COVID-19 VACCINATION

Get Educated

Get Vaccinated

Get Skilled
About Us

19 To Zero is a group of health professionals and community members working to shift public perceptions around COVID-19 behaviours and vaccination. See 19ToZero.ca for more info.

This town hall was organised in collaboration with [list community partners]

Presenters: [list names]
Objectives

At the end of this session, participants will be able to:

• List the four COVID-19 vaccines approved for emergency authorization in Canada
• Outline the contraindications and precautions of these vaccines and side effect profile
• Describe hesitancy around COVID-19 vaccine and have a communication framework to use in their practice
• Dispel common myths and misconceptions around these vaccines
A Primer on the COVID-19 Vaccines Authorized in Canada
Over 56 million doses have been administered in Canada

% OF ELIGIBLE POPULATION (12+):
87.54% at least one dose; 81.11% fully vaccinated

TOTAL DOSES ADMINISTERED
56,438,036

Map of Canada
## COVID-19 Vaccines for Canada & Interim Authorization Status

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Vaccine Type</th>
<th>Clinical Trial Efficacy to prevent COVID-19 Infection</th>
<th>Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>2 dose mRNA encoding spike</td>
<td>95% <strong>efficacy</strong> (≥7 days after 2nd dose) vs PCR+ infection&lt;br&gt;Real world data: single dose was 72% (3 weeks after first dose) and 86% after 2 doses (14 days after second dose)</td>
<td>✓ Dec 9, 2020</td>
</tr>
<tr>
<td>Moderna</td>
<td>2 dose mRNA encoding spike</td>
<td>94% <strong>efficacy</strong> (≥14 days after 2nd dose) vs PCR+ infection</td>
<td>✓ Dec 23, 2020</td>
</tr>
<tr>
<td>AstraZeneca/Verity Pharma</td>
<td>2 dose viral vector with spike DNA</td>
<td>63% <strong>overall efficacy</strong> (post 2nd dose) vs PCR+ infection&lt;br&gt;82% if 2nd dose after 12 weeks after first&lt;br&gt;US: 76% against symptomatic disease and 100% against hospitalisation&lt;br&gt;*real world data for adults over 70, 1st dose 73% overall vs infection, 80-100% vs hospitalization</td>
<td>✓ Feb 26, 2021</td>
</tr>
<tr>
<td>Janssen/Johnson &amp; Johnson</td>
<td>1 dose viral vector with spike DNA</td>
<td>66% <strong>overall efficacy</strong> vs PCR+ and moderate/severe disease&lt;br&gt;85% <strong>efficacy vs severe disease</strong></td>
<td>✓ Mar 5, 2021</td>
</tr>
<tr>
<td>Novavax</td>
<td>2 dose recombinant spike nanoparticle</td>
<td>Press release: 90% <strong>overall efficacy</strong> (7 days post 2nd dose) vs PCR+ infection&lt;br&gt;89% efficacy in UK (&gt;50% variants), 49% efficacy in South Africa (&gt;90% variants, 6% HIV+)</td>
<td>Submitted Jan 29, 2021</td>
</tr>
<tr>
<td>Medicago/GSK</td>
<td>2 dose spike virus-like particle</td>
<td>Phase 2-3 RCTs have commenced</td>
<td>Not submitted</td>
</tr>
<tr>
<td>Sanofi &amp; GSK</td>
<td>Protein subunit</td>
<td>Phase 1-2 trials – initial dose was not effective</td>
<td>Not submitted</td>
</tr>
</tbody>
</table>
Clinical trial efficacy for mRNA vaccines

**Pfizer (BNT162b2)**
40,000+ participants

95% protection from having the disease

**Moderna (mRNA-1273)**
30,000+ participants

94.1% protection from having the disease

Similar efficacy with different race, ethnicity and age

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mRNA Vaccines

- Give instructions for our cells’ ribosomes to make the “spike protein” found on the surface of the COVID-19 virus.
- Spike protein recognized by immune cells and antibodies against it are made.
- Every minute of every day, mRNA is used in our body to make proteins we need.


## A Closer Look at Pfizer-BioNTech Vaccine Clinical Trial Data

<table>
<thead>
<tr>
<th>Clinical Trial Efficacy to prevent COVID-19 Infection</th>
<th>Timing &amp; Location</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infection risk:</strong> One dose decreased risk of infection by 70%, rising to over 85% after second dose</td>
<td><strong>SIREN prospective cohort study - United Kingdom</strong> (Dec 2020 - Feb 2021)</td>
<td><strong>Completed when Alpha (B.1.1.7) was the dominant strain</strong></td>
</tr>
<tr>
<td><strong>Symptomatic COVID-19 disease</strong>&lt;br&gt;<strong>Under 65 years of age:</strong> Single dose was 72% effective and two doses were 86% effective.&lt;br&gt;<strong>Over 80 years of age:</strong> Single dose was 57% effective and two doses were 85% effective</td>
<td></td>
<td>Vaccine coverage was 89%&lt;br&gt;HCWs tested every 2 weeks via PCR and serology</td>
</tr>
<tr>
<td>• Asymptomatic infection: 91.5%&lt;br&gt;• Symptomatic illness: 97.0%&lt;br&gt;• Hospitalisation: 97.2%&lt;br&gt;• Severe/critical illness: 97.5%&lt;br&gt;• Death: 96.7%</td>
<td><strong>Israel observational national surveillance</strong> (Jan - April 2021)</td>
<td><strong>Alpha (B.1.1.7) was the dominant strain, comprising 94.5% of infections</strong>&lt;br&gt;72.1% of all people over 16 yrs and 90% of people over 65 yrs received 2 doses</td>
</tr>
</tbody>
</table>

A note on first doses: A study in Scotland reported 85% effectiveness against hospitalization 28-34 days after first dose of Pfizer-BioNTech vaccine


ISRAEL: Pfizer-BioNTech

- As more of the population was vaccinated, sharp declines in incidence of infection also occurred, proportionately to age stratification of vaccine rollout

Previous studies in the region demonstrated:
- Vaccines seem to begin to have some effect 12 days after the first dose
- The vaccine remained effective in all age groups, being equally effective in young adults as in elders over 70
- The vaccine-maintained effectiveness for people who are obese and have up to two chronic health conditions.
ISRAEL: Recent rise in COVID-19 cases

On Friday June 25th Israel’s Health Ministry reinstated mask mandate due to a recent rise in COVID-19 infections attributed to the delta variant

- 0.6% current test positivity rate
- Number of active cases is doubling every few days
- Despite the new outbreak, current death rate remains near zero and only 26/729 (3%) active COVID-19 patients are hospitalized
US: Pfizer-BioNTech & Breakthrough Cases

- Prospective cohort study of close to 4,000 health care workers, first responders and other essential workers
- Looked at effectiveness of preventing infection after one or two doses of vaccine

**Effectiveness:**
- Vaccine effectiveness against infection was 90% ≥14 days after the second dose
- Vaccine effectiveness of a single dose was 80% ≥14 days after the first dose

US: Breakthrough Cases

As of September 27, 2021

- The CDC has reported more than 183 million people have been fully vaccinated in the US. Of those, there have been 22,115 reported breakthrough infections resulting in hospitalization or death.
- Thus, there is some indication of severe disease which was different from original trials reporting 100% effectiveness against severe disease and death.

COVID-19 Breakthrough Case Investigations and Reporting | CDC. (2021, September 27).
US: Breakthrough Cases

During May 2021:

- Breakthrough infections in fully vaccinated individuals accounted for 1.1% COVID-19 hospitalizations (1,200 of >853,000)
- Only 0.8% COVID-19 deaths were in fully vaccinated people (150 of >18,000)

Associated Press Analysis of CDC data
## COVID-19 Vaccination in Alberta

Information as of October 4, 2021

### Effectiveness

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Vaccine Effectiveness: 1 dose</th>
<th>Vaccine Effectiveness: 2 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>81% (95% CI: 80-82%)</td>
<td>92% (95% CI: 89-93%)</td>
</tr>
<tr>
<td>Pfizer</td>
<td>75% (95% CI: 74-76%)</td>
<td>90% (95% CI: 89-91%)</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>61% (95% CI: 58-63%)</td>
<td>88% (95% CI: 80-93%)</td>
</tr>
</tbody>
</table>

### Effectiveness against variants of concern

<table>
<thead>
<tr>
<th>Variant</th>
<th>Vaccine Effectiveness: 1 dose</th>
<th>Vaccine Effectiveness: 2 doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha B.1.1.7 UK</td>
<td>76% (95% CI: 75-77%)</td>
<td>91% (95% CI: 89-92%)</td>
</tr>
<tr>
<td>Gamma P1 Brazil</td>
<td>72% (95% CI: 67-76%)</td>
<td>89% (95% CI: 82-93%)</td>
</tr>
<tr>
<td>Delta B.1.617</td>
<td>57% (95% CI: 51-63%)</td>
<td>85% (95% CI: 78-89%)</td>
</tr>
</tbody>
</table>
COVID-19 Vaccination in Alberta
Information as of October 4, 2021

Vaccines work!

Since Jan 1, 2021
- **0.3% of people** with one dose were diagnosed with COVID-19
- **0.6% of people** with two doses were diagnosed with COVID-19

Unvaccinated people or those diagnosed less than two weeks after their first dose made up:

- **86.3%** of COVID-19 cases
- **86.2%** of hospitalized cases
- **78.8%** of COVID-19 deaths

COVID-19 Alberta Statistics
COVID-19 Vaccination in Alberta
Information available as of October 4, 2021

Vaccination and hospitalization
Herd immunity

Herd immunity is dependent on a number of factors

- Transmissibility of the virus
  - Intrinsic properties of the virus and **variants**
  - Public health measures
- Vaccine supply, rollout, and uptake
- How long vaccine immunity lasts

While it was originally reported that we would need 75-80% of the population to be vaccinated in order to achieve herd immunity, **this number is likely higher (~80-90%).**

**Around 29 million people in Canada have said they will get vaccinated, but this is not enough to reach herd immunity**

To reach herd immunity, Canadians must be vaccinated with two doses of the vaccine and children will also need to receive the vaccine.
Six month safety and efficacy of Pfizer vaccine

New Preprint

- Randomized, placebo-controlled, observer-blind study assessing safety, tolerability, efficacy and immunogenicity of vaccine in adolescents and adults
- Between July 27 - October 29 2020, 45,165 individuals over 16 years old were randomized at 152 sites across the US, Argentina, Brazil, South Africa, Germany and Turkey in the phase 2/3 portion of the study
- During the blinded period, 8% of Pfizer recipients and 6% placebo had >6 months follow up post-dose 2
- During blinded and open-label periods combined, 55% of BNT162b2 recipients had ≥6 months follow-up post-dose 2.
- Vaccine efficacy against COVID-19 was 91% (95% CI: 89-93.2%) through up to 6 months of follow-up
- No new safety signals in cohort with 6 month follow up data
- Safety monitoring to continue for up to 2 years

Pfizer Vaccine Waning Immunity

New Preprint

- n=56 healthy volunteers who received 2 doses of Pfizer vaccine demonstrated waning of antibody and T cell immune responses at 6 months
- significant proportion of participants had antibody levels below detection limit

Implications: a 3rd booster shot may be warranted to improve immune responses

[Preprint] Suthar et al. (Sept 2021). Durability of immune responses to the BNT162b2 mRNA vaccine. bioRxiv
FDA Approval

On August 23, 2021 the US Food and Drug Administration formally approved the Pfizer-BioNtech vaccine for prevention of COVID-19 disease in individuals 16 years of age and older.

The vaccine continues to be available for individuals 12-15 years of age through Emergency Use Authorization.
Effectiveness of vaccination incentives

A study in the US compiled information on statewide incentive programs and daily doses administered

- There was no significant difference in vaccination trends between states with and without incentives in any of the 14 days before or after incentives were introduced
- Daily vaccination rates declined in the 14 days post-incentives (351/100,000) compared to 14 days pre-incentives (486/100,000)
- Incentives programs were associated with a non-significant decline in daily vaccination rates of 8.9 per 100,000 individuals
- Small rewards (e.g. $5-$50) or low-probability lotteries may be insufficiently persuasive to unvaccinated individuals

Can the virus still spread after vaccination

**Data from Israel:** After 2 doses, asymptomatic infection was reduced by 90%. The vaccine prevents people from getting infected without symptoms, meaning they are less likely to spread it.

**Data from the UK:** One dose of mRNA vaccines or the AstraZeneca vaccine reduce symptomatic infection by 60-70%. A single dose also prevented spread by 50%.

This evidence and data showing rapid spread of variants in households is another reason to get vaccinated.

Good news for being able to lift restrictions as more Canadians get immunized.

Vaccines cut household COVID-19 transmission by up to a half, English data shows. (2021). Reuters.
Novavax Vaccine

- **Type of vaccine**: Protein based vaccine, 2 doses, 21 days apart
- **A recombinant nanoparticle vaccine** constructed from the full-length (i.e., including the transmembrane domain), wild-type SARS-CoV-2 spike glycoprotein
- **Uses**: baculovirus in moth cells

**Trials**
- Over 20,000 participants: UK and S. Africa
- Ongoing study in Mexico: 16,000 out of 30,000 recruited

**Press release**
- Clinical efficacy in Phase 3 in UK: 89% efficacy
  - 50% of the cases were predominantly the UK variant
- Phase 2b in S. Africa: 60% efficacy
  - 90% of cases the new South Africa variant

**Variants of Concern**
## COVID-19 Vaccine Impact vs. Variants

### Clinical Trial Efficacy* or Real World Effectiveness^ Against Symptomatic Disease or Any Infections (Asymptomatic or Symptomatic)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>D614G (“Ancestral”)</th>
<th>Alpha (B.1.1.7, UK Origin)</th>
<th>Beta (B.1.351, South Africa Origin)</th>
<th>Gamma (P1, Brazil origin)</th>
<th>Delta (B.1617, India origin)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>43-90% more transmissible</td>
<td>Estimated to be 2.5x more transmissible</td>
<td>~1.4-2.2x more transmissible</td>
<td>~26-50% more transmissible</td>
</tr>
<tr>
<td></td>
<td>Estimated mortality risk increased from 2.5 to 4.1 per 1000</td>
<td></td>
<td></td>
<td>~6.4% reinfection probability</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptomatic</th>
<th>Severe disease</th>
<th>Symptomatic</th>
<th>Severe disease</th>
<th>Symptomatic</th>
<th>Severe disease</th>
<th>Any Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>95%* mild+</td>
<td>100%*</td>
<td>87-89% (1 dose: 50%)</td>
<td>97%</td>
<td>72-75%</td>
<td>90-97%</td>
</tr>
<tr>
<td>Moderna</td>
<td>94%* mild+</td>
<td>100%*</td>
<td>Half dose booster, variant booster</td>
<td>= Neutralizing antibody data</td>
<td>= Neutralizing antibody data</td>
<td>= Neutralizing antibody data</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>63%* mild+</td>
<td>100%*</td>
<td>74.6% (1 dose: 50-60%)</td>
<td>95+</td>
<td>10%*</td>
<td>64-81%</td>
</tr>
<tr>
<td></td>
<td>76% (US)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>58%</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>72%*</td>
<td>85%*</td>
<td>?</td>
<td>?</td>
<td>85%</td>
<td>82%*</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>68%</td>
</tr>
</tbody>
</table>

* Efficacy
^ Effectiveness

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**Symptomatic Severe disease Symptomatic Severe disease Symptomatic Severe disease Any Infection**

<table>
<thead>
<tr>
<th>Pfizer</th>
<th>95%* mild+</th>
<th>100%*</th>
<th>87-89% (1 dose: 50%)</th>
<th>97%</th>
<th>72-75%</th>
<th>90-97%</th>
<th>= Neutralizing antibody data</th>
<th>88% (1 dose: 33%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>94%* mild+</td>
<td>100%*</td>
<td>Half dose booster, variant booster</td>
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</tr>
<tr>
<td>AstraZeneca</td>
<td>63%* mild+</td>
<td>100%*</td>
<td>74.6% (1 dose: 50-60%)</td>
<td>95+</td>
<td>10%*</td>
<td>64-81%</td>
<td>58%</td>
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<tr>
<td>Johnson &amp; Johnson</td>
<td>72%*</td>
<td>85%*</td>
<td>?</td>
<td>?</td>
<td>85%</td>
<td>82%*</td>
<td>68%</td>
<td>?</td>
</tr>
</tbody>
</table>
**Delta (B.1.617.2) Variant**

- This variant is responsible for most COVID-19 cases
- This VOC is **more transmissible** (~50% more than the Alpha variant), and *may* lead to more severe disease as indicated by increased risk of hospitalization
- Greatest risk of transmission is among unvaccinated people
- Evidence suggests that people infected with the Delta variant may spread the virus before developing symptoms compared to people infected with other variants (Kang et al., 2021).

- **Number of Spike Mutations:** 11-15
- **Receptor binding domain mutations:** (K417N* - detected in some sequences but not all), L452R, T478K, P681R?
- **Attributes:** Increased transmission, potential reduced Ab efficacy, reduced neutralization by vaccine sera


# Vaccine Effectiveness against Delta Variant

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Effectiveness against emergency department or urgent care visits</th>
<th>Effectiveness against hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>80% (95% CI: 73-85%)</td>
<td>77% (95% CI: 74-80%)</td>
</tr>
<tr>
<td>Moderna</td>
<td>95% (95% CI: 92-97%)</td>
<td>92% (95% CI: 89-93%)</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>60% (95% CI: 31-77%)</td>
<td>65% (95% CI: 56-72%)</td>
</tr>
</tbody>
</table>

Effectiveness among adults ages 18 and older during June-August 2021 when the Delta variant became the predominant strain.

Grannis, S. et al. (2021) Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021. MMWR
Delta (B.1.617.2) Variant

Vaccination & the Delta Variant:

- The vaccines may not be as effective against the Delta variant (as seen with AB data)
  - Single doses of Pfizer and AZ are less effective against symptomatic disease compared to Alpha variant but two vaccines appear to provide strong immunity.
- Different countries are considering a third dose for those who may be more vulnerable.
- Fully vaccinated individuals with the Delta variant can spread the virus to others; however, vaccinated people with the Delta variant appear to be infectious for a shorter period of time than unvaccinated people with this variant.

Dosing Intervals and Mixing of COVID-19 Vaccines
NACI Recommendation on Interchangeability of Vaccines

Interchangeability: you can receive one vaccine product for your first dose and a different vaccine product for your second dose to complete the vaccine series

NACI recommendation:
As of June 17, 2021, the National Advisory Committee on Immunization is recommending that an mRNA vaccine is now preferred as a second dose for individuals who received a first dose of the AstraZeneca vaccine. This recommendation was based on:

- Emerging evidence of a better immune response with this pairing
- Mitigating any potential risk associated with rare blood clotting complications

Individuals who received 2 doses of AstraZeneca are still well protected, especially against new variants like the delta variant.
Mix-and-match vaccination

NACI recommendation on mixing mRNA vaccines (Pfizer and Moderna)

If you received Pfizer or Moderna for your first dose, it is recommended that you receive the same vaccine for your second dose.

If the same vaccine is not readily available, a different mRNA vaccine can be used for the second dose to complete the series.
Vaccine Mixing

Spain: CombivacS trial

- 676 participants who had already received first dose of AZ vaccine.
- 66% of participants received the Pfizer vaccine as their second dose.
- Mix-and-match group showed strong immune response evidenced by high titres of neutralizing antibodies.
- Mild effects were common in group receiving Pfizer vaccine as second dose, similar to homologous vaccine regimes. No severe effects were reported.

Borobia, AM, et al. (2021) Immunogenicity and reactogenicity of BNT162b2 booster in ChAdOx1-S-primed participants (CombiVacS): a multicentre, open-label, randomised, controlled, phase 2 trial. Lancet.
Vaccine Mixing

UK: Com-COV study

- Adults > 50 years (n = 463) randomised across eight groups to receive AZ/AZ, Pfizer/Pfizer, Pfizer/AZ or AZ/Pfizer administered at 28 day intervals
- **Endpoint of interest:** geometric mean ratio of serum SARS-CoV-2 anti-spike IgG levels at 28 days post second dose in homologous (Pfizer/Pfizer, AZ/AZ) and heterologous schedules (Pfizer/AZ, AZ/Pfizer)

**Key findings**

Immune response:
(SARS-CoV-2 anti-spike IgG and neutralizing antibodies)
- AZ/Pfizer was superior to the AZ/AZ schedule
- Pfizer/Pfizer was superior to Pfizer/AZ

- Higher reactogenicity observed overall in heterologous schedules.

Third Dose vs. Booster Dose

Third or additional dose after primary vaccine series:
Administration of an initial vaccine dose when the initial immune response following the first and second doses (series) is likely to be insufficient.

Booster:
Administration of a vaccine dose when the initial sufficient immune response to the primary series (dose 1 and 2) has likely to have waned over time. Whether we will need a booster has not yet been determined.
Booster Dose in the US

The US had planned to start offering COVID-19 booster shots beginning in the Fall. Individuals would be able to receive a booster dose 8 months after the second dose of an mRNA vaccine.

As of September 23rd, the FDA has authorized booster shots of the Pfizer vaccine for people over 65 and those who are in high risk of developing COVID-19.

The CDC ACIP is currently recommending boosters for older adults and younger people at high risk for the disease.
Vaccine side effects/Expected immune response
## Side Effect Comparisons

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Shingrix</th>
<th>Moderna</th>
<th>Pfizer-BioNTech</th>
<th>Johnson &amp; Johnson</th>
<th>Oxford- AstraZeneca</th>
<th>Flucelvax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Pain</td>
<td>88.4%</td>
<td>90.1%</td>
<td>77.8%</td>
<td>58.6%</td>
<td>54.2%</td>
<td>45.4%</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7%</td>
<td>9.0%</td>
<td>5.9%</td>
<td>9.0%</td>
<td>N/A</td>
<td>13.4%</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5%</td>
<td>12.6%</td>
<td>6.3%</td>
<td>7.0%</td>
<td>N/A</td>
<td>11.6%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9%</td>
<td>61.3%</td>
<td>37.3%</td>
<td>39.1%</td>
<td>48.6%</td>
<td>15.4%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57%</td>
<td>67.6%</td>
<td>59.4%</td>
<td>43.8%</td>
<td>62.3%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6%</td>
<td>62.8%</td>
<td>51.7%</td>
<td>44.4%</td>
<td>57.5%</td>
<td>18.7%</td>
</tr>
<tr>
<td>Chills</td>
<td>35.8%</td>
<td>48.3%</td>
<td>35.1%</td>
<td>2%*</td>
<td>31.9%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8%</td>
<td>17.4%</td>
<td>15.8%</td>
<td>12.8</td>
<td>33.6%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Overall Grade 3</td>
<td>5.2%</td>
<td>4.1%</td>
<td>1.5%</td>
<td>0.54%</td>
<td>N/A</td>
<td>0.45%</td>
</tr>
<tr>
<td>Overall incidence of SEs</td>
<td>48%</td>
<td>46%</td>
<td>36%</td>
<td>27%</td>
<td>N/A</td>
<td>15%</td>
</tr>
</tbody>
</table>
What should I remember from the side effects of this vaccine?

- 8 in 10 people complain of sore arm
  - BUT only 1 in 100 call that soreness severe
- 5 in 10 people complain of fatigue and headache
  - BUT only 1 in 10 need Advil or Tylenol
- Some reaction to the vaccine is to be expected, but the majority are mild and easily manageable at home
Side effect profile of the Pfizer-BioNTech vaccine at the population level

Study on safety of Pfizer vaccine in Israel including close to 900,00 vaccinated individuals and 233,392 people infected with SARS-CoV-2 >16 years of age

- The Pfizer vaccine was not associated with an elevated risk of most of the adverse events examined
- The Pfizer vaccine was associated with an excess risk of myocarditis (1-5 events per 100,000 persons). However, the risk of myocarditis was substantially increased after contracting COVID-19. (Risk ratio for myocarditis was 3.24 after vaccination and 18.28 after COVID-19)

SARS-CoV-2 infection was associated with a significantly increased risk of myocarditis, pericarditis, arrhythmia, deep-vein thrombosis, kidney injury, pulmonary embolism, myocardial infarction, intracranial hemorrhage, and thrombocytopenia compared to those who received the COVID-19 vaccine.

Regulatory Systems & Surveillance
Vaccine Development & Approval in Canada

**VACCINE DEVELOPMENT**

- **EXPLORATORY**
  - Scientists develop a potential vaccine

- **PRECLINICAL**
  - Scientists conduct lab and animal studies before testing on humans

- **CLINICAL TRIALS**
  - **PHASE 1**
    - 10s of volunteers
    - Is the vaccine safe?
    - What is a safe dose?
    - Are there any side effects?
  - **PHASE 2**
    - 100s of volunteers
    - How well does the vaccine work?
    - Is it safe on a larger number of people?
    - Safest and most effective dose?
  - **PHASE 3**
    - 1000s of volunteers
    - Does the vaccine prevent disease?
    - What are the side effects?

- **APPLICATION**
  - Manufacturer submits application to Health Canada for review

**REVIEW & APPROVAL**

- **SCIENTIFIC REVIEW**
  - Teams of Health Canada experts conduct a thorough and independent review of all vaccine data

- **APPROVAL**
  - Health Canada approves a vaccine if it is safe, it works, it meets manufacturing standards, and the benefits outweigh the risks

- **DISTRIBUTION**
  - Government coordinate the purchase, logistics and distribution of vaccines across Canada

- **VACCINATION**
  - All Canadians have access to the vaccine

- **ONGOING MONITORING & REVIEW**
  - Continuous monitoring and review to confirm the safety of the vaccine, and that benefits outweigh the risks
What’s missing after Rapid Vaccine Development and Regulatory Approval?

**Safety ✓ ✓ ✓**
- New adverse events very unlikely to emerge > 6 weeks after vaccine administration

**Efficacy ✓ ✓ ✗**
- Longer term duration of protection (>2-3 months) not known
- **But** >90% short term efficacy could not be ignored during raging pandemic

**Populations ✓ ✗ ✗**
- Not all populations studied e.g., *children*, pregnant/breastfeeding women, immunocompromised person
"Bridging" Clinical Trials

**Bridging trial**
- Dose
- Immune Response
- Safety
- +/- efficacy
- Smaller sample size e.g., 3000

If safety and immune response in smaller trial similar to larger trial

Then clinical efficacy of main trial is extrapolated (bridged) to smaller trial and similar vaccine benefit is expected

**Main clinical trial(s)**
- Phases 1, 2, 3
- Dose
- Dose interval
- Immune Response
- Safety
- **Efficacy to prevent infection**
- Very large sample size in phase 3 e.g., 30,000

If safety and immune response in smaller trial similar to larger trial

Then clinical efficacy of main trial is extrapolated (bridged) to smaller trial and similar vaccine benefit is expected
Adverse Effects Following Immunization (AEFI) in Canada

• Vaccines on the market in Canada are monitored continuously
• An AEFI is a medical incident that may occur following immunization
  • AEFI’s are reported and reviewed by PHAC
• The Canadian Vaccine Safety Network (CANVAS) assesses vaccine safety immediately after implementation of vaccine campaigns
AEFI Monitored in Real Time: Canada

WHAT YOU NEED TO KNOW up to and including September 24, 2021

No new safety signals have been identified in Canada (three continue to be monitored)

211 total new AEFI reports since last update (112 new non-serious and 99 new serious)

17,079 total AEFI reports (0.031% of all doses administered)

12,616 total AEFI reports were non-serious (0.023% of all doses administered)

4,463 total AEFI reports were serious (0.008% of all doses administered)

55,519,317 total doses administered as of Sep 24, 2021

Special Circumstances & Populations
COVID-19 Vaccine Contraindications

- Severe allergic reaction after previous administration of these or any mRNA vaccines.
- Proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container, including polyethylene glycol and polysorbate.


Precautions for COVID-19 vaccines

• New NACI statement recommends that there be no waiting period between COVID vaccine and other vaccines. They can be administered simultaneously.
COVID-19 vaccines may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines.

- NACI’s previous precautionary recommendation to space out COVID-19 vaccine administration ≥28 days before, 14 days after other vaccines no longer necessary.

- No specific safety concerns have been identified when routine vaccines were given at same time or within days of COVID-19 vaccine, however possibility of increased temporary side effects.

- COVID-19 and influenza vaccine same-visit, different injection sites administration is preferred.
Influenza and COVID-19 vaccination

Concomitant vaccination with both influenza and COVID-19 vaccines was found to be safe in adults

Findings:
- Pre-print of a large randomized controlled trial in UK (n = 679) followed adults in 6 cohorts randomized to 2 main groups: COVID-19 vaccine+influenza vaccine or COVID-19 vaccine+placebo
- Median age ranged from 51 - 69 years for each cohort
- No new safety concerns with concomitant vaccination
- Most reactions were mild or moderate and systemic reactions were similar between groups
- The immunogenicity of both vaccines was preserved

Interpretation:
Vaccination with both COVID-19 and influenza vaccines over the immunization season may safely confer protection from both viruses for those in need

[Preprint] Lazarus et al. (Sep 2021). The Safety and Immunogenicity of Concomitant Administration of COVID-19 Vaccines (ChAdOx1 or BNT162b2) with Seasonal Influenza Vaccines in Adults: A Phase IV, Multicentre Randomised Controlled Trial with Blinding (ComFluCOV). The Lancet.
Vaccination for those with previous COVID-19 infection

- Safe for those with previous COVID-19 infection but not while they are infectious
- A 90 day period is recommended for:
  - People who have received convalescent plasma
  - People who have received antibody treatment specific for COVID-19

Dosage for those with previous COVID-19 infection

- Cohort of 1,090 individuals who received the Pfizer-BioNTech vaccine
- Individuals with confirmed prior infection were compared to those without prior evidence of infection.
- Individuals who had prior COVID-19 infection (n=35) had similar protection after one dose of vaccination compared to those who received two doses of the vaccine and had no prior infection (n=228)

Protection for those with prior COVID-19 infection

• Retrospective cohort study of 150,325 patients suggested those with prior COVID-19 infection had low rates of reinfection but protection is not as good as vaccination

• Protection due to previous infection was 81.8% and against symptomatic infection was 84.5%

**Natural Immunity vs. Vaccination-acquired Immunity**

*Effectiveness against Delta Variant*

- Preprint, retrospective observational study in Israel
- Compared rates of breakthrough infection in vaccinated individuals with rates of reinfection in unvaccinated individuals
- Natural immunity conferred lasting protection against reinfection with the Delta variant
- However, **unvaccinated individuals were twice as likely to contract the infection again**, compared with those who had been infected and had received one dose of the Pfizer vaccine

COVID-19 vaccination in people with cancer

UK: 54 healthy controls and 151 mostly elderly patients with solid and haematological malignancies

- Three weeks after one dose of the Pfizer vaccine, they measured antibody-seroconversion, T cell responses and neutralizing antibodies (immune efficacy)
- 13% of people with blood cancer showed neutralizing antibody response
- Even patients with blood cancers NOT undergoing therapy had significantly reduced antibody responses
- 39% of solid cancer patients
- Solid cancer patients immune efficacy boosted to 95% with second dose
- Compared to 97% healthy people antibody response
COVID-19 vaccination in people with cancer

233 patients, used a validated antibody assay against spike protein, completed TWO doses of vaccine (mRNA or J&J)

- Overall 94% seroconversion rate
- 98% seroconversion in solid tumors
- 85% seroconversion in hematological malignancies
- 73% seroconversion stem cell transplants

Lower IgG titres with J&J vs mRNA (Moderna higher than Pfizer)

Prior COVID diagnosis had heightened antibody responses (22 patients)
COVID-19 vaccination in people with transplants

658 SOT recipients

Semi-quantitative serologic assays, Roche

Three weeks after one dose of the Pfizer vaccine, compared to 97% healthy people antibody response:

- 15-17% of SOT recipients mounted a positive antibody response after one dose mRNA vaccine
- 54% of patients with solid organ transplants showed antibody response
COVID-19 vaccination in people with transplants

Case series of 30 SOT recipients receiving a third dose of vaccine against COVID-19 (J&J, Moderna or Pfizer/BioNTech)

All had previously received two doses of an mRNA vaccine

14-17 days after the third dose:

- Of 6 patients that had low-positive antibody titers after two doses, all had high-positive antibody titers
- Of 24 patients with negative antibody titers after two doses, 6 (25%) had high-positive antibody titers, 2 (8%) had low-positive antibody titers and 16 (67%) remained negative

Third Dose for Immunocompromised People

**Immunocompromised people:** Defined as people with a medical condition(s) or people receiving treatment associated with compromise to the immune system.

Immunocompromised people
- Are more likely to get severe illness from COVID-19
- Are at higher risk for prolonged SARS-CoV-2 infection and shedding, viral evolution during infection and treatment
- Have lower Ab/neutralization titers to SARS-CoV-2 variants compared to non-immunocompromised people
- Are more likely to transmit to household contact
- Are more likely to experience breakthrough infection (40-44% of hospitalized breakthrough cases are immunocompromised people in one US study).

Other considerations
- Lower vaccine effectiveness (59-72%) among immunocompromised people vs. non-immunocompromised people after second dose (over 90%)
- Among immunocompromised people who had no detectable antibody response to an initial mRNA vaccine series, 33-50% developed an Ab response to an additional (third) dose. No serious adverse events reported after administration of the third dose and no acute rejection episodes occurred.
NACI Recommendation on Additional Dose for Immunocompromised People

- Moderately to severely immunocompromised individuals who had previously received a primary COVID-19 vaccine series should be offered an additional dose of an authorized mRNA COVID-19 vaccine

- Moderately to severely immunocompromised individuals who have not yet been immunized, should receive a primary series of three doses of an authorized mRNA vaccine

National Advisory Committee on Immunization (NACI) rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series. September 10, 2021
Albertans with specific conditions are now eligible to receive a follow-up vaccine a minimum of eight weeks after their second dose. (A similar program already exists in Ontario).

Conditions that qualify include:

- Transplant recipients including solid organ transplant and hematopoietic stem cell transplants
- Individuals with chronic kidney disease who are receiving regular dialysis
- Individuals in active cancer treatment (chemotherapy, immunotherapy or targeted therapies) excluding those receiving only hormonal therapy, radiation therapy or surgery
- Individuals on medication for autoimmune diseases including rituximab, ocrelizumab and ofatumumab

Seniors living in congregate care are also eligible to receive a third dose. This cohort will be eligible to receive their third dose approximately five months after their second dose.
Can these vaccines be given to pregnant and breastfeeding women?

Patients who are pregnant or breastfeeding should be offered vaccination at any time if they are eligible and if no contraindications exist.

When planning conception, complete both doses of vaccination before pregnancy.

Pfizer-BioNTech in pregnant individuals

BNT162b2 vaccination was associated with a lower risk of SARS-CoV-2 in pregnant women compared to no vaccination

- Large retrospective observational study including pregnant individuals in Israel (n = 15,060)
- Pregnant women vaccinated between December 19, 2020 - February 28, 2021 were matched to unvaccinated women
- Mean age: 31.1 years (SD: 4.9 years)

**Results:**

118 vaccinated women and 202 unvaccinated women were infected with SARS-CoV-2 during a median follow-up of 37 days.

Cumulative incidence was 1.85% among those vaccinated and 3.90% among unvaccinated women. COVID-19-related hospitalization rates were 0.2% in vaccinated women and 0.3% in unvaccinated women

**Estimated vaccine effectiveness of 78%**

Goldshtein et al. (July 2021). Association Between BNT162b2 Vaccination and Incidence of SARS-CoV-2 Infection in Pregnant Women. JAMA.
Pfizer-BioNTech in pregnant individuals

- Risk reduction rose over time post-vaccination (measured by time-varying covariate)
- Among those infected, there was no significant difference in incidence of symptomatic infection between the groups
- No severe adverse events
- Most common side effects were headache, general weakness, unspecified pain, stomach ache, dizziness, rash

There were no differences in preeclampsia, intrauterine growth restriction, infant birth weight, stillbirth, miscarriage, maternal death or pulmonary embolism in the vaccinated compared to unvaccinated groups.

Goldshtein et al. (July 2021). Association Between BNT162b2 Vaccination and Incidence of SARS-CoV-2 Infection in Pregnant Women. JAMA.
Putting Vaccine Risks vs Disease in Perspective for Pregnant Women

INTERCOVID STUDY
Multinational prospective, longitudinal cohort study
- n = 656 women with lab confirmed COVID-19; n = 1424 women without COVID-19

Women with COVID-19 diagnosis had
- Higher rates of pregnancy-induced hypertension
  Preeclampsia/eclampsia
- Infections requiring antibiotics
- Greater risk of admission to ICU and referral to higher level care

Pregnant women with COVID-19 were 22 times more likely to die compared to women without COVID-19

The risk of severe neonatal morbidity index was higher in neonates born to women with a COVID-19 diagnosis

COVID-19 infection poses serious risks to the health of pregnant individuals and their children.

USA Data V-Safe: USA (May 28, 2021)
• 121,244 pregnant women
• No increase in reactogenicity, adverse events
• 4,218 completed pregnancies – no increase in miscarriage, preterm, stillborn, congenital anomalies vs usual population rates
• V-safe pregnancy registry with 5000+ women
• Interim data: 827 completed pregnancies
• Adverse outcomes NOT increased in vaccinated pregnant women
What about fertility?

- Early rumor that antibodies against the spike protein will also target a protein in the placenta of pregnant mothers, syncytin-1.
- There is no data suggesting that these antibodies will affect syncytin-1, as they are different proteins.
- If this was true, you would expect COVID-19 infection to be associated with increased rates of miscarriage.
- Whereas COVID-19 in pregnant women leads to severity and ICU admissions, it is NOT associated miscarriages.
- Recent study that looked at placentas of vaccinated and unvaccinated women: no damage from the vaccine to the placenta (no placental histopathological lesions)
COVID-19 vaccination in children

The Pfizer BioNTech and Moderna vaccines have been authorized by Health Canada for kids 12 and older.

The Pfizer vaccine was found to be 100% effective in preventing COVID-19 in a phase 3 trial (n = 2,260) conducted in children ages 12-15 years old.
- They began dosing the first children ages 6 months - 12 years in a clinical trial in late March.

The Moderna vaccine trial (TeenCOVE study) showed the vaccine 100% effective in preventing COVID-19 after two doses (n = 3,700).

AstraZeneca, Novavax & Johnson & Johnson are also conducting clinical trials in children.

Why do children need to be immunized?

**To protect their health:** While COVID-19 infection is usually milder in adults, some kids can become very sick and develop complications or long-lasting symptoms.

**To prevent virus transmission:** Children can transmit the virus to family members and friends even if they are asymptomatic.

**To protect the broader community:** Each child or adult infected provides a chance for the virus to mutate and new variants to develop.

**To return to in-person learning:** To return to school with fewer restrictions, it is important children receive the vaccine. Some schools may require your child to receive a COVID-19 vaccination.
COVID-19 vaccination in children: Pfizer-BioNTech

Efficacy

- Immune response to this vaccine in SARS-CoV-2 50% neutralizing titers in 12-15 year olds exceeded the immune response seen in young adults
- **100% efficacy** was observed for those without evidence of prior infection and for those with evidence of prior infection (95% CI 75.3% to 100.0%)
- Phase 3 study ongoing to collect information on the long-term safety and efficacy of the vaccine.

COVID-19 vaccination in children: Pfizer-BioNTech

Safety

- 98.3% had ≥1 month of follow-up, & 57.9% had ≥2 months of safety follow-up after Dose 2
- Overall, solicited adverse reactions (AR), within 7 days after any dose, included (frequency in %):
  - pain at injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), and injection site redness (8.6%)
  - Most reactions were mild or moderate in severity. Severe solicited adverse reactions were reported in ≤1.5% for local ARs and in ≤3.5% for systemic ARs.
- Observed unsolicited AEs did not suggest any serious safety concerns for adolescents 12 to 15 years of age.
- Adverse events of special interest (AESI): lymphadenopathy (0.8% vaccines, 0.2% in the placebo); no cases of Bell's palsy, thrombocytopenia, DVT, anaphylaxis

COVID-19 vaccination in children: Moderna

- More than 3700 adolescent participants, randomized to either receive vaccine (two-thirds) or a placebo (one-third)
- Vaccine efficacy rate of 93% after the first dose and 100% after second dose, with no reported cases of COVID-19 among vaccinated participants.
- The most common side effects include injection site pain, headache, fatigue, myalgia and chills
- No serious safety signals
Myocarditis in kids post second dose of vaccine?

- Case series of 7 patients published, teens 14-19
- All male
- All developed symptoms 2-4 days after second dose
- Primary symptom: chest pain (all) with 5/7 reporting fever
- All of the teens had elevated troponin levels and abnormal electrocardiogram and cardiac MRI results
- None fit criteria for MIS-C, 6/7 no evidence of previous COVID infection
- Treatment: 6/8 had NSAIDS, 4/7 IVIG and steroids

All recovered
Myocarditis following mRNA COVID-19 vaccination in the US

- The CDC has reported increasing reports of myocarditis and pericarditis after mRNA vaccination
- Observed reports > expected cases after dose 2 for individuals 12-39 years old (excess cases per million second doses = 14.4 for Pfizer and 19.7 for Moderna)
- Most cases occurred within 7 days following vaccination and were most commonly observed after dose 2
  - 12-15y: 20.9 cases per million 2nd doses (Pfizer)
  - 16-17y: 34.0 cases per million 2nd doses (Pfizer)
  - 18-24y: 18.5 cases per million 2nd doses (Pfizer); 20.2 cases per million 2nd doses (Moderna)
- Myopericarditis reports after dose 2 are predominantly young males
- **Most patients have had full recovery of symptoms**

Risk of Myocarditis: COVID-19 vs vaccines

- MMWR report (CDC). Hospital records from COVID-19 patients (1.5 million) vs non COVID-19 patients (35 million) Mar2020-Jan2021
- The risk for myocarditis among patients with COVID-19 was nearly **16 times higher** (0.146% for COVID-19 patients vs 0.009% in non-COVID-19 patients)
- The risk among COVID-19 patients was most pronounced in those <16 years old who had a **37-fold increased risk of myocarditis**
- The risk of myocarditis is far higher after COVID-19 compared to vaccination
  - Compared to a recent Israeli study, **Risk ratio 3.2** after vaccination **vs. 18.3** after SARS-CoV-2 infection
  - In line with current recommendations stating **the benefits of COVID-19 vaccinations outweigh the risks of vaccine-caused myocarditis** especially when community transmission is high


NACI recommendation on the use of Pfizer and Moderna mRNA vaccines in adolescents 12-17y

- mRNA vaccines are very effective and **have a favourable benefit versus risk profile in adolescents 12+**

- A complete series with an mRNA vaccine should be offered to adolescents 12-17y without contraindications

- People who experienced myopericarditis after their first dose of an mRNA vaccine should wait to get their second dose until more information is available

- Individuals with a history of myocarditis unrelated to mRNA vaccination should consult their clinical team

- People previously diagnosed with myocarditis who are no longer being followed by a medical professional for heart issues should receive the vaccine

National Advisory Committee on Immunization (NACI) rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series. September 10, 2021
Pfizer and Moderna mRNA vaccines in adolescents 12-17y

- Higher rates of cases of myocarditis/pericarditis have been reported after vaccination with Moderna compared to the Pfizer vaccine - verification of the difference is ongoing

- On Sept 29 2021, Ontario issued preferential recommendation on the use of Pfizer-BioNTech vaccine for individuals aged 18-24 years out of an abundance of caution
Consent & Vaccination for Mature Minors

- In Canada, we respect the rights of teenagers (mature minors) to make decisions including those to protect their own health

- If a teen has the capacity to consent to COVID-19 vaccination, parental consent is not necessary and parents do not have standing to be the decision makers in place of their teen
How to communicate the safety

• Brisk immune response
• 9/10 kids had sore arm, 7/10 had headache or fatigue, 5/10 had chills, 1 in 4 had fever
• No bell’s palsy, DVT, thrombocytopenia or anaphylaxis
Press release: Pfizer vaccine in children 5-11 years of age

- Pfizer and BioNTech announced the vaccine is safe and highly effective in children aged 5-11 using a two-dose regime of 10 µg, given 21 days apart.
- The vaccine elicited neutralizing antibodies (nAb) to a level comparable to the 16-25 age group.
  - 5-11y nAb geometric mean titer 1197.6 (95% CI, 1106.1, 1296.6)
  - 16-25y nAb geometric mean titer 1146.5 (95% CI: 1045.5, 1257.2)
- The vaccine was well-tolerated, with side effects comparable to the 16-25 age group.
What is next for Trials in Kids and Authorization

- Currently Pfizer-BioNTech and Moderna vaccines are authorized for teenagers 12 to 18 in Canada
- Pfizer-BioNTech has applied to Health Canada authorization for a vaccine in children aged 5-11y (early October 2021)
- Moderna expects results from 6 month-11 year old studies in early fall (KidCOVE)
- Pfizer-BioNTech expects results from 6 month-5 year old studies in the fourth quarter
# Vaccine Trials in Younger Kids

<table>
<thead>
<tr>
<th>Vaccine Clinical Trial</th>
<th>Trial Details</th>
<th>Results Timeline</th>
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</table>
| Pfizer NCT04816643     | • Recruiting; 6 mos - 11 y/o in 3 age groups (5-11y; 2-4y; 6-23m, in sequence); n=4644  
  • Phase 1 is dose finding (10/20/30 mcg mRNA)  
  • Phase 2/3 is safety, immunogenicity, clinical efficacy - bridging trial | Results for 6m-5y expected in the fourth quarter |
| Moderna NCT04796896    | • Recruiting; 6 mos - 11 y/o in 3 age groups (6-11y; 2-5y; 6-23m, in sequence); n=13275  
  • Phase 1 is dose finding (25/50/100 mcg mRNA)  
  • Phase 2/3 is safety immunogenicity, clinical efficacy - bridging trial | Results for 6-11y expected later than Pfizer |

*It is estimated that potentially vaccines will be available to kids under 12 years of age by the end of October*
COVID-19 cases, severity and children

- Kids make up over 20% of COVID-19 cases in most jurisdictions in Canada and similarly in the USA
  - In USA, more than 3.78M kids have been infected and 303 have died

- COVID-19 is in the top 10 causes of death for kids currently

- In Canada, kids make up 2% of hospitalisation
Long-term effects of vaccine

- Vaccine side effects occur within 6 weeks.
- Protection seems to last a minimum of 6 months.
- It is understandable to worry about long term effects, but so far and from previous vaccines we do not have any evidence that effects would be noted longer than 6 weeks post vaccine.
Long-term effects of COVID-19

- We are starting to understand more about COVID-19 (the disease) long term effects:
  - Long covid or post covid syndrome, has been described in as many as 1 in 4 adults who had COVID (including those who had mild disease)
  - Most of these people are previously very healthy and fit
  - We are seeing PCS being described more and more in children! Long term effects are: organ damage, shortness of breath, decreased exercise tolerance, extreme fatigue, debilitating headaches, brain fog
  - More than 50% of adults with PCS, IMPROVE after they have their vaccine (this is a correlation, not causation, but reason to hope!)

What about allergies?

- Anaphylaxis Pfizer: 4.7 cases/million doses; Moderna: 2.5 cases/million doses
- 82% after 1st dose, 79% history of allergies, 32% previous anaphylaxis
- History of anaphylaxis to other allergens is NOT a contraindication to the mRNA vaccine but it is recommended that such people wait 30 mins post vaccine administration (vs 15 mins).
- 90% of anaphylaxis happened within 30 mins of the vaccine administration.
- Other vaccines – rate of anaphylaxis ~1-10/million doses
- Polyethylene glycols (PEGs) may be main allergen of concern (in Pfizer & Moderna vaccines)
Long-term protection

Vaccine side effects occur within 6 weeks.

We need longer-term follow up to understand how long you are protected. Protection occurs after each dose and is the best **after the second dose**.

The Phase III Pfizer clinical trial has shown the vaccine continues to provide strong protection six months after the second dose.

  • If you have already been infected with COVID-19, the vaccine will likely help you stay immune much longer.
Vaccine Passports

What are they?
• Proof of immunization status in order to participate in certain activities
• Two main cases in which they may be used: international travel and domestic use

International travel - Travelers may require proof of full vaccination series to:
• Enter certain countries
• Avoid quarantine when reaching their travel destination or returning home to Canada.

Domestic use - Proof of vaccination to:
• Work in certain settings, particularly those with people at high risk for infection
• Participate in activities like sports events, concerts, crowded gatherings etc.
Vaccine Passports (AB)

Proof of vaccination program

- As of Sept. 20 Albertans 12+ are required to provide government-issued proof of vaccination or a negative COVID-19 test to enter businesses and social events.

International travel

- Some jurisdictions outside of Canada may not accept visitors who have been vaccinated with AstraZeneca or who have received mixed doses.
- Additional mRNA doses will be made available at least 28 days after a second dose to Albertans who are travelling to a jurisdiction that does not accept visitors who have been vaccinated with AstraZeneca or mixed doses.
Mitigating Pain at Administration
4 Key Groups to First Receive COVID-19 Vaccinations

Based on the NACI’s recommendation

- Those at risk of severe illness and death from COVID-19 (i.e. advanced age, high risk health conditions)
- Individuals most likely to transmit COVID-19 to those at high risk (i.e. household contacts of those at high risk, healthcare providers at assisted living facilities)
- Those who are essential to maintaining COVID-19 response or contribute to essential services (first responders, healthcare workers, others who cannot work remotely)
- Those at high risk of infection based on living or working conditions where infection could lead to disproportionate consequences (i.e. Indigenous communities)
Pain is an important factor in vaccine uptake.

- Meta-analysis, 35 studies included in the final analysis.
- Avoidance of influenza vaccines related to needle fear in influenza vaccine occurred in:
  - 16% of adult patients.
  - 27% of hospital employees.
  - 18% of workers at long term care facilities.
  - Important factor in COVID-19 vaccines as they are reported to have more pain and injection site reactions than influenza vaccines.
5 Commitments to Comfort Principles

1. Create a Comfort Plan
   a. Ask if the person being vaccinated has preferences or concerns with their comfort management and offer choice when able (e.g., preferred pain management strategies, comfort positions).

2. Use Numbing Cream

3. Use Simple, Positive Language
   a. This makes it more likely a person will return for vaccinations in the future.
   b. Communicate in a way that reduces fear and distress prior, during, and after the immunization.
      i. Avoid saying “it will be over soon” or “it will be OK” or words that amplify fear or pain, for example “this is a really painful shot”.
      ii. Talk about what is going well/went well, for example “you did a great job relaxing your arm”
      iii. After the immunization is over tell the individual “they did well”, or “by doing this today you are saving lives/keeping yourself and others safe.

4. Use Comfort Positions: Upright comfortable position
   a. If they feel faint or has a history of fainting with needles:
      i. encourage alternating muscle tension and relaxation (for 15 seconds increments), or have them lie down.

5. Shift Attention
   a. Examples: using electronics (music/games), slow deep breathing, asking ‘small talk’ friendly questions, or focusing on a picture or poster on the wall.
Vaccine Acceptance & Hesitancy
Concerns and hesitancy are natural.

Hesitancy doesn’t stem from ignorance.
Key Factors

- Demographic
- Geographic
- Psychographic
HOW DOES CANADA VACCINE ACCEPTANCE COMPARE TO THE WORLD

A global survey with around 14,000 from 19 countries

Nature Medicine, 2020

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<tr>
<th>Country</th>
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<td>65.23</td>
</tr>
<tr>
<td>Nigeria</td>
<td>65.22</td>
</tr>
<tr>
<td>France</td>
<td>58.89</td>
</tr>
<tr>
<td>Poland</td>
<td>56.31</td>
</tr>
<tr>
<td>Russia</td>
<td>54.85</td>
</tr>
</tbody>
</table>
WILLINGNESS TO BE VACCINATED

If a vaccine against COVID-19 became available to you, would you get vaccinated or not?

Source: Angus Reid, 2020
WILLINGNESS TO BE VACCINATED ACROSS CANADA

COVID-19 vaccine: Percentage unwilling to get vaccinated or unsure

Source: Angus Reid, 2021
If a vaccine against COVID-19 became available to you, what would you do?

- **NOT get a vaccine**
  - No Concern: 14%
  - Slightly Concerned: 20%
  - Concerned: 4%
  - Very Concerned: 1%

- **Eventually get a vaccine, but wait a while first**
  - No Concern: 1%
  - Slightly Concerned: 9%
  - Concerned: 4%
  - Very Concerned: 1%

- **Get vaccine ASAP**
  - No Concern: 9%
  - Slightly Concerned: 19%
  - Concerned: 7%
  - Very Concerned: 38%

- **Unsure**
  - No Concern: 1%
  - Slightly Concerned: 13%
  - Concerned: 45%
  - Very Concerned: 3%

Source: Angus Reid, 2020
Vaccine Hesitancy in Ethnic Communities

<table>
<thead>
<tr>
<th>Community</th>
<th>Vaccine Hesitancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>47%</td>
</tr>
<tr>
<td>Indiginous</td>
<td>38%</td>
</tr>
<tr>
<td>Middle Eastern</td>
<td>35%</td>
</tr>
<tr>
<td>Latinx</td>
<td>32%</td>
</tr>
<tr>
<td>South Asian</td>
<td>30%</td>
</tr>
<tr>
<td>East Asian</td>
<td>28%</td>
</tr>
<tr>
<td>White</td>
<td>25%</td>
</tr>
</tbody>
</table>
Vaccine hesitators in Canada tend to be:

- 18-34 years old
- A visible minority
- Have children
- Have a household income <$40k/yr
- Unsure of vaccine safety

Leger, 2021 and Garretson, 2020
Racialized Canadians have suffered disproportionately during the pandemic and have higher distrust of vaccines.

Histories of trauma related to medical experimentation and discrimination has earned the government and biomedical institutions distrust from minority communities.
Key Factors

- Demographic
- Geographic
- Psychographic
Where are we at in Alberta?

CBC Poll: 20% wait and see, 14% refused

- Factors contributing to vaccine hesitancy:
  - Populists
    - Trusting non experts, strong leadership over debate and deliberation, support for referendums and pebicites, believing politicians are removed from their electorate
  - Lower level of education

The Road Ahead: CBC Poll May 14, 2021: [CBC poll: Results give us an idea of who the vaccine hesitant in Alberta really are](https://www.cbc.ca) | CBC News
Health Care Workers (HCW) Can Be Vaccine Hesitant Themselves

Rates of vaccine hesitancy in healthcare workers mirrors that of the rest of the population

- 76% are strong supporters, 17% are ambivalent, and 7% oppose the vaccine
- 49% of personal support workers were hesitant about the COVID-19 vaccine
- Healthcare workers who are lower wage, racialized, female and part time workers were more likely to be vaccine hesitant.
Healthcare Workers’ Vaccine Hesitancy
Declining confidence over time

If a safe COVID-19 vaccine becomes available and is recommended, would you get it?

Insights from COSMO

- The number of respondents reporting that they agree that they will get a safe COVID-19 vaccine has declined gradually since the beginning of the pandemic. 67% of healthcare workers agreed in Wave 3 but this percentage has declined to 58% by Wave 9.

- Healthcare workers have also been slightly less likely to agree that they would get an effective COVID-19 vaccine since Wave 3 compared to non-healthcare workers. 63% agreed in Wave 3, while only 51% agree in Wave 9.

*Note that two studies use different wording and scales for this question:

- COSMO: “If a safe COVID-19 vaccine becomes available and is recommended, would you get it?” (7-pt scale)
- Deep dive study: “If a COVID-19 vaccine became available and is recommended for me, I would get it.” (5-pt scale)
- Data points based on small sub-sample size. Statistically significant but not generalizable beyond sample (see Annex)
32 cross sectional survey-based studies
5/32 Canadian Studied vaccine acceptance

HCW and Hesitancy Crawshaw et al. The Ottawa Hospital Research Institute. March 2021

- Acceptance rates ranged from 57% - 80%
- Negative beliefs about COVID-19 vaccine safety, efficacy, and necessity were associated with lower vaccination acceptance
- Lower vaccination acceptance rates were found among non-physician HCWs (e.g., nurses, PSW)
- History of accepting influenza vaccination were more accepting of COVID-19 vaccines.
Key Factors

Demographic

Geographic

Psychographic
CONFIDENCE  CONVENIENCE

COMPLACENCY

COLLECTIVE RESPONSIBILITY

CALCULATION
Facets of the Problem

**TRUST**

**PAIN POINTS**
- Misinformation
- Changing messages
- Media and social media distortion
- Distrust of government
- Uncertainty of decisions

**OPPORTUNITIES**
- Frame vaccination as essential BECAUSE OF mistrust of institutions (i.e. “take matters into your own hands, protect yourself”)

**CONCERN**

**PAIN POINTS**
- Pandemic fatigue
- Low or no perceived risk
- Hopelessness
- Brand concerns: side effects outweigh risk of COVID

**OPPORTUNITIES**
- Encouraging individual agency
- Increasing concern with COVID

**CONVENIENCE**

**PAIN POINTS**
- Supply vs. demand
- Lack of clarity around availability and priority
- Hassle of waiting lists, phone numbers, scheduling
- “Healthcare apathy” (i.e. dislike of doctors, paperwork)

**OPPORTUNITIES**
- Streamline process and incentivize early registration
- Hyper-target message/audience based on clinics and availability
Discourse Themes

Vaccine discourse on social media: a guide to the narratives

Source: "COVID-19 Vaccine Rhetoric on Twitter: A Report on April 2 2021"
Jean-Christophe Boucher, Henry Smith, Abbas Badami

Source: First Draft News,
Encompassing factors
Multilevel social and structural constraints, affordances, and experiences over time influencing vaccination acceptance and uptake

Capability
Knowledge/Awareness
Skills
Memory/Attention/Decisions

Opportunity
Social influences
Context & Resources

Motivation
Beliefs about consequences
Beliefs about capabilities
Goals
Role & identity
Optimism
Reinforcement
Emotion

Vaccination intention
Behavioural regulation

Getting vaccinated

Diagram showing the relationships between capability, opportunity, motivation, vaccination intention, and behavioural regulation leading to getting vaccinated.
YOU DESERVE PROTECTION
Roll up your sleeves, get vaccinated

VISIT WWW.PROTECTCANADA.ORG AND BOOK YOUR APPOINTMENT
What do we know about VH and vaccine communication?
Is the Messenger More Important Than the Message?

<table>
<thead>
<tr>
<th>Most Trusted Messenger</th>
</tr>
</thead>
<tbody>
<tr>
<td>83% - My doctor, nurse or pharmacist</td>
</tr>
<tr>
<td>13% - Celebrities</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Most Convincing Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>72% - Protecting yourself and your loved ones</td>
</tr>
<tr>
<td>64% - Return to normal</td>
</tr>
</tbody>
</table>

Nationally, there is much more variation (70%) between trust in messengers than there is between trust in messages (8%).

Source: Reagan-Udall Foundation for the FDA
● Connect before you communicate
● Show true curiosity and meet them where they are at
● Keep it very personal
How to Build the Connection and Show Curiosity

Clinical setting:
• Get to know the patient and their social history
• Validate their emotions behind their story
• Listen to their previous experiences
• Bring in anecdotes

Non-Clinical Setting
• Share your story
• Validate the emotion (and identify with it)
How to craft the message

• Keep the conversation around their identity
• Focus on the personal benefit
  • Vs collective benefit
• Directly address safety concerns
  • Stay away from platiitudes

A few pointers on the message:

• Remember the gist of what you’re trying to communicate
  • People make decisions on gist!

• Keep Messaging simple: use simple numbers

Behavioural Science Principles for Supporting COVID-19 Vaccine Confidence and Uptake Among Ontario Health Care Workers - Ontario COVID-19 Science Advisory Table (covid19-sciencetable.ca)
The Gist of Vaccine Information

1. Does it work?
2. I am not at risk.
3. Vaccine safety and rare side effects

Address safety concerns head on.

Risk of COVID-19 to self and others.

It’s the way out.
COVID-19 Vaccine Communication Framework

Proactively starting the conversation with a Presumptive statement.

Offer to share your knowledge about the facts and your experience with having had the vaccine.

Tailor the recommendations to their specific health concerns.

Address specific concerns (should not be the bulk of the conversation).

Talk through a specific plan for where and when to get the vaccine.
Proactively starting the conversation with a Presumptive statement.

Offer to share your knowledge about the facts and your experience with having had the vaccine.

Tailor the recommendations to their specific health concerns.

Address specific concerns (should not be the bulk of the conversation).

Talk through a specific plan for where and when to get the vaccine.

I am here to support you as you make the decision to take the vaccine. I had the chance to take the vaccine myself and am happy to help you get protected too.

I have been thinking a lot about this vaccine for my patients and educating myself on the science around it. Can I share some of what I know with you?

Here is why you are the right person for this vaccine: you have high blood pressure and diabetes but good quality of life. Because of your conditions, you at high risk of being hospitalized with COVID, so we need to maintain the good quality of life you have right now.

I had the chance to take the vaccine myself and am happy to help you make the decision too, so you can be protected.

You can do the following the get the vaccine. Provide schedule (2 doses).
Objectives

These slides outline practical, evidence-based principles that can guide your engagement with vaccine-hesitant individuals online.

They will show examples of how to respond (and how not to respond) to vaccine-hesitant posts, using real comments from social media.
Principle #1: Engage, don’t attack

- Mimic “active listening”: acknowledge what the individual has said, and provide validation where you can.
- Avoid judgement and labels.
- Use positive emotions to motivate, rather than negative emotions to shame or create fear.
Caroline Lovel
“Get your vaccine or not, and let others make this choice for themselves too.” Couldn’t agree more.

Like · Reply · 2h

Brandi Stenberg
Your decision to get the vaccine affects other people. By exercising your “freedom” not to get vaccinated, you are threatening the lives of people who medically cannot get the vaccine (like children), or who are profoundly immunocompromised. Please get the vaccine!

Like · Reply · 26m

- Mocking tone (quotation marks around “freedom”)
- Negative framing - your decision threatens others
Caroline Lovel
"Get your vaccine or not, and let others make this choice for themselves too." Couldn't agree more.

Brandi Stenberg
Of course, it is everyone's individual choice to get the vaccine or not. But I hope that most people do choose to get it. The vaccine keeps you and the people around you safe, and will let us get back to normal as soon as possible. I am a family doctor, and am happy to answer any questions you might have that will help you make this important decision!

- Acknowledges the poster's perspective
- Uses positive framing ("the vaccine keeps you safe")
- Invites further discussion
Principle #2: Humanize yourself

- Provide some information about yourself ("I am a registered nurse and a mom of 3")
- Adopt a friendly tone
- Use personal anecdotes to make your point
Adrian Curry
Hydrochloroquine, like ivermectin, has a 99%+ recovery rate, relief of symptoms shortly after its first dose, and eliminates the virus after 7 days. Both meds are safe, low-cost, and well-known. Trudeau has interfered with responsible practice of medicine for over a year.

Like · Reply · 4h

Brian Wise
The available scientific evidence does not support the use of either hydrochloroquine or ivermectin for the treatment or prevention of COVID-19. The original study that showed ivermectin had therapeutic effects was withdrawn due to fraudulent data.

Like · Reply · 14m

- Gives no information about who is responding to the comment
- Dry/scientific tone
Greets the other user in a friendly way, and introduces himself

Uses a personal anecdote to make his point

Adrian Curry
HCQ and Ivermectin have a 99%+ recovery rate, relief of symptoms shortly after its first dose, and eliminates the virus after 7 days. Both meds are safe, low-cost, and well-known. Trudeau has interfered with responsible practice of medicine for over a year.

Like · Reply · 4h

Brian Wise
Hi Adrian! I am a family doctor in Orillia, Ontario – and I promise, if we had a treatment for COVID that was this effective, we would use it. I recently had a 27-year old patient with two small children die from COVID, and I would give anything to avoid that outcome. Unfortunately, the evidence suggests that these drugs are ineffective. Until we have a better treatment, your best protection is the vaccine. Reach out if you want help finding one in your area.

Like · Reply · 14m
Principle #3: Tailor your response

- Address the specific concern that was brought up. Don’t expand the scope of the conversation to include other potential concerns about the vaccine.
- When possible, use facts and figures that are specific to the individual’s age, gender, city, or other life circumstances.
- If you suspect that cultural background may play a role in the individual’s vaccine hesitancy, find a team member who shares that background to respond.
Jeanette Leonard
HELL NO TO VACCINE PASSPORTS IN ALBERTA!!! If those who choose to get vaxxed are protected, why does it matter?

Like · Reply · 1h

Ross Ferguson
The vaccines are safe and effective at combatting COVID-19. They don’t change your DNA, affect fertility, or “shed”. Let me know if you want more information on how to get a vaccine!

Like · Reply · 8m

- Doesn’t address the original commenter’s specific argument
- Mentions concerns about the vaccine not present in the original comment, which can reinforce these concerns through familiarity/repetition effects
Jeanette Leonard
HELL NO TO VACCINE PASSPORTS IN ALBERTA!!! If those who choose to get vaxxed are protected, why does it matter?
Like · Reply · 1h

Ross Ferguson
Just a friendly reminder that not everyone can get a vaccine! I have 3 kids under 12, and I can’t wait until it’s safe to bring them to a hockey game (go Flames!) or a restaurant again. By getting a vaccine, you’re not only protecting yourself – you’re helping everyone get back to normal.
Like · Reply · 8m

- Answers original commenter’s question/concern
- Uses information in the comment or user profile (Alberta/Flames connection) to connect with the individual
Principle #4: Be clear and concrete

- Use plain language; avoid technical terms or jargon.
- When expressing odds, use concrete framing (e.g., “If 100,000 people got the vaccine, just 2 would have any adverse reaction”, not “There is a 0.002% chance of adverse reactions.”
- Analogies are a great way to make abstract concepts clearer.
Richard Yang
Wait, so the virus isn’t serious in kids, but heart inflammation is… so how is COVID-19 riskier than the vaccine for this specific age group? Missing something here.

Denise Martinez
Myocarditis has been reported in a small number of cases following immunization with COVID-19 vaccines, usually following vaccination with an mRNA vaccine. These cases have been resolved with symptomatic therapy within days. The risk of COVID-19 still far outweighs the risk of myocarditis, even for younger age groups.

- Dry language
- Uses technical terms where simpler words are available (e.g. “symptomatic therapy”, “myocarditis”)
- Vague: states that risk of COVID-19 outweighs the risk of myocarditis, but doesn’t show this with facts
Richard Yang
Wait, so the virus isn’t serious in kids, but heart inflammation is...so how is covid-19 riskier than the vaccine for this specific age group? Missing something here.

Denise Martinez
Hi Richard! Happy to explain why COVID is riskier than vaccination for young people. Heart inflammation is a rare and usually mild side effect of mRNA vaccines. Out of 41 million vaccinations in Canada, we’ve had only 163 cases of heart inflammation. In contrast, more than 4,000 people under 30 have been hospitalized because of COVID-19, and 76 of them have died. So vaccination is still the better bet!

- Uses plain language
- Illustrates the relative risk with easy-to-understand numbers
Principle #5: Be accurate and transparent

- Make sure any factual claims you make are accurate, and support them with links to relevant sources.
- Don’t make claims that go beyond the science. If there is genuine uncertainty around a subject, acknowledge this; but also explain why you think getting a COVID vaccine is still a good idea.
Bhavna Jani
How could a pregnant woman possibly give her informed consent when these vaccines haven’t even been tested in pregnant women? We have no idea about long term effects on the fetus, yet we’re being told that it’s fine for pregnant women to get the vaccine. I think it’s crazy.
Like · Reply · 44m

Angelo Curtis
There is no reason for pregnant women to worry about getting the vaccine. Randomized trials have shown that the vaccine is safe in pregnancy, and millions of pregnant women have received it.
Like · Reply · 19m

- Dismissive
- Goes beyond the science: randomized trials on pregnant women have not yet been completed
- Does not address the concern about long term effects
Acknowledges gaps in our understanding of the vaccine's effects

Gives a good reason to get the vaccine, despite some uncertainty

Bhavna Jani
How could a pregnant woman possibly give her informed consent when these vaccines haven’t even been tested in pregnant women? We have no idea about long term effects on the fetus, yet we’re being told that it’s fine for pregnant women to get the vaccine. I think it’s crazy.

Like · Reply · 44m

Angelo Curtis
I understand your concern – it is true that there are still things we don’t know about pregnancy and the vaccine. We do know that millions of pregnant women have received the vaccine without adverse effects, and that most vaccines are safe for pregnant women and their babies. We also know that COVID-19 is dangerous in pregnancy – it is associated with much higher risk of hospitalization, ICU admission, and premature birth. So the balance of risk suggests that getting the vaccine is the safer choice.

Like · Reply · 19m
Common Misconceptions & Questions
COMMON MISCONCEPTIONS AND QUESTIONS

Will I still have to mask?

All public health guidance must still be followed until we learn more. This means you will continue to need to wear a mask.
mRNA cannot go back into the nucleus where the DNA is - humans just don’t have these enzymes.

Our bodies use mRNA all the time to make proteins.

The vaccine mRNA and the protein it makes are dissolved within minutes to hours.

We also consume mRNA in our diet (such as meat!)
Deaths investigated in 23 elderly patients in Norway who received Pfizer/BioNTech vaccine.

This is being looked at in terms of baseline rate of death in this population: it seems so far this may be coincidental.

In Norway, 400 people die weekly in nursing homes/long term care facilities.

In the USA from the CDC reports so far, the data does not suggest a signal to safety or deaths following vaccine in older adult residents of LTC facilities.

Deaths in this population following vaccination are consistent with expected all cause mortality.
Vaccine Ingredients:

- Medicinal ingredient: BNT162b2 (mRNA)
- Non-medicinal ingredients:
  - 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
  - dibasic sodium phosphate dihydrate
  - monobasic potassium phosphate
  - potassium chloride
  - sodium chloride
  - sucrose
  - water for injection

It does not contain mercury, formaldehyde, aluminum.
There is a rumor that antibodies against the spike protein will also target a protein in the placenta of pregnant mothers, syncytin-1.

There is no data suggesting that these antibodies will affect syncytin-1, as they are different proteins.

If this was true, you would expect COVID-19 infection to be associated with increased rates of miscarriage.

Whereas COVID-19 in pregnant women leads to severity and ICU admissions, it is NOT associated with miscarriages.

Recent study that looked at placentas of vaccinated and non-vaccinated women: no damage from the vaccine to the placenta.
COMMON MISCONCEPTIONS AND QUESTIONS

Can the vaccine affect the menstrual cycle

- There have been some reports of this phenomenon whereby women have heavier or irregular periods
- This has not been studied in the trials but should be reported if noted
- Many theories as to why that can happen:
  - Could be that a “stress” response can affect the regularity of the periods
  - Could be that there is an immunological phenomenon at level of endometrium causing shedding
- Many OBGYN experts have weighed in on this and they recommend that this is NOT a contraindication to a vaccine, it is short lived if happens at all.
Tell us what you think

Complete our survey:

19tozero.ca

This survey has ethical clearance from the University of Calgary, a partner of 19 To Zero.