

COVID-19 Vaccine (Moderna) FAQs

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December 18, 2020: FDA EUA Approval

- FDA grants approval (Emergency Use Authorization) for the second COVID19 Vaccine in the United States (Moderna)
- A 7–10-year process vaccine development process “condensed” into almost 12 months, combined with the name “Operation Warp Speed” was bound to raise questions about safety and efficacy
- The information on this presentation will hopefully give you the answers you need to make an informed decision about whether to get the MODERNA COVID19 vaccine when it is available to you
 - **Information current as of 12/20/2020 using CDC, FDA, Moderna Trial and EUA information publicly available online**
- **For more detailed information regarding Pfizer’s COVID19, Operation Warp Speed, and most FAQs asked, please refer to the COVID19 Pfizer Powerpoint from 12/11/2020.**

Pfizer and Moderna Vaccine Similarities

- Both use mRNA to induce immunity (not an actual COVID virus being injected)
- They are both extremely effective at preventing COVID-19 Illness
 - Pfizer is 95%
 - Moderna 94.1%

The vaccine goal required by the FDA was to be at least 50% effective.

- Both have nearly identical side effects

Pfizer and Moderna Vaccine Key Differences

- **Storage:**
 - Moderna's vaccine protein is protected by different type of lipid layer which allows it to be stored at a less cold temperature than Pfizer
 - Moderna stored between -13 & -5 degrees Fahrenheit (average medical/lab freezer)
 - Pfizer stored between -112 & -76 degrees Fahrenheit ("ultra-cold" storage)
- **Dosing Interval:**
 - Moderna : 28 days between 1st and 2nd doses
 - Pfizer: 21 days between 1st and 2nd doses
- **Approved for:**
 - Moderna: 18 years and older
 - Pfizer: 16 years and older

What's in the Vaccine?

- There are currently multiple vaccine candidates in various stages of clinical trials.
- The first two vaccines anticipated to be available are not live, attenuated, or inactivated vaccines.
 - The vaccines contain the gene for a virus protein only.
 - **One cannot contract COVID-19 from the vaccine.**

What's in the Moderna Vaccine? (Ingredients)

- The 5 ml vaccine (100 micrograms) contains a **synthetic messenger ribonucleic acid (mRNA)** encoding the pre-fusion stabilized spike glycoprotein (S) of SARS-CoV-2 virus.
- The vaccine also contains the following ingredients:
- **lipids** (SM-102, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG])
- **Cholesterol**
- **1,2-distearoyl-snglycero-3-phosphocholine [DSPC])**
- **Tromethamine**
- **tromethamine hydrochloride**
- **acetic acid**
- **sodium acetate**
- **sucrose**

How Long is the Immunity from the COVID-19 Vaccine effective for?

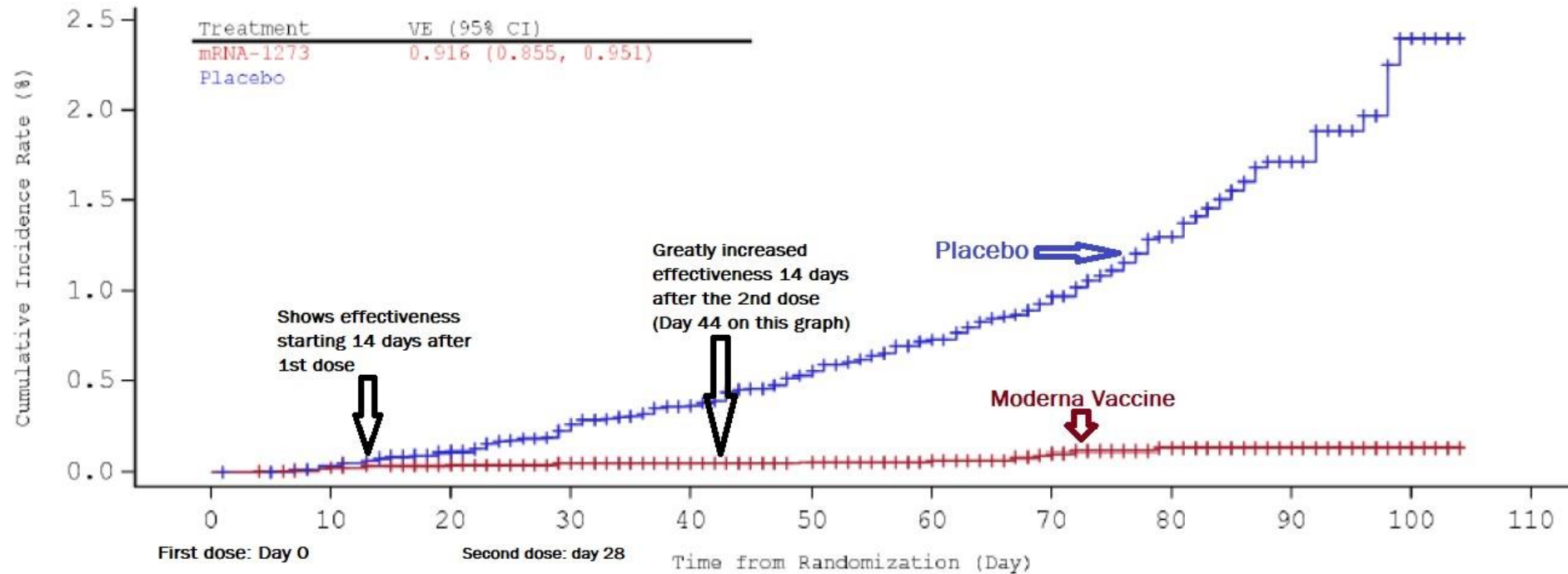
- Currently the exact information is unknown. We do not know how long protection will last following vaccination. **But further information will become public over time from ongoing clinical trials.** In comparison, immunity to two similar coronaviruses, SARS and MERS, lasted at least 3 years
- The data shows that it is **very likely that the immunity that you get from being vaccinated will last longer** than the immunity one may get after an infection
- The data shows a more robust immune response to the vaccination as compared to some low-level types of COVID infections (ie asymptomatic or mild infections)

How is the COVID-19 Vaccine Different Than Other Vaccines?

- They are essentially similar to other vaccines in the way that they trigger an immune response
- However, they differ because none of the US vaccines will be using the actual COVID19 virus (neither live nor killed), so there will be no chance of one getting COVID19 from the vaccine
- The actual vaccines will differ in how they trigger an immune response, and some may require 2 shots (a “primer” and a “booster” shot) while others may require only one

Effectiveness of Moderna Vaccine

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Randomization, mITT Set



Efficacy of Moderna Vaccine: 94.1% Overall

Table 17. Final Scheduled Efficacy Analysis, Primary Endpoint, COVID-19 Starting 14 Days After the Second Dose per Adjudication Committee Assessments, Per-Protocol Set

Primary Endpoint: COVID-19 (per adjudication committee assessment)	Vaccine Group N=13934 Cases n (%) (Incidence Rate per 1,000 person- years)*	Placebo Group N=13883 Cases n (%) (Incidence Rate per 1,000 person- years)*	Vaccine Efficacy (VE) % (95% CI)**	Met Predefined Success Criterion***
All participants	11 (<0.1) 3.328	185 (1.3) 56.510	94.1% (89.3%, 96.8%)	Yes
18 to <65 years ¹	7/10551 (<0.1) 2.875	156/10521 (1.5) 64.625	95.6%; (90.6%, 97.9%)	NA
65 years and older ²	4/3583 (0.1); 4.595	29/3552 (0.8); 33.728	86.4%; (61.4%, 95.5%)	NA

Efficacy of Moderna Vaccine: 100% Effective at Preventing Severe COVID-19

Table 14. Severe COVID-19 Cases Starting 14 Days After Second Dose Based on Adjudication Committee Assessment, Per-Protocol Set

	Vaccine Group N=13934 Cases n (%)	Placebo Group N=13883 Cases n (%) Incidence rate per 1,000 person-years	Vaccine Efficacy (VE) % (95% CI)*
Severe COVID-19	0	11 (<0.1); 4.072	100%

^a EUA request (interim analysis): November 07 2020 efficacy data cutoff.

* VE is calculated as 1-ratio of incidence rates (mRNA-1273/Placebo) and 95% CI from the stratified Cox proportional hazard model. The VE 95% confidence interval is not presented when the lower bound was not evaluable by the statistical methods used for the analysis.

Side Effects

- Adverse reactions following the Moderna COVID-19 Vaccine that have been reported in clinical trials include:
 - **Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness**
 - **General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever**
- Serious adverse reactions following the Moderna COVID-19 Vaccine were reported in 1.0% of participants who got the vaccine and in 1.0% of participants who got the placebo
- Two people who received the actual vaccine experienced facial swelling- those 2 people had a history of having had dermatological fillers in the past (facial cosmetic fillers) and appeared within the first 2 days after receiving the vaccine.
 - . Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine

Bell's Palsy: Insufficient evidence to show casual relationship

In the Moderna Vaccine trial:

- There were **3 reports of Bell's Palsy among 15,181 vaccine recipients** and 1 among the placebo

In the Pfizer Vaccine trial:

- There were **4 reports of Bell's Palsy among the 21,720 vaccine recipients** and 0 among the placebo

Currently available information on Bell's Palsy is insufficient to determine a casual relationship with the vaccine (not enough information to say that the vaccines caused those cases of Bell's Palsy).

- **FDA and CDC will monitor recipients of both vaccines for Bell's Palsy** to determine if there is a casual relationship between the vaccines and Bell's Palsy

*Some context regarding incidence of Bell's Palsy

In the general population: the annual incidence is 15 to 20 per 100,000 people per year = **0.015% to 0.020% of the general public**

In the two studies combined there were 7 cases of Bell's Palsy among 36,901 = **0.01896% of vaccine recipients**

Safe for Pregnant or Breastfeeding Women?

- **Short Answer: No Data; Should weigh Risk vs Benefit**
- Not studied in pregnant or breastfeeding women before the EUA issued (however currently being studied in pregnant and breastfeeding women in new trial)
- Not contraindicated but generally presumed safe, however this requires a discussion with your healthcare provider
 - COVID19 can cause severe illness in pregnant women, much higher than in non-pregnant women
 - If you are pregnant and work in an environment with significant high-risk exposures to COVID19, the benefits of getting the vaccine may outweigh the risks of not getting the vaccine and contracting COVID19
 - However, discuss this with your healthcare provider before deciding to do so

Is Moderna's Vaccine approved for all ages?

- The Moderna vaccine was granted Emergency Use Authorization for ages 18 and older
- Pfizer's Vaccine was studied and approved for ages 16 and older.

Safe for People with Underlying Health Conditions?

- **Short Answer: Yes**
- Longer Answer:
 - People with underlying severe chronic conditions are encouraged to get the COVID19 vaccine because they are at highest risk of severe illness and death if they contract COVID. They are among the highest prioritized group slated to get the vaccine.
 - Note: those with immunocompromised immune systems or who are taking immunosuppressant medications may have less of an immune response to the vaccine

Are there Contraindications To Getting the Vaccine?

- Do not administer Moderna COVID-19 Vaccine to individuals with known **history of a severe allergic reaction** (e.g., anaphylaxis) to **any component** of the Moderna COVID-19 Vaccine OR if you had a **severe allergic reaction (anaphylaxis) to the first dose of the Moderna COVID-19 Vaccine**

Should Someone With Confirmed/Suspected Active COVID19 get the Vaccine?

No, they should isolate until their isolation period is complete

Is There Any Risk to Those Around Me After Getting the Moderna Vaccine?

- No, there is no increased risk to anybody around you to get COVID after you get vaccinated with either the Pfizer or Moderna vaccination because they are not composed of the actual virus that causes COVID19.
- As a matter of fact, their risk of COVID may decrease after you get vaccinated, as you will have protection against COVID once your antibodies develop.

Summary

- Pfizer and Moderna both very high efficacy at 94-95% . Among the most effective vaccines ever produced
- Short and medium term (to 9 months) side effect profile is good and nearly similar for both, long term side effects expected to be none, however FDA will monitor for the usual 2 years before making that determination
 - FDA will monitor to determine if casual relationship with vaccines to Bell's Palsy; thus far there is not enough evidence to show the link
- Will not cause COVID in vaccine recipient
- Duration of vaccine immunity not yet known due to this being a new vaccine and novel virus, expected to be longer than natural post-infection immunity
- FDA EUA for Moderna: age 18 and older and for those with most chronic health conditions; Pfizer approved for age 16 and older
- Pregnant/Breastfeeding: No data; discussion with healthcare provider regarding risks vs benefits
- Contraindicated only if history of severe reaction (anaphylaxis) to vaccine components