VIEWPOINT

Mandating COVID-19 Vaccines

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Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines hold promise to control the pandemic and help restore normal social and economic life. The US Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for 2 messenger RNA vaccines and will likely issue full biologics licenses in the coming months. Anticipating vaccine scarcity, the Advisory Committee on Immunization Practice (ACIP) published guidance on vaccine priorities.

Data for the vaccines granted an EUA reportedly demonstrate 95% efficacy, but even highly effective vaccines cannot curb the pandemic without high population coverage and maintenance of other mitigation strategies. Recent data from 1676 adults surveyed November 30 to December 8, 2020, found that when a COVID-19 vaccine is approved and widely available: 34% would get it as soon as possible; 39% would wait; 9% would only get it if required for work or school; 15% would definitely not get it. Black persons, at high risk of infection and hospitalization, are less likely to report vaccine intent with only 20% reporting they would get the vaccine soon and 52% intending to wait.[1] Intent to vaccinate has changed substantially over time and is likely to continue to evolve. In this Viewpoint, we examine whether vaccine mandates would be lawful and ethical and whether they could boost vaccine uptake.

From EUAs to BLA Approvals

Mandating COVID-19 vaccines under an EUA is legally and ethically problematic. The act authorizing the FDA to issue EUAs requires the secretary of the Department of Health and Human Services (HHS) to specify whether individuals may refuse the vaccine and the consequences for refusal. Vaccine mandates are unjustified because an EUA requires less safety and efficacy data than full Biologics License Application (BLA) approval. Individuals would also likely distrust vaccine mandates under emergency use, viewing it as ongoing medical research.

Should SARS-CoV-2 Vaccines Be Mandatory?

Once SARS-CoV-2 vaccines receive a BLA, policy makers must determine to which, if any, populations mandates should apply. Vaccine mandates could be imposed in multiple sectors, each with their own legal and ethical considerations.

State Mandates | Since *Jacobson v Massachusetts* (1905), the judiciary has consistently upheld vaccination mandates. All states require childhood vaccines as a condition of school entry, which are demonstrated to maintain high coverage and prevent vaccine-preventable diseases.[2] All states grant medical exemptions, and 45 states and Washington, DC, grant religious exemptions, with 15 states also allowing philosophical exemptions. Vaccine exemptions often cluster geographically and socially and are associated with a higher risk of outbreaks. Strengthening the rigor of the application process and enforcement are associated with improved vaccination rates.[3] Adult vaccine mandates are rare, but at least 16 states require influenza or hepatitis B vaccinations for postsecondary education. Given the rarity of adult mandates, states are unlikely to enact mandatory COVID-19 vaccinations for the adult population, especially in the absence of long-term safety data.

Health Care Facilities | Health care workers are at increased risk of contracting infectious diseases and transmitting to vulnerable populations. Consequently, health care institutions must institute infection control protocols, and many require health care workers to receive the influenza vaccination. These institutions owe both legal and ethical duties to staff and patients to ensure a safe environment. Additionally, because vaccines prevent hospitalizations, their wide use in health care settings may reduce worker shortages. Even among health workers, however, SARS-CoV-2 vaccine mandates could be counterproductive, given the stress of working during a pandemic. Offering nonmedical exemptions could reduce health worker concerns over mandates.

Businesses | In a recent Yale CEO survey of 150 executives, 71% supported companies requiring COVID-19 vaccines.[4] The Equal Employment Opportunity Commission (EEOC) has ruled that businesses can compel employees to submit to SARS-CoV-2 tests as a condition of employment. Recently, the agency determined that employers can require COVID-19 vaccines and bar employees from the workplace if they refuse.[5] The Occupational Safety and Health Administration earlier issued guidance permitting employers to require influenza vaccinations. The EEOC, however, requires employers to grant medical exemptions and offer reasonable accommodations based on religion or disability.[6]

Businesses will rely on high vaccine coverage to facilitate a return to normal operating practices. Sectors ranging from food service and transportation to the arts and sports have been economically harmed by public health restrictions, as well as by consumer reluctance to risk SARS-CoV-2 exposure. In many settings, like meatpacking plants, there is high occupational risk of virus transmission. Businesses have an ethical and legal duty to keep their workers and customers safe. Thus, businesses that require in-person attendance, cater to vulnerable customers, or both may consider mandates with accommodations for medical, religious, or disability reasons.

Postsecondary Education | Colleges and universities will also need high vaccine coverage to safely reopen in-person learning. Sitting in a crowded classroom for long durations poses a high risk of transmission. Postsecondary institutions have often been loci for vaccination

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campaigns, and many have required influenza vaccines during the COVID-19 pandemic. It is foreseeable that institutions of higher education may require SARS-CoV-2 vaccines for students, faculty, and staff as part of fall 2021 reopening plans.

Primary and Secondary Education | Returning to in-person child education is a vital social goal, given rising achievement gaps between high- and low-income students as well as parental needs to return to the workforce. At-home schooling is suboptimal for student learning and can cause increased mental distress in households. There are also public health justifications for safely reopening schools. While COVID-19 is generally less severe among children, older children are a source of disease transmission. Teachers, moreover, are vulnerable to SARS-CoV-2, including serious disease. Requiring SARS-CoV-2 vaccines of schoolchildren and teachers and staff could enable students to safely return to in-person education.

School mandates for COVID-19 vaccines could occur, as an addition to ACIP-recommended childhood vaccinations. Yet mandates are not warranted until the FDA licenses a vaccine with reliable data on vaccine safety and efficacy among school-aged children. Even after phase 3 vaccine studies among children are completed and after full vaccine licensure is obtained, postmarketing safety monitoring is essential to fully characterize the risks. In 2006, the Association of Immunization Managers (AIM) advised, "School and child care immunization requirements must be used sparingly, approached cautiously, and considered only after an appropriate vaccine implementation period."[7] At that time, AIM also recommended broad public and professional support for any vaccine prior to implementing mandates. Costs and vaccine supplies must also be at acceptable levels.

Vaccination as a Condition of Service

Businesses have a duty to safeguard their customers and often impose safety precautions as a condition of providing services to customers. During the pandemic, many businesses have required masks and distancing for consumers. Even before the pandemic, customers could not enter certain premises in possession of a firearm or other hazardous substance. It is foreseeable that businesses in certain high-risk settings could require proof of vaccination as a condition of service, such as in long-distance travel (plane, rail, bus), restaurants, and entertainment (sports, movies, theater). While states might be constitutionally barred from requiring vaccines to participate in religious worship, it is conceivable that some churches, synagogues, or mosques might consider such conditions for congregants.

Local or state governments could also require vaccination as a condition of service. To ensure safety, research must first ascertain whether vaccines prevent infection or only prevent disease. The duration of immunity from vaccines is also unknown. Beyond gaps in scientific knowledge, so-called "immunity passports" face logistical challenges, including implementing a novel policy approach in the US. Any certification or immunity passport, moreover, should be explicit about what is being attested to and avoid guarantees of protection against COVID-19.[8] If scientific and logistical challenges can be overcome, linking vaccinations as a condition of providing service could be an effective incentive for vaccination.

Acceptance and Implementation

Legal mandates signal clear policy support for immunizations, which can also increase resources for a vaccine infrastructure. Yet mandates can undermine public support, creating a backlash and even reducing vaccine uptake. Mandates may be useful in the future, but their implementation among any population that does not widely support vaccination could be counterproductive. The purpose of risk communication is to inform decision-making, respecting individual choice. Mandates fundamentally alter this dynamic by overriding personal autonomy. Furthermore, although employers, health care, and educational institutions can monitor conformance with mandates, there are no clear mechanisms to enforce population-wide vaccination requirements.

Immunization coverage sufficient to achieve community immunity will reap enormous health, social, and economic benefits. Limited vaccine mandates with public support, in special high-risk or high-value settings, and with longer-term safety data can be part of a comprehensive package of interventions to return society to prepandemic life.

ARTICLE INFORMATION

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REFERENCES

1. Hamel L, Kirzinger A, Muñana C, Brodie M. KFF COVID-19 vaccine monitor. Kaiser Family Foundation. Posted December 15, 2020. Accessed December 16, 2020. https://www.kff.org/coronavirus-covid-19/report/kff-covid-19-vaccine-monitor-december-2020/

2. Centers for Disease Control and Prevention. State vaccination requirements. Last reviewed November 15, 2016. Accessed December 16, 2020. https://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html

3. Phadke VK, Bednarczyk RA, Salmon DA, Omer SB. Association between vaccine refusal and vaccine-preventable diseases in the United States. *JAMA*. 2016;315(11):1149-1158. doi:10.1001/jama.2016.1353

4. Virtual Yale CEO summit: finding common ground across a divided land. Yale School of Management. December 15, 2020. Accessed December 16, 2020. https://som.yale.edu/event/2020/12/virtual-yale-ceo-summit-finding-common-ground-across-divided-land-getting-your-workforce-shareholders-customers-and-communities-back-to-business

5. What you should know about COVID-19 and the ADA, the Rehabilitation Act, and other EEO Laws. December 16, 2020. Accessed December 19, 2020. https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=

6. Bellon T. US employers could mandate a COVID-19 vaccine, but are unlikely to do so–experts. Reuters. December 2, 2020. Accessed December 16, 2020. https://www.reuters.com/article/us-health-coronavirus-vaccine-companies/u-s-employers-could-mandate-a-covid-19-vaccine-but-are-unlikely-to-do-so-experts-idUSKBN28C2LL

7. Association of Immunization Managers. Position statement: school and child care immunization requirements. 2006. Accessed December 16, 2020. https://cdn.ymaws.com/www.immunizationmanagers.org/resource/resmgr/files/aimpositionstatement.pdf

8. Cash-Goldwasser S, Kardooni S, Cobb L, Bochner A, Bradford E, Shahpar C. Immunity passports. COVID-19 Science Review. Posted December 15, 2020. Accessed December 16, 2020. https://preventepidemics.org/covid19/science/weekly-science-review/december-5-11-2020/

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