

Recommendations Regarding the Bivalent COVID-19 Booster Vaccine

DATE:	09/14/2022
TO:	Health Alert Network
FROM:	Denise A. Johnson, M.D., FACOG, FACHE, Acting Secretary of Health
SUBJECT:	Recommendations Regarding the Bivalent COVID-19 Booster Vaccine
DISTRIBUTION:	Statewide
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COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a

This transmission is a “Health Advisory,” and provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

SUMMARY

- CDC [Guidance](#) released on September 1, 2022 recommends that patients 12 and older who received the primary series of any of the authorized COVID-19 vaccines should receive a booster dose of a mRNA bivalent COVID-19 vaccine.
- The mRNA bivalent booster dose should occur at least 2 months after the last dose of a COVID-19 vaccine.
- The bivalent Pfizer BioNTech booster is approved for patients aged 12 years and older
- The bivalent Moderna booster is approved for patients aged 18 years and older.
- The mRNA bivalent vaccines are only available for booster vaccinations. The original monovalent COVID-19 vaccine must be used for the primary series. The original monovalent COVID-19 vaccine can no longer be used for booster doses except for children aged 5-11 who are not eligible for the booster dose of the bivalent COVID-19 vaccine.
- Since there are now multiple formulations of the mRNA COVID-19 vaccines it will be extremely important for vaccine providers to make sure that the correct vaccine is given to each patient.
- The CDC [definition of up to date](#) with COVID-19 vaccine is someone who has completed their primary vaccine series and received the most recent COVID-19 booster vaccine recommended for them by the CDC
- It is highly recommended that patients also receive their Influenza vaccine this fall and can receive both the COVID-19 bivalent booster and the influenza vaccine during the same visit
- If you have any questions, please call PA DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

Background

On September 1, 2022, the CDC reviewed the current data about the continuing effectiveness of COVID-19 vaccines and [recommended](#) a booster dose of the new bivalent mRNA COVID-19 vaccines. The bivalent vaccines consist of a combination of the original strain of the COVID-19 virus and the omicron BA.4 and BA.5. The FDA approved both Moderna and Pfizer-BioNTech bivalent booster vaccines in an [Emergency Use Authorization](#) (EUA) on August 31, 2022.

Bivalent COVID-19 Vaccines

- Pfizer-BioNTech Bivalent COVID-19 Vaccine:
 - Patients 12 and older who completed their primary series with any COVID-19 vaccine are eligible for a booster dose of the bivalent Pfizer BioNTech COVID-19 vaccine at least 2 months after their primary series is complete and/or at least 2 months after their last booster vaccine
 - The Pfizer-BioNTech COVID-19 vaccine bivalent booster dose is the same as the primary series dose: 0.3ml via intramuscular injection
 - The Pfizer-BioNTech COVID-19 vaccine booster dose may be given in conjunction with other vaccines without regard to timing including on the same day except for the JYNNEOS monkeypox vaccine
 - Patients who received JYNNEOS monkeypox vaccine should wait 4 weeks until receiving their COVID-19 bivalent booster. However, JYNNEOS vaccine should not be delayed because of recent receipt of a COVID-19 bivalent booster
 - [Contraindications](#) for the Pfizer-BioNTech COVID-19 vaccine bivalent booster dose are as follows:
 - Severe allergic reaction (anaphylaxis) after a previous dose or to a component of the Pfizer-BioNTech COVID-19 vaccine
 - Immediate allergic reaction of any severity to a previous dose or known allergy to a component of the Pfizer-BioNTech COVID-19 vaccine
 - Myocarditis after a dose of an mRNA vaccine is very rare and is not an absolute contraindication; however, the booster dose should be deferred until myocarditis has completely resolved
 - The Pfizer-BioNTech COVID -19 bivalent booster is **not** authorized for anyone under the age of 12 regardless of medical condition or occupation.
 - Patients aged 6-11 who received a primary series with Pfizer-BioNTech vaccine should receive a single booster dose of the original monovalent vaccine at least 5 months after the completion of their primary series
- Moderna Bivalent COVID-19 Vaccine:
 - Patients 18 and older who completed their primary series with any COVID-19 vaccine are eligible for a booster dose of the bivalent Moderna COVID-19 vaccine at least 2 months after their primary series is complete and/or at least 2 months after their last booster vaccine
 - The Moderna COVID-19 vaccine bivalent booster dose is the same volume as the primary series dose: 0.5ml via intramuscular injection
 - It is a 50mcg dose rather than the primary series dose of 100mcg.
 - The Moderna COVID-19 vaccine bivalent booster dose may be given in conjunction with other vaccines without regard to timing including on the same day except for the JYNNEOS monkeypox vaccine
 - Patients who received JYNNEOS monkeypox vaccine should wait 4 weeks until receiving their COVID-19 bivalent booster. However, JYNNEOS vaccine should not be delayed because of recent receipt of a COVID-19 bivalent booster
 - [Contraindications](#) for the Moderna COVID-19 vaccine bivalent booster dose are as follows:

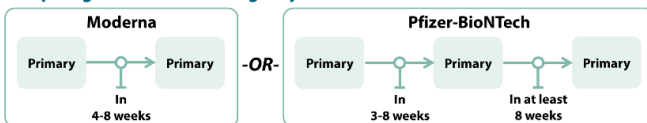
- Severe allergic reaction (anaphylaxis) after a previous dose or to a component of the Moderna COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known allergy to a component of the Moderna COVID-19 vaccine
- Myocarditis after a dose of an mRNA vaccine is very rare and is not an absolute contraindication; however, the booster dose should be deferred until myocarditis has completely resolved
- The Moderna COVID -19 bivalent booster is **not** authorized for anyone under the age of 18 regardless of medical condition or occupation.
 - Patients aged 12-17 who received a primary series with the Moderna monovalent COVID-19 vaccine should receive a single booster dose of the Pfizer BioNTech bivalent COVID-19 booster vaccine at least 2 months after the completion of their primary series
 - Patients aged 6-11 should receive a single booster dose of the original monovalent mRNA COVID-19 vaccine at least 5 months after the completion of their primary series.
- Heterologous (Mix and Match) dosing can be considered for the bivalent COVID-19 booster
- Since there are now multiple formulations of the mRNA COVID-19 vaccines it will be extremely important for vaccine providers to make sure that the correct vaccine is given to each patient.

Current COVID-19 Vaccination Schedule

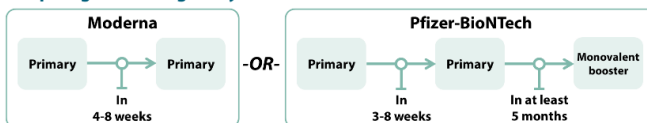
From the [CDC](https://www.cdc.gov):

COVID-19 Vaccination Schedule for People who are NOT Moderately or Severely Immunocompromised

People ages 6 months through 4 years



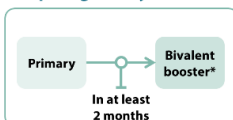
People ages 5 through 11 years



People ages 12 years and older



People ages 18 years and older who previously received Janssen primary series dose[†]



*The bivalent booster dose is administered at least 2 months after completion of the primary series. For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.

[†]Janssen COVID-19 Vaccine should only be used in certain limited situations. See: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a>

COVID-19 Vaccination Schedule for People who are Moderately or Severely Immunocompromised

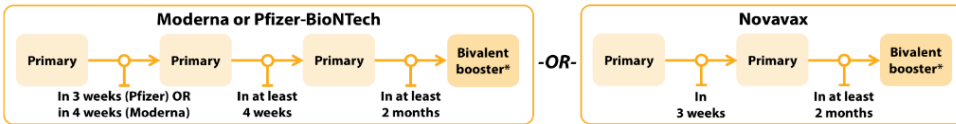
People ages 6 months through 4 years



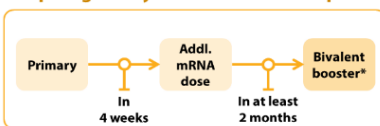
People ages 5 through 11 years



People ages 12 years and older

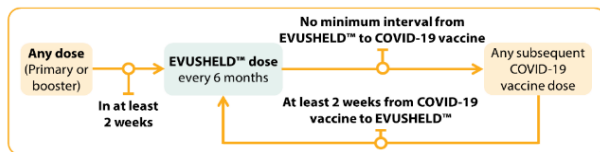


People ages 18 years and older who previously received Janssen primary series dose[†]



Monoclonal antibodies (EVUSHELD™) for COVID-19 pre-exposure prophylaxis

People ages 12 years and older (must weigh at least 40kg)



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Heterologous (Mix and Match) Dosing:

- Heterologous (mix and match) dosing may occur for the bivalent booster dose. In other words, a different COVID-19 mRNA vaccine product from the original vaccination series can be used for the booster dose.
- The determination of whether to use a different product from the original series is decided between the provider and the patient.

Up to Date with COVID-19 Vaccinations

- The CDC [definition of up to date](#) with COVID-19 vaccine is someone who has completed their primary vaccine series and received the most recent booster recommended for them by the CDC

COVID-19 Bivalent Booster vaccines and the Influenza Vaccine

- It is highly [recommended](#) that patients also receive their Influenza vaccine this fall and can receive both the COVID-19 bivalent booster and the influenza vaccine during the same visit

If you have any questions, please call PA DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of September 14, 2022 but may be modified in the future.