(C)//D-19 vaccine guidance



10 Things You Should Know About VACCINE DEVELOPMENT



Consistent with our guidance throughout the pandemic, the COVID-19 vaccination is not something we can say is 100% effective nor 100% without risk.

But it is an <u>extremely</u> promising tool in the fight against COVID-19 because it provides immunity to large portions of our community, which will reduce the spread significantly. Like everything, the vaccine is something you need to learn more about from <u>trusted</u> sources so you can make an informed, personal choice.

There's much we still don't know about the COVID-19 vaccine. But, there are significant developments and findings that you should be aware of as we await delivery and distribution.

1 Planning

The federal government, through **Operation Warp Speed**, has been working since the pandemic started to make COVID-19 vaccine available as soon as possible. The CDC has been working closely with health departments and partners to develop vaccination plans.

Thus far, initial shipments (especially those with ultra-cold storage requirements) will be prepositioned at hospitals, federally qualified health centers, health departments and pharmacies for administration to priority groups.

Manufacturers

There are several COVID-19 vaccine candidates in development with clinical trials being conducted simultaneously with large-scale manufacturing. Two – **Pfizer and Moderna** – have successfully completed three phases of clinical trials and have applied for Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). More will follow.



2 Clinical Trials

These trials are following strict protocols. No steps are being skipped, and no short-cuts have been taken. By the time a drug or vaccine has gone through three phases of clinical trials, it has been tested on thousands of people. Its effectiveness and side effects are documented. The only thing missing is the "one in a million" side effects that only come with time and...millions of people getting it.

Efficacy

Vaccine "efficacy" or **effectiveness** is determined by studying two groups: one receiving the vaccine and another receiving a placebo (no therapeutic value). Both groups are studied to see how many people get COVID-19. In Pfizer trials conducted over two months with 19,000 people, 10 people in the vaccinated group developed COVID-19 (no severe cases) and 1,062 people developed it in the placebo group. Moderna found similar results.



Vaccine Availability

Once the FDA authorizes use of COVID-19 vaccine(s), limited quantities will be available in Saginaw County and throughout the nation because of advanced planning.

At first, vaccine distribution will be limited and prioritized to **health care** workers and residents of long-term care facilities. Next will be essential workers. Then, the vaccine will likely go to high-risk populations such those with high-risk medical complications and adults 65+.

Supply will increase substantially in 2021. Current models suggest that anyone not within the initial priority groups who wants a vaccine will be able to get one by April or May 2021. The vaccines themselves are free to all. Those who administer or give the shots may bill insurances a small fee but may not charge people – no out of pocket costs. More information will be available soon on HOW and WHERE vaccines are being administered.

Safety

Safety of COVID-19 vaccines is a top priority. LOTS of eyes are watching! Our nation's vaccine safety system is strong and robust, with the capacity to effectively monitor COVID-19 vaccine safety. Your doctors, hospitals, and all of us here at the Saginaw County Health Department are being asked to play a role as well. Remember, local healthcare workers – the first to receive the vaccine – will be using an "after vaccine health checker" called **V-SAFE** to provide additional data to the COVID-19 vaccination effort. In addition, ANYONE getting the vaccine may use the <u>Vaccine Adverse Event</u> <u>Reporting System (VAERS)</u>, just as we do with all existing vaccines, to report undocumented side effects. This alerts vaccine developers and health authorities to any potential issues immediately.



7 Doses

Of the five major vaccines currently close to completion, four of them require **two doses**. First and second doses must be the same vaccine. The time between doses will vary. But for all, it is critical to get both doses within the established timeline! One dose will not provide the required immunity. And with all, it may take one to two weeks for immunity to be established, so washing hands, wearing masks, and watching our distance will remain critical.



Side Effects

Anywhere from 2-10% of those receiving the vaccines in clinical trials experienced side effects ranging from **high fever**, **fatigue**, **joint and muscle aches**, **and headaches to just redness at the injection site**. No one was hospitalized during either the Pfizer or Moderna trials. There was one death during the Astra Zeneca trial, but the subject was later discovered to have received the placebo (this is why trials stopped and restarted).

Children

At first, COVID-19 vaccines will likely not be authorized, approved, or recommended for children. Trials thus far have focused on higher risk groups. However, clinical trials continue to expand who is recruited to participate, so we may see a COVID-19 vaccine for children in the future.

For more information about the rapidly changing COVID-19 vaccine development process, follow the Saginaw County Health Department online and on Facebook. Additional information is available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fag.html

Your Vaccine

You may not get to "choose" which manufacturer's vaccine you receive. Each will likely be licensed for use on specific populations. You will likely get the one designated for you. When you receive the vaccine, you will get plenty of documentation and instructions.

It is not yet known if COVID-19 vaccination will be required annually. And, as you weigh your decision to get the COVID-19 vaccination, understand that its effectiveness in creating "herd immunity" will require more than 70% of the population to be vaccinated.

