Considerations for vaccination of people with certain underlying medical conditions by Centers for Disease Control and Prevention (CDC)

Any currently authorized COVID-19 vaccine can be administered to people with underlying medical conditions who have no contraindications to vaccination; ACIP does not state a product preference. Clinical trials demonstrated similar safety and efficacy profiles in people with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to people without comorbidities. Additional information for people with specific underlying medical conditions is included below.

Immunocompromised people

People with HIV infection or other immunocompromising conditions or people who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. No data are available to establish COVID-19 vaccine safety and efficacy in these groups. However, the currently authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people. People with stable HIV infection were included in the COVID-19 vaccine clinical trials, though data remain limited.

Immunocompromised people can receive COVID-19 vaccination. Data are currently insufficient to inform optimal timing of COVID-19 vaccination among people who are

planning to receive immunosuppressive therapies. However, based on general best practices for vaccination of immunocompromised people, ideally COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies. When it is not possible to administer a complete COVID-19 vaccine series (i.e., two doses of an mRNA vaccine or a single dose of Janssen COVID-19 vaccine) in advance, people on immunosuppressive therapy can still receive COVID-19 vaccination. Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the person's risks related to their underlying condition.

Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination. At this time, revaccination is not recommended after people who received COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs regain immune competence. Recommendations on re-vaccination or additional doses of COVID-19 vaccines may be updated when additional information is available.

People should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, the potential for reduced immune responses, and the need to continue to follow current guidance to protect themselves against COVID-19.

People with autoimmune conditions

No data are available on the safety and efficacy of COVID-19 vaccines in people with autoimmune conditions, though these people were eligible for enrollment in mRNA COVID-19 vaccine clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received COVID-19 vaccine compared to placebo. People with autoimmune conditions may receive any authorized COVID-19 vaccine.

People with a history of Guillain-Barré syndrome

No cases of Guillain-Barré syndrome (GBS) were reported following vaccination among participants in the mRNA COVID-19 vaccine clinical trials. One case of GBS was reported in a participant in the vaccine group in the Janssen COVID-19 vaccine clinical trial, compared to one GBS case among those who received placebo. With few exceptions, ACIP's general best practice guidelines for immunization do not include history of GBS as a contraindication or precaution to vaccination. People with a history of GBS may receive COVID-19 vaccination. Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS.

People with a history of Bell's Palsy

Cases of Bell's palsy were reported following vaccination of participants in the COVID-19 vaccine clinical trials. However, the FDA does not consider these to be above the frequency

expected in the general population and has not concluded that these cases were causally related to vaccination. Post-authorization safety surveillance will be important to further assess any possible causal association. In the absence of such evidence, people with a history of Bell's palsy can receive a COVID-19 vaccine. Any occurrence of Bell's palsy following COVID-19 vaccination should be reported to VAERS.

People with a history of dermal filler use

Infrequently, people who have received dermal fillers might experience swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine (no similar occurrences were observed in the Janssen COVID-19 vaccine clinical trials). The swelling appears to be temporary and resolves with medical treatment, including corticosteroid therapy. COVID-19 vaccines can be administered to people who have received injectable dermal fillers who have no contraindications or precautions for vaccination. However, these people should be advised to contact their healthcare provider for evaluation if they experience swelling at or near a dermal filler site following vaccination.

Vaccination of pregnant or lactating people

Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people; ACIP does not state a product preference.

Pregnant people

Observational data demonstrate that pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in intensive care admission, mechanical ventilation, extracorporeal membrane oxygenation, or death, though the absolute risk for these outcomes is low. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preeclampsia, coagulopathy, and preterm birth.

Data on the safety of COVID-19 vaccines in pregnant people are limited. No female reproduction or fetal, embryonal, or postnatal development safety concerns were demonstrated in animals that received Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccines before or during gestation. In addition, the adenovirus vector platform used in the Janssen COVID-19 vaccine has also been used for other Janssen vaccine development programs that have included pregnant people vaccinated during any trimester, including in a large-scale Ebola vaccination trial. No adverse pregnancy-related outcomes—including infant outcomes—were determined to be related to the vaccine in these trials.

Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or fetus because the currently authorized COVID-19 vaccines are non-replicating vaccines and cannot cause infection in either the mother or the fetus. No evidence exists of risk to the fetus from vaccinating pregnant women with non-replicating vaccines in general. However, the potential risks of COVID-19 vaccines to

the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people. Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant people are underway or planned. Vaccine manufacturers are also following outcomes in people in the clinical trials who became pregnant.

Pregnant people may choose to receive a COVID-19 vaccine. A conversation between the patient and their clinical team may assist with decisions about the use of a COVID-19 vaccine, though a conversation with a healthcare provider is not required before vaccination. When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the limited data about the vaccine during pregnancy. Pregnant people who choose to receive COVID-19 vaccine are encouraged to enroll in **v-safe**. A **v-safe** pregnancy registry has been established to follow outcomes among pregnant people who are vaccinated. Based on self-reported information, no specific safety signals have been observed among pregnant vaccine recipients included in the **v-safe** registry. However longitudinal follow-up is needed to fully evaluate pregnancy and birth outcomes.

Side effects can occur with COVID-19 vaccine use in pregnant people, similar to those expected among non-pregnant people. Acetaminophen can be offered as an option for pregnant

people experiencing fever (which has been associated with adverse pregnancy outcomes) or other post-vaccination symptoms.

There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination. There is no evidence that any of the COVID-19 vaccines affect future fertility.

Lactating people

There are no data on the safety of COVID-19 vaccines in lactating people or the effects of COVID-19 vaccines on the breastfed infant or milk production or excretion. Because non-live vaccines pose no risk for lactating people or their infants, COVID-19 vaccines are also not thought to be a risk. Therefore, lactating people may choose to be vaccinated.

Vaccination of children and adolescents

Adolescents aged 16–17 years are included among people eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to differ from those observed in people 18 years of age and older. Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech COVID-19 vaccine with appropriate assent. Children and adolescents

younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.

Children and adolescents younger than 18 years of age are not authorized to receive the Moderna or Janssen COVID-19 vaccines at this time.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html