

COVID-19 Update

December 29: Vaccine Distribution and Recommendations for Those Who Are Pregnant or Have Allergies, Epic Vaccination Designation, and Last Week's Clinical Insights Panel

Today's issue features an update on Northwestern Medicine vaccine distribution. In addition, Immunologist **Anju Tripathi Peters, MD**, offers vaccination guidelines for those who have severe allergies, and Maternal Fetal Medicine Specialist **Emily S. Miller, MD, MPH**, addresses considerations for those who are pregnant. It also includes details about the new COVID-19 vaccine designation in Epic and a link to view the December 22 Clinical Insights Panel for CME credit.

VACCINE DISTRIBUTION UPDATE AND RECOMMENDATIONS

Northwestern Medicine has vaccinated more than 12,000 physicians and employees, and continues to receive doses of both the Pfizer-BioNTech and Moderna COVID-19 vaccines. Supply remains limited at some hospitals, so physicians who want to get vaccinated may schedule their appointment at any hospital in the health system. Remember, you must receive the second dose of the vaccine at the same hospital where you received the first.

On **NM Interactive** (login required), a graphic has been added that provides a snapshot of the number of vaccine doses NM has received, as well as the number of employees and physicians who have been vaccinated to date.

Anaphylaxis and allergic reactions

During the past three weeks, the Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for two COVID-19 vaccines. Since the EUA, a total of eight instances of anaphylaxis with the Pfizer-BioNTech vaccine and one with the Moderna vaccine have been reported in the U.K. and U.S. In all nine cases, symptoms occurred rapidly after the vaccine was administered, which is expected of anaphylactic reactions, and more importantly, all nine individuals responded to treatment.

Interestingly, anaphylaxis was not observed during the phase 3 clinical trials for either the Pfizer-BioNTech or the Moderna vaccine, which enrolled about 44,000 and 30,420 subjects, respectively. Adverse effects — including local reactions such as redness, swelling and pain at the injection site, as well as systemic symptoms, such as fever, myalgias, headache and fatigue — were reported in both clinical trials at a higher frequency among individuals who received the

vaccine compared to placebo. These reactions may occur during vaccine administration and indicate the robust immune response generated by the vaccines.

In general, anaphylaxis from vaccines is rare and estimated to occur in 1.3 people per 1 million doses. The mechanism of the reported anaphylaxis to either mRNA vaccine is not known. Both vaccines contain lipid nanoparticles, which surround the mRNA to stabilize it. One potential agent being investigated as the cause of anaphylaxis is the polyethylene glycol (PEG) that is attached to the lipid layer and is present in both vaccines. PEG is also present in many medications, cosmetics and household products, and has been reported to cause rare allergic reactions associated with medications. While PEG may be suspected, other components of the vaccine may be responsible for causing anaphylaxis in certain individuals, and currently, **we don't know the exact cause or mechanism of the reported anaphylactic reactions.**

The Centers for Disease Control and Prevention (CDC) recommends a minimum 15-minute observation period for all persons following COVID-19 vaccination, and a 30-minute observation period for those with a history of severe allergic reactions due to any cause.

- The vaccine should not be administered to those with a history of an allergic reaction to either one of the mRNA vaccines or their components.
- Those with a history of anaphylaxis to any vaccine (other than mRNA vaccines) or a severe allergic reaction to an injectable medication should consider the risk/benefits of vaccination, potentially defer the vaccine or be observed for 30 minutes if vaccinated.
- Food, oral medication, venom, latex, environmental and mild vaccine allergies are not contraindications to receive an mRNA vaccine.

The CDC also has recommended that vaccination providers have appropriate medications and equipment — such as epinephrine, antihistamines, stethoscopes, blood pressure cuffs and timing devices to check pulses — at all COVID-19 vaccination sites. If an individual has a severe allergic reaction after receiving the COVID-19 vaccine, they should receive emergency treatment and be observed for several hours. For more information, please view [Triage for Persons Presenting for mRNA COVID-19 Vaccination](#).

In summary, although severe allergic reactions are rare after the mRNA COVID-19 vaccines, they may occur, and vaccination providers should be prepared to recognize and treat anaphylaxis. NM has all these safeguards in place for vaccine administration.

Recommendations for pregnant individuals

Pregnant individuals have been excluded from all COVID-19 vaccine randomized trials to date. Now that vaccine efficacy data are available, pregnant healthcare workers are left to make a difficult decision: Should they receive the vaccine as soon as they are eligible or wait until more data about the vaccine in pregnancy are available?

The benefits of vaccination for reducing the risk of SARS-CoV-2 infection and severe morbidity in the general population are encouraging. While there are no data specific to pregnant individuals, there is reason to believe that vaccination during pregnancy would have similar efficacy with limited risks. Importantly, pregnant individuals who acquire SARS-CoV-2 are at a higher risk of ICU admission, intubation and death. Pregnant individuals with other risk factors — such as older age, obesity, high blood pressure or diabetes — have even greater risks. The risk of severe morbidity and mortality must be taken into account when making the decision about vaccination.

Safety data for the vaccine are limited. What is known comes from combined developmental and perinatal/postnatal reproductive toxicity studies. Vaccination during mating or gestation did not have any observed adverse reactions on female reproduction, embryonic/fetal development or postnatal development in animal models. In addition, while pregnant individuals were excluded from vaccine trials, 36 women did become pregnant during the course of study enrollment. Of these, 18 had been randomized to receive the vaccine. Four pregnancy-related adverse events were reported, all occurring in the placebo arm. Thus, while certainly not definitive, early data are reassuring.

While definitive safety data will require years of study, the biologic plausibility of pregnancy risks is low. The decision about vaccination requires balancing these unknowns against the risks of exposure to SARS-CoV-2 and risk factors for severe COVID-19. For most pregnant healthcare workers with ongoing exposure to SARS-CoV-2, the balance likely favors vaccination. For additional information and resources to support pregnant individuals in making an informed decision, please visit the [American College of Obstetricians and Gynecologists](#) and the [Society for Maternal Fetal Medicine](#) websites.

Please note that a **COVID-19 Adverse Reaction Tile** has been added to the **NM Workforce app**. If members of the workforce experience an adverse reaction to one of the COVID-19 vaccines, they should visit the **COVID-19 Vaccination Adverse Reaction** section on the app. Get there by opening the NM Workforce app and tapping **NM COVID-19 Applications**. Users can also find the **COVID-19 Vaccination Enrollment link** and the **COVID-19 Employee Triage Questionnaire** within the COVID-19 Applications section.

Please continue to visit the [Vaccine and Treatment Resources page on Physician Forum](#) and the [Vaccine and Treatment Resources page on NMI](#) for answers to frequently asked questions, vaccine enrollment information, education resources and more.

EPIC COVID-19 VACCINATION INFORMATION

Physicians and providers are now able to document patient COVID-19 vaccination activity in the medical record. To document vaccination information, simply navigate to Immunization Activity, select the Historical tab, and then search "COVID." Both vaccine options will be available for documentation.

The screenshot displays the 'Immunizations - Immunizations' interface in Epic. At the top, there are navigation options: 'All Admin Types', 'Incomplete Admins', 'Historical Admins', 'Immunization Report', 'Imm Registry', and 'Refresh'. Below this is the 'Single Historical Immunization' form. The 'Name' field contains 'covid', and the 'Given' dropdown is set to 'Given'. Other fields include 'Date', 'Time', 'Given by', 'Lot #', 'NDC', 'Manufacturer', 'Product', and 'Expires'. A 'Record Select' pop-up window is overlaid on the form, showing a search for 'covid' with two results: '202 Moderna Sars-cov-2 Vaccination (aka COVID)' and '203 Pfizer-BioNTech Sars-COV-2 VACCINATION (aka COVID)'. The first result is highlighted.

DECEMBER 22 CLINICAL INSIGHTS PANEL NOW AVAILABLE FOR CME CREDIT

If you missed the December 22 COVID-19 Clinical Insights Panel, you can view the session by simply clicking the link below:

December 22 Clinical Insights Panel: COVID-19 Vaccines

Discussion features the latest information about the COVID-19 vaccine, including allergic reactions and considerations for pregnant women. Panelists include Infectious Disease Specialist **Michael G. Ison, MD**, professor of medicine in the Division of Infectious Diseases and professor of surgery in the Division of Transplant Surgery; Maternal Fetal Medicine Specialist **Emily S. Miller, MD, MPH**, assistant professor of obstetrics and gynecology, and psychiatry and behavioral sciences; and Immunologist **Anju Tripathi Peters, MD**, professor in the Department of Medicine and Otolaryngology Head & Neck Surgery, and director of clinical research in the Division of Allergy-Immunology.

This year has been one that none of us anticipated, and I remain humbled by and grateful to all of our physicians and clinicians who have worked tirelessly to face the challenges presented by this pandemic. Thank you for your continued commitment to our *Patients First* mission. I wish you and your family a happy and healthy New Year.



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