



COVID-19 Vaccine Guidance for People with Special Health Circumstances

Updated July 8, 2021

COVID-19, the disease caused by SARS-CoV-2, continues to affect people across the United States. COVID-19 is a preventable and treatable disease. Widespread vaccination has played an important role in decreasing spread across Rhode Island.

The Rhode Island Department of Health (RIDOH) is increasingly getting questions about vaccinating people with special health circumstances, such as people who are immunocompromised. The purpose of this guidance is to offer perspective while respecting the importance of an individual physician-patient relationship.

Vaccinating patients who are immunocompromised with a third dose of a COVID-19 messenger RNA (mRNA) vaccine, either Pfizer or Moderna

The current CDC recommendations for Moderna and Pfizer vaccines include a two-dose series. RIDOH has received questions about patients who are significantly immunocompromised and whether they should receive a third dose of either the Pfizer or Moderna vaccine for protective immunity. Some providers have obtained Sars-CoV-2 antibody levels in these patients and are concerned when their results do not detect antibodies.

During phase 3 clinical trials, measuring symptomatic disease was a clinical endpoint, not measuring serum antibodies. It's therefore not clear that having measurable serum antibodies clinically equates to protective immunity or, conversely, that the absence of measurable serum antibodies reflects inadequate immunity.

RIDOH recognizes that at times, however, physicians and other healthcare providers make personalized recommendations for their patients that may differ from national guidelines. It's important that physicians and healthcare providers have the autonomy to act in their patient's best interest, yet they need to have tailored, documented discussions with patients about the risks and benefits of these recommendations.

RIDOH is not aware of sufficient scientific evidence or national recommendations supporting a vaccination series that includes additional doses of COVID-19 vaccine beyond current Emergency Use Authorization (EUA) recommendations. RIDOH understands that in certain patients, and in discussion with a patient, a physician may decide to administer a third dose of either the Pfizer or Moderna vaccine. RIDOH will respect and support the autonomy of physicians in these situations.

It's important to note that the current EUAs for mRNA vaccines require healthcare providers to report any COVID-19 vaccine administrative errors to VAERs. Administering an additional vaccine dose is considered an administrative error/deviation, so should be reported to VAERs.

Vaccinating patients who have had a Johnson & Johnson (Janssen) COVID-19 vaccine with additional mRNA COVID-19 vaccine

RIDOH has recently gotten questions about patients who have received one dose of the Johnson & Johnson vaccine, and whether they should also receive mRNA vaccine due to the increasing prevalence of the Delta variant. There are currently no clinical trials that support this approach.

RIDOH recognizes that at times, however, physicians and other healthcare providers make personalized recommendations for their patients that differ from national guidelines. It's important that physicians and healthcare providers have the autonomy to act in a patient's best interest, yet they need to have tailored, documented discussions with patients about the risks and benefits of these recommendations.

RIDOH is not aware of sufficient scientific evidence or national recommendations that support giving mRNA vaccine to patients who have had Johnson & Johnson vaccine. RIDOH understands that in certain clinically appropriate patients and on a case-by-case basis, this may be appropriate and acceptable medical practice. This course of action should be appropriately documented in the medical record including rationale, risks, and potential benefits.

It's important to note that the current EUAs for mRNA and Johnson & Johnson vaccines require healthcare providers to report any COVID-19 vaccine administrative errors to VAERs. Administering doses of different types of COVID-19 vaccines to the same individual is considered an administrative error/deviation and should be reported to VAERs.

Conclusion

Individual patient-healthcare provider relationships are built on respect and trust. These therapeutic relationships generally improve over time and lead to personalized evidence-based decisions. RIDOH offers this cautionary guidance advising healthcare providers to practice evidence-based medicine and follow applicable state and national guidance. Physicians should work with their patients and determine the best treatment plan.