

# Immunization Branch Updates

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# COVID-19 Vaccination in Pregnancy

- [CDC COVID Data Tracker](#)
  - Only ~20% of pregnant people in US have received at least one dose of COVID-19 vaccine
- [American College of Obstetricians and Gynecologists \(ACOG\) and Society for Maternal-Fetal Medicine \(SMFM\) Recommend COVID-19 Vaccination for Pregnant Individuals | ACOG – July 30, 2021](#)
  - “COVID-19 vaccination is the best method to reduce maternal and fetal complications of COVID-19 infection among pregnant people” - William Grobman, MD, MBA, president of SMFM
- [Western States Scientific Safety Review Workgroup – August 6, 2021](#)
  - Reiterates strong recommendation for the immunization against COVID-19 of pregnant and recently pregnant women
  - No evidence that any vaccines, including COVID-19 vaccines, adversely affect fertility and that many women have become pregnant after receiving COVID-19 vaccine.

# COVID-19 Vaccination in Pregnancy

- [New CDC Data: COVID-19 Vaccination Safe for Pregnant People | CDC Online Newsroom | CDC](#) – August 11, 2021
  - New data from v-safe pregnancy registry did not find an increased risk of miscarriage among nearly 2,500 pregnant women who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy.
  - “CDC encourages all pregnant people or people who are thinking about becoming pregnant and those breastfeeding to get vaccinated to protect themselves from COVID-19. The vaccines are safe and effective, and it has never been more urgent to increase vaccinations as we face the highly transmissible Delta variant and see severe outcomes from COVID-19 among unvaccinated pregnant people.”  
-CDC Director Dr. Rochelle Walensky

# Additional doses: CDC Advisory Committee on Immunization Practices (ACIP)

- [ACIP August 13, 2021 Presentation Slides | Immunization Practices | CDC](#)

## Roles of an Additional Dose

There are two distinct potential uses for an additional dose:

- **Additional dose after an initial primary vaccine series**: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.
- **Booster dose**: a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established

# Additional dose in immunocompromised people

- Immunocompromised patients:
  - More likely to get severely ill from COVID-19
  - Higher risk for prolonged SARS-CoV-2 infection, shedding, incubation
  - Lower antibody/neutralization titers to SARS-CoV-2
  - More likely to transmit SARS-CoV-2 to household contacts
  - More likely to have breakthrough infection: one US study showed 40-44% of hospitalized breakthrough cases were in immunocompromised people
  - Lower vaccine effectiveness: 59-72% VE among immunocompromised people vs. 90-94% among non-immunocompromised people

# Additional dose in immunocompromised people

## **Potential benefits of additional dose in immunocompromised people:**

- Emerging data in adults suggest that an additional mRNA COVID19 vaccine dose in immunocompromised people enhances antibody response and increases the proportion who respond to COVID-19 vaccine
- No efficacy or effectiveness studies of COVID-19 prevention following a 3rd dose

## **Potential harms of additional dose:**

- No serious adverse events observed in studies in adults
  - Reactogenicity of the 3rd dose of mRNA vaccine was similar to prior doses
- mRNA COVID-19 vaccines are associated with rare but serious adverse events, including anaphylaxis as well as myocarditis and pericarditis in young adults. The impact of immunocompromising conditions on these rare events is unknown.

# Recommendation of additional dose in immunocompromised people

- An additional dose of mRNA COVID-19 vaccine after an initial 2-dose primary mRNA vaccine series should be considered for people with *moderate to severe immune compromise*
- *A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.*

# Moderate to severe immunocompromise:

- Active treatment for solid tumor and hematologic malignancies
- Solid-organ transplant and taking immunosuppressive therapy
- CAR-T-cell or hematopoietic stem cell transplant
- Moderate or severe primary immunodeficiency
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e.,  $\geq 20$ mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory



# Clinical Considerations of additional dose in immunocompromised people

- The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series:
  - Pfizer-BioNTech: aged  $\geq 12$  years
  - Moderna: aged  $\geq 18$  years
- Additional mRNA COVID-19 vaccine dose should be the same as initial primary series (Pfizer or Moderna).
- Additional dose should be administered at least 28 days after completion of the initial 2-dose series

# Additional Considerations of additional dose in immunocompromised people

- Timing of additional dose
  - Providers should take into consideration current or planned immunosuppressive therapies to optimize both the patient's medical condition and response to vaccine. When possible, all doses should be administered at least two weeks before initiation or resumption of immunosuppressive treatment.
- A person should not receive more than 3 mRNA COVID-19 vaccine doses.
- Post-vaccination antibody testing **is not recommended** at this time.

# Immunocompromised Should Continue Prevention Measures

- Immunocompromised patients should be counseled about the potential for a reduced immune response to COVID-19 vaccines, even after an additional dose.
- Immunocompromised patients should continue to follow current prevention measures (including mask wearing, maintaining 6-foot distance, and avoiding crowds and poorly ventilated indoor spaces).
- Close contacts of immunocompromised people should also be strongly encouraged to be vaccinated against COVID-19 to protect these people.

# Resources

- *COVID-19 Vaccination in Pregnancy*
  - COVID-19 Vaccines While Pregnant or Breastfeeding (CDC):  
[www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html)
  - [COVID-19 Vaccines and Pregnancy](#) factsheet (CDPH)
  - [COVID, Pregnancy and Breastfeeding for Patients](#) FAQs (ACOG)
  - [COVID-19 Vaccines and Pregnancy: Conversation Guide for Clinicians](#) webpage (ACOG)
- *Additional doses in immunocompromised people*
  - COVID-19 Vaccines for Moderately to Severely Immunocompromised People (CDC):  
[www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html)
  - Talking with Patients Who are Immunocompromised (CDC):  
[www.cdc.gov/vaccines/covid-19/clinical-considerations/immunocompromised-patients.html](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/immunocompromised-patients.html)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)