

## **COVID-19 VACCINATION UNDER EMERGENCY USE AUTHORIZATION: IMPORTANCE OF INFORMED CONSENT**

A foundational principal for the ethical practice of medicine in America is informed consent.

Informed consent means the patient, or their guardian understands the rationale for the treatment being offered, and its benefits, risks, and alternatives to the proposed intervention. Proper consent also assumes each person has a right to refuse such treatment.

The following information is intended to inform individuals so that they can weigh their own personal risk of infection, versus the potential benefits and risks of accepting a Covid vaccination approved under an **Emergency Use Authorization (EUA)** by the FDA.

### **What is SARS-CoV-2 or COVID-19?**

COVID-19 is a type of coronavirus. Coronaviruses are a large family of common viruses. Some cause mild disease like the common cold, and others may cause severe respiratory disease and death like SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome).

Although COVID-19 has distinct properties, it shares many qualities of other coronaviruses. It is a similar size; it is highly contagious; and transmitted by respiratory droplets and aerosol. Mutation of this class of virus occurs with high frequency.

Until November of 2020, a vaccine against any type of coronavirus had never been approved, even under EUA for use in humans. Earlier attempts to develop a safe and effective vaccine in animals against SARS were unsuccessful.

### **How dangerous is the Covid infection?**

It is important to assess your own personal risk when considering if a vaccination is right for you.

The numbers below are an attempt to address the question, "If I get sick, what is the chance that I will die?"

## Infection Fatality Rates for SARS-CoV-2

(source: European Journal of Epidemiology Meta-Analysis from 34 separate locations based upon seroprevalence data. These numbers are consistent with NIH data)

Age	Risk %	Per 100,000	Increased Risk Compared to Age 10
At 10	.002	2	---
At 25	.01	10	5X
At 55	.04	40	20X
At 65	1.4	1,400	700X
At 75	4.6	4,600	2300X
At 85	15	15,000	7500X

The risk of dying is over 1000 times higher in the older demographic as compared to children age 10 and younger. This difference in risk depending on one's age is vital to understand when considering whether to receive a vaccine.

Those over the age of 60 currently have a higher risk of dying of Covid than the commonly quoted infection fatality risk of the flu, while those under the age 60 currently have a lower risk of dying from Covid-19 than the flu. The current average life expectancy in the United States is 76.1 years for a man and 81.1 years for a woman.

How do these numbers compare to case fatality rates for other viruses?

Disease	Estimated case fatality rate (CFR)
SARS-CoV	10% Venkatesh and Memish (2004) Munster et al. (2020)
MERS-CoV	34% Munster et al. (2020)
Seasonal flu (US)	0.1 to 0.2% US CDC
Ebola	50% 40% in the 2013-16 outbreak WHO (2020) Shultz et al. (2016)

Beginning at age 20 and continuing through age 80, men who are infected with COVID-19 are over 1.5 times more likely to die as compared to women.

In addition to age and sex, other health factors correlate with increased Covid related death rates including:

1. Obesity
2. Diabetes
3. Obstructive Sleep Apnea
4. Heart and lung disease

### **How do current Covid mRNA vaccines work?**

Evergreen offers Pfizer and Moderna immunizations to our community. These companies developed a completely new vaccine technique to produce an immune response against SARS-CoV-2.

The vaccines inject messenger RNA (carrying genetic code) to instruct our own cells to produce a protein fragment that is identical to a spike protein of the SARS-CoV-2 virus. This protein produced by the vaccine cannot cause an infection, but it induces our immune system to block the “business end” of the SARS-CoV-2 virus from entering cells. This antibody response prevents the natural virus from replicating in the body.

In the phase 3 human trials, vaccinated people were followed for approximately 3.5 months. The Pfizer and Moderna vaccines induced a robust antibody response and appeared to prevent infection 94-95% of the time. At this time, it is unknown how long the immunity will last or how effective they will be against other variants as they emerge.

The FDA approved the vaccines under an Emergency Use Authorization.

### **How does natural immunity work if one is infected and recovers from the virus?**

Natural immunity has been shown to protect people who have recovered from infection for at least one year. This includes many in our population who tested positive for the Covid virus but were without symptoms. Multiple studies have validated this finding.

## **Was the Covid Vaccine rushed?**

Yes, and for good reason. Covid was considered an emergency. It was released under an emergency-use-authorization.

- Covid-19 vaccines were developed and distributed faster than ever before in history.
- The previous record time of production was 4 years to develop and implement a widespread vaccination program for the Mumps Vaccine. Scientists at the time used an existing well-researched technique.
- Typically, vaccines take 10 – 15 years to develop.
- The SARS-CoV-2 vaccines were developed, tested, and mass produced for distribution within 9 months.

## **What are the possible adverse effects to the Covid vaccine?**

- Much is unknown. There has never been a vaccine successfully created against any coronavirus before. There has been insufficient time and data to fully understand all the potential harms or adverse effects that may occur in years to come.
- Rare occurrence of life-threatening anaphylaxis reactions has occurred immediately after receiving a Covid vaccination.
- The spike protein may create inflammation of the lining of blood vessels in some people. Inflammation in the walls of arteries is known to be a factor in causing clots and heart attacks.
- The duration of spike protein production in humans following vaccination has not been extensively studied.
- People who have already recovered from a natural infection may have an enhanced inflammatory reaction to the vaccine. This may cause more severe symptoms of headache, fatigue, muscle pain, chills, and fever. Studies have shown that after a single (first) mRNA vaccine dose, health care workers who recovered from a natural COVID infection have antibody titers of 35 to 50 times more than those workers who had not been exposed to the virus.
- Some physicians and research scientists have raised concerns that the vaccine may lead to increased allergic reactions and vascular inflammation that may lead to blood clots, heart attacks, or strokes in vaccine recipients. These concerns are currently unsettled science.

## **What are Evergreen Family Medicine's recommendations regarding Covid Vaccinations?**

1. We recognize that it is a very personal decision. There is not a one answer that will fit all people and all situations. Please consult your provider if you remain undecided.
2. Vaccinations released under an Emergency Use Authorization and those without long term safety data (years), should not be mandated or coerced. Private medical decisions should not be mixed with ideology or politics.
2. If you are over age 60 or an adult with chronic disease placing you at risk, we would recommend a Covid vaccine.
3. If you have had a confirmed infection with SARS-CoV-2, and you want to be vaccinated as well, we recommend waiting at least 90 days prior to receiving the vaccine. Also, there is very good evidence that natural immunity is protective against reinfection for at least a year. We have not found conclusive evidence that a Covid vaccine offers a higher level of protection than those who have had a documented natural infection. In our opinion, vaccination in naturally immune individuals would not receive a clear benefit, but they would be exposed to risk.
4. Parents who decide that there is a lack of scientific justification for subjecting healthy children to vaccines to be given under EUA, given that the Centers for Disease Control and Prevention estimates that they have a 99.997% survival rate if infected with SARS-CoV-2, are making a reasonable choice at this time.
5. As further information becomes available regarding Covid variant disease and vaccine safety, our recommendations may change.

## Other frequently Asked Questions:

- How effective are the mRNA vaccines against COVID-19?

Authorities have reported protection from infection 95% of the time.

- Will the virus mutate?

Yes, there are over 130 “Variants of concern” that are being monitored by authorities.

- Will the vaccine work against these mutations?

Public health authorities are actively monitoring for resistant variants. So far, vaccines are thought to be generally effective against variants in our community.

- How long will protection last for those who are vaccinated?

Some authorities have suggested that immunity will last 6 months to a year based upon sustained antibody titers.

- Do I need the vaccine if I have had the natural disease?

The CDC has recommended everyone over the age of 12 be vaccinated, including pregnant women. However, they suggest waiting at least 90 days before receiving a Covid vaccination. Many physicians disagree with this recommendation since natural immunity has been shown to be effective to date, and the vaccines remain under EUA. It would seem to expose individuals with natural immunity to potential adverse effects without measurable benefit at this time.

- The estimate for Covid 19 is that 70 to 80% of the population will need to be vaccinated to reach herd immunity. Is this true?

It depends upon the criteria one uses to define herd immunity. If it means eliminating the virus entirely, this may never occur.

There are many other factors that impact virus transmission besides vaccination, including existing natural immunity from Covid and cross immunity from other coronaviruses. Many physicians and scientists believe that SARS-CoV-2 will never be eliminated from the population but will become endemic (embedded) in our population like the other 4 seasonal coronaviruses that we test for every winter.

One of Oregon's previous goals was to reduce the transmission rate to less than one. This would imply each infected person would not infect more than one person so that the health care system would not be overwhelmed and reflect existing community immunity. We achieved that goal in Oregon in February 2021.

- Will it protect against the flu? **No.**
- Will these vaccines become recommended like an annual flu vaccine?

Currently, it is unknown.

- Are Covid vaccine manufacturers held harmless for any side effects?

All entities engaged in manufacture, distribution and administration of routine vaccinations are protected by the 1986 vaccine Act. This act is a no-fault compensation program for vaccine related injuries that functions as an alternative to the civil tort system. This does not offer complete protection. Manufacturing defects can still be litigated. Claims unrelated to the vaccine itself - such as assault and battery for administering a vaccine without consent would not be covered

Covid vaccine will be governed by Public Readiness and Emergency Preparedness Act. (PREP Act). This is intended to facilitate emergency response by granting broad immunity. The Department of Health and Human Services expanded the PREP act immunity further. This probably preempts claims for manufacturing defects and even vaccine administration torts such as assault and battery.

Dr. Tim Powell

EFM CEO

Dr John Powell

EFM Medical Director