

Facts and Fiction: COVID-19 mRNA Vaccinations

Disclaimer

- Please note that the information provided is the opinion of the presenter and is not a substitute for obtaining medical advice as required from one's own physician.

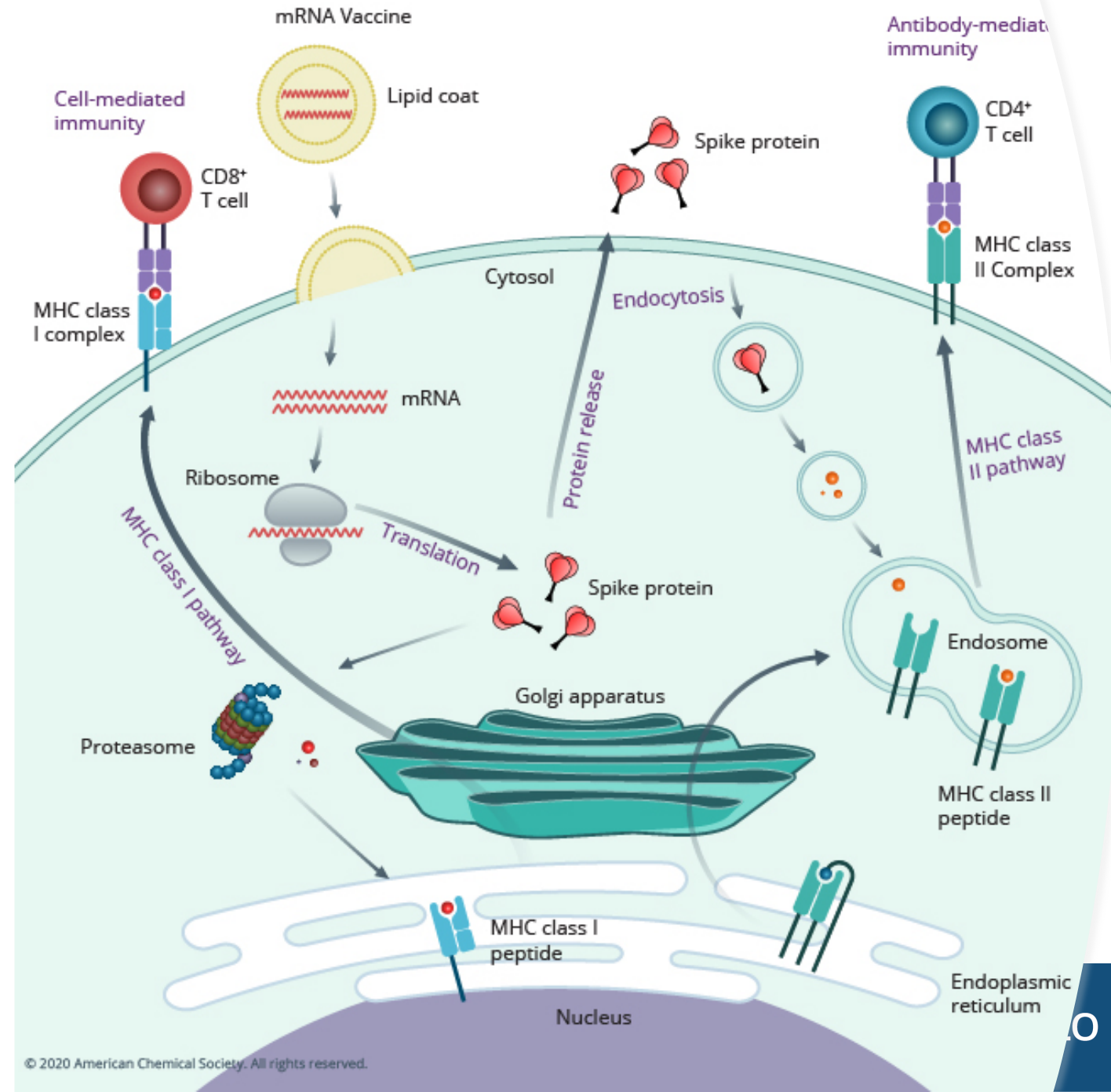
mRNA Vaccines

Quick facts on mRNA vaccines

- Developed over 30 years
- Recent advances in RNA technology and chemistry, and delivery methods has led to more successful vaccinations
- Clinical trials for viruses including Influenza, Zika, CMV, Rabies
- Extensively studied and tested for treatment of cancers etc.
- Not a live (attenuated) or killed vaccine like many traditional vaccinations

How do mRNA vaccines work?

- COVID-19 mRNA vaccines are given in the upper arm muscle.
- Once the instructions (mRNA) are inside the immune cells it give instructions for our cells to make **a harmless piece** of “spike protein” normally found on the surface of the virus that causes COVID-19.
- After the protein piece is made, the cell breaks down the instructions and gets rid of them. It does not enter the Nucleus (where DNA is stored) and does not modify our DNA.
- The cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn't belong there and begins building an immune response and making antibodies (which protect us), like what happens in natural infection against COVID-19.



mRNA Vaccines Approved by Health Canada

Pfizer BioNTech	Moderna
95% Effective	94.1% Effective
2 doses 21 days apart	2 doses 28 days apart
Stored in -70C Freezer, Stable for short periods (120 hours) in a vaccine fridge	Stored in -20C Freezer, Stable for long periods (1 month) in a vaccine fridge
43,651 Trial Participants	30,350 Trial Participants
Approved for Adults 16+	Approved for Adults 18+

Pfizer BioNTech Demographics

- **Study participants:**
 - Mostly white
- **Study location:**
 - Majority USA
- **Age of participants:**
 - 16-91 years

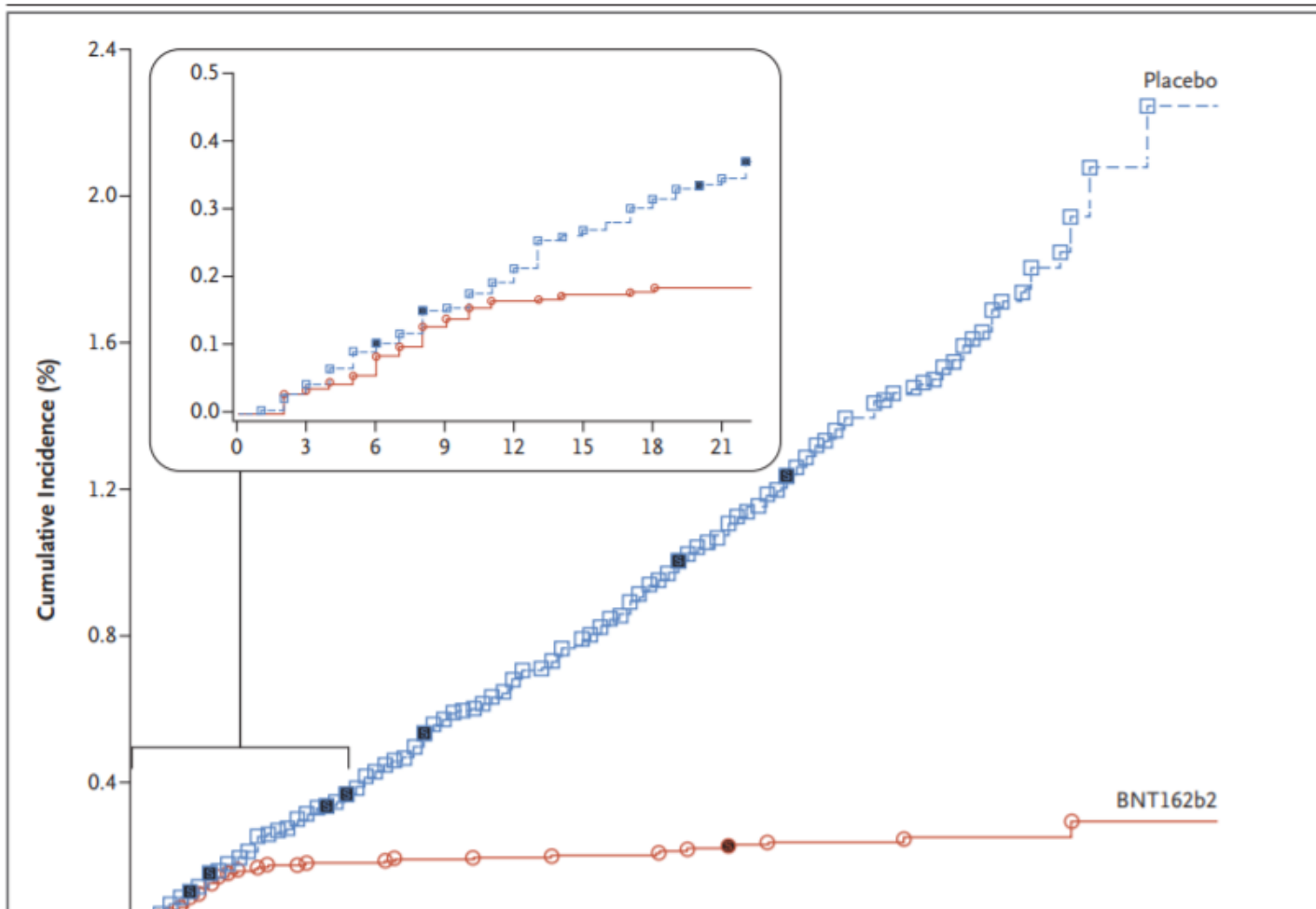
Table 1. Demographic Characteristics of the Participants in the Main Safety Population.*

Characteristic	BNT162b2 (N=18,860)	Placebo (N=18,846)	Total (N=37,706)
Sex — no. (%)			
Male	9,639 (51.1)	9,436 (50.1)	19,075 (50.6)
Female	9,221 (48.9)	9,410 (49.9)	18,631 (49.4)
Race or ethnic group — no. (%)†			
White	15,636 (82.9)	15,630 (82.9)	31,266 (82.9)
Black or African American	1,729 (9.2)	1,763 (9.4)	3,492 (9.3)
Asian	801 (4.2)	807 (4.3)	1,608 (4.3)
Native American or Alaska Native	102 (0.5)	99 (0.5)	201 (0.5)
Native Hawaiian or other Pacific Islander	50 (0.3)	26 (0.1)	76 (0.2)
Multiracial	449 (2.4)	406 (2.2)	855 (2.3)
Not reported	93 (0.5)	115 (0.6)	208 (0.6)
Hispanic or Latinx	5,266 (27.9)	5,277 (28.0)	10,543 (28.0)
Country — no. (%)			
Argentina	2,883 (15.3)	2,881 (15.3)	5,764 (15.3)
Brazil	1,145 (6.1)	1,139 (6.0)	2,284 (6.1)
South Africa	372 (2.0)	372 (2.0)	744 (2.0)
United States	14,460 (76.7)	14,454 (76.7)	28,914 (76.7)
Age group — no. (%)			
16–55 yr	10,889 (57.7)	10,896 (57.8)	21,785 (57.8)
>55 yr	7,971 (42.3)	7,950 (42.2)	15,921 (42.2)
Age at vaccination — yr			
Median	52.0	52.0	52.0
Range	16–89	16–91	16–91
Body-mass index‡			
≥30.0: obese	6,556 (34.8)	6,662 (35.3)	13,218 (35.1)

* Percentages may not total 100 because of rounding.

† Race or ethnic group was reported by the participants.

‡ The body-mass index is the weight in kilograms divided by the square of the height in meters.



Efficacy
Pfizer-
BioNTech

Pfizer BioNTech Study Highlights

- Compared to placebo, vaccine efficacy was evaluated to be 95% in research participants without prior evidence of SARS-CoV-2 infection **7 days after the second dose.**
- Evidence of partial efficacy **12 days** after first dose.
- In participants **65 years of age and older** the efficacy of Pfizer-BioNTech COVID-19 Vaccine **was 94.7%.**
- Vaccine efficacy was consistent across age, gender, race and ethnicity demographics.
- A total of 10 severe cases of COVID-19 observed in the study, with 9 of the cases occurring in the placebo group and 1 in Pfizer-BioNTech COVID-19 Vaccine group.

Pfizer BioNTech Adverse Reactions

Reaction	% of vaccine recipients
Injection site pain	84.1
Fatigue	62.9
Headache	55.1
Muscle ache	38.3
Chills	31.9
Joint pain	23.6
Fever	14.2

- Mild/moderate
- Resolved within a few days
- Also known as – an immune response...

Older adults (56 years +) had lower rates of all reactions than younger adults (18-55)

Vaccine Side Effects Compared

	 Shingrix	 COVID-19 BNT162b2	 Flu	 Placebo (saline)
Local Pain	78%	83%	45%	14%
Redness	38%	5%	13%	1%
Swelling	26%	6%	4%	1%
Myalgia	45%	21%	15%	11%
Fatigue	45%	47%	18%	33%
Headache	38%	42%	19%	34%
Chills	27%	14%	6%	6%
Fever	21%	4%	1%	1%
GI Symptoms	17%	11%	7%	12%
Overall	38% 	26% 	14% 	13%

Contraindication (allergy to any vaccine component)

Pfizer BioNTech Vaccine Ingredients:

- mRNA (named Tozinameran, encoding only the Spike protein for the SARS-CoV-2 virus)
- Lipids (designed to deliver the mRNA into the cell)
 - ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2- hexyldecanoate)
 - ALC-0159 = 2-[(polyethylene glycol)- 2000]-N,N-ditetradecylacetamide
 - 1,2-distearoyl-sn-glycero-3- phosphocholine
 - cholesterol
- Solution to make the vaccine injectable
 - dibasic sodium phosphate dihydrate
 - monobasic potassium phosphate
 - potassium chloride, sodium chloride
 - Sucrose
 - water for injection
- **No Mercury, Aluminum, Food Allergens**

What we don't know

- Pregnancy – not studied
- Breastfeeding – not studied, assess risk vs benefit
- Children under 16 years – not studied
- Autoimmune Disease* – efficacy
- Immunocompromised* – efficacy (thought to be safe as not a live vaccine)
- Protection from serious illness – preliminary data extremely promising, but not enough people with serious illness to draw conclusion
- Can recipients still be a carrier? Still need to use PPE.

* Canadian National Advisory Committee on Immunizations recommends discussion with physician about risk and benefits

Myths about mRNA COVID-19 Vaccines

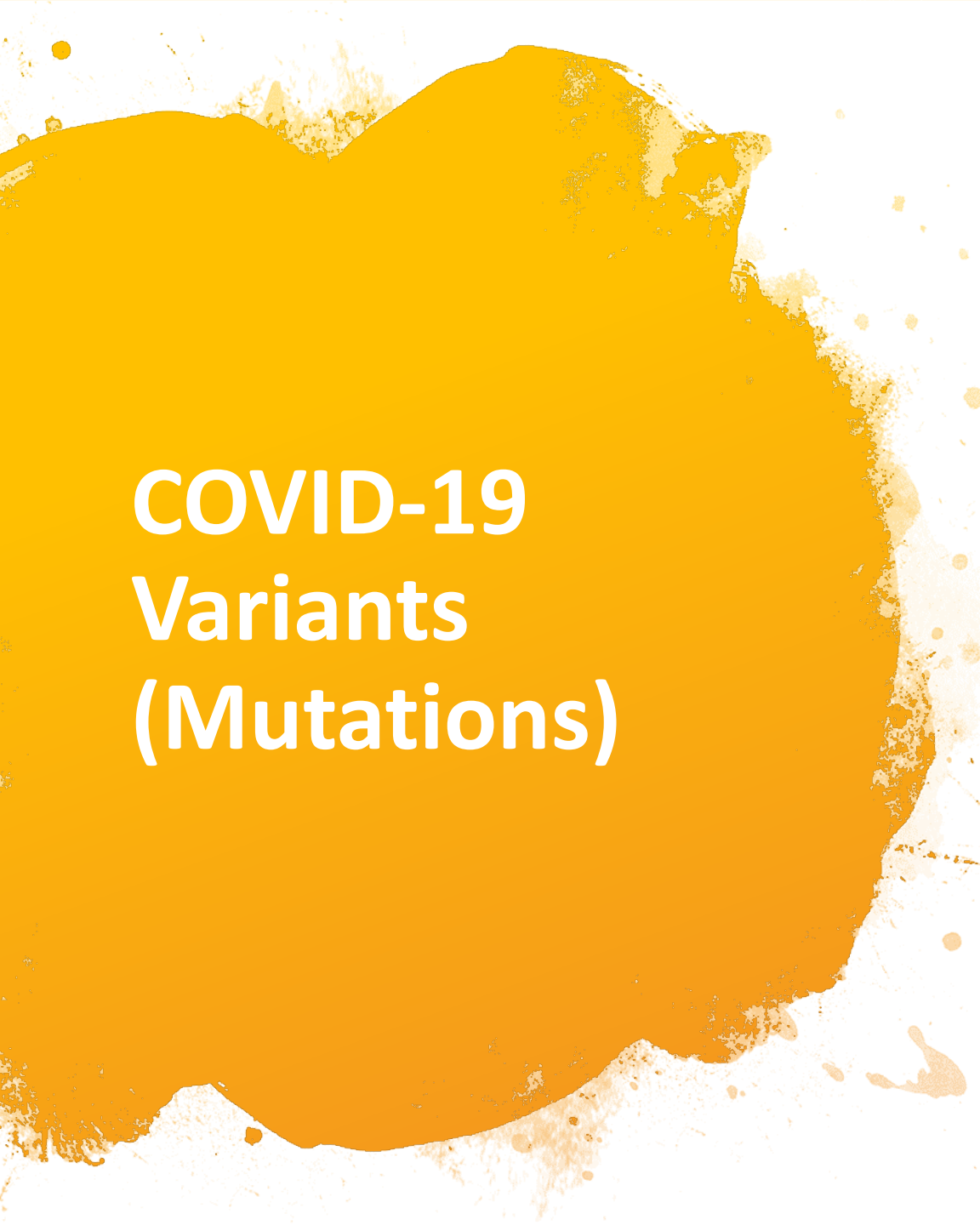
- **Myth #1: “Mortality from COVID is low – why should I be vaccinated?” and “Am I better to take my chances and get infected than to have the vaccination?”**
 - COVID-19 symptoms can persist for months (fatigue, SOB, “brain fog” etc)
 - Evidence of end-organ changes even in young healthy patients with mild symptoms
 - Lasting changes to myocardial tissues
 - Long-lasting/permanent damage to alveoli (air sacs) in lungs and scar tissue
 - Damage to blood vessels in brain, stroke, seizure, Guillan-Barre syndrome
 - Protect yourself so that you don’t infect those more vulnerable
- **Myth #2: “The COVID-19 vaccine will give me the disease.”**
 - The COVID-19 mRNA vaccines (e.g., Pfizer and Moderna vaccines) do not use the live, weakened, or inactivated virus that causes COVID-19. They use a small piece of messenger RNA (mRNA) to give instructions for our cells to make a harmless piece of what is called the “spike protein.” The spike protein is found on the surface of the virus that causes COVID-19.

Myths about mRNA COVID-19 Vaccines

- **Myth #3: “The COVID-19 vaccine will change my DNA.”**
 - The messenger RNA (mRNA) in COVID-19 vaccines does not affect or interact with our DNA in any way. mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept. If the cells divide, they will only include your natural DNA. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions to make a protein.
- **Myth #4: “The risk of getting side-effects from the vaccination is intolerably high.”**
 - The vaccinations have been extensively tested, and an estimated 4 million or more doses has been administered world-wide. Most of the side-effects are related to developing an immune response (a good thing!). The most serious reported side effect is anaphylaxis, which is still extremely rare and recipients are monitored after the vaccination with treatment readily available. There were a few instances of Bell’s Palsy but the number of cases was “consistent with the expected background rate in the general population” and not thought to be related to the vaccine.

Myths about mRNA COVID-19 Vaccines

- **Myth #5: “The vaccinations were fast-tracked and are not well tested.”**
 - All the usual steps for a new drug to be approved were taken. Health Canada and other regulators examined data while the trials were underway and prioritized the review of COVID trials over other studies. Several steps were done in parallel where it would not compromise safety. The trials were very large and close monitoring continues even after the trials are completed.



COVID-19 Variants (Mutations)

- There have been several variants identified, including “UK variant” and “South African Variant”
 - These involve mutations to the spike protein used in the vaccination
 - Travel-related cases of UK variant in Ontario
 - No Ontario cases of South African variant
- The body makes many antibodies to different parts of the spike protein
 - **Expert consensus that vaccination still effective against UK variant**
 - **Concern that vaccine will not have full efficacy for South African variant**
 - Virus regularly mutate (eg influenza) and if mutations continue to happen we might eventually need an additional vaccination (premature to speculate at this time)

The **benefits** of the COVID-19 vaccine far **outweigh the risks**, and for the benefit of the vulnerable patients we serve **we should all very seriously consider being vaccinated.**