Information Session: COVID-19 Vaccination for Children 5-11 years old

Monday, November 29, 2021

Alliance for Healthier Communities
Alliance pour des communautés en santé

afhto association of family health teams of ontario

NPLCA Nurse Practitioner-led Clinic ASSOCIATION

Acknowledgement of Indigenous Territory

The work of the Association of Family Health Teams of Ontario, the Alliance for Healthier Communities, and the Nurse Practitioner-Led Clinic Association, and that of our members, take place on traditional territories of the Indigenous nations who have lived on these lands since time immemorial.

The land we call Ontario is covered by 46 treaties, agreements, and land purchases, as well as unceded territories. It continues to be home to many Indigenous people who live alongside settlers, newcomers, and people whose ancestors were enslaved across the Americas and the Caribbean. We are grateful to live and work on this land, and to work in allyship with the Indigenous Primary Health Care Council.

Recognizing this in a meaningful way means making commitments to sharing and upholding responsibilities to all who now live on these lands and the land itself. In our work, let us be mindful of these commitments.

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COVID-19 VACCINE FOR CHILDREN AGED 5-11

Dr. Janine McCready
Infectious Diseases Physician, Michael Garron Hospital

November 2021

Create Health. Build Community.

About Dr. Janine McCready

- I'm an **Infectious Diseases Physician** at Michael Garron Hospital.
- I've been helping to keep our staff, physicians, community and schools in East Toronto safe during the COVID-19 pandemic.
- I'm a **mom of two kids aged 4 and 8.** They got vaccinated on November 27!
- My sister recently had a baby and is breastfeeding. She is planning on getting pregnant again in the future. She is fully vaccinated against COVID-19.
- **All my friends and family are fully vaccinated against COVID-19.**

What we know about the COVID-19 vaccine for children aged 5-11 in Canada

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Health Canada Santé Canada

Sept. 20:
After months of clinical trials, Pfizer says its COVID-19 vaccine is safe and effective for children aged 5-11.

Oct. 18:
Pfizer submits data to Health Canada, asking the agency to approve its COVID-19 vaccine for children aged 5-11.

Nov. 19:
Health Canada approves the Pfizer COVID-19 vaccine for children aged 5-11.

Nov. 22:
Ontario Ministry of Health announces children aged 5-11 are eligible to be vaccinated.

Nov. 23:
Children aged 5-11 can book a first dose appointment in Ontario.

Note: On Oct. 29, the U.S. Food and Drug Administration (FDA) authorized the Pfizer COVID-19 vaccine for emergency use in children aged 5 to 11 in the U.S. As of Nov.18, more than 2.6 million doses have been administered to children aged 5 to 11 in the U.S.

Risks of COVID-19 in children

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While children typically have mild symptoms, they are just as likely as adults to get COVID-19.

In Canada:

- To date, **354,890** cases of COVID-19 have been reported in **people under 19 years old.**
  - This is 20.8% of total cases reported.

- Of these, **1,735** people have required hospitalization, **230** have been admitted to the ICU and **17** people have died.

In Ontario:

Age group	Cases of COVID-19	Hospitalizations	Deaths
0-4 years old	17,124	262	2
5-11 years old	31,724	84	1
12-19 years old	53,493	479	3

Risks of COVID-19 in children

Rates of recent COVID-19 cases by age group in Ontario

Last updated November 18, 2021 at 11:30 am

The bars below show data from recent cases reported within the past 14 days with a three day lag from the time of data extraction.

Download

Risks of COVID-19 in children

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Other vaccine preventable diseases:

Deaths per year prior to recommended vaccines

	Hepatitis A[1]	Meningococcal (ACWY)[2]	Varicella[3]	Rubella[4]	Rotavirus[5]	COVID-19
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	5–11 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Oct 2020–Oct 2021
Average deaths per year	**3**	**8**	**16**	**17**	**20**	**66**

[1]Vogt TM , Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis2008; 197:1282–8.
[2]National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015-2019.
[3]Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. *J Infect Dis*. 2000;182(2):383-390. doi:10.1086/315714
[4]Roush SW , Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA2007; 298:2155–63.
[5] Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:S5-11.

Risks of COVID-19 in children

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Post-COVID Conditions in Children

- **Post-COVID conditions do occur in children**
  - Appears to be less common in children than in adults
  - A national survey in the UK found **7-8%** of children with COVID-19 reported continued symptoms >12 weeks after diagnosis[1]
  - Can appear after mild to severe infections, and after MIS-C

- **Most common symptoms:** Similar to adults and include fatigue, headache, insomnia, trouble concentrating, muscle and joint pain, and cough[2,3]

- **Impact on quality of life:** Limitations of physical activity, feeling distressed about symptoms, mental health challenges, decreased school attendance/participation[2]

[1]Office for National Statistics United Kingdom. (2021) Prevalence of ongoing symptoms following coronavirus (COVID-19) infection in the UK. Retrieved on September 17, 2021 from Office for National Statistics' website. https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/prevalenceofongoingsymptomsfollowingcoronavirus covid19infectionintheuk/1april2021
[2]Buonsenso D, Munblit D, De Rose C, et al. Preliminary evidence on long COVID in children. *Acta Paediatr.* 2021;110(7):2208-2211. doi:10.1111/apa.15870.
[3]Molteni E, Sudre CH, Canas LS, et al. Illness duration and symptom profile in symptomatic UK school-aged children tested for SARS-CoV-2. Lancet Child Adolesc Health 2021; 5: 708–18. https://www.thelancet.com/action/showPdf?pii=S2352-4642%2821%2900198-X

Household transmission of COVID-19 from children

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Table 2. Adjusted Odds Ratios and 95% Confidence Intervals for the Associations Between Index Case Age Group and Odds of Transmitting SARS-CoV-2 to Household Contacts

Characteristic	Index cases, No. (%)		Crude rate of transmission (per 100 000 households with pediatric index cases)	Odds ratio (95% CI)		
	Not associated with secondary cases in the household	Associated with secondary cases in the household		Crude model	Adjusted Model 1[a]	Adjusted Model 2[b]
Age, y						
0-3	532 (11.7)	234 (13.6)	30 548	1.20 (1.01-1.44)	1.21 (1.01-1.45)	1.43 (1.17-1.75)
4-8	909 (19.9)	348 (20.3)	27 685	1.05 (0.90-1.22)	1.06 (0.90-1.23)	1.40 (1.18-1.67)
9-13	1382 (30.3)	499 (29.1)	26 528	0.99 (0.86-1.13)	0.97 (0.85-1.11)	1.13 (0.97-1.32)
4-17	1740 (38.1)	636 (37.0)	26 768	1 [Reference]	1 [Reference]	1 [Reference]
Male	2433 (53.6)	943 (55.2)	27 932	NA	1.07 (0.95-1.19)	1.09 (0.96-1.23)
Female	2099 (46.2)	764 (44.7)	26 685	NA	1 [Reference]	1 [Reference]
Month of disease onset						
June	119 (2.6)	38 (2.2)	24 204	NA	1 [Reference]	1 [Reference]
July	113 (2.5)	35 (2.0)	23 649	NA	0.98 (0.58-1.66)	1.05 (0.58-1.89)
August	112 (2.5)	31 (1.8)	21 678	NA	0.89 (0.52-1.52)	0.93 (0.51-1.69)
September	482 (10.6)	154 (9.0)	24 214	NA	1.01 (0.67-1.51)	0.97 (0.62-1.51)
October	712 (15.6)	274 (16.0)	27 789	NA	1.22 (0.82-1.80)	1.20 (0.78-1.84)
November	1199 (26.3)	515 (30.0)	30 047	NA	1.37 (0.93-2.00)	1.38 (0.91-2.09)
December	1826 (40.0)	670 (39.0)	26 843	NA	1.16 (0.80-1.70)	1.14 (0.76-1.72)
Testing delay, d						
Asymptomatic	853 (18.8)	89 (5.2)	9448	NA	NA	0.34 (0.25-0.47)
<0	251 (5.5)	36 (2.1)	12 544	NA	NA	0.50 (0.33-0.75)
0	1076 (23.8)	206 (12.1)	16 069	NA	NA	1 [Reference]
1	570 (12.6)	209 (12.3)	26 829	NA	NA	1.24 (0.95-1.61)
2	488 (10.8)	226 (13.3)	31 653	NA	NA	1.59 (1.22-2.07)
3	361 (8.0)	200 (11.7)	35 651	NA	NA	1.97 (1.49-2.59)
4	238 (5.3)	165 (9.7)	40 943	NA	NA	2.38 (1.77-3.19)
≥5	692 (15.3)	574 (33.7)	45 340	NA	NA	2.98 (2.34-3.80)
Mean family size	3.3 (3.0-3.6)	3.4 (3.1-3.7)	NA	NA	NA	1.63 (1.43-1.86)

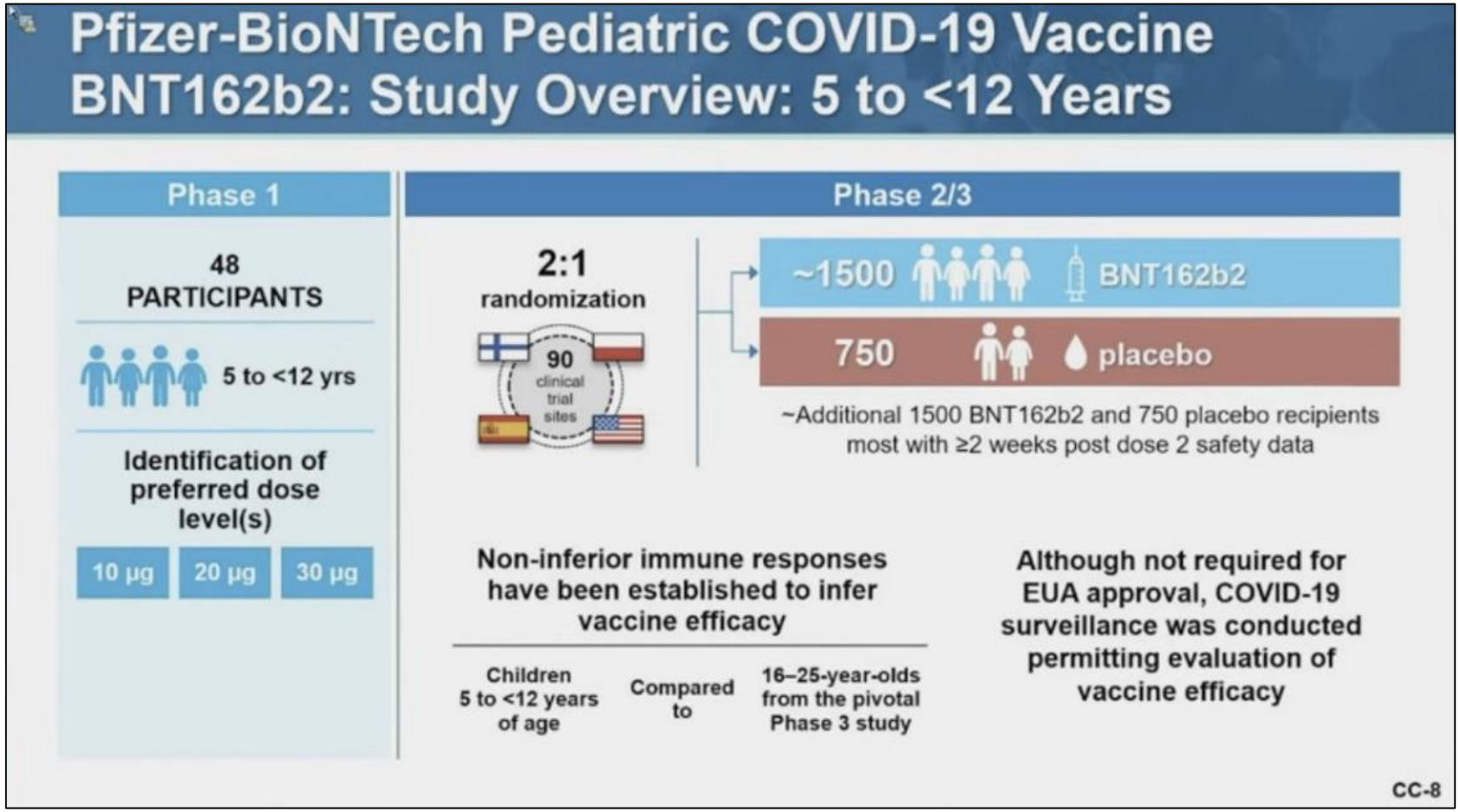
Abbreviation: NA, not applicable.

[a] Adjusted for gender and month of disease onset.

[b] Adjusted for gender, month of disease onset, testing delay, and mean family size. A total of 778 index case individuals were excluded from the model who had no COVID-19 symptoms reported in provincial reportable disease systems, were missing symptom onset date, and were not reported as asymptomatic.

- **Children aged 0-3 had greater odds of transmitting SARS-CoV-2** to household contacts compared with children aged 14-17.
- Irrespective of presence of symptoms.
- **Greater odds of household transmission by children aged 4-8** after controlling for testing delays, neighborhood-level mean family size, individual-level household size.

About the Pfizer clinical trials for children aged 5 to 11



Method:

- Administered two doses of the Pfizer COVID-19 vaccine to 3,000 children aged 5-11 in U.S., Finland, Poland and Spain in 3 phases
- Followed up with each child for at least 1-2 weeks (many for 2-3 months) to assess safety, effectiveness and effects of the vaccine

Safety and efficacy of the COVID-19 vaccine

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The benefits of the Pfizer COVID-19 vaccine outweigh the known and potential risks in children aged 5-11.

Key highlights from Pfizer clinical trials:

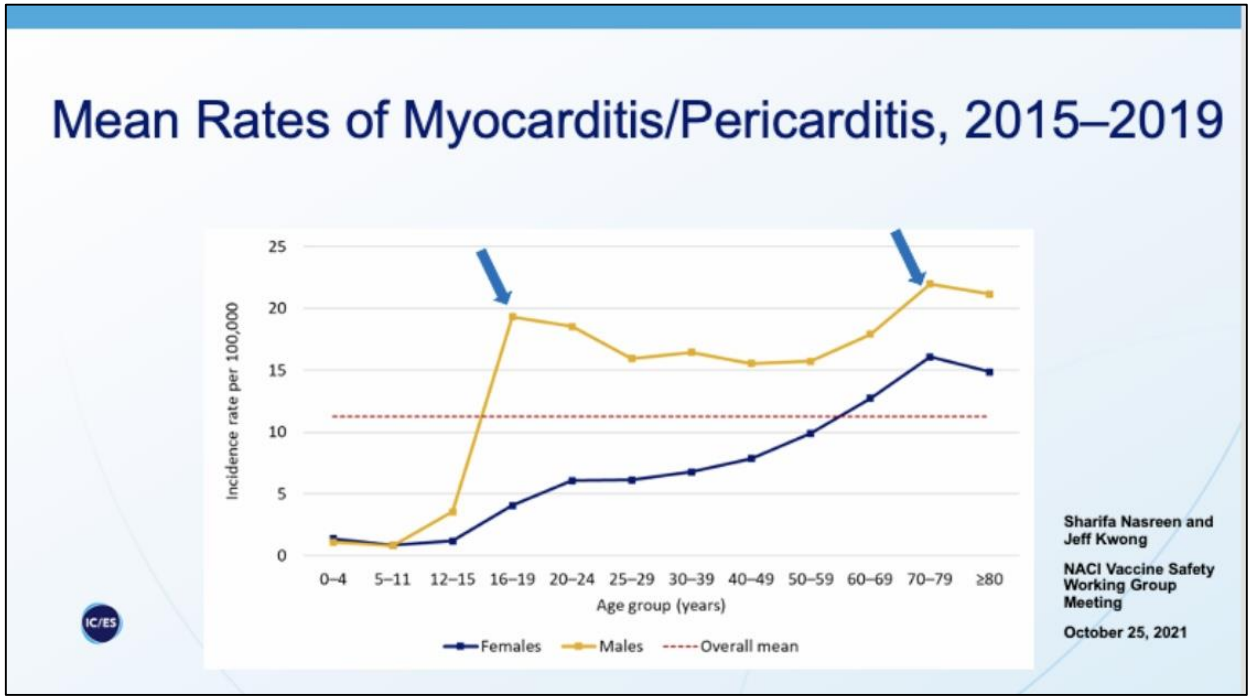
- **Two doses of a smaller, 10 µg child-sized dose, administered 21 days apart, is optimal for providing maximum protection and minimizing side effects in children aged 5-11.**

- **Two doses of the Pfizer COVID-19 vaccine was 90.7% effective in protecting against lab-confirmed symptomatic COVID-19, including the Delta variant.**

- **None of these adverse events were reported by participants during the trial:**
  - ❌ No myocarditis/pericarditis
  - ❌ No anaphylaxis or hypersensitivity
  - ❌ No impact to development or fertility
  - ❌ No multisystem inflammatory syndrome (MIS-C)
  - ❌ No severe cases of COVID-19

- **Most common temporary side effects:**
  - Pain at injection site (arm)
  - Fatigue
  - Headache
  - Muscle pain
  - Chills

Risk of myocarditis in children before and after COVID-19 vaccination



- The highest reporting rate of myocarditis/pericarditis was observed in **males aged 18-24** following second dose.
- In this age group, the reporting rate following Pfizer-BioNTech vaccine as second dose was 43.4 per million doses and was 283.4 per million following the Moderna vaccine as second dose.
- Israeli safety surveillance suggests incidence rates of rare post-vaccination myocarditis **peaks in males aged 16-19 and declines in males aged 12-15.**
- **It is reasonable to predict that post-vaccination myocarditis rates are likely to be even lower in children aged 5-11 than observed in those aged 12-15.**
- In contrast, **number of post-vaccination incidences of myocarditis, pericarditis and myopericarditis expected in the same period of time per million second doses is 21** (assuming that children aged 5-11 experience the same rates of post-vaccination as those aged 12-15 in US).

COVID-19 vaccine and fertility and reproduction

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There is no evidence of long-term effects from the COVID-19 vaccine related to fertility and reproduction in individuals of any age.

- Real-world data shows that people who have been vaccinated against COVID-19 have had **safe, successful pregnancies.** This includes almost 500 people in Ontario as of May 2021.
- Data also shows that, in IVF patients, vaccination against COVID-19 does not affect ovarian function, egg quality, fertilization or clinical pregnancy rate.

The vaccine is also safe – and highly recommended – for people who are pregnant or breastfeeding.

- Pregnant people are more likely to need intensive care if they contract COVID-19.
- Pre-term and stillbirth are more common than normal in pregnant people with COVID-19.
- In contrast, research and real-world data shows that contracting COVID-19 results in five times the risk of erectile dysfunction in males.

COVID-19 vaccine and fertility and reproduction

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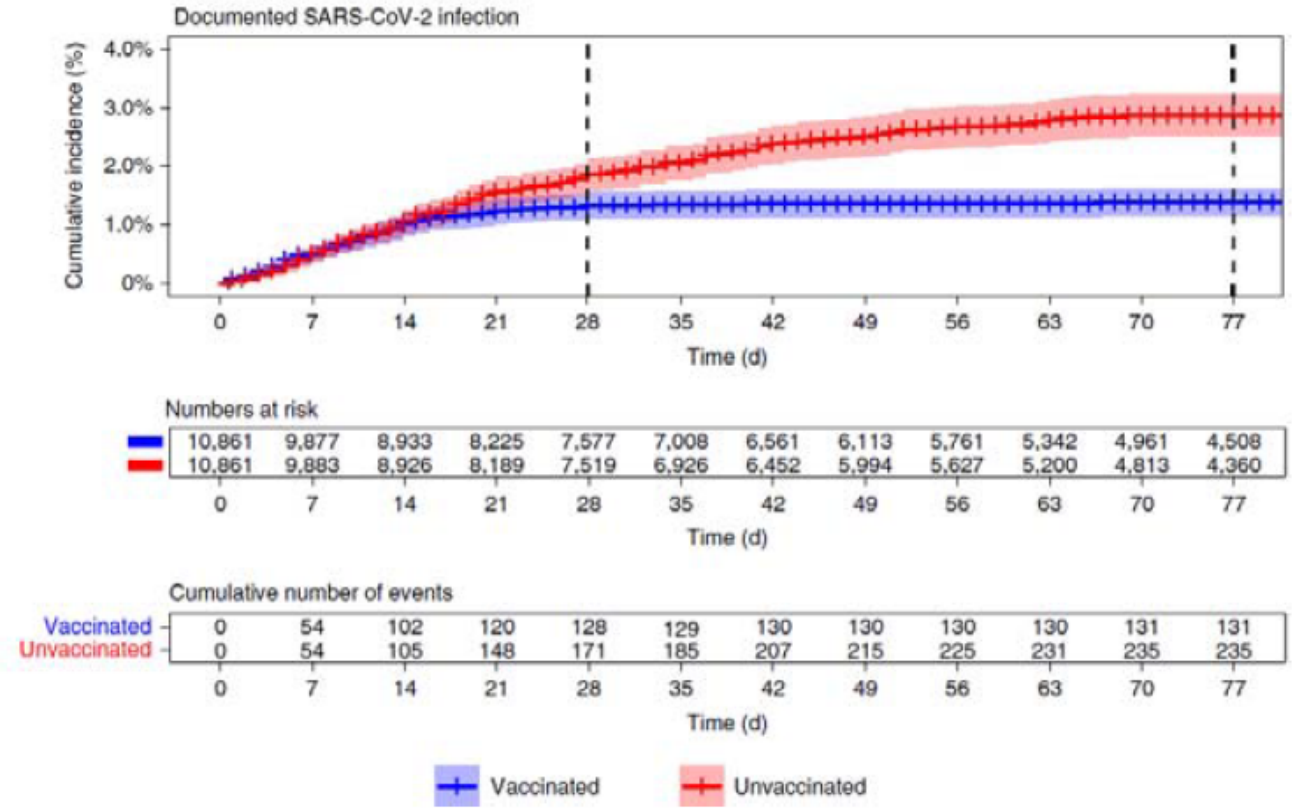
Effectiveness of the mRNA Vaccine in Pregnancy

* Pregnant vaccinated individuals matched to pregnant unvaccinated individuals (n= 10, 861)

Predominantly Alpha VOC triggered infection



96% effectiveness
at preventing infection at 7-56d after the second dose

Dagan et al, Nature Medicine (July 2021)

COVID-19 vaccine and fertility and reproduction

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Effectiveness of the mRNA Vaccine in Pregnancy

Table 1 | Vaccine effectiveness measures

Period	Documented infection		Symptomatic infection		Hospitalization		Severe disease	
	1 − RR (95% CI)	RD (95% CI)	1 − RR (95% CI)	RD (95% CI)	1 − RR (95% CI)	RD (95% CI)	1 − RR (95% CI)	RD (95% CI)
Days 14–20 after first dose	67% (40–84%)	309.22 (145.43–485.69)	66% (32–86%)	223.59 (82.44–361.63)	3 versus 0[a]		2 versus 0[a]	
Days 21–27 after first dose	71% (33–94%)	157.30 (41.42–285.23)	76% (30–100%)	116.52 (26.92–217.92)	5 versus 0[a]		0 versus 0[a]	
Days 7–56 after second dose	96% (89–100%)	933.40 (685.60–1192.33)	97% (91–100%)	621.70 (433.68–847.26)	89% (43–100%)	132.28 (31.67–241.03)	1 versus 0[a]	

RRs and RDs (per 100,000 persons) of COVID-19 outcomes for vaccination versus no vaccination at several time points after vaccination in pregnant women who are members of the CHS, 20 December 2020 through to 3 June 2021. The study population numbered 10,861 individuals in each arm and 1,529 individuals were first included as unvaccinated and then re-recruited as vaccinated.
[a]Estimates were only calculated for cells with more than five events; otherwise, raw counts are reported.

Reduced the risk of:	symptomatic disease hospitalization severe disease

Dagan et al, Nature Medicine (July 2021)

Safety of the COVID-19 vaccine

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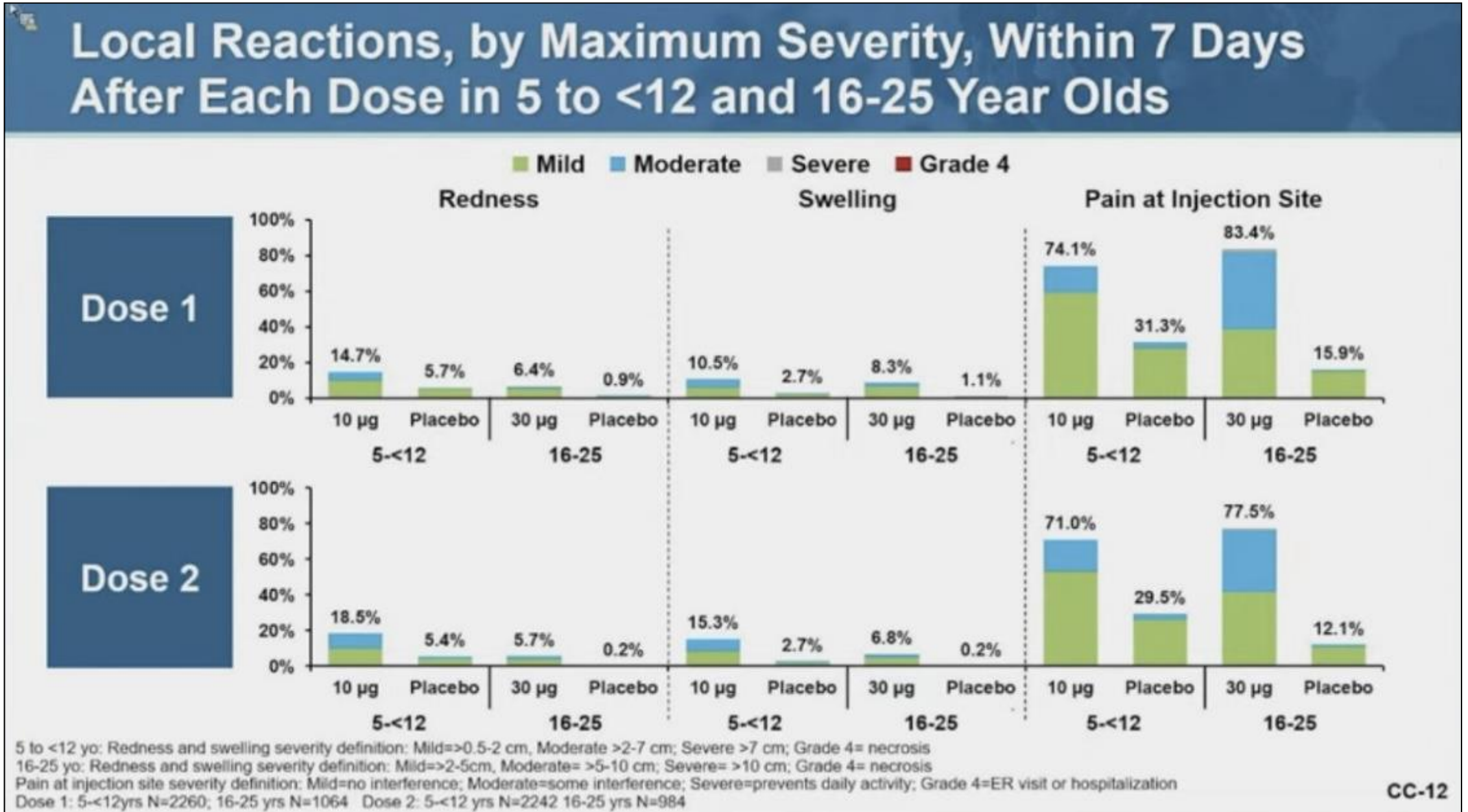

Safety of the COVID-19 vaccine

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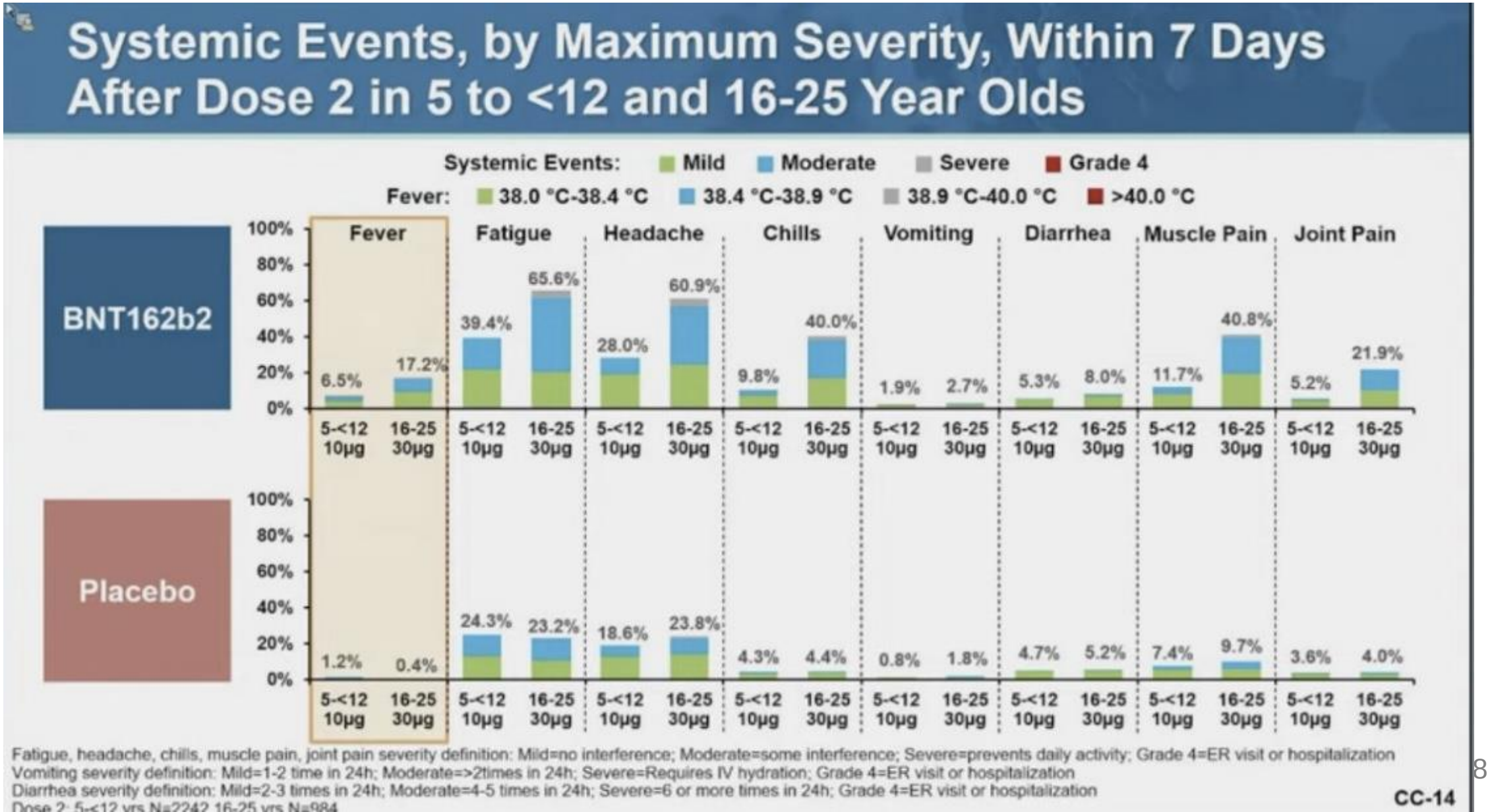
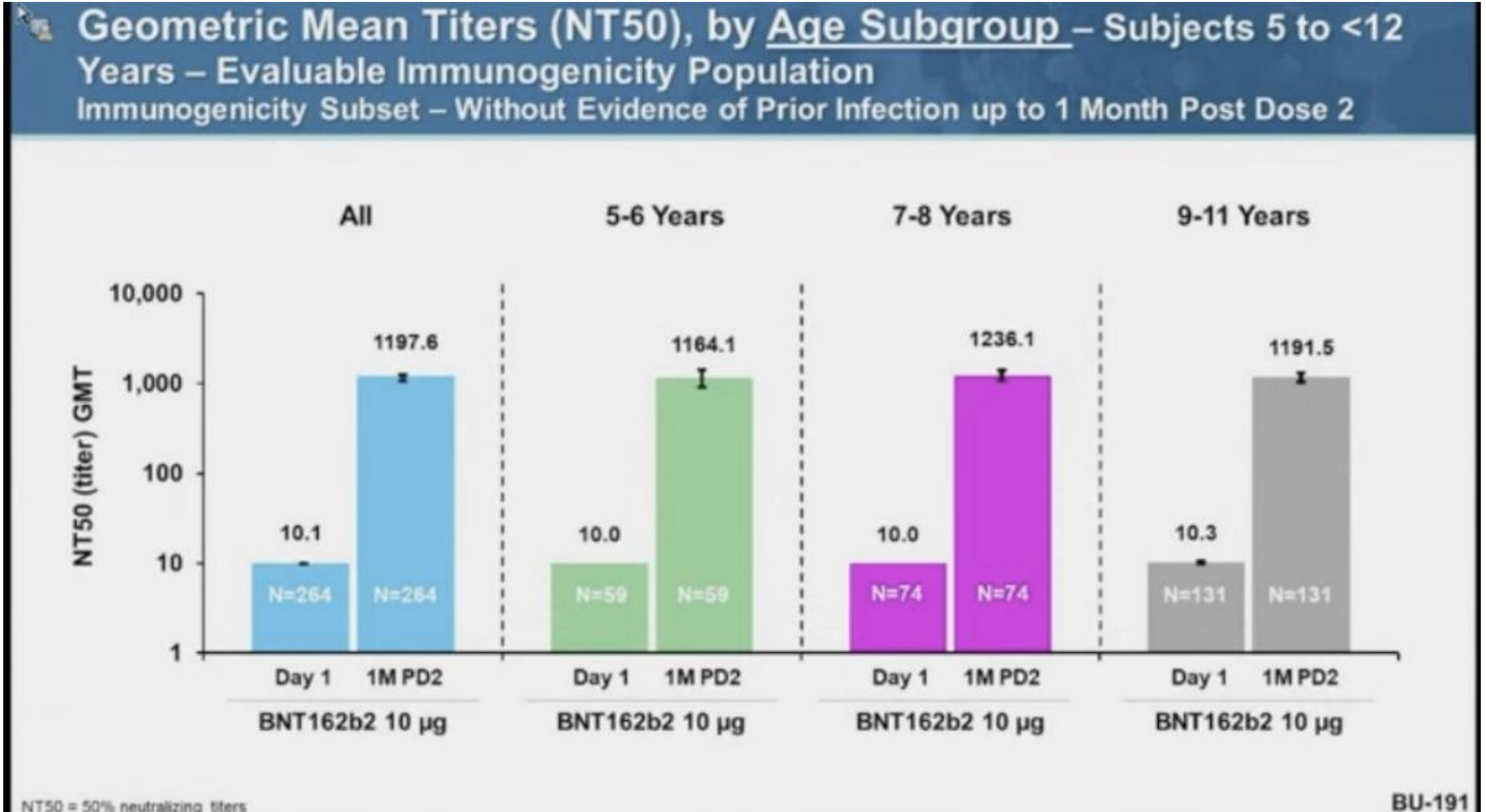


Efficacy of the COVID-19 vaccine



Storage and handling of COVID-19 vaccine for children

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U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Pfizer-BioNTech COVID-19 Vaccine Formulations

12 years of age and older:
PBS/Sucrose formulation

- Dilute before use
- Each dose:
  - 0.3 mL
  - 30 μg mRNA
- Must be stored frozen at -80ºC until expiry date or -20°C for up to 2 weeks prior to use

5 through 11 years of age:
Tris/Sucrose formulation

- Dilute before use
- Each dose:
  - 0.2 mL
  - 10 μg mRNA
- Can be stored at refrigerator temperature (2°C to 8°C) for up to 10 weeks prior to use

➢ Tris and PBS are buffering agents that help maintain the pH and stability of the product.

Storage and handling of COVID-19 vaccine for children

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Table 1: Important Differences between the two COMIRNATY Formulations/Presentations[1]

	Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial	Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial
Vial colour	Purple Vial Cap 	Orange Vial Cap 
Age range	12 years of age and older	5 to <12 years of age
Dilution required	Yes	Yes
Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)	1.8 mL per vial	1.3 mL per vial
Number of doses per vial (after dilution)	6 doses per vial	10 doses per vial
Dose amount	30 micrograms per dose	10 micrograms per dose
Dose volume	0.3 mL per dose	0.2 mL per dose
Storage conditions		
ULT freezer storage time (-90 to -60°C)	Until expiry date printed on vial label	6 months after manufacturing date printed on vial label
Freezer storage time (-25 to -15°C)	2 weeks	Do not store at -25 to -15°C
Refrigerated storage time (2 to 8°C)	1 month	10 weeks
Room temperature storage time (8 to 25°C)	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture
After first puncture (2 to 25°C)	Discard after 6 hours	Discard after 12 hours†
Expiry date	Date printed on vial label ‡	6 months after manufacturing date printed on vial label

ULT: Ultra-low temperature

Adapted from the COMIRNATY Product Monograph.[1]

†Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in the Product Monograph and here supersedes the number of hours printed on vial labels and cartons.

‡As a reminder, vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as all approved storage conditions have been maintained.

How to counsel parents and have conversations about the COVID-19 vaccine

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- **Be open, non-judgmental and willing to listen.**
- **Take the time to understand their concerns and acknowledge them.** Often, there is one key concern or piece of misinformation that is causing vaccine hesitancy. By finding out what this is, we can better address it.
- **Direct them to reliable, evidence-based resources** where they can learn more about the COVID-19 vaccine for children. Some of these resources are shared in the next few slides.
- **Let them know more than 2 million doses of the COVID-19 vaccine have been administered to children in the U.S.** – and second doses are beginning soon – so we expect to have plenty of real-life data that will teach us more about the COVID-19 vaccine's safety and effectiveness.
- **Be patient.** Some parents may need to have multiple conversations with you and other medical experts before they feel confident making a decision about vaccination. Let them know you are here for them if they have more questions or want to talk.

Where to get the COVID-19 vaccine for children aged 5 to 11 in East Toronto

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- **Book a first dose appointment for a child aged 5-11:**
  - On the Michael Garron Hospital website (tehn.ca/VaccineAppointment) or by calling 437-537-5131.
  - On the provincial booking system online (covid-19.ontario.ca/book-vaccine/) or by calling 1-833-943-3900.
  - Use the pharmacy locator to find a pharmacy near you offering the vaccine.
  - Contact your family doctor or paediatrician to confirm if they are offering the vaccine.

- **We are also operating mobile clinics at schools in priority neighbourhoods in East Toronto.**
  - If you have a child at one of these schools, information about the clinic will be shared with you.
  - Vaccines are available to children by walk-in at these clinics.

Helpful vaccine resources for families

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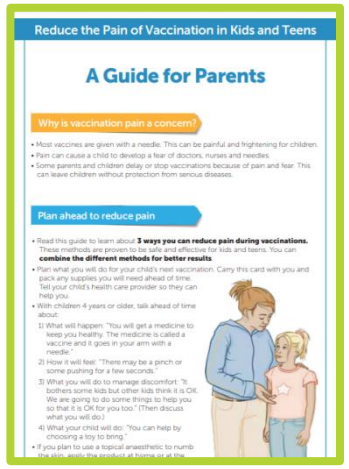
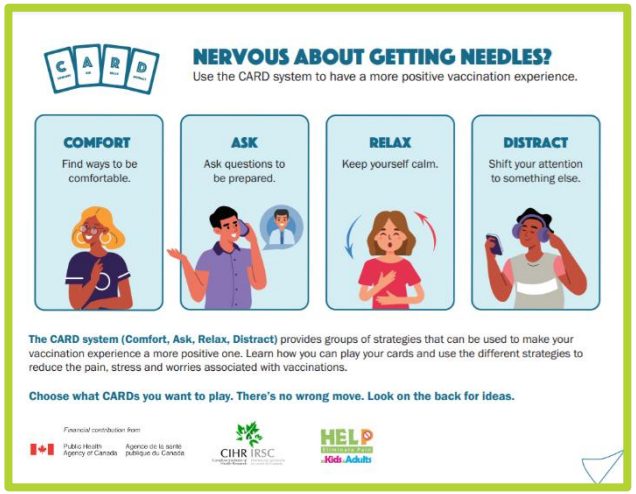


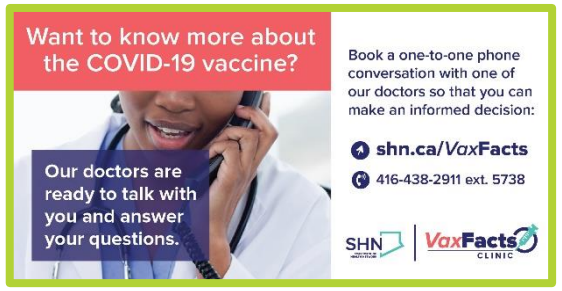
[A Guide for Parents: How to Reduce the Pain of Vaccination in Kids and Teens]



[AboutKidsHealth: Strategies to Help Cope Before and During Vaccination]

[Needles Don't Have to Hurt: How to Help Your Child Have a Comfortable Vaccination Experience]

[COVID-19 Vaccine Consult Service for Children, Youth and Their Families – SickKids]



[VaxFacts Clinic Hotline – Scarborough Health Network]

More helpful vaccine resources for families

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- MGH's Community Q&A on the COVID-19 Vaccine for Children Aged 5-11 (Michael Garron Hospital)
- Fact Sheet for COVID-19 Vaccines for Children and Youth (Ministry of Health)
- FAQ About the COVID-19 mRNA Vaccines for Children (University of Waterloo)
- Myocarditis and Pericarditis After COVID-19 Vaccines (University of Waterloo)
- COVID-19: Information About Children and Vaccines (Toronto Public Health)
- FAQ About the Paediatric Pfizer COVID-19 Vaccine (Ministry of Health)
- COVID-19 Vaccine Information for Children Aged 5-11 in Ontario (Kids Health First)
- Max the Vax: Information About the COVID-19 Vaccine for Kids and Caregivers (Ontario Association of Children's Aid Societies)
- How to Prepare Your Child for Their COVID-19 Vaccine (East Toronto Health Partners)
- Tips for Easing Children's Fears About Getting the COVID-19 Vaccine (Toronto Public Health)
- Flyer for Promoting COVID-19 Vaccine Clinic for Children Aged 5-11 at Thorncliffe Park Community Hub (East Toronto Health Partners)
- Comfort Positions for Vaccinating Children (East Toronto Health Partners)
- COVID-19 Vaccine Consult Service (SickKids)
- How to Call the Province to Book a Vaccine Appointment – Available in Multiple Languages (Ministry of Health)

Where to get a child-friendly COVID-19 test and other supports in East Toronto

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COVID-19 Outreach Centres

- Offer COVID-19 testing, vaccines and other supports by walk-in
- Locations in Flemingdon Park, Taylor-Massey, Warden Woods, Leslieville, Danforth Village and more
- Administer **child-friendly oral-nasal swab**, a less invasive testing method than the NP swab commonly used for COVID-19 tests
- **Pick up and drop off take-home test kits from MGH**
- Learn more: tehn.ca/CovidOutreachCentres

MGH COVID-19 Assessment Centre

- Offers COVID-19 testing and assessments by walk-in and appointment
- At Michael Garron Hospital
- Administers **child-friendly oral-nasal swab**, a less invasive testing method than the NP swab commonly used for COVID-19 tests
- **Pick up and drop off take-home test kits from MGH**
- Learn more: tehn.ca/AssessmentCentre

MGH Emergency Department's Child and Youth Emergency Zone

- Offers a family-friendly space for urgent and acute care if your child is experiencing a medical emergency and your paediatrician or family doctor is not available
- At Michael Garron Hospital
- Learn more: tehn.ca/EmergencyDepartment

Questions?

THANK YOU

Recording of today's session and list of resources will be shared shortly.