

COVID-19 VACCINE

Part 2

WHO SHOULD GET THE COVID-19 VACCINE?

COVID-19 VACCINATION HAS BEEN AUTHORIZED

Authorized for use under an EUA for active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.



PRIORITY GROUPS:

- CDC has recommended that the vaccine should be offered to both healthcare personnel and residents of long-term care facilities first.
- Healthcare personnel are defined as paid and unpaid people serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials. Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.
- Before making an official recommendation, ACIP considered four groups to possibly recommend for early COVID-19 vaccination if supply is limited:
 - Healthcare personnel
 - Workers in essential and critical industries
 - People at high risk for severe COVID-19 illness due to underlying medical conditions
 - People 65 years and older



SPECIAL POPULATIONS

There is currently insufficient data to make conclusions about the safety of the vaccine in subpopulations such as children less than 16 years of age, pregnant and lactating individuals, and immunocompromised individuals.

Released from the Pfizer-Biontech Committee briefing document Dec.10, 2020

PREGNANCY:

- At the time of the data cutoff in Study C4591001 (14 November 2020), a total of 23 participants had reported pregnancies in the safety database, including 9 participants who withdrew from the study due to pregnancies. These participants continue to be followed for pregnancy outcomes (Pfizer-Biontech Committee briefing document Dec.10, 2020).
- Deputy Chief Medical Officer Professor Jonathan Van-Tam said that pregnant women should hold off from getting the vaccine. The Joint Committee on Vaccination and Immunization (JCVI) has advised that pregnant women do not get the vaccine because there is “no data as yet on the safety of Covid-19 vaccines in pregnancy”.
- The CDC’s general guidelines for vaccinating pregnant women, which were last updated in 2016, notes that the benefits, in general, “usually outweigh potential risks when the likelihood of disease exposure is high.”
- <https://www.chicagotribune.com/coronavirus/ct-life-covid-pregnant-women-becoming-pregnant-vaccine-tt-20201202-xl4jvwjoqvfhfpciigjetcef5a-story.html>

THOSE WITH A HISTORY OF ALLERGIC REACTIONS TO VACCINES:

- The Medicines and Healthcare products Regulatory Agency (MHRA) has given precautionary advice to NHS trusts that anyone who has a history of "significant" allergic reactions to medicines, food or vaccines should not receive the vaccine.
- Professor Stephen Powis, national medical director for the NHS in England, said: "As is common with new vaccines the MHRA have advised on a precautionary basis that people with a significant history of allergic reactions do not receive this vaccination after two people with a history of significant allergic reactions responded adversely yesterday. Both are recovering well."
- <https://www.itv.com/news/2020-12-03/covid-can-pregnant-and-immunocompromised-people-get-the-pfizer-vaccine-who-cant-get-the-jab-and-why>

VACCINE COMPOSITION:

The Pfizer-BioNTech COVID-19 Vaccine is a white to off-white, sterile, preservative-free, frozen suspension for intramuscular injection. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2. The vaccine also includes the following ingredients: lipids, potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

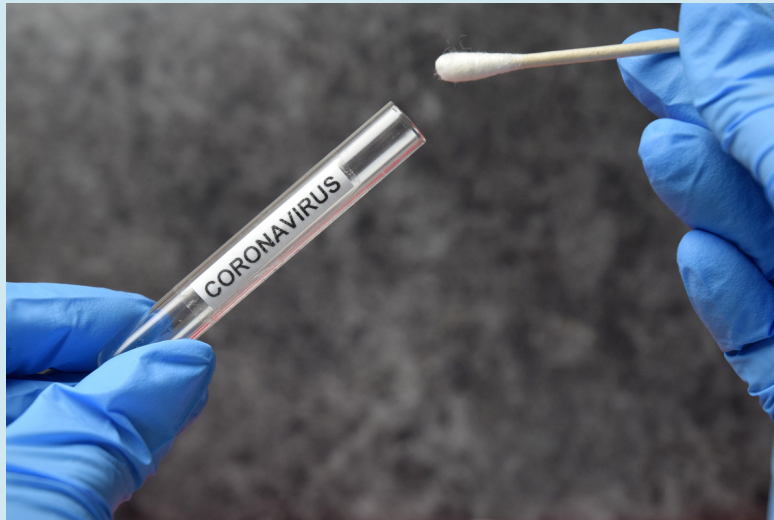
The proteins most often implicated in vaccine allergies are egg and gelatin, with perhaps rare reactions to yeast or latex.



PATIENTS WITH KIDNEY OR LIVER DISEASE:

- While these specific populations have not yet been studied, the UK renal community released these statements:
 - Vaccine development offers potential lifesaving protection to many clinically extremely vulnerable patients
 - The renal community would like to highlight the additional need to prioritize vaccination for younger people with kidney disease who fall into high-risk groups
- The UK renal community proposed the following approach to vaccination:
 - Prioritization of patients receiving hemodialysis to ensure that people with kidney disease at the highest risk of adverse outcomes are rapidly vaccinated.
 - Ensuing that all people with kidney disease under our care who are not receiving HD but who are also at high-risk are recorded on the clinically extremely vulnerable lists.
 - Continue to maximize flu vaccination coverage for people with kidney disease highlighting the need to separate flu and COVID-19 vaccinations by at least one week.
 - All patient-facing staff working in kidney care should receive priority access to COVID-19 vaccination.
 - Continued collaboration with scientific partners and industry is maintained to develop alternative therapies for COVID-19 for any renal patients who do not respond to the initial vaccination.
 - <https://britishrenal.org/covid-19-vaccination-for-adult-patients-with-kidney-disease/>





CHEMOTHERAPY PATIENTS:

- The Cancer Treatment Center of America has released these statements:
 - If you're a cancer patient, do not get any vaccine before talking to your doctor, especially if you've been diagnosed recently or are or have been in active treatment.
 - Why? Many vaccines work by educating and stimulating the immune system to recognize and attack viruses and other potentially dangerous invaders. To be effective, however, some vaccines may need a healthy immune system capable of launching a robust attack against a virus.
 - Traditionally, vaccines have worked by introducing a harmless form of a virus into the body to educate the immune system on what to look for. But some vaccines use live viruses that, if given to a cancer patient with a weakened immune system, may cause serious side effects.
 - Early information, however, indicates that the three leading COVID-19 vaccines should be safe. "Due to the nature of the vaccines, there should not be complications giving it to cancer patients," Dr. Chowdhury, MD, Infectious Disease Program Specialist for Cancer Treatment Centers of America® (CTCA).

TRANSPLANT RECIPIENTS:

- The American Society of Transplant Surgeons released these statements:
 - Neither of these vaccines have been tested in transplant candidates or recipients. Further study is necessary to determine the degree of protective immunity provided the waitlist and transplant patient. It is necessary to be mindful that the effect of the mRNA vaccines may alter other immune responses, with the potential to heighten the alloimmune response. Vigilance will be necessary to determine that the desire to induce protective viral immunity is not associated with an increased risk for rejection episodes. It is the Strike Force's belief that these two vaccines are the safest alternatives for the transplant population at this time but come with unknown consequences for our patients. Patient immunoresponsiveness and duration of antibody, will need to be studied in our patient population.
 - Two other vaccines are also preparing to file for EUA. AstraZeneca and Johnson & Johnson. These vaccines have similar side effect profiles. Historically we have not recommended live viral vector vaccines for transplant patients that take immunosuppressive agents. The safety for the severely ill waitlist population could also have difficulty clearing the viral vector
 - <https://asts.org/advocacy/covid-19-resources/asts-covid-19-strike-force/transplant-capacity-in-the-covid-19-era#.X9GXfx17k6U>

