Allergic Reactions to mRNA Vaccines

A new National Institutes of Health phase 2 trial aims to assess whether people with a history of allergies or a mast cell disorder are at a higher risk of systemic allergic reactions to the Pfizer-BioNTech and Moderna COVID-19 vaccines.

Most of the rare, severe allergic reactions to the 2 messenger RNA (mRNA) COVID-19 vaccines have been in people with a history of allergies, many of whom had previous anaphylaxis. In mast cell disorders, abnormal or overly active mast cells, a type of white blood cell, can cause life-threatening reactions that look like anaphylaxis.

The study will enroll 3400 adults aged 18 to 69 years at allergy research centers nationwide. About 60% of participants will have a history of anaphylaxis within the past 5 years or a mast cell disorder diagnosis, while the other 40% will have no history of allergy or mast cell disease. Women will comprise about two-thirds of each group because anaphylaxis after vaccination in general, and after vaccination with mRNA vaccines in particular, is more common among women.

People in each group will be randomized to receive 2 doses of the Pfizer-BioNTech vaccine, 2 doses of the Moderna vaccine, a placebo shot followed by 1 dose of the Pfizer-BioNTech vaccine, or a placebo shot followed by 1 dose of the Moderna vaccine. Investigators at each site are allergists trained to recognize and treat anaphylaxis.

Participants will be observed for at least 90 minutes after each injection in case they have any type of reaction. Investigators will compare the percentage of participants in the 2 study groups—those with allergies or mast cell disorders and those without them—who have a systemic allergic reaction.

“The information gathered during this trial will help doctors advise people who are highly allergic or have a mast cell disorder about the risks and benefits of receiving these 2 vaccines,” Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases, said in a statement. “However, for most people, the benefits of COVID-19 vaccination far outweigh the risks.”

Improving Maternal Health

The US Department of Health and Human Services (HHS) recently announced measures to improve maternal health.

Illinois became the first state to extend Medicaid coverage for beneficiaries during the entire first year after delivering a baby. Nationwide, 55% of those with Medicaid coverage at delivery experience a coverage gap in the first 6 months afterward, compared with 35% of those with private insurance at delivery, according to a recent data brief. A third of maternal deaths occur in the first year after childbirth, and Black people are at least twice as likely to die from a pregnancy-related cause than White people.

“Continuous health care coverage reduces health care costs and improves outcomes,” HHS Secretary Xavier Becerra said in a statement. “By expanding Medicaid eligibility for a full year after delivery, Illinois is setting an important model for other states across the country to follow.” Medicaid covers 1 in 5 women of reproductive age.

Becerra also announced that HHS will make $12 million available over 4 years for the Rural Maternity and Obstetrics Management Strategies Program to test models for addressing unmet needs in populations that historically have experienced health disparities.

Free, At-Home Rapid SARS-CoV-2 Tests

The National Institutes of Health and the Centers for Disease Control and Prevention recently began offering a month’s worth of free, do-it-yourself (DIY), rapid SARS-CoV-2 tests to residents of Pitt County, North Carolina, and Chattanooga/Hamilton County, Tennessee.

The counties were selected based on local infection rates, accessibility of accurate COVID-19 tracking data, local infrastructure support, and community relationships through the NIH Rapid Acceleration of Diagnostics Underserved Populations initiative.

“This testing initiative is the first of this scale to attempt to make free, rapid, self-administered tests available community-wide in order to determine their effectiveness in our nation’s comprehensive response to the COVID-19 pandemic,” NIH Director Francis Collins, MD, PhD, said in a statement.

As many as 160 000 residents can order the tests, to be used 3 times a week. “Ideal candidates” are those who haven’t received a COVID-19 vaccine or are at high risk of exposure by working or attending school outside their home, according to the Pitt County Health Department.

Participants in the “Say Yes! COVID Test” initiative can volunteer to enroll in an NIH-supported research study that aims to determine whether frequent DIY testing affects users’ behavior, knowledge about preventing virus transmission, or thoughts about COVID-19 vaccination.

Publicly available data, such as COVID-19 test positivity rates, cases, and hospitalizations from similar-sized communities without widespread DIY testing, will be compared with data from Pitt and Hamilton counties to see how effective the rapid tests are in mitigating SARS-CoV-2 transmission. – Rita Rubin, MA

Note: Source references are available through embedded hyperlinks in the article text online.