Clinical considerations for the 2nd dose of mRNA COVID-19 vaccines

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January 7, 2021

Clinical considerations for mRNA COVID-19 vaccines

- Recommendations apply to both Pfizer-BioNTech and Moderna COVID-19 vaccines
- Guidance may change as further information becomes available

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2nd dose administration: Clarification of 4-day grace period

- mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:
  - Pfizer-BioNTech: 3 weeks (21 days) apart
  - Moderna: 1 month (28 days) apart
- Persons should not be scheduled to receive the second dose earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna])
  - Second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid
- No maximum interval between the first and second doses for either vaccine
  - If the second dose is administered >3 weeks after the first Pfizer-BioNTech vaccine dose or >1 month after the first Moderna vaccine dose, no need to restart the series

Interchangeability of mRNA COVID-19 vaccines

- mRNA COVID-19 vaccines are not interchangeable, and both doses in the series should be completed with the same vaccine product
  - Safety and efficacy of a mixed-product series have not been evaluated
- If two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended

Potential strategies for 2nd dose compliance

- Complete COVID-19 vaccination record cards with accurate vaccine information, give them to each vaccine recipient, encourage recipients to keep the card and bring it to the second dose appointment
- Record each recipient’s vaccination in Immunization Information system (IIS)
- Record administration information in the patient’s medical record
- Make an appointment for the second dose BEFORE the recipient leaves
- Provide a reminder (when a dose is due) or a recall (when a dose is missed)
  - Reminders might be generated via electronic medical record, IIS, or v-safe

Timing of 2nd dose in persons who develop SARS-CoV-2 infection after the 1st dose

- 2nd dose administration should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation
  - Same recommendation as persons who have not received any doses
- For persons who received monoclonal antibodies or convalescent plasma treatment, 2nd dose vaccination should be deferred for 90 days
  - Same recommendation as persons who have not received any doses
### Patient counseling around 2nd dose

- Both mRNA COVID-19 vaccines demonstrate high efficacy after two doses
  - Efficacy after a single dose has not been systematically evaluated, so patients should be counseled on the importance of completing both doses

- Majority of vaccine recipients experience local and/or systemic reactions following vaccination (more frequent and severe following 2nd dose)
  - Most are mild-moderate in severity, occur within first 3 days of vaccination, and resolve within 1-2 days of onset
  - Patients should be counseled to complete the series even if they experience reactions after the first dose

### Contraindications to receiving the 2nd dose

- Contraindications to either of the mRNA COVID-19 vaccines:
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to any of its components
  - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
  - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

- Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines

* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

### Clinical Immunization Safety Assessment COVIDvax project

- Additional resource for safety questions, including for reactions after the 1st dose and advice for receiving the 2nd dose

- Healthcare personnel or health departments in the United States can request a consultation for a complex COVID-19 vaccine safety question about an individual patient residing in the United States not readily addressed by CDC guidance: