

# COVID Vaccine - FAQ

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Health Solutions



## Q: How is the Vaccine distribution overseen in Canada?

### Federal Government

*Working closely with PT governments and First Nations, Inuit, and Metis partners to ensure they are ready to administer vaccines*

### Provincial & Territorial Governments

*Responsible for deciding how to deploy COVID-19 vaccines within their jurisdiction (including vaccine prioritization)*

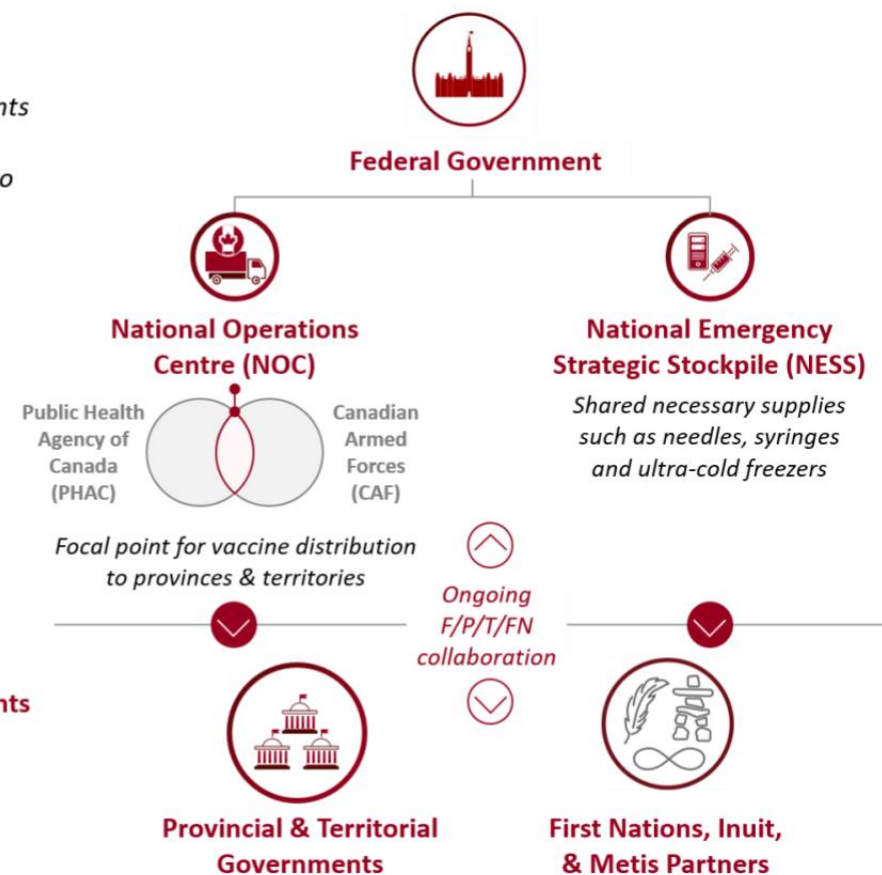


Figure: Working closely with provincial and territorial governments and First Nations, Inuit and Métis partners

## Q: How are vaccines approved in Canada?

### Vaccine development and approval in Canada

#### Vaccine development



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

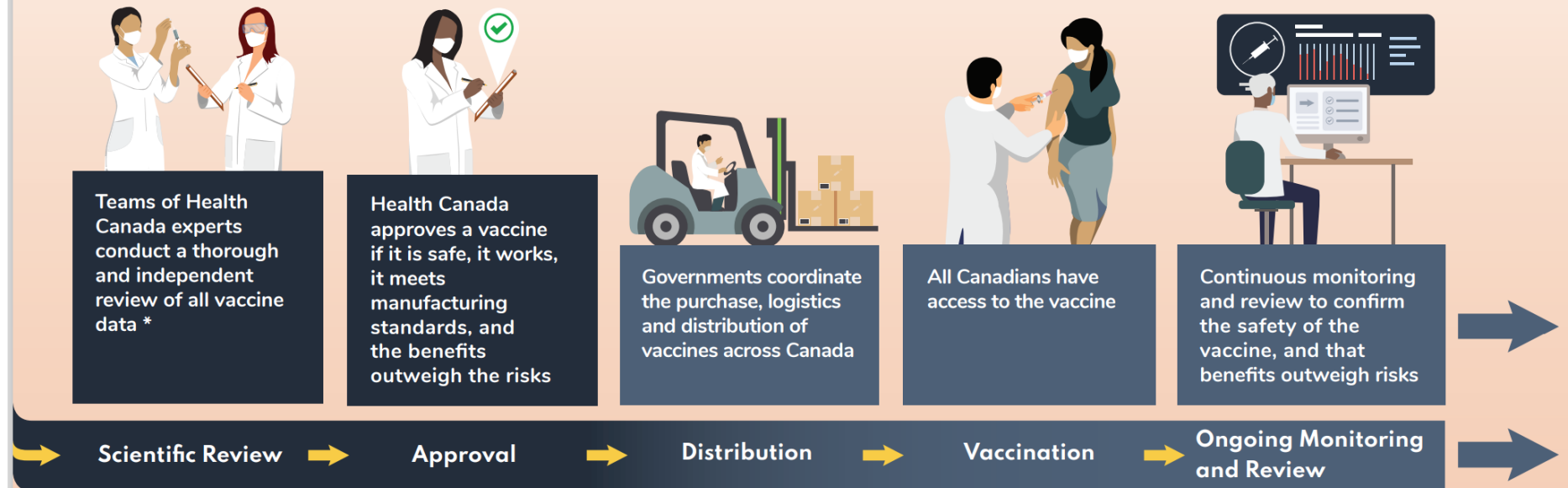
Exploratory →

Preclinical →

Clinical Trials →

Application

# Review and approval of vaccines



\* 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.**



## Q: Which vaccines has Canada secured?

Canada has secured vaccine access from 7 leading candidates	6 of 7 candidates require 2 doses, at different intervals	Health Canada has received submissions for authorization from 4 vaccine candidates
	2 doses:  → 21 days apart → 	✓
	2 doses:  → 28 days apart → 	✓
	1 dose: 	✓
	2 doses:  → 21 days apart → 	
	2 doses:  → 21 days apart → 	
	2 doses:  → 21 days apart → 	
	2 doses:  → 28 days apart → 	✓

Figure: Government of Canada has secured access for seven leading vaccine candidates

# FAQ

**Q: Which vaccines have been *approved* in Canada so far?**

**A:**

- **Pfizer-BioNTech** was the first approved COVID-19 vaccine in Canada and on December 23<sup>rd</sup> Health Canada also approved the **Moderna** Vaccine for distribution in Canada.

**Q: How does the Pfizer and Moderna vaccines work?**

**A:**

- It is a mRNA (messenger RNA) vaccine. These vaccines give instructions on how to tell a human cell to make a harmless piece of the SARS-CoV2 virus protein (called “spike protein”), so that our immune cells can learn to recognize it and produce antibodies against it.
- The mRNA vaccine *does not* use weakened or attenuated live viruses that cause COVID-19.

# FAQ

**Q: I'm concerned at the speed of which this vaccine was approved. Is it safe?**

**A:**

- The development of vaccines for COVID-19 has progressed quickly for many reasons including:
  - Reduced time delays in the vaccine approval process
  - Quick adaptation of existing research programs such as those focusing on mRNA and viral-vector based technology. Work had been ongoing to use mRNA as a delivery vehicle for a number of years already
  - International collaboration among scientists, health professionals, researchers, industry and governments.
  - Increased dedicated funding. Financial risk was also removed to allow companies to work on vaccine faster
  - Quick recruitment of participants for clinical trials
  - Rapid set-up of clinical trials to demonstrate effectiveness of the vaccine

## The expedited process

On September 16, 2020, the Minister of Health signed an Interim Order (IO) introducing temporary regulatory pathway for COVID-19 related drugs and vaccines. The IO Provided greater flexibility and a more agile review process, which allows for the issuance of an expedited authorization of COVID-19 related vaccines without compromising patient safety.

Introduced under the Interim Order, a rolling review allows a drug manufacturer to submit their request for authorization before they have completed all phases of clinical trials. Health Canada begins its review right way using the information submitted by the applicants and accepts new evidence as it becomes available, until the application is deemed complete.

When a submission is received, Health Canada's clinical reviewers thoroughly review the submission by ensuring that the benefits of the vaccine outweigh the potential risks and have assurances that the product is manufactured in a licensed facility that is up to Health Canada standards.

A submission contains data from scientific studies and information about the manufacturing processes, including:

- Pre-clinical studies – toxicology studies and other studies in animals
- Pre-clinical studies – toxicology studies and other studies in animals
- Clinical studies – all phases of clinical trials in humans, including safety and efficacy data
- Manufacturing data – information about how the vaccine is made, and the processes in place to make it consistently



# FAQ

## Q: Who should get the COVID-19 vaccine?

A:

- Residents, staff, essential caregivers, and other employees of congregate living settings (e.g., long-term care homes and retirement homes) that provide care for seniors as they are at higher risk of infection and serious illness from COVID-19;
- *health care workers, including hospital employees, other staff who work or study in hospitals, and other health care personnel; and*
- adults in Indigenous communities, including remote communities where risk of transmission is high

## Q: If I had COVID, should I still get the vaccine?

A:

- If you had, or may have had, COVID-19 the recommendation is that you should still get the vaccine. This is because you may not be immune to the virus that causes COVID-19 and may become infected again or sick.

# FAQ

**Q: How is the Pfizer-BioNTech vaccine given?**

**A:**

- It is a series of 2 doses given 21 (to 28 days) apart, for those 16 years of age and older

**Q: How effective is the Pfizer-BioNTech Vaccine?**

**A:**

- Data suggests that it is 95% effective against COVID-19 beginning 28 days after the 1<sup>st</sup> dose. Efficacy was consistent across age, gender, race and ethnicity; observed efficacy in adults ≥65 years of age was over 94%

# FAQ

**Q: How is the Moderna vaccine given?**

**A:**

- It is also a series of 2 doses given 28 days apart, for those 18 years of age and older instead (vs 16 years of age with Pfizer's vaccine)

**Q: How effective is the Moderna Vaccine?**

**A:**

- Data suggests the efficacy of the vaccine is 94.5% in preventing COVID 19 in participant without prior evidence of SARS-Co V-2 infection.

# FAQ

## **Q: What are the storage requirements of Pfizer COVID-19 Vaccines?**

**A:**

- The Pfizer vaccine must be stored at ultra-low temperatures of -80° to -60° C and be kept in original package until ready to use.
- Can be stored in dry ice for up to 30 days. Dry ice needs to be refreshed (i.e., 20 kg) every 5 days.
- The vaccine can be stored in the refrigerator at +2° C to +8°C for 5 days and no more than 2 hours at room temperature.
- Requires dilution prior to use

# FAQ

- **Q: What are the storage requirements of Moderna COVID-19 Vaccines?**

- **A:**

- The Moderna vaccine is provided as a frozen suspension in a multi dose vial containing 10 doses
- It can be stored between  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ .
- Must be thawed prior to administration but no dilution is required
- Vials can be stored in the fridge between  **$+2^{\circ}\text{C}$  to  $+8^{\circ}\text{C}$**  for up to **30 days** (instead of 5 days with Pfizer).
- When opened, the vial can be stored at room temperature up to 6 hours

This makes it a much more favorable vaccine for distribution in the long term/retirement home care setting



# FAQ

- **Q: How long does immunity last after receiving the vaccine?**

- **A:**

- It's too early to know if COVID-19 vaccines will provide long-term protection. Additional research is needed to answer this question.
- However, it's encouraging that available data suggest that most people who recover from COVID-19 develop an immune response that provides at least some period of protection against reinfection – although we're still learning how strong this protection is, and how long it lasts.

- **Q: Can I get COVID from this vaccine?**

- **A:**

- **No.** This is not a live vaccine and does not contain the virus. Therefore, the vaccine cannot give recipients infection or COVID-19.

[Coronavirus disease \(COVID-19\): Vaccines \(who.int\)](https://www.who.int/coronavirus/vaccines)

# FAQ

**Q: What are the possible reactions after the vaccine?**

**A:**

- You should expect to have similar effects, as the flu vaccine, such as soreness at injections site (84.1%), fatigue (62.9%), headaches (55.1%), muscle pains (38.3%), fever (38.3%)
- Two (2) people in the UK, who received the Pfizer vaccine did report having a severe allergic reaction, therefore those individuals prone to anaphylactic-like reactions should not take it.
- Four cases of Bell's palsy (temporarily weakening of some facial muscles) occurred in those received Pfizer's vaccine in the study, but this frequency of Bell's palsy is not unusual in the general population.
  - Note: one participant had a history of the condition
  - FDA could not link the condition to the vaccine

# FAQ

**Q: After I get vaccinated, do I still have to wear a mask?**

**A:**

- Yes, medical experts are still recommending that preventative behaviours, like mask wearing and social distancing, will still be required in order to reduce transmission.
- Studies don't yet show yet whether those vaccinated can prevent them from carrying Covid-19 (I.e., in nasal passage) and spreading it to others.
- Vaccines were given in many stages over the next year and many even though inoculated requires at least a month before they are immune.
- In addition, when community immunity is not achieved, there are potential for others not vaccinated to be infected with Covid 19.

# FAQ

## Q: Why should I get vaccinated?

A:

- The benefits of vaccination greatly outweigh the risks, and many more illnesses and deaths would occur without vaccines.
- Vaccines prevent illness and disease and save lives and livelihoods.
- Mass vaccination will protect people's lives and help Canada recover from the COVID-19 pandemic.
- It will allow us to get back to our 'normal lives', including travel
- Allows us to continue to work

**We do it for our families, local community, country and for the global community**

# FAQ

- **Q: Where can I find up-to-date information on the COVID-19 vaccine?**
- **A:**
  - Information is continuously being updated on Health Canada's website as well as provincial public health agency sites.
  - [National Advisory Committee on Immunization \(NACI\): Statements and publications - Canada.ca](#)



