AUB American University of Beirut
Faculty of Health Sciences
Knowledge to Policy | K2P | Center

Knowledge to Policy Center K2P

# A CLOSER LOOK AT COVID-19 VACCINES: THE KNOWN, THE UNKNOWN, AND THE UNCERTAIN

## Key Messages

K2P COVID-19 Series

01

This product presents the latest evidence on COVID-19 vaccines. For more details and citations, please refer to the full version of this document.

# EFFICACY OF COVID-19 VACCINES

## REPORTED EFFICACY OF VACCINES IN USE

Initial reports of COVID-19 vaccine efficacy have been very promising. Summary of the efficacy of COVID-19 vaccines in use is presented below:

Efficacy is the ability of the vaccine to reduce disease in those who received the vaccine compared to those who did not.

| | | |
|---|---|---|
| Pfizer-BioNTech 95% | Moderna 94.1% | AstraZeneca-Oxford 70.4% |
| Sinovac Biotech 50.4 - 91.75% | Sinopharm 79 - 86% | Gamaleya Sputnik 91.6% |

However, the efficacy of several vaccines has been challenged in some reports to be lower than initially stated. Other vaccine efficacies were reported to vary under different settings. More studies are needed to determine the effectiveness of COVID-19 vaccines in real life settings.

## TIMING OF PROTECTION

The exact timing when an individual becomes protected after receiving a COVID-19 vaccine is still uncertain. There is some evidence that it takes few weeks for the immune system to respond to the vaccine and provide protection against the infectious disease.


## DURATION OF PROTECTION

No information is available on how long does the protective effect of COVID-19 vaccines last. Early data from the Moderna vaccine suggested that neutralizing antibodies produced after receiving the vaccine persisted for around 4 months and then declined slightly over time. However, effectiveness and duration of protection are to be identified following vaccination in real-life settings.

## IMPACT ON VIRUS TRANSMISSION

With the current knowledge, the ability of the vaccine to slow down transmission of the virus is still undetermined. As a result, there is a need for continuous implementation of public health measures such as wearing face masks, regular hand washing, and social distancing, even after receiving the vaccine.

## PROTECTION AGAINST THE NEW COVID-19 STRAINS

Given that the new COVID-19 strains appeared after the vaccine clinical trials were conducted, it is still unknown how the available COVID-19 vaccines will act against such strains. Early studies suggest that some vaccines may be more protective against some of the strains than others.

> Antibodies are protective proteins produced by the immune system in response to the presence of a foreign body or a vaccine.

02

# SAFETY OF COVID-19 VACCINES

## COMMON SIDE EFFECTS

Results of studies have been generally reassuring regarding the side effects of the COVID-19 vaccines, which have been mostly found to be similar to those of other well-known vaccines. These typically occur in the first few days after vaccination and include local skin reactions, fever, headache, muscle pains, and fatigue.

## SERIOUS SIDE EFFECTS

A number of concerns have been raised of other more serious side effects. Some associations were denied, while others need more time and studies to be accurately determined.  A summary of safety findings is presented below:

- Bell's palsy was reported more frequently in mRNA vaccine recipients than in those who did not receive the vaccine. But it is still not known whether this increase in occurrence is due to chance only or it is a true increase in risk.
- No increased occurrence of Guillain-Barre syndrome was found.
- Three cases of transverse myelitis occurred following vaccination with the AstraZeneca-Oxford vaccine, one of which occurred 14 days after the second dose while the two other cases were considered to be unlikely related to the vaccine.
- No association has been proven yet with immune enhancement or female fertility problems, despite ongoing deliberations.
- The rates of anaphylaxis (severe allergic reaction) were 5 cases per million with the Pfizer-BioNtech vaccine and 2.8 cases per million with the Moderna vaccine.
- Despite that studies did not report an increased risk of death among recipients of the vaccine, there were reports of about 30 deaths in over 40,000 elderly individuals in Norway who received the Pfizer-BioNTech vaccine. The deaths were recorded among very frail patients, including some who were expected to only have weeks or months to live and were associated with common side effects of the vaccine including fever, nausea, and diarrhea.

## LONG TERM SAFETY

The currently available vaccines were followed up for few months only and no long-term follow up data is available. Thus, the possibility of long-term side effects cannot be fully eliminated and more studies are needed to determine whether COVID-19 vaccines can result in long-term side effects.

- Bell's palsy is a condition that causes temporary weakness or paralysis of the muscles in the face.
- Guillain-Barre and transverse myelitis are autoimmune neurological diseases that result in weakness.
- Immune enhancement, also known as immune backfiring, occurs when components of the immune system that usually protect against viral infections end up backfiring.
- Anaphylaxis is a serious allergic reaction to a trigger that results in symptoms including rash, facial swelling, dizziness, and difficulty breathing.

## SAFETY OF mRNA VACCINES

The technology of using mRNA in COVID-19 vaccines is safe since the mRNA does not interact with DNA or change the genetic composition of the vaccine recipient.

**mRNA VACCINES WORK BY GIVING INSTRUCTIONS TO OUR CELLS TO MAKE A HARMLESS PIECE OF THE SPIKE PROTEIN WHICH IS FOUND ON THE SURFACE OF THE SARS-CoV-2 VIRUS. AN IMMUNE RESPONSE WILL THEN OCCUR IN REACTION TO THIS PROTEIN.**

## VACCINE AS A CAUSE OF COVID-19 INFECTION

None of the available COVID-19 vaccines contain the live virus that causes COVID-19. As a result, these vaccines cannot induce the disease. To note, since it typically takes a few weeks for the body to build immunity after vaccination, a person could be infected with the virus just before or after vaccination and still get sick. This is because the vaccine has not had enough time to provide protection.

03

# INDICATIONS FOR USE OF COVID-19 VACCINES

## AGE RECOMMENDATION

| Vaccine | Age Recommendation |
|---|---|
| Moderna, AstraZeneca-Oxford, Sinovac Biotech, Sinopharm Gamaleya Sputnik, CanSino Biologics | Individuals 18 years of age and older |
| Pfizer-BioNtech | Individuals 16 years of age and older |

## CHOICE OF VACCINE

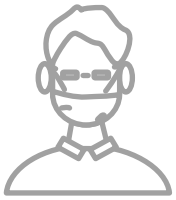
The currently available data does not allow determination which vaccines work best for which groups of people. The current advice is to receive whatever vaccine is made available. However, some early reports have reported diminished safety or efficacy of some vaccines on the elderly. More data is needed to determine which vaccine is safest and most effective in each group of people.


## CONTRAINDICATIONS TO COVID-19 VACCINES

The following are considered contraindications to mRNA COVID-19 vaccines:

- Severe allergic reaction or anaphylaxis after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA Covid-19 vaccine or any of its components, including polyethylene glycol
- Immediate allergic reaction of any severity to polysorbate

04



# USE OF COVID-19 VACCINES IN SPECIAL POPULATIONS

## PREGNANT OR BREASTFEEDING WOMEN

There is no substantial safety data on pregnant women, fetuses, or infants at this stage. Both the WHO and CDC state that if a pregnant woman is part of a group that is recommended to receive a COVID-19 vaccine, such as a healthcare worker, she may choose to be vaccinated. The same recommendation applies for lactating mothers.

## Children

Initial COVID-19 vaccine clinical trials have categorically excluded participation of children. As a result, COVID-19 vaccines are currently not approved for use in children less than 16 years of age.
More recently, studies on COVID-19 vaccines have included children, some with early promising results. As a result, it is expected that the vaccine could be approved for use in children before March 2021.

## IMMUNOCOMPROMISED INDIVIDUALS

Data is not currently available to establish vaccine safety and efficacy in immunocompromised individuals. COVID-19 vaccination might provide a lower level of protection for people in this group compared with the rest of the population. However, CDC recommends that immunocompromised individuals may receive COVID-19 vaccination if they have no reasons otherwise. Antibody testing is not recommended to assess for immunity following vaccination, neither is re-vaccination recommended after immune competence is regained.

## INDIVIDUALS WITH A HISTORY OF AN ALLERGIC REACTION

Patients with a history of allergies can still receive the vaccine, irrespective of the cause of allergy. However, patients with allergies should be observed for 30 minutes after receiving the vaccine, rather than the usual 15 minutes.

## INDIVIDUALS WITH CURRENT OR PREVIOUS COVID-19 INFECTION

Vaccines are safe and effective in patients with previous COVID-19 infections. Patients with previous COVID-19 still need to receive the vaccine due to diminished natural immunity over time. Vaccination of persons with known current COVID-19 infection should be delayed until the person has recovered from the acute illness. This recommendation applies to individuals who develop COVID-19 infection before receiving any vaccine doses as well as those who develop COVID-19 infection after the first dose but before receipt of the second dose. Individuals with documented acute COVID-19 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

## INDIVIDUALS WHO RECEIVED AN ANTIBODY TREATMENT OR CONVALESCENT SERUM FOR COVID-19

Currently, there are no data on the safety and efficacy of COVID-19 vaccines in individuals who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to persons who received passive antibody therapy before receiving any vaccine doses as well as those who received passive antibody therapy after the first dose but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy.

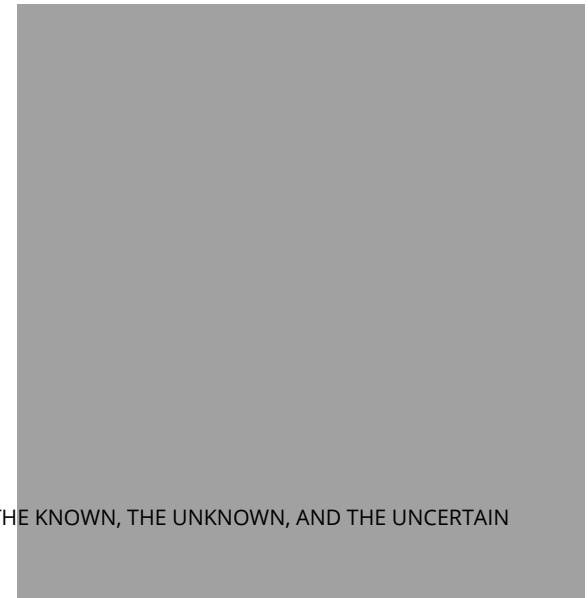
**Convalescent plasma therapy uses plasma rich with antibodies from individuals who have recovered from COVID-19 to help other patients recover.**

05

# ADMINISTRATION AND TESTING POST COVID-19 VACCINES

## SINGLE VERSUS DOUBLE DOSE

Despite evidence of some efficacy after the first dose, it is still recommended that all individuals receive their two-dose regimens. There is also no indication that delaying or advancing the second dose by few days will not incur any harms on the vaccine recipient.



## USE OF DIFFERENT VACCINE PRODUCTS

Both doses of the vaccine series should be completed with the same product as the safety and efficacy of mixing products have not been evaluated.

## NEED FOR BOOSTER DOSE

The need for and timing of booster doses for COVID-19 vaccines has not been yet determined. No additional doses beyond the two primary vaccines are recommended at this stage.

## NEED FOR POST-VACCINATION TESTING


There is no role for post-vaccination testing for COVID-19 unless clinically indicated. Individuals may have reactions such as fever, chills, fatigue, headache in the first one to two days after vaccination. However, respiratory symptoms or systemic symptoms that occur after the first couple of days following vaccination could be indicative of COVID-19 infection (that is not linked to the vaccine) and therefore require assessment for active infection.

## COVID-19 TEST RESULTS AFTER VACCINATION

None of the currently used vaccines can cause an individual to test positive on viral tests, which are used to detect existing infection. Once the body develops an immune response after vaccination, there is the possibility of testing positive on some antibody tests.

## AUTHORS

Nadeen Hilal, Nada Melhem, Fadi El-Jardali



## ACKNOWLEDGEMENT

The authors would like to thank Ms. Clara Abou Samra for document review and design, Ms. Nour Ataya and Ms. Lama Bou Karroum for document review, and Ms. Rayane Nasreddine for the Arabic translation.



## CITATION

Hilal N, Melhem N, El-Jardali F. K2P COVID-19 Series: A Closer Look at COVID-19 Vaccines: The Known, the Unknown, and the Uncertain (Key Messages). Knowledge to Policy (K2P) Center, Beirut, Lebanon, February 10, 2021



Knowledge to Policy (K2P) Center
Faculty of Health Sciences
American University of Beirut
Riad El Solh, Beirut 1107 2020
Beirut, Lebanon
+961 1 350 000 ext. 2942-2943
www.aub.edu.lb/K2P
K2P@aub.edu.lb

Follow us
Facebook Knowledge-to-Policy-K2P-Center
Twitter @K2PCenter


Knowledge to Policy Center K2P