

I-VAC NEWSLETTER SEPTEMBER 2023

2023 COVID-19 VACCINES

The FDA and CDC have given the green light on the rollout of updated 2023–2024 COVID-19 vaccines from Pfizer and Moderna. These monovalent (single) component mRNA vaccines target Omicron variant XBB.1.5. **With this decision, the bivalent COVID-19 vaccines are no longer authorized for use.** Please follow jurisdictional recommendations for disposing of bivalent vaccines. The storage and handling and dosing guidelines for these new products are available here:

- Comirnaty (COVID-19 Vaccine, mRNA) (2023-2024 Formula)
- Spikevax (COVID-19 Vaccine, mRNA) (2023-2024 Formula)
- Moderna COVID-19 Vaccine (2023-2024 Formula)
- Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

Check CDC's interim clinical guidance for additional information and I-VAC's resource page for updated dosing charts soon.

Here is a brief overview of eligibility:

- Individuals 5 years of age and older regardless of previous vaccination are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least two months since the last dose of any COVID-19 vaccine.
- Individuals 6 months through 4 years of age who have previously been vaccinated against COVID-19 are eligible to receive one or two doses of an updated mRNA COVID-19 vaccine (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
- Unvaccinated individuals 6 months through 4 years of age are eligible to receive three doses of the updated authorized Pfizer-BioNTech COVID-19 Vaccine or two doses of the updated authorized Moderna COVID-19 Vaccine.

Eligibility is as of September 14, 2023, based off of EUA guidance and subject to change.



The original Novavax COVID-19 vaccine remains authorized for use as a 2-dose primary series for those ages 12+ and as a booster dose for those ages 18+ in limited situations. Authorizations or approvals for 2023 – 2024 Novavax COVID-19 vaccine will be determined by FDA with CDC recommendations to follow.

COVID-19 VACCINE UPDATES CORNER:

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NOVAVAX SAFETY MONITORING

A total of 69,227 Novavax COVID-19 vaccine doses were given to patients over the age of 12 between July 13, 2022 and March 13, 2023. The August 4, 2023 MMWR summarizes data <u>analyzed</u> for safety and adverse events. Of the 230 adverse events (AEs) reported for Novavax administration to the Vaccine Adverse Event Reporting System (VAERS), over 90% of them were considered to be non-serious. The most reported AEs included dizziness, fatigue, and headaches. There were 8.3% AEs that were considered serious and they included thrombosis, pericarditis, Guillain-Barre syndrome, and two cases of seizures. No deaths were reported. Vaccine administration errors were also reported and can often be prevented with additional education, training, and use of a pre-vaccination checklist. This safety monitoring data does not differ from clinical trials and does not bring new safety concerns.



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EXTROVERTS MORE LIKELY TO REFUSE COVID VACCINE

A <u>recent study</u> found that extroverted personality types are more likely to refuse the COVID-19 vaccine. Researchers from the University of Texas El Paso and the University of Toronto evaluated surveys from more than 40,000 Canadians between November 2020 and July 2021. The surveys evaluated the respondents' personalities by using the "Big five" model on openness, conscientiousness, extraversion, agreeableness, and emotional stability and asked vaccine specific questions, tailored to the accessibility of the vaccines at that current point in time. Although individuals who were more open and agreeable were also more open to vaccination, those who had lower emotional stability were less likely to get vaccinated. The researchers hope their findings can provide a new perspective on vaccine hesitancy and can help cater public health messaging to these demographics.

RESERVING PFIZER & MODERNA VACCINE

Pediatricians are now able to order new Pfizer monovalent vaccines using Pfizer Prime or through wholesalers. Billing, shipping, and delivery will follow FDA approval. Vaccine dosage is expected to be 3 micrograms (mcg) for children 6 months-4 years old, 10mcg for children 5–11, and 30 mcg for children 12 years and older. The 6 month-4 year old product will come in 3-dose vials, while the others will be available as single-dose vials (with limited quantities of pre-filled syringes available for the 12 years+ product). For orders placed directly with Pfizer, 15% of total doses purchased, or the greater of the direct minimum order quantity units of sale, can be returned. Doses can be stored at -90 to -60 degrees Celsius until expiration or can be stored at 2 to 8 degrees Celsius for up to 10 weeks.



Pediatricians can also begin ordering <u>Moderna's</u> monovalent vaccine through Moderna Direct and through wholesalers. For children 6 months– 11 years old, the vaccines will come in 0.25mL single dose vials in 10 count cartons. For those 12 years and older, vaccines are expected to come in 0.5mL single dose pre-filled syringes in 10 count cartons with a blister pack or as single dose vials, also in 10 count cartons. Shipping is pending FDA approval. 10% of a received order can be returned. Doses can be stored at -50 to -15 degrees Celsius until expiration or at 2-8 degrees Celsius for 30 days before the first use. They can be stored at 8-25 degrees Celsius for up to 24hrs.



OMICRON VARIANT BA.2.86

A recent article by Your Local Epidemiologist, Katelyn Jetelina, detailed what we know about BA.2.86. This variant has heavily mutated, not following the typical pattern of Omicron variant mutations expected to be seen. BA.2.86 has 35 new mutations on the spike protein and seems to be spreading quickly and has been found in ten countries. This variant is better at immune escape, but recent lab data is only showing a 2-3x escape and not 10x more than XBB.1.5., as was originally thought. This means the variant will cause infections, but not as much as expected. The good news is that vaccinations will help protect against BA.2.86. Eric Topol, author of the Good Truths blog, noted in his September 8th post that: Data published (preprint) with Moderna's XBB.1.5 booster and show very good levels of neutralizing antibodies induced against BA.2.86, in keeping with the response to the target of XBB.1.5 (8.7X vs 10X rise, all participants, top, respectively). Also note the similar response to two of the major current circulating variants of EG.5.1 and FL.1.5.1. Paxlovid and antigen testing continue to work for BA.2.86.





RESOURCE:

The <u>COVID-19 Scenario Modeling Hub</u> is an interactive tool that allows providers to look through past, present, and projected COVID-19 models on how COVID-19 activity differs with different levels of vaccine uptake.



VIRTUAL OB-GYN COVID-19 VACCINE BOOTCAMP

Our OB-GYN Bootcamp will be held on **September 28th**. Join us for this two-hour webinar geared towards OBGYNs, family physicians, and all other providers who care for pregnant persons.

Register here.

BEYOND THE NEEDLE PODCAST

New episodes of Beyond the Needle are currently being released. Find an episode you are interested in <u>here</u> or tune in wherever you listen to your podcasts! CME is also available.

ECHO LEARNING COLLABORATIVES

ECHO-Chicago's COVID-19 learning collaboratives for those serving both pediatric and adult populations now being held biweekly. Get help with vaccine implementation and engage with peers while you get your questions answered.

Register today for the next virtual meeting, being held September 26th!

COVID-19 COMMERCIALIZATION UPDATES

ICAAP is hosting biweekly webinars with IDPH and CDPH to bring you COVID-19 commercialization updates as they happen. Upcoming webinars are on **September 29th**, **October 13th**, and **October 27th**.

Register here.



ICAAP RESOURCES FOR YOU

Explore ICAAP's new webpage for guidance on managing respiratory virus season, including flu, COVID-19 and RSV. Helpful COVID-19 resources include patient posters and handouts, as well as resources for providers. Even more resources regarding COVID-19 vaccine commercialization and updated vaccine guidance will be available soon!



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