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BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

Adverse reactions to the first dose of a covid-19 vaccine does not preclude a second dose.

As more and more of the coronavirus mRNA vaccines are administered, the rate of serious hypersensitivity reactions (i.e. inappropriate immune responses) has apparently declined by more than 50 percent. The latest estimates are that as few as 5 cases of hypersensitivity reactions per million doses have occurred as a result of the Pfizer/BioNTech vaccine and less than 3 cases per million such cases after the Moderna vaccine. Not a single death stemming from the vaccines has been reported.

Current US Centers for Disease Control and Prevention guidelines are to avoid a second dose if a recipient exhibits a hypersensitivity reaction following the first dose. There may be a better option, though.

A letter published in the *Annals of Internal Medicine* described two case reports of the successful administration of a second dose of the Moderna vaccine following an immediate hypersensitivity reaction upon receiving a first dose. Both cases come from this past winter during the initial rollout phases of the vaccine. In the first case, a 64-year-old woman with a shellfish allergy developed symptoms within 10 minutes of her first dose. She developed generalized itching, hives, and the self-reported sensation of an elevated heart rate. When examined by healthcare responders, she was found to have no significant swelling of her skin, mouth, or airway, no respiratory or gastrointestinal symptoms, and her blood pressure was normal. She was given 50mg of oral diphenhydramine (i.e. Benedryl) by the vaccine administration staff and had resolution of symptoms by 90 minutes. The second patient was a 39-year-old woman with a history of nasal allergies who developed chest and neck hives within 15 minutes of receiving her first dose. She received 25 mg of oral diphenhydramine at the vaccination site, but did go on to develop mild swelling (i.e. "angioedema") within 30 minutes. The patient was transported to a local hospital where she received famotidine ("Pepcid," an antihistamine) and steroids. Her symptoms did not worsen after two hours of observation and she was released to go home. Both patients were referred to an allergy clinic, staffed by the author of the letter, Rochester, NY. Skin testing was performed using polyethylene glycol (a substance used in the Moderna vaccine that was the target of some negative social media attention early in vaccine distribution) as well as some residual contents from previously used vials of the Moderna vaccine. All of the skin testing results were negative.

Both of the patients described in this report worked in healthcare and had increased covid-19 exposure risk. Therefore, following a detailed discussion with the allergy specialist, both patients opted to proceed with the second vaccine dose. The second dose was given without premedication (i.e. without the administration of prophylactic medications that *might* decrease hypersensitivity or allergic symptoms). However, a "graded dosing protocol" that often used for other vaccines that have caused similar adverse events was used. The protocol consisted of five small doses of diluted or partial vaccine given every 15 minutes. The first patient developed no symptoms. The second patient complained of itching after dose #2 and dose #5, both of which resolved without any medication or other medical intervention. Follow up antibody testing showed that the vaccinations were successful.

Although only two patients, these important case reports show that with close observation, it is possible to administer mRNA vaccines in patients who may have increased hypersensitivity or allergic risks. This is great news because many people with a history of drug

allergies or side effects may be nervous about receiving these new vaccines. This report should help alleviate some fears, and thus encourage the march towards herd immunity, though larger studies are necessary. The nature of a report such as this does not prove that such an approach is guaranteed to be safe, but rather that it certainly might be in some if not many instances.

—Christopher Sampson, MD, FACEP

POLICY BRIEFING

Medicare and Medicaid starts to collect payments from its pandemic hospital lifeline program.

Around the United States during the pandemic, many healthcare systems faced significant financial hardships that nearly brought them to the breaking point. In an effort to support hospitals, the Centers for Medicare and Medicaid (CMS) (an agency within the US Department of Health and Human Services) has been behind the expansion of the Medicare Advanced and Accelerated Payment Program under the CARES Act. This has allowed healthcare entities to request reimbursement for expected future income based on prior years' Medicare data, with set timelines for repayment.

Under the initial expansion, those repayments would have been due one hundred and twenty days after submission, with any failure to comply resulting in a total reduction of future Medicare funding until the balance was paid back in full. With the pandemic still raging, though, organizations like the American Medical Association petitioned CMS to extend the deadline. This goal was achieved with the Continuing Appropriations Act of 2020, which gave applicants one year from dispersal of funds to make payments back to CMS.

We have now reached that one-year mark. CMS has published guidance on recoupment of the Coronavirus Advanced and Accelerated Payments (COOPs) paid out over the pandemic. Under the terms, borrowers will essentially have seventeen months to make good on owed payments. After that time, remaining balances will begin accruing four percent interest, with the rate reassessed every thirty days. So far, there have been no public pushes to further extend the deadline. The healthcare industry is in a stronger position than it was last fall, and so it remains unclear if any effort to kick the can down the road any further would be fruitful. *Various*.

—Brief19 Policy Team

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