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

Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age

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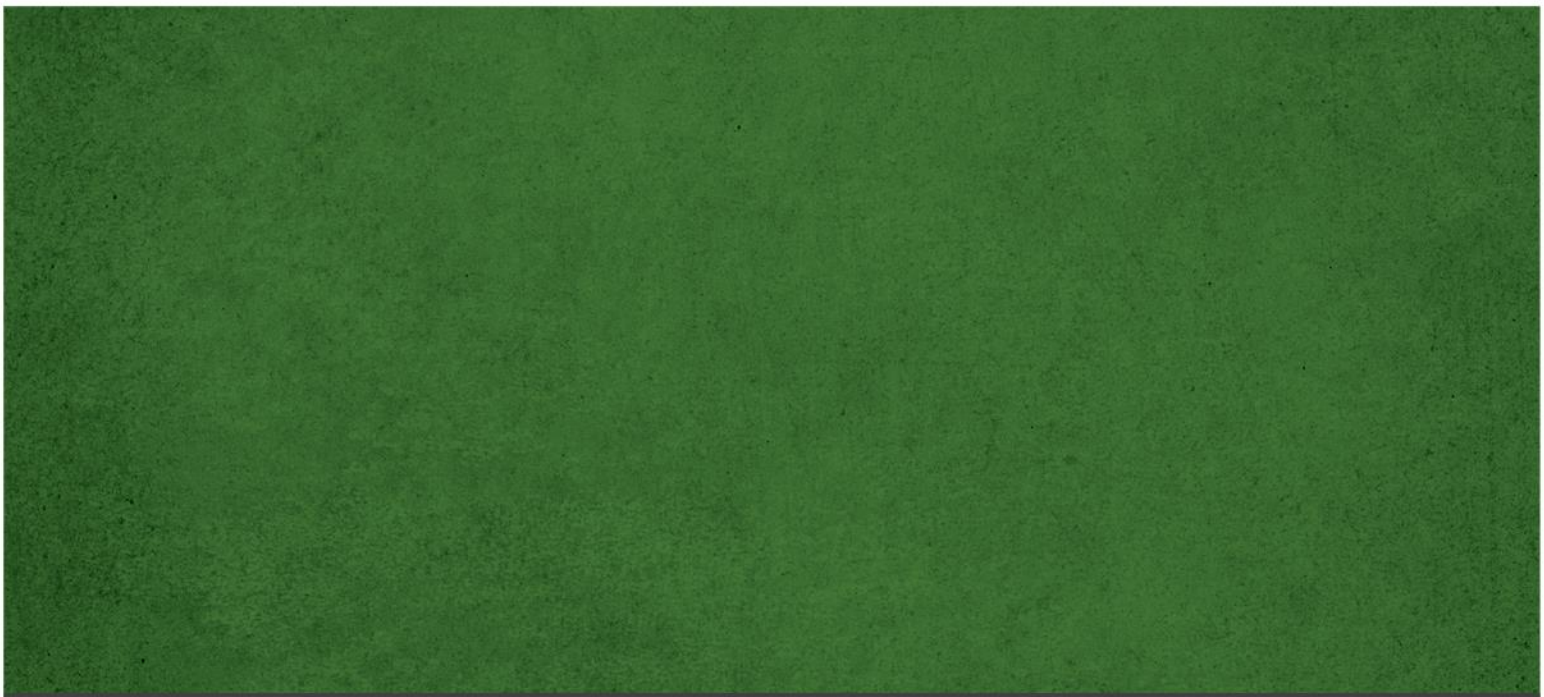

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PREAMBLE

The National Advisory Committee on Immunization (NACI) is an External Advisory Body that provides the Public Health Agency of Canada (PHAC) with independent, ongoing and timely medical, scientific, and public health advice in response to questions from PHAC relating to immunization.

In addition to burden of disease and vaccine characteristics, PHAC has expanded the mandate of NACI to include the systematic consideration of programmatic factors in developing evidence-based recommendations to facilitate timely decision-making for publicly funded vaccine programs at provincial and territorial levels.

The additional factors to be systematically considered by NACI include economics, ethics, equity, feasibility, and acceptability. Not all NACI Statements will require in-depth analyses of all programmatic factors. While systematic consideration of programmatic factors will be conducted using evidence-informed tools to identify distinct issues that could impact decision-making for recommendation development, only distinct issues identified as being specific to the vaccine or vaccine-preventable disease will be included.

This statement contains NACI's independent advice and recommendations, which are based upon the best current available scientific knowledge. This document is being disseminated for information purposes. People administering the vaccine should also be aware of the contents of the relevant product monograph. Recommendations for use and other information set out herein may differ from that set out in the product monographs of the Canadian manufacturers of the vaccines. Manufacturer(s) have sought approval of the vaccines and provided evidence as to its safety and efficacy only when it is used in accordance with the product monographs. NACI members and liaison members conduct themselves within the context of PHAC's Policy on Conflict of Interest, including yearly declaration of potential conflict of interest.

INTRODUCTION

On January 25, 2022, NACI published updated recommendations on the use of the Pfizer-BioNTech Comirnaty (10 mcg) COVID-19 vaccine in children 5 to 11 years of age, including strengthening their recommendation to strongly recommend a 2-dose primary series. In children 5 to 11 years of age who are moderately to severely immunocompromised, a 3-dose primary series is recommended.

Since this guidance:

- Health Canada authorized the use of the Moderna Spikevax (50 mcg) COVID-19 vaccine for children 6 to 11 years of age;
- Additional safety surveillance data on the use of mRNA vaccine booster Moderna Spikevax (50 mcg and 100 mcg) and Pfizer-BioNTech Comirnaty (30 mcg) among individuals aged 18 years and older has emerged; and
- Additional safety surveillance data on the 2-dose primary series of Pfizer-BioNTech Comirnaty (10 mcg) in children 5 to 11 years of age is available, further supporting that the product is well tolerated and providing preliminary estimates on the risk of myocarditis and/or pericarditis in children 5 to 11 years of age.

NACI has reviewed the evolving evidence and has updated evidence-informed recommendations on the use of COVID-19 vaccines in pediatric populations.

METHODS

On February 1, 2022, and February 15, 2022, NACI reviewed the available evidence on the use of the Moderna Spikevax COVID-19 vaccine (50 mcg dose) in children 6 to 11 years of age (including manufacturer's clinical data in the regulatory submission to Health Canada, and post-market safety data on the use of the Moderna Spikevax 50 mcg and 100 mcg dose in older age groups, see Appendix A). Ethical considerations related to COVID-19 vaccination in pediatric populations were discussed with the Public Health Ethics Consultative Group (PHECG) on May 3, 2021, July 6, 2021 and September 21, 2021.

Following a comprehensive review and discussion, NACI approved this updated guidance on COVID-19 vaccines for individuals 6 to 11 years of age on March 11, 2022.

NACI continues to review the evidence on the use of COVID-19 vaccines and will update its recommendations as needed. Details of NACI's evidence-informed recommendation development process can be found elsewhere [1, 2].

VACCINE

Moderna Spikevax COVID-19 vaccine preparations authorized for use among pediatric and adult/adolescent populations in Canada

Table 1. Use of the Moderna Spikevax COVID-19 vaccine for children (6 to 11 years of age) and adults/adolescents (≥12 years of age)

	Use in children (6 to 11 years of age)	Use in adults/adolescents (≥12 years of age; primary series)
Age	6 to 11 years	12 years of age and over
Dose	**50 mcg** (0.25 mL)	**100 mcg** (0.50 mL)
Doses per vial	**20**	**10**
Diluent	**No dilution required**	
Potential allergens	Polyethylene glycol (PEG) Tromethamine (Tris, Trometamol)[a]	
Storage[b,c,d,e]	• Frozen[c] until expiry date printed on the label • Refrigerated[c,d] for up to 30 days • Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours • Once needle-punctured, vials can be stored at room temperature[d] or refrigerated[c,d] up to 24 hours but should not be punctured more than 20 times	
Transport [c]	• Frozen[c] full cartons containing vials[e] • Refrigerated[c,d] thawed vials can be transported up to 12 hours (included in 30-day limit for refrigerated storage)	

[a]Tromethamine (Tris or trometamol) is used as a buffer in vaccines and medications, including those for use in children, to improve stability and prevent pH fluctuations in the solution. No safety concerns have been identified with tromethamine [(3)]. While tromethamine has been identified as a potential allergen, a review of existing evidence did not identify any cases of allergic reactions to tromethamine in children [(4)].

[b]Regardless of storage condition, vaccines should not be used after date of expiry printed on the vial and cartons.

[c] Frozen is -25°C to -15°C; Refrigerated is +2°C to +8°C; Room temperature is +15°C to +25°C.

[d] Once vials are thawed, they should not be refrozen. Thaw in refrigerated conditions between +2° to +8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering. Alternatively, thaw at room temperature for 1 hour.

[e] During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Vials must be kept frozen and protected from light, in the original cartons, until ready to thaw.

For complete prescribing information for the pediatric and adult formulations of the Moderna Spikevax and Pfizer-BioNTech COVID-19 vaccines, consult the product leaflets or information contained within Health Canada's authorized product monographs available through the Drug Product Database.

Schedule

Refer to Table 2 for a summary of immunization schedules for authorized COVID-19 vaccines among children 5 to 11 or 6 to 11 years of age.

Table 2. Immunization schedule for primary series, by COVID-19 vaccine

Vaccine Product	Age	Dose	Immunization Schedule	Minimum Interval	Authorized Interval	NACI - Recommended Interval[1]
Pfizer-BioNTech (Comirnaty; 10 mcg)	5 to 11 years	10 mcg (0.2mL)	2-dose schedule	19 days	21 days	At least 8 weeks
Moderna (Spikevax; 50 mcg)	6 to 11 years	50 mcg (0.25 mL)	2-dose schedule	21 days	28 days	At least 8 weeks

[1]There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response and higher vaccine effectiveness. NACI will continue to monitor the evidence and update this interval as needed.

RECOMMENDATIONS

1. **NACI recommends that a complete series with an mRNA COVID-19 vaccine should be offered to children in the authorized age groups without contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose. (Strong NACI Recommendation)**

For children 6 to 11 years of age (which is the age group in which the Moderna Spikevax 50 mcg primary series vaccine is authorized):

- **Moderna Spikevax (50 mcg dose) may be offered as an alternative to Pfizer-BioNTech Comirnaty (10 mcg dose), however the use of Pfizer-BioNTech Comirnaty (10 mcg dose) is preferred to Moderna Spikevax (50 mcg dose) to start or continue the primary vaccine series.**

- Although risk of myocarditis/pericarditis with the Moderna Spikevax (50 mcg) in children 6 to 11 years of age is unknown, with a primary series in adolescents and young adults the rare risk of myocarditis/pericarditis with Moderna Spikevax (100 mcg) was higher than with Pfizer-BioNTech Comirnaty (30 mcg).

- Indirect data from adult populations (≥18 years of age) suggest Moderna Spikevax (100 mcg) may result in higher vaccine effectiveness after a 2-dose primary series compared to Pfizer-BioNTech Comirnaty (30 mcg) and is associated with a higher seroconversion rate among adult immunocompromised patients [5]. **Given this potential benefit, administration of the Moderna Spikevax (50 mcg) vaccine as a 3-dose primary series may be considered for some immunocompromised individuals 6 to 11 years of age, as outlined in the product monograph.** Each dose would be provided 4 to 8 weeks apart, as per the NACI recommended schedule for immunocompromised populations.

Rationale and summary of evidence

- In the Phase 2/3 clinical trial on Moderna Spikevax, 3,007 children 6 to 11 years of age received the Moderna Spikevax COVID-19 vaccine (50 mcg), and 995 received the placebo; both groups were followed a median of 51 days since dose 2. The trial was conducted in the US and Canada when the Delta variant was predominant (data cut-off November 10, 2021). Interim findings did not indicate any safety concerns and preliminary efficacy against symptomatic COVID-19 was 88% starting 14 days after dose 1, which is comparable to efficacy after Pfizer-BioNTech Comirnaty among children 5 to 11 years of age.
- No cases of myocarditis/pericarditis or any other serious adverse events (SAEs) were reported among phase 2/3 trial participants that received the Moderna Spikevax COVID-19 vaccine (50 mcg). Any rare, or very rare adverse event (AEs) that occurs at the frequency less often than 1 in 1,000 to 1 in 10,000 would likely not be detected with this trial size (3,007 participants received the vaccine).
- Among individuals 12 to 29 years of age, safety surveillance data shows a lower reported rate of myocarditis/pericarditis following [6-11] Pfizer-BioNTech Comirnaty (30 mcg) compared to Moderna Spikevax (100 mcg) primary series, as well as following the Pfizer-BioNTech Comirnaty (30 mcg) booster compared to the Moderna Spikevax (50 mcg) booster, among individuals 18 years of age and older.
- Safety surveillance data on the risk of myocarditis or pericarditis within 7 days following immunization with the Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg) from the US show that among males after the 2nd dose, the risk may be substantially lower in children 5 to 11 years of age following Pfizer-BioNTech Comirnaty 10 mcg vaccine (4.3 cases per million doses) compared to adolescents following Pfizer-BioNTech Comirnaty 30 mcg [12, 13] vaccine (45.7 to 70.2 cases per million doses for adolescents 12 to 15 and 16 to 17 years of age, respectively).
- Real-world safety data from the US and Canada suggest the Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg) is well tolerated in children 5 to 11 years of age, where the majority of AEs reported are non-serious, and less frequently reported than in adolescents 12 to 15 years of age.

Additional considerations

- COVID-19 is typically mild in severity for children 6 to 11 years of age; however, while most children with COVID-19 do not require hospitalization, some children do experience severe disease. Additionally, following infection, children are at risk of multi-system inflammatory syndrome in children (MIS-C) and potentially post-COVID-19 condition (i.e. long COVID or post acute COVID-19 syndrome).
- **For children 5 to 11 years of age with a previous SARS-CoV-2 infection, the suggested interval between symptom onset or positive test (if asymptomatic) and vaccination is 8 weeks.** For guidance on COVID-19 vaccination for those with a history of SARS-CoV-2 infection (including specific guidance for individuals following MIS-C or for individuals with immunocompromising conditions), please refer to the February 4, 2022 NACI rapid response: Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2

NACI will closely review emerging evidence on the safety and effectiveness of COVID-19 vaccines in this age group, and will update their recommendations, as well as its strength, as the evidence base evolves.

For further information on NACI's recommendations on the use of pediatric COVID-19 vaccines, please refer to the COVID-19 vaccine chapter in the Canadian Immunization Guide (CIG).

For detailed NACI recommendations on the use of COVID-19 vaccines in children 5 to 11 years of age considered moderately to severely immunocompromised, please refer to the January 25, 2022 NACI Rapid Response: Updated recommendations on the use of COVID-19 vaccines in children 5-11 years of age.

ABBREVIATIONS

Abbreviation	***Term***
AE	Adverse event
AEFI	Adverse event following immunization
COVID-19	Coronavirus disease 2019
GMR	Geometric mean ratio
MIS-C	Multisystem inflammatory syndrome in children
mcg	microgram
NACI	National Advisory Committee on Immunization
PHAC	Public Health Agency of Canada
SAE	Serious adverse event
US	United States

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APPENDIX A: CLINICAL TRIAL DATA ON THE MODERNA SPIKEVAX MRNA COVID-19 VACCINE IN CHILDREN 6-11 YEARS OF AGE

Trial design

The Moderna Spikevax COVID-19 vaccine was evaluated in an ongoing, randomized, observer-blind, placebo-controlled Phase 1/2/3 clinical trial in healthy children from 6 months to 11 years of age (P204)[14]. Based on the reactogenicity and immunogenicity observed in the initial cohort of children 6 to 11 years of age in the open-label Phase 1 trial, a dose of 50 mcg was selected for the Phase 2/3 trial for this age group. A total of 4,011 participants 6 to 11 years of age were randomized 3:1 to receive either two doses of the vaccine (50 mcg mRNA) or placebo, 28 days apart. At time of reporting, median follow-up of participants was 51 days since dose 2. Follow-up is planned for up to approximately 12 months following the second dose. The trial was conducted at a time of predominant Delta variant of concern circulation (data cut off: November 10, 2021).

Study population

All pediatric study participants for the Phase 2/3 trial were recruited from the US and Canada. Individuals with known history of SARS-CoV-2 infection within 2 weeks prior to administration of vaccine or known close contact with anyone with laboratory-confirmed SARS-CoV-2 infection or COVID-19 within 2 weeks prior to administration of vaccine were excluded from the trial. Individuals with known immunodeficiency or immunocompromised conditions were excluded from the trial.

Immunogenicity comparator group

The immunogenicity comparator group for the children (6 to 11 years) was a randomly selected subset (n=295) of participants aged 18 to ≤25 years from the earlier Phase 2/3 study P301 who received two doses of the Moderna Spikevax COVID-19 vaccine (100 mcg), 28 days apart.

Demographics

Demographic characteristics were similar among vaccine and placebo groups in the P204 trial. Overall, 49.2% of participants were female, with a median age at vaccination of 8.0 years (range: 5-11 years) in the vaccine group and 9.0 (range: 6-11 years) in the placebo group. About two-thirds of participants were white (65.5%), with participants from other race/ethnic groups each comprising significantly less of the study population: Multiracial (10.8%), Black or African American (10.0% overall), Asian (9.9%), and all other groups comprising <2% of participants. All race and ethnicity groups had similar proportions in the vaccine and placebo groups. A total of 20% of participants were defined as obese. A total of 4 participants 6 to 11 years of age with known HIV were enrolled in the trial (all in the vaccine group), and 10 participants had cardiac disorders. The prevalence of SARS-CoV-2 infection or prior infection at baseline (determined by a positive RT-PCR or serological assay) in the vaccine and placebo groups in the safety population was comparable at 8.5% and 8.7%, respectively.

Safety

Safety evidence for participants is based on the phase 2/3 randomized, observer-blind, placebo-controlled expansion study of children (focused on the cohort 6 years to 11 years of age) who received 2 intramuscular injections of Moderna Spikevax 50 mcg (n=3,007) or placebo (n=995) approximately 28 days apart. Data on solicited local and systemic reactions were collected daily for 7 days following each injection. Participants (6 to 11 years of age) were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Median duration of safety follow-up after second vaccination for study participants in the blinded phase was 51 days.

Local reactions

Local reactions were increased in frequency in vaccine recipients (93.7% for dose 1, 95.3% for dose 2) compared to placebo recipients (48.3% for dose 1, 50.6% for dose 2). Most solicited local reactions were grade 1 or grade 2. Grade 3 reactions were more common in the vaccine recipients than in the placebo recipients (5.6% vs 0.8% respectively). The most frequent grade 3 reaction was injection site pain. There were no grade 4 solicited local adverse reactions in either group. The majority of solicited local reactions occurred within the first 1 to 2 days after any dose and persisted for a median of 3 days. Local reactions were very common and mostly mild to moderate in severity. In the vaccine recipient group, solicited local adverse reactions that persisted beyond 7 days after injection were injection site pain (0.8% dose 1, 0.5% dose 2), erythema (0.5% dose 1, 0.3% dose 2) injection site swelling (0.4% dose 1, 0.2% dose 2) and axillary/groin swelling or tenderness (1.7% dose 1, 0.7% dose 2). See Table 1 for the frequency of solicited local AEs for the Moderna Spikevax COVID-19 vaccine among children 6 to 11 years of age.

Systemic reactions

Systemic events were increased in frequency in vaccine recipients compared to placebo recipients, with frequencies increasing with the number of doses in vaccine recipients (57.9% after dose 1 compared to 78.1% after dose 2 in vaccine recipients, and 52.2% after dose 1 and 50.1% after dose 2 in placebo recipients). Headache (31.2% and 54.3% after dose 1 and 2 respectively in vaccine recipients, and 30.8% and 28.4% after dose 1 and 2 respectively in placebo recipients), fatigue (43.2% and 64.5% after dose 1 and 2 respectively in vaccine recipients, and 33.6% and 34.6% after dose 1 and 2 respectively in placebo recipients), myalgias (14.6% and 28.2% after dose 1 and 2 respectively in vaccine recipients, and 9.7% and 10.8% after dose 1 and 2 respectively in placebo recipients), nausea/vomiting (10.8% and 24.0% after dose 1 and 2 respectively in vaccine recipients, and 10.8% and 10.0% after dose 1 and 2 respectively in placebo recipients) and chills (10.3% and 30.3% after dose 1 and 2 respectively in vaccine recipients, and 6.7% and 7.6% after dose 1 and 2 respectively in placebo recipients) were very common after dose 1 and dose 2 in vaccine recipients. Arthralgias were common after the first dose (8.7% in vaccine recipients and 7.6% in placebo recipients) and very common after the second dose in vaccine recipients (16.1% in vaccine recipients and 8.7% in placebo recipients). Fever was common after the first dose (3.3% in vaccine recipients and 1.5% in placebo recipients) and very common after the second dose in vaccine recipients (23.9% in vaccine recipients and

2.0% in placebo recipients). Grade 3 events were more common in the vaccine recipients (1.8% after dose 1, 12.2% after dose 2) than the placebo recipients (1.3% and 1.4% respectively). There were no grade 4 events in the vaccine recipients. See Table 2 for the frequency of solicited systemic AEs for the Moderna Spikevax COVID-19 vaccine among children 6 to 11 years of age.

Serious adverse events and other adverse events of interest
There were no serious AEs assessed as related to the study interventions, either the vaccine or placebo, no deaths, no cases of MIS-C, and no cases of myocarditis or pericarditis reported during the study period. Monitoring for serious adverse events and medically attended adverse events will continue throughout the study period (up to 12 months following the second dose).

Immunogenicity

An immunobridging analysis evaluating SARS-CoV-2 50% neutralising titres (ID50) and seroresponse rates 28 days after dose 2 was conducted in subset of children 6 to 11 years of age (Study P204; N=320) and in participants aged 18 through ≤25 from the Phase 3 efficacy study (Study P301; N=295). Subjects had no immunologic or virologic evidence of prior SARS-CoV-2 infection at baseline. The geometric mean ratio (GMR) of the neutralising antibody titres in children 6 to 11 years of age compared to the 18- to 25-year-olds was 1.2 (95% CI: 1.1, 1.4). The difference in seroresponse rate was 0.1% (95% CI: -1.9, 2.1%). Both pre-specified non-inferiority criteria (lower bound of the 95% CI for GMR greater than 0.67 and lower bound of the 95% CI of the seroresponse rate difference greater than -10%) were met. Immunogenicity data was also assessed following dose 1 in the same subset of participants; at day 29 from baseline, and GMR was similar across the two groups (108.1 in children 6 to 11 years of age, compared to 96.7 in adults 18 to 25 years of age).

Samples from a randomly selected subset of 20 participants 6 to 11 years of age were assessed for neutralization titres against the Delta variant and Omicron variant. Among children 6-11 years of age, the level of neutralizing antibodies against Omicron 28 days after dose 2 were 22.1 fold lower than those against D614G. However, the neutralizing antibody response against both Omicron and D614G among children 6 to 11 years of age was higher than among adults 18 years of age and older [(15)].

As no correlate of protection has been established for any COVID-19 outcome at this time, it is unknown how reported immune responses are related to prevention of SARS-CoV-2 infection or disease or the ability to transmit infection to others.

Efficacy

The evaluable efficacy population consisted of 2,687 participants randomized to receive vaccine and 880 participants randomized to receive placebo, all of whom had a negative baseline SARS-CoV-2 serostatus. As of November 10, 2021 (data cut-off for analysis), a total of 25 confirmed, symptomatic cases of COVID-19 were identified starting 14 days after dose 1 (7 in vaccine group, 18 in placebo group) in participants 6 to 11 years of age. The estimated efficacy of the vaccine against confirmed COVID-19 from 14 days after dose 1 was 88.0% (95% CI: 70.0 to 95.8%). The estimated efficacy against SARS-CoV-2 infection from 14 days after dose 1 (regardless of

symptoms) and against asymptomatic SARS-CoV-2 infection was 74.0% (95% CI: 57.9 to 84.1%) and 62.5% (95% CI: 30.9 to 79.4%), respectively. However, these estimates of vaccine efficacy should be interpreted with caution. The definition of asymptomatic infection was based on either a positive RT-PCR result (generally performed as a result of symptoms) or a positive serology result based on samples collected at pre-specified times (Days 1, 29, 43, 57, 209 and 394). Therefore, the identification of asymptomatic cases based on positive serology do not correspond to identification of infection at a discrete point in time, but rather could reflect infection acquired at any time after collection of negative serology sample at baseline. Most confirmed cases in study participants were identified at a time when the Delta variant was the predominant circulating strain in the US and Canada. However, no sequence analysis was reported on case isolates to determine whether they were caused by the Delta variant or another variant.

There were too few cases identified beginning 14 days after dose 2 to generate estimates of vaccine efficacy for dose 2, however it is important to note the majority of participants (99.4%) randomized to receive vaccine received 2 doses, and therefore estimates of efficacy beginning 14 days after dose 1 cannot only be attributed to protection conferred from the first dose alone. There were no subgroup analyses (e.g., age, sex, race/ethnicity, presence of underlying medical conditions) presented for vaccine efficacy against any outcome.

None of the identified cases met the pre-defined criteria for a severe case of COVID-19, therefore the data did not include estimates of vaccine efficacy against severe outcomes such as hospitalization, MIS-C or death.

APPENDIX B: FREQUENCY OF SOLICITED ADVERSE EVENTS FOLLOWING IMMUNIZATION FOR COVID-19 IN CLINICAL TRIALS

Table 1. Frequency of solicited local AEFIs in 6 to 11 year olds for the Moderna COVID-19 vaccine (Spikevax™)[a,b]

AEFI	Vaccine		Placebo control	
	Dose 1 N=3004	Dose 2 N=2988	Dose 1 N=993	Dose 2 N=969
Pain at injection site	Very common	Very common	Very common	Very common
Redness/erythema	Very common	Very common	Common	Common
Swelling	Very common	Very common	Common	Common
Axillary (or groin) swelling or tenderness	Very common	Very common	Common	Common

Abbreviations: AEFI: adverse event following immunization; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients.

[b] AEFIs were solicited within 7 days after each dose in a Phase 2/3 clinical trial. The information in this table is up to date as of February 10, 2022. For updated information, please consult the Spikevax product monograph.

Table 2. Frequency of solicited systemic AEFIs in 6 to 11 year olds for the Moderna COVID-19 vaccine (Spikevax™)[a,b]

AEFI	Vaccine		Placebo control	
	Dose 1 N=3004	Dose 2 N=2988	Dose 1 N=993	Dose 2 N=969
Fatigue	Very common	Very common	Very common	Very common
Headache	Very common	Very common	Very common	Very common
Muscle Pain	Very common	Very common	Common	Very common
Chills	Very common	Very common	Common	Common
Joint pain	Common	Very common	Common	Common
Fever[c]	Common	Very common	Common	Common
Nausea or vomiting	Very common	Very common	Very common	Very common

Abbreviations: AEFI: adverse event following immunization vaccine; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients.

[b] AEFIs were solicited within 7 days after each dose in a Phase 2/3 clinical trial. The information in this table is up to date as of February 10, 2022. For updated information, please consult the Spikevax product monograph.

[c] Fever was objectively reported as having a temperature ≥38°C.

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