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Guillain-Barré Syndrome after Johnson & Johnson (Janssen) COVID-19 Vaccination

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The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) are monitoring reports of Guillain-Barré Syndrome (GBS) after Johnson & Johnson (Janssen) COVID-19 vaccination. GBS is an autoimmune neurological disorder that causes muscle weakness and sometimes paralysis. Respiratory and gastrointestinal infections are typical triggers, and the condition is thought to develop in a few thousand people in the United States every year. Most patients make a full recovery within a few weeks, although sometimes nerve damage can be permanent. There are also rare reports of the condition after COVID-19 illness.

SUMMARY POINTS

- Rare cases of Guillain-Barré Syndrome (GBS), an autoimmune neurological disorder, have been detected after Johnson & Johnson (Janssen) COVID-19 vaccination.
- The cases mostly occurred in males ≥ 50 years within six weeks of vaccination. Most patients have recovered.
- Johnson & Johnson (Janssen) EUA Fact Sheets have been updated to include this warning and symptoms requiring immediate medical attention.
- Cases of GBS occurring after vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) and PDPH.
- COVID-19 vaccination continues to be recommended for all persons aged ≥12 years.

Per the CDC, around 100 preliminary reports of GBS have been detected in the Vaccine Adverse Event Reporting System (VAERS) after 12.8 million doses of Johnson & Johnson (Janssen) COVID-19 vaccine administered. The cases have mostly occurred in males aged 50 years and older about two weeks after vaccination, mostly within six weeks. The vast majority of patients have recovered, although one fatality has been reported. These GBS cases are rare but likely indicate a small possible risk of GBS following vaccination.

On 7/12/21, the FDA updated the Johnson & Johnson (Janssen) COVID-19 vaccine Emergency Use Authorization (EUA) Fact Sheets to include a warning about the rare risk of GBS and symptoms for which to seek immediate care. These include weakness or tingling sensations in the extremities that worsen or spread, difficult ambulating, difficulty with facial movements (speaking, chewing, or swallowing), double vision or inability to move the eyes, or difficulty with bladder control or bowel function. All cases of GBS after COVID-19 vaccination should be reported promptly to the **Vaccine Adverse Event Reporting System (VAERS).** Providers also should report GBS cases to the **Philadelphia Department of Public Health (PDPH)** by telephone at 215-685-6748 during business hours or fax at 215-238-6947, as GBS is a notifiable condition in Philadelphia.

The FDA and CDC will continue to closely monitor these cases. GBS associated with Johnson & Johnson (Janssen) COVID-19 vaccine is likely to be discussed at the next meeting of the Advisory Committee on Immunization Practices (ACIP) on July 22, 2021. At this time, available data do not show an increased risk of GBS after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna) after over 321 million doses administered in the United States.

COVID-19 vaccination continues to be recommended for all persons aged ≥ 12 years. Overall, the risk of severe adverse events after COVID-19 vaccination remains rare, and robust safety monitoring systems are in place. Currently, almost all COVID-19 hospitalizations and deaths occur in unvaccinated people in the United States.

Resources (information adapted from CDC statement 7/13/21 and sources below)

- **EUA Fact Sheets**: Janssen COVID-19 Vaccine | FDA
- Guillain-Barré Syndrome and the Johnson & Johnson Vaccine: What to Know - The New York Times (nytimes.com)
- Vaccine Adverse Event Reporting System (VAERS)