IMMUNIZATION COVID-19 Update

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Question of the Week

I heard there is consideration to allow providers to draw five shots from a vial of the JYNNEOS monkeypox vaccine?

Yes, it was announced earlier that due to the public health emergency, the FDA is now allowing providers to use only one-fifth of the vial for vaccinations against monkeypox in individuals 18 years and older. The new provisions means that providers can use a single vial to administer first doses to as many as five individuals. Full vaccination is still considered to be 2 doses given 28 days apart. With this new option, doses will be given under skin (intradermal injection rather than subcutaneous injection) using just one fifth of the vaccine. Those who received a first dose already via a subcutaneous injection, can get their second dose through the newly available intradermal injection method.

FDA authorizes alternative dosing regimen for monkeypox

The FDA has issued an emergency use authorization (EUA) allowing healthcare providers to use an alternative dosing regimen of the JYNNEOS vaccine for individuals 18 years of age and older determined to be at high risk of monkeypox infection. This will increase the total number of doses available for use by up to five-fold.

The monkeypox vaccine can now be given to high-risk adults intradermally, meaning between the layers of the skin, rather than subcutaneously, or under the skin, as it has been given up until now.

This decision was made independently by the FDA based on compelling, science-based evidence that a fifth of the dose, when given intradermally on the same two-dose schedule as currently administered, produced a similar immune response to the current vaccination approach. The clinical considerations can be viewed **here**.

"We welcome today's decision from the FDA. This alternative dosing regimen has been shown in prior studies to be safe and elicit an equivalent antibody response. Importantly, it will significantly increase the number of at-risk individuals who can now benefit from protection against monkeypox. This is a potential game changer for our monkeypox response, especially ahead of upcoming large events in Louisiana," said State Health Officer Dr. Joseph Kanter.

Background on clinical data
Data from a 2015 clinical study of the JYNNEOS vaccine evaluated a two-dose series given intradermally compared to subcutaneously. Individuals who received the vaccine intradermally received a lower volume (one fifth) than individuals who received the vaccine subcutaneously. The results of this study demonstrated that intradermal administration produced a similar immune response to subcutaneous administration, meaning individuals in both groups responded to vaccination in a similar way.

Current monkeypox vaccine eligibility in Louisiana
There are three groups of individuals currently eligible for monkeypox vaccine:

- Individuals with known exposures to monkeypox patients;
- Gay, bisexual, and other (cis or trans) men who have sex with men OR transgender women and nonbinary persons assigned male at birth who have sex with men; AND
- Have had intimate or sexual contact with multiple or anonymous partners in the last 14 days; OR
- Have had intimate or sexual contact with other men in a social or sexual venue in the last 14 days; AND
- Individuals (of any sex/gender identity) who have given or received money or other goods/services in exchange for sex in the last 14 days.

Reporting of adverse events
Vaccination providers who are administering JYNNEOS under the EUA are required to report the following adverse events that occur after JYNNEOS vaccination: vaccine administration errors whether or not associated with an adverse event, serious adverse events (irrespective of attribution to vaccination), cases of cardiac events including myocarditis and pericarditis, and cases of thromboembolic events and neurovascular events.

Information on how to submit a report to VAERS is available at **https://vaers.hhs.gov** or by calling 1-800-822-7967.

Reporting vaccine administrations into the Louisiana Immunization Network (LINKS) registry
Providers that are currently administering JYNNEOS vaccine will received updated guidance from the Office of Public Health Immunization Program regarding entering JYNNEOS vaccine administrations into LINKS.

For More Information:

- **CDC JYNNEOS Vaccine Clinical Guidance**
- **CDC Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak**

Post–COVID-19 symptoms and conditions among children and youth

A recent study in the CDC's *Morbidity and Mortality Weekly* identified certain post-COVID-19 symptoms and conditions in youth ages 0–17 years for the study period of March 1, 2020–January 31, 2022.

The **study** included 781,410 children who had COVID-19, along with 2,344,257 children without COVID-19. During the study, CDC "analyzed linked and commercial laboratory data for persons with a healthcare encounter possibly related to COVID-19." Specifically, CDC-licensed Health Verity Inc. medical claims

data that was linked to SARS-CoV-2 commercial data. Eligible study participants had a health care encounter possibly related to COVID-19 on or after December 1, 2019.

Findings

The study found that children with COVID-19 were significantly more likely to develop the following symptoms: smell and taste disturbances, circulatory signs and symptoms, malaise and fatigue, and musculoskeletal pain.
Study participants with COVID-19 were also more likely than those without to develop the following post-COVID conditions: acute pulmonary embolism, myocarditis and cardiomyopathy, venous thromboembolic event, acute and unspecified renal failure, type 1 diabetes, coagulation and hemorrhagic disorders, type 2 diabetes and cardiac dysrhythmias.

Study participants with COVID-19 were less likely than those without to experience respiratory signs and symptoms, symptoms of mental conditions, sleeping disorders, neurological conditions, anxiety and fear-related disorders, mood disorders and muscle disorders.

Read the full study.

Autism and COVID-19 vaccines

Join us for a webinar presented in partnership with the Autism Society of Greater New Orleans Vaccine Education Initiative on August 25 from 1:00 to 2:00 PM.

This educational event is suitable for parents of individuals with Autism, Autistic individuals, and providers who work with Autistic patients of all ages. Dr. Elizabeth Margolis, Doctor of Osteopathic Medicine at Tulane University, and Dr. Fei Chen, Assistant Professor of Psychiatry and Behavioral Science at Tulane University will discuss COVID-19 vaccine testing and safety for Autistic individuals, safety for individuals with epilepsy, how to find information to help your adult children choose to get vaccinated, if the vaccine is “worth it” and more.

The presentation will also review information on how providers can make clinics and vaccination experiences more accessible for Autistic individuals to reduce negative experiences and increase access to vaccines.

Autism and COVID-19 Vaccines
August 25, 2022
1:00 p.m. – 2:00 p.m.
REGISTER HERE

For questions or requests for special accommodation, please contact **anna.harris@la.gov**.

Menactra discontinuation and replacement

LDH has advised all providers of children’s vaccines that Sanofi’s Menactra has been discontinued.

Menactra is now being replaced with Sanofi’s MenQuadfi. MenQuadfi provides the same protection for individuals 2–18 years of age against meningococcal disease serogroups A, C, W, and Y. Please continue to administer any remaining doses of Menactra you may have remaining in your inventory until depleted. Any pending orders for Menactra will be auto-converted to MenQuadfi.

FDA warns FluxxLab for selling unapproved products for COVID-19 treatment or prevention

On August 4, the FDA issued a warning letter to **FluxxLab LLC** for selling unapproved and misbranded tincture products as drugs for use in treating or preventing COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.

Good reads

- Louisiana State University Expands Programs to Stem Nursing Shortage
- LDH: New action aims to increase monkeypox vaccine access
- Long-COVID treatments: why the world is still waiting
- COVID sewage surveillance labs join the hunt for monkeypox
- Poor Demand for Its Covid Vaccine Prompts Novavax to Cut Sales Forecast
- Under 60, healthy, vaccinated and boosted? 'You're in a pretty good place'
- with Covid-19
- COVID-19 vaccine to be required for most public university students

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

Office of Public Health | Immunization Team | La.Immuization@la.gov