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:	October 20, 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-pm.pdf

Eligibility Criteria:

Please refer to Province of Manitoba | Eligibility Criteria (gov.mb.ca) for the most up to date information on primary series and 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 5: Bivalent Considerations

Product Information	Approved immunization Presentation intervals		Clinic Setting Considerations	Administration		
6 months to 5 years						
Primary series: 2 dose regimen 0.25mL (25mcg) Note: 3 rd dose may be recommended for some individuals. See table 2	Recommended Interval: 8 weeks * Authorized Interval: 28 days	Cap: Royal Blue Concentration: 0.10mg/ml Vial volume: 2.5ml (multidose vial) 10 doses per vial* Dose: 25mcg (0.25ml)	Thaw time*: 2° to 8°C (Refrigerator): 2 hours 15° to 25° C (Room temperature): 45 min		uscular needle le onths to under 5	years
Booster dose: Not approved for this age group	Minimum Interval: 21 days	Do not dilute	Let thawed product stand at room temperature 15	AGE	SITE	NEEDLE LENGTH
this age group 6m to 4yrs 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. 5 years of age: 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.		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.	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	Infants (6- 12months) Young children (12months-3 years) Young children (12months-3 years) Children 3+	Anterolateral thigh Deltoid Anterolateral thigh Deltoid	1" 5/8" to 1" At least 1" 5/8" to 1"
	*See Table 1, (Recommended mRNA schedule)	*Do not puncture vial more than 10 times	*Do not refreeze once thawed			
Potential allergens: Polyethylene The product is latex and preserva	• , , ,	Tromethamine or Tris)				

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

Co-administration: As a precautionary measure, 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. A 14-day interval is recommended to ensure adverse effects following immunizations (AEFIs) are attributed to the correct vaccine. Parents or guardians may still present to your facility for a COVID vaccine within 14 days of getting or have a scheduled appointment for a non-COVID vaccine. The precautionary recommendation to defer vaccination should be discussed with the parent/guardian in the informed consent process. A shortened interval or co-administration may be permitted if there are challenges of scheduling multiple visits and especially among those who are not likely to return for another visit to get either the COVID or other vaccines for their children.

Product Information	Approved immunization intervals	Presentation	Clinic Setting Considerations	Administration
Monovalent formulation: 6 to 11 ye				
Wionovalent formulation: 6 to 11 ye	ars and 2 12 years			
Primary Series:	Primary series	Cap: Red	Thaw time*:	Administered: Intramuscular
Individuals 6 to 11 years of age:	intervals:	Concentration: 0.20mg/ml	2° to 8°C (Refrigerator): 2 hours	
2 dose regimen of 0.25 mL (50 mcg)	Recommended	Vial volume: 5 ml (multidose		Site: deltoid
	Interval: 8 weeks *	vial)	15° to 25° C (Room temperature):	
Individuals ≥ 12 years of age:			45 min	Needle length:
2 dose regimen of 0.5 mL (100 mcg)	Authorized Interval:	0.25ml (50mcg) dose: 20		5/8" to 1 ½"
	28 days	doses per vial*	Let thawed product stand at	Clinical judgement should be
Note: 3 rd dose may be recommended for		0.5ml (100mcg) dose: 10	room temperature 15 minutes	used when selecting needle
some individuals. See table 2	Minimum Interval:	doses per vial*	prior to use.	length for IM injections.
	21 days	_		Consider clients weight, age,
Booster dose:		Dose:	Discard time:	gender and muscle mass.
Individuals 6 to 11 years of age:	Dooston doos intomiolo.	6 to 11 yrs: 50mcg (0.25ml)	Once the vial has been	
Moderna/Spikevax™ not approved for this	Booster dose intervals: Recommended	≥ 12 years: 100mcg (0.5ml)	punctured, refrigerate or store at room temperature for maximum	
age group.	Interval: 6 months	Do not dilute	24 hrs, then discard.	
Individuals ≥ 12 years of age:	interval. o months	Do not unute	24 ms, then discard.	
50 mcg (half dose)	Minimum Interval:	Inspect vials: White/off-white	Thawed vials and filled syringes	
So meg (num dose)	*3 months	dispersion and may contain	can be handled in room light	
*High Risk populations (first booster only):	3 1110111113	white or translucent product-	conditions.	
100mcg (full dose)		related particulates. If	conditions.	
3 3 (3 3 3 3 4)		solution contains foreign	Pre-loaded syringes can be stored	
		particulates or discoloration,	at room temperature or	
		do not administer.	refrigerated and must be used by	
			end of clinic.	
*People who are:	*For those who	*Do not puncture vial more	*Do not refreeze once thawed	
 Immunocompromised 	identify as being at	than 20 times		
 Living in a PCH/EPH 	increased risk			
• ≥ 70 years or				
 received 2 non-Health Canada 	See Table 1,			
approved vaccines	(Recommended mRNA			
	schedule)			
Potential allergens: Polyethylene glycol (PE	G), Trometamol (Trometh	amine or Tris)		
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	Recommended	Cap: Blue	Thaw time*:	Administered:
	Interval: 6 months	Label: Green	2° to 8°C (Refrigerator):	Intramuscular
Booster dose:			2 hours	
Individuals 6 to 11 years of age:	Minimum Interval:	Concentration: 0.10mg/ml		Site: deltoid
Not approved for this age group.	*3 months		<u>15° to 25° C (Room</u>	
		Vial volume: 2.5 ml	temperature): 45 min	Needle length:
Individuals 12 to 17 years of age:		(multidose vial)		≥1"
Not approved for this age group.			Let thawed product stand at	Clinical judgement should be
		Dose:	room temperature 15	used when selecting needle
Individuals ≥ 18 years of age:		0.5ml (50mcg) dose	minutes prior to use.	length for IM injections.
One dose 0.5ml (50mcg)				Consider clients weight, age,
		Do not dilute	Thawed vials and filled	gender and muscle mass.
			syringes can be handled in	
Current eligibility criteria available online:		Inspect vials: White/off-	room light conditions.	
https://www.gov.mb.ca/covid19/vaccine/eligibili	<u>ty-</u>	white dispersion and may		
<u>criteria.html</u>		contain white or	Discard time:	
		translucent product-	Once the vial has been	
		related particulates. If	punctured, refrigerate or	
		solution contains foreign	store at room temperature	
		particulates or	for maximum 24 hrs, then	
		discoloration, do not	discard.	
		administer.		
			Pre-loaded syringes can be	
			stored at room temperature	
			or refrigerated and must be	
	See Table 1,		used within 24 hours.	
	(Recommended			
	mRNA schedule)			
	*For those who	*Do not puncture vial	*Do not refreeze once	
	identify as being at	more than 20 times	thawed	
	increased risk			

Potential allergens: Polyethylene glycol (PEG), Trometamol (Tromethamine or Tris). If individual is 12+ and has a known allergy to Tromethamine they should be offered a <u>Pfizer monovalent (purple cap)</u> vaccine for their booster dose.

The product is latex and preservative free

See **Table 5: Bivalent Considerations** for detailed information about bivalent recommendations and administration.

Recommendations on COVID-19 Doses for the Primary Series:

- Children who will turn from 4 to 5 years of age between their 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.
- Children that are 5 years of age should initiate with the pediatric Pfizer COMIRNATY™ vaccine for their 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.
 - o 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.
 - o 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™).
 - o The minimum interval of 21 days is not recommended; however, would be considered a valid dose in PHIMS.
- Individuals who are moderately to severely immunocompromised are recommended to receive a third dose in the primary series. 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.

Recommendations on COVID-19 Immunization Booster doses:

- 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.
- Individuals who have already received an mRNA COVID-19 vaccine as part of a fall COVID-19 vaccine booster program will not be eligible for an additional dose of a COVID-19 vaccine at this time. This includes individuals who were vaccinated using any authorized original or bivalent mRNA COVID-19 vaccine. Both original and bivalent mRNA COVID-19 vaccines will boost immune responses and are likely to provide significant protection against hospitalization and severe disease.
- See Table 5: Bivalent Considerations for detailed information about bivalent recommendations and administration.

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 (Moderna 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	0.25ml (25mcg) Royal Blue Cap*	• 3 dose series	28 days after their second dose. Considered part of the primary series.			
6 to 11 years	0.25ml (50 mcg) Red Cap	• 3 dose series	28 days after their second dose. Considered part of the primary series.			
≥ 12 years	0.5ml (100mcg) Red Cap	• 3 dose series	28 days after their second dose. Considered part of the primary series.			

^{*}A 3 dose series of Moderna/SpikevaxTM (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/ComirnatyTM)

Table 2 (Moderna 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
Cohort	Product	Dose	Recommended interval	Two mRNA vaccines (Pfizer or Moderna)
6 months to 4 years	0.25ml (25mcg) Royal Blue Cap* * preferred over Pfizer (3mcg)	Blue Cap* additional dose dose to complete their primary series.	 Two AstraZeneca vaccines AstraZeneca and one dose of an mRNA vaccine (Pfizer or Moderna) One dose of Janssen Three non-Health Canada Approved vaccines 	
6 to 11 years	0.25ml (50 mcg) Red Cap	Administer one additional dose	≥ 28 day interval after last dose to complete their primary series.	 One or two non-Health Canada Approved Vaccines and one dose of an mRNA Vaccine (Pfizer or Moderna) For moderately to severely immunocompromised
≥ 12 years	0.5ml (100mcg) Red Cap	Administer one additional dose	≥ 28 day interval after last dose to complete their primary series.	 Three doses (any combination of AstraZeneca, Pfizer and/or Moderna) Children 6m to 4 years with 3 doses of a non-Health Canada approved vaccine.

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

⁺ Moderna/Spikevax™ is the recommended mRNA vaccine for Immunocompromised Infants and children 6 months to 4 years.

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

^{**}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).

NOTE: Moderna/SpikevaxTM 100mcg is offered as a primary series to individuals age 12 and older and as a booster dose to individuals at increased risk of severe illness. Moderna/SpikevaxTM 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 (Moderna)

COVID-19 Vaccine Product and Approved Age Indication	Ultra Low Freezer Storage Time (-90°C to -60°C)‡	Freezer Storage Time (-25°C to -15°C)	Refrigerated Storage Time Before Dilution or Puncture (+2°C to +8°C)^	Room Temperature Time Before Dilution or Puncture (+8°C to +25°C)	After Dilution or Puncture Time (+2°C to +25°C)
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

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

COVID-19 Bivalent (Omicron) booster vaccine considerations:

There are two COVID-19 mRNA bivalent Omicron-containing products available in Manitoba. Assisting the client to make an informed decision about which product is best for them can be a complex task. Please use the information provided below to help guide the informed consent process.

Key considerations:

- The bivalent vaccines contain two different mRNA components, based on the original strain and the omicron strain of SARS-CoV-2 virus.
- The bivalent vaccines help boost the immune system, creating more antibodies to fight COVID-19. Research shows they give strong protection from severe illness or hospitalization and lower the risk of symptoms and long-term complications caused by COVID-19 infection.
- Both bivalent products have been authorized for use as a booster dose and are not to be used for a primary series.
- The side effects of the bivalent are similar to the monovalent mRNA vaccines and usually mild.

Eligibility considerations:

- The bivalent Omicron-containing mRNA vaccines are the preferred booster products for those that are eligible to receive them.
- NACI recommends that all individuals 12 years of age older and especially those who are at increased risk of severe illness, may be offered a fall COVID-19 booster dose, regardless of the number of booster doses previously received. *NACI recommendations can be viewed here.*
- Everyone 12 years of age and older, who has completed their primary series should be offered a bivalent booster.
- Individuals who already received an mRNA COVID-19 vaccine as a fall booster dose will <u>not</u> be eligible for additional COVID-19 booster doses at this time. This includes the original monovalent vaccine and either bivalent vaccine.

There is no evidence indicating one bivalent vaccine is more effective than the other.

	12 to 17	≥ 18	Intervals	Additional considerations:
	years	years		Providers must ensure that the appropriate vaccine is available when offering
Pfizer (Comirnaty™) Bivalent ≥12 years	~	~	Recommended Interval: 6 months Minimum Interval: 3 months	 clinics that include the 12 to 17 age cohort, as they are only eligible to received the Pfizer/Comirnaty™ bivalent product. If there is no preference stated by the client, consider offering the product that will result in the least wastage.
Moderna (Spikevax™) Bivalent ≥18 years	×	~	The vaccine intervals are more important than which product the client receives. Those at higher risk should be immunized as early as possible.	 If the client has a strong preference for one product, do not deny access to it (if they meet the eligibility criteria). Do not engage in a difficult conversation with the client. If necessary, refer the client to their health care provider for a more comprehensive assessment and conversation about which bivalent product is right for them.

Table 5 (Bivalent Considerations)