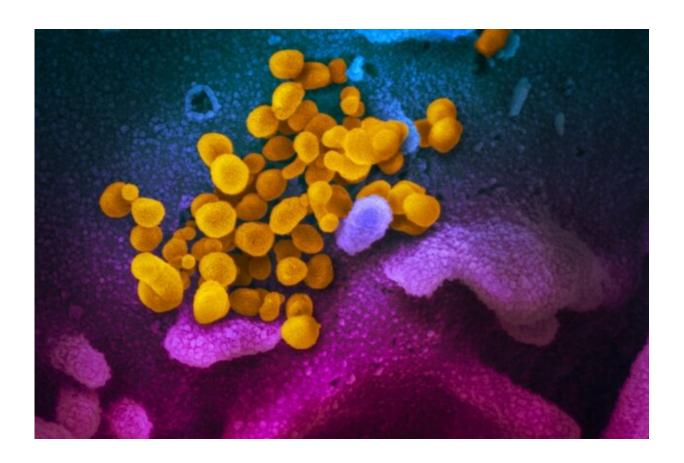


Which workers will be required to get a coronavirus vaccine when it's available?

August 13 2020, by Laura Bailey



This scanning electron microscope image shows SARS-CoV-2 (yellow)—also known as 2019-nCoV, the virus that causes COVID-19—isolated from a patient, emerging from the surface of cells (blue/pink) cultured in the lab. Credit: NIAID-RML

Vaccine confidence is historically low in the United States, yet some



workers are required to show proof of vaccination as a condition of employment. What does this mean for health care employees, and for other essential and non-essential workers, if a coronavirus vaccine is developed?

Sheria Robinson-Lane, assistant professor and gerontologist with expertise in <u>palliative care</u>, long-term care and nursing administration in the School of Nursing; Samuel Bagenstos, the Frank G. Millard Professor of Law; and Jason Pogue, clinical professor of pharmacy, address the topic of mandatory vaccines and <u>vaccine safety</u>.

Can employers legally force health care workers to show proof of certain vaccines as a condition of employment?

Robinson-Lane: Yes they can. What will likely happen is that the vaccination will become a federal regulatory requirement for facilities that receive Medicare and Medicaid funding. They currently are requiring weekly staff testing.

Generally, anyone with direct contact with patients would be required to be vaccinated, so this would include nurses, nursing assistants and activity staff. Housekeeping staff is in and out of rooms so they would be included in these measures as well.

Mandatory vaccines have been required for <u>health care workers</u> for a long time. Nursing students must show proof of childhood vaccines or obtain blood titers to show developed immunity prior to being allowed into the clinical setting and ultimately obtaining a license. Though not a vaccine, prior to the national tuberculin shortage, health care workers in facilities were tested upon hire and annually for tuberculosis. There were only a few exceptions in testing.



Currently, an annual flu vaccine is required. Some facilities will allow for employees to opt out of the vaccine and wear a face mask for the duration of flu season, generally October through March. There is generally not a whole lot these employees can do, if they don't have a medical issue that makes it contraindicated. If you want to work, you get vaccinated. The adults cared for in the facilities are very vulnerable to respiratory infections such as cold, flu and <u>coronavirus</u> so these measures are necessary to keep them safe.

Can employers legally force other essential employees, or even nonessential workers, to get a COVID vaccine if one becomes available?

Robinson-Lane: I don't know about all essential workers. It might be highly recommended, but I can't really see the local grocer or internet service provider mandating the COVID-19 vaccine for their employees. However, I do think that it is realistic for health care workers to see a vaccine mandate in their future if they provide direct care.

Bagenstos: Maybe. Under the Americans with Disabilities Act, an employer may require a vaccination only when doing so is "job-related and consistent with business necessity." Whether an employer may require a vaccination thus will turn on such questions as: (a) whether state governments require workers to be vaccinated, (b) whether the employee works in a particularly high-risk setting and (c) the effectiveness of the vaccine. And an employer will be required to provide reasonable accommodations to workers who have medical conditions that make them unable to take the vaccine. Those accommodations might include reassignment to a job where there is less risk of transmission of the virus.

What concerns do employees in nursing homes and



skilled nursing facilities have regarding a potential COVID vaccine mandate?

Robinson-Lane: Many of the essential workers that are caring for older adults in nursing homes and rehabilitation facilities identify as Black, Indigenous or other persons of color. There is still quite a bit of medical and pharmaceutical mistrust amongst these communities and there is a general concern that these vaccines have not or will not be tested very well before they are required to take them. Workers don't want to be anyone's "guinea pig." I think what has heightened fears amongst these groups is the initial virus response which left many facilities struggling to find enough PPE for staff and develop improved infection control policies, along with changing regulatory guidelines that take into consideration access to supplies, like N95 masks, and not just safety.

What steps does the FDA take to ensure a vaccine is safe for the public?

Pogue: The process for developing any vaccine comes in three phases of human testing. Phase 1 is largely a dose ranging and safety study. It is done in a small number of healthy patients to make sure that there is an immune response (we develop antibodies) and that there is no obvious safety concern. Phase 2 ramps this up in a larger population. Phase 3 is what we have recently entered. These are much larger studies with the dosing regimen that was fine-tuned in the previous phases. Because of the size of this study, we are able to further ensure the safety of the vaccine, as well as understand how well it works at actually preventing disease (it is one thing to develop antibodies, it is another to see if production of those antibodies leads to disease prevention).

In addition to getting a better understanding of the frequency of common adverse events (fever, injection site pain, "flu-like symptoms"), by



enrolling such a large number of patients in these studies we can identify if there are any rare, but serious, adverse events of concern. This safety information is then combined with the data on effectiveness of the vaccine in preventing disease and used by the FDA to determine whether or not to approve the vaccine for use. Therefore, whether the vaccine comes from the U.S. or overseas, these same types of data from Phase 3 (and Phase 1 and 2) will be used to make the decision.

How is safety enforced in the states if the vaccine is developed overseas?

Pogue: The FDA would still have to approve for use in Americans a <u>vaccine</u> developed elsewhere.

Provided by University of Michigan

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