

Today's Webinar:
December 13, 2021
Hosted by The **National Collaborating Centre for Infectious Diseases (NCCID)**, in partnership with the **Public Health Agency of Canada (PHAC)**



National Collaborating Centre
for Infectious Diseases

Centre de collaboration nationale
des maladies infectieuses

The Public Health Agency of Canada Webinar: COVID-19 vaccine for pediatric use in Canada

Moderator:

Dr. Joanne Embree, MD, FRCPC, Professor, Department of Pediatrics and Child Health, University of Manitoba

Zoom

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Speakers

Dr. Nicole Forbes, PhD, National Advisory Committee on Immunization Secretariat (NACI), Public Health Agency of Canada (PHAC).

Dr. Anne Pham-Huy, MD, FRCPC, Pediatric Infectious Diseases Specialist, CHEO. Assistant Professor, University of Ottawa.

Dr. Marina Salvadori, MD, FRCPC, Professor, McGill University, Division of Pediatric Infectious Diseases, Montreal Children's Hospital. Clinical Lead, COVID-19, PHAC.

Disclosures

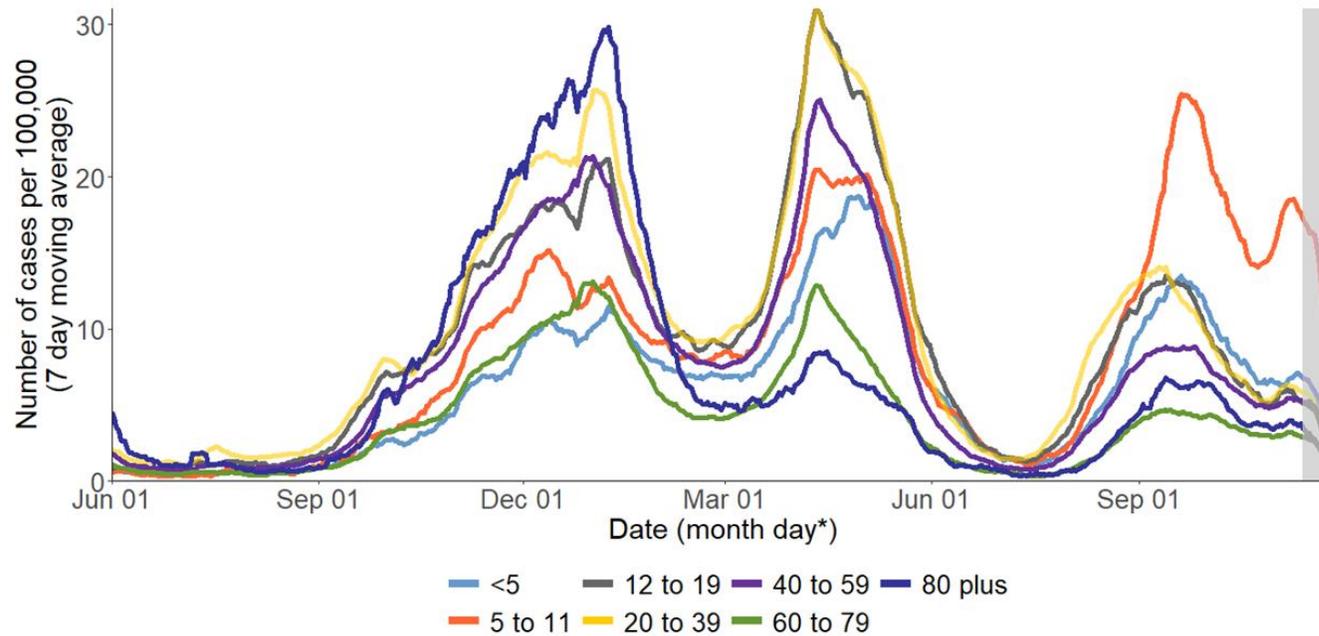
- Dr. Nicole Forbes - No disclosures
- Dr. Anne Pham-Huy - No disclosures
- Dr. Marina Salvadori - No disclosures
- Dr. Joanne Embree - No disclosures

Objectives

- Describe the COVID-19 pandemic among children 5-11 years of age in Canada.
- Summarize the clinical trial information available on the COVID-19 vaccine authorized in children 5-11 years of age.
- Explain NACI recommendations for children 5-11 years of age.
- Identify the factors that parents or guardians should consider when deciding on COVID-19 vaccination for children aged 5-11 years.

COVID-19 in pediatric populations

During wave 4, highest rate of COVID-19 infection observed for children 5 to 11 years of age



Data as of November 25, 2021.
Source: Detailed case data submitted to PHAC by the provinces and territories.
Shaded area represents period of accumulating data.

Seroprevalence estimates in children from studies based in Quebec and British Columbia suggest case-level data is likely an underestimate of infection in this age group.

COVID-19 incidence and disease severity in children

Age group years	Total cases n	Hospitalized cases n (%)	ICU admissions n (%)	Deaths n (%)
<1	7,980	388 (4.9%)	43 (0.5%)	2 (0.025%)
1 to 4	51,134	318 (0.6%)	41 (0.1%)	3 (0.006%)
5 to 11	123,379	300 (0.2%)	48 (0.0%)	2 (0.002%)

Data from March 1, 2020 to November 10, 2021

Source: Surveillance and Epidemiology Division, PHAC. Detailed case data submitted by the provinces and territories (excluding Saskatchewan due to limitations of age group data)

- Over the course of the pandemic, many children have been infected with the COVID-19 virus.
- In most cases, children have no symptoms or experience mild COVID-19 disease.
- Although less frequent than in older age groups, some children may rarely develop severe COVID-19 disease and require hospitalization.

PHAC Surveillance and Epidemiology Division, 2021; [Summary of National Advisory Committee on Immunization \(NACI\) statement](#)

Children 5-11 years: risk factors for severe COVID-19 disease

- Currently limited evidence regarding risk factors for severe disease in this age group.
- SARS-CoV-2 infection can happen to any child; even children without risk factors may develop severe forms of COVID-19.
- These risk factors, **independent of age**, are associated with a ≥ 2 -fold increase in mortality from COVID-19:
 - Epilepsy
 - Down Syndrome
 - Obesity (BMI > 40)
 - Neurological disorders
 - Diabetes (type 1 and 2)
 - End-stage kidney disease

Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare but serious condition following SARS-CoV-2 infection

Symptoms include:

- Fever
- Abdominal pain
- Vomiting
- Diarrhea
- Skin rash
- Other signs of inflammation

More common in:

- Males
- Racialized individuals

- Onset typically 2-6 weeks after SARS-CoV-2 infection.
- Risk factors and long-term effects are unknown.
- Comorbidities, aside from obesity, are rarely reported.

Multisystem Inflammatory Syndrome in Children (MIS-C) (continued)

Internationally:

- Estimated to affect between **0.5 % to 3.1%** of all pediatric COVID-19 cases.

In Canada:

- Median age is **6 years**
- While almost every child diagnosed with MIS-C required **hospitalization**:
 - Most have recovered
 - No reported deaths

Canadian MIS-C cases reported between March 11, 2020, to October 2, 2021 (n=229)

Characteristic		n	%
Sex	Male	157	58
	Female	112	42
Age (years)	Younger than 1	16	6
	1–4	96	36
	5–9	81	30
	10–14	49	18
	15–19	27	10
Hospitalization status	Hospitalized	267	99
	ICU admission	98	36
Outcome	Recovered	184	68
	Convalescing/Stable	80	30
	Deteriorating	1	0

COVID-19 pandemic: profound impact on the mental and physical well-being of children and their families

Causes:

- Prolonged schooling disruptions.
- Social isolation.
- Reduced access to academic and extra-curricular resources.

Effects:

- **Mental and physical harms** for both children and their families.
- Impacts **may further exacerbate social inequities** among racialized and Indigenous communities, refugees and other newcomers to Canada, persons living in low-income settings, as well as children with disabilities.

True or false?

Only children with risk factors develop severe forms of COVID-19.





Key takeaways: COVID-19 and pediatric populations

- During Wave 4, COVID-19 cases were highest among children 5 to 11 years of age.
- While most children with COVID-19 have mild or no symptoms, some do become ill and require hospitalization.
- Children with COVID-19 are at risk of MIS-C, a rare but serious syndrome that can occur several weeks following infection.
- COVID-19 pandemic has had a profound impact on the mental and physical well-being of children and their families; social inequities are further exacerbated.

Pediatric (<12 years) COVID-19 vaccines

Roles regarding vaccines in Canada

Health Canada

- Federal regulator of health products, including vaccines.
- Reviews scientific evidence from clinical trials, and other information, before approving vaccines for use.

National Advisory Committee on Immunization (NACI)

- Independent, volunteer committee of Canadian health experts.
- Provides advice to PHAC on optimal use of approved vaccines.
- NACI guidance helps provinces and territories plan their vaccination programs.

Public Health Agency of Canada (PHAC)

- Provides NACI the necessary data and support to inform and publish their guidance.
- Supports distribution and communication of NACI recommendations.
- Coordinates the distribution of vaccines.

Health Canada, NACI and PHAC continuously monitor vaccines for safety and efficacy.

Pediatric COVID-19 vaccine authorized in Canada

Pfizer-BioNTech Cominarty[®] (10 mcg)

- Authorized for children 5-11 years of age on November 19, 2021.
- **2 doses, 10 mcg each**
 - 1/3 of the adult/adolescent dose
- Minimum **8 weeks** interval between dose 1 and 2 recommended by NACI.
 - Differs from the Health Canada authorized interval of 21 days

New formulation:

- Tromethamine (Tris) / sucrose buffer in the pediatric formulation.
- Supports pH stability and longer storage under refrigeration (up to 10 weeks).

Pfizer-BioNTech Cominarty (10 mcg)

	Adult/adolescent formulation (Purple cap)	Pediatric formulation (Orange cap / label border)
Age	12 years of age and older	5 to 11 years of age
Diluent	1.8 ml of 0.9% Sodium Chloride Injection, USP	1.3 ml of 0.9% Sodium Chloride Injection, USP
Dose	0.3 ml (30 micrograms)	0.2 ml (10 micrograms)
Doses per vial	6	10
Potential allergens	Polyethylene glycol (PEG)	Polyethylene glycol (PEG), Tromethamine (Tris, Trometamol)
Ancillary supplies	Low dead volume needle/syringe	Low dead volume needle/syringe
Storage Ultra-frozen is -90°C to -60°C; Frozen is -25°C to -15°C; Refrigerated is +2°C to +8°C; Room temperature is up to + 25°C	<ul style="list-style-type: none"> • Ultra-frozen until expiry date on label • Frozen for up to 2 weeks • Refrigerated for up to 1 month • Room temperature for: <ul style="list-style-type: none"> - Up to 2 hours prior to dilution; - Up to 6 hours after dilution 	<ul style="list-style-type: none"> • Ultra-frozen up to 6 months from the date of manufacture printed on vials and cartons • Do not store frozen • Refrigerated for up to 10 weeks • Room temperature for: <ul style="list-style-type: none"> - Up to 12 hours prior to dilution; - Up to 12 hours after dilution
Transport	<ul style="list-style-type: none"> • Ultra-frozen (full cartons) • Frozen vials up to 2 weeks (included in 2-week storage limit) • Refrigerated thawed vials up to 12 hours (included in 1 month storage limit) 	<ul style="list-style-type: none"> • Ultra-frozen (full cartons) • Refrigerated (full cartons / individual undiluted vials)



Other pediatric COVID-19 vaccines undergoing clinical development

Pfizer-BioNTech

- Vaccine for children aged **6 months to 4 years:**
 - clinical trial underway
 - lower dose (3 mcg)
 - formulation to be determined

Moderna

- Vaccine for children aged **6 to 11 years:**
 - currently under regulatory review at Health Canada
 - same formulation as current adult/adolescent vaccine product
 - lower dose (50 mcg dose, 0.25 ml per dose; half the adult/adolescent dose)
- Vaccine for children aged **6 months to 5 years:**
 - under clinical investigation (dose and formulation to be determined)

**Clinical trial data on the Pfizer-BioNTech
(10 mcg) COVID-19 vaccine in children
5-11 years of age**

Pfizer-BioNTech vaccine (10 mcg): Clinical Trial in children 5-11 years

**Phase 1/2/3 randomized placebo-controlled trial on the safety, tolerability and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine (10 mcg)
2 doses, 21 days apart**

Cohort 1

- n=1518 vaccine
- n=750 placebo
- Median follow up 3.3 months from dose 2
 - Safety, immunogenicity and efficacy outcomes evaluated

Cohort 2

- n=1591 vaccine
- n=788 placebo
- Median follow up 2.4 weeks from dose 2
 - Interim safety data evaluated

Safety of the Pfizer-BioNTech vaccine (10 mcg) in children 5 to 11 yrs

- Reactions were mostly **mild to moderate and short lived**.
- Compared to individuals 16 to 25 years of age (30 mcg dose), children ages 5-11 reported:
 - **Slightly more local reactions** (swelling and redness)
 - **Slightly less systemic reactions** including fever
- **No cases of myocarditis/pericarditis**, death, MIS-C, anaphylaxis or anaphylactoid reactions were reported.
 - The frequency of rare adverse events (1 in a 1000 or less frequent) was unable to be determined due to the trial size.

(Detailed frequencies of safety outcomes provided in supplementary slides)

Immune response to the Pfizer-BioNTech vaccine

	5-11 year (10 mcg) n=264 (95% CI)	16-25 years (30 mcg) n=253 (95% CI)	Comparison (95% CI)
GMT	1197.6 (1106.1 to 1296.6)	1146.5 (1045.5 to 1257.2)	GMR = 1.04 (0.93 to 1.18)
Seroresponse	99.2% (97.3 to 99.9)	99.2 % (97.2 to 99.2)	Difference = 0.0% (-2.0 to 2.2)

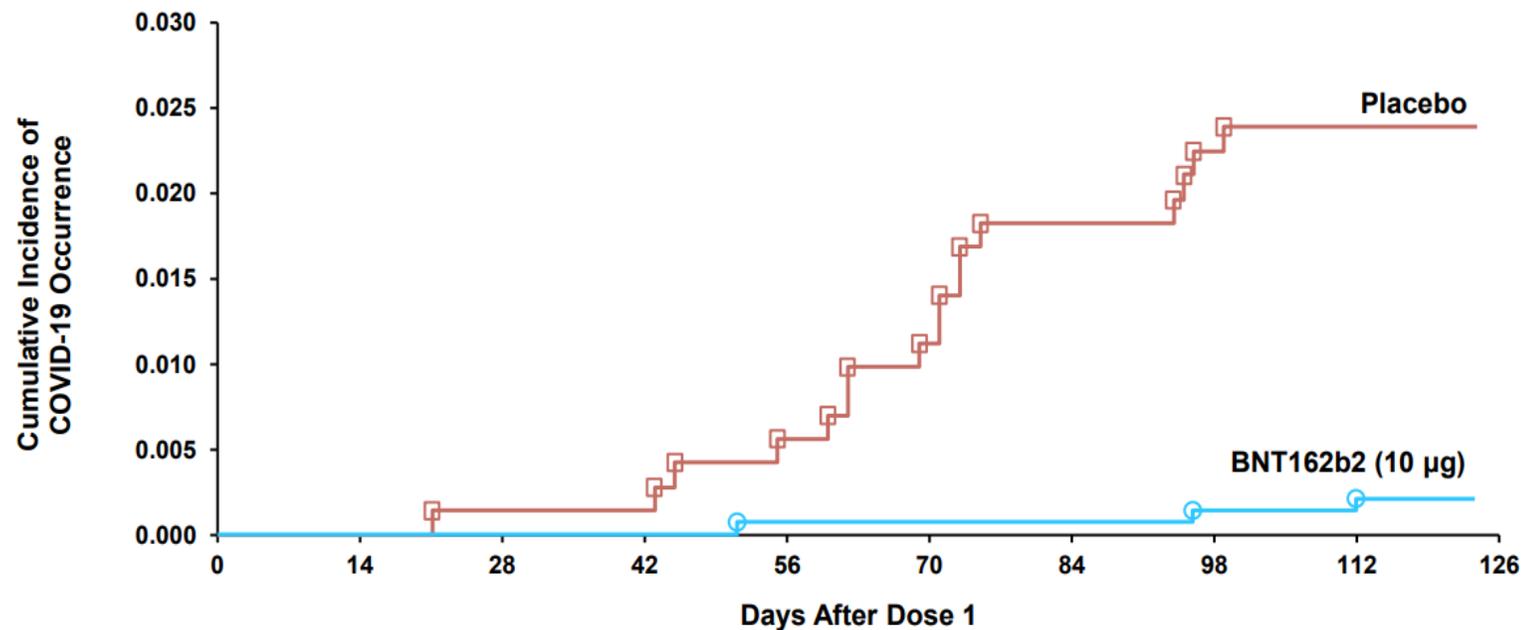
Immune response outcomes assessed following the second dose of the vaccine:

- **Both antibody levels (GMT) and the percentage of individuals that mounted an antibody response (seroresponse) were similar in children aged 5-11 years compared to individuals aged 16-25 years.**
- Additional analyses indicated antibody-mediated virus neutralization was similar following vaccination for both the **wild type and delta variant.**

Pfizer-BioNTech (10 mcg) - Results for 5-11 years: 90.7% efficacy against symptomatic COVID-19

Preliminary efficacy analysis in individuals without evidence of SARS-CoV-2 infection at baseline:

- **90.7% efficacy against symptomatic COVID-19 following dose 2**
(95% CI: 67.7 to 98.3%)
- 3 cases occurred in the vaccine group; 16 cases occurred in the placebo group.
- No severe outcomes were reported in any participant.



Cases occurred during time when the **Delta variant** was the predominant variant.

Interactive Polling

True or false?

In the clinical trials, 5-11 year olds reported slightly more redness and swelling than 16-25 year olds.



Key takeaways: Clinical trial results in 5-11 year olds



- Clinical trial data suggest the pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) produces a good immune response in children 5 to 11 years of age, similar to the response seen in young adults 16 to 25 years of age who receive the adolescent/adult formulation (30 mcg).
- Preliminary efficacy of the 10 mcg dose vaccine against symptomatic COVID-19 in children 5 to 11 years of age is estimated to be 90.7%.
- Interim clinical findings did not indicate any serious safety concerns and no cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the heart lining) related to the vaccine were reported.
- The size of the clinical trial would not detect rare or very rare adverse events that may occur at a frequency less often than 1 in 1,000 people. Post-market surveillance is ongoing.

**NACI's recommendations on the use of the
Pfizer-BioNtech COVID-19 vaccine in children
5-11 years of age**

Issued November 19, 2021

Ethics considerations on pediatric COVID-19 vaccine recommendations

Guiding principle: whether vaccination is in children's best interest

- Direct benefits for children are an important consideration.
- Generally, a vaccination program is justified if its anticipated benefits outweigh its potential risks.
- Indirect, population-level benefits of vaccination can also benefit children.
- Overall safety and effectiveness data for the Pfizer-BioNTech COVID-19 vaccine are limited for children.
 - The precautionary principle justifies taking action under conditions of scientific uncertainty to mitigate vaccine-related risks, including considering data from other age groups and applying vaccination principles.
- Children and their parents or guardians should be supported and respected in their decisions regarding COVID-19 vaccinations for the child, whatever decisions they make, and should not be stigmatised for accepting, or not accepting, the vaccination offer.

These considerations are informed by the Public Health Ethics Consultative Group

[NACI Statement on Nov 19, 2021](#)

NACI Recommendation

NACI recommends that a complete series with the Pfizer-BioNTech COVID-19 vaccine (10 mcg) may be offered to children 5-11 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between first and second dose.

(discretionary NACI recommendation).

- NACI will closely review emerging evidence and will update their recommendation, as well as its strength, as the evidence base evolves.

NACI considerations on the recommended interval between dose 1 and 2

- NACI recommends a **dosing interval of at least 8 weeks between 1st and 2nd dose.**
- The Pfizer-BioNTech vaccine for children 5-11 years of age is authorized as a primary series of two doses given 21 days apart.

NACI rationale for an extended interval

In adolescents/adults, emerging evidence suggests that:

- **longer intervals between the first and second doses of a primary series result in a stronger immune response and higher vaccine effectiveness** that is expected to **last longer** compared to shorter intervals
- **an extended interval may also be associated with a reduced risk of myocarditis/pericarditis** following a second dose of an mRNA COVID-19 vaccine

NACI Guidance for children with previous SARS-CoV-2 infection/MIS-C

- Two doses of a COVID-19 vaccine may be offered to children 5-11 years with a previous history of SARS-CoV-2 infection:
 - Children should **no longer** be considered **infectious** based on current criteria, and symptoms of an **acute illness should be completely resolved** prior to vaccination.
- For children with a previous history of MIS-C:
 - **Vaccination should be postponed until clinical recovery** has been achieved or until it has been **≥ 90 days since diagnosis**, whichever is longer.

NACI Guidance on concomitant administration of other vaccines

COVID-19 vaccines for children 5-11 years old should not routinely be given concomitantly (i.e., same day) with other vaccines (live or non-live)

- Thorough post-market safety surveillance will be required to inform risk estimates of any adverse events that may occur in children 5-11 years of age.
- Avoiding concomitant vaccine administration may help prevent erroneous reporting of adverse events from another vaccine with that of the COVID-19 vaccine.
- For feasibility reasons, **concomitant administration or a shortened interval** between COVID-19 vaccines and other vaccines **may be warranted on an individual basis** in some circumstances at the clinical discretion of the healthcare provider.

As a precaution, **NACI suggests waiting 14 days between the COVID-19 vaccine and other vaccines** in those 5-11 years to reduce reporting errors for adverse events.

NACI Guidance on children aged 11 who turn 12 during their vaccine series

- Children who receive the 10 mcg Pfizer-BioNTech COVID-19 vaccine for their first dose and who then turn 12 years may receive the 30 mcg Pfizer-BioNTech COVID-19 vaccine that is authorized for individuals aged 12 years and older to complete their primary series.
- If a second dose of 10 mcg is given, the dose should still be considered valid and the series complete.

Additional NACI considerations: Myocarditis/pericarditis

- As a precautionary measure, and consistent with current recommendations for adolescents and adults, **the second dose in the mRNA COVID-19 vaccination series should be deferred in children who experience myocarditis or pericarditis following the first dose of the Pfizer-BioNTech COVID-19 vaccine until more information is available.**
- **Children who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations.**
 - If they are no longer followed clinically for cardiac issues, they may receive the vaccine.
- NACI will continue to monitor the evidence and update recommendations as needed.
- Caregivers are advised to **seek medical attention for children if they develop symptoms** including chest pain, shortness of breath, or palpitations following receipt of the Pfizer-BioNTech vaccine.

Additional NACI considerations: Pediatric COVID-19 vaccine program planning

- Emphasis on **equitable access** to vaccination information and services to minimize inequities in vaccine acceptance and uptake based on socioeconomic status.
- Children aged 5-11 years and their parents should be **supported and respected in their decisions** regarding COVID-19 vaccinations for their children, whatever decisions they make, and are not stigmatised for accepting, or not accepting, the vaccination offer.
- Adults including caregivers and youth who interact with children should be vaccinated to ensure protection for themselves and to offer additional protection to children.
- Beyond vaccination, **public health measures are very important for preventing transmission in children.**
 - It is important that everyone, regardless of vaccination status, continue to follow recommended public health measures.
- The Pfizer-BioNTech COVID-19 vaccine is not authorized for use in children under 5 years of age at this time.

Interactive Polling

What does NACI recommend for children who received 10 mcg of Cominarty for their 1st dose who then turn 12?

- A. No need to give a 2nd dose
- B. Give 30mcg for 2nd dose
- C. If received 10mcg for 2nd dose, series is considered complete
- D. Both B & C



Key Takeaways: NACI Recommendations



- NACI reviewed the available evidence on the use of the Pfizer-BioNTech COVID-19 mRNA vaccine (10 mcg) in children 5 to 11 years of age, as well as ethical considerations related to COVID-19 vaccination in children.

NACI recommends that:

- A complete series of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) may 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.
- To see the full guidance, including the evidence and rationale behind these recommendations, visit [NACI recommendations on the use of the Pfizer-BioNTech COVID-19 vaccine \(10 mcg\) in children 5 to 11 years of age.](#)

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.**
- Authorization of the COVID-19 vaccine in age this group was based on **benefits outweighing the risks for the child.**

Factors parents will be considering when deciding about vaccination

Risks of being vaccinated

- Known risk of mild-moderate side effects
- Unknown risk of side effects occurring at a rate of less often than 1 per 1,000 doses

Benefits of being vaccinated

- Expected protection against symptomatic infection
- Expected less disruption to school or social engagements

Other Considerations

- It is expected that most children will be exposed to COVID-19 in the coming year
- Vaccination may offer parents a sense of security:
 - more comfort letting children engage in social and extracurricular activities after vaccination
 - less social isolation for children
- Any underlying health conditions in the child
- Local epidemiology/exposure risk at any given time
- Personal and cultural experiences with vaccines, illness and medical institutions
- Pain/anxiety for the child
- Risk of exposing more vulnerable community and family members



Overall key takeaways: COVID-19 vaccine for pediatric use in Canada

- Authorization was based on benefits outweighing the risks for the child.
- COVID-19 infection have disproportionately affected children 5-11 years old during the 4th wave.
- Reduced disruptions to their education and in-person activities are important for their mental and physical health and development.
- NACI recommends that a complete series of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) may 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.

Question and Answer Session

COVID-19 vaccine for pediatric use in Canada

Zoom

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National Advisory Committee on Immunization (NACI): Statements and publications

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NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted. NACI knowledge syntheses, analyses and recommendations on vaccine use in Canada are published in literature reviews, statements and updates.

New statements are those which have been published within the past five years. Previous statements are those which were published over five years ago and have been archived.

NACI recommendations are also published in vaccine-specific chapters of the [Canadian Immunization Guide](#). Email updates are available through our mailing list.

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If other category, please specify:

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

For more PHAC webinars and videos on COVID-19 vaccines, visit:



COVID-19 for health professionals: Training

www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals/training.html



National Collaborating Centre for Infectious diseases

nccid.ca/phac-webinars-on-covid-19-vaccines



Canadian Vaccination Evidence Resource and Exchange Centre

www.canvax.ca/canvax-webinar-series



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Eventbrite and will be available at nccid.ca after the webinar.**

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Supplementary Slides

Resources for health care providers:

- [NACI recommendations COVID-19 vaccine for children 5-11 years of age](#)(Canada.ca)
- [CPS Position Statement: COVID-19 vaccine for children 5 to 11 years of age](#) (Canadian Paediatric Society)
- [CCMOH Statement: COVID-19 Vaccination in Children 5-11 years of age](#) (Canada.ca)
- [Reporting adverse events after immunization in Canada](#)(Canada.ca)
- [Planning guidance for immunization clinics for COVID-19 vaccines](#) (Canada.ca)
- [Quick reference guide on use of COVID-19 vaccines](#) (Canada.ca)
- [Vaccination pain management for children: Guidance for health care providers](#) (Canada.ca)
- [COVID-19 for health professionals: Vaccines webpage](#) (Canada.ca)
- [Pfizer-BioNTech Cominarty® COVID-19 Vaccine Product Monograph](#)

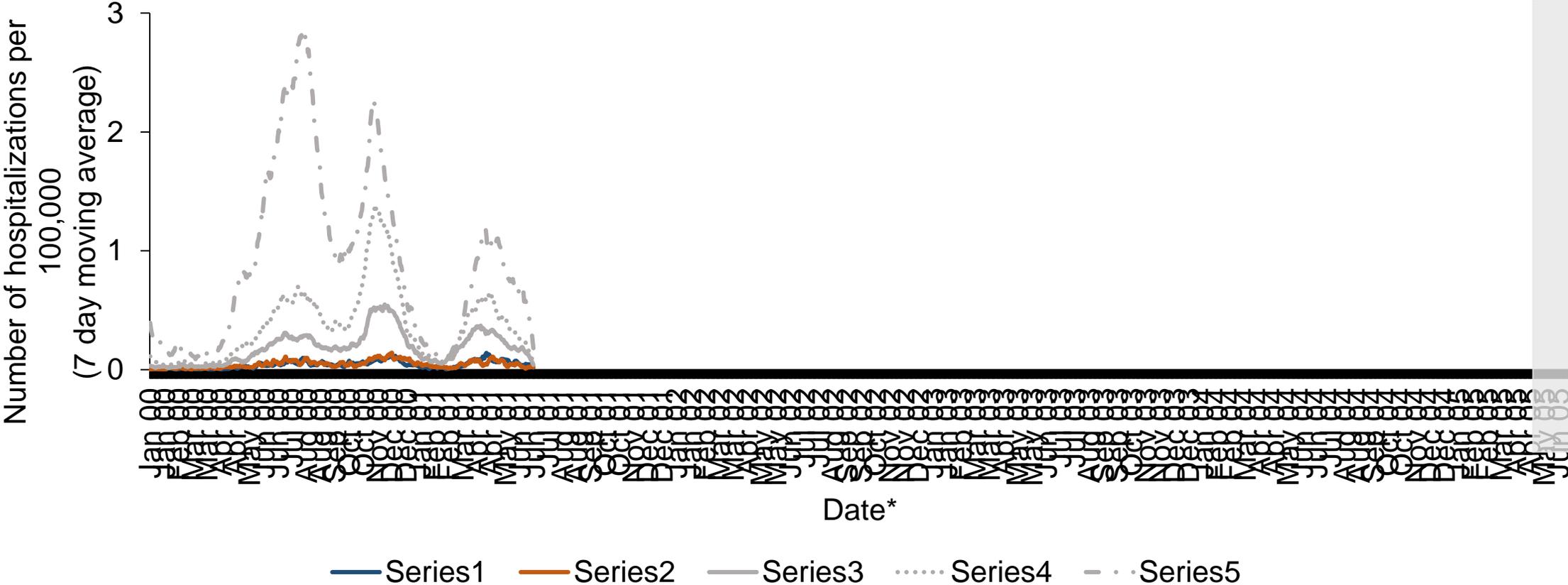
Resources for parents/caregivers:

- [Caring for Kids - COVID-19 vaccine for children and youth](#)(Canadian Paediatric Society)
- [The Benefits of Vaccination Children Against COVID-19](#) (University of Waterloo)
- [FAQ COVID-19 mRNA Vaccines for Children](#) (University of Waterloo)
- [Immunize Canada - CARD system for parents](#)
- [CANImmunize](#)
- [Reducing the Pain and Anxiety of Vaccination in Children](#) (Government of Quebec)

The COVID-19 pandemic continues to create stress and anxiety for many people living in Canada, particularly those who do not have ready access to their regular support networks.

Through the [Wellness Together Canada](#) online portal, people of all ages across the country can access immediate, free and confidential mental health and substance use supports, 24 hours a day, seven days a week.

Compared to older cohorts, COVID-19 hospitalization rates among children and youth remain low



*The earliest of: symptom onset date, lab specimen collection date, lab result date, date reported to the province/territory, and date reported to PHAC. Source: Detailed case data submitted to PHAC by the provinces and territories. The shaded area represents a period of time (accumulating data period) where it is expected that cases have occurred but have not yet been reported nationally. Data as of November 24, 2021

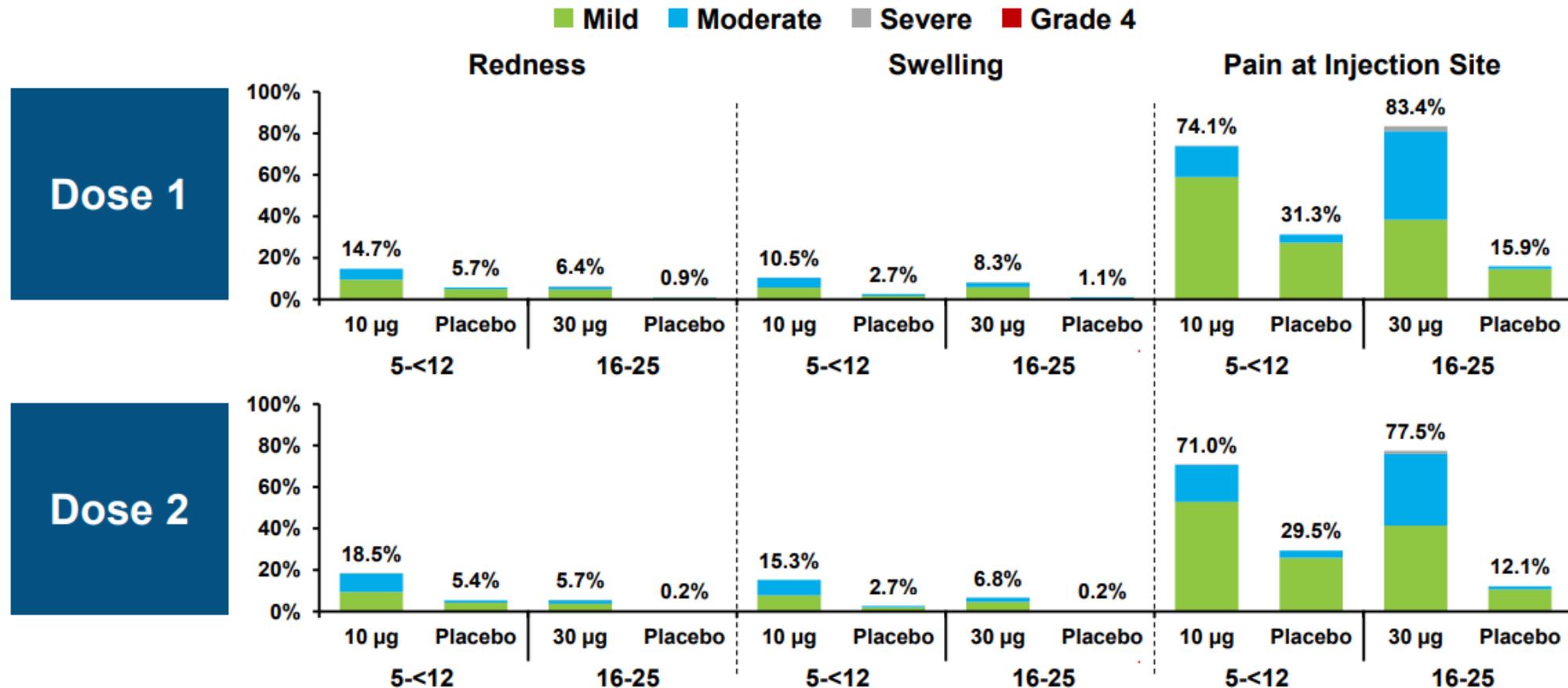
Overview of Pfizer-BioNTech (10 mcg) Clinical Trial for children aged 5-11 years

Component	Description	No. active vaccine	No. placebo
Safety – original phase 2/3 cohort	Median follow-up 3.3 months from Dose 2	1518	750
Safety – additional cohort based on FDA request	Median follow-up 2.4 weeks	1591	788
Immunogenicity	Immunobridging to 16 to 25 year olds (30 microgram dose) from the original adolescent/adult trial at one month after second dose	264 children, 5-11 years old (10 micrograms) 253 individuals, 16-25 years old (30 micrograms)	130 children, 5-11 years old 45 individuals, 16-25 years old
Immunogenicity against Delta	Supporting analysis in 5 to 11 year olds	34	4
Efficacy	Evaluable efficacy population after exclusions from phase 2/3 cohort; not previously infected	1305	663

[Summary of NACI statement on November 19, 2021](#)

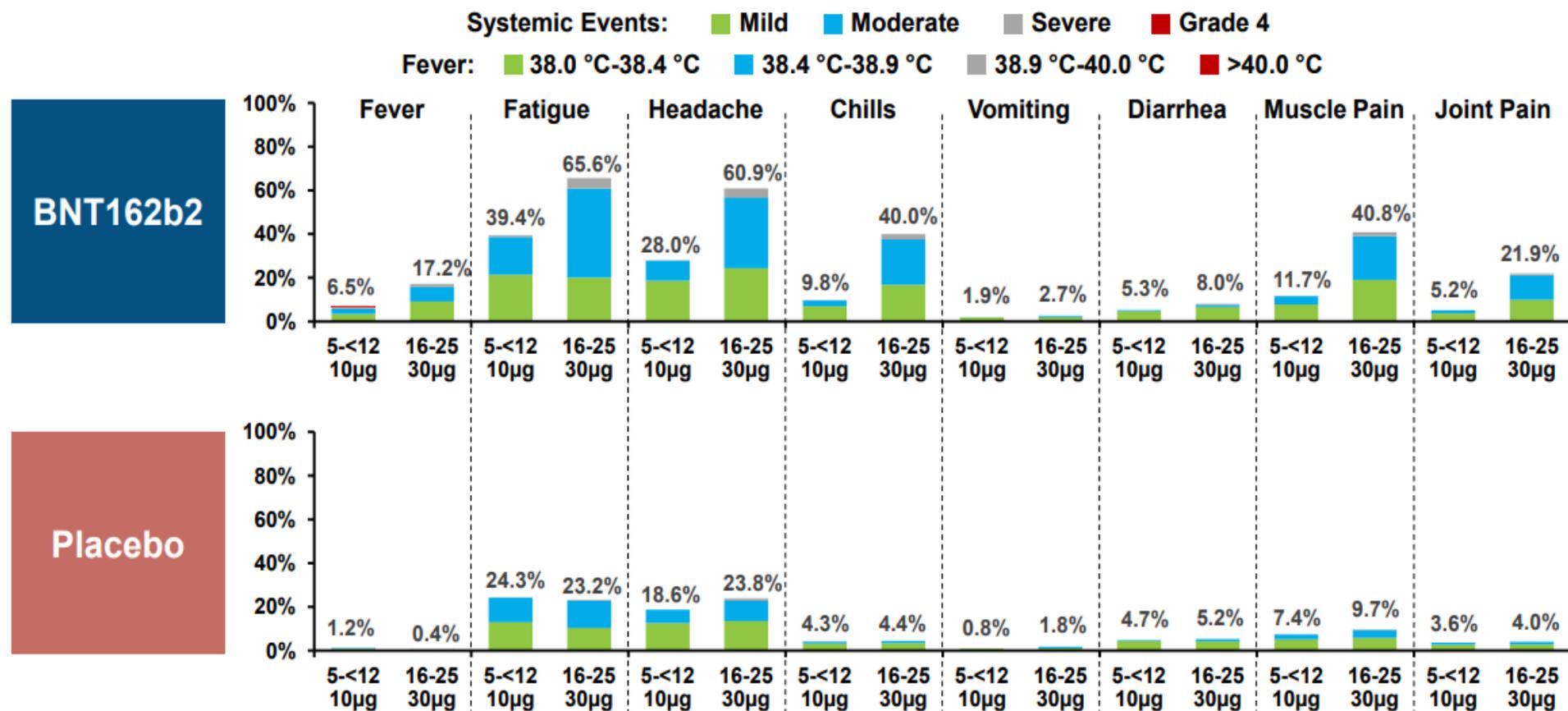
Pfizer-BioNTech safety data:

Local reactions, by severity within 7 days after each dose in children ages 5-11 years and young adults ages 16-25



Redness and swelling severity definition: Mild= >2-5cm, Moderate= >5-10 cm; Severe= >10 cm; Grade 4= necrosis
 Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Dose 1: 5-<12yrs N=2260; 16-25 yrs N=1064 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

Pfizer-BioNTech safety data: Systemic events, by Maximum Severity within 7 days after dose 2 in children ages 5-11 years and young adults ages 16-25 years



Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
 Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

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