The COVID-19 Vaccine: What's it all about?

Dr Meb Rashid and Isaac Bogoch
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Gratitude to Vanessa Redditt and Vanessa Wright for sharing some of their slides
Uptake for the COVID-19 vaccine has been high among Toronto’s long-term-care home residents. For staff, not so much
Why the reluctance?

- Important to recognize how individuals and communities have been marginalized by the health care system
- Where are people getting their information?
- Critical to ensure that people have access to accurate information to ensure they can make the correct decisions when they are offered the vaccine
Overview

• How do the vaccines work?
• How effective are the COVID-19 vaccines?
• What are the side effects?
• Use in special populations?
• How were the vaccines produced so quickly?
• Was there testing in diverse populations?
• Can you get allergies to the vaccine?
• Do distancing precautions/masks still need to be used after vaccination?
• What is the current roll-out and eligibility for the vaccine?
How do mRNA vaccines work?

- mRNA instructions for spike protein
- Body produces spike proteins that trigger immune response
### Pfizer-BioNTech and Moderna Vaccine Clinical Trials (studies)

<table>
<thead>
<tr>
<th></th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>43,538</td>
<td>30,420</td>
</tr>
<tr>
<td>Age</td>
<td>≥ 16 years</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>Vaccine schedule</td>
<td>2 doses,</td>
<td>2 doses,</td>
</tr>
<tr>
<td></td>
<td>21 days apart</td>
<td>28 days</td>
</tr>
<tr>
<td>Follow-up period*</td>
<td>8 weeks</td>
<td>8 weeks</td>
</tr>
</tbody>
</table>
How effective are the vaccines in protecting against COVID-19 illness?

<table>
<thead>
<tr>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td>95%</td>
<td>94.1%</td>
</tr>
<tr>
<td>(7 days after 2\text{nd} dose)</td>
<td>(14 days after 2\text{nd} dose)</td>
</tr>
</tbody>
</table>

Efficacy consistent across age, gender, race and ethnicity demographics
What are common side effects?

Very common ≥10% (more than 1 in 10 doses)
- pain at the injection site
- headache, feeling tired
- muscle or joint pain
- fever or chills
- swelling or tenderness under the armpit

Common 1%-10% (1 in 100 to 1 in 10 doses)
- redness & swelling at the injection site
- nausea & vomiting

Uncommon 1% (1 in 100 doses)
- enlarged lymph nodes

Very rare
- serious allergic reactions such as anaphylaxis

Source: Toronto Public Health

Similar to side effects from other vaccines
Generally resolve in 1-3 days
Special considerations

• Immunocompromising disorders (from illness or medications)

• Autoimmune disorders
Can I get the vaccine if I am pregnant or breastfeeding?

- Based on how mRNA vaccines work → unlikely to pose a specific risk
- Increased risks of severe illness from COVID-19 infection during pregnancy
- Further studies underway
Should I get the vaccine if I already had COVID-19?

- Yes!
- Even if you had COVID-19 in the past, it is uncertain how long the antibodies (immune protection) will last
"The vaccines were produced very quickly—were steps missed in the process that may make the vaccine less safe?"
Vaccine development and approval in Canada

Vaccine development

- genetic sequence developed very quickly
- funding not an issue
- mRNA technology already existed

-no shortage of volunteers
-no shortage of illness

"Rolling review process"

Scientists develop a potential vaccine

Scientists conduct lab and animal studies before testing on humans

10s of volunteers
Phase I
- Is the vaccine safe?
- What is a safe dose?
- Are there any side effects?

100s of volunteers
Phase II
- How well does the vaccine work?
- Is it safe on a larger number of people?
- Safest and most effective dose?

1000s of volunteers
Phase III
- Does the vaccine prevent disease?
- What are the side effects?

Manufacturer submits application to Health Canada for review

Exploratory  Preclinical  Clinical Trials  Application
Rolling review process

Teams of Health Canada experts conduct a thorough and independent review of all vaccine data.

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

Governments coordinate the purchase, logistics and distribution of vaccines across Canada.

All Canadians have access to the vaccine.

Continuous monitoring and review to confirm the safety of the vaccine, and that benefits outweigh risks.

For COVID-19 vaccines, Health Canada is using a fast-tracked process that allows manufacturers to submit data as it becomes available, and for Health Canada experts to start the review process right away. Vaccines will only be authorized once we have all necessary evidence.
✓ No steps were skipped in the vaccine testing or approval process.

✓ These trials were 10x larger than other vaccine trials in the past.

✓ We have it so soon because:
  ✓ Health Canada received and reviewed data regularly as it was available – not just at the end of the research.
  ✓ Drug companies skipped the time it takes to ensure a vaccine can sit in a family doctor’s fridge for several months.

✓ They did NOT skip the safety testing
Can we get COVID-19 from the vaccine?

NO

- the vaccines do not contain live virus
- they stimulate production of a protein not the virus itself
- although the possible side effects of the vaccine may overlap with symptoms of COVID-19, one cannot get covid-19 from the vaccine
Was the vaccine tested on diverse populations?

The evidence showed that there was no difference in the effectiveness of the vaccine in different populations.

<table>
<thead>
<tr>
<th>Population</th>
<th>Moderna</th>
<th>Pfizer</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>79.1%</td>
<td>82.9%</td>
</tr>
<tr>
<td>Black or African American</td>
<td>10.1%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Asian</td>
<td>4.8%</td>
<td>4.2%</td>
</tr>
<tr>
<td>American Indian or Alaska native</td>
<td>0.8%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Multi-racial</td>
<td>2.1%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Other</td>
<td>2.1%</td>
<td>2.1%</td>
</tr>
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</table>
What is in the Pfizer vaccine?

• Medicinal ingredient: mRNA vaccine
• Non Medicinal ingredients:
  - Fats
  - Salts
  - Sugar
  - Water
What is in the Pfizer vaccine?

- Medicinal ingredient: mRNA vaccine
- Non Medicinal ingredients:
  - Fats: 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:
  - Salts: (Dibasic sodium phosphate dihydrate; Monobasic potassium phosphate; Potassium chloride; Sodium chloride)
  - Sugar: sucrose
  - Water
What is in the Moderna vaccine?

- Medicinal ingredient: mRNA vaccine
- Non Medicinal ingredients:
  - Fats
  - Salts
  - Acid stabilizers
  - Sugar
  - Water
What is in the Moderna vaccine?

- Medicinal ingredient: mRNA vaccine
- Non Medicinal ingredients:
  - **Fats:** Lipid SM-102 PEG2000 DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol); 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); Cholesterol
  - **Salts:** Sodium acetate
  - **Acid stabilizers:** Tromethamine; Tromethamine hydrochloride
  - **Sugar:** sucrose
  - **Water**
What is polyethylene glycol?

- Found in laxatives and bowel preparations given before procedures
- Also found in certain cosmetics although no cases of allergy to PEG in cosmetics
- Is found in ES Tylenol, Tylenol EZ tabs, Tylenol gel caps, Benadryl 25mg or 50mg pink caplets, Laxaday, Go-lytely, Reactine 5-10mg tablets, Advil liquid gels, Enteric coated ASA 81mg-if can take any of above then not likely to have PEG allergy
What is not in the vaccines

- Food products
- Nuts
- Antibiotics
- Thimerosal
- Formaldehyde
- Microchips
What to do for severe pre-existing allergies?

- At all injection sites, there are staff available to deal with serious allergic reactions

- If history of severe allergies (anaphylaxis), should stay 30 min after vaccination

- Is a concern if people have an allergy to a constituent of the vaccine
What happens after receiving the vaccination?

Must still take precautions

- Unclear if can still carry virus
- Some people will still get symptomatic illness
- If fever after vaccine, must still rule out COVID-19 infection
AS OF JAN 29th, NEARLY 91 MILLION DOSES OF VACCINES HAVE BEEN PROVIDED WORLDWIDE

Do we really know enough about the side effects of the vaccine?
1. Provincial Roll Out Plan

**Phase 1**
Limited doses of the vaccine available for healthcare workers in hospitals, long-term care homes and retirement homes, other congregate care settings and remote Indigenous communities.

Starting: December 15, 2020

[Learn more about phase 1](#)

**Phase 2**
Increasing stock of vaccines, available to all healthcare workers, residents in long-term care homes, retirement homes, home care patients with chronic conditions and additional Indigenous communities.

Starting: This winter

[Learn more about phase 2](#)

**Phase 3**
Vaccines available widely across Ontario for anyone who wants to be immunized.

Starting: When vaccines and doses are available

[Learn more about phase 3](#)

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Who can be vaccinated

Vaccines are available to health care workers and essential caregivers who work in:
- hospitals
- long-term care homes
- retirement homes
- other congregate settings caring for seniors

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Phase 2

Phase 2 will begin when more doses become available to Ontario. This is expected to begin later this winter.

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Summary

• Both vaccines available at present have been well studied
• Newcomers are high risk for COVID-19 and deserve to be well informed about the vaccine
• The information is best received from a trusted source: settlement and community workers may be best placed to provide this information