

July 22: Risk of Guillain-Barré Syndrome, New Patient Vaccination Options and the COVID-OUT Outpatient Treatment Trial

Today's issue features information from **Neurology Critical Care Specialist Edward M. Manno, MD**, about the risk of Guillain-Barré syndrome in individuals who have been vaccinated with the Johnson & Johnson COVID-19 vaccine. It also includes an update on vaccination options for patients and an overview of Northwestern Medicine's participation in the COVID-OUT trial.

COVID-19 VACCINES AND RISK OF GUILLAIN-BARRÉ SYNDROME

Last week, the U.S. Food and Drug Administration (FDA) issued a new warning on the Johnson & Johnson COVID-19 vaccine after an analysis of data from the Vaccine Adverse Event Reporting System (VAERS) identified 100 cases of Guillain-Barré syndrome (GBS). Approximately 70% of the reported cases were considered mild, but 95 patients required hospitalization, and one death was reported. Most of the patients were men older than 50, and all cases were reported within 42 days of administration. No similar signals have been identified with either the Pfizer-BioNTech or Moderna vaccines.

GBS, or acute inflammatory demyelination polyneuropathy (AIDP), is an autoimmune process that affects the peripheral nervous system. There are about 6,000 cases reported in the U.S. annually. Most cases primarily affect the myelin, or outer covering of the nerves, leading to a slowing and occasional blocking of peripheral nerve function. Symptoms range from mild paresthesia of the extremities to an ascending paralysis and dysautonomia requiring respiratory support. Many cases are idiopathic, but a slight majority are preceded by a viral or bacterial illness. It is believed that the immune response to the offending agent may induce an attack on the myelin or peripheral nerve itself. The connection between GBS and vaccination remains unproven.

The available data clearly reveals that the Johnson & Johnson vaccine remains safe and effective since there are only 100 reported cases of GBS among the 13 million patients who have received the vaccine. Given the spectrum and high incidence of neurological complications after COVID-19 infection, the risk benefit profile strongly supports continued use of the vaccine. In addition, a **recent review and meta-analysis** of observational cohorts and case series reported the incidence of GBS to approximate 15 cases per 100,000 after COVID-19 infection. Thus, the incidence of GBS is estimated to be much greater in those who contract the virus.

For more information about COVID-19 vaccination, please visit the **Vaccine and Treatment Resources page** on Physician Forum and **NM Interactive** (login required).

NEW PATIENT VACCINATION OPTIONS

The vaccination process for patients has been updated for both the Johnson & Johnson and Pfizer-BioNTech vaccines.

Johnson & Johnson

The one-dose Johnson & Johnson COVID-19 vaccine is now available for patients 18 and older on a walk-in basis at all but three Northwestern Medicine Immediate Care Centers. Mokena, Orland Park and Sycamore are not offering the vaccine at this time.

Vaccinations will be offered on a walk-in basis only on Wednesdays and Saturdays during regular operating hours. No appointment is needed. Patients should let the registrar know they wish to receive a Johnson & Johnson COVID-19 vaccine upon arrival.

Pfizer-BioNTech

Current NM patients may receive the Pfizer-BioNTech vaccine at the following NM Primary Care sites. They do not need to be a patient of the clinic where the vaccine is offered. Vaccinations are offered to patients 12 and older except where noted.

- **NM Family Medicine Grayslake Outpatient Center**
- **NM Primary Care Lavin Pavilion Suite 2150 – 18 and older only**
- **NM General Internal Medicine Clinic – 18 and older only**
- **NM Primary Care DeKalb**
- **NM Family Medicine Huntley**
- **NM Internal Medicine SoNo**
- **NM Family Medicine Aurora**

All Primary Care locations require an appointment, but a physician's order is not required to schedule an appointment. Patients may schedule their vaccination by calling the location where they wish to receive the vaccine.

For additional information about patient vaccinations, visit the [COVID-19 Vaccines page](#) on nm.org. You can also visit the [Vaccine and Treatment Resources page](#) on Physician Forum and [NM Interactive](#) (login required).

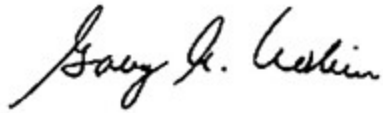
COVID-OUT: OUTPATIENT TREATMENT FOR SARS-CoV-2 INFECTION TRIAL

Northwestern Medicine is collaborating with the University of Minnesota on the COVID-OUT study investigating use of three different medications and their effects on COVID-19. This randomized, blinded and controlled study previously included only metformin and has added arms for fluvoxamine and ivermectin.

Potentially eligible patients with a positive COVID-19 test will be contacted via phone by either a research coordinator or via MyNM for possible enrollment. All study materials and investigational drugs are shipped to enrolled subjects' homes, so no in-person visits are required. Please send any questions to Primary Investigator David Liebovitz, MD, at david.liebovitz@nm.org.

For more information, please visit the [COVID-OUT: Outpatient Treatment for SARS-CoV-2 Infection, a Factorial Randomized Trial](#) page on the University of Minnesota website.

Over the past several weeks, COVID-19 cases are increasing in communities where vaccination rates are low, leading to a pandemic of the unvaccinated. The good news is that the vaccines are safe and effective. Continuing to encourage vaccination among our colleagues and patients is the most effective method to prevent hospitalizations and sadly, deaths among the unvaccinated.

A handwritten signature in black ink that reads "Gary A. Noskin". The signature is written in a cursive style with a large, prominent initial "G".

Gary A. Noskin, MD
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