Effectiveness of vaccination mandates in improving uptake of COVID-19 vaccines in the USA

Michelle M Mello, Douglas J Opel, Regina M Benjamin, Timothy Callaghan, Renee DiResta, Jad A Elharake, Lisa C Flowers, Alison P Galvani, Daniel A Salmon, Jason L Schwartz, Noel T Brewer, Alison M Buttenheim, Richard M Carpiano, Chelsea Clinton , Peter J Hotez, Rekha Lakshmanan, Yvonne A Maldonado, Saad B Omer, Joshua M Sharfstein, Arthur Caplan

Introduction

Many high-income countries have rapidly pivoted from hard decisions about who may receive COVID-19 vaccines, due to shortages, to equally hard decisions about who must receive them. As lasting containment of COVID-19 remains elusive, many nations—from Costa Rica, to Austria, to Turkmenistan—are turning to vaccination mandates of various kinds.[1] Mandates, however, are controversial in many countries. Austria's proposed mandate for adults, for example, provoked mass protests. Some objectors argue mandates represent undue encroachment on individual liberty. Some other objectors maintain that mandates will not be an effective policy for COVID-19 because many individuals will seek to evade them, and mandates might erode support for other public health measures such as mask wearing.

In this Viewpoint we consider the likely effectiveness of policies that require COVID-19 vaccines in improving vaccine uptake and reducing disease in the USA, in view of the evidence from past vaccination mandates and distinctive aspects of COVID-19. Two dimensions of effectiveness in improving uptake are relevant: (1) target-group effectiveness (the extent to which a mandate improves uptake of vaccines in the group covered by the policy) and (2) population effectiveness (the extent to which mandate policies improve vaccination coverage in the US population).

By vaccination mandate, we refer to requirements issued by government or private educational institutions or employers that condition access to an important benefit (typically school or employment) on having received a vaccine, unless an exemption applies. Exemptions can be available on religious or philosophical grounds; as legal matter, they must also be provided for valid medical contraindications. Compulsory vaccinations—requirements that carry civil or criminal penalties for non-compliance—are rare. We distinguish both mandatory and compulsory vaccination from policies that merely require unvaccinated individuals to submit to alternative measures to prevent spreading disease to others, such as undergoing testing for disease.

Evidence for the effectiveness of vaccination mandates

Substantial evidence shows that vaccination mandates in the USA performed well on both dimensions of effectiveness before the COVID-19 epidemic. Cross-state comparisons show that states' school-entry mandates (eg, for pertussis and measles) are effective in improving vaccination coverage among schoolchildren and greatly reduced disease outbreaks in the USA.[2,3] This has already led two states (California and Louisiana) and the District of Columbia to adopt COVID-19 vaccination mandates for schoolchildren.

The stringency and enforcement of school-entry mandates matter. States that have eliminated personal-belief or religious exemptions (while maintaining medical exemptions) have lower exemption rates and higher vaccination rates.[2,3] Further, outbreaks of vaccine-preventable disease have disproportionately occurred in areas with higher exemption rates.[2–4] Such evidence has prompted California, Connecticut, Maine, Mississippi, New York, Washington, and West Virginia to remove religious or personal-belief exemptions from some or all vaccination requirements.[5] Likewise, states that impose burdensome procedural requirements to obtain exemptions—such as counselling, annual reapplication, notarisation, or clergy attestation—have lower exemption rates and lower risk of disease outbreak.[2,3] Vaccination mandate laws with gaps or loopholes (eg, delayed effective date) have prompted strategic behaviour among vaccine objectors.[6] Mandate laws can also provoke controversy related to the specific targets of the vaccine. For example, the attempt to require adolescents to receive human papillomavirus vaccines following the first vaccine approval in 2006 sparked heated debate. Some people questioned requiring a vaccine for a virus that is not transmitted through casual contact, even though the virus can cause six different types of cancer. The perception that the vaccine manufacturer was involved in political efforts to adopt mandates created additional controversy.

Compared with childhood vaccination mandates, less evidence is available concerning mandates for adults. Many states and universities require college students to be up to date on meningitis and other vaccines, but there is little reliable information about how such requirements have affected vaccine uptake or disease outbreaks. Facility and state policies requiring influenza vaccination for health-care workers significantly increase vaccination rates, decrease inpatient influenza diagnoses, and reduce influenza mortality for long-term care residents and the general population.[7,8]

There are growing reports (albeit not systematic evaluations) that COVID-19 vaccination mandates for health-care workers, emergency first responders, federal workers, school staff, university students and staff, and other groups have garnered high levels of compliance.[9,10] Among US adults vaccinated from June to

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Stanford Law School (Prof M M Mello PhD), **Department of Health Policy** (Prof M M Mello), **Department of Epidemiology and Population Health** (Prof Y A Maldonado MD), **Department of Pediatrics** (Prof Y A Maldonado MD), **School of Medicine, Freeman Spogli Institute for International Studies** (Prof M M Mello), **and Stanford Internet Observatory** (R DiResta BS), **Stanford University, Stanford, CA, USA; Department of Pediatrics, University of Washington School of Medicine, Seattle, WA, USA** (Prof D J Opel MD); **Treuman Katz Center for Pediatric Bioethics, Seattle Children's Research Institute, Seattle, WA, USA** (Prof D J Opel); **Gulf States Health Policy Center, Bayou La Batre, AL, USA** (R M Benjamin MD); **Department of Health Policy and Management, School of Public Health, Texas A&M University, College Station, TX, USA** (T Callaghan PhD); **Yale Institute for Global Health and Department of Internal Medicine (Infectious Diseases), Yale School of Medicine** (J A Elharake MPH, Prof S B Omer PhD), **Center for Infectious Disease Modeling and Analysis** (Prof A P Galvani PhD), **Department of Health Policy and Management** (J L Schwartz PhD), **and Department of Epidemiology of Microbial Diseases** (Prof S B Omer), **Yale School of Public Health, New Haven, CT, USA; Yale School of Nursing, Orange, CT, USA** (Prof S B Omer); **Department of Obstetrics & Gynecology, Emory University, Atlanta, GA, USA** (Prof L C Flowers MD); **Institute for Vaccine Safety, Department**

of International Health (Prof D A Salmon PhD) and Department of Health Policy and Management (Prof J M Sharfstein MD), Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD, USA; Department of Health Behavior, Gillings School of Global Public Health and Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC, USA (Prof N T Brewer PhD); Department of Family and Community Health, School of Nursing, and Center for Health Incentives and Behavioral Economics, University of Pennsylvania, Philadelphia, PA, USA (A M Buttenheim PhD); School of Public Policy, University of California, Riverside, CA, USA (Prof R M Carpiano PhD); Clinton Foundation, New York, NY, USA (C Clinton DPhil); Clinton Health Access Initiative, Boston, MA, USA (C Clinton); Mailman School of Public Health, Columbia University, New York, NY, USA (C Clinton); Texas Children's Center for Vaccine Development, Departments of Pediatrics and Molecular Virology & Microbiology, National School of Tropical Medicine, Baylor College of Medicine, Houston, TX, USA (Prof P J Hotez MD); James A Baker III Institute for Public Policy, Rice University, Houston, TX, USA (Prof P J Hotez, R Lakshmanan MHA); Department of Biology, Baylor University, Waco, TX, USA (Prof P J Hotez); Hagler Institute for Advanced Study and Scowcroft Institute of International Affairs, Bush School of Government and Public Service, Texas A&M University, College Station, TX, USA (Prof P J Hotez); The Immunization Partnership, Houston, TX, USA (R Lakshmanan); Langone School of Medicine, New York University, New York, NY, USA (Prof A Caplan PhD)

Correspondence to: Prof Michelle M Mello, Stanford Law School, Stanford University, Stanford, CA 94305, USA
mmello@law.stanford.edu

September, 2021, 35% report that a major reason they got vaccinated was to participate in recreational activities that required proof of vaccination and 19% said their employer's requirement was a major reason.[11]

Considerations that might reduce the effectiveness of COVID-19 vaccination mandates

Several aspects of the COVID-19 pandemic create uncertainty as to whether COVID-19 vaccination mandates will produce outcomes as favourable as those of school-entry mandates for other vaccines, particularly for population-wide effectiveness.

Political polarisation and resistance

Resistance to COVID-19 vaccination mandates is markedly higher than for other vaccination mandates.[12] Political polarisation and propagation of vaccine scepticism by conservative media and political leaders have fostered anti-vaccine views among an unusually high proportion of the population in some areas of the country.[13] For both adults and children, this resistance jeopardises the target-group and population effectiveness of COVID-19 vaccination mandates. Further, government requirements could strengthen anti-vaccine sentiment generally,[14] add fuel to organised campaigns to roll back other mandates (which have already resulted in proposed legislation in some states), and reduce acceptance of other vaccines.

Another source of mandate resistance in the USA is the view that those who have been infected with the virus do not need vaccination, thereby making mandates less essential. Evidence suggests that the immunity produced by natural infection varies by individual, and that people with previous infection benefit from vaccination.[15] New variants further undercut the case for the adequacy of previous infection[16] (although they could also mean reduced vaccine effectiveness, at least until vaccines can be reformulated).

Differential adoption

Except for entities subject to federal regulation, COVID-19 vaccination mandates remain the responsibility of states, localities, and businesses. Ideological divides mean that mandates will be differentially adopted across the country. Areas with the lowest vaccination rates are least likely to mandate vaccination. Some states have adopted laws prohibiting some or all COVID-19 vaccination mandates.[17] This phenomenon does not affect target-group effectiveness, but does weaken the population effectiveness of mandates.

Enforceability

Some potential COVID-19 vaccination mandates would be challenging to enforce, undercutting both target-group and population effectiveness. No strong levers exist for enforcing a general-population mandate for adults. The main available mechanism—a civil fine—is regressive, would be very difficult to implement, and might intensify political opposition. College attendance, loans, and government benefits could be conditional on COVID-19 vaccination, but most people in the USA are not students. Many government benefits (eg, Medicaid coverage and unemployment benefits) support vulnerable populations. Withholding them could undercut pandemic control and health equity.

In contrast, employer-based vaccination requirements are relatively straightforward to enforce through adverse employment consequences. A few large US employers have terminated hundreds of workers for non-compliance.[18] Of course, employer-based mandates do not reach everyone. Moreover, employers' cooperation in enforcing them is not universal. Employers who disagree with vaccination requirements, face pushback from labour unions, or are unwilling to lose workers in a tight labour market might not insist on vaccination. Workforce concerns have led some school districts and correctional institutions to add a testing alternative to vaccination.

School-entry mandates rely on mechanisms (eg, administrative review of student registration data or completion of state reporting requirements) that function best at the start of the academic year. Imposing such mandates mid-year would mean that unvaccinated students could be moved to remote learning programmes or forced to find another district that is willing to accept them in the middle of a school grade—an undesirable prospect given the educational disruption children have already endured. This enforcement problem eases with the advent of a new academic year.

As to the ultimate impact of school mandates on COVID-19 spread, in areas with high vaccination coverage for adults and adolescents, the marginal reduction in cases from school mandates compared with voluntary vaccination coupled with universal mask wearing might be modest. Mandates for adults can help lessen the need for school-entry mandates by reducing community prevalence. However, as mask mandates are lifted and childhood COVID-19 vaccines receive full government approval, the case for adding COVID-19 to the list of vaccines required for school entry will strengthen. Full licensure, which requires submission of additional evidence of vaccine effectiveness and safety beyond the relatively small clinical trials supporting emergency use authorisation, is possible by the start of the 2022–23 academic year.

A final enforceability concern relates to legal challenges. COVID-19 vaccination mandates adopted by both public and private organisations are being heavily litigated, with the decisions issued to date sending confusing signals about their legality. On Jan 13, 2022, the Supreme Court invalidated a federal requirement that large employers mandate vaccines, adopting a surprisingly narrow view of federal authority, but upheld a federal mandate for health-care facility employees. Lower court decisions, too, have sent conflicting messages about legal requirements for

both federal and state mandates. Individuals and organisations subject to mandates could delay compliance in the belief that it will ultimately not be needed, thereby jeopardising target-group effectiveness. State and local governments and other organisations might not adopt mandates until the legal issues are resolved, reducing population effectiveness. Indeed, some employers pulled back from mandate plans in the wake of the Supreme Court decisions even though those decisions had no bearing on what private employers can require.

Safety evidence

Because safety is the main concern among people in the USA who have not yet been vaccinated against COVID-19,[19] the target-group effectiveness of vaccination mandates—and political support for adopting mandates—are closely linked to assuring the public that the vaccines are safe. Post-licensure safety data can improve confidence that the expected benefits of a vaccine outweigh its risks. During COVID-19, widespread administration in adults has quickly generated a large evidence base supporting the vaccines' safety, including evidence from active-surveillance studies.[20] Although initial signals of vaccine safety for children have been favourable, the evidence base is still evolving. Additional analyses on the risk of adverse events should be conducted using active-surveillance data before school-entry mandates are implemented.

Public communication of studies showing the vaccines' safety has been suboptimum. Media reports have given greater prominence to vaccines' association with specific adverse events than to their overall favourable benefit-to-risk ratio. These problems could reduce compliance with COVID-19 vaccination mandates in the absence of a concerted, sophisticated effort at public education.

Conclusions

COVID-19 vaccines have shown higher effectiveness in preventing infection with some variants than others, but their great value in preventing severe illness and death is clear.[21] Mandates can play a role in promoting uptake of these vaccines. Our review supports several specific conclusions.

First, abundant evidence shows that school-entry mandates have been highly effective in improving uptake of childhood vaccines. Second, the current evidence regarding the safety of COVID-19 vaccines in adults is sufficient to support mandates. Third, because of distinctive implementation challenges, the effectiveness of adult COVID-19 vaccination mandates in increasing vaccination uptake might be lower than the very high effectiveness of school-entry mandates observed for other vaccinations in the past. Therefore, mandate policies cannot be the only approach, especially given the ongoing legal uncertainties surrounding them. Fourth, COVID-19 vaccine requirements will probably be most effective when enforced by employers and educational institutions. Fifth, consideration of school-entry mandates should follow review of real-world safety data and full licensure of the vaccines for children, which could come as soon as the start of the 2022–23 school year.

Finally, active surveillance for adverse events following immunisation and clear, sophisticated communication of findings to the public are essential for effective vaccination policies, including mandates. Imposing mandates does not remove the need for effective messaging to overcome vaccine hesitancy. Giving appropriate emphasis to the major headline of the accreting vaccine safety studies—the vaccines are indeed safe—can create more fertile soil for vaccination mandates to take root.

Contributors

MMM wrote the first draft of the manuscript, following input from a writing group comprised of DJO, RMB, TC, RDR, JAE, LCF, APG, DAS, JLS. All authors provided critical intellectual content for revising the draft manuscript. MMM further revised the manuscript following peer review. All authors had full access to the information described in the manuscript.

Declaration of interests

PJH is a developer of a COVID-19 vaccine construct, which was licensed by Baylor College of Medicine to Biological E, a commercial vaccine manufacturer for scale-up, production, testing, and licensure. NTB reports personal fees from WHO, US national Centers for Disease Control and Prevention, and Merck outside the submitted work. RMC received research grant funding from Novo Nordisk Foundation, outside the submitted work. RL reports grants from Pfizer, GlaxoSmithKline, Sanofi Pasteur, and Merck, and personal fees from BIO and the Infectious Disease Prevention Network, outside the submitted work. YAM is a member of a data safety monitoring board for Pfizer and a site Principal Investigator for a Pfizer vaccine trial, outside the submitted work. MMM reports personal fees from law firms representing retail pharmacies and generic drug companies that have sued other drug companies for antitrust law violations, outside the submitted work, and served as an advisor to Verily Life Sciences on an app designed to facilitate safe return to work and school during the COVID-19 epidemic. DJO reports grants from the US National Institutes of Health, outside the submitted work. DAS reports grants from Merck and personal fees from Pfizer and Janssen, outside the submitted work. The other authors declare no competing interests.

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