Chicago Department of Public Health



Health Alert



Lori E. Lightfoot, Mayor

www.chicagohan.org

Chicago Department of Public Health Allison Arwady MD MPH, Commissioner

Moderna COVID-19 Vaccine Update

December 19, 2020

Summary and Action Items

- The Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to the Moderna COVID-19 vaccine on December 18, 2020.
- On December 19, 2020, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend the vaccine for ages 18 years and above.
- Additional educational materials will be released from CDC after the ACIP recommendations are signed by the CDC Director and officially released and published.
- Check www.chicagohan.org/covidvax and www.chicago.gov/covidvax for updates.
- A vote on Tier 1b and 1c COVID-19 vaccine allocation is expected by ACIP tomorrow.

<u>Background:</u> The second COVID-19 vaccine (Moderna) was officially granted Emergency Use Authorization (EUA) by the FDA on December 18, 2020 and recommended unanimously by the CDC Advisory Committee on Immunization Practices (ACIP) on December 19, 2020. Two doses of the Moderna COVID-19 vaccine delivered intramuscularly 28 days apart are required to achieve 94.1% efficacy [95% CI 89.3%-96.8%]. A standardized query was conducted for anaphylaxis within 48 hours of doses and no participants met criteria. Two anaphylactic reactions occurred as unsolicited adverse reactions, one in placebo group (10 days after 1st dose) and one in the vaccine group (63 days after 2nd dose). No participants were excluded for history of anaphylaxis, urticaria, or other significant hypersensitivity. The Phase III trial is ongoing but no serious adverse events have been identified so far.

Similar to the Pfizer-BioNTech COVID-19 vaccine, initial supply of the Moderna COVID-19 vaccine will be limited. Vaccinators must report all serious adverse events, vaccine administration errors, hospitalizations, deaths, and cases of Multi-system Inflammatory Syndrome in Children and Adults (MIS-C/MIS-A) following the administration of COVID-19 vaccine to the FDA and CDC through the Vaccine Adverse Event Reporting System (VAERS). Also, ensure that V-safe (a voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination) is available to vaccine recipients.

Harmonization of CDC Clinical Considerations guidance to include both mRNA vaccines (Pfizer-BioNTech and Moderna) is expected.

	Moderna website	FDA website	Notes
EUA Fact sheet and full PI for Vaccination Providers	<u>Link</u>		For clinicians and techs who will administer and handle, store vaccine.
EUA Fact Sheet for Vaccine recipients and caregivers	<u>Link</u>	<u>Link</u>	For clinicians to share with vaccine recipients

Resources for Vaccine Administration and Recipient Counseling:

- Moderna: Information about Moderna COVID-19 Vaccine can be found by visiting https://www.modernatx.com/covid19vaccine-eua including:
 - o Fact sheet, prescribing information, and important safety information
 - A tool to determine the expiration date of each lot of vaccine
 - Storage & handling requirements
 - Dosing & administration information
 - The Moderna Call Center is available from 8am to 8pm EST, Monday through Friday and can be reached at 1-866-MODERNA (1-866-663-3762). The caller will be routed to:
 - General Moderna Questions
 - Healthcare Provider Questions (clinical)
 - Product Quality or Technical Questions
 - Pregnancy Registry
- FDA FAQ page: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine
- CDC Vaccine Clinical Inquiry Line: 800-CDC-INFO (800-232-4636) TTY 888-232-6348
- CDC Resources:
 - COVID-19 Vaccination for Healthcare Professionals
 - o Healthcare Professionals: Preparing for COVID-19 Vaccination
 - o CDC Communications Toolkit
 - o Engaging in Effective COVID-19 Vaccine Conversations
 - o Toolkit for Medical Centers, Clinics and Clinicians
 - o Post Vaccine Considerations for Healthcare Personnel | CDC
 - o Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC
- CDC COCA Call recording: Webinar December 18, 2020 What Clinicians Need to Know About the Pfizer-BioNTech and Moderna COVID-19 Vaccines (cdc.gov)
- American Society of Clinical Oncology (ASCO) / Infectious Diseases Society of America (IDSA)
 Webinar recording (12/18): The COVID-19 Vaccine & Patients with Cancer (idsociety.org)
- CDC/IDSA Learning Network: www.COVID19LearningNetwork.org
- Vaccination Options for Healthcare Personnel Not Affiliated with Hospitals or Health Systems:
 - Healthcare providers and persons at risk of exposure to patients who could be infected with COVID-19 are one of the first groups recommended for COVID-19 vaccination.
 - The Chicago Department of Public (CDPH) is making vaccination plans for the staff of clinics and facilities not associated with a hospital or their health system. This will include the staff of outpatient clinics, dental offices, urgent care facilities, independent pharmacies, home care companies, dialysis centers, and mortuary services staff (including morticians and funeral home workers). Visit www.chicagohan.org/covidvax for more information.
 - To assist with planning, one representative from your clinic/facility (e.g., the clinic administrator or business owner) must complete: https://redcap.link/StaffVaccinationInquirySurvey