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Perspective

Ensuring Uptake of Vaccines against SARS-CoV-2

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As Covid-19 continues to exact a heavy toll, development of a vaccine appears the most promising means of restoring normalcy to civil life. Perhaps no scientific breakthrough is more eagerly anticipated. But bringing a vaccine to market is only half the challenge; also critical is ensuring a high enough vaccination rate to achieve herd immunity. Concerningly, a recent poll found that only 49% of Americans planned to get vaccinated against SARS-CoV-2.[1]

One option for increasing vaccine uptake is to require it. Mandatory vaccination has proven effective in ensuring high childhood immunization rates in many high-income countries. However, except for influenza vaccination of health care workers, mandates have not been widely used for adults.

Although a vaccine remains months to years away, developing a policy strategy to ensure uptake takes time. We offer a framework that states can apply now to help ensure uptake of the vaccine when it becomes available — including consideration of when a mandate might become appropriate. Our approach is guided by lessons from U.S. experiences with vaccines for the 1976 "swine flu," H1N1 influenza, smallpox, and human papillomavirus (HPV).

We believe that six substantive criteria should be met before a state imposes a SARS-CoV-2 vaccine mandate (see box). The first is the existence of evidence that Covid-19 is inadequately controlled in the state by other measures, such as testing, contact tracing, and isolation and quarantine — as indicated by sustained, troubling trends in new cases, hospitalizations, or deaths. Principles of public health law and ethics require that interventions that impinge on autonomy be reasonable and necessary; therefore, Covid-19 must present an ongoing threat. By the time a vaccine is available, more will be known about natural immunity in the population, the consequences of relaxing community mitigation measures, and the feasibility of scaling up test-and-trace strategies. There should be a reasonable indication as to whether further measures are needed.

The second criterion is that the Advisory Committee on Immunization Practices (ACIP), after reviewing the safety and efficacy evidence, has recommended vaccination for the persons who would be covered by a mandate. Currently available evidence suggests that the elderly, health professionals working in high-risk situations or working with high-risk patients (e.g., nursing home residents and patients with severe respiratory symptoms), and persons with certain underlying medical conditions may be high-priority groups for the ACIP's consideration, along with other

Six Trigger Criteria for State Covid-19 Vaccination Mandates.

- Covid-19 is not adequately contained in the state.
- The Advisory Committee on Immunization Practices has recommended vaccination for the groups for which a mandate is being considered.
- The supply of vaccine is sufficient to cover the population groups for which a mandate is being considered.
- Available evidence about the safety and efficacy of the vaccine has been transparently communicated.
- The state has created infrastructure to provide access to vaccination without financial or logistic barriers, compensation to workers who have adverse effects from a required vaccine, and real-time surveillance of vaccine side effects.
- In a time-limited evaluation, voluntary uptake of the vaccine among high-priority groups has fallen short of the level required to prevent epidemic spread.

workers with frequent, close, on-the-job contacts and persons living in high-density settings such as prisons and dormitories. When a vaccine nears approval, the ACIP should review the updated evidence and develop recommendations. Only recommended groups should be considered for a vaccination mandate, though health officials can encourage voluntary uptake for others, using means such as public education campaigns and free vaccination.

The fact that a vaccine has received Food and Drug Administration (FDA) approval — whether under an Emergency Use Authorization (EUA) or ordinary review processes — is an insufficient basis on which to conclude that it should be required. FDA approval reflects a determination that clinical trial evidence shows that the benefits of a vaccine outweigh its risks. ACIP recommendations reflect broader considerations, including values and preferences of affected groups, implementation issues, and health economic analyses. Overweighting FDA decisions would be particularly problematic for SARS-CoV-2 vaccines because EUAs may be based on very limited evidence and consciously or unconsciously influenced by the intense pressure to speed countermeasures to market.[2]

The third criterion is that there is an adequate supply of vaccine to cover the groups for which a mandate is being considered. Initially, global demand for SARS-CoV-2 vaccines will outstrip supply, making the salient question not who must get them but who will be granted access to them. New York State's unsuccessful attempt to mandate H1N1 influenza vaccination for health care workers demonstrates that imposing requirements before adequate supply has been secured needlessly provokes controversy and alienates people who have already made sacrifices to fight an epidemic.[3]

The fourth criterion is that there has been transparent communication of the best available evidence about the vaccine's safety and efficacy.[4] Particularly given the possibility that the evidence underlying FDA approval of SARS-CoV-2 vaccines may be more modest than usual, policymakers and the public will need to understand the limits of what is known. Public trust has already been compromised by federal officials' endorsement of hydroxychloroquine as a Covid-19 treatment without evidentiary support; the same must not occur for vaccines.

The fifth criterion is that the government has put in place certain support mechanisms for persons required to receive the vaccine. Lessons from past vaccination campaigns suggest that a generous compensation program for people who have serious vaccine side effects should be a centerpiece of these efforts. A federal compensation fund like the Smallpox Vaccine Injury Compensation Program is one attractive model, although identifying compensable injuries may be challenging with a novel vaccine. States will also have to create distribution systems to provide SARS-CoV-2 vaccine to high-priority groups with near-zero financial and logistic barriers — for example, bringing free vaccine to points of care, pharmacies, and work sites. It is equally critical to have a safety-assessment plan in place before vaccines are widely distributed to enable health officials to evaluate safety evidence in real time. States should work with health systems to ensure that reporting systems for vaccine-related adverse events are consistently used and specify a process for reconsidering mandate decisions as evidence evolves.

The last criterion is that vaccination mandates are imposed only after a time-limited trial of voluntary vaccine provision has proved unsuccessful. Principles of public health ethics support trying less burdensome policies before moving to more burdensome ones whenever possible. In this case, the costs of a failed voluntary scheme are sufficiently high that the attempt should be limited to a matter of weeks. States should implement a system for measuring vaccine uptake within each high-priority group against a set of coverage targets. Ensuring that the economic and logistic supports described above are in place will maximize the chances for success.

If the proposed trigger criteria were met, what might a vaccination mandate look like? Because the constitutional power to protect public health rests primarily with states, each state will need to adopt its own legislation. Proposed legislation should be supported by attestations from the state health officer, the ACIP, or another expert committee that all trigger criteria have been met. Targeted SARS-CoV-2 vaccination mandate policies may also be appropriate in certain federal contexts, including high-risk groups in active-duty military environments, Veterans Affairs facilities, federal prisons, and immigration detention centers.

Although state vaccination mandates are usually tied to school and day care entry, that approach is not appropriate for SARS-CoV-2 because children won't be a high-priority group. In addition, state mandates should not be structured as compulsory vaccination (absolute requirements); instead, noncompliance should incur a penalty. Nevertheless, because of the infectiousness and dangerousness of the virus, relatively substantive penalties could be justified, including employment suspension or stay-at-home orders for persons in designated high-priority groups who refuse vaccination. Neither fines nor criminal penalties should be used, however; fines disadvantage the poor, and criminal penalties invite legal challenges on procedural due-process grounds. Both are bad public health policy for a Covid-19 vaccine because they may stoke distrust without improving uptake.

The need to build public trust requires that state officials implement vaccination policy through a transparent and inclusive process, working closely with stakeholder groups such as local health officers, health professional and hospital associations, representatives of high-risk population groups, and groups concerned about vaccine safety. States' experience with HPV vaccination mandates offers another process tip: vaccine manufacturers should stay on the sidelines. The HPV vaccine manufacturer's direct involvement in crafting and lobbying for mandate legislation raised suspicion that profit rather than public health motives lay behind such proposals, undercutting support for vaccination even without a mandatory regime.[5]

As with social distancing orders, we can expect that the advent of SARS-CoV-2 vaccines will spark intense clashes of feeling about what people owe to one another in the fight against the pandemic. In contrast to earlier phases of the pandemic, though, we currently have some time on our side. Careful deliberation now about state vaccination policy can help ensure that we have a strategy when the breakthrough comes.

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