

Updated Recommendations Regarding the Monovalent and Bivalent mRNA COVID-19 Vaccines

DATE:	4/28/2023
TO:	Health Alert Network
FROM:	Debra L. Bogen, M.D., FAAP, Acting Secretary of Health
SUBJECT:	Updated Recommendations Regarding the Monovalent and Bivalent mRNA COVID-19 Vaccines
DISTRIBUTION:	Statewide
LOCATION:	n/a
STREET ADDRESS:	n/a
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

- The FDA [announced](#) on April 18, 2023 that it had rescinded the authorization for the monovalent Pfizer-BioNTech and monovalent Moderna COVID-19 vaccines and that the [bivalent Pfizer-BioNTech](#) and [bivalent Moderna](#) vaccines are now authorized for all doses for individuals 6 months and older.
- The FDA authorization for the [Novavax](#) vaccine is unchanged.
- The definition of up to date for COVID-19 vaccination was simplified and now all individuals 6 years and older who have received a single dose of a bivalent COVID-19 vaccine, regardless of past history of receiving monovalent COVID-19 vaccine, are considered [up to date](#).
- Children 6 months through 4 years of age who are unvaccinated may receive a 2-dose series of the Moderna bivalent or a 3-dose series of the Pfizer-BioNTech bivalent vaccine.
- Children who are 5 years old and are unvaccinated may receive 2 doses of the Moderna bivalent vaccine or 1 dose of the Pfizer-BioNTech bivalent vaccine.
- Children 6 months to 5 years of age who received one, two, or three doses of monovalent COVID-19 vaccine may receive bivalent vaccine but the number of doses that they receive will depend upon the vaccine given and their vaccination history.
- Individuals 65 and older and those with certain [immunocompromising conditions](#) may choose to receive an additional dose of the bivalent Pfizer-BioNTech or bivalent Moderna vaccine.
- 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 April 18, 2023, the FDA [rescinded its authorization](#) for the monovalent Pfizer-BioNTech and the monovalent Moderna COVID-19 vaccines. On April 19, 2023, the CDC reviewed the current data on the continuing effectiveness of COVID-19 vaccines and [recommended](#) that the current bivalent mRNA vaccines should be used for COVID-19 vaccination. This will decrease the number of different COVID-19 vaccine products providers store in their clinics and should reduce COVID-19 vaccine administration errors. The CDC also further simplified the COVID-19 vaccination schedule by updating its definition of [up to date](#) for all individuals 6 years old and older to simply having one dose of either the [Pfizer-BioNTech bivalent](#) or [Moderna bivalent](#) vaccine. Children between the ages of 6 months to 5 years still need a combination of one, two or three doses of a bivalent vaccine depending on the child's age, vaccination history, and brand of vaccine given to be considered up to date.

Current Updated COVID-19 Vaccine Recommendations

- Monovalent Pfizer-BioNTech and monovalent Moderna vaccines are no longer authorized by the FDA and can no longer be given.
 - Any doses of monovalent Pfizer-BioNTech or monovalent Moderna COVID-19 vaccine given after April 18, 2023 should have a [VAERS](#) form completed since they were given without FDA authorization.
 - All doses of monovalent Pfizer-BioNTech and monovalent Moderna vaccines should be disposed of immediately and in an appropriate manner.
 - Monovalent [Novavax](#) vaccine can still be given but needs to be followed up by a bivalent mRNA vaccine at the appropriate interval to be considered up to date with COVID-19 vaccination.
 - Individuals who received the [Janssen](#) vaccine should receive a single dose of a bivalent mRNA vaccine to be considered up to date with COVID-19 vaccination.
- All individuals 6 years and older who have received a single dose of a bivalent COVID-19 vaccine regardless of past history of receiving monovalent COVID-19 vaccine are now considered [up to date](#).
- [Recommendations for children 6 months through 5 years:](#)
 - Children 6 months through 4 years of age who are unvaccinated may receive a 2-dose series of the Moderna bivalent or a 3-dose series of the Pfizer-BioNTech bivalent vaccine.
 - Children who are 5 years old who are unvaccinated may receive two doses of the Moderna bivalent vaccine or one dose of the Pfizer-BioNTech bivalent vaccine.
 - Children 6 months to 5 years of age who received one, two, or three doses of monovalent COVID-19 vaccine may receive bivalent vaccine but the number of doses that they receive will depend upon the vaccine given and their vaccination history.
- All individuals 65 and older and those individuals 5 years old and older with certain [immunocompromising conditions](#) may choose to receive an additional dose of the bivalent Pfizer-BioNTech or bivalent Moderna vaccines.
 - Individuals 65 and over may choose to receive an additional dose of a bivalent COVID-19 vaccine at least four months after their initial dose of the bivalent COVID-19 vaccine.
 - Individuals with certain immunocompromising conditions may choose to receive an additional dose of bivalent COVID-19 vaccine at least 2 months after their initial bivalent vaccine and may receive additional doses at the discretion of, and at intervals determined by, their healthcare provider.
 - Immunocompromising conditions include the following:
 - Active treatment for solid tumor and hematologic malignancies
 - Hematologic malignancies associated with poor response to COVID-19 vaccines regardless of current treatment status

- Receipt of solid organ or islet transplant and taking immunosuppressive therapy
- Moderate or severe primary immunodeficiency
- Advanced HIV infection
- Active treatment with high-dose steroids, alkylating agents, antimetabolites, transplant related immunosuppressive drugs, cancer chemotherapeutic agents classified as immunosuppressive, tumor necrosis factor blockers, and/or other biologics considered immunosuppressive or immunomodulatory
 - However, for immunocompromised individuals 6 months to 4 years of age, eligibility for additional doses will depend upon vaccine already administered.
- However, the definition of being up to date with COVID-19 vaccine is the same for individuals 65 and older and for those individuals 5 years and older with certain immunocompromising conditions as it is for the rest of the population.
 - A single dose of a bivalent COVID-19 vaccine is the only requirement for all individuals aged 6 years and older to be considered up to date with COVID-19 vaccination.

There are still multiple formulations of the bivalent mRNA COVID-19 vaccines, so it is 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: [COVID-19 Vaccination schedule](#)

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 April 28, 2023 but may be modified in the future.
