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## **GUEST ESSAY**

## **Do You Need Another Covid Shot?**

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## By Céline Gounder, John P. Moore and Carlos del Rio

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The spread of Delta and rising reports of breakthrough infections raise questions about whether the vaccinated might need a "booster" dose. For Americans who received the Pfizer or Moderna mRNA vaccines, that may mean a third shot. For people who got the Johnson & Johnson vaccine, that could mean a second dose of the same vaccine or even an mRNA shot instead.

Some places are already providing additional doses. The San Francisco Department of Public Health is allowing people who got the Johnson & Johnson vaccine to get another dose. Countries like Britain, France, Israel and Germany are giving additional doses to certain groups, like older people and those who have compromised immune systems.

We think "booster" isn't the right terminology to describe these additional doses because, for many people, the word might imply yearly booster shots, as are given for the flu. We do not believe that everyone will need yearly Covid-19 vaccinations. The crucial questions are whether people are getting the right dosage of vaccine for the best protection and whether multiple doses are better than one?

These are the questions on which scientists should be focusing their research, and the public should be prepared for vaccination guidelines to shift with that science.

Here's why. The only vaccine people receive as a single dose is for yellow fever. People get two doses of vaccines for measles-mumps-rubella, chickenpox, hepatitis A, meningitis and human papillomavirus. They get three or more doses of the polio and diphtheria-tetanus-pertussis vaccines. In adults, we mix and match two types of pneumonia vaccines.

So why was there such early confidence in a single, low dose of the Johnson & Johnson

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## vaccine?

The intentions behind developing a one-dose Covid-19 vaccine were noble. Such a vaccine not only simplifies logistics, but it's also more equitable because many people find it much easier to schedule a one-time appointment. But as variants like Delta emerge, there are questions among scientists around whether a single dose will be sufficient for everyone over the long term. It's not clear from the data so far, but it's likely that certain groups who received the Johnson & Johnson vaccine will need more than the single dose.

Johnson & Johnson has already been studying different dosages of its vaccine, including comparing a low dose versus a high dose and a single-dose regimen versus a two-dose regimen in a late-stage trial, with results expected soon. That new data may change how the Johnson & Johnson vaccine is administered in the future. Animal and human studies of the vaccine have shown that two doses provide stronger immune responses than a single dose.

Other Covid-19 vaccines that use the same technology as Johnson & Johnson, like the Oxford-AstraZeneca vaccine and Sputnik V vaccine, were rolled out as two-dose vaccines from the start.

One of the reasons for making vaccines with multiple doses is that the immune system recognizes repeat exposures as an increased threat, which can help the body strengthen its ability to fight an invader. That's why a standard, old-school vaccine regimen is often to administer doses at around one, three and six months.

When the Food and Drug Administration granted emergency-use authorizations for the Pfizer, Moderna and Johnson & Johnson vaccines, it went with the dosing that was tested by the companies in the late-stage clinical trials. But as the F.D.A. evaluates these vaccines for full approval, it should determine the best dosing regimen to recommend. That calculation has become more complicated. Now, the F.D.A. must assess whether people who received Johnson & Johnson may need a second dose of a Pfizer or Moderna vaccine, and whether people who got the mRNA vaccines might one day need a third dose to protect against the Delta and other variants — and if so, which people?

While there are reports of infections after vaccination with all the vaccines, severe disease — in which people end up hospitalized or dead — is very rare. Most cases of severe disease after vaccination involve elderly nursing home residents who have been infected by unvaccinated staff. Right now, it makes more sense to vaccinate more nursing home staff than to give the elderly more doses, but additional doses might be needed at some point.

Severely immunocompromised people — such as organ transplant recipients — also have weaker responses to vaccination, and studies show that a third dose of an mRNA vaccine (like the vaccines from Pfizer or Moderna) can increase their protection against the coronavirus. The F.D.A. could recommend additional doses for high-risk groups that could benefit most.

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And high-risk people who haven't been vaccinated yet may need to start on the new dosing regimen, if that's determined to be the best approach. We hope the F.D.A. will make this clear. Reporting suggests that the agency may have a plan for follow-up shots by early September, and that it is hurrying efforts to authorize extra doses for Americans with weakened immune systems.

Once the F.D.A. fully approves the Covid-19 vaccines, health care providers and public health agencies would be free to recommend additional doses for off-label use. However, giving additional shots to already vaccinated persons must not come at the expense of doses going to the unvaccinated and most vulnerable, which would save the most lives. Only 0.3 percent of all vaccine doses have been administered in low-income countries.

Because of this, the World Health Organization has called for a temporary moratorium on the use of additional Covid-19 shots for the vaccinated in wealthy countries, arguing that the focus should be on getting first doses to countries that remain unable to protect health care workers and older adults. We agree.

Making sure all people worldwide have vaccine access should be the highest priority, because population immunity is the best way to protect individuals, too. Only then should additional doses be given to already vaccinated people. But we should be prepared to accept that some groups may eventually need an additional dose for full protection.

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