



Health Alert Network Message 21-09: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the U.S.

Origination Date:
January 26, 2021

Revision Dates (List All Revision Dates):

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Summary of recent changes: Updated January 21, 2021:

- Updated recommendations on intervals between the first and second dose
- Updated recommendations on interchangeability of vaccine products
- Updated language on vaccination of persons with a history of SARS-CoV-2 infection
- New vaccination recommendations in persons with a history of dermal fillers
- Additional resources on vaccine excipients (Appendix B)

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States.

These interim CDC clinical considerations are informed by data submitted to the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the vaccines, other data sources, [general best practice guidelines for immunization](#), and expert opinion. These considerations for mRNA vaccines only apply to the currently authorized vaccine products in the United States (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines). Considerations will be updated as additional information becomes available and/or if additional vaccine products are authorized.

In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines.

Full documentation of the Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States can be found at:

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html

Updated recommendations on intervals between first and second dose of COVID-19 Vaccine:

- The second dose should be administered as close to the recommended interval as possible. If it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. This allowance is to accommodate situations when it is not possible to administer the second dose at the recommended interval, not to recommend a new or lengthened follow up interval. The goal should remain to administer second doses at 21 days for Pfizer vaccine and 28 days for Moderna vaccine.
- However, if second dose is administered beyond these intervals, there is no need to restart the series.

Updated recommendations on interchangeability of vaccine products:

- mRNA COVID-19 vaccines are not interchangeable. See added language below to provide suggested strategies to help ensure patients receive second dose with appropriate product and interval between doses include:
 - Provide COVID-19 vaccination record cards to vaccine recipients, ask recipients to bring card to their appointment for second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of card on their phone).
 - Encourage vaccine recipients to enroll in VaxText, a free text message to receive COVID-19 vaccination second-dose reminders.
 - Record each recipient's vaccination in LINKS as required by the State of Louisiana.
 - Record vaccine administration information in patient's medical record.
 - Make appointment for second dose before vaccine recipient leaves, to increase likelihood patients will return to same vaccination site for the second dose.

Using the above strategies, every effort should be made to determine which vaccine product was received as first dose, in order to ensure completion of the vaccine series with same product.

In exceptional situations in which first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimal interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.

If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

Updated language on vaccination of persons with history of SARS-CoV-2 infection:

- Data from clinical trials indicate that mRNA COVID-19 vaccines can safely be given to persons with evidence of a prior SARS-CoV-2 infection.
- Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess prior infection for the purposes of vaccine decision-making is not recommended.
- While there is no recommended minimum interval between infection and vaccination, [current evidence](#) suggests that risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity.
- **While vaccine supply remains limited**, persons with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired, recognizing risk of reinfection, and need for vaccination, may increase with time following initial infection.

New vaccination recommendations with a history of dermal fillers:

- Infrequently, persons who have received dermal fillers may develop swelling at or near site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. This appears to be temporary and can resolve with medical treatment, including corticosteroid therapy.
- mRNA COVID-19 vaccines may be administered to persons who have received injectable dermal fillers who have no contraindications to vaccination. No additional precautions are needed.
- These persons should be advised to contact their healthcare provider for evaluation if they develop swelling at or near site of dermal filler following vaccination.

Additional resources on vaccine excipients:

- The language added in Appendix B is “As of January 21, 2021, mRNA COVID-19 vaccines are the only currently available vaccines in the United States that contain PEG, though several vaccines contain polysorbate (more information found in [CDC’s vaccine excipient summary](#)).

The State of Louisiana is also in the process of updating clinical-related documents including standing orders, the pre-vaccination screening form, and vaccine administration guidance. These materials will be available on-line early next week at <https://ldh.la.gov/covidvaccine/> under the “provider” tab.

Expectation for vaccine providers to enter appropriate demographic information in LINKS

- COVID-19 vaccine providers are expected to enter accurate demographic information into LINKS for each vaccine administration, particularly race and ethnicity information. Lack of accurate racial and ethnic information hinders the state’s ability to understand any disparities that may exist in vaccination allocation and uptake. If a particular patient does not yet have a file in LINKS and the vaccine provider must create a new patient file, race and ethnicity are required fields of entry. If a patient does have an existing LINKS file, we are urging providers to edit the patient’s demographic information and enter accurate race and ethnicity data. On the demographics page of a patient’s file in LINKS, race is a drop-down menu of multiple possible choices; ethnicity is a drop-down menu of

“Hispanic or Latino” or “Not Hispanic or Latino.” Both race and ethnicity fields should be completed for any given patient. If a vaccine provider is communicating with LINKS via an automated feed with their electronic health record system, we urge the provider to ensure race and ethnicity data are being properly transmitted.

For questions on COVID-19 vaccine, please email: la.immunization@la.gov.