

THE QUARTERLY CONNECTION

Quarterly Report from Pharma-Care, Inc. / Creative Care Consulting

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P: (732) 574-9015 (PCI) / (732) 574-9434 (CCC)

136 Central Ave., Clark, New Jersey 07066

F: (732) 499-6778

Who should receive additional COVID-19 vaccine doses?*

(New Jersey Department of Health)

Additional (3rd) Dose of a COVID-19 Vaccine

The **CDC** recommends that people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after completion of the initial mRNA COVID-19 vaccine series.

Emerging evidence show people who are immunocompromised experienced a reduced immune response to the initial COVID-19 vaccine series. This update (additional dose of covid19 vaccine) aims to prevent serious and possibly life-threatening COVID-19 within this population.

Q: Who is eligible to get the additional dose?

A: The additional vaccine should be considered for people with moderate to severe immune compromise due to a medical condition, or receipt of immunosuppressive medications or treatments. This includes people who have:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of a solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (=20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Q: What is the difference between an “additional dose” and a “booster dose?”

A: An “**additional dose**” refers to people who are moderately to severely immunocompromised receiving an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series. This is because they may not have received adequate protection from their initial 2-dose vaccine series.

A “**booster dose**” is a supplemental vaccine dose given to people when the immune response to a primary vaccine series is likely to have waned over time. The need for and



timing of a COVID-19 booster dose has not been established, and no booster doses are recommended at this time

Q: Can you mix and match the mRNA vaccines?

A: The additional dose should be the same vaccine product as the initial two-dose mRNA COVID-19 vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses

Q: What should immunocompromised people who received the J&J/Janssen vaccine do?

A: There is not enough data at this time to determine whether immunocompromised people who received Janssen (J&J/Janssen) COVID-19 Vaccine also have an improved antibody response following an additional dose of the same vaccine.

Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots.*

On August 18th, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released the following statement on the Administration’s plan for COVID-19 booster shots for the American people.

The statement is attributable to Dr. Rochelle Walensky, Director of the Centers for Disease Control and Prevention (CDC); Dr. Janet Woodcock, Acting Commissioner, Food and Drug Administration (FDA); Dr. Vivek Murthy, U.S. Surgeon General; Dr. Francis Collins, Director of the National Institutes of Health (NIH); Dr. Anthony Fauci, Chief Medical Advisor to President Joe Biden and Director of the National Institute of Allergy and Infectious Diseases (NIAID); Dr. Rachel Levine, Assistant Secretary for Health; Dr. David Kessler, Chief Science Officer for the COVID-19 Response; and Dr. Marcella Nunez-Smith, Chair of the COVID-19 Health Equity Task Force:

“The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant. Recognizing that many vaccines are associated with a reduction in protection over time and acknowledging that additional vaccine doses could be needed

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*DISCLAIMER: ALL INFORMATION IS CORRECT AT TIME OF RELEASE. DETAILS MAY BE SUBJECT TO CHANGE BASE ON UPDATED RELEASES FROM NJDH, CDC, AND HHS AFTER 9/15/2021



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Health Care Consultation Specialists
WWW.PHARMACAREINC.COM

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Joint Statement ...

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to provide long lasting protection, we have been analyzing the scientific data closely from the United States and around the world to understand how long this protection will last and how we might maximize this protection. The available data make very clear that protection against SARS-CoV-2 infection begins to decrease over time following the initial doses of vaccination, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease. Based on our latest assessment, the current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout. For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and prolong its durability.

“We have developed a plan to begin offering these booster shots this fall subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC’s Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence. **We are prepared to offer booster shots for all Americans beginning the week of September 20 and starting 8 months after an individual’s second dose. At that time, the individuals who were fully vaccinated earliest in the vaccination rollout, including many health care providers, nursing home residents, and other seniors, will likely be eligible for a booster.** We would also begin efforts to deliver booster shots directly to residents of long-term care facilities at that time, given the distribution of vaccines to this population early in the vaccine rollout and the continued increased risk that COVID-19 poses to them.

“We also anticipate booster shots will likely be needed for people who received the Johnson & Johnson (J&J) vaccine. Administration of the J&J vaccine did not begin in the U.S. until March 2021, and we expect more data on J&J in the next few weeks. With those data in hand, we will keep the public informed with a timely plan for J&J booster shots as well.

“Our top priority remains staying ahead of the virus and protecting the American people from COVID-19 with safe, effective, and long-lasting vaccines especially in the context of a constantly changing virus and epidemiologic landscape. We will continue to follow the science on a daily basis, and we are prepared to modify this plan should new data emerge that requires it.

“We also want to emphasize the ongoing urgency of vaccinating the unvaccinated in the U.S. and around the world. Nearly all the cases of severe disease, hospitalization, and death continue to occur among those not yet vaccinated at all. We will continue to ramp up efforts to increase vaccinations here at home and to ensure people have accurate information about vaccines from trusted sources. We will also continue to expand our efforts to increase the supply of vaccines for other countries, building further on the more than 600 million doses we have already committed to donate globally.”



CMS Five Top Areas of Focus

August 19, 2021

On August 10, 2021, Evan Shulman, Deputy Director of the Division of Nursing Homes, Centers for Medicare & Medicaid Services (CMS) in Baltimore Maryland spoke at the 34th Annual NADONA Conference on the top five current areas of surveyor focus. The following is a summary of his presentation.

1. **Vaccinations:** Currently, data shows that 81% of residents and 60% of staff are vaccinated against COVID-19. The number one factor for occurrence in facilities is the infection rate in the surrounding local community. The rate of breakthrough infections is still too high. COVID infections in residents have dropped significantly, and now it is staff who have the highest infection rates. They are bringing it to the facility from their interactions in their communities. Innovate and work with your communities to improve vaccination rates for all.
2. **Infection Control:** Don't let your guard down. **F-Tag 880** is being cited for noncompliance with simple basics such as wearing PPE correctly, testing, hand hygiene, and screening for symptoms. Staff are taking risks outside the facility. Encourage them to continue proactive measures when they leave work. Encourage everyone to wear a mask, even if vaccinated. Some people wear their mask below their nose or under their chin – we are only as strong as our weakest link.
3. **Manage Visitation:** Safely increase visitation with residents. The March 10, 2021, CMS memo lists the federal requirements. [Nursing Home Visitation - COVID-19 \(REVISED\)](#) | [CMS Watch](#) to ensure that physical distancing still occurs. On holidays and other special days, if too many visitors are coming to your facility to maintain social distancing, schedule visitation in advance of the holiday to control the number of visitors at any one time. At non-holiday times, allow free visits. It is so important for the residents to have safe visits with loved ones.
4. **Get Back to Non-COVID Care Areas:** CMS is seeing an increase in pressure ulcers, insufficient staffing, decline in Quality Measures, and increased use of antipsychotics without adequate monitoring for side effects, the worst of which is death. Refine your QAPI plans; track everything; crack down on abuse, and in particular social media abuse – there should be no photos from staff on the internet. Phase 3 Guidance is being worked on and could be released momentarily. Read the regulations – every facility must have an Infection Preventionist. There is free training from CMS and the CDC that meets the requirements. As a result of COVID, there are increased mental health and substance abuse admissions, which is a big problem that must be managed. CMS will address this and is looking at proposed Guidance.
5. **Staffing:** This is the #1 issue for residents, families, stakeholders, the facility, and staff, and it is very complex. PBJ data is used to calculate the Five Star Rating on Care Compare. CMS will be enforcing numbers during surveys. The PBJ system will be sending staffing data for weekends to survey teams, and those facilities with the worst weekend staffing levels will have off-times surveys starting on weekends. Higher staffing is linked to better outcomes and fewer antipsychotics. Using PBJ data, CMS plans to begin reporting turnover rates for facilities. This has been delayed due to COVID and the related staffing issues, but it is coming. Staff with longevity know residents better and know the policies and procedures. Look at your nurse aid training programs and get back to training.

Beyond those five top issues, know that CMS is also looking at state survey inconsistencies. The process should be applied the same in all states, but currently is not. CMS has a goal of making surveys and enforcement consistent. CMS, like those working in nursing homes, is there for the mission, not the money. As you manage COVID, don't let up on the other things.



Pharma-Care, Inc.
Health Care Consultation Specialists
WWW.PHARMACAREINC.COM



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