ADDITIONAL VACCINE DOSES

KEY PIH-US TALKING POINTS & FAQ

Updated October 22, 2021

The approval and provision of additional vaccine doses has been widely discussed and debated in recent weeks. Currently data indicate that COVID-19 vaccines are highly effective in preventing severe outcomes, including hospitalization and death, among the general population—even against the more transmissible Delta variant. Immunocompromised individuals require an additional layer of protection to ensure they are adequately safeguarded; the FDA approved a third dose accordingly. The FDA recently approved Pfizer, Moderna, and Johnson & Johnson booster shots (including in a heterologous mix-and-match strategy) for certain groups of adults. However, at this time, there are insufficient data to advocate for more widespread booster shots in the general population.

Continued effort to expand first and second doses more widely and evenly across the United States and around the world will not only offer better protection for everyone, but it is also in line with a drive for global vaccine equity as a moral and epidemiologic imperative.

COVID-19 Vaccination

• Three vaccines are currently approved for use in the U.S., in one- and two-dose primary series regimens:
  o Pfizer/BioNTech’s two-dose mRNA vaccine has been granted full FDA approval for those 16+.
  o Use of the two-dose mRNA vaccine developed by Moderna and the single-dose adenovirus vector vaccine developed by Janssen/Johnson & Johnson (J&J) are in use under FDA’s Emergency Use Authorization (EUA). Additionally, use of the Pfizer/BioNTech’s two-dose vaccine for individuals ages 12-15 is in use under the EUA, as are both Pfizer/BioNTech and Moderna’s vaccines for third doses for immunocompromised individuals.
• The available vaccines remain effective against severe disease and hospitalization against COVID-19, including the more dangerous and transmissible Delta variant.
  o Data from two-dose mRNA vaccines show a high degree of effectiveness (90%+) against severe disease, hospitalization, and death from both the Alpha and Delta variants. These studies found lower effectiveness against asymptomatic and symptomatic infection for Delta compared to Alpha.
  o Early data from South Africa show a high degree of effectiveness of the single-dose J&J vaccine against severe illness and death from both the Delta and Beta variants.
  o Effectiveness estimates from clinical trials differ from real-world effectiveness, particularly across different geographies and phases of the pandemic—including after the spread of the Delta variant.
• Vaccination remains our most powerful tool for protection against COVID-19. Currently rates of full vaccination are insufficient to effectively prevent continued spread.
  o As of mid-October, less than 60% of the entire U.S. population (and less than 70% of those currently eligible age 12+) is fully vaccinated, with coverage rates varying widely from community to community—there are still millions of people in the U.S. who have not initiated or completed full vaccination. Access to vaccination remains a significant barrier for many.

Additional Doses

COVID-19 vaccines are effective tools, but are less effective for immunocompromised individuals

• Most people who are fully vaccinated against COVID-19 are highly protected from severe disease and hospitalization, however, those with compromised immune systems require additional layers of protection.
• Vaccine effectiveness for those who are immunocompromised is significantly lower when compared to those who are not immunocompromised. Studies indicate that vaccine effectiveness is around 59-71% against infections for immunocompromised people versus 90-94% overall.

FDA approval for immunocompromised
• FDA amended the EUAs for both the Pfizer and Moderna vaccines to allow for the use of a third dose in certain immunocompromised individuals. This specifically includes solid organ transplant recipients or those diagnosed with conditions with similar levels of immunocompromise. Those who are eligible may receive a third dose at least 28 days after their second dose of the same vaccine.
• Immunocompromised individuals who have received the J&J vaccine are not yet eligible for a second dose (with exception to those who reside in San Francisco).

Data necessitating booster shots for the general public is not yet sufficient, but some populations may access booster shots now
• FDA recently approved Pfizer and Moderna booster shots for certain groups of adults—including those over 65 and others at high risk of severe COVID-19 due to underlying health conditions and occupational exposure—at least six months after their second dose of the primary series vaccine, and J&J booster shots for anyone who received a J&J initial dose, at least two months after the initial dose.
• On October 20, 2021, FDA authorized providers to boost people with a different vaccine from the one they initially received, known as a heterologous or “mix-and-match” strategy. However, FDA did not recommend any one vaccine over another to be used as a booster, nor did they issue guidance on if consistent use of a single vaccine type is preferable for any of the available vaccines. When a mixed-and-matched dose strategy is followed, eligible recipients may receive a booster of any of the three vaccines at the recommended dosing interval for the booster dose of the vaccine used for primary vaccination.
• Those who are at an increased risk due to a compromised immune system are currently eligible for and advised to receive a third dose as a part of their recommended vaccine regimen.
• In the absence of supportive data for vaccines booster shots for the general population, first and second doses—both in the U.S. and globally—should be prioritized to have a greater impact on community spread.
• The observed benefit of boosters against hospitalization and death is fairly small compared to the benefit of going from unvaccinated to full (two-dose) vaccination.

PIH-US Recommendations
Continue to focus the majority of efforts on widespread and even coverage of first and second dose vaccination ("breadth over depth")
• Higher vaccination rates will reduce transmission, severe disease, and serious outcomes.
• We must ensure that the approval of additional doses does not detract from the important operational focus on vaccinating those who have not received a first or second dose. Accessible, small-scale, community-based vaccination opportunities (accompanied by consistent outreach from trusted sources) remain the most effective options to vaccinate those most in need.

Advocate for global vaccine equity: as a moral, ethical, and epidemiologic imperative
• Getting shots to everyone in all areas of the world—especially low-resource settings—is not only a moral imperative but will also protect us all by ensuring more people are protected against COVID-19.
• Decreased transmission at the global level is necessary to prevent the emergence of new variants, which may be even more dangerous and threaten efforts to contain the virus.
• “Vaccine nationalism” ignores ethical responsibility and epidemiologic reality: we are part of a global community. Countries should not be prioritized simply because they are high-income; all lives must be valued and preserved.
Support continued commitment to proven mitigation measures: masking, social distancing, contact tracing, testing, supportive isolation, and quarantine.

Additional Doses FAQ

What is a booster shot and why might it be needed?
A booster shot is an additional dose of a vaccine given after the initial recommended dose. Boosters are typically offered for populations whose immunity from those initial doses has started to naturally wane, or whose risk of severe disease is highest, as an additional layer of protection. For most people under age 65, the vaccines offered in the U.S. provide effective protection against severe disease, hospitalizations, and death.

Who is eligible to receive a booster shot?
The FDA recently authorized booster shots for certain groups of people who received their second dose of the Pfizer or Moderna COVID-19 vaccine at least six months ago, and for anyone who received the J&J vaccine at least two months ago. Those who receive the Pfizer or J&J booster will receive the same/full original dose, while those who receive the Moderna booster will receive half of the original dose as a booster. Anyone who received an initial J&J dose is eligible for a booster dose, while the CDC recommends the following eligibility for an additional booster dose of the Pfizer or Moderna vaccine:

- Adults 65+ and residents of long-term care facilities should receive a booster dose
- Adults 50-64 with underlying medical conditions should receive a booster dose
- People 18-49 with underlying medical conditions may receive a booster dose, based on individual risks and benefits
- People 18-64 who are at increased risk of COVID-19 exposure and transmission because of occupational or institutional settings may receive a booster shot, based on individual risks and benefits (this currently includes health care workers, teachers, day care workers, grocery staff, staff of congregate settings, etc.)

People who are immunocompromised who received either the Pfizer or Moderna vaccines (for first and second doses) are also eligible for a third dose of the shot they received, at least four weeks after their second dose. The third shot for these patients who suffer from compromised immune systems and need an additional layer of protection is not technically considered a “booster,” but rather as part of their recommended vaccine series. At this time, there is not enough data to determine the effectiveness of the J&J vaccine for those who are immunocompromised with an additional dose of the J&J vaccine, and thus the FDA’s EUA amendment only applies to mRNA COVID-19 vaccines for this population.

If you are not eligible for a booster shot, it is recommended that you adhere to CDC and local mitigation guidance for masking and social distancing.

What is a third dose? Is it different than a booster?
In short, a third dose is for people who are severely immunocompromised to complete their initial series and a booster is an additional dose recommended for some members of the general public to “boost” their immunity and offer an initial layer of protection from the vaccine.

Vaccine effectiveness for those who are immunocompromised is significantly lower when compared to those who are not immunocompromised. The third shot for patients who suffer from compromised immune systems and need an additional layer of protection is not technically considered a “booster,” but rather as part of their recommended vaccine series. This is known as a third dose. People who are severely immunocompromised who received either the Pfizer or Moderna vaccines (for first and second doses) are eligible for a third dose of the shot they received, at least four weeks after their second dose.
**What vaccines have been approved for a booster shot?**

Currently the Pfizer, Moderna, and J&J vaccines have all been approved for use as booster shots. Pfizer and J&J booster shot doses will be the same dosage as each of the primary series doses; Moderna’s booster shot will be half of the primary series dose.

Certain immunosuppressed people who received either the Pfizer or Moderna vaccine for their primary series may receive a third dose of either Pfizer or Moderna (of the type matching their initial doses), but this is only approved for use in that population.

**If I received one type of vaccine, can I receive a different type of vaccine as a booster dose?**

Yes. FDA authorized providers to boost people with a different vaccine from the one they initially received. If you are eligible, you may choose which vaccine you receive as a booster shot. If you do receive a booster vaccine that is different from the one you received for your primary dose, you should do so that the recommended interval for the booster dose of your original vaccine. For example, if you initially received the single-dose J&J vaccine, you are eligible to receive a booster of any kind (J&J, Moderna, or Pfizer) at least two months after your initial dose. If you initially received either the Pfizer or Moderna vaccines for your primary series, you are eligible to receive a booster dose of any kind (J&J, Moderna, or Pfizer) at least six months after your second dose of that primary series.

**When should a booster shot be administered?**

Booster shots for the above-mentioned groups who received the Pfizer or Moderna vaccines during their primary series should be administered at least six months after the second dose. Booster shots for those who initially received the J&J vaccine should be administered at least two months after the first shot. Immunosuppressed individuals may receive their recommended third dose four weeks after their second Pfizer or Moderna dose.

**How do I get a booster shot?**

Booster shots will be distributed in similar ways as first and second doses. You can search online for vaccine locations in your area here: [https://www.vaccines.gov/search/](https://www.vaccines.gov/search/). Refer to your local health department or doctor for more details, as there may be opportunities not listed on this website. Speak with your doctor to discuss if your underlying health condition qualifies you for a booster dose, or with any additional questions about eligibility or access.

**What side effects should I expect from a booster dose?**

Side effects from the third dose of the vaccine are similar to those observed from second doses. These side effects can include pain or swelling at the injection site, fatigue, fever, headache and are generally mild and most common the day after vaccination.
The ideas presented in this document reflect the latest public health thinking and scientific evidence as of October 2021. You are advised that the COVID-19 vaccine landscape remains highly fluid, and it is your responsibility to ensure that decisions are made based on the most up-to-date information available. Partners In Health does not provide medical advice, diagnosis or treatment in the United States. Always seek the advice of a physician or other qualified health care provider with any questions regarding a medical condition. The information, including but not limited to, text, graphics, images and other material contained in this document, are intended for informational purposes only.