



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



Is It Time for Coronavirus Disease-2019 Vaccine Mandates?

Henry H. Bernstein, DO, MHCM, FAAP¹, Veronica Valentine McNally, JD², and Walter A. Orenstein, MD, DSc (Hon)³

The coronavirus disease 2019 (COVID-19) pandemic continues, and we are not yet approaching herd (community) immunity in many parts of the country. The increased transmissibility of the delta (B.1.617.2) variant makes attaining the goal of herd immunity even harder, as it now is the dominant strain. Receipt of 2 doses of an mRNA vaccine appears to be highly protective against serious illness and death from the delta variant, but tens of millions of individuals have not yet received any doses, and millions more have missed their second dose. Unfortunately, increased transmissibility of the delta variant, coupled with pockets of low vaccination rates, has led to many healthcare systems being overwhelmed yet again. Vaccination protects not only the individual, but also the community in important ways. First, by reducing severe illness, vaccination decreases stress on healthcare systems, which can help hospitals avoid exceeding intensive care unit capacity and postponing care that is necessary but not urgent, such as pediatric well visits, cancer screenings, and elective surgeries. Second, vaccination has the potential to reduce transmission and indirectly protect persons who cannot be vaccinated or who may not make a protective immune response after vaccination (eg, immunocompromised). Thus, a decision by an individual to not get a vaccine not only increases the risk that individual will suffer from a vaccine-preventable disease but also increases the risk that other members of the community can be infected, especially those who cannot get vaccinated.

By September 2021, the American public had seen several COVID-19 vaccine mandates levied, including those imposed by the federal government, employers, and universities. President Biden issued a new set of mandates that covers millions of Americans, including all federal workers and contractors, companies with more than 100 employees, and facilities that receive Medicaid or Medicare funding. Previously, less-sweeping mandates included military members, some state government employees, health system employees at various institutions, more than 600 college communities, and employees at several high-profile private companies. Mandatory vaccination is not a novel concept and may be the most efficient way to protect the vulnerable population. However, the legal basis for vaccine mandates varies among the federal government, state governments, and private employers. The Public Health Service Act authorizes the Health and Human Services Secretary to adopt quarantine and isolation measures to prevent the spread of communicable disease among states, but it does not mention federal vaccine mandates specifically.

A court recently examined a private employer's authority to mandate the COVID-19 vaccine. The US District Court for the Southern District of Texas upheld a COVID-19 vaccine mandate as a condition of employment in a hospital system. In the Order on Dismissal, the Honorable Lynn Hughes wrote, "Methodist [the defendant] is trying to do their business of saving lives without giving them the COVID-19 virus. It is a choice made to keep staff, patients, and their families safer. [The plaintiff] can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else." The federal court cited the Equal Employment Opportunity Commission guidance issued in May 2021 regarding vaccine mandates, which permits an employer to require all employees physically entering a workplace to be vaccinated against COVID-19, subject to reasonable accommodations for a disability or a sincerely held religious belief. The Court appropriately noted that the guidance was not binding. Moreover, the Equal Employment Opportunity Commission opined only on the legal implications under federal discrimination laws, not on the overall legality of mandates.¹ The full licensure of COVID-19 vaccine(s) by the US Food and Drug Administration should not only increase individual uptake but could also make public mandates more legally and ethically justifiable.²

Since the US Supreme Court's holding in 1905 in *Jacobson v. Massachusetts*, states have had broad power to require immunization if vaccination is necessary to protect the public health or safety of the people. This century-old case focuses on a reasoned analysis of the overlap between individual and collective interests in public health. Indeed, all 50 states, the District of Columbia, and Puerto Rico have regulations requiring proof of immunization for child care and school attendance as a public health strategy to protect children in these settings and secondarily to serve as a mechanism to promote timely immunization of children.³ All laws have exemptions for medical reasons (ie, contraindications). Many have exemptions for religious beliefs, and some have exemptions for personal beliefs or both (<https://www.>

From the ¹Department of Pediatrics, Zucker School of Medicine at Hofstra/Northwell, Cohen Children's Medical Center, New Hyde Park, NY; ²Michigan State University College of Law, East Lansing, MI; and ³Emory University School of Medicine, Atlanta, GA

H.B. is the immediate past voting member of the Advisory Committee on Immunization Practices/Centers for Disease Control and Prevention (CDC); Editor - Office Pediatrics Series, *Current Opinion in Pediatrics*; Faculty, Masters Program in Healthcare Management/Harvard T. H. Chan School of Public Health; serves on the Data and Safety Monitoring Board of Takeda; and is the PI of a Breastfeeding Promotion grant, New York State Department of Health. V.M. is a voting member of the Advisory Committee on Immunization Practices/CDC and President of the Franny Strong Foundation. W.O. serves on the Scientific Advisory Board for Moderna.

0022-3476/\$ - see front matter. © 2021 Elsevier Inc. All rights reserved.
<https://doi.org/10.1016/j.jpeds.2021.11.023>

immunize.org/laws/laws-exemptions.asp). The fewer the types of nonmedical exemptions available or the more difficult they are to obtain, the greater the vaccine coverage.⁴

Requests for medical and religious exemptions in the workplace are not uncommon. Medical exemptions may require documentation from a physician who establishes that an individual has allergies to vaccine components, a history of Guillain-Barré syndrome, or other health ailments that heighten the individual's risk for vaccine-associated adverse events. When an employee raises a medical basis for an exemption, an employer is required to follow the interactive process outlined by the Americans with Disabilities Act, which includes recognizing an accommodation request, gathering information, exploring accommodation options, choosing accommodation, implementing the accommodation, and monitoring the accommodation. Employers must determine whether the employee has a qualifying disability under the Americans with Disabilities Act and whether an alternative accommodation can be offered.

Under Title VII of the Civil Rights Act of 1964, individuals have the right to be free from discrimination on the basis of religion. Some individuals object to vaccines on the basis of their "religion," which is broadly defined and includes not only organized religions, but also informal beliefs. "Religion" under the law can also encompass nontheistic and moral beliefs. For example, in one court case that examined a challenge to a hospital influenza vaccine requirement on the basis of a religious exemption, the court stated that in some circumstances veganism may constitute a sincerely held religious belief. The plaintiff in that case cited 29 C.F.R. § 1605.1, which states, "whether or not a practice or belief is religious is not an issue ... the Commission will define religious practices to include moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of religious views."⁵

Calling for the elimination of nonmedical exemptions from state school-entry immunization laws has merit and is appealing from a public health perspective. However, the reality of such regulations is subject to political influence and also faces substantial challenges on both legislative and judicial fronts.⁶ Some states are considering or have enacted legislation that would prohibit employers from mandating vaccinations or ban businesses from requiring proof of vaccine status. For example, Indiana Code § 16-39-11-5 prohibits the state or a local unit from issuing or requiring a COVID-19 "immunization passport." Nevertheless, Indiana University, a public institution, mandated vaccination for its students, faculty, and staff, and was sued by several students for its decision. The students alleged that the requirement violated their Fourteenth Amendment right to due process and Indiana Code § 16-39-11-5. The 7th US Circuit Court of Appeals upheld the Indiana district court judge's ruling that found that the university was acting reasonably "in pursuing public health and safety for its campus communities." The US Supreme Court declined review of the case. The colleges and universities that have imposed mandates include both public and private institutions.

Nine standard vaccine-, disease-, or implementation-related criteria intended to guide whether a COVID-19 vaccine for children should be mandated in schools have been suggested to help ensure getting such a decision right.⁷ Important considerations have been highlighted in a critique of this approach and the criteria for evaluating vaccines for inclusion in mandatory school immunization programs adopted by the Washington State Board of Health by illustrating how these criteria might be applied to the human papillomavirus vaccine.⁸ Frameworks combining epidemiologic, economic, and ethical concerns can help us better understand the tradeoffs between alternative immunization policies, thereby guiding us toward a course of action that best aligns with our fundamental values.⁹

Mandates clearly succeed in providing widespread protection against vaccine-preventable diseases. For example, vaccination rates among healthcare personnel who have reported a mandatory institutional requirement for annual influenza vaccination exceed 94% each year.¹⁰ In contrast, voluntary campaigns have resulted in drastically lower vaccination rates, ranging from 65% to 77%. Strict enforcement of immunization mandates is associated with lower disease incidence.¹¹

Providers also must continue to play significant roles in strengthening vaccine confidence. To protect our nation, we must empower families, in all communities and across generations, to feel confident in the decision to vaccinate.¹² Physician/provider support has been proposed as one of several critical elements that must be in place to support a school/childcare requirement for a vaccine.^{13,14} Providers are well positioned to counsel parents and families about the value of vaccination. Research supports how provider recommendation is the greatest predictor of vaccination uptake for some vaccines. Maternal influenza and tetanus, diphtheria, and acellular pertussis vaccination coverage rates reported as of April 2019 were 53.7% and 54.9%, respectively. Among women whose healthcare providers offered vaccination or provided referrals, 65.7% received influenza vaccine and 70.5% received tetanus, diphtheria, and acellular pertussis.¹⁵ In addition, a patient who receives a provider recommendation is 4 to 5 times more likely to receive the human papillomavirus vaccine.^{16,17} It is likely that provider recommendations will be similarly effective in increasing COVID-19 vaccine coverage. In a study that over-sampled Blacks and Latinos compared with the representation of the general US population, vaccine hesitant individuals were more likely to prefer a conversation with their doctor when being informed about vaccines compared with non-vaccine-hesitant participants; Black participants were more likely to prefer conversation than Latino or White participants.¹⁸ Further study will be crucial for our understanding of providers' roles in counseling patients and families in this new and specific context.

We also must ensure that reliable information is not drowned out by misinformation, educate key stakeholders about vaccines, and engage trusted local messengers to provide accurate information about vaccines.¹² Delivering strong

recommendations to patients to get vaccinated against COVID-19 makes all the difference in the fight to save lives. Persons who have a regular healthcare provider in essence trust their lives to that provider. Hence, a strong recommendation from their provider helps overcome vaccine hesitancy, often driven by complacency, convenience, and confidence. A well-informed practitioner who effectively addresses parental concerns and strongly supports the benefits of vaccination has enormous influence on parental vaccine acceptance.¹⁹ However, providers fail to lead by example if they recommend vaccination to their patients but do not require it of themselves. By failing to follow the recommendations and guidelines of the US Food and Drug Administration and Centers for Disease Control and Prevention including declining vaccination or administering COVID-19 vaccines off label, providers may fuel public distrust and fear of vaccines.

The pandemic is a reminder of the threat of infectious diseases. Vaccines are among the greatest public health achievements of the past century, leading to substantial reductions in morbidity and mortality.²⁰ Yet, vaccine hesitancy is a complex and growing challenge facing all of us. A strategic framework for strengthening vaccine confidence and preventing outbreaks of vaccine-preventable diseases in the US advances 3 key priorities: to protect communities, empower families, and stop myths.¹² Vaccine mandates coupled with provider recommendations are immensely effective strategies in doing just that to increase COVID-19 vaccination rates. ■

Reprint requests: Henry H. Bernstein, DO, MHCM, FAAP, 410 Lakeville Rd, Suite 311, New Hyde Park, NY 11042. E-mail: hbernstein@northwell.edu

References

1. Equal Employment Opportunity Commission. What you should know about COVID-19 and the ADA, the Rehabilitation Act, and other EEO laws. Accessed July 7, 2021. <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>
2. Gostin LO, Salmon DA, Larson HJ. Mandating COVID-19 vaccines. *JAMA* 2020;325:532-3.
3. AAP Committee on Practice and Ambulatory Medicine, AAP Committee on Infectious Diseases, AAP Committee on State Government Affairs, AAP Council on School Health, AAP Section on Administration and Practice Management. Medical versus nonmedical immunization exemptions for child care and school attendance. *Pediatrics* 2016;138:e20162145.
4. Bednarczyk RA, King AR, Lahijani A, Omer SB. Current landscape of nonmedical vaccination exemptions in the United States: impact of policy changes. *Expert Rev Vaccines* 2019;18:175-90.
5. *Chenzira v. Cincinnati Children's Hosp. Med. Ctr.*, NO. 1:11-CV-00917 (S.D. Ohio Dec. 27, 2012).
6. Goldstein N, Suder J, Bendistis B. The politics of eliminating non-medical vaccination exemptions. *Pediatrics* 2017;139:e20164248.
7. Opel DJ, Diekema DS, Friedman Ross L. Should we mandate a COVID-19 vaccine for children? *JAMA Pediatr* 2021;175:125-6.
8. Opel DJ, Diekema DS, Marcuse EK. A critique of criteria for evaluation vaccines for inclusion in mandatory school immunization programs. *Pediatrics* 2008;122:e504-10.
9. Feudtner C, Marcuse EK. Ethics and immunization policy: promoting dialogue to sustain consensus. *Pediatrics* 2001;107:1158-64.
10. Black CL, Yue X, Ball SW, Donahue SM, Izrael D, de Perio MA, et al., Centers for Disease Control and Prevention (CDC). Influenza vaccination coverage among health care personnel—United States, 2013-14 influenza season. *Morb Mortal Wkly Rep* 2014;63:805-11.
11. Orenstein WA, Hinman AR. The immunization system in the United States—the role of school immunization laws. *Vaccine* 1999;17:S19-24.
12. Mbaeyi S, Cohn A, Messonnier N. A call to action: strengthening vaccine confidence in the United States. *Pediatrics* 2020;145:e20200390.
13. Association of Immunization Managers. Position statement: school and child care immunization requirements. 2006. Accessed October 20, 2021. <https://cdn.ymaws.com/www.immunizationmanagers.org/resource/resmgr/files/aimpositionstatement.pdf>
14. Policies & Positions. Vaccinate Your Family. Accessed November 2, 2021. <https://vaccinateyourfamily.org/about-us/policies-positions/>
15. Lindley MC, Kahn KE, Bardenheier BH, D'Angelo DV, Dawood FS, Fink RV, et al. Vital signs: burden and prevention of influenza and pertussis among pregnant women and infants—United States. *Morb Mortal Wkly Rep* 2019;68:885-92. <https://doi.org/10.15585/mmwr.mm6840e1>
16. Ylitalo KR, Lee H, Mehta NK. Health care provider recommendation, human papillomavirus vaccination, and race/ethnicity in the US National Immunization Survey. *Am J Public Health* 2013;103:164-9. <https://doi.org/10.2105/AJPH.2011.300600>
17. Lau M, Lin H, Flores G. Factors associated with human papillomavirus vaccine-series initiation and healthcare provider recommendation in US adolescent females: 2007 National Survey of Children's Health. *Vaccine* 2012;30:3112-8.
18. Fisher KA, Nguyen N, Crawford S, Fouayzi H, Singh S, Mazor KM. Preferences for COVID-19 vaccination information and location: associations with vaccine hesitancy, race and ethnicity. *Vaccine* 2021;39:6591-4.
19. Edwards KM, Hackell JM, AAP The Committee on Infectious Diseases, the Committee on Practice and Ambulatory Medicine. Countering vaccine hesitancy. *Pediatrics* 2016;138:e20162146.
20. Centers for Disease Control and Prevention (CDC). Ten great public health achievements—United States, 2001-2010. *MMWR Morb Mortal Wkly Rep* 2011;60:619-23.