Chicago Department of Public Health

Health Alert

CDPH Chicago Department of Public Health

City of Chicago
Lori E. Lightfoot, Mayor

www.chicagohan.org

Chicago Department of Public Health
Allison Arwady MD MPH, Commissioner

URGENT COVID-19 Vaccine Update

December 12, 2020

Summary and Action Items

- The Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020.
- On December 12, 2020, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend the vaccine for ages 16 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 (anticipated December 13, 2020).
- CDPH expects to receive a limited supply of vaccine within the next 1-2 weeks.
- Over the next 2 weeks, distribution will occur to hospitals with capacity for ultra-cold storage, and local pharmacies federally contracted to vaccinate long-term care facility residents and staff.
- **Ensure that your healthcare system vaccine liaisons are on-call to receive vaccine as well as updated resources over time. Check www.chicagohan.org/covidvax for updates.**
- CDPH summarized considerations for sub-prioritization of healthcare personnel based on risk of exposure and risk of severe COVID-19 disease in a Health Alert released November 25, 2020.

Background: The first COVID-19 vaccine (Pfizer-BioNTech) was officially granted Emergency Use Authorization (EUA) by the FDA on December 11, 2020 and recommended by the CDC Advisory Committee on Immunization Practices (ACIP) on December 12, 2020. Two doses of the Pfizer-BioNTech COVID-19 vaccine delivered intramuscularly 21 days apart are required to achieve 95.0% efficacy [95% CI 90.3-97.6%].

Currently, due to vaccine supply constraint, the ACIP vaccine recommendation must be used in conjunction with Phase 1a vaccine allocation guidance[1] as published by ACIP in an MMWR on December 11, 2020 entitled *The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020*[1] which includes healthcare personnel (HCP)[2] and long-term care facility residents and staff. CDC secured an agreement to ensure that insurance companies will have 15 business days (rather than 1 year, historically) to cover vaccine administration fees for COVID-19 vaccines. For clarity, the cost of federally distributed no-cost outbreak vaccine is not reimbursable.

Initial supply of COVID-19 vaccine will be limited but delivery to Chicago Department of Public Health (CDPH), hospitals and pharmacies with ultra-cold storage, is expected within the next 1-2 weeks. 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 (CDC's downloadable vaccine safety monitoring app) is available to your employees.

Resources for Vaccine Administration and Recipient Counseling:

- FDA Resources: For the most up-to-date FDA materials including the FDA COVID-19 Vaccine Fact Sheets are available at: www.cvdvaccine.com. FDA fact sheets, trainings, and resources will also be posted at www.chicagohan.org/covidvax and are attached to this health alert.

- CDC Resources: COVID-19 Vaccination for Healthcare Professionals, Healthcare Professionals: Preparing for COVID-19 Vaccination, CDC Communications Toolkit
- **CDC COCA Call Sunday December 13th at 1:00pm CT**: "What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine": https://www.zoomgov.com/j/1615052786
- **CDC COCA call Monday December 14th at 12:00pm CT**: "What Every Clinician Should Know about COVID-19 Vaccine Safety" https://emergency.cdc.gov/coca/calls/2020/callinfo_121420.asp

ACIP Considerations for Immunocompromised Persons:

- Persons with immunocompromising conditions or who take immunosuppressive medications might be at increased risk for COVID-19 but can generally receive vaccines that are not live viral vaccines. More information will be forthcoming.
- Data are not currently available to determine safety and efficacy within this group.
- These individuals may still receive vaccine unless otherwise contraindicated after counseling with their healthcare provider on risks (typically reduced immune response to the vaccine) and benefits.

ACIP Considerations for Pregnancy and Breastfeeding:

- Only data on safety and efficacy in animal studies are available for this vaccine in pregnancy but expert opinion expressed during the ACIP meeting reported that there is no biologic plausibility of placental transfer of the vaccine.
- Data are not currently available to determine safety and efficacy within lactating individuals. mRNA vaccines are NOT considered live viral vaccines and therefore are not thought to be a risk to the breastfeeding infant.
- Pregnant or lactating persons recommended to be vaccinated in Phase 1a may choose to be vaccinated. A discussion with the individual's healthcare provider can help make an informed decision.
- Routine testing for pregnancy prior to vaccination is not recommended.
- Pregnant women who experience fever after vaccination should be counseled to take an anti-pyretic approved in pregnancy, because fever has been associated with adverse pregnancy outcomes.

ACIP Considerations for Personal History of Anaphylaxis:

- In addition to the contents of the FDA fact sheet, a CDC screening tool will be made available to guide vaccinator counseling regarding risk of anaphylaxis.
- Severe reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine is a contraindication to vaccination.
- Appropriate medical treatment used to manage immediate allergic reaction that occurs following administration of the vaccine must be immediately available in the event of acute anaphylactic reaction occurring following administration.

ACIP Recommended Counseling Regarding Vaccine Reactogenicity and Return to Work:

- Anti-pyretic or analgesic medication may be taken for treatment of post-vaccination symptoms but routine *pre-vaccination* use for the prevention of symptoms is NOT recommended due to lack of information on impact of use on vaccine-induced antibody responses.
- CDC has created a forthcoming guidance surrounding "Infection Prevention and Control considerations for healthcare personnel regarding management of post-vaccination side effects" (in consultation with IDSA and SHEA) and include staggering of HCP vaccination to limit HCP shortages, post-vaccination anti-pyretic/analgesic upon occurrence of side effects, and a suggested approach to management of specific signs and symptoms observed following vaccination concerning return to work.

---

[1] Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1857-1859. DOI: http://dx.doi.org/10.15585/mmwr.mm6949e1 and https://www.cdc.gov/vaccines/acip/meetings/slides-2020-11.html

[2] HCP definition: https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html