Q: Who's currently eligible to receive a third dose of the Pfizer vaccine?
A: Under the current emergency use authorization (EUA), immunocompromised people can receive a third dose. Now that the Pfizer vaccine is fully approved by the FDA, people over the age of 16 can also get a prescription from their physician for a booster dose of the vaccine if their physician believes it is appropriate for them.

The term “third dose” is used for a third dose of a two-dose vaccine that is given as part of the primary vaccination series to increase immunization in people with immune compromise. The term “booster dose” is used for a third dose of a two-dose vaccine that is given at some time (usually months) after the primary vaccination series in order to “top up” immunity. Off-label prescriptions are only available for people 16 years and older, as 12-15-year-olds are still under the EUA restrictions.

The FDA's vaccine advisory panel recently recommended expanding the EUA for the Pfizer vaccine to include a booster for people 65 and older as well as those considered high-risk for contracting severe COVID-19 disease. We expect that the FDA will follow this recommendation, but this is not part of the official EUA just yet. The panel also suggested adding to the EUA a booster dose for health care workers and others at high risk of occupational exposure. Once the FDA issues its rules, the CDC's advisory committee will then fine-tune the precise guidance for use of boosters. We expect the FDA to issue its rules within days and the CDC to follow suit the week of Sept. 20.

Q: Who will benefit from a third shot of an mRNA vaccine?
A: Immunocompromised people who will benefit from a third dose include recipients of solid organ or hematopoietic stem cell transplants, people with severe primary immunodeficiencies, and people receiving treatment using immunosuppressive medications such as cancer chemotherapeutic agents, TNF blockers, certain biologic agents and high-dose corticosteroids.

Clinical trials have proven that the mRNA vaccine efficacy weakens over time. Once the FDA and CDC fully approve the booster, it should be administered eight months after the last dose of the mRNA vaccine. Currently, the third dose and booster shot are only available to immunocompromised patients or with doctor's prescription (a doctor-prescribed dose) from your licensed health care provider.

The FDA's vaccine advisory committee recently discussed expanding the use of booster shots under the EUA for the Pfizer vaccine. The committee was unanimous in recommending the booster for people 65 years and older and those considered high-risk for contracting severe COVID-19 disease. They also unanimously suggested that those at high risk of exposure to COVID-19, such as health care workers, should be considered for a booster shot.

Q: Why did the FDA committee recommend the Pfizer booster for people 65 and older and those who are at high risk for contracting severe COVID-19 disease?
A: Based on the totality of scientific evidence available, including the safety and effectiveness data from clinical trials, the known and potential benefits outweigh the known and potential risks of a Pfizer booster administered at least six months after the primary series, according to the FDA's advisory panel.
Q: Why did the FDA not expand the EUA for the Pfizer booster shots to the rest of the general population?
A: The FDA committee overwhelmingly voted that the safety and efficacy of a booster was not yet proven to their satisfaction in ages 16 and up. As with the initial EUA approval of the Pfizer vaccine, the FDA committee wanted to have enough data to be sure a third vaccine dose will benefit the broader American population. They felt that expanding the EUA incrementally, while continuing to collect safety and efficacy data, was the best and most responsible way to do this.

Q: Will immunocompromised people get sicker if they contract COVID-19?
A: Yes. Research from the CDC suggests that immunocompromised people are more likely to get severely ill from COVID-19, are more likely to transmit it to household contacts and have breakthrough infections. According to the study from the CDC, in the U.S., 44% of hospitalized breakthrough cases are immunocompromised people.

Q: Why do immunocompromised patients need a third shot?
A: For a vaccine to work, it needs to activate the immune system to create B-cell responses, T-cell responses and antibody responses. However, for people who have underlying conditions or take immunosuppression medications – such as organ transplant recipients – these medications specifically target certain parts of the immune system to prevent their immune systems from attacking themselves to fight the disease. As a result, their immune systems aren’t able to respond normally to a vaccine.

According to researchers at Johns Hopkins, after one dose of the vaccine, 100% of people with normal immune systems will have some detectable antibody, while only 20% of transplant patients show detectable antibodies after one dose.

Q: Is the third shot safe for immunocompromised people?
A: The CDC studied what happened when immunocompromised patients – including solid organ transplant recipients and patients on hemodialysis – were given a third dose of an mRNA vaccine.

None of the transplant patients reported any serious adverse events after administration of the third dose, and no acute rejection episodes occurred. None of the patients on hemodialysis developed critical side effects requiring hospitalization. Symptoms reported were consistent with previous doses and the intensity of the symptoms was mostly mild or moderate.

Q: I’m immunocompromised, and I’m worried about the safety of the third dose. What should I do?
A: Please contact your health provider with any concerns so you can make an informed decision.

Q: Should I get a booster shot to protect myself further, too, even if I’m not older or immunocompromised?
A: Now that the Pfizer vaccine is fully approved by the FDA, you can get a prescription from your physician for a booster dose of the vaccine. The FDA also expanded the EUA for the Pfizer booster to include people 65 years old and older as well as those considered high-risk for contracting severe COVID-19 disease. Please contact your health care provider with any questions or concerns so you can make an informed decision. You and your physician should discuss if a booster dose is appropriate for you.

Q: Can you mix and match vaccines for the third dose?
A: The FDA indicates that attempts should be made to match the additional dose type to the mRNA primary series. However, if that is not feasible, a heterologous additional dose is permitted. The additional dose of mRNA COVID-19 vaccine should be administered at least 28 days after completion of the primary mRNA COVID-19 vaccine series.

Accordingly, the Houston Methodist Vaccine Scientific Committee is comfortable with mixing COVID-19 vaccines to the extent allowed by government regulations.

Q: Is there any difference in the composition of a third shot and a regular shot?
A: No. The current boosters are another dose of the same COVID-19 vaccines used for the primary vaccine.
series. The purpose of a booster is to prolong or refresh protective immunity. A booster can also be tweaked and tailored to target particular variants of the virus. So, it is possible there will be different boosters in the future.

HOUSTON METHODIST VACCINE SCIENTIFIC COMMITTEE (VSC) RECOMMENDATIONS

Q: Is a third dose recommended? If so, who should get one?
A: The VSC recommends a third dose to be used according to the ACIP guidance, as follows:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of 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 (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory
- Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be given at least two weeks before initiation of immunosuppressive therapies

The FDA's advisory committee has also recommended expanding the EUA for the Pfizer vaccine booster to include people 65 years and older, those considered to be high risk for contracting severe COVID-19 disease and certain people with high risk of occupational exposure such as health care workers.

Q: When will COVID-19 vaccine booster shots be available to fully vaccinated people who are not immunocompromised?
A: Now that the Pfizer vaccine is fully approved by the FDA, people who are not immunocompromised can get a prescription from their physician for a booster shot. The FDA likely will follow the recommendation of its advisory committee and expand the EUA for the Pfizer vaccine booster to include people 65 years and older, those at risk for contracting severe COVID-19 disease and occupationally exposed workers, but it has not done so yet. Please note that the data regarding boosters is evolving rapidly, so our guidance will be updated to continue to take account of newly developed facts.

Q: Is testing recommended/required before administration of a third dose (i.e. antibody titers)?
A: The evidence that antibody titers are correlated with protection from COVID-19 is sufficient for broad public policy recommendations, such as the FDA and CDC approval of third doses for immunocompromised individuals. However, the data are not yet sufficient to guide clinical management of individual patients through an algorithm. The CDC ACIP specifically recommends against measurement of antibody titers for clinical decision-making. Accordingly, titers are not required prior to a third dose and anyone who has had two doses of the mRNA vaccines and wishes to have a booster eight months or more after the second dose should be allowed to receive one.

Q: Can you switch vaccines?
A: Although the data on existing COVID-19 vaccines is limited, this is an accepted strategy with several other vaccines and the data in regard to mixing vector and mRNA vaccines for COVID-19 is supportive. The ACIP guidance regarding vaccine administration includes several specific items:
• The additional dose should be the same mRNA vaccine as the primary series — but — alternate mRNA product can be used if primary series product not available.

• Until more data are available, the additional dose should be administered at least 28 days after completion of the initial primary series.

• Currently there are no data to support the use of an additional mRNA COVID-19 vaccine dose after a primary Johnson and Johnson's Janssen COVID-19 vaccine in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue.

• The FDA and CDC do not believe that there is enough data at this time to determine whether immunocompromised people who received the Johnson & Johnson's Janssen COVID-19 vaccine also have an improved antibody response following an additional dose of the same vaccine.

Q: Will Houston Methodist vaccine clinics start accepting prescriptions from a physician for vaccination people who fall outside of the FDA approval?

A: Yes, our vaccine clinics will accept physician-prescribed doses for the Pfizer vaccine for people 16 and older now that it is approved with a full biologics license.