



## COVID-19 mRNA Vaccine Frequently Asked Questions

### How Do I get general assistance with questions about and eligibility for the COVID-19 Vaccine?

Wisconsin residents can now call the COVID-19 Vaccine Assistance Hotline at 844.684.1064 for assistance.

### How Do I Find Out When I Can Get a COVID-19 Vaccine?

State health departments decide when each group can get the vaccine. Please check the DHS website periodically at: <https://www.dhs.wisconsin.gov/>

### Where Can I Get a Vaccine Once They are Widely available to the Public?

Once the vaccine is widely available, you will be able to go to <https://vaccinefinder.org/find-vaccine> and choose COVID-19 from the vaccine list. Then, enter your ZIP code.

### Do I Have to Go to an In-Network Pharmacy to Get a Vaccine?

No. Once widely available to the public, you can get a COVID-19 vaccine at most pharmacies. You will not need a prescription to get a vaccine.

Check with your State health department to find out where to get it near you: <https://www.dhs.wisconsin.gov/>

### Will There be Any Out-of-Pocket Costs for the COVID-19 Vaccines?

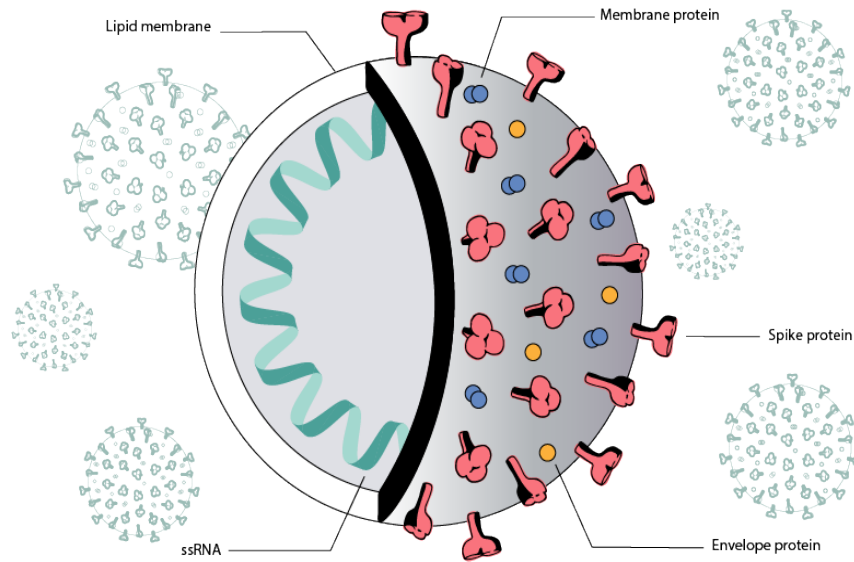
No. The vaccines will have a zero-dollar (\$0) cost share during the emergency health period.



### How, Specifically, do the mRNA Vaccines Work?

The *Pfizer-BioNTech* and *Moderna* vaccines are similar in that they were created by synthesizing (producing) the region of the genetic material (RNA) of the SARS-CoV-2 (COVID-19) virus that codes for the virus's **spike (S) protein** (fig. 1).

Figure 1



Foreign proteins in the human body are known as **antigens**. That is, they cause the human body to mount an immune response once they are detected. The spike (S) protein on the surface allows the virus to attach to respiratory cells in the nasopharynx (nose and throat) and lungs. It is a strong antigen.

The mRNA vaccines genetically “code” for the spike (S) protein contained on the outer capsule of the SARS-CoV-2 (COVID-19 Virus), which is a good target for our immune system to attack because it is located on the virus surface and is already known to stimulate our immune system to search out and neutralize (destroy) the virus before it can cause illness.

If you’d like more detail about how mRNA vaccines are made, please click here:



mRNA  
Vaccine.Synthesis.pdf

### Can Vaccinated People Still Transmit the Virus?

It remains to be seen whether vaccinated individuals will still be able to spread the virus with a subclinical infection; that’s why it will still be advised to social distance and wear a mask during the pandemic – even if you’re already vaccinated.

### We’ve Heard in the News that the COVID-19 Virus has Mutated. Will the Vaccines Currently Developed Still Provide Protection?

Recent research has shown that the vaccines currently available will provide the same level of protection. Although the genetic variation that has occurred does make the virus more easily transmissible, it won’t make you more sick or cause the vaccines to be any less effective.

RNA viruses like COVID-19 are quite prone to frequent **mutation** (spontaneous change of their genes). The Influenza (flu) virus is an mRNA virus that actually acts similarly. One way influenza viruses change is known as “**antigenic drift.**” These are slight changes (or mutations) in the genes of influenza viruses that can lead to changes in the surface proteins that are expressed by the virus.

The slight changes that occur from antigenic drift usually produce viruses that are closely related to one another genetically. Viruses that are closely related to each other usually have similar antigenic properties. This means that the antibodies your immune system creates against one virus will likely recognize and respond to antigenically similar viruses. This is called “**cross-protection.**”

However, the small changes associated with antigenic drift can accumulate over time and result in viruses that are antigenically different. It is also possible for a single (or small) change in a particularly important location in the **viral genome** (RNA) to result in antigenic drift. When significant antigenic drift occurs, the body’s immune system may not recognize and prevent sickness caused by the newer viruses. As a result, a person becomes susceptible to infection again, as antigenic drift has changed the virus enough that a person’s existing antibodies won’t recognize and neutralize the newer virus.

Antigenic drift is the main reason why people can get the flu, for example, more than one time, and it’s also a primary reason why the flu vaccine composition must be reviewed and updated each year (as needed) to keep up with evolving influenza viruses. COVID-19 may ultimately behave in this manner, requiring new vaccines to be periodically developed. Right now, it’s too soon to tell how often we’ll need to be immunized against COVID, but it’s possible that COVID-19 may ultimately become a **seasonal virus** much like the flu.

### **How Effective are mRNA Vaccines from Pfizer-BioNTech and Moderna?**

#### **Efficacy vs Effectiveness – Not the Same**

It is worth noting that “effectiveness” and “efficacy” are not the same. Despite news outlets frequently conflating these terms (i.e., using them interchangeably), **efficacy** refers to how a vaccine performs under ideal clinical trial conditions. In contrast, **effectiveness** refers to how it performs in the real world. In other words, in a clinical trial, a 90% efficacy rate means that there are 90% fewer cases of disease in the group receiving the vaccine compared with the **placebo** (trial participants who weren’t given the active vaccine) group.

However, the participants chosen for a clinical trial tend to be healthier and younger than those in the general population, and they generally have no serious underlying conditions. Furthermore, researchers do not normally include certain groups in these studies, such as children or pregnant people. So, while a vaccine can prevent disease in a trial, we might see this effectiveness drop a bit when administered to the wider population.

Compared to other vaccines, the mRNA vaccines developed to date are likely to be nearly as effective as other developed vaccines and likely more effective than the yearly influenza (flu) vaccine, which may be only 40-60% effective, according to the Centers for Disease Control and Prevention (CDC)<sup>14</sup>.

Both *Moderna* and *Pfizer* have reported Phase 3 trial efficacy at approximately 95%. This represents the degree to which the vaccines prevent the occurrence of **symptomatic** COVID-19 disease in trial participants.

## Are These New mRNA-Based Vaccines Safe?

When compared to other vaccines, these vaccines appear quite safe.

Vaccines of all types have historically enjoyed a track record of incredible safety over the years.<sup>6-13</sup> As to the currently approved mRNA-platform-based vaccines, the following is safety information related to the *Pfizer-BioNTech* COVID-19 Vaccine (fig. 2):

Figure 2: **Serious Adverse Events Reported in the Pfizer-BioNTech Vaccine**

Serious Adverse Events in Vaccine Study Group	Serious Adverse Events in Placebo (no vaccine given) Study Group
0.4% (Age 16-55)	0.3% (Age 16-55)
0.8% (Age 56+)	0.6% (Age 56+)

As this table shows, there was only an increase of 0.1% serious adverse reactions and 0.2% in the vaccine group vs the placebo group (the group that did not get the vaccine).

Based upon the prevailing clinical evidence, the technology supporting this new mRNA platform is scientifically sound, and these vaccines will be deemed overwhelmingly safe and effective for the vast majority of people who receive them.

In sum, and in general, the *Pfizer-BioNTech* mRNA and *Moderna* vaccines have been considered safe and effective for the vast majority of study participants followed for at least a two-month period post-immunization.

## What is an FDA EUA (Emergency Use Authorization)?

So as not to confuse the reader, the bottom line is that vaccines, medications, and similar biotherapeutics with an EUA designation are actually not FDA-approved through the usual and customary processes. And yes, this can be considered a bit of a compromise, attempting to balance the risks and benefits of doing nothing versus something, even if imperfect, during a public health emergency.

The EUA process is different than an FDA approval or clearance. Under an EUA, in an emergency, the **FDA makes a product available to the public based on the *best available* evidence, *without waiting for all the evidence that would be needed for customary FDA approval or clearance.***

An Emergency Use Authorization (EUA) is one of several tools the FDA can use to help make certain medical products available quickly during the COVID-19 pandemic. In certain emergencies, the FDA can issue an EUA to provide access to medical products that may potentially be used when there are no adequate, approved, and available alternative options.

When evaluating an EUA, the FDA carefully balances the potential risks and benefits of a product based on the data currently available.

## When Will the General Public Be Able to Get the COVID-19 Vaccine?

Presently, there is not enough vaccine supply for everyone in Wisconsin. Until vaccine supply increases, the WI Department of Health Services (DHS) is following vaccine prioritization guidelines from the Federal Advisory Committee on Immunization Practices (ACIP) and the Wisconsin State Disaster Medical Advisory Committee (SDMAC).

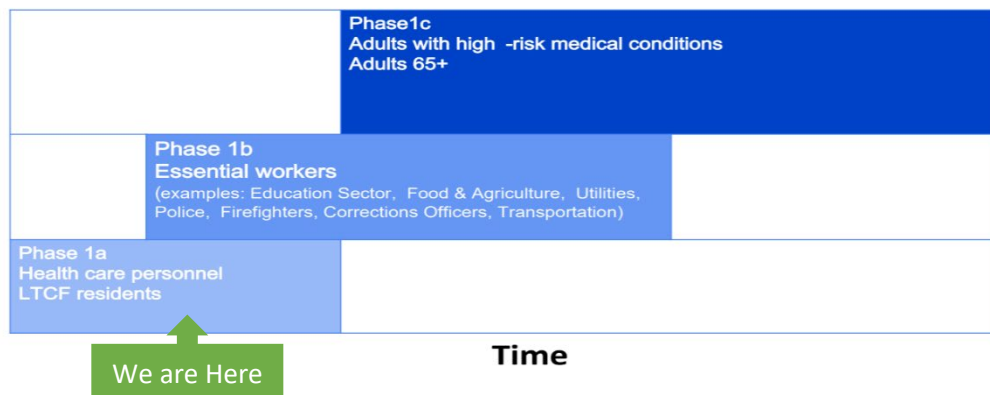
There will be Multiple Phases of Vaccine Deployment. We are still in **Phase 1a** according to the vaccine prioritization guidelines (see figure 4 below). This is the first phase of vaccine distribution. Right now, in the early weeks of Phase 1a, the limited doses available will be given to frontline health care providers and skilled nursing facility staff and residents. As vaccine supply increases, additional health care personnel and long-term care facility residents and staff will be offered COVID-19 vaccination. It will likely take several weeks to vaccinate everyone eligible in Phase 1a.

### ACIP Interim Phase 1 Sequence

ACIP (Advisory Committee on Immunization Practices) has not yet determined, exactly, when the preset two vaccines will be available to the public at-large. ACIP will consider vaccine-specific recommendations and additional populations for vaccine allocation beyond Phases 1a-c when an **FDA-authorized** vaccine is available. However, the following schedule has been recommended as interim guidance<sup>5</sup> (fig. 3):

Figure 3

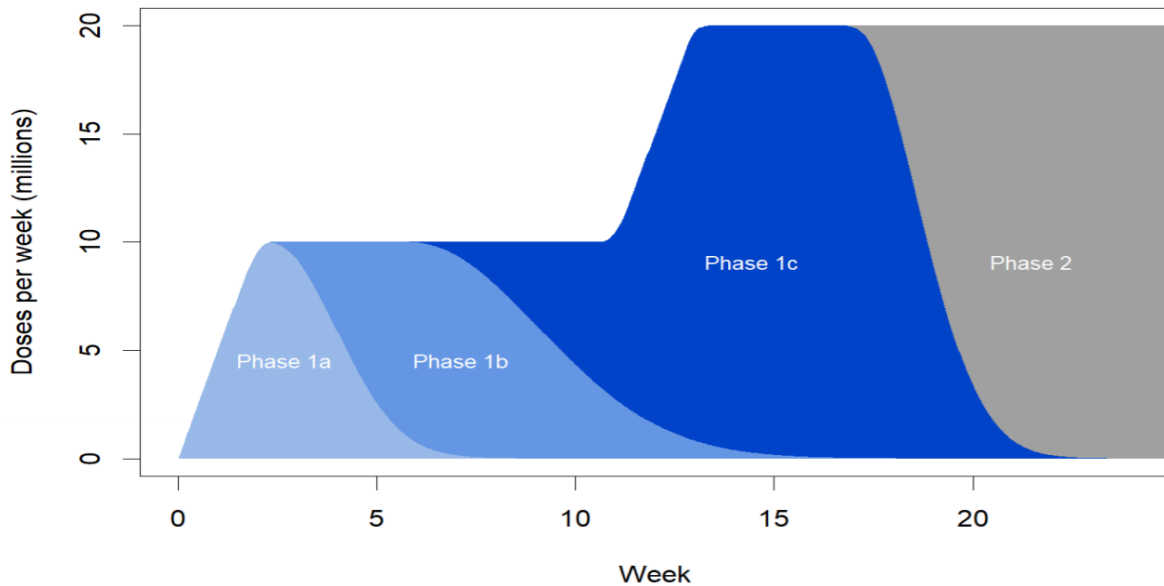
### Work Group Proposed Interim Phase 1 Sequence



After the state receives more vaccine supply and vaccinates those in Phase 1a, we anticipate that **Phase 1b** will begin, which may include persons aged  $\geq 75$  years and non-health care frontline essential workers (e.g., police officers, firefighters, teachers). Then, we expect in **Phase 1c**, persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and essential workers not included in Phase 1b will start receiving COVID-19 vaccine.

For now, the distribution is still in Phase 1a. Therefore, we can expect it may be several weeks before there is a vaccine supply adequate to progress to even Phases 1b, 1c and, in turn, the general public (fig. 4). Notably, there is overlap between these phases. Thus, vaccine deployment may be considered to be a rolling process based on supply and distribution channels.

Figure 4



**While you are waiting for your turn to get the vaccine, there are a few things you can do.**

Learn more about the COVID-19 vaccine on the CDC's website and become a vaccine advocate for your friends and family. **Importantly, if you currently do not fit into a category defined by Phases 1a-1c of the deployment, above, do not contact your provider or provider's office at this time. It may take weeks or months for individuals in these phases to be vaccinated, and likely, the vaccines will not be available for more widespread distribution until the spring or early summer of 2021.\***

Bookmark the WI DHS website at <https://www.dhs.wisconsin.gov/covid-19/vaccine-data.htm> and check back in a few weeks as they plan to update information frequently. Here is a graphic that shows how many of each of the mRNA vaccines had been distributed in Wisconsin as of January 15, 2021 (fig. 5).

Figure 5



Source: WI DHS

**It is important to continue wearing masks, physical distancing, washing our hands, and getting tested and isolating if you have signs and symptoms of COVID-19. If we continue to use all these COVID-19 precaution tools, we stand the best chance of getting our families, communities, schools, and workplaces back to normal sooner.**

\*This is subject to change based on production, vaccine availability, state & federal legislation

## How Are the Vaccines Currently Being Distributed?

The federal government has indicated that allocations will be determined based on the provider (1) size and reach, (2) capability to store vaccines and ensure cold chain management, (3) ability to meet data reporting requirements to jurisdictions and the CDC, and (4) estimated daily number of doses each facility is able to administer. Pharmacies may also register to receive vaccines through their local jurisdictions.

The *Pfizer-BioNTech* vaccine will be distributed by *Pfizer* itself without a wholesaler due to the cold chain shipping storage requirements necessary to preserve the vaccine, which requires extremely cold temperatures. Likely the *Pfizer* vaccine will be administered within certain health care facilities, including long-term care facilities (skilled nursing facilities), with the ability to vaccinate large numbers of individuals quickly, due to the storage requirements.

The *Moderna* vaccine remains stable at refrigerated conditions, which allows for storage at most pharmacies in addition to hospitals and health care providers' offices. Now that it has been approved for emergency use, *Moderna* will be distributing the vaccines via *McKesson*, the federally contracted distributor.

In Wisconsin, this will be a hub-and-spoke distribution. Upon guidance from the federal government, The Wisconsin Department of Health Services designated the University of Wisconsin Health as a regional distribution hub for the *Pfizer-BioNTech* COVID-19 vaccine due to its inherent temperature instability and strict cold-chain requirements. UW Health will store the vaccines in specially designated freezers to ensure they are kept at below -94 degrees Fahrenheit and will control their distribution to health systems and long-term care facilities within the region. The *Moderna* vaccine, due to its more permissive cold-chain requirements, will be distributed directly to healthcare systems and facilities.

## How is the Vaccine Administered and What is the Vaccine Schedule?

Both the *Pfizer-BioNTech* and *Moderna* vaccines require two intramuscular (deltoid muscle) injections in the upper arm: a priming dose, followed by a booster dose. The interval between *Pfizer-BioNTech* vaccines is 21 days. The interval between *Moderna* doses is 28 days (fig. 6).

Figure 6

<i>Pfizer-BioNTech</i> Vaccine (BNT162b2)	<i>Moderna</i> Vaccine (mRNA-1273)
One dose per 21 days	One dose per 28 days
Two (2) doses per year	Two (2) doses per year
Minimum age of 16 years	Minimum age of 18 years

## Do I Have to Get Two (2) Doses of the COVID-19 Vaccine?

If you forget or choose not to get the second dose, the vaccine may be less effective. You may still have some protection with just one dose. You need to get two (2) doses to make sure the vaccine will protect you as intended. Although other schedules have been contemplated, notably in the United Kingdom, the United States will continue to follow the vaccine manufacturers' recommendations as their studies do not prove that the vaccine schedules can be altered with similar effectiveness.

## What If I Forget the Second Dose?

Contact your health care provider to get your second dose as soon as possible.

## What are the Common Side Effects and How Can I Expect to Feel After Receiving a COVID-19 mRNA Vaccine?

In short, at worst, you are more than likely to feel as though you've had a mild to moderate case of the flu for a few days. This isn't a bad thing, necessarily, but likely a sign that your body is going through the process of priming its immune system. Though serious side effects are rare, both versions of the mRNA vaccines share a similar side effect profile. These side effects may include, but are not limited to:

- Pain, swelling and redness at the injection site
- Headache
- Malaise (feeling generally unwell) and fatigue
- Muscle and joint pain
- Chills
- Fever
- Nausea

For the *Pfizer-BioNTech* vaccine, specifically, in clinical studies adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (a general feeling of discomfort, illness, or uneasiness whose exact cause is difficult to identify) (0.5%), and lymphadenopathy (lymph node swelling or "swollen glands") (0.3%).

Severe allergic reactions have been reported following the *Pfizer-BioNTech* COVID-19 Vaccine during mass vaccination outside of clinical trials. It is still unclear what clinical significance these reactions will ultimately have in the post-deployment phase of the vaccine, as allergic reactions, including anaphylaxis, have been reported with other, pre-existing vaccines. Thus far, all serious reactions have been successfully treated by medical personnel.

## Who Should I Contact if I Have a Problem or Side Effects After I Get the Vaccine?

If you have a severe reaction after the COVID-19 vaccine, call 911 or go to the nearest hospital. Call your vaccination provider or healthcare provider right away if you have any side effects that bother you or will not go away. You can also access the **V-Safe Post-Vaccination Health Checker** app at: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html> to inform the CDC of any adverse reactions or side effects. Once enrolled, they will text you daily to check on you so that you can document how you are feeling.

## Should I Get the COVID-19 Vaccine if I Have Had Severe Allergic Reactions to Other Vaccines?

It is important to speak with your provider or healthcare provider about past reactions to vaccines **prior to** receiving one of the COVID-19 vaccines.



## **Can I Get the COVID Vaccines if I Have an Allergy to Eggs?**

The new COVID vaccines have been developed with technology that does not utilize eggs. Therefore, egg allergy alone should not prevent you from getting either mRNA-based vaccine. However, if you have concerns regarding any allergies, it is always best to notify your health care professional prior to receiving the vaccine.

## **I've Heard Some Disturbing Myths About These Vaccines on Social Media and Through Other Sources Including:**

- The vaccine was developed far too quickly to be safe
- I don't need the vaccine if I've already had COVID
- I'll actually get COVID from the vaccine
- The vaccine will alter my DNA
- Once I'm vaccinated, I don't need to wear a mask or social distance
- Maybe I shouldn't get the vaccine, because the risk of the vaccine is greater than the chance of me getting very sick or dying of COVID disease
- The COVID-19 vaccine was developed to control the general population either through microchip tracking or "nanotransducers" in our brains
- COVID-19 vaccines were developed using fetal tissue
- COVID-19 vaccines have been linked to infertility or miscarriage
- These vaccines have to be stored at very cold temperatures due to the many preservatives in the vaccines

## **Are Any of The Above Claims True?**

None of the above claims are true. In fact, the people spreading vaccine misinformation and conspiracy theories on social media and through other outlets are only frustrating public health efforts to get the COVID-19 pandemic under control. This misinformation is borne out of ignorance, not evidence, and only serves to sow discord and create confusion by attempting to erode trust in well-settled science and time-honored public health practices. At worst, individuals continuing to spread these myths undermine our attempt to save lives, decrease suffering, engage in meaningful economic recovery, and get back to a normal, pre-pandemic way of life.

## **How Long will the COVID-19 Vaccine Protect Me?**

At this time, it is not known how long the vaccine can protect you. Data is limited and research is ongoing. Vaccines mimic a natural infection to trigger an immune response. But vaccines may require a boost to keep that immunity strong. The memory B cells that target the coronavirus that causes COVID-19 may not have the same power that protects us from other viral illnesses, for instance. Thus far, scientists have observed that these memory B cells have persisted for many months following a case of COVID-19, but it's too early to say anything about whether they will eventually fade. Other immune cells, like T cells, stay in the tissues of the upper and lower airways (nose/throat and lungs) and don't react until they encounter actual infection. Therefore, they are more difficult for scientists to study in the lab.

### **Should I Get a COVID-19 Vaccine if I Have Already Been Infected?**

The CDC recommends getting a COVID-19 vaccine even if you have been infected. Health officials will keep the public informed with more details.

### **Should I Get BOTH a Flu Shot and the COVID-19 Vaccine During the Flu Season (Fall and Winter)?**

Yes. The flu and COVID-19 vaccines are for different illnesses. A seasonal flu shot will not protect you from COVID-19. Getting both vaccines will help protect you the most and will decrease the possibility you will need to go to the hospital for severe influenza.

### **Can My Child/Children Be Vaccinated?**

Currently, the *Pfizer-BioNTech* vaccine is only approved for those aged 16 and older. The *Moderna* vaccine is approved for persons aged 18 and above. Thankfully, research during the pandemic has shown that younger children are less likely than adults to experience serious COVID-19 complications. As research progresses, it is very likely that these vaccines will ultimately be approved for broader pediatric use in order to obtain optimal herd immunity. In addition, there is a chance that other vaccines in development may be available for pediatric use in the future.

### **Can I be Vaccinated if I'm Pregnant or Lactating (breastfeeding)?**

Neither of the vaccines have been tested in these two groups.

*Moderna* has completed animal studies the FDA required of manufacturers; these studies look for evidence that the vaccine might harm the pregnancy or the developing fetus. The company said it saw no such signals.

*Pfizer-BioNTech* has only interim data from its animal studies, but said it likewise saw no concerning adverse signals.

The authorizations for both vaccines state there are not enough data to gauge whether they are safe for pregnant or lactating people. FDA's Peter Marks, director of the Center for Biologics Evaluation and Research, said recently that those who are pregnant should choose whether to be vaccinated after discussing the risks and benefits with their physicians, as pregnant women that become very ill with, or have complications from COVID, may also risk harming their unborn babies.

As research progresses, it is very likely that these vaccines will ultimately be approved for obstetric use in order to obtain optimal herd immunity and to reduce complications that could occur during pregnancy with concurrent active COVID-19 infection.

## **Weighing the Potential Risks and Benefits of a New Vaccine**

### **Potential Risks of Not Getting the COVID-19 Vaccine**

The risks of not getting a COVID-19 vaccine cannot be adequately described, exactly, because the risks of contracting COVID-19 and having a serious or fatal outcome are largely based upon age, the presence or absence of other, pre-existing medical conditions, occupation, lifestyle choices, exposure history, etc. We know that some people that contract COVID may become very ill or even die. Some may have complications for months or years after contracting COVID-19. Others will have only mild disease and yet others will remain completely asymptomatic. Presently, it is impossible to determine who will get very ill with COVID-19. However, the greatest benefit to being immunized is that you can become part of the solution to help stop this pandemic as soon as possible. The more people that get vaccinated, the sooner we will achieve herd immunity (immunity for the vast majority of people), and the sooner the pandemic will be over.

### **Persons at Increased Risk of Complications with COVID-19 Disease**

**Adults of any age** with the following conditions are at **increased risk of severe illness** from the virus that causes COVID-19:

- **Cancer**
- **Chronic kidney disease**
- **COPD (chronic obstructive pulmonary disease)**
- **Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies**
- **Immunocompromised state (weakened immune system) from solid organ transplant**
- **Obesity (body mass index [BMI] of 30 kg/m<sup>2</sup> or higher but < 40 kg/m<sup>2</sup>)**
- **Severe Obesity (BMI ≥ 40 kg/m<sup>2</sup>)**
- **Pregnancy**
- **Sickle cell disease**
- **Smoking**
- **Type 2 diabetes mellitus**

As to the risks of COVID-19 to our society, we know that there are well-established potential complications and high mortality associated with the virus, and we have much data to indicate that, in the absence of effective vaccines and therapeutics, we will continue to experience a significant disease burden that will lead to greater morbidity (illness), mortality (deaths) and taxing of our health care system resources. With this much illness burden we will undoubtedly experience significant socioeconomic harm that may take years to recover from.

### **Potential Risks of the COVID-19 Vaccine**

It is completely reasonable to be concerned about the rapid pace at which these vaccines have been developed and produced. However, the platform for these vaccines had already been in development for many years, and phase III clinical trials have shown that mRNA vaccines are likely to be no riskier than any other developed vaccine and have demonstrated good safety signals. As with all vaccines and essentially all medications, there is always the chance for a serious side effect or reaction. The most serious side effect noted thus far with mRNA vaccines has been anaphylaxis (a severe allergic reaction

that can cause a rash and affect breathing). These reactions have occurred quite rarely in the United States and other countries during mass vaccinations and have been treated successfully by medical personnel. However, in studies of thousands of participants, these risks were found to be exceedingly small, and the vast majority of people will have some mild injection site tenderness and could feel like they have a mild case of the flu with muscle and joint aches, fatigue, etc. These symptoms generally resolve within a few days.

What we do know, is that **no shortcuts were taken** in the process to establish the safety and efficacy of these vaccines.

## Conclusion

As we all consider balancing potential risks and benefits of the COVID-19 vaccines, the bottom line is that, although the decision to be vaccinated is highly personal, we are also in the middle of a public health crisis that stands to hospitalize and kill hundreds of thousands more Americans and risks creating unprecedented health care shortages due to the immense strain being placed on our health care system. The pandemic also, quite literally, poses an existential risk to our national security, economic well-being, and very way of life. These factors should be, perhaps, equally considered as we weigh the significant benefits of the vaccine versus the largely theoretical risks of the novel COVID-19 vaccines causing any significant long-term harm.

More information is available from the WI DHS at:

<https://www.dhs.wisconsin.gov/covid-19/index.htm>

More information is available from the CDC at:

<https://www.cdc.gov/coronavirus/2019ncov/vaccines/faq.html>

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