KEY MESSAGES AND TALKING POINTS

- Yesterday, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommended certain populations receive a booster shot of Pfizer-BioNTech's COVID-19 Vaccine at least six months after the completion of their Pfizer vaccine primary series.
- In addition, the <u>CDC Director recommended</u> a booster dose for those in high risk occupational and institutional settings.
- CDC recommends:
 - people 65 years and older and residents in long-term care settings should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series;
 - people aged 50 to 64 with <u>certain underlying medical conditions</u> should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series;
 - people 18 to 49 who are at high risk for severe COVID-19 due to certain underlying medical conditions may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks; and
 - people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.
- This updated interim guidance from CDC applies to millions of adults in the U.S., and follows the Sept. 22 decision by the U.S. Food and Drug Administration (FDA) in support of this allowance.
- The decision followed a <u>careful examination of the latest data</u>, and robust and deliberative discussion around booster shots. This includes:
 - Data from a small clinical trial show that a booster dose of Pfizer-BioNTech COVID-19
 vaccine increased immune response in those who completed a primary series six months
 prior;
 - Among adults 65 years and older, data show vaccines remain effective in preventing hospitalization and severe disease, but recent evidence suggests they are less effective in preventing infection or milder symptomatic illness due to waning over time and the Delta variant; and
 - Emerging evidence show that among healthcare and other frontline essential workers, vaccine effectiveness is waning against COVID-19 infections.
- With the Delta variant surging and cases of COVID-19 increasing significantly across the United States, a booster shot will help provide continued protection against severe disease in these populations who are especially at risk for severe COVID-19. For example:
 - Because residents in long-term care (LTC) settings live closely together in group settings and are often older adults and/or have underlying medical conditions, they are at increased risk of infection and severe illness from COVID-19.
 - The risk of severe illness from COVID-19 increases with age, and can also increase for adults of any age with certain underlying medical conditions. This is why CDC recommends that individuals 50 to 64 with underlying medical conditions receive a Pfizer-BioNTech booster shot. Individuals 18-49 with underlying medical conditions may also receive a booster if they determine the personal benefits outweigh the risks.
 - And while COVID-19 vaccine effectiveness against severe disease remains high for healthcare personnel and other essential workers, those with even mild illness often cannot work. In addition, some individuals may care for or live with at-risk people, such as the

immunocompromised, and others may live in a congregate setting such as a homeless shelter or correctional facility where there is higher risk for transmission. For these reasons — as well as continued strain on the U.S. healthcare infrastructure due to the widely circulating Delta variant — CDC recommends that adults at high risk of disease from occupational and institutional exposures to COVID-19 get the Pfizer booster based on their individual benefits and risks.

- It's important to note that ACIP and CDC's recommendations are bound by what <u>FDA's authorization</u> allows. At this time, the FDA's Pfizer-BioNTech booster authorization only applies to these select populations who received the Pfizer vaccine as their primary series.
 - People in the recommended age groups who received the Moderna or J&J/Janssen vaccine
 will likely need a booster shot, and more data on the effectiveness and safety of these
 booster shots are expected in the coming weeks.
- ACIP will continue to meet to evaluate new data and may recommend booster shots for other populations and vaccine recipients soon.
- Along with today's recommendation, CDC and ACIP emphasized that the populations most vulnerable to COVID-19 are those who are unvaccinated, and the nation's priority should remain getting everyone fully vaccinated with their primary series.
 - The <u>COVID-19 vaccines approved and authorized in the United States</u> continue to be <u>effective</u> in reducing risk of severe disease, hospitalization, and death, even against the widely circulating <u>Delta variant</u>.
 - Nearly all the cases of severe disease, hospitalization, and death from COVID-19 continue to occur among those not yet vaccinated.
 - Data presented today showed hospitalization rates are 10 to 22 times higher among the unvaccinated compared to vaccinated adults.
- As <u>previously recommended</u>, moderately to severely immunocompromised individuals who are
 eligible for an additional dose of an mRNA vaccine should get that dose at least 28 days after the
 completion of their primary series.
- CDC and ACIP will continue to follow the science, and evidence will inform decision-making about booster shot recommendations.
- For those eligible, getting a Pfizer booster shot is convenient, and it can be found at many local pharmacies or doctor's offices.
- Vaccines.gov can make the process easier. This free resource provides accurate and up-to-date information about vaccination services in your area.
 - You can also text your ZIP code to 438829, or call 1-800-232-0233 to find locations near you in the U.S.
- For more information, visit:
 - o https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
 - o https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

FREQUENTLY ASKED QUESTIONS

Q: When can I get a COVID-19 vaccine booster if I am NOT in one of the recommended groups?

A: Additional populations may be recommended to receive a booster shot as more data becomes available. The <u>COVID-19 vaccines approved and authorized in the United States</u> continue to be <u>effective</u> at reducing risk of severe disease, hospitalization, and death. However, the virus that causes COVID-19 constantly evolves. Experts are looking at all available data to understand how well the vaccines are working for different populations. This includes looking at how new variants, like Delta, affect vaccine effectiveness.

Q: If we need a booster shot, does that mean that the vaccines aren't working?

A: No. <u>COVID-19 vaccines are working well</u> to prevent severe illness, hospitalization, and death, even against the widely circulating <u>Delta variant</u>. However, public health experts are starting to see reduced protection, especially among certain populations, against mild and moderate disease.

Q: What should people who received Moderna or Johnson & Johnson's Janssen vaccine do?

A: The Advisory Committee on Immunization Practices (ACIP) and CDC's recommendations are bound by what the U.S. Food and Drug Administration's (<u>FDA</u>) <u>authorization</u> allows. At this time, the Pfizer-BioNTech booster authorization only applies to people whose primary series was Pfizer-BioNTech vaccine. People in the recommended groups who got the Moderna or J&J/Janssen vaccine will likely need a booster shot. More data on the effectiveness and safety of Moderna and J&J/Janssen booster shots are expected in the coming weeks. With those data in hand, CDC will keep the public informed with a timely plan for Moderna and J&J/Janssen booster shots.

Q: What are the risks to getting a booster?

A: For many who have completed their primary series with Pfizer-BioNTech vaccine, the benefits of getting a booster shot outweigh the known and potential risks. So far, <u>reactions reported</u> after the third Pfizer-BioNTech shot were similar to that of the 2-shot primary series. Fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the 2-shot primary series, <u>serious side effects are rare</u>, but may occur.

Q: Does this change the definition of "fully vaccinated" for those eligible for booster shots?

A: People are still considered fully vaccinated two weeks after their second dose in a 2-shot series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine. This definition applies to all people, including those who receive an additional dose as recommended for moderate to severely immunocompromised people and those who receive a booster shot.

Q: Can you explain these "permissive" recommendations related to people 18 to 49 with underlying medical conditions, and people 18 to 64 who may be exposed due to occupational/institutional setting? How are these different from the other two recommendations?

A: Adults 18–49 who have underlying medical conditions are at increased risk for severe illness from COVID-19, as are people 18-64 are in an occupational or institutional setting where the burden of COVID-19 infection and risk of transmission are high. However, that risk is likely not as high as it would be for adults 50 years and older who have underlying medical conditions, or people who live in long-term care settings. With the lower risk, the data do not support that everyone who falls into this group should get a booster shot. Therefore, CDC's recommendation is not as strong for these populations, but still allows a booster shot to be available for those who would like to get one. People 18 and older who are at high risk for severe COVID-19 due to underlying medical conditions or their occupation should consider their individual risks and benefits when making the decision of whether to get a booster shot. This recommendation may change in the future as more data become available.

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

A: It's important to note that individuals can self-attest (i.e. self-report that they are eligible) and receive a booster shot wherever vaccines are offered. This will help ensure there are not additional barriers to access for these select populations receiving their booster shot.