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FDA NEWS

FDA Authorizes Updated COVID-19 Booster Vaccines

On August 31, 2022 the U.S. Food and Drug Administration announced the emergency authorization of updated COVID-19 booster vaccines by Pfizer-BioNTech and Moderna. The new vaccines, referred to as bivalent, contain components of both the original strain of the virus and the Omicron BA.4/BA.5 variants. Here are some key points about the new boosters:

- **Pfizer COVID Vaccine, Bivalent:** Individuals 12 years of age and older are eligible for a single bivalent booster dose if it has been at least 2 months since they have completed primary vaccination or have received the most recent booster dose with any authorized monovalent COVID-19 vaccine.
- **Moderna COVID Vaccine, Bivalent:** Individuals 18 years of age and older are eligible for a single bivalent booster dose if it has been at least 2 months since they have completed primary vaccination or have received the most recent booster dose with any authorized monovalent COVID-19 vaccine.

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CDC Advice on Influenza Vaccination for 2022/2023 Season

The United States Centers for Disease Control and Prevention (CDC) has published its annual report on the prevention and control of seasonal influenza with vaccines. This year's guidelines, issued on August 26, 2022, include three significant updates:

1. **The composition of the 2022-23 U.S. seasonal influenza vaccine has changed. Of the four antigens in each quadrivalent vaccine, one influenza A and one influenza B strain has been updated from last year's vaccine. For details on the specific antigens in the current vaccines, see page 3 of this issue.**
2. **Flucelvax Quadrivalent influenza vaccine has been approved for children 6 months of age and up. Previously, Flucelvax was restricted to ages 2 years and older.**
3. **The CDC now officially recognizes three different influenza vaccines as being preferred for adults 65 years of age and older. See discussion below for specifics.**

In addition to the above listed changes, the CDC report also addressed several frequently asked questions regarding influenza vaccination. Here are a few of the key points for pharmacists:

- **Can COVID-19 vaccines and influenza vaccines be administered at the same time?** Current guidance for the administration of COVID-19 vaccines state that they may be administered with other vaccines, including flu vaccines. Providers should be aware, however, of the potential for increased reactogenicity with coadministration. If given together, COVID-19 and flu vaccines that might be more likely to cause a local reaction (for example, High Dose and adjuvanted [Fluad] influenza vaccines) should be administered in different limbs.
- **Can other routine vaccinations and influenza vaccines be administered at the same time?** Inactivated influenza vaccines may be administered concurrently or sequentially with other live or inactivated vaccines. Injectable vaccines given simultaneously should be administered at separate anatomic sites. Since the immunogenicity and safety of simultaneous or sequential administration of two vaccines containing non-aluminum adjuvants has not yet been evaluated, **Shingrix** should not be coadministered with **Fluad**. Patients ≥65 years old requiring a shingles vaccine at the time of their flu vaccine should receive a non-adjuvanted influenza vaccine if possible (**Fluzone High Dose**, **Flublok**).
- **When is the best time to get my influenza vaccine?** September and October are generally good times to be vaccinated. Ideally, everyone should be vaccinated by the end of October. Adults, especially those older than 65, SHOULD NOT get vaccinated early (in July or August) because protection in this group may decrease over time.
- **Which influenza vaccines are recommended for people aged 65 years and older?** Persons aged ≥65 years may receive any age-appropriate inactivated influenza vaccine. However, data support greater benefit from three specific formulations: **Fluzone High Dose**, **Fluad**, and **Flublok**. This year, for the first time, the CDC recommends that adults aged ≥65 preferentially receive any one of these three vaccines. Fluzone High Dose contains 4 times the amount of antigen as a standard dose vaccine. Fluad is a standard dose vaccine to which a non-aluminum adjuvant has been added to boost immune response. Both Fluzone High Dose and Fluad are indicated for use only in patients 65 years of age and older. Flublok is a recombinant influenza vaccine, which contains 3 times the amount of antigen as a standard dose vaccine, and is indicated for use in patients 18 years and older.

Pneumonia Vaccines? Which One, for Whom, and When?

One Of the most commonly administered immunizations in the community pharmacy setting is the pneumococcal vaccine. The introduction of several new vaccines since 2021, and the recent changes to CDC recommendations have led to some confusion among physicians and pharmacists alike. Since pharmacists are now recognized as the “vaccine experts,” it is important to keep abreast of all these recent updates. For this article we have focused on the age groups which pharmacists in New York State are authorized to immunize: patients 65 years of age and older and those 18 to 64 with qualifying medical conditions.

Medical Conditions/Risk Factors Indicating Use of Pneumococcal Vaccine in Patients 18 to 64 Years of Age

- Alcoholism
- Cerebrospinal fluid leak
- Chronic heart disease
- Chronic liver disease
- Chronic lung disease
- Chronic renal failure
- Cigarette smoking
- Cochlear implant
- Congenital or acquired asplenia
- Congenital or acquired immunodeficiency
- Diabetes mellitus
- Generalized malignancy
- HIV infection
- Hodgkin's disease
- Iatrogenic immunosuppression (long-term corticosteroids, radiation)
- Leukemia
- Lymphoma
- Multiple myeloma
- Nephrotic syndrome
- Sickle cell disease
- Solid organ transplant

Pneumococcal Conjugate Vaccine (PCV)

Pneumovax 13 (PCV13) has long been the recommended vaccine for the 4-dose childhood series (given at 2, 4, 6, and 12-15 months). It is no longer part of the 2-dose series for people over 65.

Pneumovax 20 (PCV20) is now the recommended single-dose vaccine for people 65 and older who have not previously received a pneumococcal vaccine.

Vaxneuvance (PCV15) can be used as part of a 2-dose series for people 65 and older and was recently approved for use in the 4-dose childhood series (given at 2, 4, 6, and 12-15 months).

Pneumococcal Polysaccharide Vaccine (PPSV)

Pneumovax 23 (PPSV23) is the oldest of the current pneumococcal vaccines. At one time it was recommended as a 2-dose series, one dose given before age 65 and one dose given after. More recently it was indicated as part of a 2-dose series with **Pneumovax 13** for patients 65 and older. The latest CDC recommendations allow for Pneumovax as the second dose in a 2-dose series beginning with **Vaxneuvance** as an alternative to the single-dose **Pneumovax 20** regimen. For those patients who have received a dose of **Pneumovax 13** in the past, it is still recommended that the series be completed with Pneumovax.

DECISION TREE FOR PNEUMOCOCCAL VACCINES

ADULTS 65 YEARS OR OLDER AND THOSE 18 TO 64 WITH QUALIFYING MEDICAL CONDITIONS WHO:

A. Have not previously received any pneumococcal vaccine:



Give **PREVNAR 20**
(no follow-up with Pneumovax 23 is indicated)

OR

Give **VAXNEUVANCE** followed by **PNEUMOVAX 23** at least one year later

B. Have only received Pneumovax 23:



Give **PREVNAR 20** OR **VAXNEUVANCE** at least one year after Pneumovax 23

C. Have only received Prevnar 13:



Give **PNEUMOVAX 23** as previously recommended.

(If Pneumovax 23 is unavailable, for adults 65 and older the series may be completed with **PREVNAR 20**. For these patients, their pneumococcal vaccine series would then be considered complete.)

Update on Vaccines for the 2022-23 Flu Season

Looking Back on the first two post-Covid flu seasons, it is difficult to predict what this year's will be like. In 2020-21 flu activity was at a historic low, perhaps due to COVID-related mask-wearing and social distancing. Last year saw an increase in cases, but was still below average, although there were two waves of cases, the second lasting until well into the month of May. Below is a review of the vaccines which will be available for the 2022-23 influenza season.

Influenza Vaccine Updates for 2022-23

The 2022-23 quadrivalent egg-based influenza vaccines contain the following 4 antigens:

- **A/Victoria/2570/2019 (H1N1) pdm09-like virus**
- **A/Darwin/9/2021 (H3N2)-like virus**
- **B/Austria/1359417/2021 (Victoria lineage)-like virus**
- **B/Phuket/3073/2013 (Yamagata lineage) -like virus**

The 2022-23 quadrivalent cell- or recombinant-based— influenza vaccines (**Flucelvax** and **Flublok**) contain one slightly different “A” (H1N1) component:

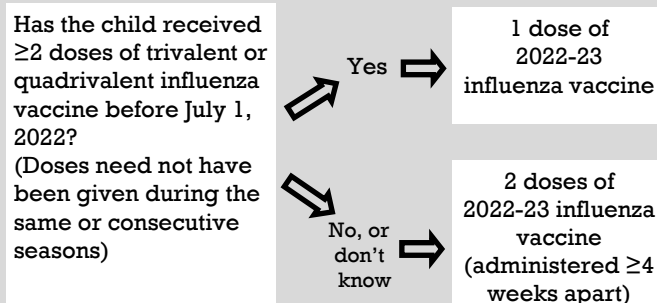
- **A/Wisconsin/588/2019 (H1N1) pdm09-like virus**

Licensure on one vaccine has changed: Flucelvax Quadrivalent is now approved for people 6 months of age and older (it was previously approved for 2 years and up).

The CDC now recommends that people age 65 and over receive one of the following vaccines: **Fluzone High-Dose**, **Flublok**, or **Fluad**. Fluzone High Dose and Flublok contain higher levels of antigen, while Fluad is adjuvanted.

Special Considerations for Pediatric Patients

Legislation signed into law in 2018 authorizes pharmacists in New York State to administer influenza vaccine to patients 2 years of age and older (previously, pharmacists were limited to patients 18 years old and up). There are several clinical issues pharmacists must familiarize themselves with in regard to vaccinating this population. For example, children under the age of 9 **may** require 2 doses of the influenza vaccine, administered at least 4 weeks apart, depending on prior history. Here is an algorithm to determine if a child under age 9 will need 2 doses of vaccine¹:



Quadrivalent Influenza Vaccines (prefilled) for the 2022-2023 Season

Vaccine Trade Name (Manufacturer)	Presentation	Age Indication	Vaccine type
AFLURIA (Seqirus)	0.5 mL Prefilled Syringe	≥ 3 years old (for 6 to 35 months use MDV)	Inactivated quadrivalent egg-based (IIV4)
FLUARIX (GlaxoSmithKline)	0.5 mL Prefilled Syringe	≥ 6 months old	Inactivated quadrivalent egg-based (IIV4)
FLULAVAL (GlaxoSmithKline)	0.5 mL Prefilled Syringe	≥ 6 months old	Inactivated quadrivalent egg-based (IIV4)
FLUZONE (Sanofi Pasteur)	0.5 mL Prefilled Syringe	≥ 6 months old	Inactivated quadrivalent egg-based (IIV4)
FLUCELVAX (Seqirus)	0.5 mL Prefilled Syringe	≥ 6 months old	Inactivated quadrivalent cell-based (ccIIV4)- EGG FREE
FLUBLOK (Sanofi Pasteur)	0.5 mL Prefilled Syringe	≥ 18 years old (and recommended for ≥ 65 y.o.)	Recombinant influenza quadrivalent (RIV4)- EGG FREE
FLUAD (Seqirus)	0.5 mL Prefilled Syringe	≥ 65 years old	Adjuvanted quadrivalent egg-based (aIIV4)
FLUZONE HIGH-DOSE (Sanofi Pasteur)	0.7 mL Prefilled Syringe	≥ 65 years old	High Dose inactivated quadrivalent egg-based (HD-IIV4)

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ASK PRN...

What is the latest guidance regarding influenza vaccination of people with a history of egg allergy?

The latest CDC guidance states the following:

- Persons with a history of egg allergy who have experienced only urticaria (hives) after exposure to egg should receive influenza vaccine. Any licensed, recommended influenza vaccine that is otherwise appropriate for the recipient's age and health status can be used.
- Persons who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention can similarly receive any licensed, recommended influenza vaccine

that is otherwise appropriate for their age and health status. However, if a vaccine other than **Flucelvax** or **Flublok** is used, the selected vaccine should be administered in an inpatient or outpatient medical setting (including but not limited to hospitals, clinics, health departments, and physician's offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. No postvaccination period is recommended specifically for egg-allergic persons. However, ACIP recommends that vaccine providers consider observing patients (seated or supine) for 15 minutes after administration of any vaccine to decrease the risk for injury should syncope occur.

GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at:
questions@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that the word "vaccine" is derived from the Latin word *vaccinus*, which means "derived from a cow"? The first successful vaccine, used to prevent smallpox, was developed in 1796 by English physician Edward Jenner. Jenner had noticed that milkmaids who had contracted cowpox (*variola vaccinae*), a virus similar to, but much milder than smallpox, seemed to be immune to smallpox, a disease responsible for hundreds of millions of deaths through the centuries. He prepared an inoculation made from the scrapings of cowpox lesions and tested it on 24 subjects, all of whom developed immunity to smallpox. After centuries of devastation, it was announced on May 8, 1980 that smallpox had been eradicated, and the world was finally free of the disease.

PHARMACY FUN

In keeping with this issue's theme, this edition of Pharmacy Fun is all about vaccines. Specifically, the inventors of some of our most important immunizations. These days, vaccine development is a group effort, combining scientists, universities and government, but there was a time when one man or woman would be credited with the discovery. Name the scientist who is best known for each of the following vaccines. The first reader to submit the correct answers to us at puzzle@prnnewsletter.com will win a \$25 gift card from Amazon, which will be sent electronically to the winner's Amazon account.

- | | |
|------------------------|-----------------|
| 1. Cholera | 5. Pertussis |
| 2. Diphtheria | 6. Rabies |
| 3. Polio (inactivated) | 7. Tetanus |
| 4. Polio (live) | 8. Tuberculosis |

Answers to last month's **PHARMACY FUN**:

1. Pneumovax 2. Rubella 3. Edward Jenner 4. Varicella 5. EUA 6. Neisseria 7. Tetanus 8. Salk or Sabin
Hidden Word: PREVENTS !

References:

1. Adapted from CDC Morbidity and Mortality Weekly Report. August 27, 2022. Retrieved from www.cdc.gov/mmwr