COVID-19 Evidence Digest 02/05/21

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021 (CDC MMWR)

Bottom Line: Anaphylaxis is a rare allergic reaction after receiving the Moderna COVID-19 vaccine. Patients should be screened to determine if they might be at risk for anaphylaxis and be observed after receiving the vaccine. Vaccine locations should have the necessary supplies and staff available to treat anaphylaxis if it should occur.

Details: Vaccine Adverse Event Reporting System (VAERS) is a national surveillance system that monitors adverse events after immunizations. Of the 4,041,396 individuals who received the first dose of the Moderna COVID-19 vaccine during December 21, 2020—January 10, 2021, 1,266 (0.03%) adverse events were submitted to VAERS. Of these, 108 cases were identified as possible cases of severe allergic reaction for further review, including 10 confirmed anaphylaxis (a life-threatening allergic reaction) cases. Of these, 9 cases had a reaction within 15 minutes of receiving the vaccine. The median age of cases with anaphylaxis was 47 years. The median time from receiving the vaccine to symptom onset was 7.5 minutes. There were no deaths due to anaphylaxis reported. There were 43 cases of non-anaphylaxis allergic reactions, with the most common symptoms being pruritus (itch), rash, itchy mouth and throat, feeling of throat closing, and other respiratory symptoms. 60% had a history of allergies and reaction to food and/or drugs. Median age of non-anaphylaxis allergic reactions was 43 years with 91% being women. Median time from receiving the vaccine to symptom onset was 15 minutes. The Moderna vaccine is still highly effective in reducing the risk of COVID-19 and the Center for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are continuously monitoring adverse events.

Key Takeaways:
- Those with an allergic reaction to the Moderna vaccine after the first dose, should not receive the second dose of the Moderna or Pfizer vaccine.
- Vaccine locations should have the supplies and staff to treat someone who experiences anaphylaxis and patients should be monitored after receiving the vaccine.
- Healthcare providers should be identifying and reporting adverse events after vaccinating to VAERS.

Single Dose Administration, And The Influence Of The Timing Of The Booster Dose On Immunogenicity and Efficacy Of ChAdOx1 nCoV-19 (AZD1222) Vaccine (SSRN-Preprints with THE LANCET)

Bottom Line: Based on this preprint article, the preliminary analysis of data collected from the phase III efficacy trials of ChAdOx1nCoV-19, an adenovirus vector vaccine through December 7, 2020, found a vaccine efficacy of 76% after a single standard dose from day 22 to 90, with modelled analyses showing protection did not fall in the 3 month period. The efficacy following the second standard dose at 12 weeks was 82.4% (95% CI 62.7% - 91.7%).

Details:
This is a preprint, non-peer reviewed article that presents data from pre-specified and exploratory analyses. The analysis presents data collected from the phase III efficacy trials of ChAdOx1nCoV-19 in the UK and Brazil and phase I/II trials in Brazil and South Africa through December 7, 2020. Participants were over the age of 18 and randomized 1:1 to receive two standard doses (SD) of ChAdOx1 nCoV-19 (5x1010 viral particles) or a placebo. A subset of

participants received a lower first dose (LD, 2.2x1010 viral particles) of the ChAdOx1 nCoV-19. The primary study endpoint was symptomatic infection more than 14 days after the second dose. Additional exploratory analyses were conducted to assess single dose efficacy, with an endpoint of symptomatic infection more than 21 days after the first dose. Patients were censored at time of their second dose.

A total of 17,177 participants were included in the efficacy analysis. A total of 332 cases of symptomatic COVID-19 occurred more than 14 days after the second dose. Overall vaccine efficacy 14 days after the second dose was 66.7% (95% CI: 57.4% - 74.0%) based on the pre-specified criteria. There was a vaccine efficacy of 76% after a single standard dose from day 22 to day 90, with modelled analyses showing protection did not fall in the 3 month period. Vaccine efficacy following the second standard dose at 12 weeks was 82.4% (95% CI: 62.7% - 91.7%), while vaccine efficacy was 54.9%, (95% CI: 32.7% - 69.7%) with a second standard dose at <6 weeks. The number of any PCR+ cases was reduced by 67% (95% CI: 49% - 78%) after one dose. The exploratory analysis results show protection with a 4-12 week dosing interval, and potential for reduced transmission.

Key Takeaways:

- This preprint study found a vaccine efficacy of 76% after a single standard dose of the ChAdOx1 nCoV-19 vaccine from day 22 to 90, with modelled analyses showing protection did not fall in the 3 month period.
- The efficacy following the second standard dose at 12 weeks was 82.4% (95% CI: 62.7% - 91.7%).
- The number of any PCR+ cases was reduced by 67% (95% CI: 49% - 78%) after one dose.

Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia (Lancet)

Bottom Line: In a phase 1/2 trial in Russia, a COVID-19 vaccine consisting of two recombinant adenovirus vectors showed a good safety profile and strong humoral and cellular immune responses in 76 participants (38 in each study).

Details: In these open, non-randomized phase 1/2 studies conducted at 2 hospitals in Russia, healthy adult volunteers were enrolled to study a COVID-19 vaccine consisting of two recombinant adenovirus vectors delivered as a prime-boost vaccine. The vaccine is composed of a recombinant adenovirus type 26 (rAd26) vector administered on day 0 and a recombinant adenovirus type 5 (rAd5) vector administered on day 21, both carrying the gene for the SARS-CoV-2 spike glycoprotein. The vaccine was developed as two formulations, frozen and lyophilized, and both formulations were studied in two parallel study groups. Volunteers were healthy adults aged 18-60. In phase 1 of each study, 18 adults were enrolled in both the frozen and lyophilized arms, with 9 receiving the rAd26 vaccine and 9 receiving the rAd5 vaccine. Safety of the two components were assessed at 28 days, with no serious adverse events detected. The most common adverse events were pain at injection site, hyperthermia, and headache. In phase 2 of each study, 20 participants received prime-boost vaccination in both frozen and lyophilized arms, with rAd26 given on day 0, and rAd5 given on day 21. Primary outcomes were antigen-specific humoral immunity on day 0, 14, 21, 28 and 42; secondary outcomes were antigen-specific cellular immunity and change in neutralizing antibodies. At day

42, seroconversion rate was 100%, with receptor-binding IgG titers and neutralizing antibodies higher with the frozen formulation than with the lyophilized formulation. Cell-mediated responses were detected in all participants at day 28, and were slightly higher with the frozen formulation.

Key Takeaways:

- In phase 1/2 trials, a novel adenovirus vector COVID-19 vaccine developed in Russia was found to have a good safety profile and induce strong humoral and cellular immune responses in 76 participants.
- Humoral and cellular immune responses were stronger using a frozen formulation of the vaccine compared to a lyophilized formulation.
- Further investigation is needed to determine effectiveness of the vaccine at preventing COVID-19 infection.