

Recommendations of the National Advisory
Committee on Immunization (NACI) on the use of
the Moderna COVID-19 vaccine

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Declaration of interests – Dr. Shelley Deeks

- Nothing to declare

Objectives

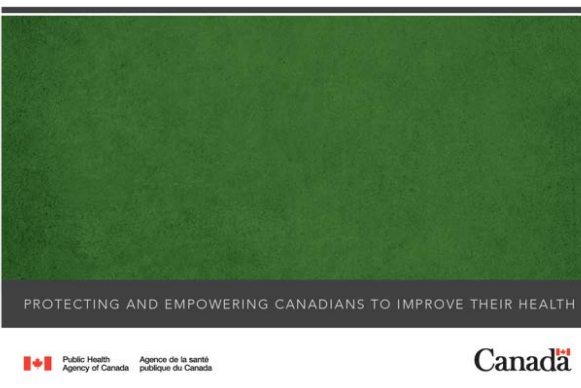
- To describe the characteristics of the Moderna COVID-19 vaccine platform.
- To summarize the clinical evidence for the Moderna COVID-19 vaccine.
- To summarize NACI recommendations on the use of the Moderna COVID-19 vaccine.
- To summarize key information on handling and administering the Moderna COVID-19 vaccine.

Preamble

- The Moderna COVID-19 vaccine was authorized on December 23, 2020 by Health Canada for use in Canada for individuals 18 years of age and older.
- The following slides summarize NACI's recommendations on the use of currently available COVID-19 vaccines. These recommendations apply to the Moderna and Pfizer-BioNTech mRNA COVID-19 vaccines, which are the only ones available in Canada at the time of this webinar.
- Up-to-date recommendations on the use of COVID-19 vaccines and full details of supporting evidence and rationale can be found in the NACI statement:
 - <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html>

An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Recommendations on the use of COVID-19
Vaccine(s)



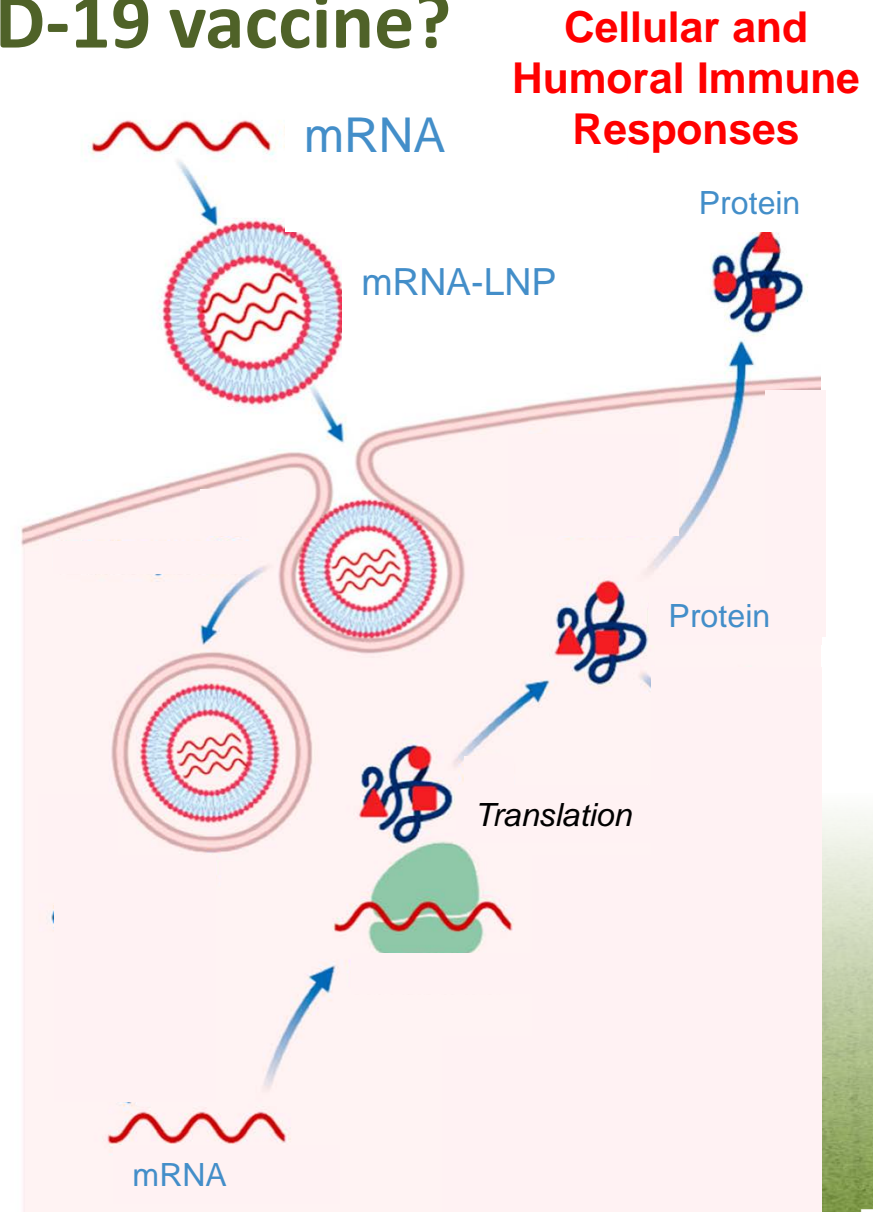
What is NACI?

- NACI is an external advisory body to the Public Health Agency of Canada that develops evidence-based advice on vaccines approved for use in Canada.
- NACI is comprised of experts in the fields of pediatrics, infectious diseases, immunology, pharmacy, nursing, epidemiology, pharmacoeconomics, social science, and public health.
- NACI advice is published in the form of NACI Statements that are typically summarized in the Canadian Immunization Guide (CIG). For COVID-19 vaccines, *NACI Recommendations on the use of COVID-19 vaccines* are evergreen and are not yet integrated to the CIG.
- More information about NACI can be found at: www.canada.ca/naci

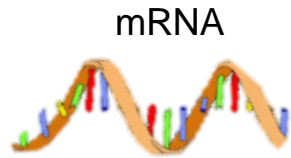
Characteristics of the Moderna COVID-19 vaccine

What is the Moderna COVID-19 vaccine?

- The Moderna COVID-19 vaccine is an mRNA vaccine
 - Lipid nanoparticles are used to deliver mRNA directly into cells
 - mRNA coding for spike protein gets translated
 - New technology
 - Elicitation of antibodies and T-cells
 - Fast manufacturing timeline
 - The Pfizer-BioNTech COVID-19 vaccine is also an mRNA vaccine

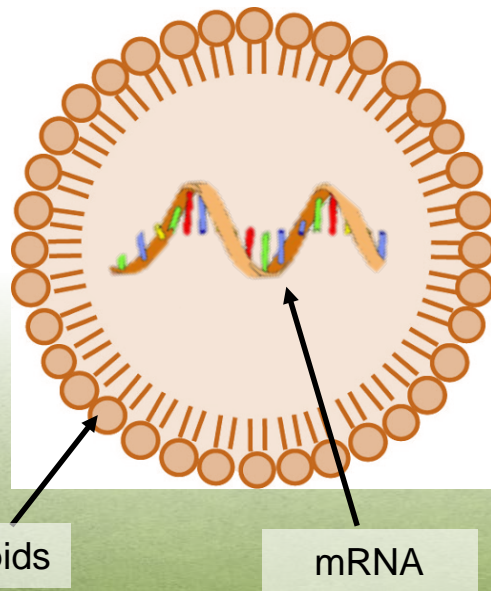


How does an mRNA COVID-19 vaccine work?



- Vaccine antigen is mRNA encoding for SARS-CoV-2 spike protein
- mRNA is very unstable

mRNA lipid nanoparticle



- mRNA lipid nanoparticles are made of two parts:
 - mRNA
 - Lipids
- The lipids allow the mRNA to enter into the cell and the spike gene to be translated into protein
- Lipids do not mix well with water so the mRNA lipid nanoparticle vaccines have special storage and handling requirements (i.e., no shaking)

mRNA COVID-19 vaccine characteristics

	Moderna COVID-19 vaccine	Pfizer-BioNTech COVID-19 vaccine
Type of vaccine	COVID-19 mRNA	COVID-19 mRNA
Date of authorization in Canada	December 23, 2020	December 9, 2020
Authorized ages for use	18 years of age and older	16 years of age and older
Dose	100 mcg of mRNA per 0.5 mL (no dilution)	30 mcg of mRNA per 0.3 mL (after dilution)
Schedule	2 doses, a minimum of 21 days apart (authorized interval: 1 month apart)	2 doses, a minimum of 19 days apart (authorized interval: 21 days apart; NACI recommended interval: 28 days apart)
Route of administration	IM	IM
Nature of the antigen	Prefusion spike protein	Prefusion spike protein
Adjuvant	None	None
Formats available	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (5 doses), preservative-free

Clinical evidence for the Moderna COVID-19 vaccine

Clinical trial characteristics – Moderna

- Pivotal Phase 1, 2, and 3 trials are being conducted for the Moderna COVID-19 vaccine.
- Evidence on efficacy, immunogenicity, and safety is available for adults ≥ 18 years of age.
- Studies did not include participants from long-term care facilities.
- The Phase 3 portion of the trial involved 30,413 study participants randomized (1:1) to receive either the vaccine (2 doses of 100 mcg) or placebo.
- Trial data available to date are for an interim analysis; therefore the time of follow-up is not consistent but was a median of two months after the second dose (maximum follow-up of about 14 weeks as of November 25th) for all participants.

Clinical trial characteristics – Moderna (cont'd)

- Important exclusion criteria in the Phase 3 trial include:
 - Pregnancy and breastfeeding
 - Immunodeficient or immunosuppressed (did not exclude stable HIV infection)
 - Known history of SARS-CoV-2 infection
 - Known or suspected allergy or history of anaphylaxis, urticaria, or other significant adverse reaction to the vaccine or its excipients.
 - Those who have contraindications to IM injection
 - Receipt of blood/plasma products or immunoglobulin 3 months before vaccine administration
- People with chronic conditions were **not** excluded from the study.

Clinical evidence – Moderna

- In clinical trials, the Moderna COVID-19 vaccine was efficacious against symptomatic, confirmed COVID-19 over the short-term.
 - 185 confirmed COVID-19 cases in the placebo group occurred at least 14 days after dose 2 compared to 11 cases in the vaccine group.
 - For those who only received one dose, 39 confirmed COVID-19 cases in the placebo group occurred at least 14 days after dose 1 compared to 7 cases in the vaccine group.
- The Moderna COVID-19 vaccine was efficacious against severe COVID-19 over the short-term.
 - 30 confirmed severe COVID-19 cases in the placebo group occurred at least 14 days after dose 2 compared to 0 cases in the vaccine group.

Clinical evidence – Moderna (cont'd)

Outcome	Population	Vaccine efficacy (95% confidence interval)
Confirmed cases of COVID-19 starting 14 days after dose 2	Participants without prior evidence of SARS-CoV-2 infection at baseline	94.1 % (89.3 to 96.8%)
Confirmed cases of COVID-19 starting 14 days after dose 2	Participants who had received at least one dose, regardless of prior SARS-CoV-2 infection	93.8% (88.6 to 96.5%)
Confirmed cases of COVID-19 starting 14 days after dose 1 *	Participants without prior evidence of SARS-CoV-2 infection at baseline	95.2% (91.2 to 97.4%)
Severe confirmed cases of COVID-19 starting 14 days after dose 2	Participants without prior evidence of SARS-CoV-2 infection at baseline	100.0% (not evaluable to 100.0%)

* >90% of participants in analysis received a second injection approximately 28 days after dose 1.

Clinical evidence – Moderna (cont'd)

- There is currently insufficient evidence on the duration of protection and on the efficacy of the Moderna COVID-19 vaccine in:
 - preventing hospitalization
 - preventing death
 - asymptomatic infection (*14 participants in the vaccine arm who were previously seronegative before dose 1 who had asymptomatic infection at the second time point vs. 38 participants in the placebo arm; no formal efficacy data are available*)
 - reducing transmission of SARS-CoV-2
- Studies are ongoing.

Safety – Moderna

- Safety evidence was based on interim analyses of 30,350 participants with a median follow-up time of 49 days after dose 2 (78 days after dose 1).
 - The maximum follow up for the safety cohort was 2 months after dose 2 as of November 25th.
- No serious safety concerns have been identified to date in clinical trials; however, studies are ongoing.
 - Seven serious adverse events in vaccine recipients were considered to be related to the trial intervention (2 cases of autoimmune diseases were reported) versus 5 in placebo recipients.

Safety – Moderna (cont'd)

- Some adverse events were very common (particularly after the second dose) and they were reported to affect more than 10% of people who receive the vaccine. However, they were mild or moderate and transient, resolving within a few days.
 - These included: pain at the injection site, fatigue, headache, muscle pain, joint pain, axillary swelling/tenderness, chills, and nausea/vomiting. All adverse events were more frequent after dose 2.
- Participants who inadvertently received the vaccine (n=6) or placebo (n=7) while pregnant are being followed.

NACI recommendations on the use of COVID-19 vaccines

Notes

- The following recommendations apply to both available COVID-19 vaccines (Moderna and Pfizer-BioNTech), unless specified.
- Both available COVID-19 vaccines are mRNA vaccines.

Vaccine administration

- Both the Moderna and Pfizer-BioNTech COVID-19 vaccines are administered intramuscularly in a 2-dose schedule.

Vaccine product	Immunization schedule	Dose volume	Minimum interval	Authorized interval	Alternate interval
Moderna COVID-19 vaccine	2-dose schedule	0.5 mL	21 days	1 month	None
Pfizer-BioNTech COVID-19 vaccine	2-dose schedule	0.3 mL	19 days	21 days	28 days

- The same vaccine product should be used to complete the vaccine series.
- If administration of the second dose of a COVID-19 vaccine is delayed, the second dose should be provided as soon as possible.
 - No data on a maximum interval between doses or on medium- or long-term efficacy of COVID-19 vaccines are available.
 - Peak humoral response occurs after a second dose.
 - Long-lasting immunity may not be activated without a second dose.

Vaccine administration (cont'd)

- Serologic testing is not needed before or after receipt of a COVID-19 vaccine to assess susceptibility to SARS-CoV-2 or immune response to the vaccine.
- COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated) at this time, unless other vaccines are required for post-exposure prophylaxis.
- COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

Contraindications

- The authorized COVID-19 vaccine are contraindicated in individuals with a history of anaphylaxis after previous administration of the vaccine.
- Individuals with a history of severe allergic reaction to a component of the COVID-19 vaccine should not receive the vaccine.
 - Polyethylene glycol is a potential allergen in the Moderna and Pfizer-BioNTech COVID-19 vaccines known to cause type 1 hypersensitivity reactions.
- In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, investigation is indicated which may lead to immunization in a controlled setting. Consultation with an allergist is advised.
 - If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted.

Precautions

- In individuals with bleeding disorders, the condition should be optimally managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.
- As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, it would be prudent to wait until all symptoms of an acute illness are completely resolved before vaccinating with an authorized COVID-19 vaccine.

Precautions (cont'd)

- Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, in order to avoid attributing any complications resulting from infection with SARS-CoV-2 to vaccine-related AEFI and to minimize the risk of COVID-19 transmission at an immunization clinic/venue.
- If any persons are identified with symptoms on arrival at the venue, they should be instructed to follow current local public health measures.

Post-vaccination counseling

- NACI recommends that prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination.
 - There is currently no evidence on the benefit from administration of oral analgesics for the prevention of immunization injection pain or systemic reactions.
- Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination.

Recommendations – Main

NACI recommends that a complete vaccine series (i.e., 2-doses) of COVID-19 vaccine should be offered to individuals in the authorized age group without contraindications to the vaccine. In the context of limited vaccine supply, initial doses of COVID-19 vaccine should be prioritized for the key populations outlined in NACI's [Guidance on the Prioritization of Initial Doses of COVID-19 Vaccine\(s\)](#). (Strong NACI Recommendation)

Rationale

- Available COVID-19 vaccines are highly efficacious in the short-term against COVID-19 disease and there are no significant safety concerns.
- COVID-19 vaccines are authorized in individuals 18 years of age and older (Moderna) and in individuals 16 years of age and older (Pfizer-BioNTech) based on the pivotal clinical trial data conducted in these age groups.
- Medium- and long-term follow-ups are needed and will be done.

Recommendations – Public health measures

NACI recommends that all individuals should continue to practice recommended public health measures for prevention and control of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time. (*Strong NACI Recommendation*)

Rationale

- Insufficient evidence on the duration of protection of COVID-19 vaccines and the effectiveness of COVID-19 vaccines in preventing asymptomatic infection and reducing transmission of SARS-CoV-2.
- There is preliminary descriptive evidence suggesting the Moderna COVID-19 vaccine may reduce asymptomatic infection, but the evidence is insufficient at this time to recommend discontinuation of public health measures.
- No evidence on the use of COVID-19 vaccine for post-exposure prophylaxis.

Recommendations – Previous infection

NACI recommends that a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who have had previously PCR-confirmed SARS-CoV-2 infection. In the context of limited vaccine supply, initial doses may be prioritized for those who have not had a previously PCR-confirmed SARS-CoV-2 infection. (*Discretionary NACI Recommendation*)

Rationale

- Lack of evidence in this group, but level of protection from previous infection unknown.
- Testing for previous SARS-CoV-2 infection is **NOT** needed prior to COVID-19 vaccination.
- Vaccination may be delayed for 3 months following a PCR-confirmed infection, as reinfections reported to date have been rare within the first 3 months following the first infection.
- All symptoms of an acute illness should be completely resolved before vaccinating.

Recommendations – Immunosuppressed

NACI recommends that COVID-19 vaccine should not be routinely offered to individuals who are immunosuppressed due to disease or treatment until further evidence is available. (*Strong NACI Recommendation*)

However, a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group in this population if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. (*Discretionary NACI Recommendation*)

Rationale

- Immunosuppressed were excluded from trials. There is a lack of evidence on efficacy and safety in this group.
- No safety signals of concern have been noted to date in non-immunosuppressed participants with an immunocompromising condition included in the clinical trials.
- People living with HIV that are considered immunocompetent may be vaccinated.

Recommendations – Autoimmune condition

NACI recommends that COVID-19 vaccine should not be routinely offered to individuals with autoimmune conditions until further evidence is available. (*Strong NACI Recommendation*)

However, a complete series with a COVID-19 vaccine may be offered to individuals in the authorized age group in these populations if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the insufficiency of evidence on the use of COVID-19 vaccine in these populations. (*Discretionary NACI Recommendation*)

Rationale

- Very limited data on COVID-19 vaccination in individuals who have an autoimmune condition.
- The spectrum of autoimmune conditions is diverse; the balance of benefits and risks must be made on a case-by-case basis.
- Previous mRNA vaccine technologies may have elicited inflammation and theoretically exacerbated existing autoimmune disease. Current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk; however, further evaluation is needed.

Recommendations – Pregnancy & breastfeeding

NACI recommends that COVID-19 vaccine should not be routinely offered to individuals who are pregnant until after completion of pregnancy, until further evidence is available. (*Strong NACI Recommendation*)

However, a complete series with a COVID-19 vaccine may be offered to pregnant individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. (*Discretionary NACI Recommendation*)

Same recommendation for breastfeeding.

Recommendations – Pregnancy & breastfeeding (cont'd)

Rationale

- Anyone who was known to be pregnant or breastfeeding at time of first vaccination were excluded from trials. There is a lack of evidence on efficacy and safety in this group, as only a few individuals became pregnant during the trial.
- There is currently no evidence to guide the time interval between the completion of the COVID-19 vaccine series and conception.
 - In the face of scientific uncertainty, it would be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of an mRNA COVID-19 vaccine.
 - An mRNA COVID-19 vaccine may be administered anytime after pregnancy taking into consideration whether an individual is breastfeeding.
- Individuals who become pregnant during their vaccine series or shortly thereafter should not be counselled to terminate pregnancy based on having received the mRNA vaccine.

Recommendations – Children & adolescents

NACI recommends that COVID-19 vaccine(s) should not be offered to individuals who are not in the authorized age group. (*Strong NACI Recommendation*)

However, a complete series with a Pfizer-BioNTech may be offered to individuals 12–15 years of age who are at very high risk of severe outcomes of COVID-19 (e.g., due to a pre-existing medical condition known to be associated with increased risk of hospitalization or mortality) and are at increased risk of exposure (e.g., due to living in a congregate care facility) if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent with the individual and the parent or guardian includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in this population. (*NACI Discretionary Recommendation*)

Rationale

- Limited clinical data on the safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine in those aged 12 to 15 years is available.
- The Moderna COVID-19 vaccine clinical trials only included adults 18 years of age and older.

Handling and administering the Moderna COVID-19 vaccine

Storage and handling

- **Storage**

- -25 to -15°C until expiry.
- +2 to +8°C for up to 30 days. Do not refreeze.
- Do not store on dry ice.

- **Transport to another site**

- Frozen transport is recommended, however limited transport in the liquid state at refrigerator temperatures (+2 to +8°C) is possible with special attention to temperature control and limiting jostling.
- Do not store on dry ice.
- Monitor temperatures.

Thawing

- **Thaw:**
 - From the **freezer to room temperature**
 - Requires 1 hour to thaw.
 - Can remain at room temperature for 12 hours (but only 6 hours after vial punctured).
 - From the **freezer to the refrigerator**
 - Requires 2.5 hours to thaw.
 - Can stay in the refrigerator (+2 to +8°C) for 30 days.
 - Needs to be kept at room temperature for at least 15 minutes before administering.
 - Do not refreeze.
- **Must be used within 6 hours of first puncturing the vial.**
- Indicate the appropriate dates and times on the vial, so that the expiry point is clear:
 - Indicate the start times
 - Can also indicate the end times, but be clear which time is which

Drawing up

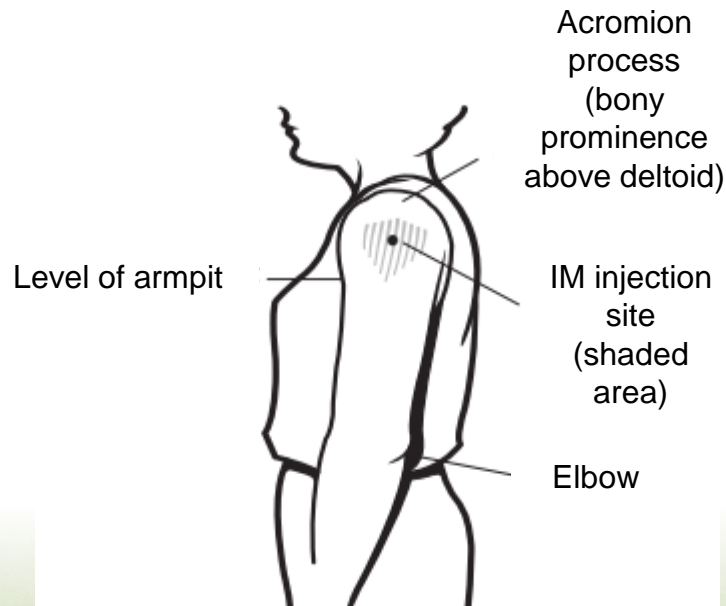
1. Check for foreign particulates or discoloration (expect a white to off-white suspension; may contain white or translucent product-related particulates).
 2. Use alcohol-based hand rub
 3. Gently swirl the vial (**do not shake**).
 4. Swab the vial stopper with the alcohol wipe and let dry
 5. Ensure that the needle is tightly attached to the syringe by giving it an extra turn
 6. Using aseptic technique and a new needle and syringe, draw up 0.5 ml
 7. Mark the date and time of first puncture on the vial (must be used within 6 hours of first puncture)
 8. Repeat steps 2, 3, 4, 5, and 6 to obtain 10 doses per vial .
 9. Discard the used vial into the sharps container.
- The manufacturer has indicated that the product is stable in the syringe for up to 6 hours. Must be used within 6 hour of the first time the vial is punctured. If pre-loading, only draw-up enough to keep the clinic running smoothly and use as soon as possible.

Administering the vaccine

1. Use alcohol-based hand rub.
 2. Check syringe to ensure no particulates or discoloration (translucent to white color expected) and correct dose (0.5 ml).
 3. Prepare the skin with alcohol wipe from the centre moving outwards – allow to dry.
 4. Give 0.5 mL dose intramuscularly in the deltoid.
 5. Discard needle and syringe immediately (or after activating the safety-engineered device) into the sharps container.
 - Do not put used needle down on the workstation.
 6. Use alcohol-based hand rub.
- **Return 1 month later for second dose.**
 - Do not re-start series if delayed

Landmarking for the deltoid

Intramuscular (IM) injection site for children and adults



Give in the central and thickest portion of the deltoid muscle – above the level of the armpit and approximately 2–3 fingerbreadths (~2") below the acromion process.

To avoid causing an injury, do not inject too high (near the acromion process) or too low.

Summary of key storage and handling requirements

	Moderna COVID-19 vaccine	Pfizer-BioNTech COVID-19 vaccine
Storage	-25 to -15°C (do not store on dry ice)	-80 to -60°C
Onward transportation	Frozen recommended (can be transported carefully as a liquid at +2 to +8°C)	If must be transported, ultra-frozen recommended (can be transported carefully as a liquid at +2 to +8°C)
Dilution	No dilution	1.8 mL 0.9% sodium chloride provided by the National Operation Centre (NOC)/manufacturer
Time in refrigerator	30 days at +2 to +8°C	5 days at +2 to +8°C
Use after first puncture	Up to 6 hours	Up to 6 hours (first puncture will be for dilution)
Maximum time at room temperature	Up to 12 hours (but only 6 ours after first puncture of vial)	Up to 8 hours <ul style="list-style-type: none"> • Up to 2 hours before mixing with diluent • Up to 6 hours after mixing with diluent
Preloading in syringe	Stable for 6 hours if pre-loaded	Stable for 6 hours if pre-loaded
Dose	0.5 mL	0.3 mL
Second dose	1 month	21 to 28 days

NACI membership

- **Members:** Dr. C Quach (Chair), Dr. S Deeks (Vice-Chair), Dr. J Bettinger, Dr. N Dayneka, Dr. P De Wals, Dr. E Dube, Dr. V Dubey, Dr. S Gantt, Dr. R Harrison, Dr. K Hildebrand, Dr. K Klein, Dr. J Papenburg, Dr. C Rotstein, Dr. B Sander, Ms. S Smith, and Dr. S Wilson.
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NACI High Consequence Infectious Disease Working Group

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- **Project management support:** Veronica Ferrante, Michelle Matthieu-Higgins

Additional resources

- [Research priorities for COVID-19 vaccines to support public health decisions](#)
 - NACI guidance to inform clinical trials of candidate COVID-19 vaccines.
- [Preliminary guidance on key populations for early COVID-19 immunization](#)
 - NACI guidance to plan for the efficient, effective, and equitable allocation of an eventual COVID-19 vaccine when limited initial vaccine supply will necessitate the immunization of some populations earlier than others.
- [Guidance on the prioritization of initial doses of COVID-19 vaccine\(s\)](#)
 - NACI guidance for the efficient and equitable prioritization of initial doses of COVID-19 vaccines to assist with the planning for allocation of the first COVID-19 immunization programs.