



July 30, 2021

Dear Colleague,

On July 22, 2021, the Advisory Committee on Immunization Practices (ACIP) reviewed the benefit-risk assessment for Johnson & Johnson/Janssen's COVID-19 vaccine after reports of Guillain-Barré syndrome (GBS) in vaccine recipients and considerations for additional COVID-19 vaccine doses in people who are immunocompromised. Meeting materials can be found [here](#). This letter summarizes the information presented.

Reports of Guillain-Barré syndrome (GBS) after Johnson & Johnson COVID-19 Vaccine

[GBS](#) is an acute autoimmune condition of the peripheral nerves, causing muscle weakness and sometimes paralysis. Most people recover fully, but some have permanent nerve damage. In the United States, an estimated 3,000 to 6,000 people develop GBS each year, often following a bacterial or viral infection, including COVID-19. As of June 30, 2021, 100 potential cases of GBS among recipients of the Johnson & Johnson COVID-19 vaccine have been reported to the Vaccine Adverse Event Reporting System (VAERS), out of over 12.8 million recipients of the vaccine. The median age of people with GBS in VAERS was 57 years (range, 24-76 years); 61% were male. Median time to symptom onset was 13 days (range, 0-75 days) after vaccination, with 98% occurring within 42 days after vaccination. Out of the 100 patients, 95 were hospitalized and one patient died (cause of death is still under investigation).

Although reports of GBS to VAERS after receipt of the Johnson & Johnson COVID-19 vaccine were rare, with a crude reporting rate of 8.1 cases per million doses administered, they likely indicate a small risk of this side effect. Based on data from the [Vaccine Safety Datalink](#), rates of GBS after the Johnson & Johnson COVID-19 vaccine were elevated compared to rates of GBS after receipt of mRNA COVID-19 vaccines (crude reporting rate of 1.1 cases per million doses of mRNA vaccine administered). An increase in GBS reports has also been seen after receipt of the AstraZeneca adenovirus vector COVID-19 vaccine, used outside of the United States.

ACIP concluded that, although [the balance of benefits and risks varies by age and sex](#), the overall benefits of vaccination are clear and thousands of hospitalizations are estimated to be prevented as a result of Johnson & Johnson COVID-19 vaccination. People with a history of GBS can receive any COVID-19 vaccine and should discuss the risk and benefits of the Johnson & Johnson COVID-19 vaccine and the availability of mRNA COVID-19 vaccines with their health care provider. [Updated clinical materials](#) are in development. Report all serious events after vaccination, including GBS, to [VAERS](#). **ACIP continues to recommend use of the Johnson & Johnson COVID-19 vaccine following current guidelines.**

People Who Are Immunocompromised

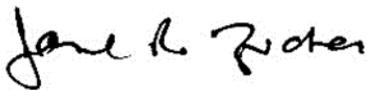
People who are immunocompromised are at increased risk of poor outcomes from COVID-19. [Studies](#) indicate that people who are immunocompromised have a reduced antibody response following COVID-19 vaccination, compared to healthy vaccine recipients. Emerging data suggest an additional COVID-19 vaccine dose enhances antibody response for some immunocompromised recipients, with an increased proportion of recipients developing an antibody response after an additional dose, though many continue to have a poor immunologic response. In an [evaluation](#) of a small cohort of people who are immunocompromised, reactogenicity to a third dose of mRNA vaccine was similar to reactogenicity following two doses.

The safety, efficacy, and benefit of additional doses of COVID-19 vaccine in people who are immunocompromised continues to be evaluated, including determining subpopulations who may benefit most, acceptable dose intervals and the potential for mixing vaccine types. ACIP is continuing to assess data and clinical considerations for people who are immunocompromised and is awaiting regulatory allowance before making policy recommendations (e.g., an amendment to the FDA's Emergency Use Authorizations or a Biologics License Application for the COVID-19 vaccines). **At this time, ACIP has not recommended additional doses of COVID-19 vaccine in people who are immunocompromised.**

People who are immunocompromised should be counseled about the potential for reduced immune responses to COVID-19 vaccination and the need to continue to follow [prevention](#) measures such as wearing a mask, avoiding crowds, and physical distancing until advised otherwise by their health care provider.

We urge you to continue having conversations about COVID-19 vaccination with your patients and to offer vaccination at every opportunity. Your recommendation can play a crucial role in vaccination decisions. For the latest information on COVID-19 vaccines, visit nyc.gov/health/covidvaccineprovider.

Sincerely,



Jane R. Zucker, MD, MSc
Assistant Commissioner
Bureau of Immunizations
New York City Department of Health and Mental Hygiene