April 22: Vaccination Card Distribution, Clinical Trial Investigating Allergic Reactions to the COVID-19 Vaccine and New Treatment Reduces Lung Damage in a Preclinical Study

Today's issue includes an update on vaccination card distribution, details of a new clinical trial investigating allergic reactions to the COVID-19 vaccine, and information about a new treatment being developed by NM researchers that significantly reduced lung damage, symptoms and mortality in a preclinical study.

VACCINATION CARD DISTRIBUTION

Patients

As of April 12, patients who receive a final COVID-19 vaccine dose at NM are given a CDC-issued COVID-19 vaccination record card. Patients who received their final dose prior to April 12 can request that the CDC card be mailed to their home following **this process**. Duplicate CDC cards are not available due to limited supply.

Workforce

Physicians and employees who were vaccinated at an NM workforce vaccine clinic can print COVID-19 vaccine record card information from **NM Interactive** (log-in required). Go to *NMI > Applications > Safety & Risk > SafetyNet Admin*. Click on *COVID-19 Vaccination Record Card*, which will create a digital version of the card with all the information prepopulated.

If there is a specific circumstance that requires you to have the CDC card, submit a ticket by visiting the MyNM Service Center on NMI or calling 312.926.HELP. Completed cards will be available for pickup at an NM vaccine clinic site. The process is expected to take a couple of weeks but will vary depending on the volume of requests. Additionally, this process may change based on the status of vaccine clinics.

CLINICAL TRIAL INVESTIGATING ALLERGIC REACTIONS TO COVID-19 VACCINE

The National Institute of Allergy and Infectious Diseases of the National Institutes of Health is conducting a Phase 2, randomized, initially blinded clinical trial to determine whether people who are considered highly allergic individuals or who have mast cell disorders are at increased risk for an immediate, systemic allergic reaction to the Pfizer-BioNTech or Moderna COVID-19 vaccines. The biological mechanism, genetic patterns and other risk factors will be investigated for reactions through urine testing and bloodwork. Northwestern University is one of 35 academic medical centers that are participating in this study, and **Anju Peters, MD,** Department of Medicine, Division of Allergy and Immunology, is leading this effort.

There are two patient populations (ages 18 through 69) eligible for the study. Primary criteria include:

- **Allergic individuals:** Patients with mast cell disorder **or** who have used EpiPen® within the last five years for a food, drug, or venom allergic reaction **or** who have a history of immediate allergic reaction to a vaccine or one or more drugs in the last five years
- **Nonallergic control patients:** Patients with no history of asthma, environmental, food or drug allergies

The study will be conducted over two to three visits, and subjects will be randomized to receive either Pfizer-BioNTech vaccine, Moderna vaccine or placebo followed by Pfizer-BioNTech vaccine or Moderna vaccine. Neither participants nor study team members will know what the participant is receiving. If a subject is randomized to the placebo arm at the first visit, they will get either the dose of Pfizer or Moderna vaccine series at the second and third visits. All participants will ultimately receive either the Pfizer-BioNTech vaccine or Moderna vaccine and will be paid $50 per visit.

Allergists will monitor subjects for 90 minutes after each injection for any allergic reaction. Rare reactions to these vaccines tend to occur in patients with a past food or drug allergy, so this is an opportunity for individuals with a history of a severe allergy to medications or foods to get the mRNA vaccine in a monitored setting. For more information or to refer patients for the trial, contact Amina Guo at 312.695.3530 or **amina.guo@northwestern.edu**.

NEW TREATMENT FOR COVID-19 MARKEDLY REDUCES LUNG DAMAGE, SYMPTOMS AND MORTALITY IN A PRECLINICAL STUDY

A novel protein designed by a team of Northwestern Medicine scientists, led by Nephrologist **Daniel Batlle, MD**, significantly reduced lung damage and resulted in only mild symptoms in mice infected with SARS-CoV-2, while untreated animals in this model all succumbed to the infection.

The protein is a variant of angiotensin-converting enzyme-2 (ACE2), the receptor the coronavirus uses to enter and infect human cells. The modified protein intercepts the S spike of the coronavirus and fools it into binding to it, rather than to the real ACE2 receptor, in cell membranes.

A prior study was the first proof of concept that a soluble human ACE2 protein is effective in vivo in a preclinical study using an animal model. The soluble ACE2 protein variant developed by Dr. Batlle and colleagues, as part of their longstanding work with ACE2, has been enhanced to have a stronger binding to the virus spike and also to last for days. The study findings should be considered preliminary until it is published in a peer-reviewed journal.

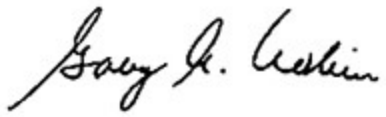
“We envision this novel soluble ACE2 protein will attenuate the entry of coronavirus into cells in the body mainly in the respiratory system and, consequently, the serious symptoms seen in severe COVID-19,” says Dr. Batlle, who is also a professor of medicine at Northwestern University Feinberg School of Medicine. “We have converted a lethal disease into a milder lung disease that is fully reversible. The protein could be complimentary to other potential treatments or effective alone.”

This new research is an extension of a study previously conducted by Dr. Batlle and his team, titled, **A Novel Soluble ACE2 Variant With Prolonged Duration of Action Neutralizes SARS-CoV-2 Infection in Human Kidney Organoids** and published in the *Journal of the American Society of Nephrology*, which demonstrated the ability of a novel ACE2 protein to neutralize COVID-19 using

kidney organoids as a model. The new work, however, uses an improved ACE2 protein bioengineered by **Jan Wysocki, MD**, PhD, Nephrology and Hypertension, and the team in Dr. Batlle's lab. This protein was given to transgenic mice that develop severe COVID-19 manifestations when infected with SARS-CoV-2 and do not survive. **Anjana Yeldandi, MD**, Pathology, and Ian Gelarden, MD, resident, Pathology, documented a significant improvement in lung histology in animals treated with the new ACE2 protein. "The treated animals, by contrast, had a spectacular response in that all but one survived and recovered," Dr. Batlle says.

Next steps involve the planning of safety studies needed before applying for Investigational New Drug approval for future studies in patients with COVID-19. "The treatment is directed primarily to the lungs but should benefit all the organs of the body that can be affected by COVID-19," says Dr. Batlle. "To be able to have this treatment available for patients is usually a long process, but we hope that an expedited review by the FDA and appropriate resources will make this possible in the not-too-distant future."

As we continue to accelerate our vaccination efforts, please remind your patients and colleagues that compliance with public health guidelines remains necessary. Thank you to all of the physicians and providers across NM for your continued commitment to our *Patients First* mission.



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