Recommendations Regarding the Bivalent COVID-19 Booster Vaccine

<table>
<thead>
<tr>
<th>DATE:</th>
<th>09/14/2022</th>
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<tbody>
<tr>
<td>TO:</td>
<td>Health Alert Network</td>
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<tr>
<td>FROM:</td>
<td>Denise A. Johnson, M.D., FACOG, FACHE, Acting Secretary of Health</td>
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<tr>
<td>SUBJECT:</td>
<td>Recommendations Regarding the Bivalent COVID-19 Booster Vaccine</td>
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<td>DISTRIBUTION:</td>
<td>Statewide</td>
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<td>LOCATION:</td>
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<td>STREET ADDRESS:</td>
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<td>COUNTY:</td>
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<td>MUNICIPALITY:</td>
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<td>ZIP CODE:</td>
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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

<table>
<thead>
<tr>
<th>People ages 6 months through 4 years</th>
<th>Moderna</th>
<th>Pfizer-BioNTech</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 4-8 weeks</td>
<td>Primary</td>
<td>Primary</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>People ages 5 through 11 years</th>
<th>Moderna</th>
<th>Pfizer-BioNTech</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 4-8 weeks</td>
<td>Primary</td>
<td>Primary</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>People ages 12 years and older</th>
<th>Moderna, Novavax, or Pfizer-BioNTech</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary 4-8 weeks (Novavax, Pfizer) OR 4-8 weeks (Moderna)</td>
<td>Bivalent booster*</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>People ages 18 years and older who previously received Janssen primary series dose†</th>
<th>Primary 4-8 weeks</th>
<th>Bivalent booster*</th>
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*Heterologous (Mix and Match) dosing can be considered for the bivalent COVID-19 booster

†Janssen COVID-19 vaccine should only be used in certain limited situations. See [https://www.cdc.gov/vaccines/priorities/technical-considerations/interventions-concerns-for-specific-conditions.html](https://www.cdc.gov/vaccines/priorities/technical-considerations/interventions-concerns-for-specific-conditions.html)
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.