KEY MESSAGES AND TALKING POINTS FOR PARTNERS

- Today, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommended that people whose immune systems are moderately to severely compromised receive an additional dose of mRNA COVID-19 vaccine at least four weeks after an initial two-dose mRnA series.
- ACIP, CDC's independent vaccine advisory committee, develops vaccine recommendations that go to the CDC director for approval before becoming official CDC policy.
- ACIP's recommendation follows the decision by the U.S. Food and Drug Administration (FDA) on Aug. 12th to amend Pfizer-BioNTech and Moderna's COVID-19 vaccine Emergency Use Authorizations (EUAs) in support of this allowance.
- People who have a weakened immune system (immunocompromised) make up about 3 percent of U.S. adults, and are especially vulnerable to COVID-19 because they are more at risk of serious, prolonged illness.
- CDC's recommendation includes people with a range of conditions, such as recipients of organ or stem cell transplants, people with advance or untreated HIV infection, active recipients of treatment for cancer, people who are taking some medications that weaken the immune system, and others. A full list of conditions can be found on CDC's website.
- With the Delta variant surging and cases of COVID-19 increasing significantly across the United States, an additional dose could help prevent serious and possibly life-threatening COVID-19 in immunocompromised people.
- ACIP's Aug. 13th decision followed a careful examination of available data, and robust and deliberative discussion around allowing an additional dose of either of the two FDA-authorized mRNA COVID-19 vaccines for moderately to severely immunocompromised individuals who have already received an initial two doses of mRNA COVID-19 vaccine.
- Studies show that some people who are immunocompromised don't build adequate levels of protection after receiving their 2-dose initial mRNA COVID-19 vaccination.
- In small studies, fully vaccinated immunocompromised people have accounted for a large proportion of hospitalized breakthrough cases.
- In addition, people who are immunocompromised are more likely to spread the virus that causes COVID-19 to household contacts.
- Emerging evidence shows that some within this population benefit from an additional dose of an mRNA vaccine to develop as much protection as possible against COVID-19.
- It's important to note that an additional dose is only recommended for individuals who are moderately or severely immunocompromised —CDC does **not** recommend additional doses or booster shots for any other population at this time.
- Additional updates in CDC guidance would require FDA approval of a Biologics License Application (BLA) for the COVID-19 vaccines or another amendment to the EUA(s).
- Vaccine providers should administer vaccine in accordance with the updated EUA per the COVID-19 vaccine provider agreement.
- For more information, visit:
    - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
    - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

Q&A

Q: Can you explain this new guidance for immunocompromised persons?
A: CDC recommends that people who are moderately to severely immunocompromised receive an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after completion of the initial mRNA COVID-19 vaccine series. With emerging evidence showing some people who are

immunocompromised experienced a reduced immune response to the initial COVID-19 vaccine series, this update aims to prevent serious and possibly life-threatening COVID-19 within this population.

Q: Who is eligible to get the additional dose?
A: The additional vaccine should be considered for people with moderate to severe immune compromise due to a medical condition, or receipt of immunosuppressive medications or treatments. This includes people who have:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of a solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (≥20mg 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.

Q: Why only this population? What about people in nursing homes, or those over 65?
A: Studies suggest some people with moderately to severely compromised immune systems don't always build the same level of immunity after vaccination the way non-immunocompromised people do – and may benefit from an additional dose to make sure they have enough protection against COVID-19. In addition, small studies have found that among fully vaccinated people hospitalized with COVID-19, immunocompromised people accounted for a large proportion (40–44%) of those breakthrough cases even though they only make up about 3 percent of the adult population. These updated recommendations will help to potentially protect these individuals at a time when COVID-19 cases are on the rise.

Q: What about booster doses for the broader population? Are there new data supporting another dose in other groups?
A: At this time, additional doses are only recommended for people with moderately to severely compromised immune systems since they may not have received adequate protection from their original vaccine series. This recommendation helps to increase the likelihood this population is protected against COVID-19, especially as the more transmissible Delta variant spreads. CDC and FDA continue to review available evidence and data on whether or when booster doses for other populations, including seniors, may be needed. Available data right now show the vaccines continue to be strongly protective against severe illness and death caused by COVID-19.

Q: What is the difference between an "additional dose" and a "booster dose?"
A: An "additional dose" refers to people who are moderately to severely immunocompromised receiving an additional dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the initial mRNA COVID-19 vaccine series. This is because they may not have received adequate protection from their initial 2-dose vaccine series.
A "booster dose" is a supplemental vaccine dose given to people when the 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 has not been established, and no booster doses are recommended at this time. CDC and FDA continue to review evidence and data as it is available about whether or when booster doses for the broader U.S. public may be needed, and will update guidance as more information becomes available.

Q: Will providers accept anyone who says they're immunocompromised to receive a third dose? Will people need to show a doctor's note/prescription or other documentation?

A: Immunocompromised individuals may discuss with their health care provider whether getting an additional dose is appropriate for them. If their health care provider is not at a site administering vaccines, these individuals can self-attest and receive the additional dose wherever vaccines are offered. This will help ensure there are not additional barriers to access for this vulnerable population receiving a needed additional dose. CDC is providing further information regarding vaccine administration to immunocompromised individuals to states, pharmacies, health centers, and all vaccine providers.

Q: How long after completion of the initial vaccine series are you recommending the additional dose?
A: We're recommending the additional dose of an mRNA COVID-19 vaccine be administered at least 28 days after completing the initial two-dose mRNA COVID-19 vaccine series (such as for Pfizer-BioNTech and Moderna). The exact timing can be determined in consultation with a person's healthcare provider to optimize both immunosuppressive treatments, as well response to vaccination.

Q: Can you mix and match the mRNA vaccines?
A: The additional dose should be the same vaccine product as the initial two-dose mRNA COVID-19 vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three mRNA COVID-19 vaccine doses.

Q: What should immunocompromised people who received the J&J/Janssen vaccine do?
A: There is not enough data at this time to determine whether immunocompromised people who received Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine also have an improved antibody response following an additional dose of the same vaccine. One small study showing immunocompromised people have a more robust immune response to two doses of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) than to a single dose of Janssen COVID-19 vaccine support use of mRNA COVID-19 vaccines as the primary vaccination series for this population. FDA and CDC are actively working to provide guidance on this issue.