

Hiawatha
First Nation
Vaccine
Information
Session

January 11, 2021



Agenda

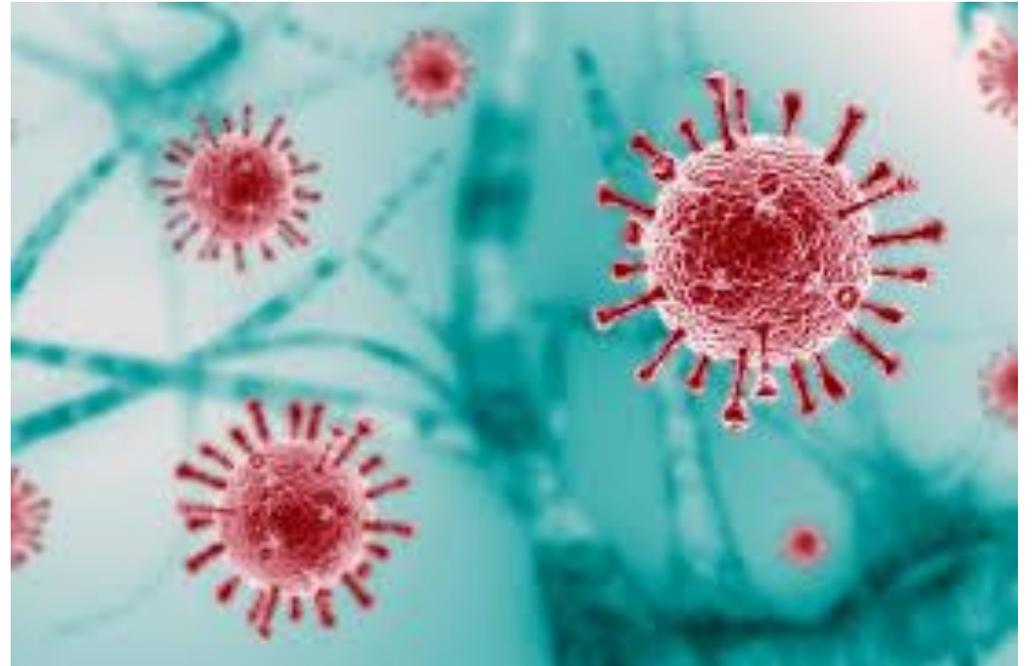
- First, we will start with **what we don't know yet about COVID and the vaccines**
- Then I will share **what we know**: how the vaccines work, how helpful they will be to protect you against COVID-19, what the side effects will be
- We will talk about when and how you will be able to be **immunized against COVID-19**
- There will be lots of opportunities to ask **questions** about the vaccines

What do we **NOT** know about
mRNA vaccines yet?

Some answers to our questions need more time and research

What do we **NOT** know about mRNA vaccines yet?

We are still learning which type of immune responses are important for protection from infection, severe disease, or transmission. We don't know that yet.



What do we **NOT** know about mRNA vaccines yet?

We don't know how long the vaccines will work and whether their protection may change over time.

The clinical trials will continue for 2 years so we will learn more about whether the vaccines will need a booster shot as more research is done.



What do we **NOT** know about mRNA vaccines yet?

We still need to understand whether the immune system acts differently, depending on whether it has been triggered by a vaccine or by natural infection.



What do we **NOT** know about mRNA vaccines yet?

We still don't understand yet how immune responses differ in different groups of people, such as those whose immune systems may not be working well, or in children.

These studies have yet to be completed.



What do we **NOT** know about mRNA vaccines yet?

Coronaviruses cause cold-like illnesses in humans and some, like MERS-CoV or SARS, can cause severe disease.

We still don't know if people who have had other coronavirus diseases in the past will have a different immune response to the vaccine against COVID-19.

What **DO** we know about the
COVID-19 vaccines?

We are learning more every day!!

So how does the Moderna or Pfizer Vaccine work?

- The coronavirus that causes COVID-19 uses a “spike” protein that is on its surface to attach to our body’s cells.
- This creates the door for the virus to enter, or infect, our cells.
- The vaccine works by helping our immune system recognize the spike protein so that if the virus is detected, our immune system can respond quickly and effectively to prevent infection. It recognizes the virus before it can even knock on the door.



The vaccine is NOT a magic wand



- If you are already infected when you are immunized, you will still get COVID-19
- If you are infected before your body's immune system is fully armed, you may still get sick with COVID-19.
- Even if the vaccine has worked and your immune system is now armed and activated, it's not 100% effective. It may help prevent severe disease.

Can I get COVID from an mRNA vaccine?

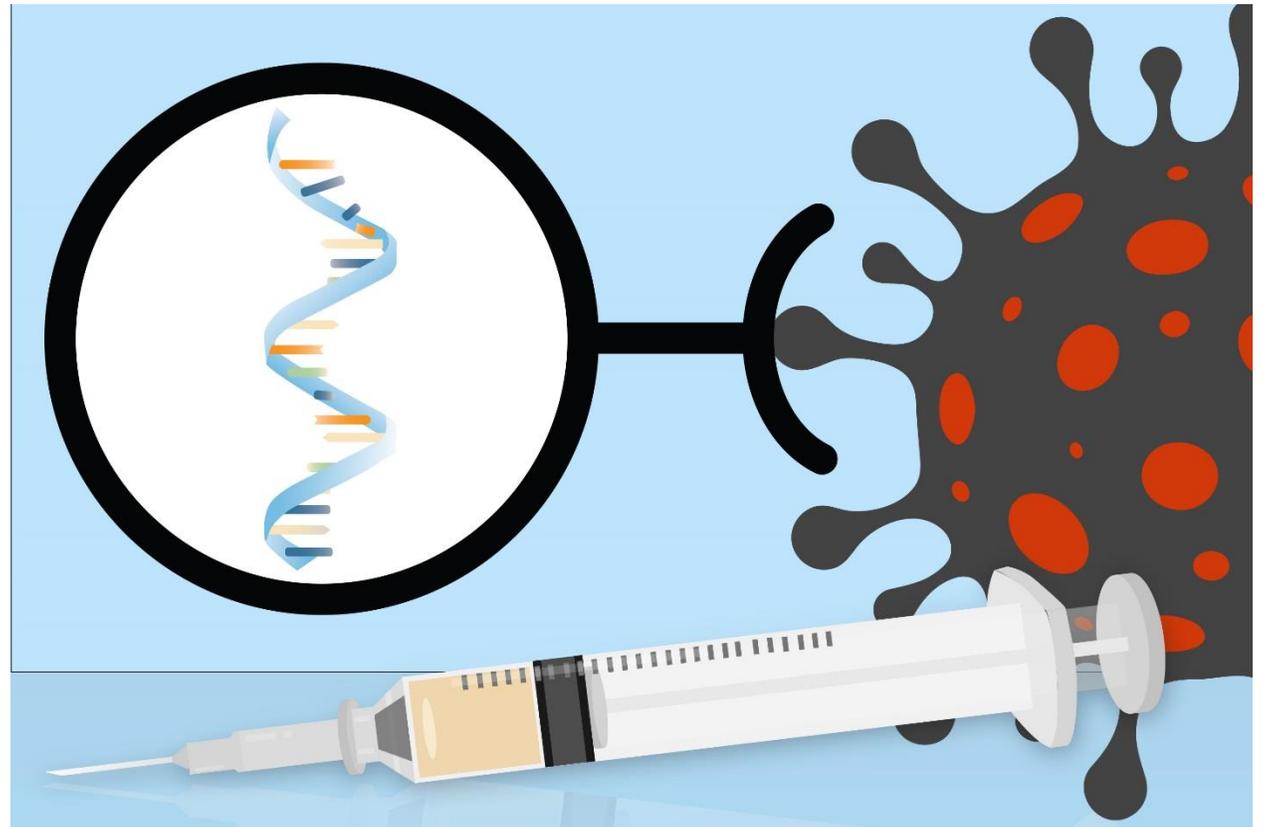
The vaccine **does not contain the virus** so you can't catch COVID from it.

However, the immune system takes 14 days to respond, and protection is not optimal until 2 weeks after the second dose.



What is “messenger RNA” and how does it work as part of the Pfizer and Moderna vaccines?

We all have Messenger RNA as part of our cells. Usually it is very busy, travelling back and forth from the nucleus of the cell to the ribosomes, which are the protein factories in the cell.



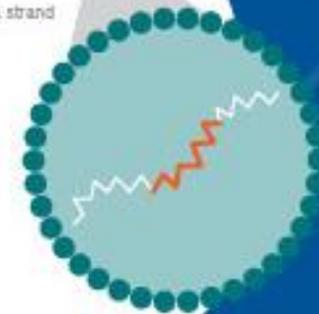
HOW IT WORKS

Through a COVID-19 mRNA vaccine, you receive pieces of mRNA*, harmless genetic material used to create proteins.

*mRNA, which is separate from DNA, is a component found in all cells.



mRNA strand



mRNA strand

Spike proteins

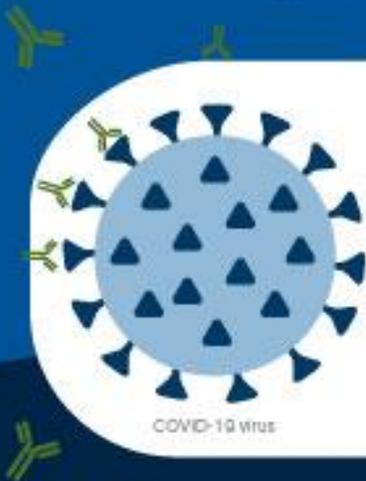
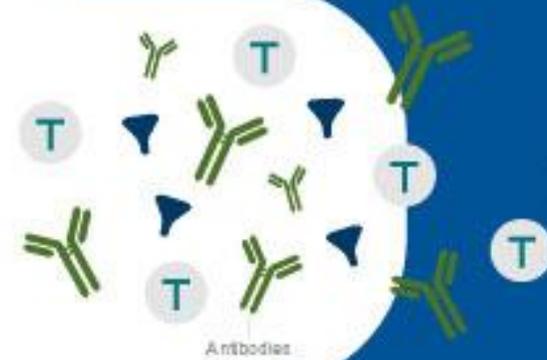
CREATE

Your body uses the mRNA to manufacture a version of the spike protein¹ found on the COVID-19 virus.

T

¹Spike protein: A component on the outer shell of the COVID-19 virus. By itself, the spike protein is completely harmless.

LEARN The newly created spike protein triggers an immune response — teaching your body to recognize and respond to the virus in a variety of ways.



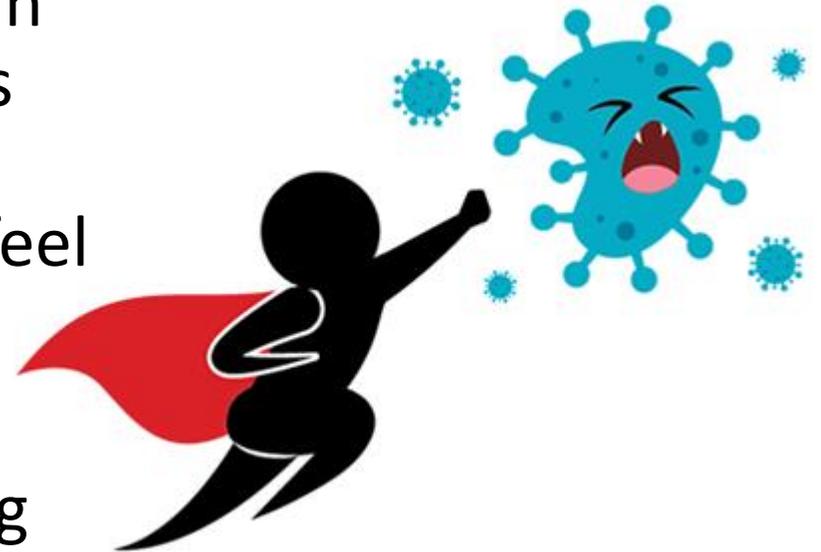
REACT If you are exposed to the virus in the future, your immune system will quickly recognize the spike protein and begin destroying the virus (i.e., you may never feel sick).

The Benefit of Getting Vaccinated

The COVID-19 virus replicates quickly.

Without the vaccine, your body has to identify the virus, learn how to fight it, and carry out an immune response. In the meantime, the virus can replicate to a level beyond what your immune system can handle at once (i.e., you feel sick).

With the vaccine, your body can more quickly identify the virus and skip straight to mounting its immune response.



Does the mRNA in the vaccine pose any risk to my DNA?

- Your DNA is your genetic code for all the different proteins that keep your body running – this master recipe book is very precious and can't leave the nucleus of the cell.
- The vaccine does not enter the nucleus of the cell and does not interact with the DNA. It goes straight to the factory, the cell's ribosomes, where it provides the instructions for the spike protein.
mRNA vaccines do not change your DNA.
- Human beings do not have the enzymes to convert RNA into DNA. In fact, our cells have enzymes that destroy the mRNA after the protein is made – which is why the vaccine doesn't stay in your body for long.



How long do those spike proteins stay on our muscle cells?

- Both the vaccine mRNA and spike protein are cleared by the immune system.
- This usually takes anywhere from a few hours to a few days.

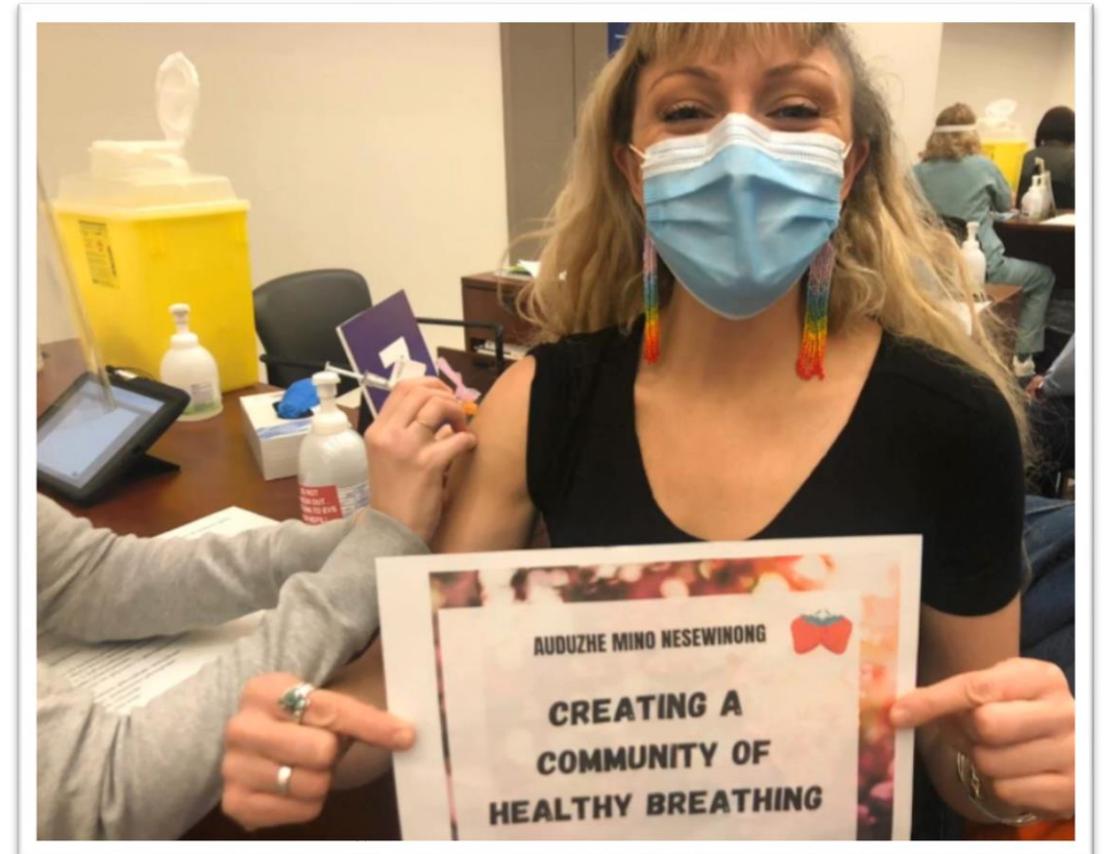


How safe is the Moderna Vaccine?

The most frequently reported adverse reactions after any dose were:

- pain at the injection site (92.0%),
- fatigue (70.0%),
- headache (64.7%)
- myalgia (61.5%)
- chills (45.4%)

The majority of local and systemic adverse reactions had a median duration of 1 to 3 days. These are all signs that the immune system is being activated!



Source: Women's College Hospital Indigenous Health

Does the Pfizer Vaccine have the same side effects?

- YES
- Common symptoms after immunization are a sore arm (81%), fatigue (63%), Headache (55%), Muscle and joint aches (24-39%)
- Fever is NOT common (only 14%) so if you are ill after your immunization and have a fever or other symptoms of COVID, please get a medical assessment +/- COVID test as you may have been incubating
- Symptoms usually last about 1-3 days, are more common with the second dose and milder with older age

Who shouldn't get the COVID-19 Vaccine?

- Groups that were not included in the clinical trials: Children, Pregnant and Breastfeeding Women. There is no data on these groups.
- Anyone with an anaphylactic reaction to any of the vaccine ingredients (Polyethylene Glycol, or PEG)
- Anyone who is acutely sick
- Uncertain benefit in people who are immunocompromised
- Moderna COVID-19 vaccine should be given with caution in individuals with bleeding disorders, such as haemophilia, or individuals currently on anticoagulant therapy (what's your INR?)

Safety analysis of Phase III Moderna Trial:

- 30,351 subjects who received at least one dose of Moderna COVID-19 Vaccine (n=15,181) or placebo (n=15,170)
- Subjects were followed for a median of 92 days from first injection and 63 days from second injection
- Were reduced in older recipients
- Were more common after the second dose
- 3 “serious” adverse events: 2 cases of facial swelling occurring within 7 days of receiving dose 2; 1 case of N,V,H and fever requiring in-hospital treatment in a recipient with past medical history of H, N, and V requiring hospitalization.

Safety analysis of Phase III Pfizer Trial:

- 44,000 subjects who received at least one dose of Pfizer COVID-19 Vaccine (n=21,720) or placebo (n=21,728)
- Subjects were followed for a median of 2 months from first injection for 19,067 recipients who were part of the safety analysis
- Similar symptoms as with Moderna vaccine
- Were reduced in older recipients
- Were more common after the second dose
- In 16-55 years, 0.4% reactions classified as serious. For recipients 56 years of age and older, this was 0.8%

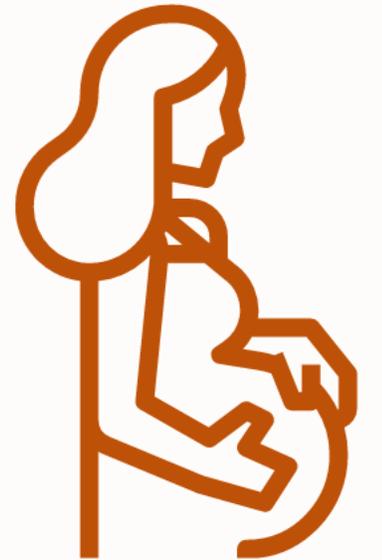
Can I still get the vaccine if I have existing health conditions (such as diabetes, high blood pressure, hepatitis, HIV)?

Yes. People with stable health conditions, including HIV, may be vaccinated with the COVID-19 vaccine as long they are not on medications that weaken the immune system. This also includes people with stable hepatitis B or C.



Can I still get the vaccine if I'm trying to get pregnant?

- There is limited information on the use of this Pfizer vaccine in pregnant people.
- If you are pregnant, breastfeeding, or planning to have a baby, talk to your health care provider before getting the vaccine.
- As a precaution, avoid trying to get pregnant for one to two months after finishing this two-dose vaccine.



Post-Marketing Surveillance

- Adverse event following immunization (AEFI) reporting




IPHIS case ID

Enhanced reporting form for events managed as anaphylaxis following immunization

Please complete this form for any reported adverse event following immunization (AEFI) that meets the criteria for "event managed as anaphylaxis" in Section 5.0 (C.1) of [Appendix B: Provincial Case Definitions for Adverse Events Following Immunization \(AEFI\)](#). (See Criteria for Provincial Reporting of Anaphylaxis)

This form is designed for use by public health units for provincial surveillance purposes only. It is *supplementary* to Public Health Ontario's [Report of Adverse Events Following Immunization \(AEFI\) Form](#) which should be completed in addition to this form.

All events managed as anaphylaxis should be reported in iPHIS. Once completed, please save and send this form via iPHIS referral to Public Health Ontario. If you have any questions about investigation of an event managed as anaphylaxis or completion of the form please contact the Immunization & Vaccine-Preventable Diseases team at IVPD@oahpp.ca.

Date of report Date of event

Person completing form Contact email / phone #

Health Unit Health Unit incident form completed

CLIENT INFORMATION							
Date of birth <input style="width: 100px;" type="text"/>	Sex <input type="checkbox"/> Female <input type="checkbox"/> Male						
CLIENT HISTORY							
Prior anaphylaxis? <input type="checkbox"/> Yes <input type="checkbox"/> No	Prior allergic reaction(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No						
Details (severity & allergen)	<input style="width: 100%; height: 20px;" type="text"/>						
IMMUNIZATION INFORMATION							
Date of vaccine administration <input style="width: 100px;" type="text"/>	Time of vaccine administration (24 hr clock) <input style="width: 100px;" type="text"/>						
Vaccine(s) administered	<input style="width: 100%; height: 20px;" type="text"/>						
<input type="checkbox"/> Details about vaccine(s) administered completed on the Report of Adverse Events Following Immunization (AEFI) Form .							
EVENT INFORMATION							
	Yes/No/Unknown	Time(24hr)	Pulse(per min.)	Resp.(per min.)	Blood pressure	Dose	Administered by
Epinephrine #1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Epinephrine #2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Epinephrine #3	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other (specify)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Additional details	<input style="width: 100%; height: 20px;" type="text"/>						

How effective is the COVID vaccine?

- Both mRNA vaccines compared vaccine recipients to those who received a placebo.
- In both trials, everyone was followed for 2 months after the second dose
- For the **Moderna vaccine**, there were 11 confirmed COVID-19 cases in the vaccine group and 185 in the placebo groups (**94.1%** efficacy) For participants 65 years of age and older, efficacy was **86.4%**. None of the vaccine recipients had severe cases.
- For the **Pfizer vaccine**, there were 8 cases in the vaccine group and 162 in the placebo. Efficacy reported at **95%**. For participants 65 years of age of older, it was **94.7%**.

What's in the vaccine?

Non-medicinal ingredients:

- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) (a phospholipid),
- acetic acid (vinegar),
- cholesterol,
- **PEG2000 DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol),**
- lipid SM-102 (lipid nanoparticle that carries the mRNA),
- sodium acetate (a salt),
- Sucrose (sugar),
- Tromethamine (a buffer)
- tromethamine hydrochloride,
- water for injection.



If I have had COVID-19 and recovered, do I still need the vaccine?

Yes. There is some evidence to suggest that natural immunity from a COVID-19 illness may not last very long. It is best to get the vaccine to stay protected.



Do I still need to wear a mask and avoid close contact with others if I have received this two-dose vaccine?

Yes. It is still important for everyone to continue with public health measures like wearing a mask, physical distancing and washing hands often until we can be sure that the vaccine prevents the spread of most COVID-19 infections.



When will Hiawatha Citizens get their vaccine?

- Those working in **long-term care or hospitals** will probably be immunized first, as part of Phase 1b of the provincial roll-out. This is happening at different times, depending where the LTCH or hospital is located.
- FN communities in the north are being immunized now.
- We are still waiting more information on when COVID vaccine will be available for southern FN communities.
- Were advised it would be Moderna, but that may change, depending on vaccine supply.

