



COVID-19 Clinical Advisory Task Force

October 23, 2021

Commissioner Howard A. Zucker, M.D., J.D.
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Commissioner Zucker,

The Clinical Advisory Task Force met via Webex at 7:00 PM on Thursday, October 21, 2021 to discuss booster injections in individuals who have received the two-dose primary vaccination series with the Moderna mRNA Covid-19 vaccine or the single dose primary vaccination with the Janssen Covid-19 vaccine. This issue was addressed by two federal agencies in the approval, regulatory, and public health recommendation pathways of Covid-19 vaccines. The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), through the vehicles of their advisory committees – the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and Advisory Committee on Immunization Practices (ACIP), respectively – thoroughly reviewed the available data on the safety and effectiveness of the Moderna mRNA and Janssen vaccines. The Task Force members monitored these proceedings and discussed them via conference call.

The Task Force commends the VRBPAC (FDA) and ACIP (CDC) for the quality of the presentations, the airing of varied viewpoints, and the thoughtful independence of their advisory committee members. Discussion and debate of the recommendations during each proceeding highlighted issues to resolve and the need for more data in many areas. Following their respective council recommendations, the FDA authorized the Moderna mRNA and Janssen booster injections on October 20, and CDC recommended the same on October 21, 2021.

Specifically, on October 20, 2021, the FDA took action to amend the emergency use authorizations (EUA) for COVID-19 vaccines to allow for the use of a single booster dose as follows:

- The use of a single booster dose of the Moderna COVID-19 Vaccine may be administered at least 6 months after completion of the primary series to individuals:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

- The use of a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccine may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.
- The use of each of the available COVID-19 vaccines as a heterologous (or “mix and match”) booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine.
- To clarify that a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered at least 6 months after completion of the primary series to individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.

The FDA further noted the Moderna COVID-19 single booster dose is half of the dose that is administered for a primary series dose and is administered at least six months after completion of a primary series of the vaccine.

ACIP endorsed the FDA action and made identical recommendations on October 21, 2021, which the CDC then immediately adopted. These new statements are considered to supersede ACIP’s and CDC’s previous Pfizer recommendation.

Specifically, CDC recommends for individuals who received a Pfizer-BioNTech or Moderna COVID-19 vaccine, the following groups are eligible for a booster shot at 6 months or more after their initial series:

- 65 years and older
- Age 18+ who live in [long-term care settings](#)
- Age 18+ who have [underlying medical conditions](#)
- Age 18+ who work or live in [high-risk settings](#)

Additionally, for the nearly 15 million people who got the Johnson & Johnson [Janssen] COVID-19 vaccine, booster shots are also recommended for those who are 18 and older and who were vaccinated two or more months ago.

There are now booster recommendations for all three available COVID-19 vaccines in the United States. Eligible individuals may choose which vaccine they receive as a booster dose. Some people may have a preference for the vaccine type that they originally received and others, may prefer to get a different booster. CDC’s recommendations now allow for this type of mix and match dosing for booster shots.

The Task Force endorses these recommendations from the CDC as they provide additional flexibility at the public health and individual care levels such that access will be available to all who would potentially benefit from a booster. The Task Force maintains the list of qualifying medical conditions that potentially put an individual at higher risk of severe COVID-19 and the occupational or institutional settings that potentially convey frequent exposure, as outlined in the September 24, 2021 Task Force letter.

The Task Force further notes that the definition of “fully vaccinated” remains unchanged and consists of either a single dose of the Janssen COVID-19 vaccine, a two-dose series of the Moderna COVID-19 vaccine or a two-dose series of the Pfizer COVID-19 vaccine. Guidance for people who are considered immune-compromised similarly remains unchanged and recommends an additional dose of the primary series COVID-19 vaccine to strengthen immune response; a booster dose (i.e., a fourth shot) is not currently recommended.

Additional details on administration of boosters, including clinical considerations, are forthcoming from CDC as guidance and as a publication in the Morbidity and Mortality Weekly Report on October 29, 2021.

The Task Force recognizes the multiple booster dose options authorized by FDA and recommended by CDC, depicted in Table 1. Table 2, at the end of this letter, depicts the full range of COVID-19 vaccination steps currently authorized and recommended, including primary, additional and booster doses, based on age, presence of immunocompromising condition, and primary vaccine series.

Table 1. Booster dose options and timing based on primary series vaccine received.

Eligible population	Primary series vaccine	Booster dose option and dosing	Booster dose timing
<ul style="list-style-type: none"> Persons 18 years of age or older 	Janssen	Booster dose should be same as primary series unless primary series product is unavailable or another product is preferred. Options are: <ul style="list-style-type: none"> Janssen* Moderna-Half dose (50 µg (0.25 mL)) Pfizer 	At least 2 months following completion of primary series
<ul style="list-style-type: none"> Persons 65 years of age or older 	Janssen	Booster dose should be same as primary series unless primary series product is unavailable or another product is preferred. Options are: <ul style="list-style-type: none"> Janssen* Moderna-Half dose (50 µg (0.25 mL)) Pfizer 	At least 2 months following completion of primary series
<ul style="list-style-type: none"> Persons 18 through 64 years of age at high risk of severe COVID-19 	Moderna		At least 6 months following completion of primary series
<ul style="list-style-type: none"> Persons 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2 	Pfizer		At least 6 months following completion of primary series

*People who developed thrombosis with thrombocytopenia syndrome (TTS) after Janssen COVID-19 primary vaccine should not receive a booster dose of Janssen vaccine. These individuals may receive a dose of either mRNA COVID-19 vaccine as a booster at least 2 months following the Janssen dose and after the clinical condition has stabilized. People who had Guillain-Barré Syndrome (GBS) after the Janssen primary vaccine may receive any COVID-19 vaccine as a booster at least 2 months after the Janssen dose, but should be made aware of the option to receive an mRNA COVID-19 booster instead of a Janssen booster.

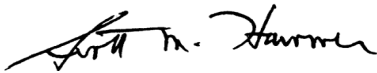
Table 2. COVID-19 vaccination steps currently authorized and recommended, including primary, additional and booster doses, based on age, presence of immunocompromising condition, and primary vaccine series.

Vaccine	Primary Series/Dose			Additional 3 rd Dose for Immunocompromised			Definition of Fully Vaccinated
	Dose (Volume)	Number of doses (Interval)	Age (Years)	Dose (Volume)	Number of doses (Interval Since Primary Series)	Age (Years)	
Pfizer-BioNTech	30 ug (0.3 ml)	2 (21 days)	≥ 12	30 ug (0.3 ml)	1 (≥ 28 days)	≥ 12	People who have completed the primary vaccine series (i.e., 2-dose mRNA vaccine series or a single dose of the Janssen vaccine) are considered fully vaccinated ≥ 2 weeks (i.e., ≥ 15 days) after the completion of the primary series.
Moderna	100 ug (0.5 ml)	2 (28 days)	≥ 18	100 ug (0.5 ml)	1 (≥ 28 days)	≥ 18	
Janssen/Johnson & Johnson	5 x10 ¹⁰ VP (0.5ml)	1 (N/A)	≥ 18	N/ A See Booster Dose			
Booster dose							
	Dose (Volume)	N doses (Interval)	Age (Years)				
Pfizer-BioNTech	30 ug (0.3 ml)	1 (≥ 6 months)	≥ 18	A booster dose does not change the definition of 'Fully Vaccinated' People who receive a booster dose should continue to follow guidance for fully vaccinated persons to minimize the spread of SARS-CoV2			
Moderna	50 ug (0.25 ml)	1 (≥6 months)	≥ 18				
Janssen/Johnson & Johnson	5 x10 ¹⁰ VP (0.5ml)	1 (≥ 2 months)	≥ 18				

The proceedings and guidance described above put into relief two pressing issues that need to be addressed:

- Primary vaccination of unvaccinated persons should remain the top priority. Boosting already vaccinated individuals is secondary to this over-riding objective.
- No guidance has been provided for booster doses for people under age 18 years. A booster dose may not be needed for this age group.

Respectfully,



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