 8% of medical practitioners in the UK (73 000 people) remained unvaccinated.¹¹⁰ In late 2021, Quebec (Canada) dropped its proposed mandate for HCWs, citing the devastating labour shortage it would cause in hospital systems (3% of staff, or 14 000, were unvaccinated).¹¹¹ Both cases created immense stress on already overburdened health staff and administrators, and were decried for their lack of clarity and clumpy policy process.¹¹²

Exclusion from work and social life

COVID-19 vaccination policies that disproportionately restrict people’s access to work, education, public transport and social life can be considered a violation of constitutional and human rights.¹¹³ The economic effects of restricting access to work may also have indirect implications for dependents of the unvaccinated. A survey in October 2021 in the USA found that 37% of unvaccinated participants (5% of participants overall) would leave their job if their employer required them to get a vaccine or get tested weekly; this rose to 70% of unvaccinated participants (9% of all participants) if weekly testing was not an option.¹¹⁴ Economic deprivation and parental stress resulting from restricted access to work and exclusion from social life may have long-term psychological and livelihood consequences on individuals, families and especially children.³⁰ Commentators have also highlighted the potential impact of mandates in creating supply chain bottlenecks in certain commodities and with cross-border trade and argued that changing vaccine rules and regulations threaten to negatively impact overall economic recovery in some sectors of the economy including tourism.¹¹⁵

THE INTEGRITY OF SCIENCE AND PUBLIC HEALTH

Erosion of key principles of public health ethics and law

Current vaccine policies may erode core principles of public health ethics. As some of those supporting

mandates recognise,^{113 116} and contrary to the media portrayal that ‘the unvaccinated are entirely free to decline’, many COVID-19 vaccine policies clearly limit choice and the normal operation of informed consent. This has placed medical professionals in an awkward position, blurring the lines between voluntary and involuntary vaccination. It is clear that many who are vaccinated did so because of the serious consequences of refusal, such as loss of employment and livelihood or access to social events and travel. We should pause to consider the extent to which current policies, and how they are implemented in clinical settings, sets a precedent for the erosion of informed consent into the future and impact the attitude of the medical profession to those who are reticent to undergo a specific medical procedure.

According to public health ethics, the principle of proportionality requires that the benefits of a public health intervention must be expected to *outweigh* the liberty restrictions and associated burdens.³² It would violate the proportionality principle to impose significant liberty restrictions (and/or harms) in exchange for trivial public health benefits, particularly when other options are available. Evidence shows that the efficacy of current COVID-19 vaccines on reducing transmission is limited and temporary,⁷⁻¹⁶ likely lower in younger age groups targeted for vaccine mandates and passports³⁶ and that prior infection provides, roughly speaking, comparable benefit.^{18 31 80} The effectiveness of vaccine mandates in reducing transmission is likely to be smaller than many might have expected or have hoped for, and decrease over time. These issues have been widely discussed in the public arena, raising the idea that many current vaccine policies are no longer being guided by the best science but are rather being used to punish individuals who remain unvaccinated and to shape public opinion and compliance. Some governments have publicly admitted this much; in the words of French President Emmanuel Macron, the aim is to ‘piss off [the unvaccinated] ...to the end. This is the strategy.’¹¹⁷ Mandating a third dose for young boys to attend college or university in America has been widely discussed in the US media despite the lack of evidence for substantial clinical benefit,^{59 118} and with evidence of small but still significant risk of myocarditis that compounds with each dose.¹¹⁹⁻¹²¹ Scandinavian countries have taken a precautionary and voluntary approach in their recommendations to the vaccination of children, with Swedish authorities stating that ‘[because of] a low risk for serious disease for kids, we don’t see any clear benefit with vaccinating them’.¹²² This furthers the perception that current COVID-19 school vaccine mandates (eg, in California) are disproportionate, especially as safety studies in young children remain relatively sparse.¹²³

Proportionality is also a key condition from a constitutional and human rights perspective.^{113 124 125} The formal requirements of legal proportionality tests, which differ slightly depending on jurisdiction and context, generally reflect a balancing similar to the one in public health

ethics. In part because of legally required restraint when it comes to assessing the reasonableness of complex policy interventions, several courts, human rights tribunals and committees, and labour arbitrators have upheld mandates as proportionate or made statements as to their legitimacy.¹¹³ This appears to have led to a broad presumption that mandates are legally unproblematic. But a common requirement of legal proportionality is that no other, less rights-restricting measures are available that can reasonably achieve the key public health goal. Accommodation of the workplace, or alternatives to vaccination such as testing, should be and have often been identified by courts, tribunals and arbitrators, as being a core element of the legality of mandates.^{81 113 124 126} Mandates imposing unconditional vaccination, those ignoring the role of prior infection, and those ignoring a shifting risk/benefit balance depending on specific populations, should be considered suspect from a legal proportionality perspective.

When members of the public perceive mandates to be ethically and legally problematic and in violation of established norms of informed consent and proportionality, this will erode trust in public health and scientific institutions and even courts that endorsed or actively promoted such policies. This presents a challenging paradox for experts and authorities: will pro-mandate scientists and organisations come to acknowledge that mandates and passports were disproportionate policy responses? One key aspect of building trust in science and public health involves the open acknowledgement of when experts are wrong and when policies were misguided; however, it appears that many officials have doubled down in their narratives. This may undermine key ethical and legal criteria for policy and have damaging effects on the integrity of public health itself.

Erosion of trust in regulatory oversight

COVID-19 vaccines were developed in record time to meet an urgent public health need and have been accepted by billions of people, preventing deaths, severe hospitalisation and long-term sequelae from SARS-CoV-2.³⁻⁶ COVID-19 vaccines have also generated at least \$100 billion profit for pharmaceutical companies, especially Pfizer.¹²⁷ Has the acceptance of mandates and passports—and the rhetoric around ‘anti-vaxxers’—contributed to a cultural shift in norms of scientific and corporate transparency and accountability?

Governments have refused to disclose the details of contracts with manufacturers, including for additional doses or ‘next-generation’ vaccines.⁹⁹ Vaccines are typically not approved until 2 years of follow-up data are gathered,² but given the urgency of the COVID-19 pandemic and international harmonisation of new agile regulations, the novel mRNA COVID-19 vaccines were placed into emergency use in Europe and North America in late 2020.¹²⁸ There is concern that, in the fog of crisis, vaccine policy is being driven by vaccine manufacturers rather than independent scientific and regulatory review. For

example, in April 2021, Moderna informed their investors that they were expecting a robust ‘variant booster market’ as a source of profits. Similarly, Pfizer CEO Albert Bourla suggested that a fourth dose of vaccine would be necessary, without any clinical trial data or independent evaluation that the benefits of subsequent doses outweigh any risks, nor consideration of the changing clinical dynamics with the Omicron variant.¹¹⁸ This only adds to distrust over decision-making around vaccine use and ensuing mandates. The public is aware of the history of corporate pharmaceutical malfeasance and criminal and civil settlements in the billions of dollars, including with Pfizer, in part resulting from marketing practices and misrepresentation of safety and efficacy of medicines.^{50 51 129}

The nature of mandates, passports and restrictions has increased public demands for scientific accountability and transparency—shown to be fundamental to building long-term confidence in vaccination.¹³⁰ This has increased the need to diligently track all safety signals for adverse effects in specific demographics¹³¹ and explore trends in overall population mortality and potential non-specific effects.¹³² However, the original clinical trial data remain unavailable for independent scientific scrutiny^{50 51}; a whistleblower raised important concerns about data integrity and regulatory oversight practices at a contract company helping with Pfizer’s clinical trials in the USA.¹³³ After a Freedom of Information Act (FOIA) request by a civil society group (see: <https://phmpt.org>), the US Food and Drug Administration (FDA) requested (ultimately denied by a federal judge) 75 years to fully release internal documents and communications related to the regulatory process between FDA and Pfizer. In September 2021, an FDA advisory committee voted 16–2 against boosting healthy young adults in the USA but was over-riden by the White House and CDC, leading to the resignation of two top FDA vaccine experts.¹¹⁸ Such efforts have only increased the perception that regulatory agencies are ‘captured’ by industry and would conveniently ignore a higher than usual adverse effect ratio to control the pandemic. Concerns have been raised about the lack of due process in vaccine injury compensation claims for the COVID-19 vaccines,¹⁰⁰ which are to be borne by governments and not pharmaceutical companies. A video of a US congressional roundtable on COVID-19 vaccine adverse events with medically confirmed vaccine-injured individuals from the original clinical trials, a US military clinician and Peter Doshi (senior editor of the BMJ) was permanently removed by YouTube.¹³⁴ These practices do not reinforce confidence that authorities are being transparent or applying optimal standards for regulatory safety, efficacy and quality for these novel vaccines—standards which should arguably be more stringent given the legal precedent for mandates and passports.

CONCLUSION

The adoption of new vaccination policies has provoked backlash, resistance and polarisation. It is important to emphasise that these policies are not viewed as ‘incentives’ or ‘nudges’ by substantial proportions of populations^{25–28 41 45} especially in marginalised, underserved or low COVID-19-risk groups. Denying individuals education, livelihoods, medical care or social life unless they get vaccinated—especially in light of the limitations with the current vaccines—is arguably in tension with constitutional and bioethical principles, especially in liberal democracies.^{30–33} While public support consolidated behind these policies in many countries, we should acknowledge that ethical frameworks were designed to ensure that rights and liberties are respected even during public health emergencies.

Vaccination policies can be an important tool in the promotion of the right to health, but they need to be proportionate and designed to achieve a clearly defined goal. Some of those supporting current restrictions based on vaccination status¹¹⁶ seem to accept too easily that these measures are indeed proportionate; that they are not more restrictive than necessary; that they are effective in preventing transmission and protecting the healthcare system from collapse; and that there are no options available other than punitive mandates, passports and segregated restrictions. As illustrated above, we believe that current vaccine policies have failed on these fronts and are no longer fit for purpose.

We encourage social and behavioural scientists, bioethicists, epidemiologists, legal scholars, and others to assess the benefits and harms of COVID-19 vaccination policies, along with wider open multidisciplinary discussion and debate. Empirical assessments may or may not validate the concerns presented in this paper—but their generation is critical in engagement with politicians, scientists, and organisations to reconsider current policies affecting those who remain unvaccinated as well as those who vaccinated due to threats and pressure. COVID-19 will not be the last public health emergency and it remains critical that we understand the reasons these approaches were adopted and provide robust evidence to improve future policymaking in times of health emergencies.¹³⁵ If not, the proclivity for mandates, passports, restrictions, fines and punishments is likely to become an accepted policy response for the next pandemic irrespective of whether such policies are truly effective, ethical and socially harmful.

If current policies are to continue, public health-associated bureaucracies and society will have to increase coercion to address current and future resistance and, in the process, come to leverage strategies more consistent with policing than public health. We may also see political forces double down and use people who have chosen not to get vaccinated as a collective, psychological and political tool to scapegoat and reinforce a false notion of safety among vaccinated people as they yearn to resume social and economic life. Policymakers should

reflect on the necessity of enforcing what is essentially a new two-tier, segregated social system and how this will affect different social groups now and into the future—behaviourally, politically and socioeconomically—as well as the impact of such policies on the integrity of science and public health itself.

There are other options to address the pandemic and it is not too late to return to non-coercive public health measures, including pro-social language and community leadership for vaccination, especially to protect high-risk groups.⁷ Future investments in public health capacity, especially health providers who build relationships of trust working in communities, will be essential to engage in positive reforms. Improving data transparency, media independence and broad public debate and scrutiny about COVID-19 vaccine policies will also be essential to maintain population trust, help people better understand the risks and benefits of the continued use of current vaccines, and to inform research on improvements and future policies.

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COVID-19 vaccine boosters for young adults: a risk benefit assessment and ethical analysis of mandate policies at universities

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ABSTRACT

In 2022, students at North American universities with third-dose COVID-19 vaccine mandates risk disenrolment if unvaccinated. To assess the appropriateness of booster mandates in this age group, we combine empirical risk-benefit assessment and ethical analysis. To prevent one COVID-19 hospitalisation over a 6-month period, we estimate that 31 207–42 836 young adults aged 18–29 years must receive a third mRNA vaccine. Booster mandates in young adults are expected to cause a net harm: per COVID-19 hospitalisation prevented, we anticipate at least 18.5 serious adverse events from mRNA vaccines, including 1.5–4.6 booster-associated myopericarditis cases in males (typically requiring hospitalisation). We also anticipate 1430–4626 cases of grade ≥ 3 reactogenicity interfering with daily activities (although typically not requiring hospitalisation). University booster mandates are unethical because they: (1) are not based on an updated (Omicron era) stratified risk-benefit assessment for this age group; (2) may result in a net harm to healthy young adults; (3) are not proportionate: expected harms are not outweighed by public health benefits given modest and transient effectiveness of vaccines against transmission; (4) violate the reciprocity principle because serious vaccine-related harms are not reliably compensated due to gaps in vaccine injury schemes; and (5) may result in wider social harms. We consider counterarguments including efforts to increase safety on campus but find these are fraught with limitations and little scientific support. Finally, we discuss the policy relevance of our analysis for primary series COVID-19 vaccine mandates.

INTRODUCTION

COVID-19 vaccine booster mandates have been controversial, especially in younger age groups. Two main factors continue to drive scientific controversy: a lack of evidence that booster doses provide a meaningful reduction in hospitalisation risk among healthy adolescents and young adults, and mounting evidence that widespread prior infection confers significant protection against hospitalisation due to (re)infection. Further, mandates have deleterious societal consequences and are eroding trust in scientific and government institutions.¹ In North America, as of May 2022 at least 1000 colleges and university campuses required COVID-19 vaccination, and over 300 required boosters.² More than 50 petitions have been written opposing these vaccine mandates,³ raising specific legal and ethical

complaints.⁴ To our knowledge, few have changed their vaccine guidance for the 2022–2023 academic year and several have mandated the new bivalent booster.

Policymakers, public health scholars and bioethicists have argued both for and against COVID-19 vaccine mandates. The strongest argument made by proponents of vaccine mandates is based on the harm principle: insofar as vaccines prevent transmission and thereby reduce harm to others, restrictions on individual freedom are viewed as more ethically justifiable.⁵ However, a reduction in risk to others (especially if this is a small or temporary effect) might not alone be sufficient to justify a booster mandate in young people. Savulescu⁶ and Giubilini and colleagues⁷ have argued that, to be ethical, vaccine mandates require four conditions: that the disease be a grave public health threat; that there is a safe and effective vaccine; that mandatory vaccination has a superior cost/benefit profile in comparison to other alternatives; and that the level of coercion is proportionate.

Proportionality is a key principle in public health ethics.¹ To be proportionate, a policy must be expected to produce public health benefits that outweigh relevant harms, including harms related to coercion, undue pressure, loss of employment and education and other forms of liberty restriction. Williams⁸ has argued that COVID-19 vaccine mandates may be justified for older but not younger people, among whom such policies are not proportionate given a lack of clarity that benefits outweigh harms. Such ethical assessments should rely on empirical data: thorough risk-benefit assessment requires quantification (where possible) of relevant risks and benefits *for the group affected by the policy*. With respect to poor outcomes due to COVID-19, the most consistent predictors are age⁹ and comorbidities.¹⁰ Similarly, age and sex are prominent risk factors for vaccine-associated reactogenicity¹¹ and serious adverse events (SAE) such as myocarditis, which is more common in young males.¹² Vaccine requirements should therefore be predicated on an age-stratified and sex-stratified risk-benefit analysis and consider the protective effects of prior infection.¹³

In this paper, we integrate a risk-benefit assessment of SARS-CoV-2 boosters for adults under 30 years old with an ethical analysis of mandates at universities. Our estimate suggests an expected net *harm* from boosters in this young adult age



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group, whereby the negative outcomes of all SAEs and hospitalisations may on average outweigh the expected benefits in terms of COVID-19 hospitalisations averted. We also examine the specific harms to males from myo/pericarditis. We then outline a five-part ethical argument empirically assessing booster mandates for young people informed by the quantitative assessment. First, we argue that there has been a lack of transparent risk-benefit assessment; second, that vaccine mandates may result in a net expected harm to individual young adults; third, that vaccine mandates are not proportionate; fourth, that US mandates violate the reciprocity principle because of current gaps in vaccine injury compensation schemes; fifth, that mandates are even less proportionate than the foregoing analyses suggest because current high levels of coercion or pressure may create wider societal harms. We consider possible counter-arguments including potential rationales for mandates based on a desire for social cohesion or safety and summarise why such arguments cannot justify current COVID-19 vaccine mandates. We suggest that general mandates for young people ignore key data, entail wider social harms and/or abuses of power and are arguably undermining rather than contributing to social trust and solidarity.

BACKGROUND

To provide background for our risk-benefit assessment and ethical arguments, we outline recent controversies among experts regarding vaccine boosters and summarise current data on COVID-19 vaccines, specifically: vaccine effectiveness against transmission, effectiveness in those with prior infection and the age-stratified risk of severe COVID-19.

Controversy among experts

Most countries outside of North America have not required or mandated booster doses for young healthy adults at universities,¹⁴ suggesting that, at a minimum, there is a diversity of expert views on whether the expected benefits of such policies outweigh their potential harms. In July 2021, the Centers for Disease Control and Prevention (CDC) released a joint statement with the Food and Drug Administration (FDA)¹⁵ reassuring the public that boosters were not necessary. Just 2 months later, in September 2021, a US FDA advisory committee overwhelmingly voted 16-2 against boosting healthy young adults.¹⁶ Yet, this recommendation was over-ruled by the White House and CDC leading to the resignation of two high-level FDA vaccine experts. These experts wrote in *The Lancet* about the ‘...need to identify specific circumstances in which the direct and indirect benefits of doing so are, on balance, clearly beneficial’.¹⁷ To date, the only risk-benefit assessment made public has narrowly focused on myo/pericarditis in the absence of sufficient safety data from an appropriately powered trial.¹⁸ In fact, the CDC’s own evidence-to-risk framework found no COVID-19 hospitalisation in either booster (three-dose) or placebo (two-dose) groups of the BNT162b2 booster trial.¹⁹

Because the mRNA vaccine third-dose booster trials were too small to measure important clinical endpoints, additional doses have been granted Emergency Use Authorization (EUA) based on observational data suggesting benefits in older populations.¹⁹ Prior to the emergence of the Omicron variant, the US CDC estimated¹⁹ that administering a booster dose to 8738 (BNT162b2) or 11994 (mRNA-1273) 18–29 year-olds would prevent one COVID-19 hospitalisation over 6 months. As of August 2022, this estimate had not been updated to reflect increasing natural immunity or waning vaccine effectiveness.

Data on booster vaccine effectiveness specific to young adults are scarce; reports typically either do not provide stratified data below a certain age (eg, 50 years²⁰) or use younger adults as the baseline to assess effectiveness in older adults (in part because severe disease is already extremely rare in non-boosted young adults).²¹ In a recent CDC publication, which stratified for ages 18–49, a booster dose increased effectiveness against emergency department encounters and hospitalisations among immunocompetent adults during the Omicron wave, but the analysis did not adjust for comorbidities and excluded those with a history of prior infection ‘to reduce the influence of protection from previous infection’.²²

Risk-benefit calculations for the primary series among younger children and adolescents are similarly limited. A cohort study conducted in Hong Kong estimated the number needed to harm (NNH) from myo/pericarditis for dose 2 of BNT162b2 was 2563 among adolescent males,²³ yet there was no US-specific NNH published by the CDC, nor did the agency recommend shifting to a one-dose policy for adolescents as did the UK, Norway, Taiwan and Hong Kong.²³ The CDC first presented a risk-benefit analysis of booster vaccination in September 2021, yet the harms focused strictly on myocarditis versus all SAEs and collapsed age strata with very disparate myocarditis risks.²⁴ Moreover, the CDC’s outdated risk-benefit analysis for adolescents and young adults does not distinguish important subgroups such as or those who have recovered from previous infection or healthy young people (as opposed to those with comorbidities or immunocompromised status).²⁴

Current data regarding COVID-19 vaccines

A thorough ethical evaluation of risks and benefits requires relevant empirical data, especially where risks and benefits can be quantified to a reasonable degree of certainty. Relevant data include those regarding average individual vaccine safety and effectiveness and age stratification of these data as well as the protective effect of prior infection and the effectiveness of vaccines against transmission.

Proponents of mandates have argued that current vaccines prevent transmission, which would support a standard ethical reason in favour of mandates: the protection of others. Yet it is increasingly clear that current vaccines provide, at most, partial and transient protection against infection, which decreases precipitously after a few months,^{25 26} with limited effects on secondary transmission.^{27 28} The CDC states: ‘anyone with Omicron infection, regardless of vaccination status or whether or not they have symptoms, can spread the virus to others.’²⁹ It is therefore inaccurate in 2022 to infer a sustained or long-term reduction in transmission from a short-term reduction in infection.³⁰

A second limitation is ignoring the protective effects of prior infection. In February 2022, the CDC estimated that 63.7% of adults aged 18–49 years had infection-induced SARS-CoV-2 antibodies, up from 30% in September 2021.¹³ By September 2022, the majority of young adults, both vaccinated and unvaccinated, are estimated to have been previously infected with COVID-19. Evidence increasingly shows that prior SARS-CoV-2 infection provides at least similar (and perhaps more durable) clinical protection to current vaccines,^{31–33} which current university policies fail to acknowledge (in addition to more general uncertainties about risks and benefits in relevant age groups³⁴).

Mass vaccination had been proposed as a way to ‘end the pandemic’.³⁵ However, elimination or eradication of the virus is not a tenable goal with vaccines that provide only temporary and incomplete reduction in infection risk, and the presence of

multiple animal reservoirs. Because of this, nearly all human beings will eventually be infected with SARS-CoV-2, as with other endemic coronaviruses (and every pandemic influenza virus on record), many times in their life.³⁶ Denmark has, for example, acknowledged vaccinating children was not effective at curbing spread of the virus and is no longer recommending vaccination against COVID-19 for most children.^{37 38} Taking population immunity into account with variant severity and projected coincident surges of influenza, SARS-CoV-2 and respiratory syncytial virus in the winter of 2022–2023, the UK's Joint Committee on Vaccination and Immunisation (JCVI) currently recommends that high-risk groups be offered a booster.³⁹

A fourth point relates to the burden of COVID-19 in young adults under 40. Using pre-COVID-19-vaccinera mortality data from 190 countries, the adjusted infection fatality ratio for 18–29-year-olds ranged from 100 per million (18 year-olds) to 500 per million (29 year-olds) with significant variation by country within each age stratum.⁴⁰ A recent study from South Africa during the Omicron BA.1–BA.4/5 wave demonstrates that despite a high proportion of breakthrough infections, the risk of hospitalisation remains lowest among young adults.⁴¹

While both vaccination and prior infection can substantially reduce the likelihood of COVID-19 mortality,^{32 33 39} the protection against hospitalisation afforded by a booster wanes rapidly.⁴¹ The study from South Africa demonstrated that protection waned to less than 50% after 3–4 months.⁴¹ Protection against symptomatic disease can be initially restored but wanes approximately 10 weeks after a booster dose⁴²; in the study from England, protection against severe disease could not be measured with the test-negative case-control design due to the few cases of severe disease during Omicron.⁴² Using a national population-wide data set in Qatar, both previous infection alone and vaccination alone were found to provide >70% protection against severe Omicron (BA.1 or BA.2) disease.⁴³ However, the stratified data in Altarawneh, et al. supplemental table S5 show that prior infection alone was 91% effective against severe Omicron disease, whereas protection from two or three doses of vaccine alone was 66% and 83%, respectively.⁴³

Finally, COVID-19 does cause acute illness, and may have long-term effects (Long COVID) for some, particularly those who develop critical illness, but vaccination may not entirely prevent longer term sequelae⁴⁴ and the existing data are non-randomised, from variants that predate Omicron and with unclear relevance for adults under age 40. The existence of effective treatments for clinical management⁴⁵ is also an argument against vaccine mandates, especially for groups not considered at risk for severe illness.

RISK-BENEFIT ASSESSMENT

In a recent editorial, vaccine developer and paediatrician Paul Offit³⁴ argued: ‘because boosters are not risk-free, we need to clarify which groups most benefit.’ⁱ Below, we provide an Omicron-specific risk-benefit assessment of booster vaccination for young adults aged 18–29 years for both Pfizer (BNT162b2) and Moderna (mRNA-1273) vaccines. This analysis builds on a stratified risk-benefit analysis of vaccination among adolescents aged 12–17 years.⁴⁶ For the booster among young adults aged 18–29 years, the calculations use the

CDC's pre-Omicron number needed to vaccinate (NNV),¹⁹ the estimated reduction in severity of Omicron versus Delta⁴⁷ and current estimated seroprevalence.¹³ While harms from COVID-19 vaccines are uncommon,⁴⁸ they should be factored into policy recommendations. This risk-benefit analysis considers the overall rate of reported SAEs (figure 1A) and grade ≥ 3 reactogenicity (figure 1B) and myo/pericarditis among males (figure 1C). Rates and definitions are consolidated in table 1A,B,C.

SAEs⁴⁹ include those that: result in death or are life threatening; result in hospitalisation, prolongation of hospitalisation or significant disability/incapacity; cause a congenital anomaly/birth defect; or cause other medically important events.ⁱⁱ Grade 3 or 4 reactogenicity is defined as local/systemic events that prevent daily routine activities or require use of a pain reliever (grade 3) or resulting in an emergency room visit or hospitalisation (grade 4).^{49 50}

To estimate the expected harms (SAEs including myo/pericarditis and grade ≥ 3 reactogenicity) and benefits (COVID-19 hospitalisations prevented) specific to boosting young adults aged 18–29 years, we used data reported by CDC from phase II/III clinical trials,^{19 50–52} peer-reviewed observational data from large integrated health systems^{53–57} and postmarketing surveillance collected via V-Safe by the CDC.⁵⁸ We compute harms and benefits per single hospitalisation averted as well as per million third doses administered.

Hospitalisations prevented

To estimate the benefits of hospitalisations prevented by boosters, we updated the CDC's estimated NNV¹⁹ for Omicron, which was found to be markedly less virulent than Delta.⁴⁷ We selected Trobajo-Sanmartín *et al* because the analysis provides stepwise comparisons of Omicron BA.1 to Delta (adjusted OR (aOR)=0.28, 95% CI 0.16 to 0.47), as well as the more recent BA.2 to BA.1 (aOR=0.52, 95% CI 0.29 to 0.95). To be conservative, we used the BA.1 versus Delta aOR rather than attempting to estimate the combined BA.2 versus Delta risk reduction. Scaling the CDC's NNV estimates of 8738 for BNT162b2 and 11994 for mRNA-1273 by this reduced severity, we estimate that 31207 (8738/0.28) to 42836 (11994/0.28) young adults would need to be boosted with BNT162b2 or mRNA-1273, respectively, to prevent one COVID-19 hospitalisation over a 6-month period. Hospitalisations prevented per million BNT162b2 and mRNA-1273 doses administered are 32.0 and 23.3, respectively (table 1).

SAE rates reported from manufacturer-provided data

Of the 12 SAEs reported in the intervention arm of the randomised controlled trial (RCT) for BNT162b2 (n=5055), three were found by blinded investigators to be attributable to the vaccine, providing a rate of 1 in 1685 (3/5055).¹⁹ The three SAEs considered vaccine related included: moderate persistent tachycardia, moderate transient elevated hepatic enzymes and mild elevated hepatic enzymes.¹⁹ Based on 31207 in this age group needing to receive the first BNT162b2 booster to prevent one hospitalisation over a 6-month period, the expected SAE rate is 18.5 (3/5055*31207). (Table 1A) Per million doses administered, the SAE rate is 593.5. Although the safety populations were small, we also

ⁱOffit recommended that his own son not receive a booster dose due to concerns that benefits would not outweigh risks (see: <https://www.theatlantic.com/health/archive/2022/01/should-teens-get-booster-omicron/621222/>).

ⁱⁱSee also: <https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event> (accessed 20 October 2022).

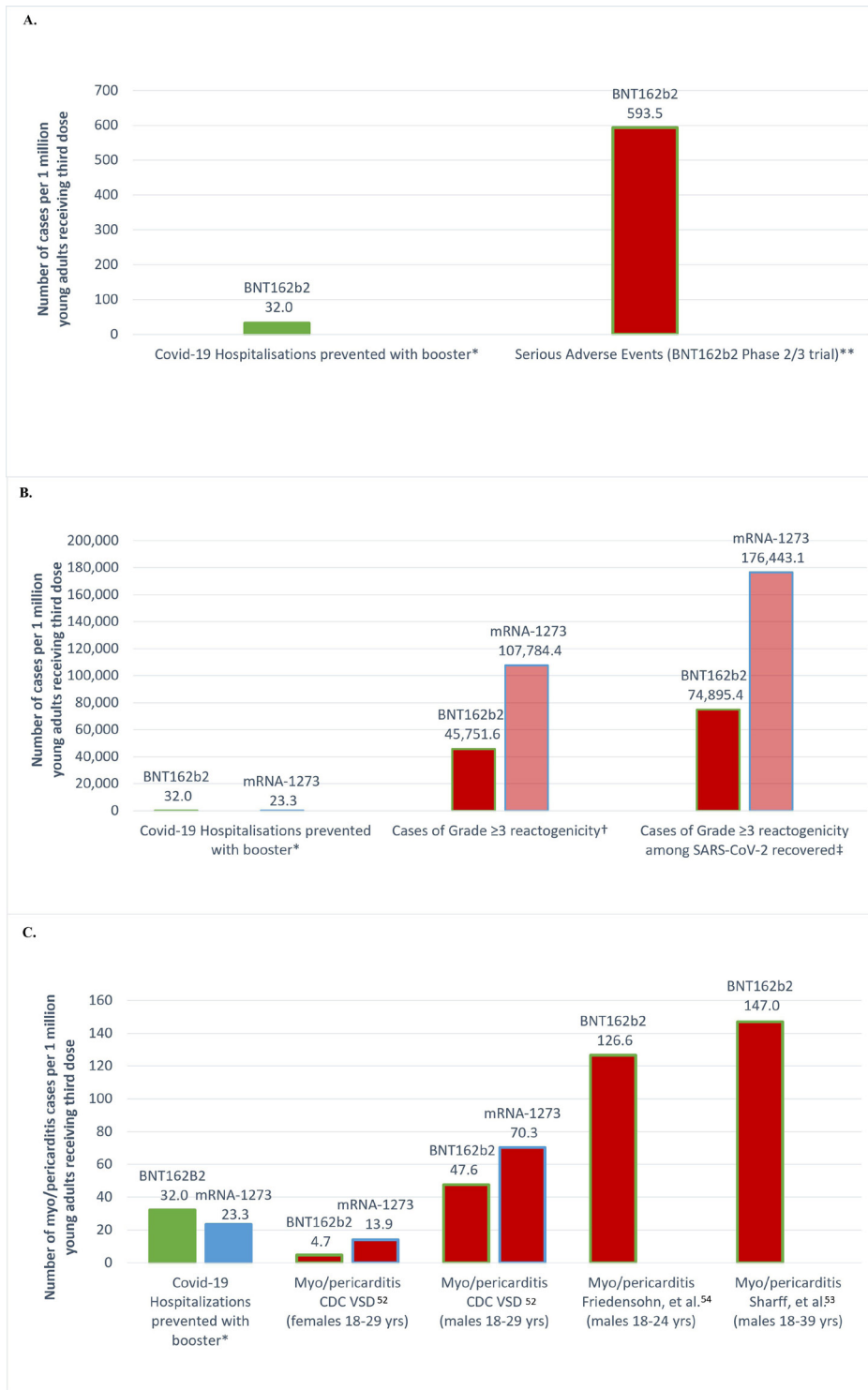


Figure 1 (A, B, C) Expected hospitalisations prevented over six months and serious adverse events (SAEs), cases of grade ≥ 3 reactogenicity, and vaccine-associated myo/pericarditis among 18–29-year-olds per million BNT162b2 and mRNA-1273 booster vaccinations. *CDC-estimated number needed to vaccinate (NNV) with a booster to prevent 1 hospitalisation over 6 months in 18–29-year-olds¹⁸ was adjusted for reduced Omicron severity (aOR=0.28)⁴⁷ as follows: BNT162b2 (8738/0.28=31 207) and mRNA-1273 (11 994/0.28=42 836). Per million third doses, hospitalisations prevented for BNT162b2 were computed as follows: $1/(8738/0.28) \times 10^6 = 1/31\,207 \times 10^6 = 32.0$ and $1/(11\,994/0.28) \times 10^6 = 1/42\,836 \times 10^6 = 23.3$ for mRNA-1273 **SAEs: Three serious adverse events among BNT162b2 booster recipients were deemed by blinded investigators to be related to vaccination (3/5055). These included: moderate persistent tachycardia, moderate transient elevated hepatic enzymes, and mild elevated hepatic enzymes.^{18 50} †Reactogenicity rates are BNT162b2 (14/306) and 45 751.6 per million third doses; mRNA-1273 (18/167) and 107 784.4 per million third doses.⁵⁰ ‡Estimated reactogenicity rates were computed assuming 63.7% seroprevalence¹³ and at least 2x reactogenicity among those with prior SARS-CoV-2 infection.^{56 57}

Table 1 Risk-benefit analysis of third mRNA vaccination: definitions and rates for serious adverse events (SAEs), grade ≥3 reactogenicity and myo/pericarditis in 18–29 year-olds by manufacturer

1A. Serious adverse events (SAE) and risk-benefit analysis	Rate	Risk	Harms per 1 million third doses	Hospitalisations prevented per 1 million third doses Absolute risk reduction=(1/adj NNV)×10 ⁶	Risk-benefit ratio of third-dose SAEs per COVID-19 hospitalisation prevented	
SAE An adverse event that results in any of the following conditions: death, life threatening at the time of the event, inpatient hospitalisation or prolongation of existing hospitalisation; persistent or significant disability/incapacity, a congenital anomaly/birth defect or a medically important event, based on medical judgement.	BNT162b2 3/5055 ¹⁹ Slide 26	1 in 1685	593.5 (10 ⁶ /1685)	BNT162b2 ^{19 47} 1/(8738/0.28)×10 ⁶ =1/31 207×10 ⁶ =32.0 hospitalisations prevented per million third doses	18.5/1 593.5/32.0=18.5 (BNT162b2 SAE ¹⁹ /BNT162b2 hospitalisations prevented)	
	mRNA-1273 0/171 ⁵⁰ Table 4b	Not calculable*	Not calculable*	mRNA-1273 ^{19 47} 1/(11 994/0.28)×10 ⁶ =1/42 836×10 ⁶ =23.3 hospitalisations prevented per million third doses	Not calculable*	
1B. Grade ≥3 reactogenicity and risk-benefit analysis	Rate	Risk	Harms per 1 million third doses	Hospitalisations prevented per 1 million third doses (as above)	Risk-benefit ratio of third-dose grade ≥3 reactogenicity per COVID-19 hospitalisation prevented	
Grade ≥3 reactogenicity Defined as local/systemic adverse events that prevent daily routine activity or require use of a pain reliever (grade 3) or require an emergency room visit or hospitalisation (grade 4).	BNT162b2 14/306 ⁵⁰ Table 3f	1 in 22	45 751.6 (14/306)×10 ⁶	BNT162b2: 32.0	1429.7/1 (45 751.6/32.0)	
	mRNA-1273 18/167 ⁵⁰ Table 3f, 4b	1 in 9	107 784.4 (18/167)×10 ⁶	mRNA-1273: 23.3	4625.9/1 (107 784.4/23.3)	
	2x reactogenicity among SARS-CoV-2 recovered					
	BNT162b2 ^{50 56}	1 in 11	74 895.4 0.637*2*(14/306)×10 ⁶ + 0.363*(14/306)×10 ⁶	BNT162b2: 32.0	2340.5/1 (74 895.4/32.0)	
mRNA-1273 ^{50 56}	1 in 4.5	176 443.1 0.637*2*(18/167)×10 ⁶ + 0.363*(18/167)×10 ⁶	mRNA-1273: 23.3	7572.7/1 (176 443.1/23.3)		
1C. Myo/pericarditis and risk-benefit analysis	Harms per 1 million third doses (males)	Harms per 1 million third doses (females)	Hospitalisations prevented per 1 million third doses (as above)	Risk-benefit ratio of third-dose myo/pericarditis per COVID-19 hospitalisations prevented		
Myocarditis Presence of ≥1 new or worsening†: ▶ Chest pain/pressure/discomfort ▶ Dyspnoea/shortness of breath/pain with breathing ▶ Palpitations ▶ Syncope AND ≥1 new finding of: ▶ Troponin above normal limit ▶ Abnormal ECG, EKG or rhythm monitoring findings consistent with myocarditis ▶ Abnormal cardiac function or wall motion abnormalities on ECHO ▶ cMRI findings consistent with myocarditis AND ▶ No other identifiable cause of symptoms	Ages 18–39	Ages 18–39	BNT162b2: 32.0 mRNA-1273: 23.3	Males	Females	
	BNT162b2 147/million ⁵³ (Sharff <i>et al</i>)	n/a		BNT162b2: 32.0	BNT162b2 4.6/1 (147.0/32.0)	n/a
	Ages 18–29	Ages 18–29				
	BNT162b2 (VSD): 47.6/million ⁵² Slide 23	BNT162b2 (VSD): 4.7/million ⁵² Slide 23			BNT162b2 1.5/1 (47.6/32.0)	BNT162b2 0.2/1 (4.7/32.0)
	mRNA-1273 (VSD): 70.3/million ⁵² Slide 23	mRNA-1273 (VSD): 13.9/million ⁵² Slide 23			mRNA-1273 3.0/1 (70.3/23.3)	mRNA-1273 0.6/1 (13.9/23.3)
	Ages 18–24	Ages 18–24				
BNT162b2 126.6/million ⁵⁴ (Friedensohn <i>et al</i> **)	n/a			BNT162b2 3.9/1 (126.6/32.0)	n/a	
Pericarditis Presence of ≥2 new or worsening: ▶ Acute chest pain‡ ▶ Pericardial rub on exam ▶ New ST-elevation or PR-depression on EKG ▶ New or worsening pericardial effusion on echocardiogram or MRI	Ages 16–17†	Ages 16–17†				
BNT162b2 (VSD): 200.3/million ⁵¹ Slide 25	BNT162b2 (VSD): 44.0/million ⁵¹ Slide 25			BNT162b2 6.3/1 (200.3/32.0)	BNT162b2 1.4/1 (44.0/32.0)	

*Footnote (h) from GRADE Table 3e: Overall, 4/344 (1.2%) participants experienced five SAEs during a median follow-up of 5.7 months after booster dose (administered at least 6 months after a 50 µg (n=173) or 100 µg (n=171) two-dose primary series); the sponsor deemed these unrelated to mRNA-1273. Data on an equivalent primary series comparison group were not available at the time of the GRADE assessment.⁵⁰
 **Based on hospitalised cases only within 21 days of receipt of mRNA-1273.⁵⁴
 †COVID-19 hospitalisation risk for aged 16–17 years is lower than for those aged 18–29 years, thus the risk/benefit ratio provided is an underestimate.
 ‡Criteria for probable case. Confirmed case requires symptoms plus histopathological evidence OR elevated troponin AND cMRI findings.
 §Typically described as pain made worse by lying down, deep inspiration or cough and relieved by sitting up or leaning forward, although other types of chest pain may occur.
 cMRI, cardiac MRI; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; NNV, number needed to vaccinate; VSD, Vaccine Safety Datalink.

reviewed SAEs reported from these cohorts. Pfizer reported 1/306 but the event was not considered related to the vaccine (1/306=0.3%). Similarly, Moderna found that none of the five SAEs experienced by 4 of 344 participants⁵⁰ in its safety population (4/344=1.2%)ⁱⁱⁱ were attributable to the vaccine,

ⁱⁱⁱTable 3e footnote h: Overall, 4/344 (1.2%) participants experienced five SAEs during a median follow-up of 5.7 months after booster dose (administered at least 6 months after a 50 µg (n=173) or 100 µg (n=171) two-dose primary series); the sponsor deemed these unrelated to mRNA-1273. Data on an equivalent primary series comparison group were not

thus our SAE estimates rely on the only available RCT data (BNT162b2).

Reactogenicity rates

According to self-report data, side effects from the booster dose prevent on average 28.3% of mRNA vaccine recipients from being able to carry out normal daily activities, typically the

available at the time of the GRADE assessment.

day after vaccination.⁵⁵ Sponsor-reported rates from the safety studies for grade ≥ 3 reactogenicity are 1 in 22 (14/306)⁵⁰ for the BNT162b2 booster to 1 in 9 (18/167)⁵⁰ for the mRNA-1273 booster. Per million third doses, reactogenicity rates are therefore 45 751.6–107 784.4, respectively (table 1B). Per COVID-19 hospitalisation prevented over 6 months in adults aged 18–29 years, the expected number of grade ≥ 3 reactogenicity cases is therefore 1429.7 (45 751.6/32.0) to 4625.9 (107 784.4/23.3), respectively.

In those with a prior SARS-CoV-2 infection, postvaccination symptoms causing missed work or daily activities are reported twofold⁵⁶ to threefold⁵⁷ more often than those without a history of infection, a major concern given that seroprevalence among adults aged 18–49 years is now well above the February 2022 estimate of 63.7%.¹³ Conservatively assuming 63.7% as the proportion with a history of COVID-19 infection, and a twofold increased likelihood of systemic effects, expected grade ≥ 3 reactogenicity cases per single hospitalisation prevented would be at least 2340.5–7572.7 for BNT162b2 and mRNA-1273 boosters, respectively (table 1B). Even without taking into account prior infection, the proportion reporting to V-Safe being ‘unable to perform daily activities’ was between 20% and 40% depending on booster product, and higher among those receiving a heterologous booster.⁵⁸

Booster vaccine-associated myocarditis rates in university-age males 18–29 years

The CDC estimated the rate of postbooster myocarditis during days 0–7 following BNT162b2 vaccine administration in males aged 16–17 years to be approximately 1 in 41 500⁵¹ using passive surveillance through the Vaccine Adverse Event Reporting System (VAERS), and approximately 1 in 5000⁵¹ using active surveillance with the Vaccine Safety Datalink (VSD). In males aged 18–29 years, the postbooster myocarditis rate for both products combined using VAERS was reported to be 1 in 101 000⁵² (ages 18–24) to 1 in 208 000⁵² (ages 25–29) while the VSD rate was much higher at 1 in 14 200⁵² (mRNA-1273) to 1 in 21 000⁵² (BNT162b2). Two other population-based studies from the USA and Israel in males aged 18–39 years found the rate to be 1 in 7000 (147.0 per million third doses)⁵³ to 9000 (126.6 per million third doses).⁵⁴ In both of these studies, BNT162b2 was the vaccine administered prior to diagnosis. For our estimates, and assuming a precautionary stance, we have used active surveillance rates or population-based rates. For males aged 18–29 years we consider the rate 1 in 7000⁵³ to be the most reliable because the method relies on CDC definitions and databases.⁵⁹ We also provide a 16–17 year-old rate because academic acceleration allows some older adolescents to attend college along with the freshman cohort, and in some cases students need to be vaccinated before their 18th birthday to enrol or be assigned to housing. For males aged 16–17 years, we use the VSD rate of 1 in 5000.⁵¹ In table 1C, we provide a range of myopericarditis estimates for consideration.

Risk-benefit estimates

The figures display benefits and harms per million third doses administered: SAEs (figure 1A), grade ≥ 3 reactogenicity (figure 1B) and myopericarditis (figure 1C). At this scale, and as shown in figure 1A, boosting young adults with BNT162b2 could cause 18.5 times *more* SAEs per million (593.5) than COVID-19 hospitalisations averted (32.0).

To prevent one hospitalisation over 6 months by boosting 31207–42836 students, a large university campus may also expect 1429.7–4625.9 young adults to experience grade ≥ 3

reactogenicity disrupting daily activities or requiring medical care when vaccinated with a third dose of BNT162b2 or mRNA-1273, respectively. Per million third-doses of mRNA vaccine administered, between 45 751.6 and 107 784.4 cases of grade ≥ 3 reactogenicity may be created (figure 1B). Given that prior SARS-CoV-2 infection increases the rate of systemic reactions by twofold to threefold,^{56 57} the number of young adults expected to experience disruptions in their school and daily activities is likely to exceed 74 895.4 with BNT162b2 and 176 443.1 with mRNA-1273 (figure 1B).

Per million third doses of mRNA vaccine administered, 23.3–32.0 hospitalisations may be averted while 47.6–147.0 cases of myo/pericarditis may be caused among young males aged 18–29 years (figure 1C). Thus, to prevent a single hospitalisation among young males aged 18–29 years, we estimate between 1.5 and 4.6 occurrences of myo/pericarditis (rates up to 1 in 7000⁵³) among males aged 18–29 years (figure 1C). For adolescents aged 16–17 years and using available data from CDC’s VSD,⁵¹ we expect 6.3 cases of myo/pericarditis among males and 1.4 among females. Thus, per single hospitalisation averted by boosting 31 207–42 836 young males in this age group, approximately 1.5–6.3 cases of myopericarditis may result.

Most media reports, as well as a recent systematic review⁶⁰ and expert opinion from the American College of Cardiology (ACC),⁶¹ present vaccination-associated myo/pericarditis as rare, (typically) ‘mild’ and followed by rapid recovery with anti-inflammatory treatment. The reviews have not framed vaccine-associated risks versus infection-associated risks using compatible denominators based on exposure (vaccination) and infection (seroprevalence), thus the infection-associated risks may have been overstated by at least a factor of 4 according to CDC estimates of the burden of COVID-19 illness.⁶² However, vaccine-associated myocarditis has been found to occur in as many as 1 in 2652 males aged 12–17 years and 1 in 1862 males aged 18–24 years after the second dose⁵⁹ (and as high as 1/1300 after the second dose in a BNT162b2–mRNA-1273 combination).⁶³ An Israeli study described one in five cases among 16–29 year-olds to be of intermediate severity, meaning these cases had persistent new/worsening abnormalities in left ventricular function, or persistent ECG anomalies, or frequent non-sustained ventricular arrhythmias without syncope.⁶⁴ The CDC reported that 1200 of the 1314 verified myocarditis cases with known hospitalisation status following the primary series or booster had been hospitalised.⁶⁵ Among adolescents, 69%⁶⁶–80%⁶⁷ of those diagnosed with vaccine-associated myo/pericarditis had findings consistent with cardiac inflammation on MRI testing 3–8 months after the second dose. The potential long-term impact of scar tissue on heart conduction remains unknown.^{66 67} Postvaccination myocarditis has been found to be equivalent to or exceed the risk of post-COVID myocarditis in males less than 40 years old despite the lack of seroprevalence-based estimates of COVID-associated myocarditis.⁶⁸ Rare incidences of death in young males attributed to mRNA vaccine-induced myocarditis have also been reported.^{69 70}

Limitations of analysis

These estimates have a number of limitations. First, our estimates rely on sponsor-reported and CDC summaries of AEs; we cannot account for failures to report small sample sizes, poor quality evidence subject to serious bias or loss to follow-up during the clinical trials. Second, our SAE estimate does not distinguish between specific types or the clinical significance of SAEs because of scarce data. The BNT162b2 RCT found more SAEs in the placebo group (24/5020) than the booster group

(16/5055). However, blinded investigators attributed as vaccine-related three SAEs in the vaccine group (moderate persistent tachycardia, moderate transient elevated hepatic enzymes and mild elevated hepatic enzymes) and two SAEs in the placebo group (myocardial infarction and chest pain of unknown origin).¹⁹ Per million doses, the SAEs were therefore 593.5/million in the vaccine group vs 398.4/million in the placebo group, resulting in a risk difference of 195.1/million doses. The phase II/III BNT162b2 booster trial participants were of median age 42.0 and the company's adolescent booster trial, for example, included only 78 individuals aged 16–17 years randomised to receive booster or placebo.⁷¹ Nevertheless, one male in this age group was hospitalised with myopericarditis after receiving a third dose of BNT162b2.⁷¹ It is possible that multiple severe side effects were reported by the same participant in the RCT trials and that the number of people impacted by such reactions is lower than our estimate. Hence, the causal relationship between our estimated SAEs and the COVID-19 vaccines needs to be approached with caution. We are extrapolating SAE data to young adults (18–29 years old) that were originally generated in clinical trials involving all age groups. However, studies have shown that younger people have a greater likelihood of vaccine-related AEs.⁷²

More generally, data limitations affect the CDC's ability to evaluate both BNT162b2 and mRNA-1273. For example, the CDC's Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) review⁵⁰ noted 'serious' risk of bias for SAEs and 'very low' certainty of evidence (type 4) for all measures. While Pfizer conducted an RCT among 10 000 participants assigned 1:1 to booster or placebo, a sample size of 5000 is not sufficient to detect SAEs occurring at a rate of 1 in 7000 (such as vaccine-associated myo/pericarditis) among a subset of the population aged 18–29 years at highest risk. However, the trial data do suggest that the rate of AEs was higher among the intervention group than the placebo group (25.2% vs 6.8%).⁷³ Moderna conducted a small, non-randomised safety study among 344 participants who elected to get a booster, and the reported SAEs were subject to serious risk of bias.^{50 iv}

Despite these limitations, we believe that the data suggest caution is warranted. Haas *et al*⁷⁴ suggested that many systemic AEs in the RCTs (76% of systemic and 24% of local reactogenicity) may have been due to a nocebo effect—anxiety, expectations and background symptoms. It is very likely, however, that real-world severe or serious AEs may be greater than those reported in the RCT data because standard trials are underpowered to detect rare AEs and there may also be selection bias: those who had a reaction during the primary series may have a greater expectation of harmful side effects to the booster and are less likely to enrol in a trial. In fact, these data are usually collected after a drug has been approved and is on the market (phase IV clinical trial data). Such limitations show the need for more robust postmarketing data and ideally large, controlled

trials to determine risks and benefits for any future booster doses, especially in younger age groups.

Universities have not published cumulative AE rates on their COVID-19 dashboards, thus there is no current way to validate these estimates with real-world data. Even with the residual uncertainties, our risk-benefit assessment shows that it is at least plausible that expected individual harms outweigh benefits for young healthy people (ie, most young adults), and it is implausible that individual benefits significantly outweigh risks. Pfizer's own booster data support this inference.⁷¹ In requesting the EUA for boosting adolescent males, the BNT162b2 risk-benefit analysis estimated 23–69 cases of myocarditis per 1 million booster doses administered and 29–69 COVID-19 hospitalisations averted,⁷¹ yet this estimate of 23–69 cases of myocarditis per million third BNT162b2 doses administered is now known to be an order of magnitude below the 200.3 per million reported by the US CDC among adolescents aged 16–17 years.⁵¹ Finally, our NNV with a booster dose to prevent one hospitalisation likely errs on the side of overestimating the effectiveness of the booster. We do not incorporate the protective effects of prior infection, for example. Recent studies have found rapid waning of effectiveness against hospitalisation during Omicron to <50% by 3–4 months,⁴¹ with some studies failing to detect any significant benefit against hospitalisation of a booster dose among those <40.²¹ If accurate, these data would render our booster risk-benefit analysis even less favourable.

FIVE ETHICAL ARGUMENTS AGAINST UNIVERSITY BOOSTER MANDATES

Below, we present five ethical arguments against university booster mandates informed by our risk-benefit assessment and ethical analysis of mandatory policies to date. These arguments relate to (1) the importance of transparent, peer-reviewed risk-benefit analyses in policy, (2) the potential for net individual harm, (3) the lack of a proportionate public health benefit, (4) the lack of reciprocity in terms of compensation for vaccine-related harms and (5) the wider social harms of vaccine mandates.

Transparency

Risk-benefit assessment is essential to the ethical acceptability of public health policy, and transparent, peer-reviewed assessments help maintain trust in public health, especially in the context of controversial policies. There is an even stronger rationale for thorough and transparent risk-benefit assessment when interventions are mandated or when (given uncertainty or relevant population differences) some people might face harms not outweighed by individual benefits. In such cases, risk-benefit assessments should be stratified by demographic factors and updated as new data become available to reduce uncertainty. At a minimum, if an intervention is implemented despite significant uncertainty (especially if it is mandated), there is a strong ethical rationale to collect (controlled) data to resolve relevant uncertainties.

An Omicron-era risk-benefit assessment published by the CDC and FDA could provide additional insight into the appropriateness of university booster mandates. However, such a risk-benefit assessment has not been published to date. Without such a formal analysis, professional associations (such as the ACC expert panel⁶¹) have been forced to infer from the literature and CDC's own analyses. For example, the ACC expert panel produced a graphic displaying a favourable harms versus benefits ratio for the second dose among young adults aged 12–29 years.⁶¹ The ACC's widely promoted graphic is tied to data presented by the

^{iv}Table 3e, footnotes (h), (i), (j): h. Overall, 4/344 (1.2%) participants experienced five SAEs during a median follow-up of 5.7 months after booster dose (administered at least 6 months after a 50 µg (n=173) or 100 µg (n=171) two-dose primary series); the sponsor deemed these unrelated to mRNA-1273. Data on an equivalent primary series comparison group were not available at the time of the GRADE assessment. i. Comparator group is 100 µg primary series recipients in the phase II randomised dose confirmation study. j. Participants' ability to choose whether to receive a booster likely introduced selection bias (eg, those with adverse events or reactions with the primary series may have been less likely to choose a booster).

CDC⁷⁵ and relies on four key assumptions which bias the findings in favour of vaccination: (1) vaccine effectiveness of 95% over 120 days to prevent COVID-19 cases and hospitalisations; (2) myocarditis rates were derived from passive surveillance in VAERS instead of active surveillance available to the CDC (VSD) resulting in harms being underestimated by a factor of 10^{51 52}; (3) harms and benefits were averaged across ages 12–29 when the risk may be highest among those aged 16–19 years^{51 52}; and (4) hospitalisation rates were tied to May 2021 data, more than a year prior to the ACC’s review and pre-Omicron. Nevertheless, for adolescent males aged 12–17 years, the CDC estimated 56–69 myocarditis cases would be expected while 71 intensive care unit admissions could be averted.⁷⁵

It was foreseeable that the decision to recommend boosters for all adults (against the advice of the FDA panel) would be followed by booster mandates since pandemic vaccine mandates were already in place in many universities and colleges throughout the USA at the time.¹³ Universities rely on public health agencies such as the CDC for guidance. Thus, we maintain that if mandates remain then it is critically important to update public risk-benefit estimates for boosters among adults younger than 40, stratified by sex, comorbidity status and history of infection to provide evidence that the intervention confers an expected net benefit to younger individuals in the context of the prevailing SARS-CoV-2 variants and pre-existing immunity. Without this, it is problematic to repeatedly and emphatically claim that COVID-19 vaccines are ‘safe and effective’ without specific risk-benefit analyses for different age categories and with consideration for individual health status, including evidence of prior infection, because risks of both disease and vaccination are highly variable according to these factors.^{9 10}

Since there has not been any RCT specific to evaluating boosters in young adults, the CDC relied on data from an older cohort with a median age of 42.0–51.7^{71 73} and incorrectly assumed that the benefits would also outweigh risks for younger age groups. As we have shown, it is likely that this assumption is incorrect. Under such uncertainties, ethical vaccine policy-making arguably requires transparency about scientific knowledge and uncertainties regarding vaccine risks and benefits (ie, even more transparency than where certainty is high), and at the very least allows for shared decision-making aligned with an appreciation of stratified risks instead of placing the emphasis on simplistic messaging.

Transparent policymaking can encounter a ‘trust paradox’ in providing information about vaccine risks to the public. As noted by Petersen *et al*,⁷⁶ governments have a perverse incentive to withhold negative information about vaccines since they are actively promoting such products and negative information about vaccines reduces vaccination uptake. And yet transparent disclosure about negative information (eg, side effects) helps sustain trust in health officials and reduces the politicisation of vaccines.⁷⁷ Transparency may reduce the uptake of vaccination in the short term but will uphold trust in health authorities and vaccines in the longer term—just as open disclosure regarding clinical harms promotes trust in medicine.⁷⁸ To address the ‘trust paradox’ in regulatory politics, and to maintain trust in government and scientific institutions, greater data accountability (in this case, a risk-benefit analysis) should precede any policy debate about mandates. Given concerns about pharmaceutical influence on the political process^{78 79} this should be facilitated by mechanisms to ensure independent scrutiny of regulatory science.⁷⁹

Potential net expected individual harm

The reasonable possibility of a net harm to individuals (as presented in our risk-benefit assessment) should provide a strong basis to argue for the ethical case against booster mandates for young adults. Mandates at institutions of higher education serve the age group with one of the lowest public health burdens from COVID-19. Hence, boosters provide a low and transient impact on transmission and hospitalisation for an age group with a vague and unquantified prospect of benefit. Arguably, this has been considered by most universities and colleges and is the reason why most do *not* have booster mandates for the fall of 2022. In fact, this is also likely why European countries, including the UK, France, Germany, Norway, Sweden and Denmark (to our knowledge), never had university-implemented mandates.¹⁴ When the European Centre for Disease Prevention and Control (ECDC), a body serving some 300 million European residents, recommended boosters in November 2021, priority was focused on those over age 40.⁸⁰ Taking a different view of the data, in the fall of 2021 the US CDC recommended boosters for all adults and recommended a *second* booster for all Americans aged 50 years or more for fall 2022.⁸¹ The ECDC, in contrast, recommended that first boosters be ‘offered’ with prioritisation for those over 40 years, and now recommends second boosters for the 2022 autumn campaign only for those over age 60 and those with an immunocompromised status or high-risk medical conditions.⁸²

Reflecting again to fall of 2021, the UK’s JCVI provides an example of using the potential for net harm to advise *against* the primary vaccination series for 12–15-year-olds.⁸³ The JCVI argued that the potential benefit of vaccination in this age group was only ‘marginally greater than the potential known harms’, since healthy 12–15 year-olds are at very low risk of serious outcomes from COVID-19. Although it may be the case that the JCVI adopted worst-case estimates,⁸⁴ such an approach reinforces the need to act judiciously under conditions of uncertainty where the clear benefits of an intervention are not confidently above the potential harms. Note also that they mention ‘potential known harms’ without taking into consideration potential long-term effects. The UK Health Ministers subsequently voted to offer a single dose of vaccination to adolescents aged 12–15 years in consideration of: ‘...the health and wider social benefits to this cohort’.⁸⁵ A second dose was offered to those with underlying health conditions. There are important parallels between the JCVI decision and the outcome of the FDA panel that recommended against universal booster recommendations for adults in the USA in the fall of 2021: in both cases, the US and UK governments disregarded these recommendations. A key ethical difference is that the UK has not implemented any COVID-19 vaccine mandates at schools or universities, and the mandate proposed for care home and healthcare workers was withdrawn.⁸⁶

As noted above, blanket mandates ignore widely available critical data, such as the benefits of prior infection and data on adverse effects. These factors make an expected net harm now even more likely than when mandates began and make it more urgent to update COVID-19 vaccine policy. Policies for other vaccines have been updated following the accumulation of new data. For example, adult boosters for tetanus and diphtheria vaccines (though previously widely administered) have been shown to provide no benefit.⁸⁷ Vaccines for influenza, dengue and rotavirus have been withdrawn or had strict limitations placed on their use in children due to unexpected harms.⁸⁸ Adenovirus-vectored COVID-19 vaccines have been limited in their use due to thrombosis (especially in younger women).⁸⁹ Uncertainties remain regarding mRNA

vaccines, for example, related to their effects on menstruation and fertility,⁹⁰ shingles⁹¹ or the overall safety of current formulations in younger adults and children as well as evidence in support of booster vaccination.⁹²

There are two other theoretical problems that could be factored into mandatory programmes from a precautionary standpoint: original antigenic sin and the non-specific effects of vaccines. Original antigenic sin refers to the decreased ability of an individual to respond to a new viral variant because the immune system has been 'locked' onto the original immunogen.⁹³ While data have not shown this to occur with COVID-19 vaccine, it cannot yet be ruled out as an important side effect of repeat vaccination, including with the new bivalent booster. Non-specific effects of vaccination refer to the effects of a vaccine on overall health and all-cause mortality, which have been shown to differ based on the type of vaccine (eg, live vs non-live) and age/sex.^{94 95} Both of these theoretical issues are at the frontiers of our current knowledge of vaccinology and are rarely considered in the media and by the lay public. We cite these examples to support our main point: proportionality of mandates should account for uncertainty regarding evidence that benefits outweigh harms, especially as the marginal benefits of vaccination and boosting for young adults become vanishingly small with increased population immunity.

Lack of proportionate public health benefit

Proportionality, a key principle in public health ethics, requires that the benefits of a public health policy must be expected to outweigh harms, including harms arising from the restriction of individual liberty and basic human rights such as access to education and employment.^{1 5-8 86} Where mass vaccination involves harm to a minority of individuals, or coercion or undue inducements are used to increase vaccine uptake, proportionality requires that these considerations be outweighed by public health benefits, typically in the form of reduced transmission from vaccinated individuals to others.⁹⁶

COVID-19 booster mandates often involve a degree of coercion, including the threat of loss of access to education and free choice of occupation, disproportionately affecting disenfranchised groups.⁹⁶ Contrary to those who restrict the concept of coercion to situations of a direct threat to something people should have access to as a matter of right,⁹⁷ we endorse here a broader concept of coercion that includes situations of structural pressure that deprive people of reasonable options.^{98 99} To be ethically acceptable, such severe restrictions of individual liberty need to be justified by an individual benefit and by the expectation that vaccination reduces harm to others. Booster doses of COVID-19 vaccines provide limited lasting reduction in the probability of infection or transmission,²⁷⁻²⁹ hospitalisation⁴¹ and limited expected benefits to young healthy individuals, especially those who have already been infected.^{31-33 100-102} The net expected harms to individuals and the harms of coercive mandates themselves are not counterbalanced by a large public health benefit (and in fact may harm the public health through the attrition of healthcare workers); such harms and restrictions of liberty are therefore disproportionate and ethically unjustifiable.

Failure of reciprocity

The use of booster mandates raises an additional ethical problem of *reciprocity* for institutions of higher education and public health authorities.^{103 104} Most vaccines are covered in the USA¹⁰⁵ and Canada¹⁰⁶ by an injury compensation programme based on fair (reciprocal) compensation for those who experience a vaccine-related harm. Mandatory vaccines arguably require even stronger protections for individuals who experience consequences that lead to permanent harm¹⁰⁷ because their free choice regarding

vaccination has been limited. While institutions of higher education are mandating boosters, the US and Canadian compensation programmes have failed to uphold their social justice responsibility to injured individuals. In the USA, COVID-19 vaccines and therapeutics are processed by the Countermeasures Injury Compensation Program (CICP) which is designed to cover epidemics, pandemics and security threats as designated by the Secretary of Health and Human Services and as authorised by the Public Readiness and Emergency Preparedness (PREP) Act.¹⁰⁵ As of 1 August 2022, thirty-seven claims have been denied compensation because 'the standard of proof for causation was not met' or 'a covered injury was not sustained'.¹⁰⁸ No claims have been paid out by the US CICP but one claim for anaphylaxis has been approved for compensation and payout is currently pending assessment of eligible expenses.¹⁰⁸

The federal US vaccine injury programme has failed to compensate but one COVID-19 vaccine-injured individual in the context of booster mandates in place at hundreds of US universities.¹⁰⁸ It is also important to note that boosters have been granted an EUA by the FDA, but are still not fully approved.¹⁰⁹ Thus, universities and colleges that mandate COVID-19 boosters are pressuring young adults to receive a vaccine that, in case of injury, has no transparent legal route to adequate compensation. In sum, one core precondition for vaccine mandates is a functioning and fair compensation programme, which has not been achieved for COVID-19 vaccines.

Wider social harms

Strong coercion may create significant social harms. COVID-19 vaccine mandates have generally involved a high degree of coercion, effectively ostracising unvaccinated individuals from society. University mandates involve significant coercion in that they exclude unvaccinated people from the benefits of university education (or employment) and thereby entail major infringements to free choice of occupation and freedom of association. When such mandates are not supported by a *compelling* public health justification and where exemptions are not easily available, the likelihood of reactance and negative social effects are increased.¹ The social harms of university COVID-19 mandates have not been formally studied, but there is reason to think that they will be significant.¹ Policies can have wide-ranging consequences for non-compliance, such as loss of employment, loss of internet use, restriction to off-campus versus on-campus housing, delays or refusal to process student housing requests, loss of enrolment, a hold placed on grades, inability to use recreational facilities to train or compete in sports, access to scholarships for competitive sports, registration for class and delays in ability to repay student loans after graduation. A number of young adults and professors affected by mandates have outlined publicly their perspectives and the social harms of these policies, such as loss of access to schooling and social services,¹¹⁰ psychosocial stress, reputational damage and lost income and threats of being disenrolled or deported.¹¹¹ This punitive public health approach may also provoke reactance in young adults,¹ with long-term negative consequences on trust in society and institutions and vaccine confidence in general, including vaccine hesitancy for routine paediatric and adult vaccines, a problem which predated the pandemic and is considered one of the WHO's top 10 threats to global health.¹¹²

OBJECTIONS: POSSIBLE RATIONALES FOR MANDATES

Despite the considerations above, proponents of university COVID-19 booster mandates might argue that such policies are justified (even if some individuals experience uncompensated harms) because they: (1) help *normalise* compliance with vaccination as a social duty (thereby promoting solidarity or provaccine attitudes that undermine antivaccination sentiment) and/or (2)

help to increase the safety of the university environment or wider society. Mandates may help some people ‘feel better’, knowing that everyone in a crowd, dorm or classroom is vaccinated, that they are among peers who have ‘done the right thing’ and ‘care about the safety of others’. For instance, some faculty and staff may ‘feel protected’ by the new booster mandate introduced at Western University in Ontario, Canada, on 22 August 2022.¹¹³ From this perspective, if a majority of university policymakers (whether clinical advisory group members, administrators and/or professors) or students *believe* that vaccination should be socialised to promote solidarity, counteract antivaccination sentiment or create a safe environment, then such beliefs (and values) should guide policy.

However, even if many people hold such beliefs and even if such goals are laudable, policy must be predicated on methods and models which are open to public scrutiny. Risk-benefit assessments should remain objective and avoid the use of some people feeling better or safer to justify behavioural rules with sanctions for non-compliance in the absence of rational justification. While many vaccines do improve group safety by reducing transmission, the current generation of COVID-19 vaccines does not provide significant lasting effects of this kind, and repeated doses appear to provide diminishing benefits (in terms of reduced infection) per dose, especially among young adults.¹¹⁴ It therefore makes little sense to claim, as a matter of policy, that COVID-19 vaccination is a prosocial act or that the unvaccinated are a disproportionate threat to others. Moreover, it is unclear whether *mandating* COVID-19 boosters will produce a net positive effect on provaccine sentiment in society—in fact, booster mandates may increase antivaccination beliefs and reduced uptake of other (non-coronavirus) vaccines.^{186 96} As highlighted above, there are also wider social harms of policies that purport to reduce transmission of a ubiquitous virus: such policies may create a fear of infection among young healthy people (out of proportion to the actual risks) and contribute to worsening mental health, an issue which predates the pandemic.¹¹⁵

Moreover, the claim that the *socialisation* of compliance with public health measures can justify those measures is problematic for three other reasons. First, such an argument is circular: compliance *should not be* an end itself; policy must be justified by the expectation of public health benefit. Second, people have different attitudes to compliance depending on their values (eg, the views regarding the importance of individual liberty) and experiences (eg, those with low baseline levels of trust in public health due to negative experiences of health professionals or government agencies). Policies that require people to comply against their values and preferences require ethical justification, especially where voluntary compliance is likely to be lower among those who are disempowered (eg, students) or marginalised for other reasons,^{5 116} for example, those from social groups which have been mistreated by government agencies or by the medical system in the past, including in the context of research.¹¹⁷ Third, the socialisation argument is based, in part, on concepts of civic duty and responsibility to others. Pushing for boosters even when these will not significantly contribute to overall risk reduction runs counter to the responsible use of public resources. Policies that encourage waste of valuable healthcare resources, to make some feel better, are sending a distorted message about important societal obligations.

The proclivity for university vaccine mandates may also reflect harmful trends towards intolerance in university bureaucracies that value compliance over individual freedoms. Mandates, by their nature, encourage conformity and acquiescence to authority, and exclude those with different views or values. Though universities might take pride in being places that permit the free exchange of ideas, mandates reduce the scope for reasoned debate regarding scientific uncertainties or conflicts of ethical values.¹¹⁸ For example,

how many universities have held public debates about mandatory COVID-19 vaccination? To our knowledge, very few such debates have taken place in North American institutions. We are aware of only one academic event¹¹⁹ which some of us organised, in which mandates were critically debated. Sanctions for lack of full vaccination imposed on university professors who publicly voiced their opposition against mandates could arguably also have been intended to suppress public debate or be interpreted as such.

IMPLICATIONS FOR BROADER COVID-19 VACCINE MANDATES FOR YOUTH IN SCHOOLS AND OTHER INSTITUTIONS

The arguments presented above are relevant to third, fourth or fifth-dose booster mandates and to university or school policies that maintain primary two-dose COVID-19 vaccine mandates in 2022 in the face of high rates of previous SARS-CoV-2 infection.¹³ Two-dose mandates are being upheld in at least 1000 universities and colleges across the USA, far more than the 300 or so maintaining booster mandates,² and also some primary and secondary schools in the nation’s largest public school systems¹²⁰ which instituted mandates then extended the deadline for compliance when it was apparent that serious inequities in access to education would result.¹²¹ It is even harder to justify a two-dose primary vaccine mandate in late 2022 than when such policies began in mid-2021.⁴⁶ This rationale is weak at best and wrong at worst. Consistent with our argument above, the now high prevalence of prior infection, data regarding the lack of sustained transmission reduction by current vaccines and the age at peak risk for myo/pericarditis being young adults aged 16–17 years⁵¹ all undermine the case for two-dose vaccine mandates. Students heading to colleges with mandates must currently upload proof of vaccination in order to enrol or be assigned to on-campus housing. We would therefore urge universities and schools to rescind all COVID-19 vaccine mandates. Strong statements in support of mandates made in 2021 by organisations such as the Association of Bioethics Program Directors in North America,¹²² the American Civil Liberties Union¹²³ and the Ontario Human Rights Commission¹²⁴ are now obsolete. Such organisations have an ethical obligation to revise these public statements and consider whether they are valid in light of current data.

The continued policy of two-dose mandates may represent *status quo* bias: when indiscriminate regulations are normalised they often remain even when it has no (current) rational basis. The more rules, the more paperwork and cumbersome ‘busy work’ administrators and young students and professionals need to complete. Yet rules come with consequences: how much are universities, corporations, consulting firms and the military paying in staff time to monitor and maintain vaccine mandates? How much time and energy are young adults using to comply with these policies? How much frustration and psychosocial stress is this causing? What are the consequences of attrition of healthcare workers and military service members at times when the labour market is tight and recruitment is difficult? When vaccine mandates are unethical, individuals may have an ethical duty to oppose them, in part to promote tolerance and prevent further bureaucratic encroachment and disenfranchisement of individuals with reasoned arguments against such mandates. Finally, we argue that institutions have an ethical duty to evaluate the effectiveness of such programmes if the status quo is to be maintained.

CONCLUSION

Based on public data provided by the CDC,¹⁹ we estimate that in the fall of 2022 at least 31207–42836 young adults aged 18–29 years must be boosted with an mRNA vaccine to prevent

one Omicron-related COVID-19 hospitalisation over 6 months. Given the fact that this estimate does not take into account the protection conferred by prior infection or a risk adjustment for comorbidity status, this should be considered a conservative and optimistic assessment of benefit. Our estimate shows that university COVID-19 vaccine mandates are likely to cause net expected harms to young healthy adults—for each hospitalisation averted we estimate approximately 18.5 SAEs and 1430–4626 disruptions of daily activities—that is not outweighed by a proportionate public health benefit. Serious COVID-19 vaccine-associated harms are not adequately compensated for by current US vaccine injury systems. As such, these severe infringements of individual liberty and human rights are ethically unjustifiable.

Mandates are also associated with wider social harms. The fact that such policies were implemented despite controversy among experts and without updating the sole publicly available risk-benefit analysis¹⁹ to the current Omicron variants nor submitting the methods to public scrutiny suggests a profound lack of transparency in scientific and regulatory policy making. These findings have implications for mandates in other settings such as schools, corporations, healthcare systems and the military. Policymakers should repeal COVID-19 vaccine mandates for young adults immediately and ensure pathways to compensation to those who have suffered negative consequences from these policies. Regulatory agencies should facilitate independent scientific analysis through open access to participant-level clinical trial data to allow risk-stratified and age-stratified risk-benefit analyses of any new vaccines prior to issuing recommendations.¹²⁵ This is needed to begin what will be a long process of rebuilding trust in public health.

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