





Immunizing Children with Confidence



FAQ: COVID-19 Vaccines for Children

This resource is intended for use by healthcare professionals working with children, youth, and their families. It is of relevance to those professionals who promote vaccine confidence and uptake.

Why vaccinate children against COVID-19?

Vaccination is one of the most effective ways to prevent the spread and reduce the impact of infectious diseases, whether it is the seasonal influenza or childhood infections such as chickenpox. While many people infected with COVID-19 experience only mild illness, others may get a severe illness or even die.

While children are at a reduced risk from the effects of COVID-19, that is not to say they are not at risk. Youth 19 and under now make up 21% of total cases in Canada (as of November 16 2021) with 82% of all newly reported cased coming from unvaccinated groups (children 5-11 make up one of the largest unvaccinated cohorts). In Canada, cumulative data to October 1, 2021 indicated that children aged 0 to 19 years old accounted for 20% of cases but much lower proportions of hospitalizations (2.0%), intensive care unit (ICU) admissions (1.2%), and deaths (0.1%%).

What COVID-19 vaccines are available for children aged 5-11?

Health Canada has approved the Pfizer BioNTech Comirnaty® mRNA vaccine for use in children aged 5-11 and 12-17. This vaccine is currently approved and being delivered to children aged 5-11 in the United States. ■

Moderna's Spikevax® vaccine for children 6-11 has been submitted to Health Canada for approval.

What is the Pfizer BioNTech Comirnaty® mRNA vaccine?

The Pfizer BioNTech Comirnaty® mRNA pediatric vaccine which was submitted to Health Canada consists of a 10 microgram mRNA dose, with a 21-day dose interval. In Canada, the <u>National Advisory Committee on Immunization (NACI)</u> is the body that recommends how a vaccine is used. They <u>recommended</u> an 8-week dose interval after reviewing the

data on vaccine's safety. NACI has access to the provincial vaccination surveillance data which it used to inform this decision, minimizing risk while maximizing immunity response in kids. *

What is an mRNA vaccine?

Many vaccines put a harmless piece of the virus into our bodies to trigger an immune response, but not messenger ribonucleic acid (mRNA) vaccines. Instead, mRNA vaccines use a small piece of genetic code from the SARS-CoV-2 virus that tells the body to make the spike protein of the coronavirus. The production of the spike protein is recognized by your immune system, which will create B cells who produce the antibodies that create immunity against the virus. After the vaccine causes this immune response, the body rapidly gets rid of the spike protein and the mRNA, the

Tech Sheet	Pediatric Formulation
Age	5 years to less than 12 years
Colour	Orange
	To see any
Diluant	1.3 ml
Dose	0.2 ml (10 micrograms)
Doses per vial	10
Potential allergens	Polyethylene glycol (PEG)
	Tromethamine (tris)
Post-dilution time (at	12 hours
room temperature)	
Ancillary supplies needed	Low dead volume needle/syringe
Storage	Ultra-frozen until expires
	Refrigerator for 10 weeks
	Room temperature:24 hours; no
	more than 12 hours post
	puncture (post-dilution)
Transport	Ultra-frozen

antibodies and your body's immune response memory remain.

How effective is the COVID-19 vaccine in children?

The Pfizer pediatric vaccine was shown to be 90.7% effective in clinical trials. It significantly reduces their risks of getting COVID-19 or passing COVID-19 to a loved one. Children have comparatively stronger immune systems than adults, and COVID-19 has not impacted them as severely as some other groups. However, children are still at risk of contracting COVID-19 and having severe outcomes. Children, like adults, can still pass COVID-19 to other community members. Vaccinating our children will also dramatically reduce the risk of school closures and increase the number and consistency of extracurriculars our children need for their mental health.

How is the COVID-19 vaccine formula made for children?

Child-sized and Child-friendly.

The Pfizer pediatric dose is 10 micrograms of mRNA, one third of the 30 microgram dose given to adults and teens aged 12 and older. The 10 microgram dose was carefully selected through a process called dose-escalation (they tested doses of 3, 10, 20, and 30 micrograms) and found that 10 micrograms was the preferred dose for safety, tolerability

and immunogenicity in children 5 to 11 years of age. Compared with adults, children have better immune systems and often have better responses to vaccines. Researchers pay less attention to weight or height, and more on age which is a better indicator for how readily a body is able to marshal an anti-pathogen defense.

The vaccine is not just child-size, but child-friendly, which has meant changing other aspects of the vaccine, including dosing—but also how vaccine recipes are stabilized and stored, how much dilution liquid gets injected into arms. The pediatric dose is easier to draw since it is less concentrated. While the adult/adolescent formulation contains phosphate buffers, these have been replaced with Tris/sucrose buffer Tromethamine in the pediatric formulation to support longer time in the refrigerator (10 weeks, instead of the previous 31 days).

What is tromethamine, and why is it in the Pfizer pediatric vaccine?

Adding a "tris buffer" such as tromethamine allows the mRNA to resist being degraded for a longer period of time before administration. This means the pediatric vaccine can be stored at 2-8°C in commonly available refrigerators for up to 10 weeks. Tromethamine was already used in the Moderna mRNA vaccine.

Could a mRNA vaccine affect a child's puberty, or their fertility in the future?

No

mRNA is not able to alter or modify a person's genetic makeup (DNA) or reproductive system. The mRNA from a COVID-19 vaccine never enters the nucleus of the cell, which is where our DNA is kept. This means the mRNA does not affect or interact with our DNA in any way. Instead, COVID-19 vaccines that use mRNA work with the body's natural defenses to safely develop protection (immunity) to disease.

Puberty is a period of intense growth and hormone changes, there is no evidence that mRNA vaccines interfere in any of this. The mRNA vaccine does not affect hormone levels. There is also no biological reason to expect that reproductive function could be affected by mRNA vaccines.

Should children on the cusp of 12 receive the adult dose?

It is important to remember than an immune system doesn't know exactly when your birthday is. Pfizer had some participants who turned 12 during its kids' trial, and they got the same injection each time. Pfizer tracked that the immune response following the lower dose in nine to 11 year-olds was very similar to the immune response in 16 to 25 year-olds. 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.

Children who receive the 10 mcg Pfizer-BioNTech COVID-19 vaccine for their first dose and who have turned 12 years of age by the time the second dose is due 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 the second dose of 10 mcg is given, the dose should still be considered valid and the series complete.

If a child has already had COVID-19, do they still need the vaccine?

Yes.

COVID-19 primary vaccination is recommended for everyone ages 5 years and older, regardless of a history of symptomatic or asymptomatic COVID-19 infection or seropositivity. Growing epidemiologic evidence from adults and adolescents indicates that vaccination following infection increases protection from subsequent infection, including in the setting of more infectious variants.

It is recommended that anyone who has had COVID-19 should still get the vaccine, but only after they have recovered from their illness, and they have been cleared by their local public health unit. The clinical trials included people who previously had COVID-19, and the vaccine was found to be safe for them. Because it is not known how long antibodies against COVID-19 last after infection and it is possible to get the infection again (sometimes more severely), the vaccine is recommended as it can be helpful in boosting a person's existing immunity to COVID-19.

What are the potential side effects from the vaccine?

Side effects reported with the vaccine include:

Allergic reactions; myocarditis; pericarditis; injection site pain; tiredness; headache; muscle pain; chills; joint pain; fever; injection site swelling; injection site redness; nausea; feeling unwell; swollen lymph nodes; decreased appetite, diarrhea; vomiting.^{xii}

Myocarditis/ Pericarditis didn't show up in the adult trial but came up during mass vaccine rollout, what are the risks for children of unexpected adverse events?

The risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is lower than the risk of myocarditis associated with COVID-19 infection in adolescents and adults. The incidence rate is 2.13/100,000 with 76% of cases described as mild and 22% as intermediate. Individuals should seek medical attention right away if they have any of symptoms after receiving the vaccine.

Myocarditis is a rare side effect from vaccination, found especially in males 12–29. The smaller dose is expected to reduce myocarditis and pericarditis. Some researchers also hypothesize that testosterone plays a role, by a combined mechanism of inhibition of anti-inflammatory cells 3,65-67 and commitment to a Th1-type immune response. This would further reduce the risk of this adverse event in children. No cases of myocarditis or pericarditis were reported in clinical trial for children ages 5-11 years (n=3,082), although the study was not powered to assess the risk of myocarditis.

What is Long Covid?

Those who become ill with COVID-19 are expected to recover in around 2 weeks. But an increasing number of people say they experience symptoms months after the initial illness is supposed to have worn off. This phenomenon has been called "Long Covid". Evidence from the first study of Long Covid in children suggests that more than half of children aged between 6 and 16 years old who contract the virus have at least one symptom lasting more than 120 days, with 42.6 per cent impaired by these symptoms during daily activities. These interim results are based on periodic assessments of 129 children in Italy who were diagnosed with COVID-19 between March and November 2020 at the Gemelli University Hospital in Rome.™The UK Office for National Statistics' latest report estimates that 12.9 per cent of UK children aged 2 to 11, and 14.5 per cent of children aged 12 to 16, still have symptoms five weeks after their first infection. Almost 500,000 UK children have tested positive for COVID-19 since March 2020™ Vaccination will reduce the chance of children catching COVID-19 and the potential of displaying effects of Long Covid.

Symptoms of Long Covid include:

Fatigue; Shortness of breath or difficulty breathing; Cough; Joint pain; Chest pain; Memory, concentration or sleep problems; Muscle pain or headache; Fast or pounding heartbeat; Loss of smell or taste; Depression or anxiety; Fever; Dizziness when you stand.

What is MIS-C?

Multisystem Inflammatory Syndrome in Children (MIS-C) is a post-infectious inflammatory syndrome. Fever is the hallmark of this syndrome, with affected individuals presenting on a spectrum from fever as the sole clinical symptom to patients presenting with (or progressing to) multisystem involvement. MIS-C has an estimated incidence of 316 per 1000 000 COVID-19 infections in persons younger than 21 in the United States. A temporal association with COVID-19 is clear, with cases of PIMS/MIS-C typically following 2 to 6 weeks after the peak of a COVID-19 outbreak in the local community. When PIMS/MIS-C is diagnosed and treated promptly, most children have favourable outcomes, however for children who are admitted to a pediatric intensive care unit, death was recorded in 1.4-2.2% of patients. Vaccination is the best tool we have to reduce chance of COVID-19 infections and the chance of MIS-C.

When a child is afraid of needles what should I do?

It is normal for many children to have a fear of needles <u>Solution for Kids in Pain (SKIP)</u> have created many <u>resources</u> to help. The <u>Comfort Ask Relax Distract (CARD) system</u> is another great tool to reduce fear and pain in children. Some key things to remember, be honest with the child and let them ask any questions they may have. Comfort them and consider using a topical numbing cream on the injection site if the child is sensitive to needle pain. Ensure the child is relaxed, perhaps they would like to bring a favourite stuffed animal? Distract them, maybe ask them to blow bubbles or watch a youtube clip on a phone? For more information about managing children's pain you can <u>watch this great video</u> created as part of the #ItDoesntHaveToHurt campaign.

How can I set up my clinic in a child friendly way?

Healthcare professionals providing COVID vaccines to children should create child-friendly spaces – in clinics, schools, pharmacies – for immunization experiences that promote coping and increase the likelihood your patients will complete recommended vaccination schedules, including the COVID-19 vaccination.

Resources are available to assist you:

- <u>Improving the vaccination experience: A guide for healthcare providers</u> featuring the CARDTM System (C-Comfort, A-Ask, R-Relax, D-Distract)
- <u>CARD System Learning Hub</u>
- <u>Planning guidance for immunization clinics for COVID-19 vaccines</u>
- <u>Preparing your pharmacy to deliver COVID-19 vaccinations: Tips from the front line</u> (March 24, 2021)

How can I talk to my patients about the Vaccine?

You can use this helpful resource to frame the conversation.

- 1. Keep Up to Date from Credible Information Sources
- 2. Ask and Listen
- 3. Be honest
- 4. Be ready to answer[™]

Vaccination rates among children and youth (last updated: November 16, 2021)

80.26% of Canadians 12-17 have been fully vaccinated, 86.90-% have had at least one dose. Children with certain underlying chronic medical conditions are at increased risk

for severe COVID-19. The Canadian Paediatric Surveillance Program reported that 39% of children admitted because of COVID-19 had at least one underlying comorbidity, most commonly chronic encephalopathy, obesity, asthma, chronic lung disease other than asthma, epilepsy, and neurodevelopmental disorders. Obesity, chronic neurological conditions, and chronic lung diseases other than asthma were associated with greater COVID-19 severity. Other Canadian surveillance data indicate that the proportion of COVID-19 cases being hospitalized or admitted to an ICU is 4 to 5 times higher for individuals 12 years of age and older with immunodeficiency, than for the general population.

For trusted information about COVID-19 vaccination and Kids:

Visit <u>Health Canada</u> or <u>Children's Healthcare Canada website</u> to see a list of trusted resources, including your provincial/ territorial government websites. Follow your local government for announcements as to when and where you can bring your child to be vaccinated. If you have any other questions please consult your pediatrician, family doctor, nurse practitioner or a primary care physician. To help navigate mis/disinformation online <u>Science Up First</u> has some great tips and tricks!

Last updated November 19, 2021

Have other questions? Email us at cfortier@childrenshealthcarecanada.ca We will work with the Immunizing Children with Confidence Expert Advisory Committee and the broader Children's Healthcare Canada network to get you answers.

- i https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html
- ii https://cps.ca/en/documents/position/covid-19-vaccine-for-children
- iii Health Canada announcement
- iv CDC announcement
- v https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html
- vi https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-positive-topline-results
- vii https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf
- viii https://factcheck.afp.com/http%253A%252F%252Fdoc.afp.com%252F9QX8KZ-1
- ix https://www.unambiguous-science.com/infographics/
- $\times \underline{\text{https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/pfizer-biontech-10-mcg-children-5-11-years-age/pfizer-biontech-10-mcg-children-5-11-years-age.pdf}$
- xi https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf
- xii https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-initial-data-us-fda-pivotal
- xiii https://www.nejm.org/doi/full/10.1056/NEJMoa2110737
- xiv https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.056135
- xv (medRxiv, doi.org/fv9t).
- xvi https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7927578/
- xvii https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351
- xviii https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780861
- xix https://cps.ca/en/documents/position/pims
- xx admission to a pediatric intensive care unit (PICU), with death occurring in 1.4%-2.2% of patients.
- xxi https://www.toronto.ca/wp-content/uploads/2021/10/94ff-Tips-Sheet-5-11-Talking-to-Kids-about-Getting-VaccinatedOct-19-2021.pdf
- xxii https://health-infobase.canada.ca/covid-19/vaccination-coverage/
- xxiii https://cps.ca/en/documents/position/covid-19-vaccine-for-children