SPECIAL EDITION

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Canada

Canadian Paediatric Society

COVID-19 vaccine for children 6mo – 5y Part 3

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PROTECTING AND EMPOWERING CANADIANS TO IMPROVE THEIR HEALTH

Disclosure Statement

- Faculty: maRiNA Salvadori

- I have no affiliation (financial or otherwise) with a pharmaceutical, medical device or communications organization.
- Any opinions expressed are my own


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Objectives

COVID19 vaccine for the 6mo- 5 y age group

At the end of this presentation, participants will be able to inform their patients and parents about the NACI recommendations on:

1. COVID-19 vaccine for children 6 months to 5 years of age.
2. COVID-19 boosters for children and adolescents.
3. The new bivalent original strain/omicron booster.

COVID-19 IN PEDIATRIC POPULATIONS

COVID-19 burden of disease in children in Canada

- During the summer of 2022, Canada had an increase in COVID-19 activity driven by the BA.5 and BA.4 Omicron sub-variants.

- Population level estimates of hospitalization and ICU admissions in pediatric populations have increased since Omicron became the dominant variant. This reflected an overall increase across the population since Omicron became the dominant variant.

- Canadian seroprevalence studies for children are available from Quebec (January 26, 2022 – February 17, 2022) and British Columbia (March 2022):
  - It is estimated that 45% to 70% of children 5 to 11 years of age have been infected with SARS-CoV-2 with most having occurred since Omicron became the dominant variant.

COVID-19 and Canadian Pediatric Populations:
Disease severity by age, pre- and during Omicron

	Pre-Omicron March 1, 2020 - December 31, 2021			Omicron January 1, 2022 - March 31, 2022		
Age group	Hospitalized cases, n (Average monthly rates per 100,000 population)	ICU admissions, n (Average monthly rates per 100,000 population)	Deaths, n (Average monthly rates per 100,000 population)	Hospitalized cases, n (Average monthly rates per 100,000 population)	ICU admissions, n (Average monthly rates per 100,000 population)	Deaths, n (Average monthly rates per 100,000 population)
<6m	168 (9.7)	11 (0.6)	1 (0.06)	247 (104.9)	11 (4.7)	0 (0.00)
6m to 11m	49 (2.8)	1 (0.1)	0 (0.00)	84 (35.7)	9 (3.8)	2 (0.85)
6m to 4y	**226 (1.4)**	**16 (0.1)**	**2 (0.01)**	**357 (15.9)**	**29 (1.3)**	**6 (0.27)**
5 to 11	139 (0.5)	20 (0.1)	2 (0.01)	148 (3.9)	18 (0.5)	2 (0.05)
12 to 19	428 (1.3)	53 (0.2)	6 (0.02)	277 (6.1)	20 (0.4)	5 (0.11)
20 to 39	4,792 (4.6)	717 (0.7)	172 (0.16)	1,518 (10.6)	121 (0.8)	45 (0.31)
40 to 59	9,833 (10.1)	2,440 (2.5)	972 (1.00)	2,136 (16.1)	397 (3.0)	239 (1.80)
60 plus	24,165 (26.1)	4,655 (5.0)	11,115 (12.01)	9,490 (75.2)	1,193 (9.5)	2,876 (22.80)

- While rare, children 6 months- 4 years of age do have severe outcomes of COVID-19.
- Of this age group, a disproportionate amount of hospitalizations, ICU admissions and deaths from Omicron occurred in infants 6m to 11m of age.

Source: Detailed case data submitted to PHAC by MB, NL, NT, ON PE, and YT, Data as of March 31, 2022

Knowns and unknowns on the burden of COVID-19 disease for 6 months to 5 years

	KNOWNS	UNKNOWNS
Omicron conferred protection	**High seroprevalence** (up to 70%) during Omicron wave Indirect data from adult populations suggests **prior Omicron infection confers strong protection against BA.2 infection and symptomatic disease**	Unknown trajectory for pediatric COVID-19 epidemiology **Unknown strength and duration of protection conferred by Omicron infection among young children**
Disease severity	**Most children do not have severe disease, however, some do.** Hospitalization and severe outcomes are infrequent, more during Omicron than previous waves Children who are **medically fragile or with underlying conditions** are at **increased risk** of severe disease	Unknown risk of severe disease for future VOCs **Very limited evidence to inform risk of severe disease by a specific underlying condition**

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Moderna Spikevax (25mcg) for children 6 mths to 5 yrs

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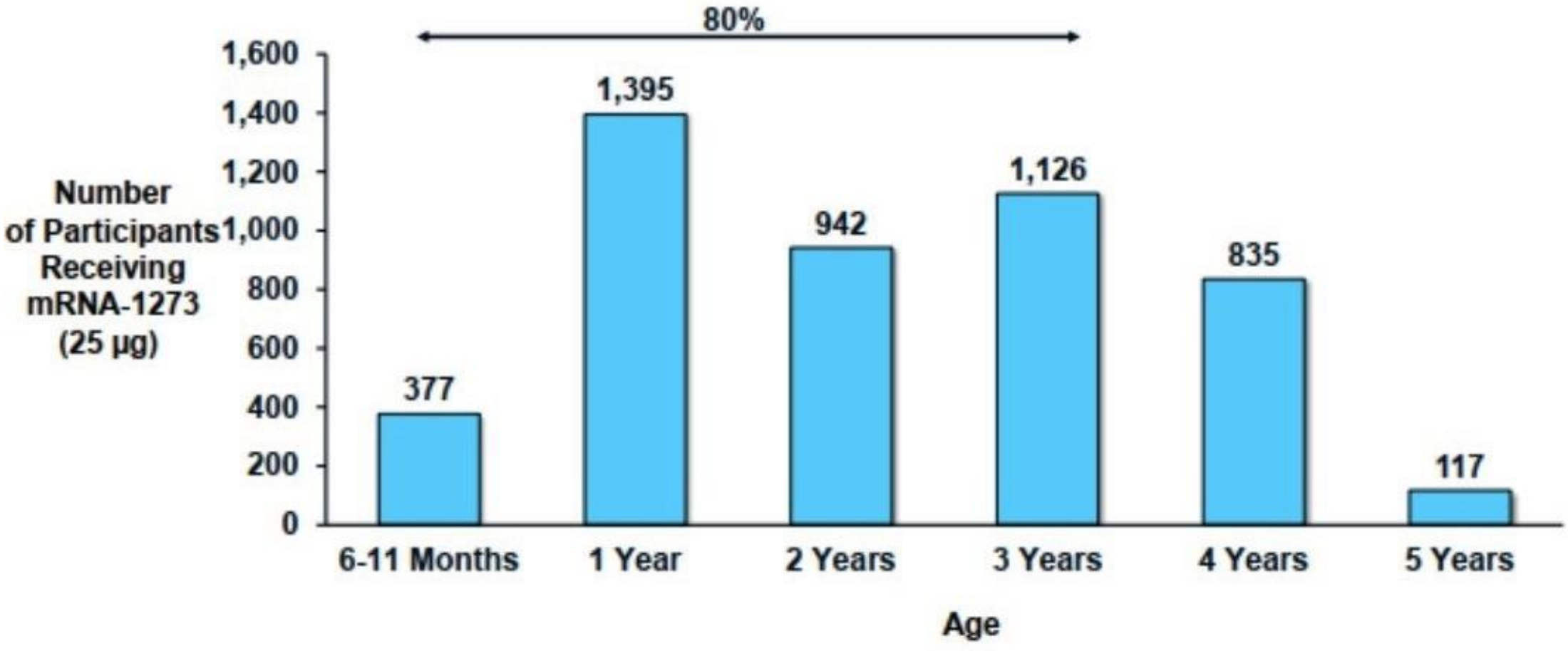
Clinical trial overview of Moderna Spikevax in children 6 mths to 5 yrs

- Vaccine clinical trials in children 6 months to 5 years of age took place in Canada and the US when Omicron was the dominant variant.
- Participants randomly assigned to receive either two doses of the vaccine (25 mcg mRNA) or two doses of placebo, 28 days apart.
- For children 6 months to <2 years, 1,730 were randomized to receive mRNA vaccine (approximately 20% were 6 months to <1 year of age), and 590 received placebo. They were followed up for a median period of 98 days after dose 1 and 68 days after dose 2 at the time of data cut-off.
- For children 2 to 5 years, 3,031 were randomized to receive mRNA vaccine, and 1,007 received placebo. They were followed up for a median period of 103 days after dose 1 and 71 days after dose 2 at the time of data cut-off.

Age Distribution of Participants Receiving mRNA-1273

Study 204 (Part 2): Infants, Toddlers, and Young Children (6 Months – 5 Years), Safety Set



IMMUNOGENICITY DATA

Immunogenicity (PsVNA) 1 Month Post-Dose 2

	Study 204		Study 301
Day 57 Analysis, Part 2 PsVNA ID50 assay	Infants/Toddlers (6-23 Months) mRNA-1273 (25µg) N=230	Young Children (2-5 Years) mRNA-1273 (25µg) N=264	Young Adults (18-25 Years) mRNA-1273 (100µg) N=295
GMT (Geometric Mean Titer) 95% CI	**1781** (1606,1974)	**1410** (1274,1561)	**1391** (1262,1532)
GMT Ratio (Study 204 vs 301) 95% CI	**1.28** (1.12,1.47)	**1.01** (0.88,1.17)	-
Seroresponse, n/N (%) 95% CI	230/230 (**100%**) (98.4,100)	261/264 (**98.9%**) (96.7,99.8)	289/291 (**99.3%**) (97.5,99.9)
Difference (Study 204 vs 301) 95% CI	**0.7** (-1.0,2.5)	**-0.4** (-2.7,1.5)	-

EFFICACY DATA

Efficacy against confirmed symptomatic COVID-19 in study participants in 6 mths to 23 mths

Analysis population	Outcome	Vaccine group (N=1,511)	Placebo group (N=513)	Vaccine efficacy (95% CI)
CDC confirmed COVID-19 case definition starting 14 days after Dose 2				
Per-protocol	Cases, n	51	34	**50.6% (21.4%, 68.6%)**
	Incidence rate per 1,000 person-years (95% confidence interval)	**138.2 (102.9, 181.8)**	**279.8 (193.8, 391.0)**	
P301 confirmed COVID-19 case definition starting 14 days after Dose 2				
Per-protocol	Cases, n	**37**	**18**	**31.5% (-27.7%, 62.0%)**
	Incidence rate per 1,000 person-years (95% confidence interval)	**100.0 (70.4, 137.8)**	**146.0 (86.5, 230.8)**	
CDC confirmed COVID-19 case definition ≥ 14 days after Dose 1 to < Dose 2				
Modified intention to treat	Cases, n	10/1,519	3/514	**-11.4% (-529.8%, 71.3%)**
	Incidence rate per 1,000 person-years (95% confidence interval)	**145.9 (69.9, 268.2)**	**130.9 (27.0, 382.7)**	

Source: Manufacturer's submission to Health Canada, ModernaTX, Inc

Efficacy against confirmed symptomatic COVID-19 in study participants 2 to 5 years of age

Analysis population	Outcome	Vaccine group (N=2,594)	Placebo group (N=858)	Vaccine efficacy (95% CI)
CDC confirmed COVID-19 case definition starting 14 days after Dose 2				
Per-protocol	Cases, n	119	61	36.8% (12.5%, 54.0%)
	Incidence rate per 1,000 person-years (95% confidence interval)	175.0 (145.0, 209.4)	277.0 (211.9, 355.8)	
P301 confirmed COVID-19 case definition starting 14 days after Dose 2				
Per-protocol	Cases, n	**71**	**43**	46.4% (19.8%, 63.8%)
	Incidence rate per 1,000 person-years (95% confidence interval)	103.8 (81.0, 130.9)	193.5 (140.1, 260.7)	
CDC confirmed COVID-19 case definition ≥ 14 days after Dose 1 to < Dose 2				
Modified intention to treat	Cases, n	150/2693	79/898	38.7% (18.5%, 53.6%)
	Incidence rate per 1,000 person-years (95% confidence interval)	214.9 (181.9, 252.2)	350.7 (277.7, 437.1)	

Source: Manufacturer's submission to Health Canada, ModernaTX, Inc

Efficacy conclusions

- VE estimates in both pediatric age groups were **consistent with vaccine effectiveness estimates in adults during the time of the Omicron surge** (Tseng et al 2022; Andrews et al 2022).
- VE against symptomatic COVID-19 ranged between 32% and 51% among children 6 months to 5 years
- Severe COVID-19 is rare in children and no such cases were reported in study P204
- A precise estimate of VE against asymptomatic infection could not be established.
  - However, available results suggest a lower VE against asymptomatic infection with the Omicron variant compared with the efficacy against clinical disease

Vaccine safety

- Moderna Spikevax COVID-19 vaccine (25 mcg) was well tolerated in children aged 6 months to 5 years. No safety signals were reported in the trial which was large enough to detect adverse events occurring at a frequency of at least every 6 in 10,000 people.
- The safety profile of Moderna Spikevax vaccine (25 mcg) was consistent with the safety and reactogenicity profile of the 50 mcg and 100 mcg Spikevax formulations used in older age groups.
- Events reported in the vaccine group were consistent with events commonly reported for other vaccines used in children 6 months to 5 years of age. The most frequently reported solicited local and systemic adverse reactions were irritability/crying, pain, sleepiness, and loss of appetite. Fatigue (48.4%) was the most frequently reported systemic adverse reaction in the participants 37 months to 5 years.
- The risk of any rare or very rare adverse events (AE), such as myocarditis and/or pericarditis, is unknown at this time.
  - Current data suggests the risk of myocarditis and/or pericarditis in younger children is lower than that of adolescents or young adults.
- Post-market vaccine safety in pediatric populations will continue to be closely monitored

Overall safety summary

- **In the vaccine group, solicited systemic AEs of all severity were more common after dose 2**.
  - In the placebo group, events were more common after dose 1
- **Majority of solicited reactions onset by 1-2 days, and lasted 2-3 days**
- **<1% persisted beyond 7 days,** and included axillary swelling, local swelling, erythema and pain.
- **Younger children had more frequent irritability/crying, sleepiness, loss of appetite; the older ones, fatigue.**
- The **incidence of overall and related unsolicited AEs, including severe AEs and medically attended adverse events, was similar in the placebo and mRNA-1273 groups** in the 28 days after any dose.
- In the mRNA-1273 group, there were 9 hypersensitivity events (7 grade 1 and 2 grade 2 events) reported by 9 participants within 48 hours after any dose
- In the placebo group, there were 5 hypersensitivity events reported by 4 participants within 48 hours after any dose, none were related to study treatment.
- 2 events of anaphylaxis were reported, deemed unrelated to vaccination
- 3 participants discontinued the study due to an AE
- **“The overall safety profile observed in this study was generally consistent with the known safety profile of mRNA-1273 observed in other clinical studies of the vaccine.”**

Moderna Spikevax (25mcg) benefits and risks:

	KNOWNS	UNKNOWNS
BENEFITS	Immunogenicity following dose 2: Met non-inferiority vs 100 µg in young adults (18-25 years) in P301 Efficacy: VE against symptomatic Omicron infection was consistent with the lower two-dose effectiveness against Omicron observed in adults. Lower VE against asymptomatic infection.	Effectiveness: Unknown effectiveness against any outcome including MIS-C Efficacy: Unknown efficacy against any severe outcome Duration of protection: Unknown duration of protection against any outcome (dose 1 or 2) Transmission: Unknown efficacy against transmission
RISKS	Clinical safety data: Well tolerated, no safety signals Indirect Safety: Risk of myocarditis/pericarditis for Pfizer vaccine among 5-11yo was higher that the expected background rate but was a much lower rate (and somewhat milder presentation) compared to adolescents and young adults.	Unknown risk of rare or very rare adverse events including myocarditis/pericarditis for: - Moderna (25mcg) for children 6m-5y - Moderna (50mcg) for children 5-11y

Recommendations

For children 6 months to 5 years of age:

NACI recommends that a complete series with the Moderna Spikevax COVID-19 vaccine (25 mcg) may be offered to children 6 months to 5 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose.

(Discretionary NACI recommendation)

2. **NACI recommends that children 6 months to 5 years of age who are moderately to severely immunocompromised may be immunized with a primary series of three doses of the Moderna Spikevax COVID-19 vaccine (25 mcg), using an interval of 4 to 8 weeks between each dose.**

(Discretionary NACI recommendation)

Recommendations

3. **NACI recommends that at this time, the Moderna Spikevax COVID-19 vaccine (25 mcg) primary series for children 6 months to 5 years of age should not routinely be given concurrently (i.e. same day) with other vaccines (live or non-live).**

(Strong NACI recommendation)

- As this is a newly authorized vaccine in this age group, evidence relating to any risk of rare or very rare AEs will be monitored. It is advised to wait **14 days** between vaccine products when administering the Moderna Spikevax (25 mcg) COVID-19 vaccine and other vaccines. This could prevent erroneous attribution of an AE to one particular vaccine or the other.

It is acknowledged that it may be challenging for both healthcare providers and parents if multiple visits are required to administer all recommended immunizations. Concurrent administration or a shortened interval between the Moderna Spikevax (25 mcg) COVID-19 vaccine and other vaccines may be warranted on an individual basis in some circumstances at the clinical discretion of the healthcare provider.

Recommendations

4. **For children 5 years of age** (the age group in which both the Moderna Spikevax (25 mcg) and the Pfizer-BioNTech (10 mcg) COVID-19 vaccine primary series are authorized):

4.1 NACI recommends that the Moderna Spikevax vaccine (25 mcg) may be offered to children 5 years of age as an alternative to the Pfizer-BioNTech Comirnaty vaccine (10 mcg); however, the use of Pfizer-BioNTech Comirnaty vaccine (10 mcg) is preferred to the Moderna Spikevax vaccine (25 mcg).

(Discretionary NACI Recommendation)

4.2 NACI recommends that children who have received the Moderna Spikevax vaccine (25 mcg) for a previous dose and turn 6 prior to completing their primary series are recommended to receive the Moderna Spikevax vaccine (50 mcg) to complete their primary series. If the primary series was completed with the Moderna Spikevax vaccine (25 mcg) or with the Pfizer-BioNTech Comirnaty vaccine (10 mcg), the dose should be considered valid and the series complete.

(*Discretionary NACI Recommendation*)

- If readily available (i.e., easily available at the time of vaccination without delay or vaccine wastage), the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with a specific mRNA COVID-19 vaccine.
- However, in following the established guidance on interchangeability of mRNA COVID-19 vaccines, when the same

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COVID-19 Boosters 5-11

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Clinical trial

- The Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg) was evaluated in an ongoing, randomized, observer-blind, placebo-controlled Phase 1/2/3 clinical trial in healthy children 6 months to 11 years of age.

- A booster dose was administered at least 5 months after the primary series, in an open-label manner to Phase 2/3 participants between 5 to 11 years of age who previously received a 2-dose primary series.
  - 3rd dose initiated January 2022, with data cut-off date of March 22, 2022
  - Immunogenicity N=130
  - Safety N=401

Immunogenicity Summary

- Waning of neutralizing antibody responses occurs over 7-9 months after Dose 2
- Neutralizing antibody responses against the original strain and Omicron significantly increase after a 3rd dose is administered 7-9 months after Dose 2
- Omicron-specific titres post-Dose 3 are lower than those for the original strain post-Dose 3, but higher than those for the original strain post-Dose 2
- These trends were observed in participants without evidence of prior SARS-CoV-2 infection and when analysed together with those with evidence of prior infection. However, results for participants with prior infection analysed alone are not available.

Recommendations –
Reiterating the primary series recommendations

1. **NACI continues to recommend that a complete series with an mRNA COVID-19 vaccine should be offered to children 5 to 11 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose.** *(Strong NACI recommendation)*

2. **NACI recommends that children 5 to 11 years of age who are moderately to severely immunocompromised should be immunized with a primary series comprised of three doses of an mRNA vaccine, using an interval of 4 to 8 weeks between each dose.** *(Strong NACI recommendation)*

Recommendations

NACI makes the following recommendations on the use of a first booster dose in children 5 to 11 years of age:

1. **NACI recommends that a booster dose of the Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg) should be offered ≥6 months after completion of a primary COVID-19 vaccine series to children 5 to 11 years of age with an underlying medical condition that places them at high risk of severe illness due to COVID-19 (including those who are immunocompromised and who received a 3-dose primary series).** (Strong NACI recommendation)

Recommendations

For all other children 5 to 11 years of age:

2. **In the context of heightened epidemiological risk, NACI recommends that a booster dose of Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg) may be offered ≥6 months after completion of a primary COVID-19 vaccine series to all children 5 to 11 years of age who do not have underlying medical conditions that could place them at higher risk of severe illness due to COVID-19.**

(Discretionary NACI recommendation)

Hybrid immunity

- A previous SARS-CoV-2 infection with the Omicron variant in fully vaccinated individuals confers protection from reinfection with Omicron BA.4 and/or BA.5 (durability of this protection to be established).

- Preliminary evidence also suggests that in fully vaccinated individuals (with and without prior infection), protection from reinfection is lower against Omicron BA.5, compared to earlier Omicron subvariants (i.e., BA.2), highlighting the potential immune-escape capability of Omicron BA.5.

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The new Moderna Spikevax COVID19 Bivalent vaccine

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New Omicron-containing Bivalent COVID19 Vaccine

Product Monograph Details	Moderna SPIKEVAX Bivalent
Dose	50 mcg (25 mcg original + 25 mcg BA.1)
Schedule	3 months after completion of primary series and/or previous booster
Presentation formation	5 doses per vial (0.5mL /dose)
Packaging	Royal blue cap, green label border

Moderna Spikevax Bivalent COVID-19 vaccine

- Phase 2/3, open-label (non-randomized) using the Moderna Spikevax Bivalent (50mcg) vaccine targeting the Omicron BA.1 subvariant
- Spikevax Bivalent (50 mcg) administered as a 2nd booster to **adults ≥18 years of age** who previously received Spikevax primary series (100mcg) and Spikevax booster (50 mcg) at least 3 months prior to enrollment
  - N=437, with median follow-up of 43 days
- Individuals with a confirmed SARS-CoV-2 infection within 3 months prior to enrollment were not eligible for inclusion
- Non-contemporaneous comparator group of individuals receiving ancestral Spikevax as a 2nd booster
  - N=377, with median follow-up of 57 days
- Study was not designed to evaluate efficacy, and there are currently no data on the efficacy, immunogenicity or safety of Moderna Spikevax Bivalent (50 mcg) in individuals <18 years of age.

Moderna Spikevax Bivalent – Immunogenicity summary

- Spikevax Bivalent elicited higher (superior) neutralizing antibody responses against the original strain, Omicron BA.1 and Omicron BA.4/BA.5 among participants with and without prior infection, compared to original Spikevax.
  - This effect was consistent across age groups, 18 – 65 years of age and >65 years of age.

- All pre-specified primary immunogenicity endpoints were met for bivalent vs original vaccine :
  - Non-inferiority of antibody response against Omicron and original strain
  - Non-inferiority of seroresponse rate
  - Superiority of antibody response against Omicron

- In individuals who had no evidence of prior SARS-CoV-2 infection, larger increases in neutralizing antibody titres against Omicron from pre- to post-booster were observed, compared to those who had evidence of prior SARS-CoV-2 infection
- In individuals who had evidence of prior SARS-CoV-2 infection, the levels of neutralizing antibody titres were significantly higher post-booster compared to pre-booster, and at both timepoints were higher compared to individuals without evidence of prior infection

Moderna Spikevax Bivalent– Safety summary

- Spikevax Bivalent had a similar reactogenicity profile to that of ancestral Spikevax given as a second booster dose.
- The frequency of adverse reactions was similar or lower relative to that of a first booster dose of ancestral Spikevax (50 mcg), and relative to the second dose of the Spikevax primary series (100 mcg).
- Frequency of unsolicited AEs was similar between Spikevax Bivalent and ancestral Spikevax recipients.
- No serious AEs were considered to be related to vaccination in either group, and there were no AEs leading to study discontinuation. No safety concerns identified when participants stratified by prior infection status.
- As of the study cut-off date, no deaths or cases of myocarditis and/or pericarditis were reported.

Moderna Spikevax Bivalent– Other considerations

- There are no data available on the use of bivalent, Omicron-containing mRNA COVID-19 vaccines as a primary series, first booster dose or in a mixed series with vaccines other than Moderna Spikevax original.
- While Moderna Spikevax Bivalent vaccine targets the Omicron BA.1 subvariant, clinical trial results also suggest the bivalent vaccine induces a stronger immune response against Omicron BA.4/BA.5, compared to the original vaccine although lesser than that against the BA.1 subvariant.
- No participants in the Moderna Spikevax Bivalent clinical trial were concurrently administered other vaccines.

Moderna Spikevax Bivalent – Efficacy

- Study P205 not designed to evaluate VE
- In adults **≥18 years of age:**
  - **Spikevax Bivalent**
    - 11 infections (3.2%)
    - Exposure adjusted incidence rate for SARS-CoV-2 infection 5.4 per 1000 person-weeks
  - **Ancestral Spikevax**
    - 5 infections (1.9%)
    - Exposure adjusted incidence rate for SARS-CoV-2 infection 2.3 per 1000 person-weeks

	Spikevax Bivalent (50 mcg) n=339	Ancestral Spikevax (50 mcg) n=266
Primary case definition of COVID-19 (per Study P301), starting 14 days after injection	4 (1.2)	1 (0.4)
Secondary case definition of COVID-19 (CDC criteria) starting 14 days after injection	5 (1.5)	1 (0.4)
SARS-CoV-2 infection starting 14 days after injection	**11 (3.2)**	**5 (1.9)**
Asymptomatic SARS-CoV-2 infection starting 14 days after injection	6 (1.8)	4 (1.5)

Recommendations

With regard to product offered:

3. **NACI recommends that the authorized dose of a bivalent Omicron-containing mRNA COVID-19 vaccine should be offered as a booster dose to the authorized age groups (≥18 years of age). If the bivalent Omicron-containing mRNA COVID-19 vaccine is not readily available, an original mRNA COVID-19 vaccine should be offered to ensure timely protection.**

(*Strong NACI recommendation*)

Bivalent should be the main program, but the ancestral vaccines remain a good alternative

Recommendations

4. **NACI recommends that the authorized dose of a bivalent, Omicron-containing mRNA COVID-19 vaccine may be offered to adolescents 12 – 17 years of age with moderately to severely immunocompromising conditions and/or who have biological or social risk factors that place them at high risk of severe outcomes from COVID-19.**

(***Discretionary NACI recommendation***)

Note: No recommendations on the use of bivalent, Omicron-containing mRNA COVID-19 vaccines for use in the general adolescent population 12 to 17 years of age are being made at this time, however NACI's previous recommendations for a fall booster dose in this population remain in place with respect to the use of original mRNA COVID-19 vaccines.

This is an off-label recommendation.

SUPPORTING PARENTAL DECISION-MAKING

Parental Decision-making

- Healthcare providers should engage parents and guardians in a respectful and culturally-safe way about COVID-19 vaccines for children and **discuss risks and benefits of vaccination for their family**
- Some risks and benefits will be direct and health related, others may be less direct and specific to each family
  - Social, economic and value-based factors will weigh differently for each family
  - Provide families with tailored advice and support
- Conversations may need to take place over several visits, families should not be rushed**. Leave the door open to come back in 4 to 6 weeks.**

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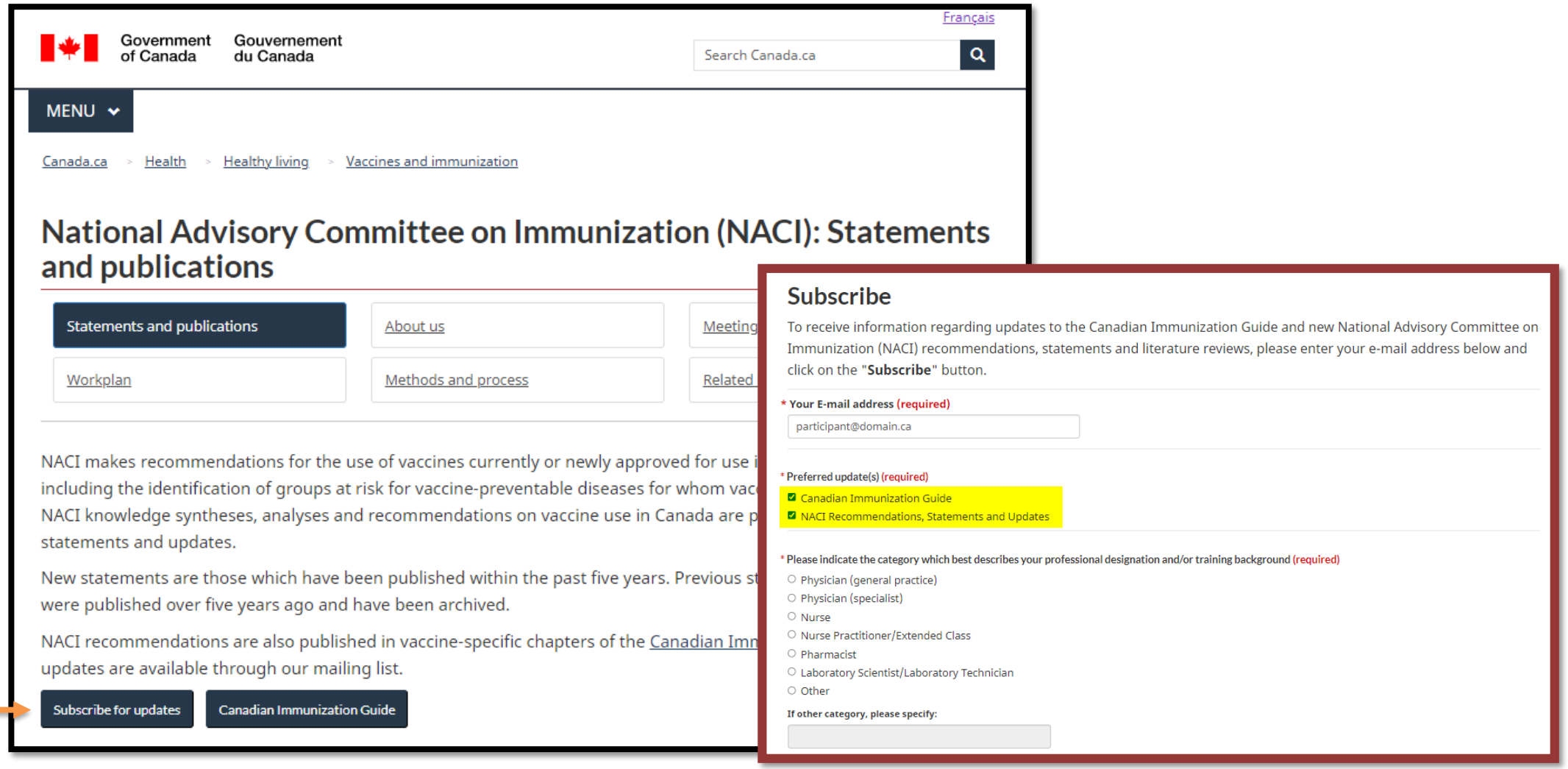

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html

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What's your superpower?