IMMUNIZATION COVID-19 Update

October 14, 2022 | Issue 81

Question of the Week

I've heard that the bivalent booster causes more heart issues for 65+ individuals than the initial series vaccine does. Is this true?

The new bivalent booster shots were studied by the U.S. Food and Drug Administration (FDA) and the CDC's Advisory Committee on Immunization Practices (ACIP) before being released the public. The question addressed was, "Does ACIP support the use of the bivalent booster dose for people age 50 and older?" For both the Modern and Pfizer-BioNTech vaccines, the answer is "yes." **Studies reviewed by ACIP** specifically considered myocarditis and pericarditis, both of which are heart inflammation conditions. The review of severe reactions to both vaccines are shown here:

- Moderna: No severe adverse events related to the vaccine, and there were no adverse events of interest for myocarditis or pericarditis.
- Pfizer-BioNTech: No severe adverse events were assessed as related to vaccine including no cases of myocarditis or pericarditis were reported.

Myocarditis and pericarditis after COVID-19 vaccination are rare across demographic groups and most likely to occur in teen boys in the week after their second shot of a two-dose vaccine, according to a study. They were also more likely to occur after a booster shot compared with a first dose of vaccine, the study showed.

When either does occur, researchers found the side effect nearly always fades within a week or so, with no further health events noted.

FDA authorized Moderna and Pfizer-BioNTech Bivalent COVID-19 vaccine boosters for younger age groups

On Oct. 12, the FDA amended the emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups.

FDA reported:

- *The Moderna COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to six years of age.*
- *The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for administration at least two months following completion of primary or booster vaccination in children down to five years of age.*

These bivalent COVID-19 vaccines include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component in common between the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant. The mRNA in these vaccines is a specific piece of genetic material that instructs cells in the body to make the distinctive "spike" protein of the original virus strain and the omicron variant lineages BA.4 and BA.5. The spike proteins of BA.4 and BA.5 are identical.

The new authorization eliminates the prior authorization of the monovalent Pfizer-BioNTech COVID-19 for individuals 5 through 11 years of age.

However, both the Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine continue to be authorized for primary series administration in individuals six months of age and older.
For more information about the authorization and associated clinical studies, **visit here**.

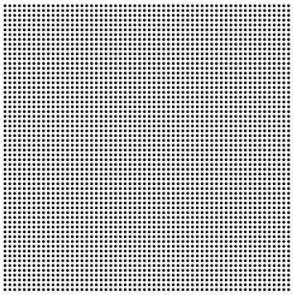
Additional resources:

- **Moderna COVID-19 Vaccine**
- **Pfizer-BioNTech COVID-19 Vaccine**
- **COVID-19 Bivalent Vaccine Boosters**
- **COVID-19 Vaccines**
- **Emergency Use Authorization for Vaccines Explained**

COVID-19 vaccine shows favorable results among Louisiana Medicare recipients

According to a new report by the U.S. Department of Health & Human Services (HHS), COVID-19 vaccines are estimated to have prevented 3,600 deaths and 8,800 hospitalizations among Louisiana's Medicare population. **Note**: Medicaid recipients account for 19% of the state's population, and the HHS data do not include all the vaccines given in 2022. **Learn more**.

Each Full of 75 People(!)



Each dot represents one of the estimated 3,600 Medicare Beneficiaries whose lives were saved from COVID-19 Vaccines in Louisiana, 2021

Immunization team announces office hours for the pediatric bivalent COVID-19 boosters

The FDA recently approved emergency use authorization (EUA) for the Moderna and Pfizer Bivalent COVID-19 vaccine boosters for individuals ages 5 through 11 years old. To assist providers, the Immunization Program will hold an informational Provider Office Hours on October 14 at 12pm to discuss the new authorizations and vaccine products.

Delivery of the initial Pfizer pediatric vaccine is expected during the week of Oct. 17. To ensure equitable distribution, the vaccine boosters will be offered to as many Louisiana COVID-19 vaccine providers as possible.

Who's eligible for the pediatric boosters?

- 5–11-year-olds at least two months since their primary series and/or last COVID-19 shot are projected to be eligible for Pfizer
- 6–11-year-olds at least two months since their primary series and/or last COVID-19 shot are projected to be eligible for Moderna
- 12–17-year-olds are also projected to be eligible for the Moderna bivalent booster with this EUA recommendation
- Mix and match is expected; children can receive either shot regardless of their primary series or previous boosters

HHS amends Public Readiness and Emergency Preparedness Act (PREP Act) to increase authorized monkeypox vaccine providers

Earlier this month, the HHS amended Public Readiness and Emergency Preparedness Act (PREP Act) declaration for smallpox medical countermeasures—effectively expanding the pool of qualified healthcare professionals authorized to administer **monkeypox** vaccines and therapeutics licensed, approved or authorized by the FDA during a declared emergency.

The following are now included in the list of authorized providers:

- Licensed or certified professional midwives
- Nurses, advanced practice registered nurses, registered nurses, licensed practical nurses
- Optometrists
- Paramedics
- Pharmacists
- Pharmacy interns, pharmacy technicians
- Physicians
- Physician assistants
- Podiatrists
- Respiratory therapists
- Veterinarians
- Recently retired healthcare professionals and students of the listed professions

The amendment also:

- Requires all authorized providers to adhere to CDC and FDA protocol.
- Specifies that the declaration applies to public health threats arising from smallpox (variola virus), monkeypox virus, and other orthopoxviruses.
- Extends the effective time period of the declaration to December 31, 2032. This extension allows coverage for manufacturers, distributors and other covered persons through that date.
- Allows coverage for the administration of countermeasures by subcutaneous, intradermal, or intramuscular injections, dermal/percutaneous scarification, orally or intranasally in response to a declared emergency by authorized qualified persons to be extended during the relevant emergency or December 31, 2032, whichever occurs first. A declared emergency can be any federal, state, regional, or local declaration.

Learn more.

Register for Joint COVID-19 Misinformation Briefing

The Centers for Disease Control and Prevention (CDC) and California Department of Public Health (CDPH) will host the next Joint COVID-19 Misinformation Briefing on Tuesday, October 18 at 3:00 PM CT via Zoom.

The monthly briefings are intended to provide public health organizations with a baseline understanding of some of the English and Spanish online narratives that may undermine confidence in COVID-19 vaccines, as well as tactics to counter them. Subsequent sessions will take place monthly.

Register in advance for this meeting:
https://us02web.zoom.us/meeting/register/tZAvc-ytqDksHdz87eSFC-nO8UZ_ibcCQ7-l

FDA issues EUA to Abbott Molecular for monkeypox detection testing

Last week, the FDA issued an **Emergency Use Authorization (EUA)** to Abbott Molecular, Inc., for the Alinity m MPXV , a real-time polymerase chain reaction (PCR) test intended to detect monkeypox DNA using lesion swab specimens from individuals suspected of monkeypox virus infection. The Alinity m MPXV test is the first commercial test kit to be authorized for detection of monkeypox.

The Alinity m MPXV test is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of PCR and in vitro diagnostic procedures and testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests.

Good reads

- **FDA authorizes bivalent COVID-19 boosters for children ages 5 to 11**
- **WHO chief urges immediate action to tackle 'devastating' long COVID**
- **Novavax says COVID booster dose shows benefit against Omicron variants**

Submit a Question of the Week

Do you have a frequently asked question that you would like to submit or have answered in the QOW?

SUBMIT HERE