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LMPCA Townhall

Update on COVID-19 Vaccination of Children 5-11

November 30, 2021

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Dr. Alex Summers

Acting Medical Officer of Health

Middlesex-London Health Unit

@alexsummers4

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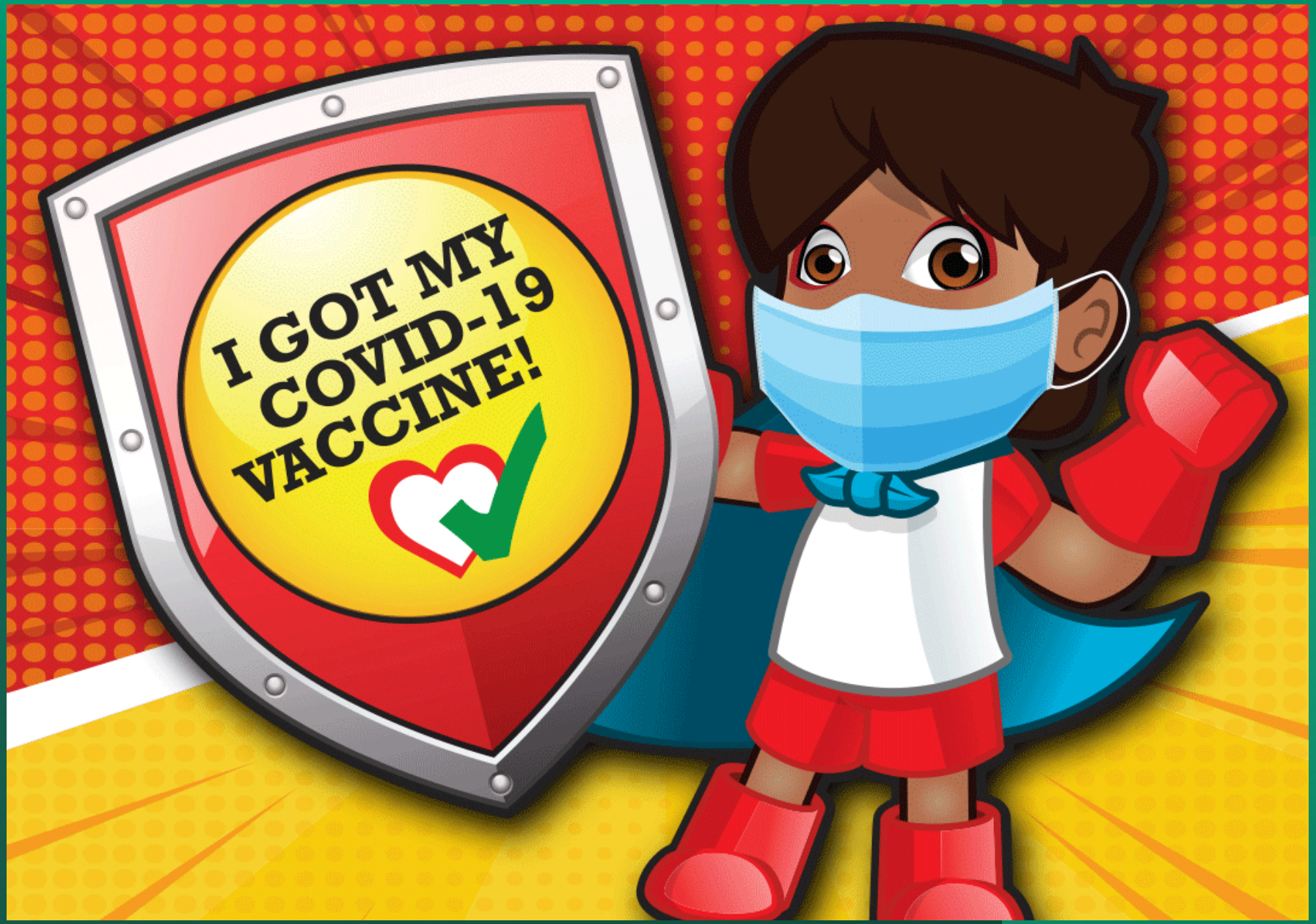
I GOT MY
COVID-19
VACCINE!

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General impact of COVID-19 Vaccination

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Public Health Ontario | Santé publique Ontario

ENHANCED EPIDEMIOLOGICAL SUMMARY

Confirmed Cases of COVID-19 Following Vaccination in Ontario: December 14, 2020 to November 14, 2021

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Summary

- COVID-19 vaccine effectiveness (VE) is estimated to be greater than 85% following two doses
- While cases occur following vaccination, there is evidence that the vaccine reduces symptomatic infection, the severity of illness, as well as transmission.
- Vaccine prevents serious outcomes such as hospitalizations and ICU admissions by 70-90%

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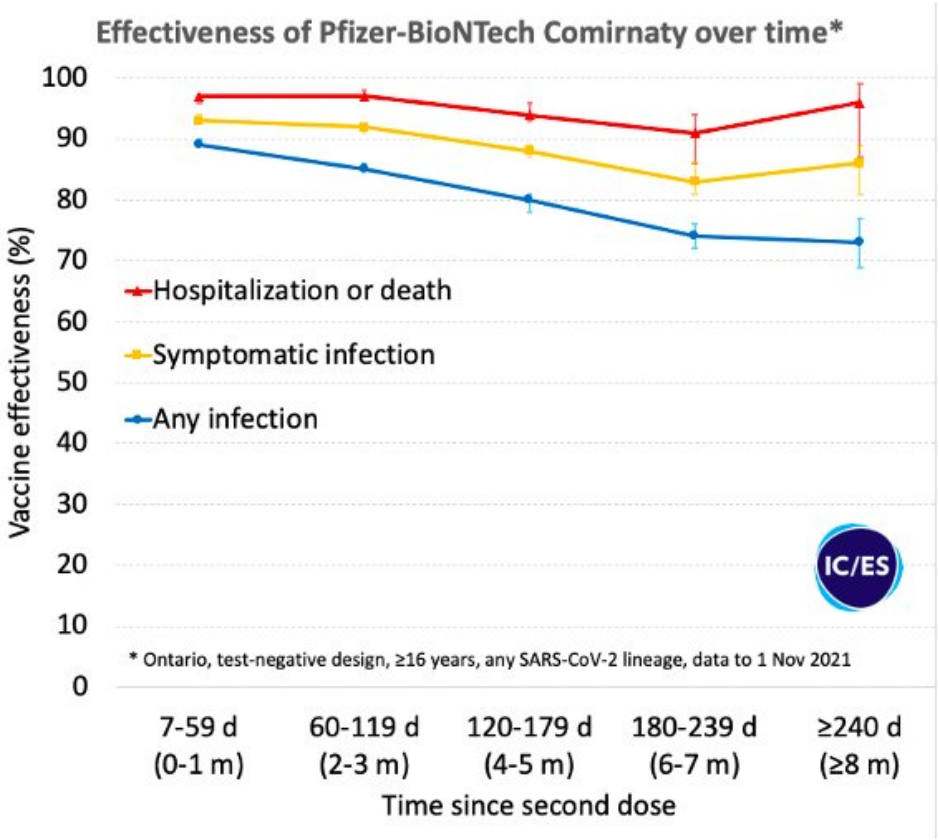
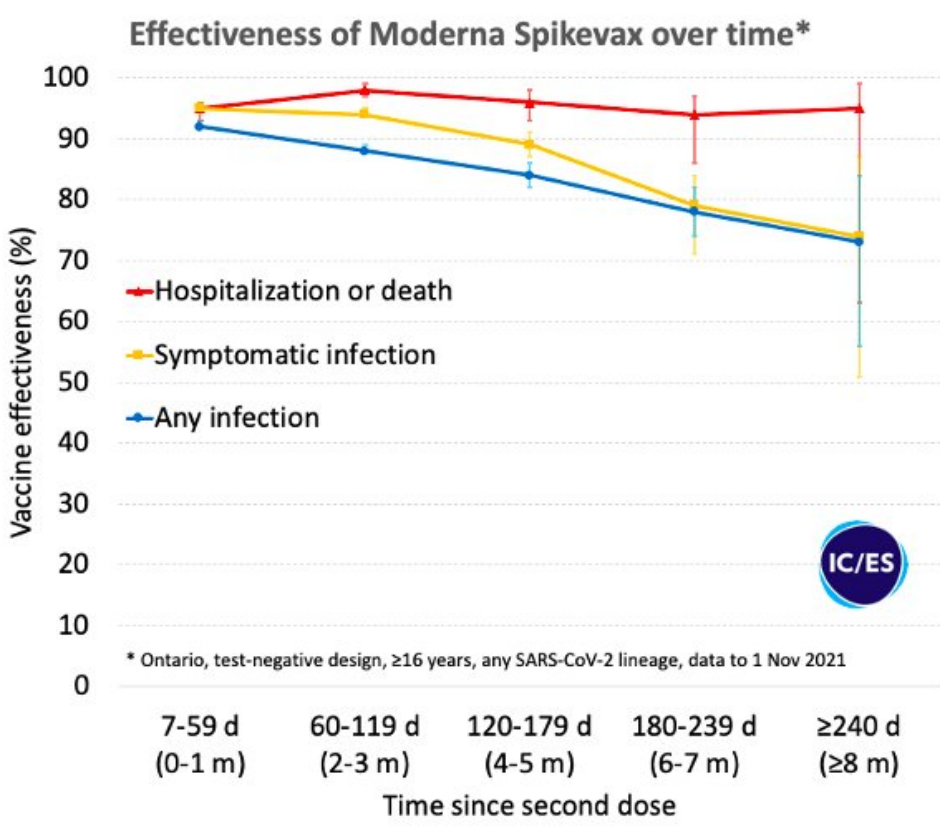
Kwong et al. Pre-print data





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Highlights

- Since the COVID-19 vaccination program began on December 14, 2020 and up to November 14, 2021, a total of 11,154,162 individuals in Ontario are fully vaccinated.
- Of these individuals, 17,596 became breakthrough (i.e. fully vaccinated) cases and 40 became cases following a third dose.

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Unvaccinated vs vaccinated

- Unvaccinated cases accounted for the majority (91.7%) of COVID-19 cases reported since December 14, 2020 and up to November 14, 2021
- Breakthrough cases accounting for 3.8% of cases, and cases following a third dose accounting for <0.1%

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Unvaccinated vs vaccinated

- Unvaccinated cases accounting for 90.9% of hospitalizations and 90.2% of deaths
- Breakthrough cases accounted for 2.7% of hospitalizations and 3.3% of deaths.
- Cases following a third dose accounted for <0.1% of hospitalizations and <0.1% of deaths

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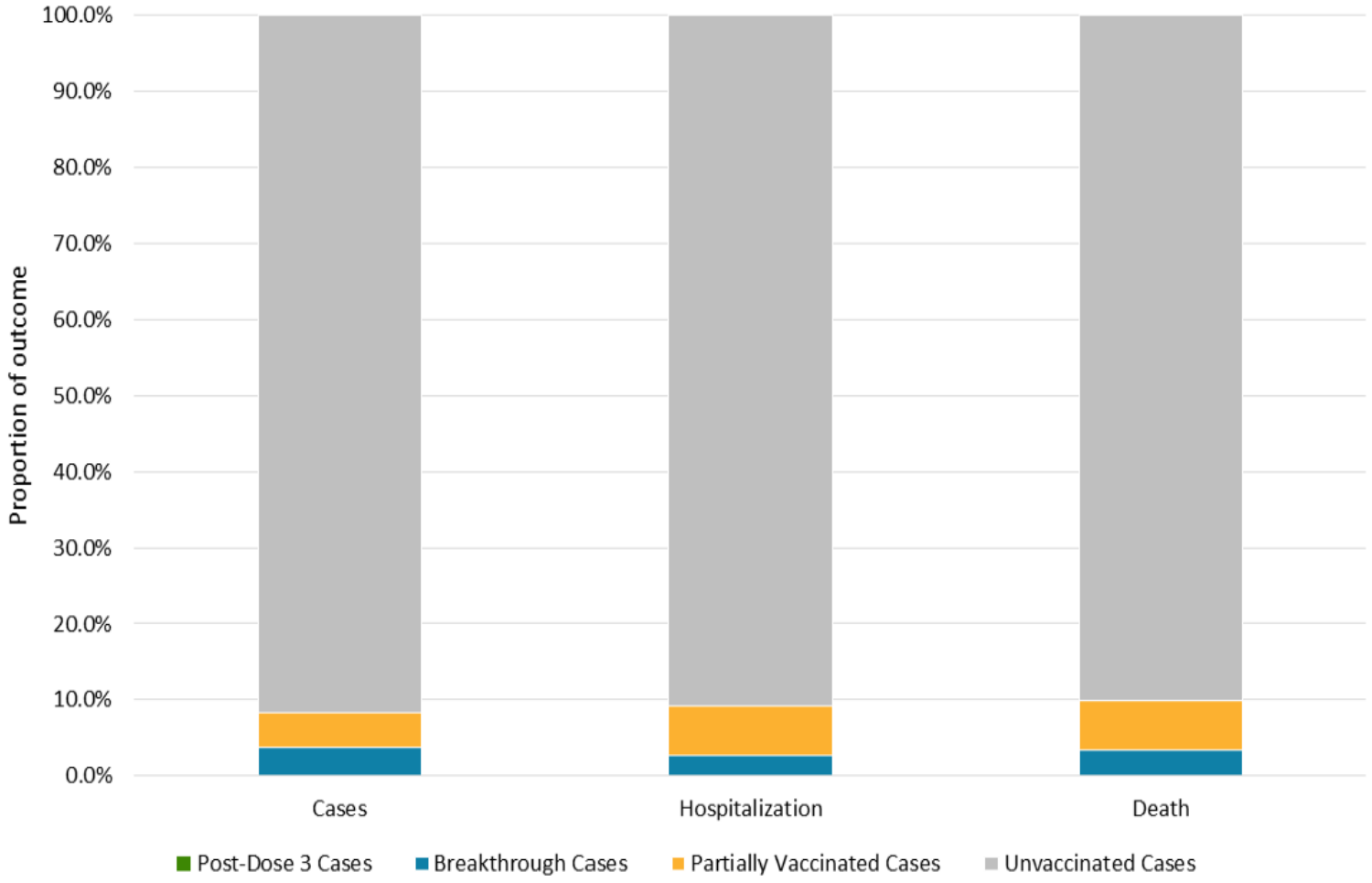
Figure 4. Proportion of confirmed COVID-19 cases, hospitalizations (including intensive care unit admissions), and deaths among unvaccinated, partially vaccinated, breakthrough, and post-dose 3 cases: Ontario, December 14, 2020 to November 14, 2021



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Changing denominators

- Over time as the population becomes more highly vaccinated, the number of post-vaccination cases will increase.
- Even with a highly effective vaccine, cases may occur among vaccinated individuals due to a larger proportion of the population being vaccinated than unvaccinated.

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Higher rates in unvaccinated individuals

- Rate of COVID-19 in unvaccinated individuals is higher compared to fully vaccinated individuals.
- Trend has remained consistent over time.

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Higher rates in unvaccinated individuals

- In the past 30 days, unvaccinated individuals were approximately 4.8 times more likely to become a case of COVID-19 compared to fully vaccinated individuals
- In the past 30 days, the rate of COVID-19 in unvaccinated individuals was higher compared to fully vaccinated individuals in every age group.

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Figure 2. Seven-day average rate of COVID-19 per 100,000 person days among unvaccinated and fully vaccinated individuals by symptom onset date: Ontario

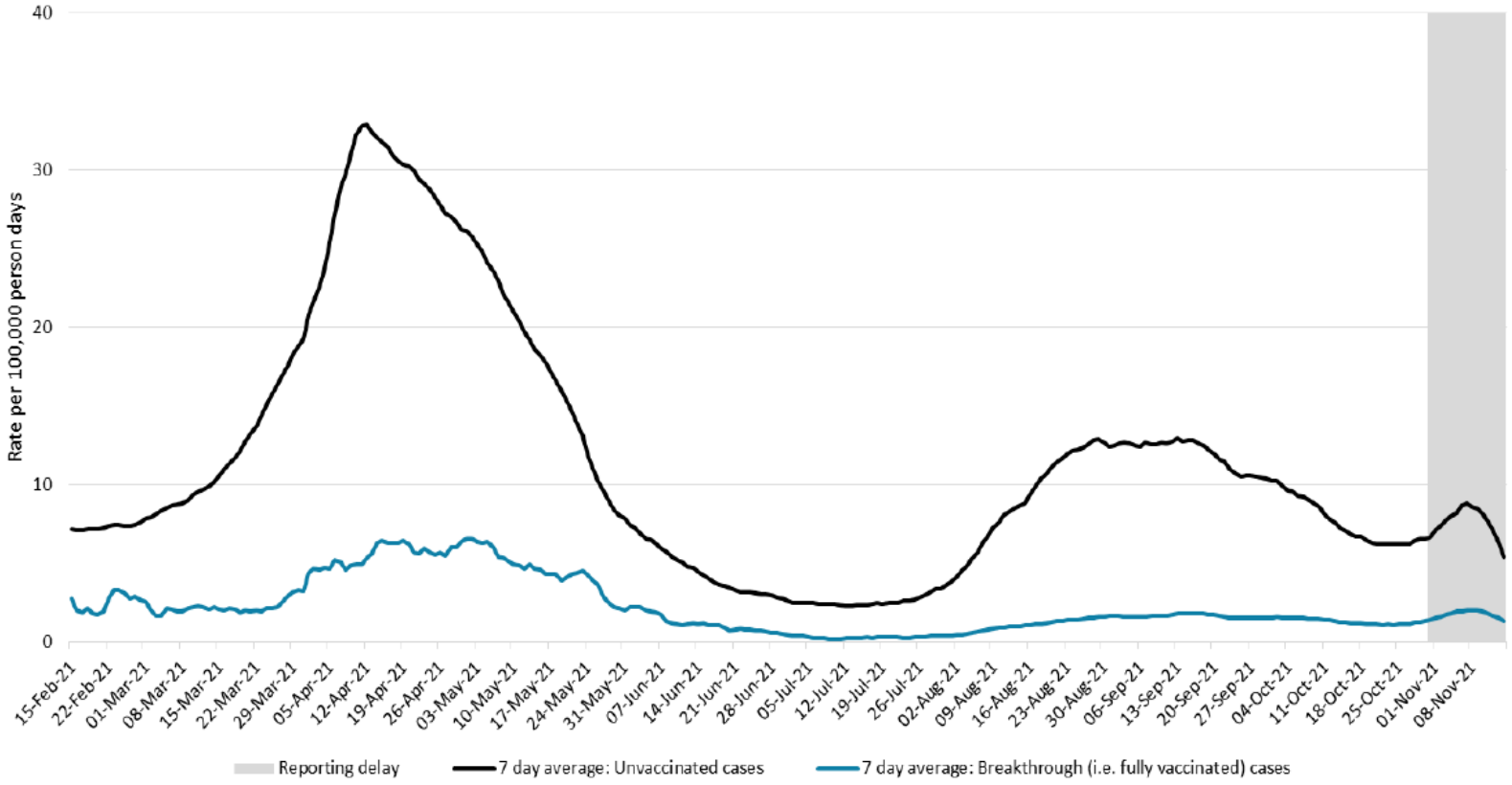

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Figure 5. Rate of COVID-19 per 100,000 person days among unvaccinated and fully vaccinated individuals by age group in the previous 30 days: Ontario

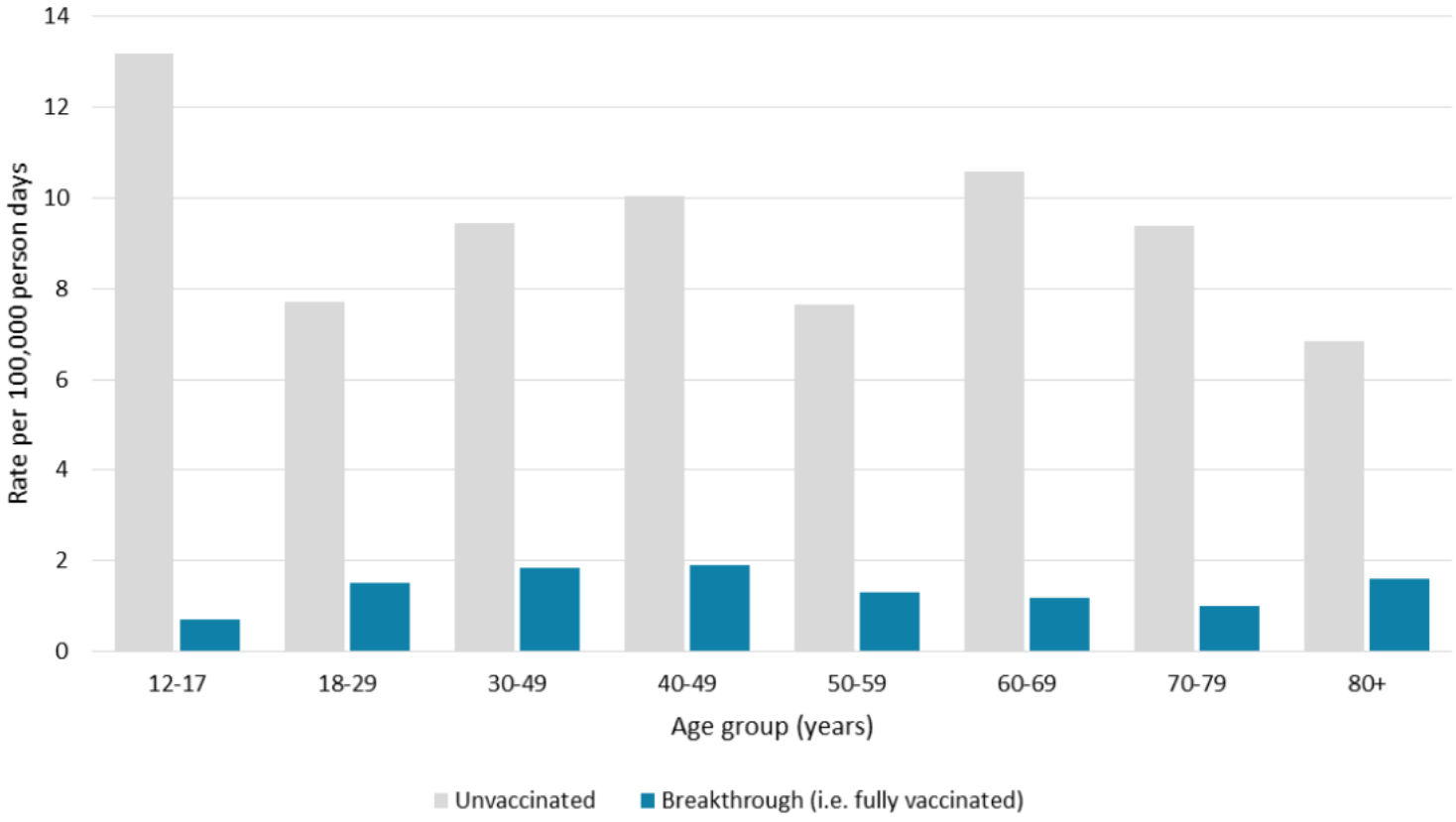

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Figure 6. Seven-day average rate of COVID-19 hospitalization per 100,000 person days among unvaccinated and fully vaccinated individuals 60 years of age and older by symptom onset date: Ontario

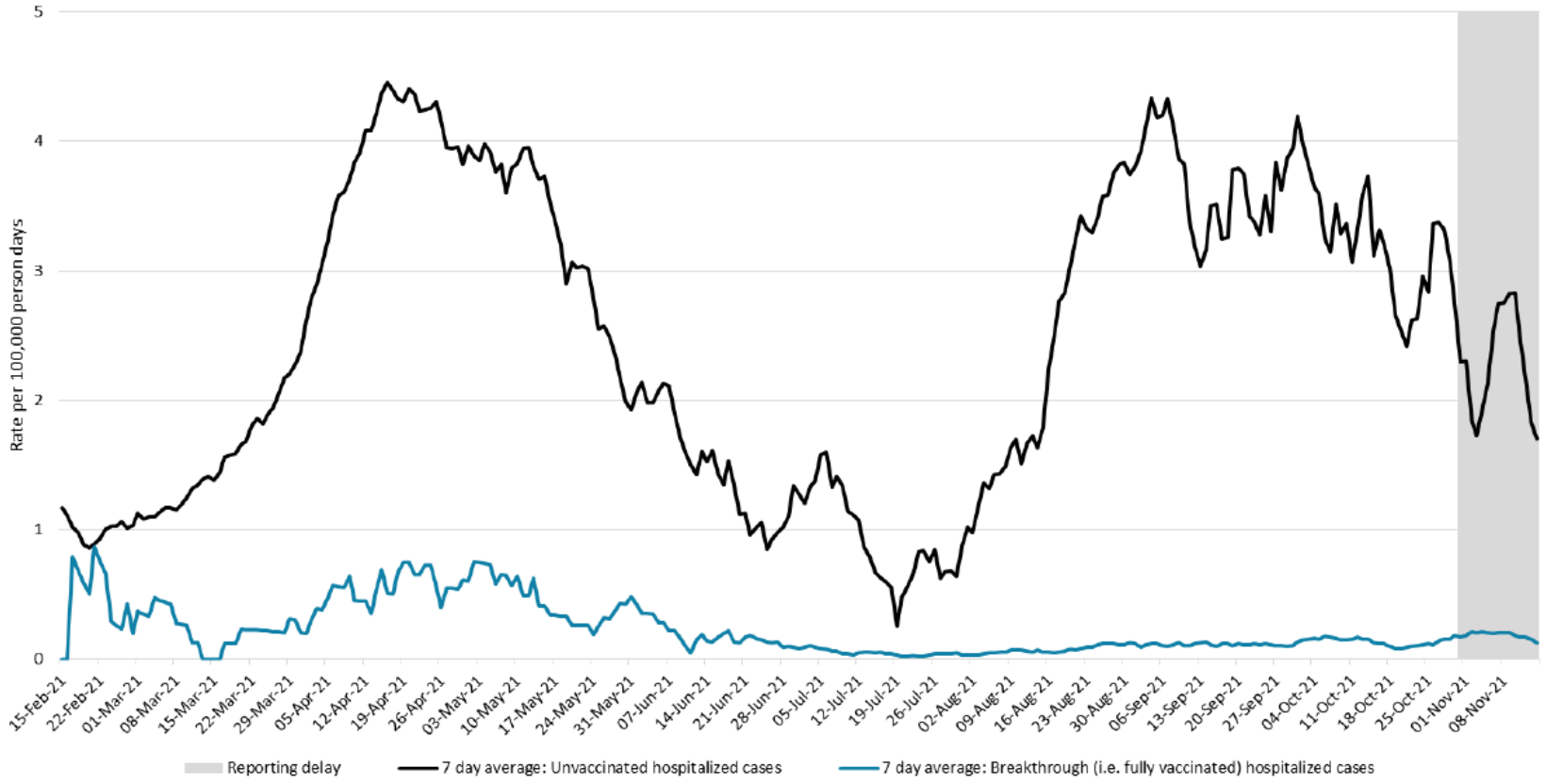

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Figure 7a. Hospitalizations (including intensive care unit admissions) among unvaccinated, partially vaccinated and breakthrough confirmed cases of COVID-19 by age group: Ontario, December 14, 2020 to November 14, 2021

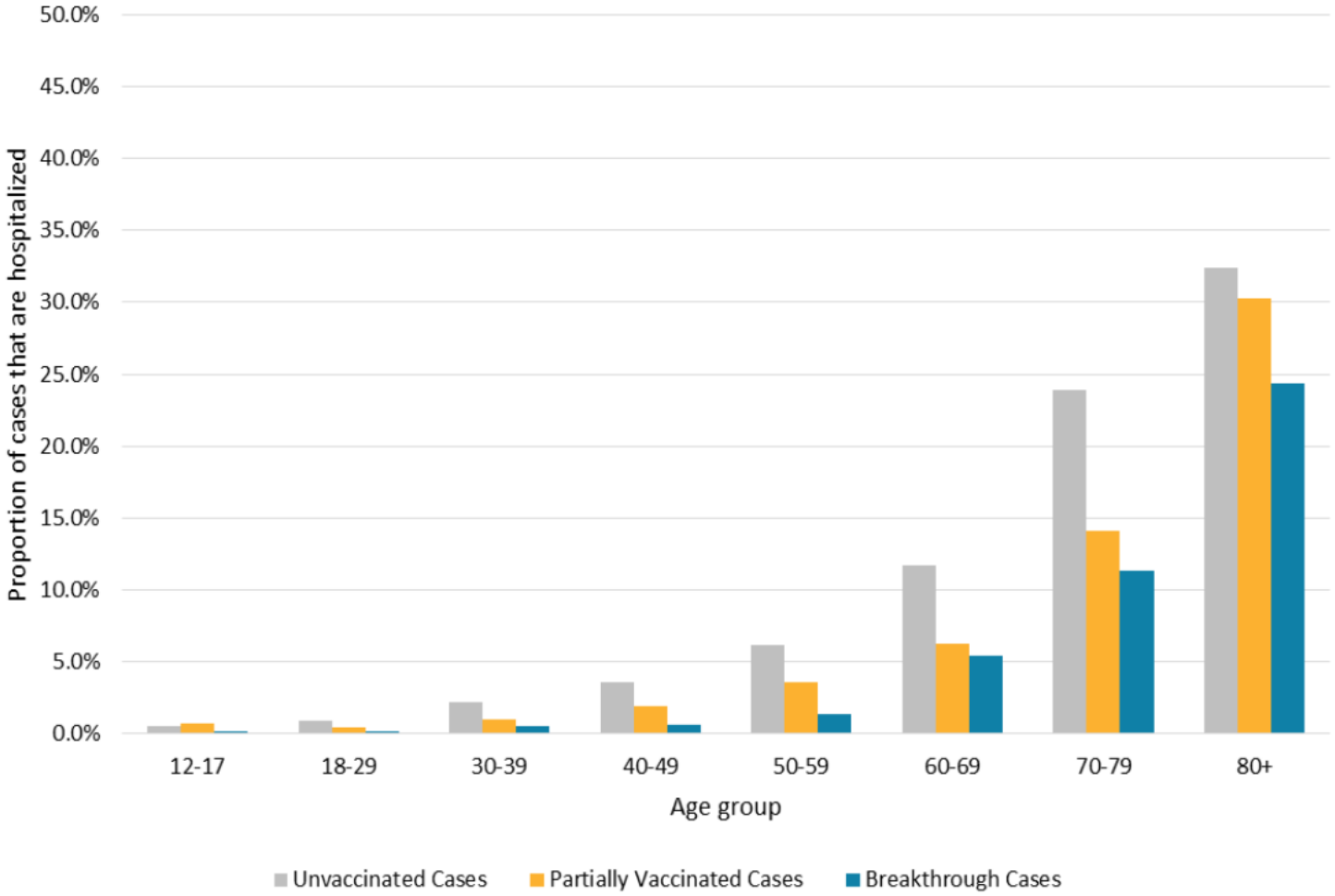

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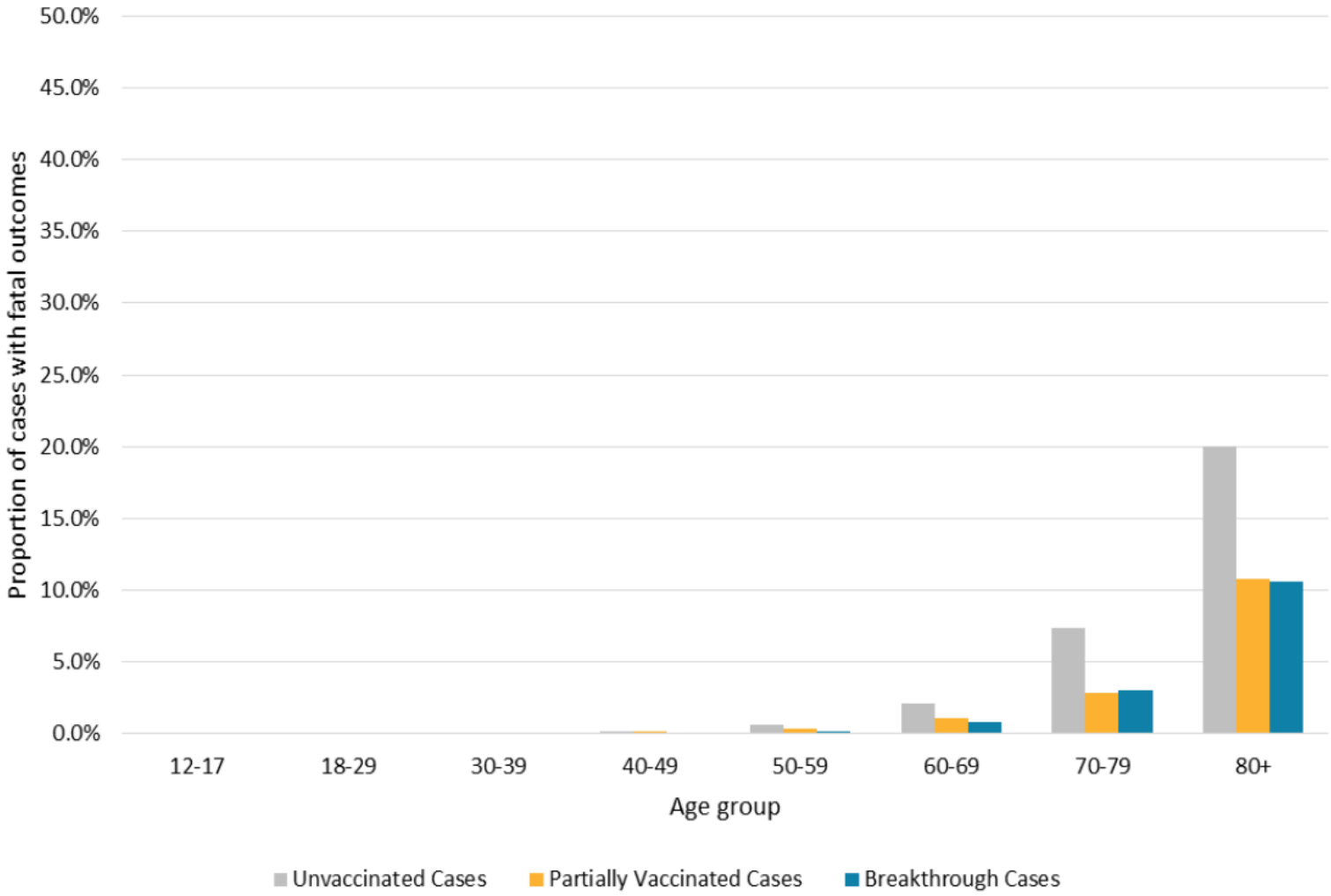
Figure 7b. Fatalities among unvaccinated, partially vaccinated and breakthrough confirmed cases of COVID-19 by age group: Ontario, December 14, 2020 to November 14, 2021



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But what about Omicron?

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COVID-19 Vaccine for children 5-11 years of age

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Reasons to recommend 5-11 vaccination for individuals

The vaccine is effective: with vaccination, personal risk of symptomatic COVID-19 infection would be 91% less than that those without the vaccine

The vaccine is safe: severe adverse events are rare and Ontario has a robust safety system

Decreased personal risk of missing school and increased confidence in school safety

Decreased risk of complications from COVID-19, including long COVID, hospitalizations, and MIS-C, especially if medical comorbidities

Less impacts on their family, including less potential burden from requirements for isolation and testing

Safer to travel and enjoy social activities

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Key Messages

- **Wide use of an effective vaccine would reduce public health burden of COVID-19 in children 5-11 years of age**
  - Since September 2021, infection rates in school-aged children have been steadily increasing
  - A reasonable prediction is that without any vaccination, most children in this age group will ultimately be infected
  - Direct vaccination benefits for children include reduction in acute COVID-19 and risk of MIS-C and other post-COVID conditions
  - Vaccination could also reduce risk of adverse mental and physical collateral harms due to disruptions in schooling and social isolation during the COVID-19 pandemic, including minimizing disproportionate impacts on equity-deserving groups

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Key Messages

- **Benefits of vaccinating children aged 5-11 outweighs harms**
  - Clinical trial demonstrated Pfizer-BioNTech COVID-19 vaccine is safe, immunogenic, and efficacious in children 5-11 years of age
  - Potential risk of rare events is low, and our vaccine safety system is robust
  - Following best practices for pain reduction and vaccinating children in environments that take into consideration their unique needs can improve the child's vaccine experience and mitigate concerns from families and children

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Pediatric Pfizer-BioNTech vaccine is more operational with longer stability after unfreezing and more doses in each vial

Pfizer-BioNTech COVID-19 vaccine formulation differences

	Pediatric, ages 5-11 (orange top)	Adult, ages >12 (purple top)
Dosage	10 µg, 0.2mL	30 µg, 0.3 mL
Doses per Vial	10	6
Diluent	1.3 mL	1.8 mL
Transport	Ultra-frozen If thawed, no limit*	Ultra-frozen / frozen
Storage	Ultralow freezer (-90 to -60°C): 6 months Freezer (-25 to -15°C): N/A Refrigerator (2 to 8°C): **10 weeks** Room temperature: **24 hours** (<12 hours post-dilution)	Ultralow freezer (-90 to -60°C): 9 months Freezer (-25 to -15°C): 2 weeks Refrigerator (2 to 8°C): **31 days** Room temperature: **8 hours** (2 hours pre-, 6 hours post-dilution)
Post-Dilution Time Can be at room temperature	12 hours	6 hours
Potential Allergens	Polyethylene Glycol (PEG) Tromethamine (Tris)	Polyethylene Glycol (PEG)
Ancillary supplies	Low dead volume needle/syringe	

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Pfizer-BioNTech COVID-19 vaccine ingredient differences

Pediatric Pfizer-BioNTech vaccine has some different ingredients, including two potential allergens polyethylene Glycol (PEG) and Tromethamine (Tris)

Ingredients		Pediatric Pfizer-BioNTech	Pfizer-BioNTech
Medical		mRNA	mRNA
Non-medical	Lipids	• (4- hydroxybutyl) zanediyl) bis (hexane-6,1-diyl) bis (2-hexyldecanoate) hexane-6,1-diyl bis (2-hexyldecanoate) • **2 [(polyethylene glycol)-2000]- N,N-ditetradecylacetamide** • 1,2-distearoyl-sn-glycero-3-phosphocholine (HSPC) • Cholesterol	• ALC-0315 • **ALC-0159 – a polyethylene glycol (PEG)** • 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) • Cholesterol
	Salts	• **Tromethamine** • **Tromethamine hydrochloride** • Sodium chloride	• Dibasic sodium phosphate dihydrate • Monobasic potassium phosphate • Potassium chloride • Sodium chloride
	Sugar	• Sucrose • Water for injection	• Sucrose • Water for injection

Pediatric formulation

- Modified formulation uses a Tris buffer (tromethamine) instead of phosphate-buffered saline (PBS) and excludes sodium and potassium chloride

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Clinical trial results

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Trial Design overview

- **Design:** Randomized, double-blind, placebo-controlled phase 1/2/3 pediatric trial
- **Phase 2/3 trial intervention:** two 10 mcg doses, 21 days apart
- **Study population:** participants from US, Finland, Poland and Spain
  - Included pediatric participants with a history of prior SARS-CoV-2 infection or clinical symptoms/signs of COVID-19, children with known HIV, hepatitis B or hepatitis C, or stable pre-existing disease
  - 48.6% of participants were female, the median age at vaccination was 8.0 years (range: 5 to 11 years), and 11.4% of participants had obesity
- **Cohorts:**
  1. Participants randomized to intervention or placebo with minimum safety follow-up of 2 months post second dose
  2. Additional safety cohort: participants randomized to intervention or placebo with a median duration of safety follow-up of 2.4 weeks post second dose
- **Endpoints:** efficacy against symptomatic COVID-19 infection, immunogenicity, and safety (reactogenicity and adverse events)
- **Follow up:** planned for 2 years from first dose

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Efficacy & immunogenicity results

Pediatric Pfizer-BioNTech vaccine as a two-dose series was protective against COVID-19 in children aged 5 to 11 when Delta variant was prominent

Objective	Description	#vaccinated	#placebo	Results
Efficacy	Observed efficacy for all evaluable data up to September 6, 2021	**1518**	**750**	**90.7%** (95% CI: 67.4 to 98.3%) efficacy against symptomatic COVID-19 during the time when the Delta variant predominated (3 cases in vaccine group; 16 cases in placebo)
Immunogenicity	Immunobridging to 16 -25 year olds from the original adolescent/adult trial at one month after second dose	**264** 5-11 year olds (10 µg) **253** 16-25 year olds (30 µg)	**130** 5-11 year olds **45** 16-25 year olds	Geometric mean titres (neutralization assay) • 5 to 11 year olds (10 µg): **1,197** • 16 to 25 year olds (30 µg): **1,147** **Level of antibody after vaccination was found non-inferior than the older age group**
Immunogenicity against Delta	Supporting analysis in 5-11 year olds	**34**	**4**	Geometric mean titre (neutralization assay) • Wild type: 365 • Delta: 295 **Neutralization of reference strain and delta variant of concern was comparable**

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Walter et al, 2021; Gurtman, 2021; Vaccines and Related Biological Products & Advisory Committee, 2021

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Safety results

Observed adverse events profile in this study did not suggest any safety concerns for 5-11 vaccination, though the trial was not large enough to properly detect rare events

Objective	Description	#vaccinated	#placebo	Results
Safety - original phase 2/3 cohort	• Median follow-up 2.3 months from Dose 2 • 95% have had 2 to less than 3 months of follow-up from Dose 2	**1518**	**750**	• Somewhat more local reactogenicity compared to 16 to 25 year olds (swelling and redness) • Less systemic reactogenicity compared to 16 to 25 year olds • **No related serious adverse events; no myocarditis**
Safety - additional cohort based on FDA request	• Median follow-up 2.4 weeks at data cutoff of October 8, 2021 • 71% have had at least 2 weeks of follow-up from Dose 2	**1591**	**788**	**No related serious adverse events; no myocarditis**

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Walter et al, 2021; Gurtman, 2021; Vaccines and Related Biological Products & Advisory Committee, 2021

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Reactogenicity and serious events

- Grade refers to severity of the reaction/adverse event
- **Grade 1 - Mild**
  - Asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention indicated
- **Grade 2 - Moderate;**
  - Minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL
- **Grade 3 - Severe or medically significant but not immediately life-threatening**
  - Hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL
- **Grade 4 - Life-threatening consequences**
  - Urgent intervention indicated
- **Grade 5 - Death related to AE**

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Reactogenicity and serious events

Most reactions were mild and there were no related serious adverse events (including no myocarditis)

	Reactogenicity	Adverse Events	
	Incidence of grade ≥3 local and systemic reactions within 7 days of either dose	Incidence of related adverse events within 1 month of first dose	Serious adverse events **(none judged to be associated with vaccine)**
Vaccinated	41/1518 (2.7%)	46/1518 (3%)	Limb fracture, infective arthritis of knee, ingestion of a penny, epiphysial fracture
Placebo	8/750 (1.1%)	16/750 (2.1%)	Pancreatitis and abdominal pain (same participant)

Walter et al, 2021; Gurtman, 2021; Oliver, 2021; Vaccines and Related Biological Products & Advisory Committee, 2021

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Reactogenicity

Children aged 5-11 had less severe systemic events (including fever and chills) after the 10 mcg vaccine dose relative to individuals aged 16-25 after the 30 mcg dose

Symptoms within 7 days after dose 2	Systemic reactions								Local reactions		
	Fever	Fatigue	Head-ache	Chills	Vomiting	Diarrhea	Muscle pain	Joint pain	Redness	Swelling	Pain at injection site
Ages 5-11 10µg dose	6.5%	39.4%	28.0%	9.8%	1.9%	5.3%	11.7%	5.2%	18.5%	15.3%	71.0%
Ages 16-25 30µg dose	17.2%	65.6%	60.9%	40.0%	2.7%	8.0%	40.8%	21.9%	5.7%	6.8%	77.5%

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Walter et al, 2021; Gurtman, 2021; Vaccines and Related Biological Products & Advisory Committee, 2021

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Myocarditis risk from COVID-19 compared to COVID-19 vaccine

Myocarditis from COVID-19 infection may be more harmful and more common than myocarditis from vaccination

- Emerging evidence suggests myocarditis associated with the COVID-19 vaccine has a **milder clinical course** and **more rapid recovery** than myocarditis associated with MIS-C or viral infection[1]
- Current evidence demonstrates risk from COVID-19 is higher than risk from the COVID-19 vaccine[2]

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1. Patel et al, 2021; 2. University of Waterloo, 2021; 3. Boehmer et al, 2021

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Myocarditis risk from COVID-19 compared to COVID-19 vaccine

COVID-associated myocarditis

- Rate of myocarditis in patients of **<16 years** hospitalized with COVID in the USA between Mar 2020 to Jan 2021 was 133 per 100,000 COVID-19 infections or 1 in almost every 750 infections

Vaccine-associated myocarditis

- Risk of myocarditis and pericarditis after vaccination in **ages 12-17** in Ontario, Canada*:
  - Females: 2 per 100K population or 1 in almost 50,000
  - Males: 12.23 per 100K population or 1 in almost 8,000

*Estimate based on CCM, Public Health Ontario AEFI system as of September 4, 2021, and COVaxON

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Details of Eligibility

- Children 5 to 11 years of age (or turning 5 in 2021) are eligible to receive the vaccine.
  - For clarity, anyone born in 2016 or earlier is eligible to receive the vaccine.
  - The province is still determining what the plan will be for the 2017 cohort as of January 1, 2022.

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Dosing Interval

- The recommended interval between the first and second dose is 8 weeks.
  - This may reduce the risk of myocarditis/pericarditis AND results in a more robust and durable immune response and higher vaccine effectiveness.

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Children turning 12 between their first and second dose

- Children under 12 should receive the 10 mcg Pfizer BioNTech COVID-19 vaccine for their first doses
- Adolescents 12 years of age and older should continue to receive the 30 mcg Pfizer BioNTech COVID-19 vaccine.

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Children turning 12 between their first and second dose

- Children who received the 10 mcg Pfizer 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 vaccine to complete their primary series.
- If the second dose 10 mcg is given, the dose should still be considered valid and the series complete.

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Children turning 12 between their first and second dose

- Children who are 11 years of age and received the 30 mcg Pfizer BioNTech COVID-19 vaccine for their first dose under Ontario's extended eligibility are recommend to complete the vaccine series with the product authorized for their age at the time of the second dose (i.e. 10 mcg if still 11 years, 30 mcg if 12 years).

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Concurrent administration of other vaccines

- Unlike adolescent and adult populations, COVID-19 vaccines for children 5-11 years old should not routinely be given concomitantly (i.e. same day) with other vaccines at this time.
- It is prudent to wait for a period of at least 14 days BEFORE or AFTER the administration of another vaccine before administrating a COVID-19 vaccine.

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Concurrent administration of other vaccines

- Purpose is to observe for AEFIs and prevent erroneous attribution of an AEFI to one particular vaccine or the other.
- However, concomitant administration or a shortened interval between COVID-19 vaccines and other vaccines may be warranted on an individual basis in some circumstances.

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Previous diagnosis of COVID-19

- Children with previous COVID-19 infection may be offered two doses of the vaccine once symptoms of acute illness have resolved and the child is no longer considered infectious.
- Children with a history of MIS-C may be vaccinated once they have recovered or once it has been more than 90 days since diagnosis, whichever is longer.

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Vaccination in Middlesex-London

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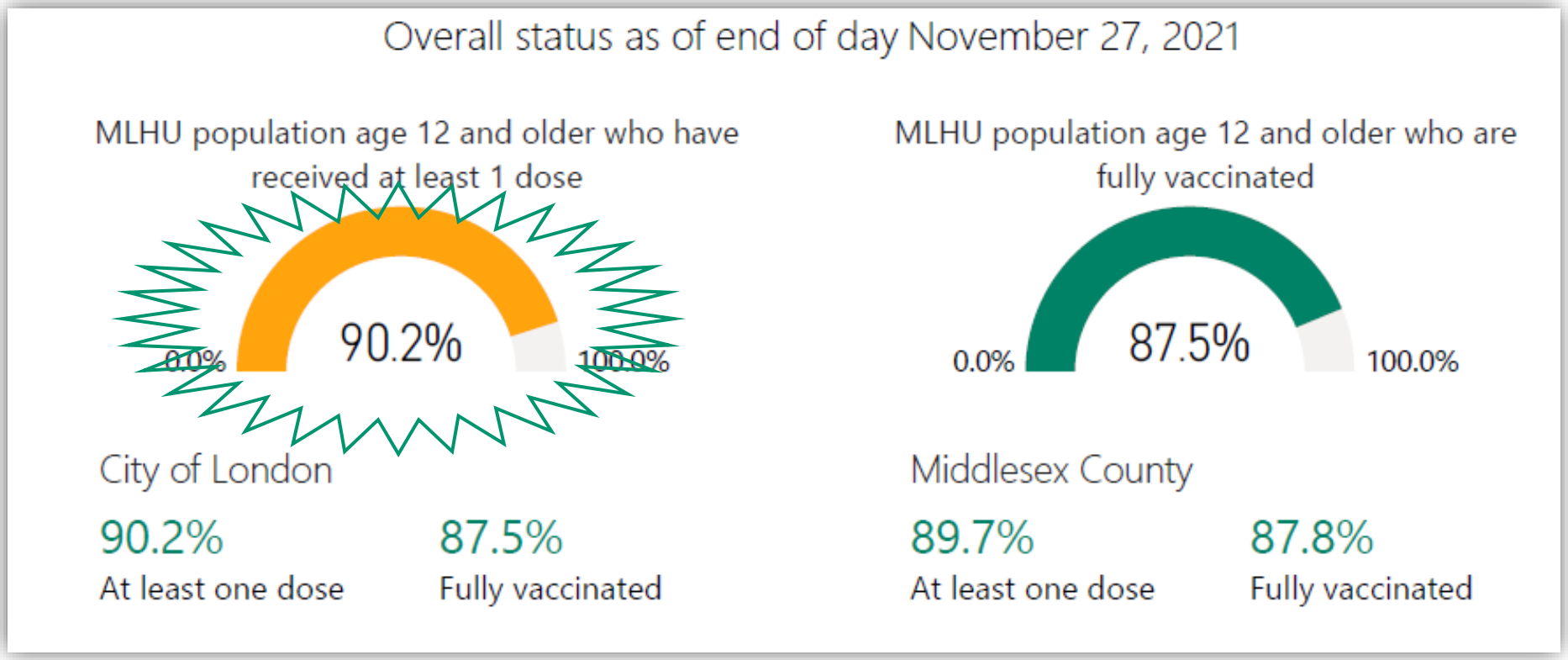
COVID-19 Vaccine Coverage



Data source: Ontario Ministry of Health (Ministry) *Public Health Case and Contact Management Solution* (CCM), extracted 2021-11-23. Data current as of the end of day 2021-11-20.

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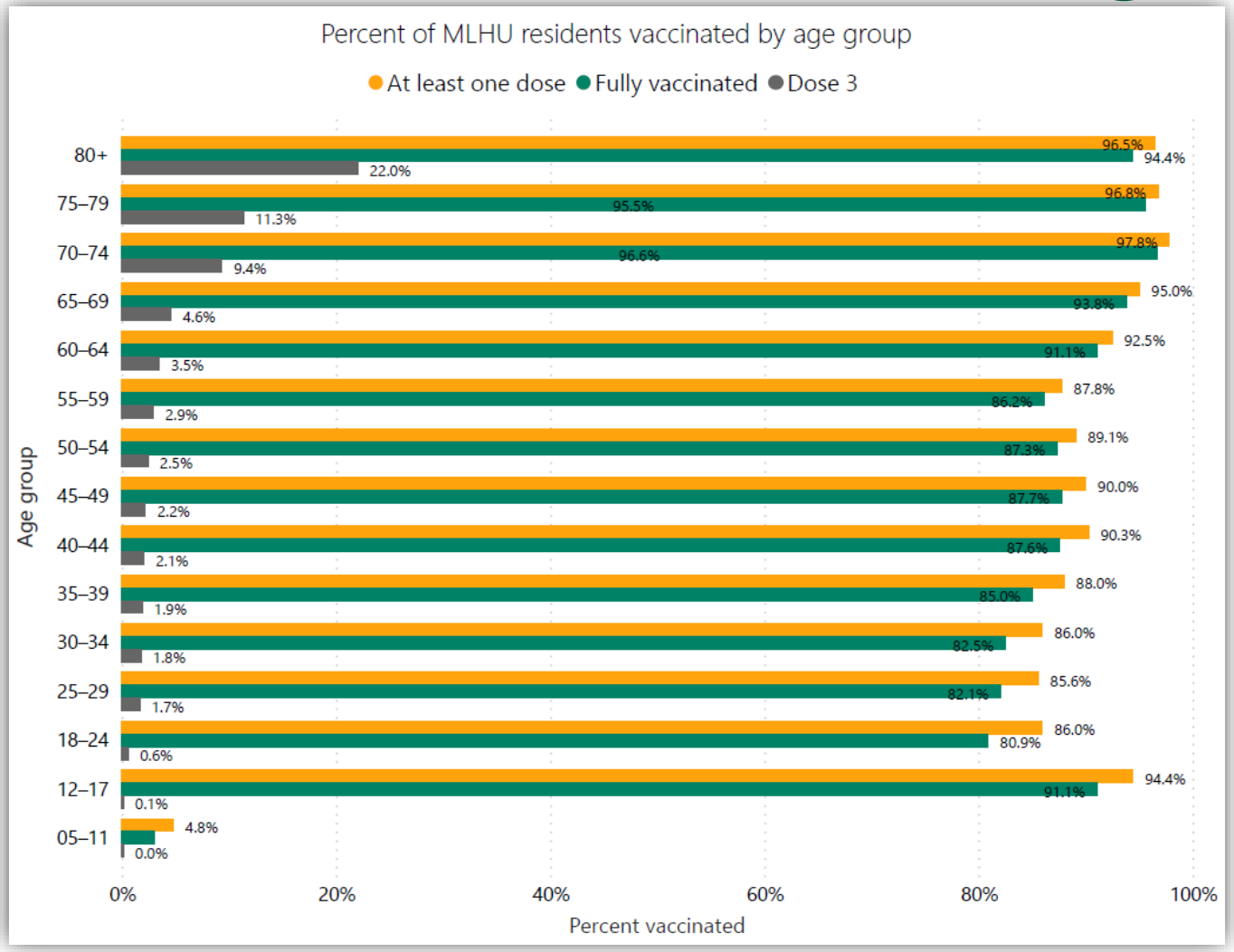
COVID-19 Vaccine Coverage



Data source: Ontario Ministry of Health (Ministry) *Public Health Case and Contact Management Solution* (CCM), extracted 2021-11-30. Data current as of the end of day 2021-11-29

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Sites for vaccination

- Mass vaccination sites (MLHU)
- Pop-up clinics (MLHU)
- Pharmacies
- Primary care

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Booking COVID-19 Vaccination Appointments for Children 5-11

- Appointment bookings opened Tuesday, November 23, 2021 at 8AM
- Appointments can be booked online at www.covidvaccinelm.ca or call 226-289-3560 (9AM-5PM, 7 days a week)
- To have multiple children from the same household booked at the same time, parents/caregivers should book an appointment for each child, on the same day, and just show up at one of the appointment times

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COVID-19 Mass Vaccination Clinics

- The clinics at the Agriplex and Mt. Brydges are welcoming children 5 to 11 years
- MLHU Staff continue to meet about pediatric vaccination to plan additional clinics and enhance pediatric vaccination experience.

Current Hours of Operation:

Clinic Locations	Hours of Operation
Western Fair Agriplex in London	Monday to Sunday 11AM to 6PM
Caradoc Community Centre in Mount Brydges	Tuesday and Wednesday 11AM to 6PM

*Stay tuned for additional COVID-19 vaccine clinic announcements coming soon to support the vaccination effort over the holiday season!

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Masonville COVID-19 Pop-up Clinic

- CF Masonville Place Walk-in Pop Up Clinic
  - Clinic will run December 1st to 31st.
  - Wednesday to Friday 12 noon to 8:00 p.m.
  - Saturday 11:00 a.m. to 6:00 p.m.
  - Sunday 11:00 a.m. to 5:00 p.m.
- Exploring other mobile opportunities for January and beyond.

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Pharmacies

Ontario

français

COVID-19

Home > COVID-19 > Vaccines > What to expect

Last updated: November 29, 2021

COVID-19 pharmacy vaccine locations

Find your closest pharmacy to get a COVID-19 vaccine.

Most pharmacies book appointments ahead of time and some allow walk-ins. Check with the pharmacy before you go.

COVID-19 vaccines available at pharmacies

- **Moderna**: age 25 or older on the day of your appointment (people aged 18 to 24 years old can still get Moderna with informed consent)
- **Pfizer**: age 12 or older in 2021
- **Paediatric Pfizer**: age 5 to 11 in 2021

The vaccine types offered by specific pharmacies may change without notice. All vaccines provided by Ontario offer strong protection against COVID-19 and the highly contagious Delta variant.

Learn about:

- COVID-19 vaccines for youth and children
- booster doses and who is eligible
- second doses and when to get one

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COVID-19 Vaccine Distribution Program

Do you serve patients between the ages of 5 and 17 years old?

With the approval of the Pfizer vaccine for this age group, now is an excellent time to join the *COVID-19 Vaccine Distribution Program*!

Why should you consider it?

- Many parents and children feel more comfortable being vaccinated by their trusted healthcare provider, where they can openly and honestly ask questions and have conversations about vaccination.
- Healthcare providers support children by providing vaccines in a calm and familiar setting, which prevents needle and procedural anxiety.
- Providing COVID-19 vaccinations adds value to your organization by providing an important service for your patients.

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COVID-19 Vaccine Distribution Program

Recent enhancements to the program...

MLHU recently conducted an evaluation of the program, and has made significant improvements to support HCPs, including:

- Streamlined and condensed training process (now 2 hrs/staff)
  - Opportunities to practice in the COVax environment
  - Virtual training for your Site Facilitator
- Enhanced Informatics support, including a **helpline**, to help navigate COVax (provincial vaccination software)
- Reduced inventory reporting from daily to weekly
- Efficient ordering using our new Vaccine Ordering App
- Access to public health nurses to answer all vaccine-related questions

If you have any questions or have an interest in the program, email COVIDVaccine.Deployment@mlhu.on.ca

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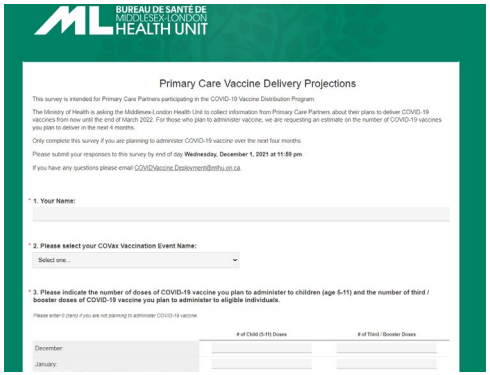
Friendly Reminder to Complete Survey:

Ministry Request for Vaccine Delivery Projections

- Are you planning to administer COVID-19 vaccine to children (ages 5-11) and/or third/booster doses between December 2021 and March 2022?
- If so, please complete the survey that was sent to our onboarded primary care providers by tomorrow, December 1st , 2021 at 11:59 pm:
  - Primary Care Vaccine Delivery Projections Survey:
  - https://chkmkt.com/PrimaryCareVaccineDeliveryProjection
- Thank you for helping us compile this information to send to the Ministry of Health later this week.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Primary Care Vaccine Delivery Projections

This survey is intended for Primary Care Partners participating in the COVID-19 Vaccine Distribution Program.

The Ministry of Health is asking the Middlesex London Health Unit to collect information from Primary Care Partners about their plans to deliver COVID-19 vaccines from now until the end of March 2022. For those who plan to administer vaccine, we are requesting an estimate on the number of COVID-19 vaccines you plan to deliver in the next 4 months.

Only complete this survey if you are planning to administer COVID-19 vaccine over the next four months.

Please submit your responses to this survey by end of day **Wednesday, December 1, 2021 at 11:59 pm**.

If you have any questions please email COVIDVaccine.Deployment@mlhu.on.ca.

* 1. Your Name:

* 2. Please select your COVax Vaccination Event Name:

Select one...

* 3. Please indicate the number of doses of COVID-19 vaccine you plan to administer to children (age 5-11) and the number of third / booster doses of COVID-19 vaccine you plan to administer to eligible individuals.

Please enter 0 (zero) if you are not planning to administer COVID-19 vaccine.

	# of Child (5-11) Doses	# of Third / Booster Doses
December:		
January:		

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MIDDLESEX-LONDON HEALTH UNIT

Information about COVID-19 Vaccinations for Kids

www.healthunit.com/covid-19-vaccine-children-and-youth

Children, Youth and the COVID-19 Vaccine

Health Canada has authorized the use of the Comirnaty COVID-19 vaccine (from Pfizer-BioNTech) for children between the ages of five and 11 and vaccination appointments are now available in London and Middlesex County for children born between January 1, 2010 and December 31, 2016. Please read the information below to learn more about the COVID-19 vaccine for children and help your family prepare to receive the vaccine.

About the vaccine:

- Should my child be vaccinated?
- Is the COVID-19 vaccine safe for children?
- What side effects can children experience after receiving the vaccine?
- How do I make an informed decision about getting the vaccine?
- What are some common myths about the vaccine?
- Frequently asked questions

Preparing your child for vaccination:

- What do I say to my child? What should I avoid saying?
- How can I help my child have a positive experience?

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