Manitoba Health

Vaccine Clinic Resource for Immunizers

Title:	**COVID-19 Vaccine Moderna SPIKEVAX™ Quick Reference Guide**
Formulations	**Monovalent**- Infant, Pediatric and Adult **Bivalent**- Pediatric and Adult
Effective Date:	February 5, 2021
Approver:	Final

Disclaimer: *this Quick Reference is not intended to replace other product specific vaccine references. The document is intended as a quick reference for frequently referred to information. Please refer to the product monograph and other Moderna SPIKEVAX™ specific resources for all current and complete information.*

COVID-19 Vaccine Resources:

Product Monographs: Province of Manitoba | Resources for Health Care Providers- product monographs (gov.mb.ca)
Storage and Handling: storage-handling-chart.pdf (gov.mb.ca)

Eligibility Criteria
For the most up to date information on primary series and booster dose eligibility criteria refer to Province of Manitoba | Eligibility Criteria (gov.mb.ca).

Manitoba COVID-19 mRNA Immunization Schedule:
Province of Manitoba | COVID-19 mRNA Immunization Schedule (gov.mb.ca)

Canadian Immunization Guide:
For additional guidance on special populations: COVID-19 vaccine: Canadian Immunization Guide- Vaccination of Specific Populations - Canada.ca
For information on allergies/contraindications/precautions: COVID-19 vaccine: Canadian Immunization Guide -Contraindications and Precautions - Canada.ca

Fact Sheets:
For information on vaccine risk and intended benefits, refer to the Province of Manitoba | Resources for the Public COVID-19 Fact Sheets (gov.mb.ca)

Summary of document tables:
Table 1: Recommendations on COVID-19 Immunization for the Primary Series
Table 2: Recommendations on COVID-19 Immunization Booster doses
Table 3: Additional Primary Series Dose Recommendations: Immunocompromised (moderately to severely)
Table 4: Additional Dose Recommendations: non-Health Canada Approved COVID-19 Vaccines

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MONOVALENT	Moderna SPIKEVAX™ Infant formulation: 6 months to less than 5 years of age[1]

Product Recommendations		Approved Intervals	Presentation	Storage and Handling	Administration
Primary Series	**Regimen:** 2 dose series **Dose:** 0.25mL (25mcg) 5 years of age[1] NACI recommends that the Moderna 25mcg may be offered to children five years of age, however **the Pfizer 10 mcg vaccine is preferred in this age group**. NACI recommends children 6 months to less than 5 years should start and finish the primary series with the same product. If mixed products are used, the Pfizer interval schedule should be used (3 doses for immunocompetent, 4 doses for immunocompromised). *An additional dose is required for those moderately to severely immunocompromised (See **Table 3**)* • **Children living in First Nation communities:** **Moderna 25mcg** is the preferred vaccine due to being a 2-dose series instead of a 3-dose series. However, Pfizer 3mcg can also be used for this age group.	**Recommended Interval**: 8 weeks **Authorized Interval**: 28 days **Minimum Interval**: 28 days	**Royal blue cap** **Purple label border** **Concentration:** 0.10mg/ml **Vial volume:** 2.5ml (multidose vial) 10 doses of 0.25ml per vial ***Does NOT require dilution*** **Inspect vials:** White/off-white dispersion and may contain white or translucent product-related particulates. **If solution contains foreign particulates or discoloration, do not administer.**	**Thaw time:** 2◦ to 8◦C (Refrigerator): 2 hours 15◦ to 25◦ C (Room temperature): 45 min **Discard time:** 24 hours at room or refrigerated temperature after first puncture. **Do Not Refreeze Once Thawed**	**Route:** Intramuscular Pediatric Intramuscular needle length selection Ages 6 months to under 5 years AGE / SITE / NEEDLE LENGTH Infants (6 to 12 months) / Anterolateral thigh / 1” Young children (12 months to 3 years) / Deltoid / 5/8” to 1” Young children (12 months to 3 years) / Anterolateral thigh / At least 1” Children 3+ / Deltoid / 5/8” to 1” Note: Concurrent administration of COVID-19 and non-COVID-19 vaccines (including live and non-live vaccines) is authorized for all age cohorts.
Booster Dose	Not approved for this age group	Not applicable			

Product is latex and preservative free
Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
*Individuals who have a known allergy to Tromethamine (trometamol or Tris), should **not** be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).*
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.

NOTE: If more than the expected number of doses are drawn from a vaccine vial (greater than 10 or 20 doses, depending on formulation), vaccine may be administered, provided the full dose can be drawn from one vial (do not pool vaccine from multiple vials).

Revision Date: April 5, 2023

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MONOVALENT	Moderna SPIKEVAX™: 6 years to less than 12 years of age

<table>
<tr><th colspan="2">Product Recommendations</th><th>Approved Intervals</th><th>Presentation</th><th>Storage and Handling</th><th>Administration</th></tr>
<tr>
<td>Primary Series</td>
<td>Regimen: 2 dose series

Dose: 0.25ml (50 mcg)

An additional dose is required for those moderately to severely immunocompromised (See Table 3)

Note: Pfizer is the recommended mRNA vaccine for the primary series for individuals 5 to less than 30 years.</td>
<td>Recommended Interval:
8 weeks

Authorized Interval:
28 days

Minimum Interval:
21 days</td>
<td>Red Cap
Light blue label border

Concentration: 0.20mg/ml

Vial volume: 5 ml
(multidose vial)

20 doses of 0.25ml per vial

Does NOT require dilution

Inspect vials: White/off-white dispersion and may contain white or translucent product-related particulates.
If solution contains foreign particulates or discoloration, do not administer.</td>
<td>Thaw time:
<u>2◦ to 8◦C (Refrigerator):</u>
2 hours and 30 minutes

<u>15◦ to 25◦ C (Room temperature):</u>
1 hour

Discard time:
24 hours at room temperature or refrigerated after first puncture

.

Do Not Refreeze Once Thawed</td>
<td>Route: Intramuscular

<table>
<tr><th>AGE</th><th>SITE</th><th>NEEDLE LENGTH</th></tr>
<tr><td>5 years and older</td><td>Deltoid</td><td>1”</td></tr>
</table>

Optional needle length:
5/8” to 1 ½”
Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age and muscle mass.

Optional site:
Anterolateral thigh can be used if deltoid site is not an available site (ie: multiple injections)</td>
</tr>
<tr>
<td>Booster Dose</td>
<td>Moderna/Spikevax is not recommended for this age group</td>
<td>Not Applicable</td>
<td colspan="3"></td>
</tr>
<tr>
<td colspan="6">Product is latex and preservative free

Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
Individuals who have a known allergy to Tromethamine (trometamol or Tris), should not be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.</td>
</tr>
<tr>
<td colspan="6"><u>NOTE</u>: If more than the expected number of doses are drawn from a vaccine vial (greater than 10 or 20 doses, depending on formulation), vaccine may be administered, provided the full dose can be drawn from one vial (do not pool vaccine from multiple vials).</td>
</tr>
</table>

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MONOVALENT | Moderna SPIKEVAX™: 12 years of age and older

<table>
<tr><th colspan="2">Product Recommendations</th><th>Approved Intervals</th><th>Presentation</th><th>Storage and Handling</th><th>Administration</th></tr>
<tr><td>Primary Series</td><td>Regimen: 2 dose series

Dose: 0.5 mL (100 mcg)

An additional dose is required for those moderately to severely immunocompromised (See Table 3)

Note: Pfizer is the recommended mRNA vaccine for the primary series for individuals 5 to less than 30 years.</td><td rowspan="2">Recommended Interval:
8 weeks

Authorized Interval:
28 days

Minimum Interval:
21 days</td><td rowspan="2">Red Cap
Light blue label border

Concentration: 0.20mg/ml

Vial volume: 5 ml (multidose vial)

10 doses of 0.5ml per vial

Does NOT require dilution

Inspect vials: White/off-white dispersion and may contain white or translucent product-related particulates. If solution contains foreign particulates or discoloration, do not administer.</td><td rowspan="2">Thaw time:
2◦ to 8◦C (Refrigerator):
2 hours and 30 minutes

15◦ to 25◦ C (Room temperature):
1 hour

Discard time:
24 hours at room or refrigerated temperature after first puncture

Do Not Refreeze Once Thawed</td><td rowspan="2">Route: Intramuscular

<table><tr><th>AGE</th><th>SITE</th><th>NEEDLE LENGTH</th></tr><tr><td>5 years and older</td><td>Deltoid</td><td>1”</td></tr></table>Optional needle length:
5/8” to 1 ½”
Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age and muscle mass.

Optional site:
Anterolateral thigh can be used if deltoid site is not an available site (ie: multiple injections)</td></tr>
<tr><td>Booster Dose</td><td>Regimen: 1 or 2 doses*

Dose: 0.25ml (50mcg)/ half dose
High Risk Populations: Dose: 0.5ml (100mcg)/full dose
Immunocompromised; Resident in a PCH/EPH; 70 years and older; those who received 2 non-Health Canada approved vaccines

*Recommendations on COVID-19 Immunization Booster Doses: for further information about booster dose recommendations including eligibility for an additional dose. (See Table 2)</td></tr>
<tr><td colspan="6">Product is latex and preservative free

Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
Individuals who have a known allergy to Tromethamine (trometamol or Tris), should not be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.</td></tr>
<tr><td colspan="6">NOTE: If more than the expected number of doses are drawn from a vaccine vial (greater than 10 or 20 doses, depending on formulation), vaccine may be administered, provided the full dose can be drawn from one vial (do not pool vaccine from multiple vials).</td></tr>
</table>

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BIVALENT BA. 4/5 | Moderna SPIKEVAX™: 18 years of age and older

<table>
<tr><th colspan="2">Product Recommendations</th><th>Approved Intervals</th><th>Presentation</th><th>Storage and Handling</th><th>Administration</th></tr>
<tr><td>Primary Series</td><td>Not for use as primary series</td><td>Not applicable</td><td rowspan="2">Royal Blue cap
Grey label border
(+Bivalent)

Concentration: 0.10mg/ml

Vial volume: 2.5 ml (multidose vial)

5 doses of 0.5ml per vial

Does NOT require dilution

Inspect vials: White/off-white dispersion and may contain white or translucent product-related particulates. If solution contains foreign particulates or discoloration, do not administer.</td><td rowspan="2">Thaw time:
2◦ to 8◦C (Refrigerator):
2 hours

15◦ to 25◦ C (Room temperature):
45 min

Discard time:
24 hours at room or refrigerated temperature after first puncture

Do Not Refreeze Once Thawed</td><td rowspan="2">Route: Intramuscular

<table><tr><th>AGE</th><th>SITE</th><th>NEEDLE LENGTH</th></tr><tr><td>5 years and older</td><td>Deltoid</td><td>1”</td></tr></table>
Optional needle length:
5/8” to 1 ½”
Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age and muscle mass.

Optional site:
Anterolateral thigh can be used if deltoid site is not an available site (ie: multiple injections).</td></tr>
<tr><td>Booster Dose</td><td>Regimen: 1 or 2 doses*

Dose: 0.5ml (50 mcg)

*Recommendations on COVID-19 Immunization Booster Doses: for further information about booster dose recommendations including eligibility for an additional dose and administration. (See Table 2)</td><td>Recommended Interval:
6 months

Minimum Interval:
6 months</td></tr>
<tr><td colspan="6">Product is latex and preservative free

Potential allergens: Polyethylene glycol (PEG), Tromethamine (trometamol or Tris)
Individuals who have a known allergy to Tromethamine (trometamol or Tris), should not be immunized with COVID-19 vaccines containing Tromethamine (trometamol or Tris).
Individuals who report an allergy to contrast material (CT dye), including gadolinium, can be immunized with vaccines containing Tromethamine (trometamol or Tris). They should be observed for 30 minutes post immunization.</td></tr>
<tr><td colspan="6"><u>NOTE</u>: If more than the expected number of doses are drawn from a vaccine vial (greater than 5 doses), vaccine may be administered, provided the full dose can be drawn from one vial (do not pool vaccine from multiple vials).</td></tr>
</table>

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For the most up to date information on primary series and booster dose eligibility criteria refer to Province of Manitoba | Eligibility Criteria (gov.mb.ca)

TABLE 1: Recommendations on COVID-19 Immunization for the Primary Series:

- Everyone 6 months of age and older are eligible to receive a primary series.
- The date the first vaccine is administered is considered "day 0" when counting minimum intervals. Interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series
- Children who will turn from 4 to 5 years of age between doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination and the interval between doses is determined by the child's age at the start of the vaccination series.
- Individuals age 5 to less than 30 years are recommended to receive Pfizer for their primary series to minimize the rare potential risk of myocarditis/pericarditis. (Note: this risk is unknown in the 5-11 year age group, but has been documented in the 12-30 year age group)
- Preferably, a person who received a first dose of an mRNA vaccine (Moderna or Pfizer) should be offered the same mRNA vaccine for their second dose.
    - If the same mRNA vaccine is not available or unknown, another mRNA vaccine can be considered interchangeable and should be offered.
    - If a different mRNA vaccine is given as a second dose with appropriate spacing, both doses are considered valid and the series complete.
- While the **recommended** interval for the primary series, of 8 weeks is preferred, if a person presents for an immunization and would otherwise not return within that recommended interval, the immunizer may proceed with administering the subsequent dose if the **authorized minimum** interval has passed, provided the first dose product received was an mRNA vaccine (Moderna or Pfizer).
    - The **minimum** interval of 19 days is not recommended; however, would be considered a valid dose in PHIMS.
- Individuals who are moderately to severely immunocompromised are recommended to receive an additional dose in the primary series (see Table 3). This requires a prescription if given outside of a physician or pharmacists office and must be given at least 28 days after the second dose.
- Bivalent products have been authorized for use as a booster dose and are not to be used for a primary series.

TABLE 2: Recommendations on COVID-19 Immunization Booster doses:

- Everyone 5 years of age and older, who has completed their primary series should be offered a fall 2022 booster dose.
- ***A bivalent Omicron-containing mRNA COVID-19 vaccine*** is the preferred booster product (there is no evidence that one bivalent vaccine is more effective than the other). The monovalent products can be administered as a booster dose to individuals who request it.
- The recommended interval for booster doses is 6 months between the most recent dose (primary series, previous booster dose) and a recommended booster as vaccine effectiveness increases with a longer duration between doses.
- It is recommended for individuals to wait 6 months since their last COVID-19 infection. At minimum, they need to be fully recovered and completed their isolation period before receiving a booster dose.
- **The following individuals are eligible to receive a spring booster dose in 2023: Individuals 65 years and older; Residents of Long-Term Care (LTC), Assisted Living (ASL) or supportive housing facilities; Adults 18 years and older who are moderately to severely immunocompromised; and Indigenous individuals 45 years and older regardless of place of residence.**
- For individuals not covered in the spring 2023 booster dose criteria listed above, health care providers may offer a bivalent vaccine to individuals who are at high risk of severe infection and have previously received a monovalent booster during the fall 2022 campaign. This requires a prescription if given outside a physician's office and must be given a minimum of 6 months after the last dose.
- It is expected that there will be a fall booster program in 2023. **It is important to take into consideration that receiving a spring 2023 booster could affect the timing of eligibility for a fall 2023 booster dose as a 6-month interval between doses is anticipated.**

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TABLE 3: Additional Primary Series Dose Recommendations: Moderately to Severely Immunocompromised[1]			
Cohort	**Product**	**Dose**	**Recommended interval**
6 months to less than 5 years	***Moderna (25mcg) preferred**** Blue cap	***3 dose series***	At least 28 days between all doses in a 3 or 4 dose series. Considered part of the primary series.
	Pfizer (3mcg) **Maroon cap**	4 dose series	
5 to less than 12 years	Pfizer (10mcg) **Orange cap**	3 dose series	At least 28 days after their second dose. Considered part of the primary series.
12 years and older	Pfizer (30mcg) **Grey cap**	3 dose series	At least 28 days after their second dose. Considered part of the primary series.

**A 3-dose series of Moderna/Spikevax ™ (25mcg) vaccine should be preferentially offered to this age group for the extended series due to the shorter 3 dose regimen, instead of 4 doses of Pfizer/Comirnaty ™ (3mcg).

Moderna (**100mcg)** may be offered (based on clinical judgement) as a primary series to individuals age 12 and older and as a booster dose to individuals at increased risk of severe illness.

NOTE: For eligible individuals 18 years and older unwilling or unable to receive an mRNA vaccine, Novavax/Nuvaxovid can be used for the additional dose.

[1]For the purposes of COVID-19 vaccine recommendations, the following individuals are considered moderately to severely immunocompromised due to a medical condition and/or treatment:

- are receiving active chemotherapy (or immunotherapy) for cancer;
- have received a solid organ transplant and are currently receiving chemotherapy or other immunosuppressive therapy;
- were born with moderate or severe dysfunction of their immune system;
- are living with untreated or advanced HIV-AIDS; or
- are taking certain medications that severely affect the immune system.

The following people should talk to their doctor to see whether they are considered to be immunocompromised:

- receiving hemodialysis or peritoneal dialysis;
- are on the list to receive a solid organ transplant; or
- have a ventricular assist device (VAD).

TABLE 4: Additional Dose Recommendations for Individuals who received 1 or 2 non-Health Canada Approved COVID-19 Vaccines			
Cohort	Product	Dose	Recommended Interval
6 months to less than 5 years	***Moderna (25mcg) preferred***	Blue cap ***Administer one additional dose***	At least 28 days after their last dose to complete their primary series.
	Pfizer (3mcg) **Maroon cap**	Administer 2 additional doses	
5 to less than 12 years	Pfizer (10mcg) **Orange cap**	Administer one additional dose	At least 28 days after their last dose to complete their primary series.
12 years and older	Pfizer (30mcg) **Grey cap**	Administer one additional dose	At least 28 days after their last dose to complete their primary series.

Manitoba Health accepted primary series combinations:

- Two mRNA vaccines (Pfizer or Moderna)
- Two AstraZeneca vaccines
- AstraZeneca and one dose of an mRNA vaccine (Pfizer or Moderna)
- One dose of Janssen
- Three non-Health Canada Approved vaccines
- One or two non-Health Canada Approved Vaccines and one dose of an mRNA Vaccine (Pfizer or Moderna)
- For moderately to severely immunocompromised
  - Three doses (any combination of AstraZeneca, Pfizer and/or Moderna)
- Children 6m to less than 5 years
  - 3 doses of a non-Health Canada approved vaccine.