COVID 19 Vaccine Implementation Task Force **Clinic Reference**	
Title:	**Moderna SPIKEVAX™COVID-19 Vaccines Quick Reference for Immunizers**
Area:	**Reference for Immunizers**
Effective Date:	February 5, 2021
Revised Date:	September, 2022
Approver:	FINAL

Moderna SPIKEVAX™ elasomeran mRNA vaccine indicated for active immunization against coronavirus disease 2019 (COVID-19) and
Moderna SPIKEVAX™ Bivalent (Original/Omicrom) elasomaran mRNA vaccine (booster dose)

Disclaimer: this Quick Reference is not intended to replace other product specific vaccine references. The document is intended 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.

Additional resources:

Monovalent Product Monograph: https://www.gov.mb.ca/asset_library/en/covidvaccine/moderna-pm.pdf
Bivalent Product Monograph: https://www.gov.mb.ca/asset_library/en/covidvaccine/moderna-bivalent-pm.pdf

Eligibility Criteria:
Please refer to Province of Manitoba | Eligibility Criteria (gov.mb.ca) for the most up to date information on booster dose eligibly criteria.

Canadian Immunization Guide:
For the guidance on special populations, please refer to and follow guidance in the Canadian Immunization Guide.

Fact Sheets:
For information on vaccine risk and intended benefits, please refer to the Provincial factsheets

Summary of document tables:
Table 1: Third dose recommendations: immunocompromised
Table 2: Third dose recommendations: non-Health Canada approved
Table 3: Manitoba Health recommended mRNA immunization schedule, based on age.
Table 4: Storage and Handling of Manitoba approved COVID-19 vaccines

<table>
<tr><th>Product Information</th><th>Approved immunization intervals</th><th>Presentation</th><th>Clinic Setting Considerations</th><th>Administration</th></tr>
<tr><td colspan="5">6 months to 5 years</td></tr>
<tr>
<td>Primary series:
2 dose regimen 0.25mL (25mcg)
Note: 3rd dose may be recommended for some individuals. See table 2

Booster dose: Not approved for this age group

<u>5 years of age:</u>
NACI recommends that the Moderna/Spikevax™ vaccine (25 mcg) may be offered to children five years of age as an alternative to the Pfizer/Comirnaty™ vaccine (10 mcg); however, the Pfizer/Comirnaty™ (10 mcg) vaccine is preferred in this age group.</td>
<td>Recommended Interval:
8 weeks *
Authorized Interval:
28 days
Minimum Interval:
21 days</td>
<td>Cap: Royal Blue
Concentration: 0.10mg/ml
Vial volume: 2.5ml (multidose vial)
10 doses per vial*
Dose: 25mcg (0.25ml)

Do not dilute

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

<u>15◦ to 25◦ C (Room temperature):</u> 45 min
Let thawed product stand at room temperature 15 minutes prior to use.

Discard time:
Once the vial has been punctured, refrigerate or store at room temperature for maximum 24 hrs, then discard.

Thawed vials and filled syringes can be handled in room light conditions</td>
<td>Administered: Intramuscular

Pediatric Intramuscular needle length selection
Ages 6 months to under 5 years
<table>
<tr><th>AGE</th><th>SITE</th><th>NEEDLE LENGTH</th></tr>
<tr><td>Infants (6-12months)</td><td>Anterolateral thigh</td><td>1”</td></tr>
<tr><td>Young children (12months-3 years)</td><td>Deltoid</td><td>5/8” to 1”</td></tr>
<tr><td>Young children (12months-3 years)</td><td>Anterolateral thigh</td><td>At least 1”</td></tr>
<tr><td>Children 3+</td><td>Deltoid</td><td>5/8” to 1”</td></tr>
</table>
</td>
</tr>
<tr><td></td><td>*See Table 1, (Recommended mRNA schedule)</td><td>*Do not puncture vial more than 10 times</td><td>*Do not refreeze once thawed</td><td></td></tr>
<tr><td colspan="5">Potential allergens: None known
The product is latex and preservative free</td></tr>
</table>

<u>NOTE:</u> Moderna SPIKEVAX™ (25 mcg) COVID-19 vaccine for 6 months to 4 years should not routinely be given concurrently (i.e., same day) with other vaccines. NACI recommends that Moderna SPIKEVAX™ (25 mcg) COVID-19 vaccine should be given 14 days before or after a different vaccine

<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), all infection control practices have been maintained, and inventory is updated accordingly.

Product Information	Approved immunization intervals	Presentation	Clinic Setting Considerations	Administration
Monovalent formulation: 6 to 11 years and ≥ 12 years				
Primary Series: Individuals 6 to 11 years of age: 2 dose regimen of 0.25 mL (50 mcg) Individuals ≥ 12 years of age: 2 dose regimen of 0.5 mL (100 mcg) *Note: 3rd dose may be recommended for some individuals. See table 2* **Booster dose:** Individuals 6 to 11 years of age: *Moderna/Spikevax™ not approved for this age group.* Individuals ≥ 12 years of age: 50 mcg (half dose) *High Risk populations (first booster only): 100mcg (full dose)	**Primary series intervals:** **Recommended Interval**: 8 weeks * **Authorized Interval**: 28 days **Minimum Interval**: 21 days **Booster dose intervals:** **Recommended Interval**: 6 months **Minimum Interval**: *3 months	**Cap**: Red **Concentration:** 0.20mg/ml **Vial volume:** 5 ml (multidose vial) 0.25ml (50mcg) dose: 20 doses per vial* 0.5ml (100mcg) dose: 10 doses per vial* **Dose**: 6 to 11 yrs: 50mcg (0.25ml) ≥ 12 years: 100mcg (0.5ml) **Do not dilute** **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 Let thawed product stand at room temperature 15 minutes prior to use. **Discard time:** Once the vial has been punctured, refrigerate or store at room temperature for maximum 24 hrs, then discard. Thawed vials and filled syringes can be handled in room light conditions. Pre-loaded syringes can be stored at room temperature or refrigerated and must be used by end of clinic.	**Administered**: Intramuscular **Site:** deltoid **Needle length:** 5/8" to 1 ½" Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age, gender and muscle mass.
*People who are: • Immunocompromised • Living in a PCH/EPH • ≥ 70 years or • received 2 non-Health Canada approved vaccines	*For those who identify as being at increased risk See Table 1, (Recommended mRNA schedule)	*Do not puncture vial more than 20 times	*Do not refreeze once thawed	
Potential allergens: None known The product is latex and preservative free				

Product Information	Approved immunization intervals	Presentation	Clinic Setting Considerations	Administration
Bivalent formulation: Original/Omicron Booster ≥ 18 years				
Not for use as primary series **Booster dose:** Individuals 6 to 11 years of age: *Not approved for this age group.* Individuals 12 to 17 years of age: *Not approved for this age group.* Individuals ≥ 18 years of age: One dose 0.5ml (50mcg) Current eligibility criteria available online: https://www.gov.mb.ca/covid19/vaccine/eligibility-criteria.html	**Recommended Interval**: 6 months **Minimum Interval**: *3 months See Table 1, (Recommended mRNA schedule)	**Cap**: Blue **Label**: Green **Concentration:** 0.10mg/ml **Vial volume:** 2.5 ml (multidose vial) **Dose**: 0.5ml (50mcg) dose **Do not dilute** **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 Let thawed product stand at room temperature 15 minutes prior to use. Thawed vials and filled syringes can be handled in room light conditions. **Discard time:** Once the vial has been punctured, refrigerate or store at room temperature for maximum 24 hrs, then discard. Pre-loaded syringes can be stored at room temperature or refrigerated and must be used within 24 hours.	**Administered**: Intramuscular **Site:** deltoid **Needle length:** ≥1” Clinical judgement should be used when selecting needle length for IM injections. Consider clients weight, age, gender and muscle mass.
	*For those who identify as being at increased risk	*Do not puncture vial more than 20 times	*Do not refreeze once thawed	
Potential allergens: None known The product is latex and preservative free				

Recommendations on COVID-19 Doses for the Primary Series:

- Children that are 5 years of age should initiate the pediatric Pfizer COMIRNATY™ primary series.
- For children 6 years to 11 years of age, the use of Pfizer COMIRNATY TM (10mcg) is preferred to Moderna Spikevax (50 mcg) to start or continue the primary vaccine series.
- Manitoba recommends that young people age 12 - 29 years receive Pfizer COMIRNATY™ for their primary series doses, to minimize the rare potential increased risk of myocarditis/pericarditis.
- A person who received a first dose of an mRNA vaccine (COMIRNATY™ or SPIKEVAX™) 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 to complete the vaccine series.
    - 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 (COMIRNATY™ or SPIKEVAX™).
    - The **minimum** interval of 21 days is not recommended; however, would be considered a valid dose in PHIMS.
- The recommended interval for booster doses is 6 months between the most recent dose (primary series, previous booster dose) and the eligible booster. However, a booster dose may be administered using a 3 month interval after discussing the risk and benefits of a shortened interval with the client.
- 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.

NOTE: The date the first vaccine was 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.

Allergies:

Refer to Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers – Appendix C for precautionary information on national guidance related to allergic responses to vaccines.

Table 1 (Third dose [primary series] recommendations, immunocompromised)

Third dose recommendations for those moderately to severely immunocompromised			
Cohort	**Product**	**Dose**	**Recommended interval**
6 months to 4 years	**Royal Blue Cap**	0.25ml (25mcg)	28 days after their second dose. Considered part of the primary series.
6 to 11 years	**Red Cap**	0.25ml (50 mcg)	28 days after their second dose. Considered part of the primary series.
≥ 12 years	**Red Cap**	0.5ml (100mcg)	28 days after their second dose. Considered part of the primary series.

Table 2 (Third dose recommendations [primary series], non-Health Canada approved)

Third dose recommendations for individuals with 1 or 2 non-Health Canada approved vaccines				**Manitoba Health accepted primary series combinations**
6 to 11 years	**Red Cap**	0.25ml (50 mcg)	≥ 28 day interval after last dose to complete their primary series.	• 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)
≥ 12 years	**Red Cap**	0.5ml (100mcg)	≥ 28 day interval after last dose to complete their primary series.	

NOTE: For people unwilling or unable to receive an mRNA vaccine, Novavax Nuvaxovid can be used for the additional dose.

Table 3 (Manitoba Health recommended mRNA immunization schedule based on age)

	Approved COVID-19 mRNA vaccine	Time between 2 doses of primary series	*Immunosuppressed:* Time between 3 doses of primary series	Time between most recent dose and any eligible booster dose
Infants and children aged 6 months to 4 years	Moderna/Spikevax™ (25mcg)	8 weeks	4 to 8 weeks between each dose	Not eligible
Children aged 5 years *	Pfizer/Comirnaty™ (10mcg) or Moderna/Spikevax™ (25mcg)	8 weeks	4 to 8 weeks between each dose	6 months **^**
Children aged 6 to 11 years *	Pfizer/Comirnaty™ (10mcg) or Moderna/Spikevax™ (50mcg)	8 weeks	4 to 8 weeks between each dose	6 months **^**
Youth aged 12 to 17 years *	Pfizer/Comirnaty™ (30mcg) or Moderna/Spikevax™ (100mcg)	8 weeks	4 to 8 weeks between each dose	6 months
Adults aged 18 to 29 years *	Pfizer/Comirnaty™ (30mcg) or Moderna/Spikevax™ (50mcg/100mcg)	8 weeks	4 to 8 weeks between each dose	6 months
Adults aged 30 years and older	Pfizer/Comirnaty™ (30mcg) or Moderna/Spikevax™ (50mcg/100mcg)	8 weeks	4 to 8 weeks between each dose	6 months

***** Pfizer/Comirnaty™ is the recommended mRNA vaccine for the primary series in individuals 5 to 29 years.

^ Pfizer/Comirnaty™ is the only vaccine approved for booster dose in this age group.

NOTE: Moderna/Spikevax™ **100mcg** is offered as a primary series to individuals age 12 and older and as a first booster dose to individuals at increased risk of severe illness.

NOTE: Moderna/Spikevax™ **50mcg** is offered as a booster dose to individuals age 12 and older who are not at risk of severe illness.

Table 4 Storage and handling of Manitoba COVID-19 approved vaccines

COVID-19 Vaccine Product and Approved Age Indication	Ultra Low Freezer Storage Time (-90ºC to -60ºC)‡	Freezer Storage Time (-25ºC to -15ºC)	Refrigerated Storage Time Before Dilution or Puncture (+2ºC to +8ºC)^	Room Temperature Time Before Dilution or Puncture (+8ºC to +25°C)	After Dilution or Puncture Time (+2ºC to +25ºC)
MODERNA					
Moderna (Spikevax™) 6 years of age and older **Red Cap**	Do not store at this temperature	Until expiry date on vial or identified extended expiry date: https://modernacovid19global.com/ca/health-product-risk-11jan2022-en.pdf	30 days	24 hours No dilution required	Must be used within 24 hours after first puncture
Moderna (Spikevax™) 6 months to 5 years **Royal Blue Cap**	Do not store at this temperature	Until expiry date on vial or identified extended expiry date. Stored in the original carton to protect from light	30 days	24 hours No dilution required	Must be used within 24 hours after first puncture
Moderna (Spikevax™) Bivalent **Blue Cap/Green Label**	Do not store at this temperature	Store 9 months at this temperature	30 days	24 hours	24 hours after first puncture
PFIZER					
Pfizer (Comirnaty™) 5-11 years of age **Orange Cap**	12 months from the date of manufacture	Do not store at this temperature	10 weeks	12 hours prior to dilution	Must be used within 12 hours after dilution
Pfizer (Comirnaty™) 12 years of age and older **Purple Cap**	Until expiry date printed on label	2 weeks	1 month prior to dilution	2 hours prior to dilution (including thaw time)	Must be used within 6 hours after dilution

Table 4 Storage and handling of Manitoba COVID-19 approved vaccines cont.

Non-mRNA vaccines					
Novavax (Nuvaxovid™) 18 years of age and older **Blue Cap**	Do not store at this temperature	Do not store at this temperature	Maximum of 9 months, not exceeding the expiry on the vial/label	Should remain stored at 2°C to 8°C before first puncture No dilution required	Must be used within 6 hours after first needle puncture
Janssen 18 years of age and older **Blue Cap**	Do not store at this temperature	Until expiry date printed on the vial and carton	11 months, not exceeding the expiry date on the vial/label	12 hours No dilution required	After first puncture it must be used within: • 6 hours if stored between +2°C to +8°C 3 hours if stored between +9°C to +25°C
‡ Expiry dates may be extended. Monitor for Health Canada announcements that may affect the expiry dates. ^ Length of time to be stored in refrigerator before puncture or dilution until being discarded, unless the manufacturer's expiry date occurs before that time.					

Note: Most vaccines are distributed to providers at +2°C to 8°C (refrigerated temperature). **Thawed or partially thawed vaccines cannot be refrozen.**

- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Product should be marked with applicable expiry dates based on time in refrigerator and time after puncture to avoid administration errors. Please refer to the product monographs for all storage and handling guidelines
- Vaccine that is expired or cannot be used if it has reached past the identified timelines are to be removed from storage, deducted from any inventory (if applicable) and returned to MDA for proper disposal following Manitoba's Return Policy and Process https://www.gov.mb.ca/health/publichealth/cdc/div/docs/vbrpp.pdf