

## SUMMARY

Today, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released the following statement on the Administration's plan for COVID-19 booster shots for the American people, pending FDA approval and ACIP recommendations.

## KEY MESSAGES

- **The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant.**
- **Although we continue to see stable and highly effective protection against hospitalizations and severe outcomes for people who are fully vaccinated, we are seeing a decrease in vaccine effectiveness against infection.**
- **It is critical that unvaccinated and partially vaccinated people get their primary series of vaccines to further reduce the risk of COVID-19 and its more severe outcomes. Nearly all the cases of severe disease, hospitalization, and death continue to occur among those not yet vaccinated at all.**
- **We have developed a plan to begin offering these booster shots this fall subject to FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC's Advisory Committee on Immunization Practices (ACIP) issuing booster dose recommendations based on a thorough review of the evidence.**
  - Only after a thorough review of the evidence will CDC's independent advisory committee make recommendations on the use of boosters for the public.
  - The Advisory Committee on Immunization Practices (ACIP), composed of medical and public health experts, develops recommendations, and provides guidance to the CDC Director on the use of vaccines for the general public.
- **Among fully vaccinated people in New York state (data includes NYC) from May 3–July 25, 2021, COVID-19 vaccines were more than 90% effective against hospitalizations.**
  - A new study finds that among all adults in New York state, overall effectiveness against new COVID-19 infections declined from about 92% to about 80%.
  - The decline in effectiveness against new infections coincides with the increase in the Delta variant in the United States, along with relaxation of masking and physical distancing recommendations.
  - The factors driving the apparent changes in vaccine effectiveness, including variations by age, are uncertain. The substantially increased infectiousness of the Delta variant might underpin its increased transmissibility and could potentially lead to reduced vaccine-induced protection against infection.
- **A new CDC study finds the Pfizer and Moderna COVID-19 vaccines were highly effective in providing at least 24 weeks of protection for fully vaccinated adults against severe COVID-19 illness requiring hospitalization.**
  - Vaccine effectiveness against COVID-19 associated hospitalization was 86% during the first 2–12 weeks post-vaccination and 84% effective during the following 12-week period.

- The vaccine was found to be 90% effective against COVID-19 associated hospitalizations for people without immunocompromising conditions.
  - For those with immunocompromising conditions, the vaccine was found to be only 63% effective against hospitalizations associated with COVID-19 (over the 24 week study). CDC now recommends that people whose [immune systems are moderately to severely compromised](#) should receive an additional dose of mRNA COVID-19 vaccine at least 4 weeks after their second dose, for a total of three doses.
  - Widespread vaccination is a critical tool to reduce the risk of hospitalization due to COVID-19.
- **Nursing home residents were prioritized for COVID-19 vaccination early in the U.S. vaccination program and might be among the first groups to show evidence of potential waning of the immunity provided by vaccines.**
    - Among nursing home residents, in the pre-Delta period two doses of mRNA vaccine were 75% effective against COVID-19 infections; but during the Delta period, mRNA vaccine effectiveness declined to 53%.
    - Investigators could not determine if the lowered vaccine effectiveness was caused by potential waning immunity, reduced protection against the Delta variant (that became the dominant strain within 6 months after vaccine rollout), or a combination of both factors.
    - Vaccination of nursing home residents, staff members, and visitors should be prioritized because residents remain at higher risk for COVID-19 despite vaccination.
    - A potential need for an additional vaccine dose exists among populations at higher risk of severe COVID-19 outcomes.
- **Our top priority remains staying ahead of the virus and protecting the American people from COVID-19 with safe, effective, and long-lasting vaccines.**
    - This virus is constantly changing, and we are following the science. Vaccines remain the most powerful tool we have against COVID-19.
    - If you haven't been vaccinated yet, you should get vaccinated right away. Nearly all the cases of severe disease, hospitalization, and death continue to occur among those not yet vaccinated.

## FREQUENTLY ASKED QUESTIONS

### **Q: When can I get a COVID-19 vaccine booster?**

A: Not immediately. The goal is for people to start receiving a COVID-19 booster shot beginning in the fall, with individuals being eligible starting 8 months after they have received their second dose of mRNA vaccine (either Pfizer-BioNTech or Moderna). This is subject to FDA approval and CDC's Advisory Committee on Immunization Practices (ACIP) authorization and recommendation.

### **Q: What's the difference between a booster shot and an additional 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). 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 was adequate but is likely to have decreased over time.

**Q: Who will be the first people to get a booster dose?**

A: Once FDA approves and ACIP recommends a booster dose, the goal is for the first people eligible to be those who were the first to receive their shots in the earlier phases of the vaccine rollout and those who are most at risk. This includes healthcare providers, nursing home residents, and other seniors.

**Q: Why are we waiting to start offering COVID-19 vaccine boosters?**

A: The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant. However, COVID-19 constantly evolves. We're looking at all available data to understand as much as we can about how well the vaccines are working, including how new variants, like Delta, affect vaccine effectiveness. Once FDA approves and ACIP recommends, the goal is for people to start receiving a COVID-19 booster shot this fall.

**Q: Will people who received Johnson & Johnson's (J&J/Janssen) COVID-19 vaccine need a booster shot?**

A: It is likely that people who received a J&J COVID-19 vaccine will need a booster dose. Because the J&J vaccine wasn't given in the United States until 70 days after the first mRNA vaccine doses (Pfizer-BioNTech and Moderna), the data needed to make this decision isn't available yet. We expect more data to come in the next few weeks. With those data in hand, we will keep the public informed with a timely plan for J&J booster shots as well.

**Q: Can people who received Johnson & Johnson's (J&J) COVID-19 vaccine get a booster dose of an mRNA vaccine?**

A: There's not enough data currently to support getting an mRNA vaccine booster dose (either Pfizer-BioNTech or Moderna) if someone has gotten a J&J vaccine. People who took the J&J vaccine will likely need a booster dose, and more data is expected in the next few weeks. With those data in hand, we will keep the public informed with a timely plan for J&J booster shots as well.

**Q: If we need a booster, does that mean that the vaccine is not working?**

A: No. The COVID-19 vaccines are working very well to prevent severe illness, hospitalization, and death, even against the widely circulating Delta variant. However, with the Delta variant, we are starting to see reduced protection against mild and moderate disease. For that reason, we are planning for a booster shot to maximize vaccine-induced protection and prolong its durability.

**NEW MMWRS ON VACCINE EFFECTIVENESS**

- **Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19-Associated Hospitalizations Among Adults — United States, March–July 2021**  
Link when live:  
[https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm?s\\_cid=mm7034e2\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm?s_cid=mm7034e2_w)
- **New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021**  
Link when live:  
[https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm?s\\_cid=mm7034e1\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm?s_cid=mm7034e1_w)

- **Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and After Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021**

Link when live:

[https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm?s\\_cid=mm7034e3\\_w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm?s_cid=mm7034e3_w)



All MMWRs on vaccine safety and effectiveness can be found here: [https://www.cdc.gov/mmwr/covid19\\_vaccine\\_safety.html](https://www.cdc.gov/mmwr/covid19_vaccine_safety.html)

#### JOINT STATEMENT

[HTTPS://WWW.CDC.GOV/MEDIA/RELEASES/2021/S0818-COVID-19-BOOSTER-SHOTS.HTML](https://www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html)

#### **Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots**

Today, public health and medical experts from the U.S. Department of Health and Human Services (HHS) released the following statement on the Administration’s plan for COVID-19 booster shots for the American people.

The statement is attributable to Dr. Rochelle Walensky, Director of the Centers for Disease Control and Prevention (CDC); Dr. Janet Woodcock, Acting Commissioner, Food and Drug Administration (FDA); Dr. Vivek Murthy, U.S. Surgeon General; Dr. Francis Collins, Director of the National Institutes of Health (NIH); Dr. Anthony Fauci, Chief Medical Advisor to President Joe Biden and Director of the National Institute of Allergy and Infectious Diseases (NIAID); Dr. Rachel Levine, Assistant Secretary of Health; Dr. David Kessler, Chief Science Officer for the COVID-19 Response; and Dr. Marcella Nunez-Smith, Chair of the COVID-19 Health Equity Task Force:

“The COVID-19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating

Delta variant. Recognizing that many vaccines are associated with a reduction in protection over time, and acknowledging that additional vaccine doses could be needed to provide long lasting protection, we have been analyzing the scientific data closely from the United States and around the world to understand how long this protection will last. The available data make very clear that protection against SARS-CoV-2 infection does begin to decrease over time following the initial vaccinations given, and in association with the dominance of the Delta variant, we are starting to see evidence of reduced protection against mild and moderate disease. Based on our latest assessment, the current protection against severe disease, hospitalization, and death could diminish in the months ahead, especially among those who are at higher risk or were vaccinated during the earlier phases of the vaccination rollout. For that reason, we conclude that a booster shot will be needed to maximize vaccine-induced protection and stay ahead of the virus.

“We have developed a plan to begin offering these booster shots this fall once FDA conducts an independent evaluation and determination of the safety and effectiveness of a third dose of the Pfizer and Moderna mRNA vaccines and CDC’s Advisory Committee on Immunization Practices (ACIP) issues booster dose recommendations based on a thorough review of the evidence. We are prepared to offer booster shots for all Americans beginning the week of September 20 and starting 8 months after an individual’s second dose. At that time, the individuals who were fully vaccinated earliest in the vaccination rollout, including many health care providers, nursing home residents, and other seniors, will likely be eligible for a booster. We would also begin efforts to deliver booster shots directly to residents of long-term care facilities at that time, given the distribution of vaccines to this population early in the vaccine rollout and the continued increased risk that COVID-19 poses to them.

“We also anticipate booster shots will likely be needed for people who received the Johnson & Johnson (J&J) vaccine. Administration of the J&J vaccine did not begin in the U.S. until March 2021, and we expect more data on J&J in the next few weeks. With those data in hand, we will keep the public informed with a timely plan for J&J booster shots as well.

“Our top priority remains staying ahead of the virus and protecting the American people from COVID-19 with safe, effective, and long-lasting vaccines especially in the context of a constantly changing virus and epidemiologic landscape. We will continue to follow the science on a daily basis, and we are prepared to modify this plan should new data emerge that requires it.

“We also want to emphasize the ongoing urgency of vaccinating the unvaccinated in the U.S. and around the world. Nearly all the cases of severe disease, hospitalization, and death continue to occur among those not yet vaccinated at all. We will continue to ramp up efforts to increase vaccinations here at home and to ensure people have accurate information about vaccines from trusted sources. We will also continue to expand our efforts to increase the supply of vaccines for other countries, building on the more than 600 million doses we have already committed to donate globally.”