

VIEWPOINT

Should We Mandate a COVID-19 Vaccine for Children?

**Douglas J. Opel,
MD, MPH**

Department of
Pediatrics, University of
Washington School of
Medicine, Seattle.

**Douglas S. Diekema,
MD, MPH**

Department of
Pediatrics, University of
Washington School of
Medicine, Seattle.

**Lainie Friedman Ross,
MD, PhD**

Department of
Pediatrics, The
University of Chicago,
Chicago, Illinois; and
MacLean Center for
Clinical Medical Ethics,
The University of
Chicago, Chicago,
Illinois.

Corresponding

Author: Lainie
Friedman Ross, MD,
PhD, Department of
Pediatrics, The
University of Chicago,
5841 S Maryland Ave,
Mail Code 6082,
Chicago, IL 60615
(lross@uchicago.edu).

jamapediatrics.com

The zeal to develop and implement a vaccine to prevent coronavirus disease 2019 (COVID-19) infection has been exceptional. Operation Warp Speed, the Trump administration's proposal, seeks to produce hundreds of millions of doses of a vaccine by January 2021. Recent polls show as many as 70% of adults in the United States plan to get vaccinated against COVID-19 once a vaccine is available.¹ And thousands of adults have registered to participate as volunteers in human challenge trials to speed up the development of a new vaccine.²

We anticipate that this fervor will eventually lead to discussions about making a COVID-19 vaccine mandatory. An obvious group to target for mandatory vaccination is children. Not only do we already mandate several vaccines for them to attend school, but strategies to reopen schools or keep them open may be predicated on it.

Some might suggest the current US approach to influenza vaccine should inform our approach to a COVID-19 vaccine: no states require influenza vaccination for children to attend school. The analogy is understandable because the virus that causes COVID-19, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is a respiratory virus transmitted by human contact, with the most common symptoms being cough and fever. In fact, President Trump compared COVID-19 to influenza, and many Americans believe that COVID-19 is like influenza.

However, there are important differences between SARS-CoV-2 and influenza viruses, and these differences can lead to very different conclusions about whether and for whom the administration of a COVID-19 vaccine should be required. One important difference is the role of children in transmission of disease. Children play a central role in the spread of influenza, sometimes with life-threatening consequences for seniors and others. However, initial reports suggest children transmit SARS-CoV-2 less easily than the influenza virus.³ Although there is much more to understand regarding the role of children in the transmission of SARS-CoV-2, it would be more difficult to justify requiring a COVID-19 vaccine in children for a disease that appears to be mild in most children, particularly if children play a minimal role in spreading the infection to others.

On the other hand, SARS-CoV-2 appears to spread more efficiently than influenza. The number of others to whom an infected person would spread the disease if he or she were placed in a totally susceptible population (ie, the reproduction number [R_0]) is approximately 1 for the influenza virus. For SARS-CoV-2, the R_0 is 2 to 2.5.⁴

It is easier to make the case for mandating a vaccine for an infectious agent with a higher R_0 because the higher the R_0 , the more individuals with immunity will be needed to prevent spread of disease, and a vaccine

mandate may be the only way to achieve the high herd immunity threshold needed to provide wide community protection. Consider the measles virus. It has an R_0 of 12 to 18; as a result, approximately 92% to 94% of the population must be immune to prevent spread. This has been achieved by requiring 2 doses of measles vaccine for children in all states before enrollment in school, with only very limited ways to opt out.

Rather than resort to analogies, we can use 9 standard criteria that can help guide whether a COVID-19 vaccine for children should be mandated (**Box**).^{5,6} These criteria can be divided into 3 categories: 4 criteria related to the vaccine, 2 related to the disease, and 3 related to implementation. Ordinarily, each of these criteria would be considered in determining whether a vaccine should be mandated for children, although the weight given to each criterion may differ. In times of great public health need, such as the present pandemic, however, we propose that each criterion continue to be evaluated in making vaccine policy, but 5 criteria should be prioritized.

The criterion that should be prioritized over all others is the first: there must be evidence that a COVID-19 vaccine is safe for children with an acceptable level of risk. Fulfilling this criterion normally requires both prelicensure safety data and data from postlicensure studies to monitor for adverse effects after the vaccine has been administered to many people. Accumulation of the data needed to fulfill this criterion often requires years of research.

It would be a mistake to consider making a COVID-19 vaccine mandatory without these data. Vaccine safety is fundamental to maintaining the public's trust in vaccines, and skirting this safety criterion could have far-reaching consequences. Although less stringent safety benchmarks may be used to justify emergency or voluntary uses of a COVID-19 vaccine, it is imperative that any policy mandating use of a COVID-19 vaccine follow the fullest assessment of its safety. As such, this first criterion should function more as a precondition rather than a consideration that can be weighed against other criteria.

There are 4 other criteria to prioritize in considering whether to make a COVID-19 vaccine mandatory for children. First, the burden of COVID-19 disease ought to be substantial in at least a subset of the population (fifth criterion). This criterion has already been met. Second, vaccinating children should reduce the risk of transmission of disease (sixth criterion). Fundamental to any mandatory vaccine policy involving children is that increasing the proportion who are immune prevents disease in others. This criterion, however, relies on the role of children in person-to-person transmission of SARS-CoV-2, which is still poorly understood. Third, the COVID-19 vaccine must also be effective in protecting a child from the disease (second criterion). It need not be 100% effective, but a COVID-19 vaccine should have effectiveness

Box. Criteria to Consider When Evaluating Antigens for Inclusion in Mandatory School Immunization Programs

1. *Vaccine related:* Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of adverse effects.
2. *Vaccine related:* The antigen is effective as measured by immunogenicity and population-based prevention.
3. *Vaccine related:* The vaccine containing this antigen is as cost-effective from a societal perspective as other vaccines used to prevent disease.
4. *Vaccine related:* The vaccine containing this antigen should bear some relationship to increasing safety in the school environment.
5. *Disease related:* The vaccine containing this antigen prevents disease(s) with significant morbidity and/or mortality in at least some subset of the population.^a
6. *Disease related:* Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.^b
7. *Implementation related:* The vaccine is acceptable to the medical community and the public.
8. *Implementation related:* The administrative burdens of delivery and tracking of vaccine containing this antigen(s) are reasonable.
9. *Implementation related:* The burden of adherence for the vaccine containing this antigen is reasonable for the parent/caregiver.

^a Adapted from Washington State Board of Health, Immunization Advisory Committee.⁵

^b Adapted from Opel et al.⁶

comparable with that of other vaccines we currently require for children. We do not yet know the effectiveness of a COVID-19 vaccine. Fourth, because the benefit of a COVID-19 vaccine will largely accrue to high-risk adults, rather than children, it should not be burdensome for a child or, more accurately, a child's parent or guardian, to comply with the vaccine mandate (ninth criterion). This means a mandated vaccine must be widely available, easily accessible, and affordable to all.

How these 4 criteria will be prioritized depends on our evolving knowledge of the candidate vaccine as well as the disease. For instance, if it becomes clear that the likelihood and magnitude of harm from COVID-19 are greater in children, which may be the case with our emerging understanding of multisystem inflammatory syndrome in children,⁷ it would be justifiable to prioritize vaccine effectiveness in mitigating those harms (second criterion) over disease transmission (sixth criterion) and burden of adherence (ninth criterion) in considering whether to mandate a COVID-19 vaccine. Alternatively, if the prevalence and severity of disease in children remain minimal, the ninth criterion should arguably be prioritized to minimize the burdens of the mandate on children, since the benefits of the mandate to children would also be minimal.

Nevertheless, with these criteria as a framework, the only logical conclusion is that we currently know too little about the performance of any of the candidate COVID-19 vaccines or the epidemiology of SARS-CoV-2 in children to make any firm judgments about whether a COVID-19 vaccine should be mandatory in children. Yet, it is not too early to begin integrating these criteria into our planning to help ensure we get this decision right. Our nation's children deserve as much.

ARTICLE INFORMATION

Published Online: September 14, 2020.
doi:10.1001/jamapediatrics.2020.3019

Conflict of Interest Disclosures: Dr Opel reported receiving grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Agency for Healthcare Research and Quality. No other disclosures were reported.

REFERENCES

1. Goldstein A, Clement S. 7 in 10 Americans would be likely to get a coronavirus vaccine, Post-ABC poll finds. *Washington Post*. Published June 2, 2020. Accessed August 6, 2020. https://www.washingtonpost.com/health/7-in-10-americans-would-be-likely-to-get-a-coronavirus-vaccine-a-post-abc-poll-finds/2020/06/01/4d1f8f68-a429-11ea-bb20-ebf0921f3bbd_story.html
2. COVID-19 human challenge trials. 1DaySooner. Accessed August 6, 2020. <https://1daysooner.org/>
3. Danis K, Epaulard O, Bénét T, et al; Investigation Team. Cluster of coronavirus disease 2019 (COVID-19) in the French Alps, 2020. *Clin Infect Dis*. 2020;71(15):825-832. doi:10.1093/cid/ciaa424
4. Riou J, Althaus CL. Pattern of early human-to-human transmission of Wuhan 2019 novel coronavirus (2019-nCoV), December 2019 to January 2020. *Euro Surveill*. 2020;25(4):2000058. doi:10.2807/1560-7917.ES.2020.25.4.2000058
5. Washington State Board of Health, Immunization Advisory Committee. Criteria for reviewing antigens for potential inclusion in WAC 246-100-166. <https://sboh.wa.gov/Portals/7/Doc/Publications/ImmunizationCriteria-Update2017-Final.pdf>
6. Opel DJ, Diekema DS, Marcuse EK. A critique of criteria for evaluating vaccines for inclusion in mandatory school immunization programs. *Pediatrics*. 2008;122(2):e504-e510. doi:10.1542/peds.2007-3218
7. Verdoni L, Mazza A, Gervasoni A, et al. An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study. *Lancet*. 2020;395(10239):1771-1778. doi:10.1016/S0140-6736(20)31103-X