19 TO ZERO

UNITED AGAINST COVID-19

COVID-19 VACCINATION IN CHILDREN

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About 19 To Zero

19 To Zero is a multisectoral coalition of health professionals and community members working to shift public perceptions around COVID-19 behaviours and vaccination based primarily at the University of Calgary but national in scope. **Please visit 19ToZero.ca for more info.**

This presentations was prepared by **19 To Zero** in conjunction with **Toronto's Women's College Hospital, University of Toronto Temerty Faculty of Medicine, and Health Commons Solutions Lab**

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19 TO ZERO
UNITED AGAINST COVID-19

HEALTH COMMONS SOLUTIONS LAB

Person putting on hand sanitizer

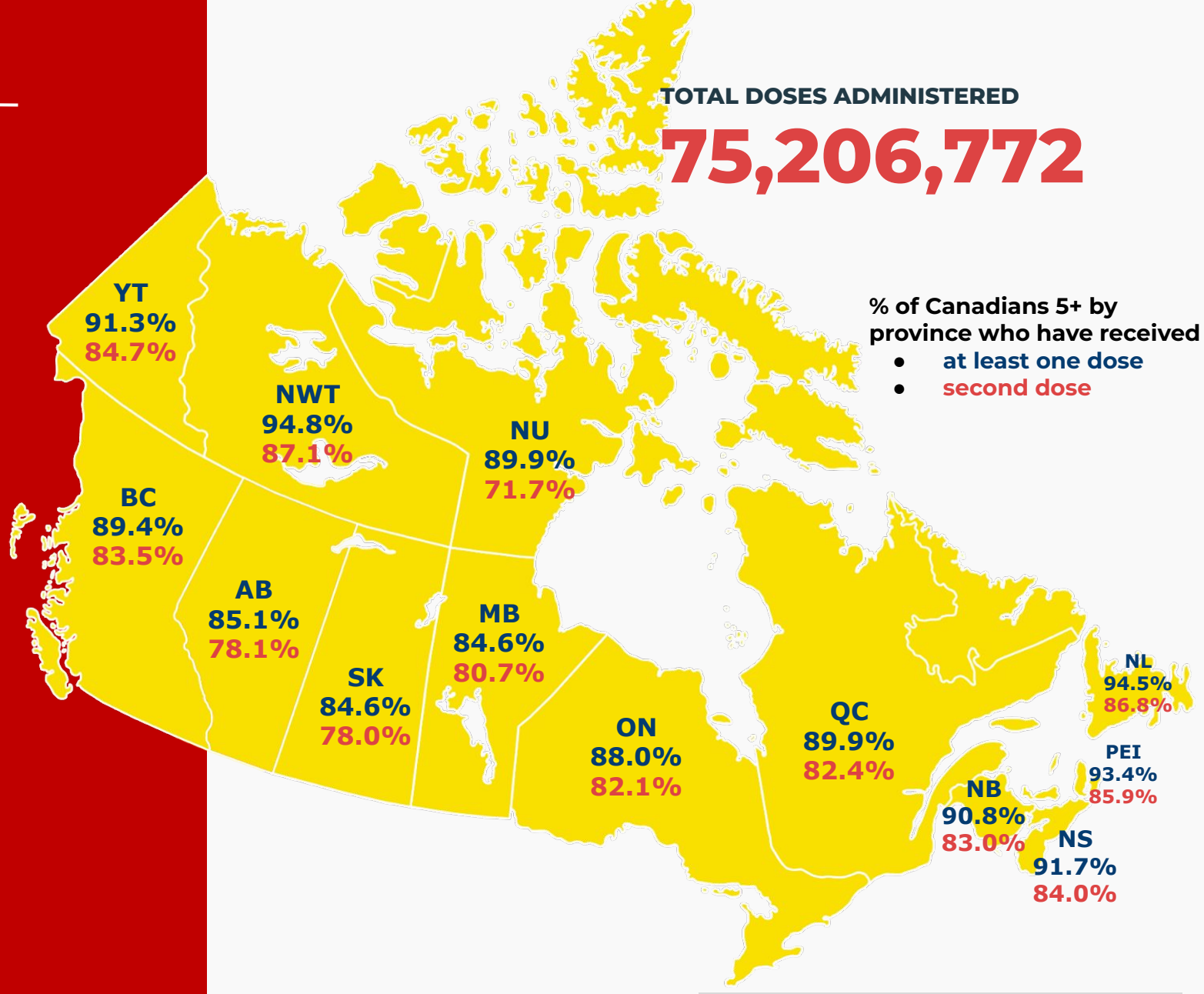
Overview of presentation

1. COVID-19 epidemiology and vaccine uptake in Canada
2. Vaccine uptake preferences among children
3. COVID-19 vaccination in children - the latest science
4. Considerations for vulnerable populations
5. Mitigating pain and anxiety during vaccination

COVID-19 Epidemiology & Vaccine Update

AS OF January 21, 2022:

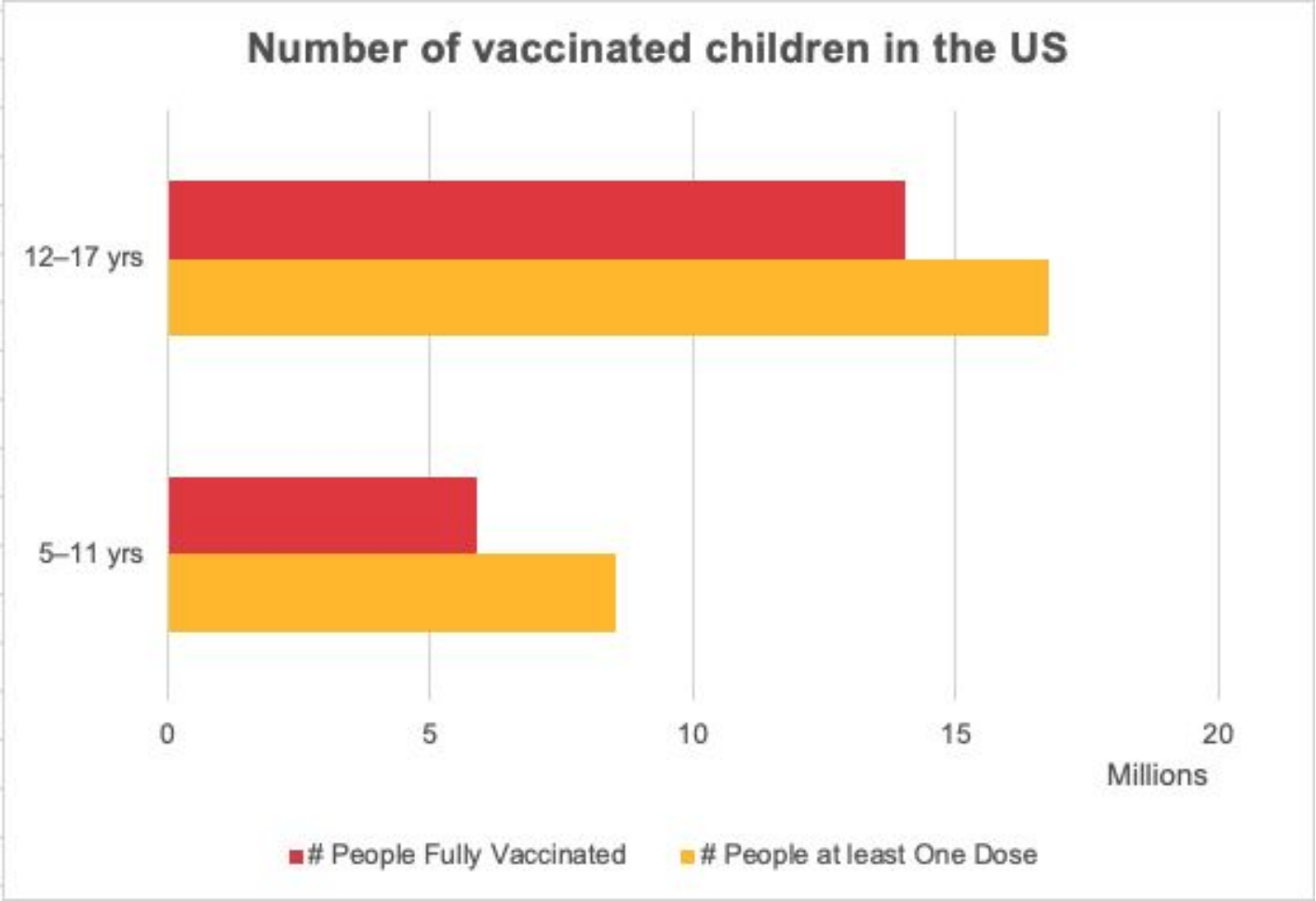
Over 75 million doses have been administered in Canada



Map of Canada

% OF ELIGIBLE POPULATION (5+):
87.31% at least one dose; 81.85% fully vaccinated

In the US >8.5 million children 5-11y have received at least one dose of the Pfizer vaccine and 5.8 million have been fully vaccinated



CDC Covid data tracker vaccination demographic. January 27, 2022

In Alberta, for the 5-11 yo age group

- In Alberta, 42.5% of 5-11 kids (total population 391,430) have been vaccinated with at least 1 dose, 6.1% with 2 doses

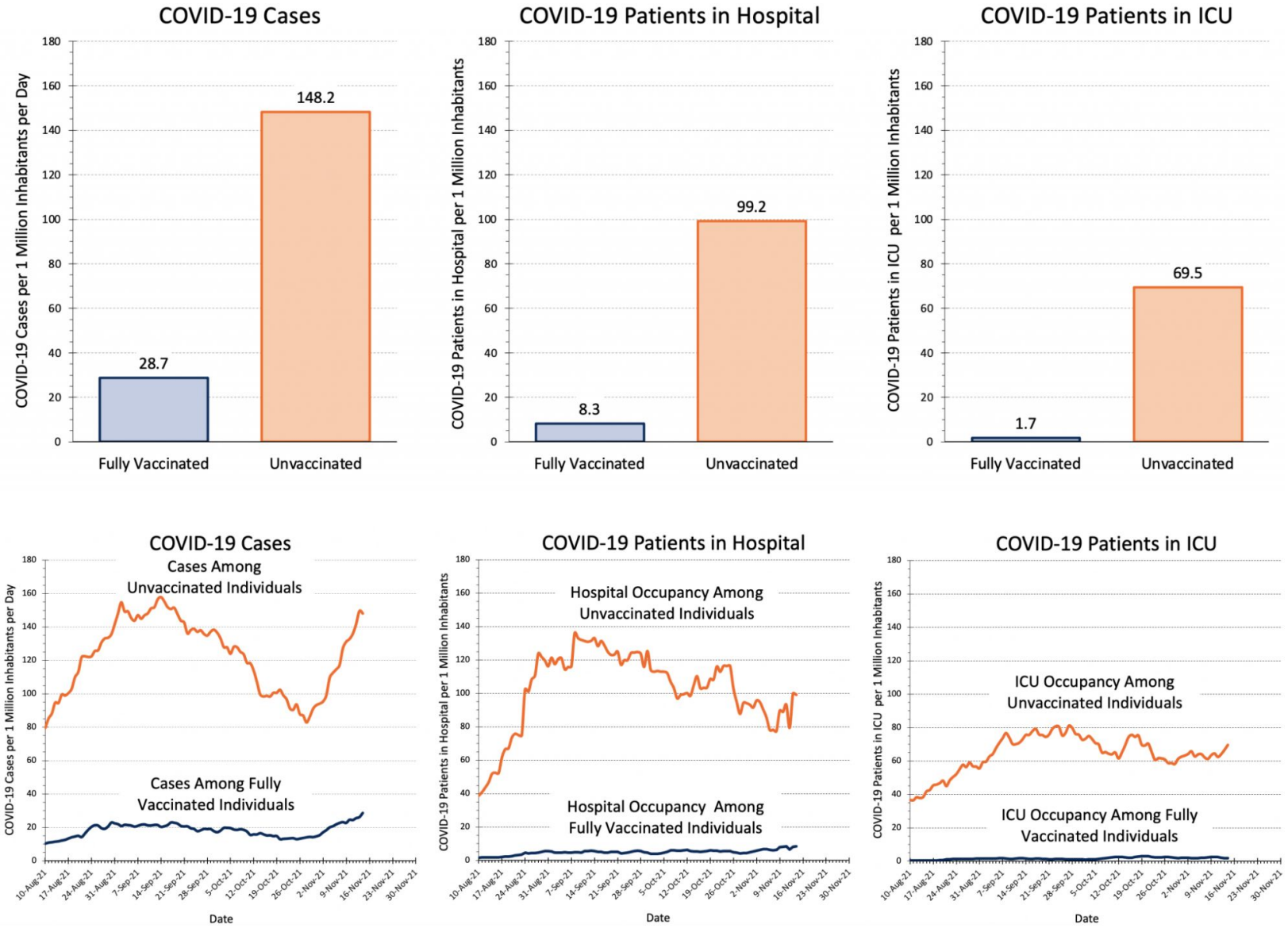
Vaccination rates in Canada are high across most age ranges, except in the 11 and under age range

Table 2. Cumulative number and percent of people in Canada who have received a COVID-19 vaccine by age group and vaccination status, January 15, 2022

Age group (years)	At least 1 dose	Partially vaccinated	Fully vaccinated	Fully vaccinated with an additional dose
0 to 4	0.02% (297)	0.02% (297)	0% (0)	0% (0)
5 to 11	51.07% (1,470,004)	46.00% (1,324,261)	5.06% (145,743)	<0.01% (18)
12 to 17	87.54% (2,160,707)	4.64% (114,476)	82.90% (2,046,231)	0.92% (16,930)
18 to 29	88.04% (5,227,430)	4.36% (258,977)	83.68% (4,968,453)	20.82% (938,465)
30 to 39	87.63% (4,700,757)	3.43% (184,226)	84.19% (4,516,531)	26.32% (1,067,016)
40 to 49	89.95% (4,401,743)	2.50% (122,453)	87.45% (4,279,290)	33.59% (1,204,290)
50 to 59	90.62% (4,649,033)	2.02% (103,547)	88.61% (4,545,486)	44.38% (1,662,604)
60 to 69	94.25% (4,562,419)	1.66% (80,335)	92.59% (4,482,084)	58.86% (2,025,990)
70 to 79	≥95% (3,029,285)	1.35% (42,326)	≥95% (2,986,959)	72.37% (1,588,467)
80 and older	≥95% (1,681,657)	1.77% (30,383)	≥95% (1,651,274)	75.22% (915,977)
Not reported	n/a (0)	n/a (0)	n/a (0)	n/a (0)
Unknown	n/a (4,040)	n/a (2,006)	n/a (2,034)	n/a (48)

https://health-infobase.canada.ca/covid-19/vaccination-coverage/ accessed Jan 21, 2022

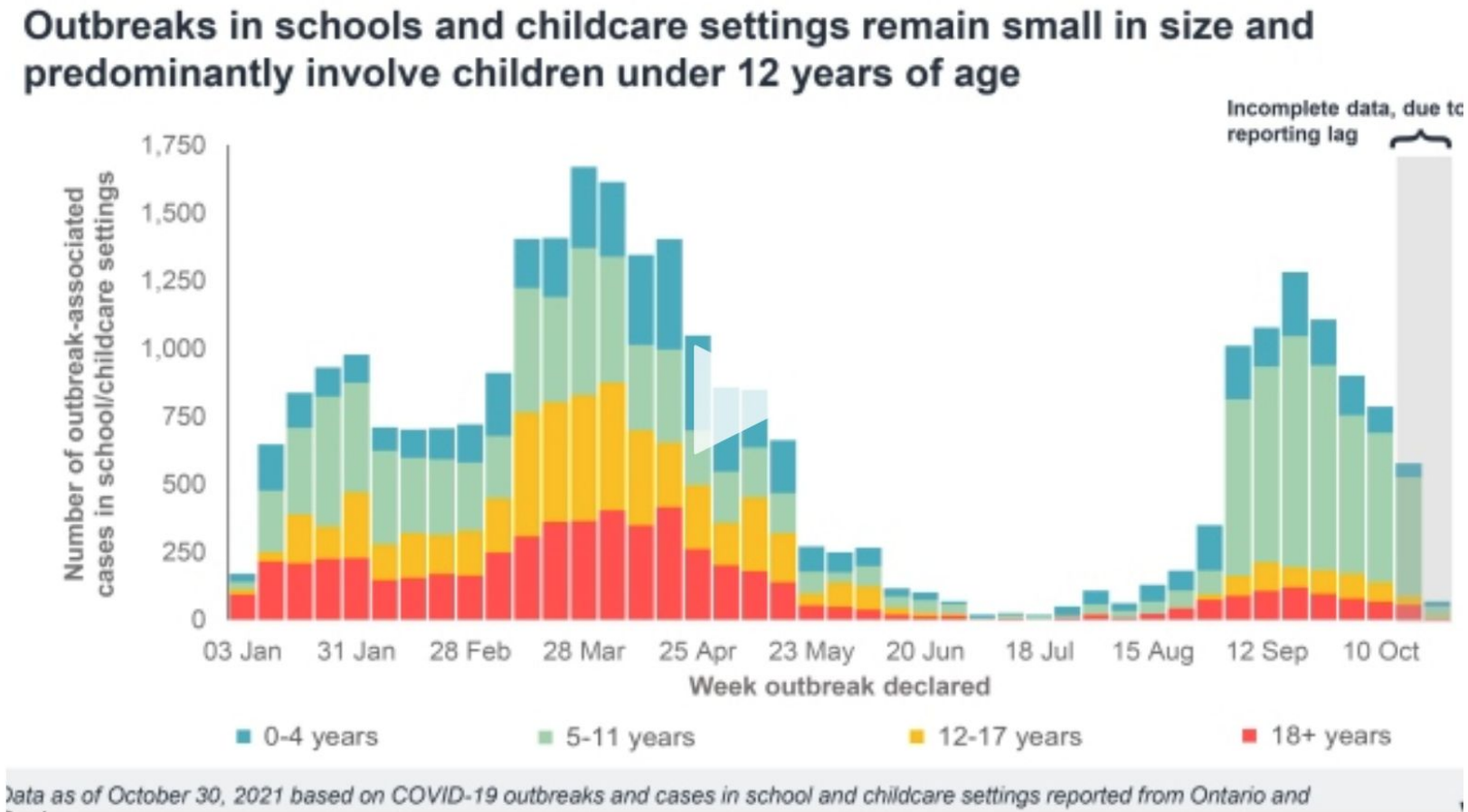
Risks of infection, hospitalization, and ICU are significantly higher among the unvaccinated



Children under 12 now account for highest number of new COVID-19 infections in Canada: PHAC

Hannah Jackson CTVNews.ca Writer
@hannahkeiko | Contact

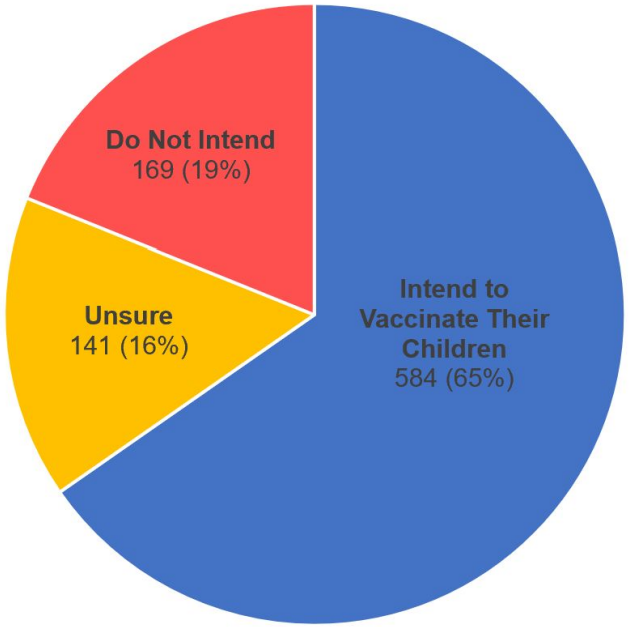
Published Friday, November 5, 2021 9:21AM EDT
Last Updated Friday, November 5, 2021 12:08PM ED



Vaccine Uptake Preferences for Children

About ⅔ of Canadian parents intend to vaccinate their children once a COVID-19 vaccine becomes available:

"Suppose one or more of the COVID-19 vaccines available for individuals 12 and older becomes available to children under 12. Would you have your child vaccinated?" n=594



Source: 19 To Zero National Survey, October 2021

Of those unwilling to vaccinate their children, the following reasons were selected:	Number of Respondents (%)
Children do not need vaccines as they are low risk of severe consequences due to COVID-19	55 (32.7%)
Other safety risks	47 (28.0%)
Natural immunity from previous COVID-19 infection is sufficient protection for my child	20 (11.9%)
Myocarditis risks	16 (9.5%)
Fertility risks	13 (7.7%)
Other reasons	17 (10.1%)

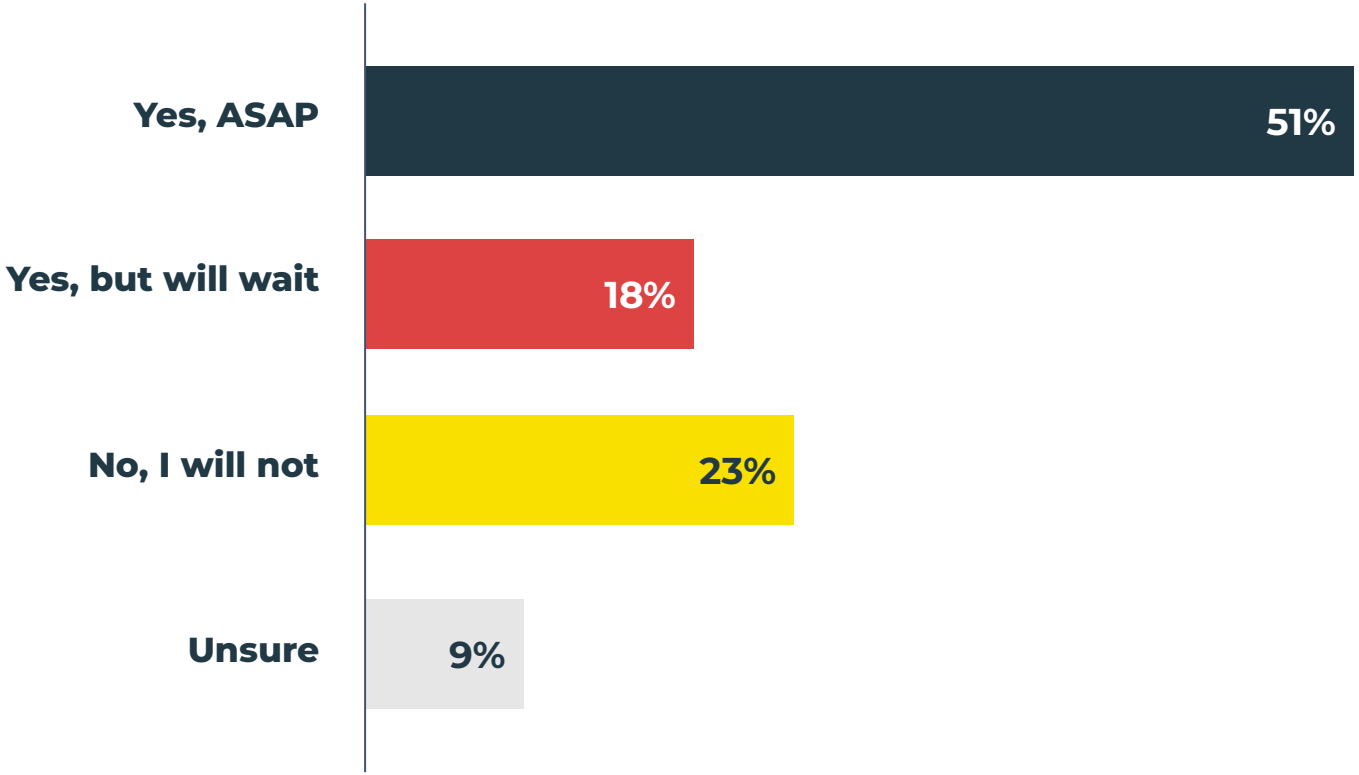
Among those unwilling to vaccine, concerns include:

- Safety - myocarditis, fertility, or other (45%)
- Lack of concern due to low risk of serious COVID-19 in children (33%)
- Natural immunity from prior infection (12%), and
- Other (10%)

Asked another way, only 50% of Canadians would immunize their children ASAP

If a COVID-19 vaccine become available to your child(ren) aged five to 11, will you get them vaccinated?

Among Canadian parents with children in this age range (n = 812)

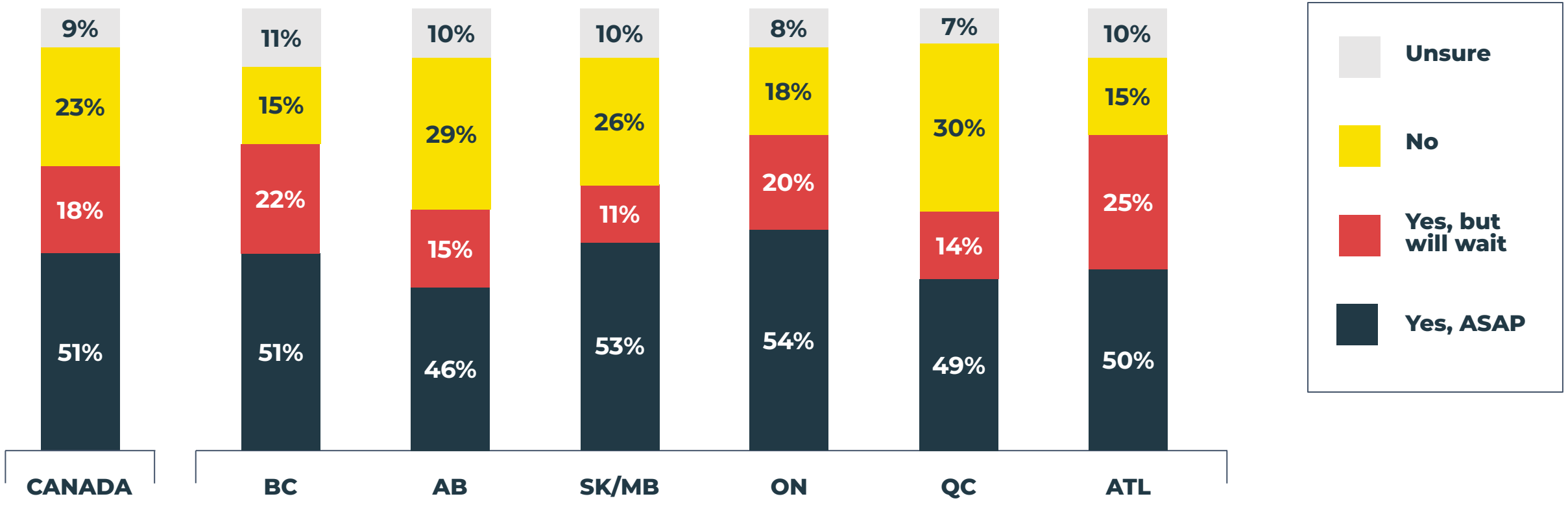


Source: Angus Reid Kids and COVID, Published online October 2021

Refusal to vaccinate is highest in Prairies and QC

If a COVID-19 vaccine become available to your child(ren) aged five to 11, will you get them vaccinated?

Among Canadian parents with children in this age range (n = 812)

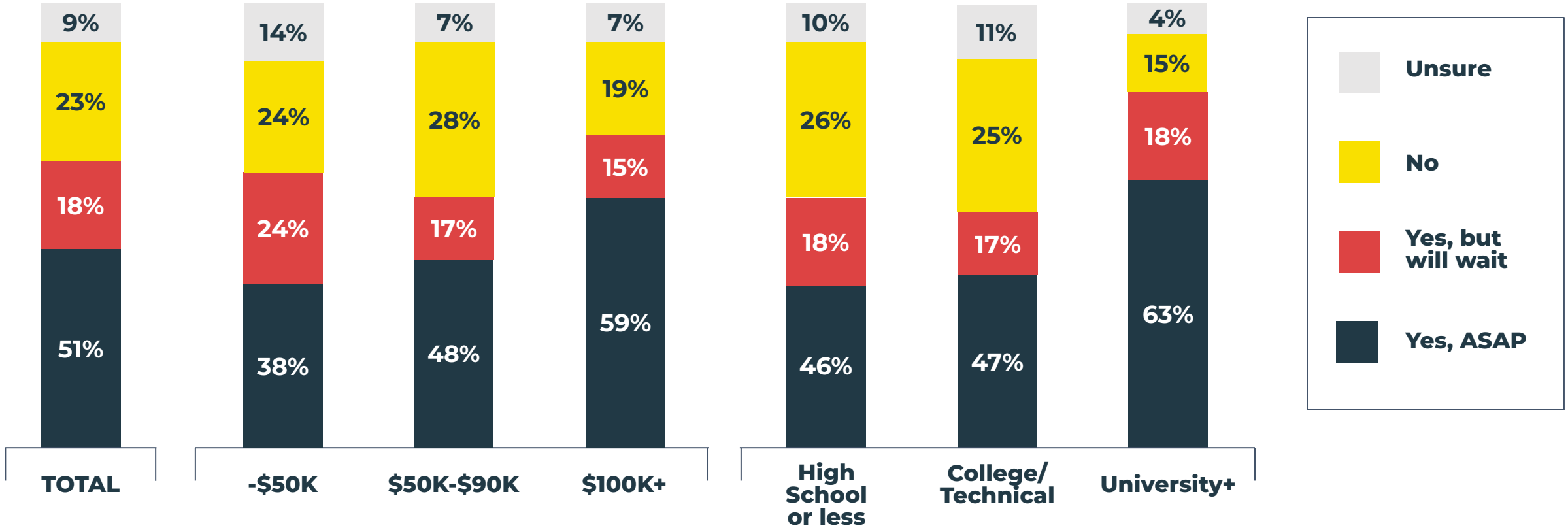


Source: Angus Reid Kids and COVID, Published online October 2021

Willingness to vaccinate children in Canada

If a COVID-19 vaccine become available to your child(ren) aged five to 11, will you get them vaccinated?

Among Canadian parents with children in this age range (n = 812)



Source: Angus Reid Kids and COVID, Published online October 2021

Vaccine Hesitant Parents

- Are more concerned about vaccine safety
- Feel their children are not at high risk of COVID-19 complications
- May feel their kids have already had COVID-19 and have natural immunity
- Don’t trust governments and health agencies
- Have had a negative interaction with healthcare providers in the past
- Have had a negative experience with vaccines in the past

COVID-19 Vaccination in Children - the Latest Science

Why do children need to be immunized?

To protect their health: Some children can become very sick and develop complications or long-lasting symptoms

To prevent virus transmission: Children can transmit the virus to family members and friends even if they are asymptomatic.

To stay in school and continue with other in-person activities: Vaccination reduces the likelihood of school closures and closure of other in-person activities critical to children's' well-being, mental health, and education and development

To protect the broader community: Each child or adult infected provides a chance for the virus to mutate and new variants to develop.

COVID-19 can be severe in children

- Kids make up about 20% of COVID-19 cases in most jurisdictions in Canada and USA
  - In USA, more than 3.78M kids have been infected, over 500 kids have died

- **It's not the flu**: COVID-19 is currently in the **top 10 causes of death for children**
  - In Canada and USA, children account for 2% of hospitalizations
  - About 2000 Canadian children have ended up in hospital so far
  - Of those hospitalized, ⅓ had no pre-existing conditions
  - Long-COVID affects 2% of kids

- Did you know: over 99% of Polio cases do not lead to paralysis.

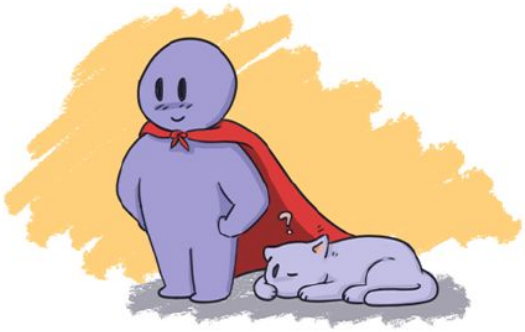
NACI rapid response: Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5-11 years of age. November 19, 2021
https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(21)00198-X/fulltext

FocusedCovid Communication

UNIVERSITY OF WATERLOO | SCHOOL OF PHARMACY

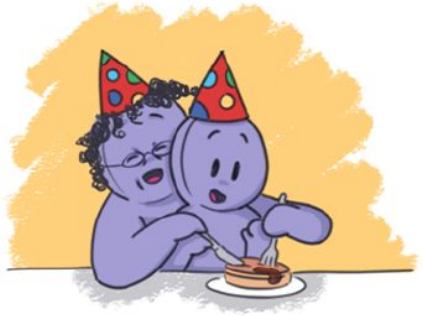
The Benefits of Vaccinating Children

Against Covid-19



Reduced risk of illness

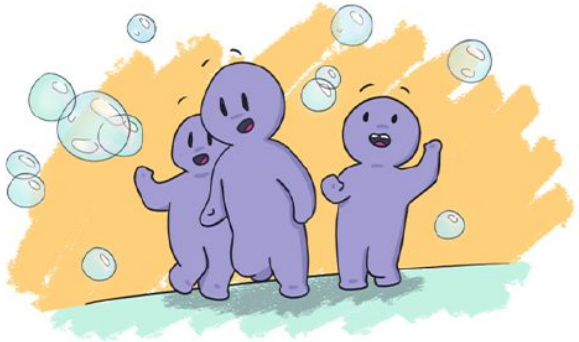
Not needing to miss school due to a case in the classroom



Reduced risk of spread to friends and family with weaker immune systems

Allowing all kids to return to clubs like choir

Allowing all kids to return to fun activities like hockey



Allow all kids to return to being kids again

Let's get all kids back to being kids.

The risks of Covid-19 may be even higher for disabled kids and those with weaker immune systems.
We're not back to normal until everyone is back to normal. Speak to your healthcare provider for advice.

COVID-19 vaccination in children aged 5-11

The **Pfizer BioNTech COVID-19 vaccine has been authorized by Health Canada** for kids 5-11y as a two-dose regimen of 10µg administered 3 weeks apart

Health Canada Statement. Health Canada authorizes use of Comirnaty (the Pfizer-BioNTech COVID-19 vaccine) in children 5 to 11 years of age. (November 19th, 2021)

Pfizer vaccine in children 5-11 years of age - Efficacy

Study Characteristics

- Randomized placebo-controlled Phase 2/3 study
- 4518 kids aged 5-11 (3018 vaccine; 1500 placebo), from Mar - Oct 2021 (when Delta present)
- 2 doses ***10µg*** each, 3 wks apart

Efficacy

- **Vaccine effectiveness was 90.7%** (against confirmed symptomatic COVID-19, assessed starting 7 days after dose 2)

Potential Impact

90% vaccine efficacy →
prevention of ~33600 cases and ~170 hospitalizations over 120 days, per million fully vaccinated children

Vaccines and Related Biological Products Advisory Committee Meeting Document. (2021 Oct 26) FDA.
Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age | NEJM(November 2021)

Pfizer vaccine in children 5-11 years of age - Safety

Side Effects

- Consistent with older children
- Transient, mild side effects 1-2 days after dose with short resolution
- Most common: injection site pain
- No severe adverse effects related to the vaccine (some unrelated were observed, e.g., swallowing a penny!)

Vaccines and Related Biological Products Advisory Committee Meeting Document. (2021 Oct 26) FDA.
Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age | NEJM(November 2021)

Pfizer vaccine in children 5-11 years of age - Myocarditis

Myocarditis Risk?

- **<u>No cases of myocarditis/pericarditis</u>** observed at 3 months post-dose 2 (small sample size)
  - Multiple long-term, five-year safety studies are planned

- Myocarditis rate is 21 per million after 2nd dose for ages 12-15 years (less than 1 in 10,000)
  - **Lower expected rate in 5 to 11 years due to lower dose of vaccine**

Vaccines and Related Biological Products Advisory Committee Meeting Document. (2021 Oct 26) FDA.
Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age | NEJM(November 2021)

Vaccination and protection against multisystem inflammatory syndrome in children (MIS-C)

- In the US, 2 doses of the Pfizer vaccine was **91% effective in protecting against MIS-C** among 102 12-18 year olds hospitalized during July-December 2021
- 95% of adolescents hospitalized who were diagnosed with MIS-C were unvaccinated
- Of the few vaccinated MIS-C patients (5 out of 102), none required life support
- Vaccination of children and adolescents is highly protective against MIS-C and COVID-19

Zambrano, L. D. et al. MMWR Effectiveness of BNT162b2 (Pfizer-BioNTech) mRNA Vaccination Against Multisystem Inflammatory Syndrome in Children Among Persons Aged 12–18 Years — United States, July–December 2021
https://www.cdc.gov/mmwr/volumes/71/wr/mm7102e1.htm

NACI recommends two 10µg doses of the Pfizer vaccine SHOULD be offered to children 5-11y

- ≥ 8 weeks between doses is recommended as:
  - longer intervals result in higher effectiveness that may last longer
  - may be associated with lower risk of myocarditis
- Children 11 years old who receive the 10µg dose but turn 12 before their 2nd dose may receive a 30µg dose
- Two doses of vaccine may be offered to children who have had COVID-19
- Children who had MIS-C should postpone vaccination until recovery or after 90 days since diagnosis
- The Pfizer vaccine should be given at least 14 days before or after another vaccine when feasible

National Advisory Committee on Immunization (NACI) rapid response: Recommendation on the use of the Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5-11 years of age.January 25, 2022

General Side Effects from mRNA vaccines

- Immunization related stress responses such as fainting, fatigue and nausea
  - Treated by managing stress using pain and anxiety reducing strategies for children
- Myocarditis and Pericarditis <1 per 10,000 cases
  - More common after the second dose
  - Symptom onset between 1-7 days after vaccination
  - Mainly adolescent males
  - MAJORITY of cases were mild illness that responded well to non steroidal anti-inflammatory medications (such as ibuprofen) and rest

- **Benefits of COVID-19 vaccinations outweigh the risks of vaccine-caused myocarditis**

Wong, P McCrindle B, et cal. Clinical guidance for youth with myocarditis and pericarditis following mRNA COVID-19 vaccination. Canadian Paediatric Society Practice Point Sept 10 2021. https://www.cps.ca/en/documents/position/clinical-guidance-for-youth-with-myocarditis-and-pericarditis
Moore, D. COVID-19 Vaccine for Children. Canadian Paediatric Society. Position Statement. July 2021. https://www.cps.ca/en/documents/position/covid-19-vaccine-for-children

Safety of the Pfizer vaccine in children 5-11y in the US

- As of December 19th, 2021, **8.7 million doses** have been administered to children 5-11 years of age
- Side effects were **mild and brief**, most commonly after dose 2. The most common reported events were:
  - Pain at injection site
  - Fatigue
  - Headache
- Few myocarditis cases have been reported (11 out of 8.7 million doses administered)
  - 7 children recovered and 4 were recovering at the time of the report

Hause, A. M. et al. MMWR COVID-19 Vaccine Safety in hildrenAged 5-11 Years - United States, November 3-December 19, 2021
https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm?s_cid=mm705152a1_w

VAERS Reporting Rate for Myocarditis among males after mRNA COVID-19 vaccine

169,740,953 doses of mRNA vaccine administered to males as of Oct 6, 2021

Highest rates of myocarditis are among male adolescents 16-17y

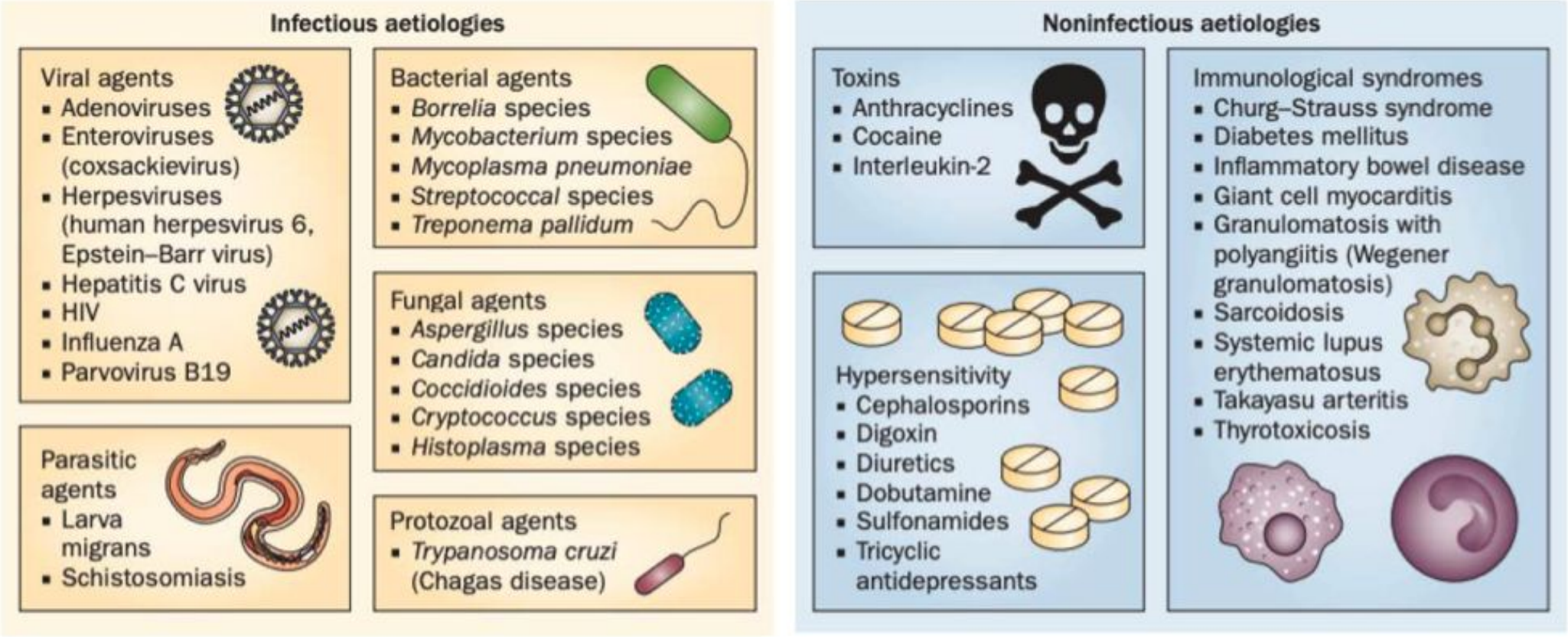
Myocarditis Rate per 1 million doses (n=797)

	Pfizer		Moderna	
	(Males)		(Males)	
Ages	Dose 1	Dose 2	Dose 1	Dose 2
12-15	4.2	39.9		
16-17	5.7	69.1		
18-24	2.3	36.8	6.1	38.5
25-29	1.3	10.8	3.4	17.2
30-39	0.5	5.2	2.3	6.7
40-49	0.3	2.0	0.2	2.9
50-64	0.2	0.3	0.5	0.6
65+	0.2	0.1	0.1	0.3

Reporting rates exceed background incidence

Vaccines and Related Biological Products Advisory Committee Meeting. mRNA COVID-19 Vaccine-Associated Myocarditis (2021 Oct 26) FDA.

Causes of myocarditis include viral infection as the most common cause

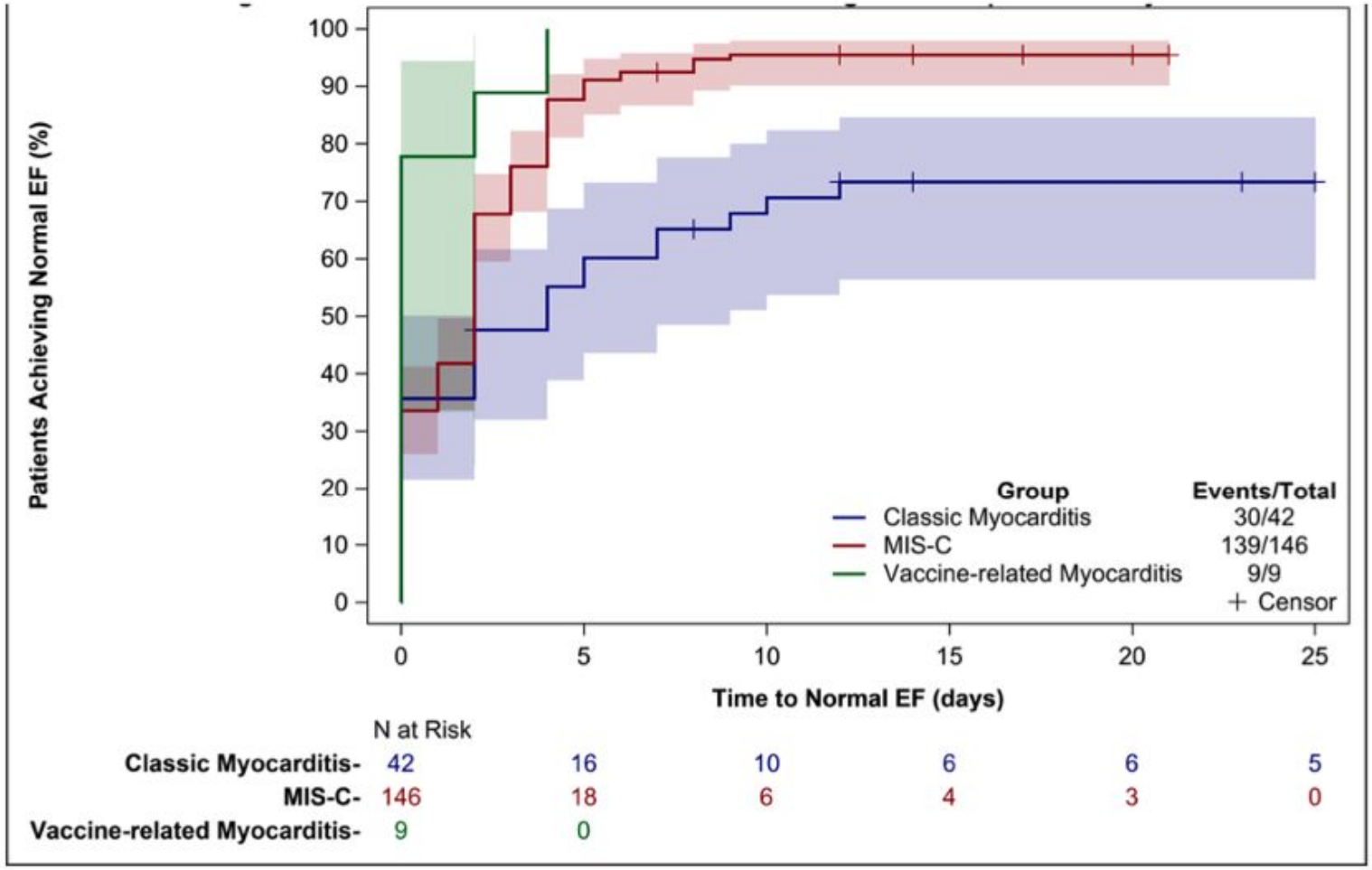


Vaccines and Related Biological Products Advisory Committee Meeting. mRNA COVID-19 Vaccine-Associated Myocarditis (2021 Oct 26) FDA.
Pollack, A. et al. Viral myocarditis—diagnosis, treatment options, and current controversies. Nat Rev Cardiol (2015).

Not all myocarditis is the same

- A retrospective cohort study (preprint) compared patients <21y with classic pre-pandemic viral myocarditis (n=43), MIS-C myocarditis (n=149) and COVID-19 vaccine-related myocarditis (n=9)

- Patients with vaccine-related myocarditis had **prompt resolution of symptoms and improvement in cardiac function**



Vaccines and Related Biological Products Advisory Committee Meeting. mRNA COVID-19 Vaccine-Associated Myocarditis (2021 Oct 26) FDA.
Patel, T. et al. Comparison of MIS-C Related Myocarditis, Classic Viral Myocarditis, and COVID-19 Vaccine related Myocarditis in Children. medRxiv 2021

ACIP: benefits outweigh risks for vaccination and recommends the vaccine to children 5-11y

COVID-19 in children is a major public health problem

- 1.9 million COVID-19 cases & 8,300 hospitalizations among U.S. children 5–11y as of Oct 10, 2021
- 5,217 total cases of MIS-C (44% in 5-11y)
- Children 5–11y represent a growing proportion of new COVID-19 cases - 10.6% of infections week of Oct 10
- COVID-19 ranks as the 8th leading cause of death in 5-11y age group
- Delta-wave surges of pediatric COVID-19 hospitalizations occurred even with a significant proportion of children previously infected

Woodworth KR et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021. MMWR Morb Mortal Wkly Rep 2021

ACIP: benefits outweigh risks for vaccination and recommends the vaccine to children 5-11y

Risk of Myocarditis

- The observed myocarditis risk is highest in males aged 12–29y. No cases of myocarditis were reported in the Pfizer trial in 5-11y.
- The baseline risk for myocarditis is much higher in 12–17y than in 5–11y. Myocarditis in adolescents might not predict risk for myocarditis in younger children.

Vaccination is important to protect children against COVID-19, even in those previously infected, and to reduce community transmission.

Woodworth KR et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021. MMWR Morb Mortal Wkly Rep 2021

More on myocarditis

Israel: 2.13 cases per 100,000 persons; the highest incidence was among male patients between the ages of 16 and 29 years.

Israel: myocarditis occurred in approximately 1 of 26,000 men and 1 of 218,000 women after the second vaccine dose.

Canada: by November 19 2021, there were 1,329 cases of myocarditis and/or pericarditis with reports submitted to the Public Health Agency of Canada (PHAC) and Health Canada from over 59 million administered doses of COVID-19 vaccines Rate of 22.2 in 1 M

Mevorach et al. DOI: 10.1056/NEJMoa2109730. Oct 6, 2021
Witberg et al. DOI: 10.1056/NEJMoa2110737. Oct 6, 2021

Risk of Myocarditis: COVID-19 vs vaccines

- MMWR report (CDC). Hospital records from COVID-19 patients (1.5 million) vs non COVID-19 patients (35 million) Mar2020-Jan2021
- The risk for myocarditis among patients with COVID-19 was nearly **16 times higher** (0.146% for COVID-19 patients vs 0.009% in non-COVID-19 patients)
- The risk among COVID-19 patients was most pronounced in those **<16 years old who had a 37-fold increased risk of myocarditis**
- The risk of myocarditis is far higher after COVID-19 compared to vaccination
    - Compared to a recent Israeli study. **Risk ratio 3.2** after vaccination **vs. 18.3** after SARS-CoV-2 infection
    - In line with current recommendations stating **the benefits of COVID-19 vaccinations outweigh the risks of vaccine-caused myocarditis** especially when community transmission is high

Boehmer TK et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data - United States, March 2020-January 2021. MMWR Morb Mortal Wkly Rep. 2021; 10.15585/mmwr.mm7035e5.

Barda N, Dagan N, Ben-Shlomo Y, et al. Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *N Engl J Med*. 2021;10.1056/NEJMoa2110475.

Disease burden and vaccine safety in children in Israel

A study from Israel highlighted many benefits of vaccination over harms:

High incidence of infection in children

- In the 5-11 age group: 43% of children and adolescents in Israel
- By Dec 2021, children <18 years comprised more than 50% of confirmed cases

COVID morbidity and mortality

- Among hospitalized children, 42% had moderate to severe degree of illness
  - 61% of these children were previously healthy
- In the US, 1/3rd of hospitalized aged 5-11 were in the ICU
- Multisystemic inflammatory syndrome in children (MIS-C) is characterized by prolonged fever, hypotension, GI symptoms, myocarditis, rish, and other inflammation
  - Children aged 5-11 comprised 44% of MIS-C cases, and the majority of children (56- 80%) admitted to ICU

Stein M et al. The Burden of COVID-19 in Children and Its Prevention by Vaccination: A Joint Statement of the Israeli Pediatric Association and the Israeli Society for Pediatric Infectious Diseases. 6 Jan 2022.

Disease burden and vaccine safety in children in Israel

COVID long-term complications:

- Increases risk of myocarditis by 30-fold in children aged <16
  - COVID-associated myocarditis occurs at rate of 1:1600 vs. vaccine-associated myocarditis at rate of 1:6000 -> **vaccination still confers net protective effect**
- School closures and isolation contribute to declining mental health, academic abilities, and social development

Stein M et al. The Burden of COVID-19 in Children and Its Prevention by Vaccination: A Joint Statement of the Israeli Pediatric Association and the Israeli Society for Pediatric Infectious Diseases. 6 Jan 2022.

Long COVID and benefits of vaccination

- "Long COVID" can occur in children, months following a positive test, involving features like fatigue, cough, and chest pain (incidence varies, reaching up to 30% depending on the study)
  - In Russia, 25% of children hospitalized experience long COVID after hospitalization
  - In the UK, three months after testing, children who tested positive had higher incidences of >3 symptoms (30% vs 16% in control group)
  - In Israel, 1.8-4.6% of children reported residual symptoms 6 months after acute illness

- COVID-19 vaccines are estimated to reduce the rate of long COVID.
  - In the UK, the risk of long COVID was reduced by 50% in vaccinated adults with breakthrough infection compared to unvaccinated infected adults

Stein M et al. The Burden of COVID-19 in Children and Its Prevention by Vaccination: A Joint Statement of the Israeli Pediatric Association and the Israeli Society for Pediatric Infectious Diseases. 6 Jan 2022.

Disease burden and vaccine safety in children in Israel

Vaccine efficacy:

- For children aged 5-11, the 10µg dose (Pfizer) with a 3 week interval between doses yielded similar antibody levels to those in people aged 16-25 years with the full 30µg dose
- 100% vaccine efficacy (Pfizer) in those aged 12-15, higher than 95% efficacy in the overall study group
- Among hospitalized adolescents, 97% were unvaccinated, and among adolescents admitted to ICU, none were vaccinated

Vaccine safety:

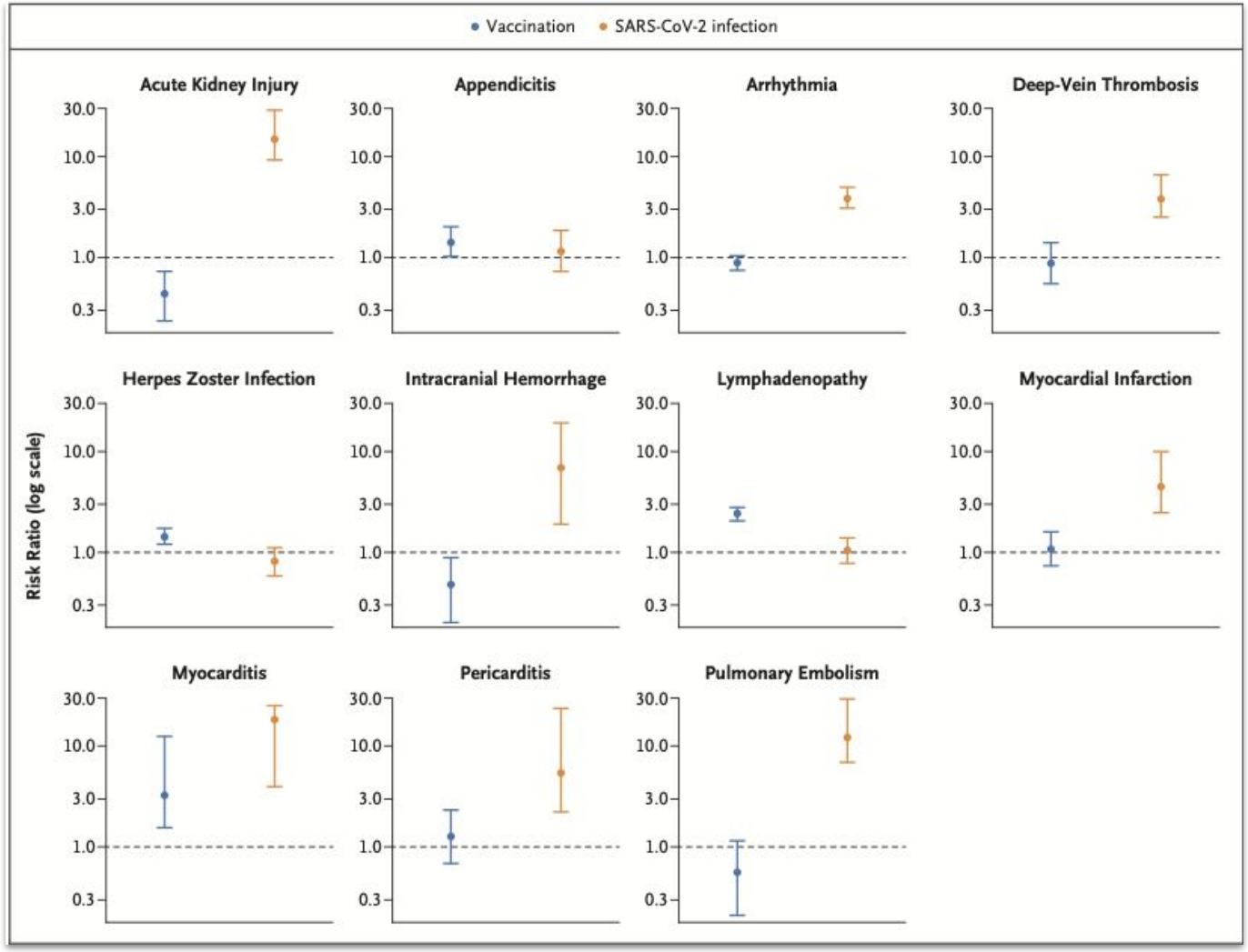
- Most common local side effect among children is pain at injection site; systemic effects are weakness, headache, chills - typically resolve within 2 days
- Rate and types of adverse and severe adverse events were similar to those among aged 16-25

Stein M et al. The Burden of COVID-19 in Children and Its Prevention by Vaccination: A Joint Statement of the Israeli Pediatric Association and the Israeli Society for Pediatric Infectious Diseases. 6 Jan 2022.

Adverse Events - *MUCH LOWER* for vaccination than for SARS-CoV-2 Infection (adult data)

SARS-CoV-2 infection was associated with a significantly increased risk of myocarditis, pericarditis, arrhythmia, deep-vein thrombosis, kidney injury, pulmonary embolism, myocardial infarction, intracranial hemorrhage, and thrombocytopenia compared to those who received the **COVID-19 vaccine**.

Choosing to gain immunity from infection rather than from vaccination is not a good bet



Barda N, Dagan N, Ben-Shlomo Y, et al. Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *N Engl J Med*. 2021;10.1056/NEJMoa2110475.

Vaccine dose timing in children

Shorter intervals between vaccine doses may be in children's best interest because of high risk of exposure to Omicron

- Canada's National Advisory Committee on Immunization (NACI) recommended 8-week interval for children aged 5-11
  - Recommendation is based on evidence from adults that longer gaps may improve immune response, reduce side-effects e.g. myocarditis

- US follows 3-week dose intervals for children, based on Pfizer's clinical programs evidence
  - Britain follows 12-week interval
- 3-week interval is approved by Health Canada

Advisory Committee Statement. National Advisory Committee on Immunization (NACI). Nov 19, 2021.
Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. CDC. Dec 21, 2021

Omicron and children: Increased hospitalizations in the US

- From Dec 25-Jan 1, a sharp increase was observed in children 0-4 years who are not eligible for vaccination

- Data include those admitted to hospitals for non-COVID reasons who then test positive - many "hospitalized with COVID, as opposed to because of COVID”

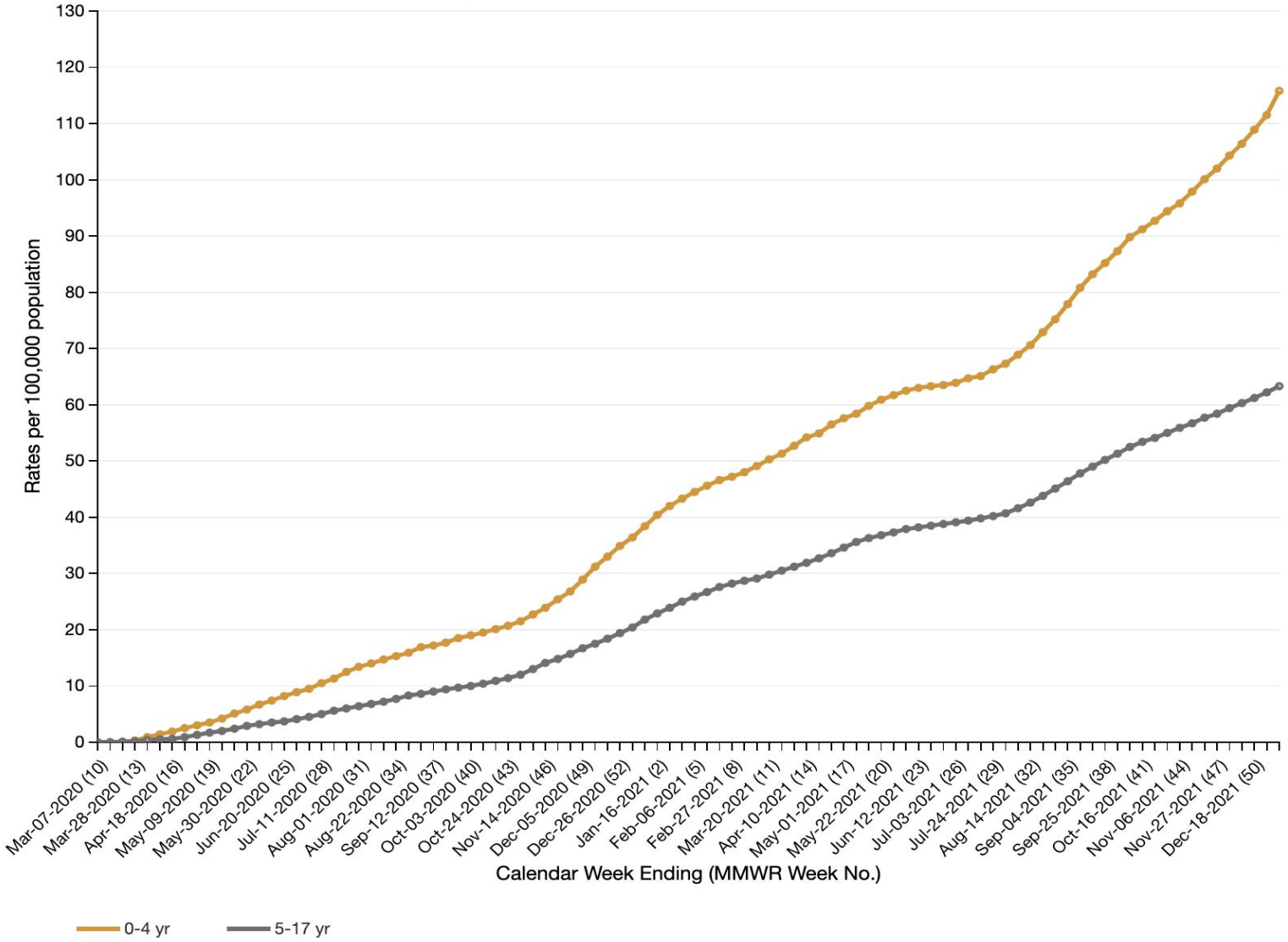
- Rate of hospitalized children aged 0-4 aged 5-11 years who were infected was 0.6 per 100,000, similar to past months

- CDC data show:
  - 0-4 years: +4.3 cases/100,000, compared to +2.6/100,000 the week before (Dec 25-Jan 1 vs. Dec 18-Dec 25) = **65% increase** in cases in one week, **double** the rate one month ago
  - 5-17 years: 1.1/100,000 vs 0.9/100,000 = **22% increase** in one week

CDC COVID Data Tracker. Accessed Jan 8, 2022

Rates of COVID-19 Associated Hospitalization in the US 0-17y population

Preliminary weekly rates as of Jan 1, 2022



CDC COVID-NET Hospitalization Network Rates of COVID-19 Associated Hospitalizations. Preliminary weekly rates as of Jan 1, 2022
https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network Accessed Jan 8, 2022

Pfizer vs Moderna in 12-29 years old

Recommendation for the 12-29y population:
To minimize the rare risk of myocarditis and/or pericarditis after receiving a COVID-19 mRNA vaccine, NACI now recommends:

- Pfizer-BioNTech Comirnaty mRNA vaccine (30 mcg) is preferred in adolescents and young adults 12 to 29 years of age over Moderna' Spikevax (100mcg)
- The second dose of a primary series should be provided 8 weeks after the first dose
- As a precaution, a booster dose of Pfizer-BioNTech Comirnaty may be preferred over a booster dose of Moderna Spikevax (i.e. 50 mcg dose) for adults 18 to 29 years of age who are recommended to receive a booster dose.

NACI: Updated recommendation on the use of authorized COVID-19 vaccines in individuals aged 12 years and older in the context of myocarditis and pericarditis reported following mRNA COVID-19 vaccination. Dec 3,2021
Amirthalingham et al. medRxIV. https://doi.org/10.1101/2021.07.26.21261140

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**

CDC ACIP Meeting November 2, 2021. EtR Framework: Pfizer-BioNTech COVID-19 vaccine in children aged 5-11 years. 1. Vogt TM et al. J Infect Dis2008; 197:1282–8. 2. NNDSS Enhanced Meningococcal Disease Surveillance Report for 2015-2019. 3. Meyer PA et al. *J Infect Dis.* 2000;182(2):383-390. 4. Roush SW et al. JAMA2007; 298:2155–63.5 Glass RI et al. J Infect Dis. 1996 Sep;174 Suppl 1:S5-11.

MODERNA's vaccine in children 6-12 years of age - early press release information

- Moderna announced the vaccine is safe and highly effective in children aged 6-12y using a two dose regime of 50 µg, given 28 days apart. (Phase 2/3 KidCOVE)
- The vaccine elicited a strong immune response evidenced by robust neutralizing antibody levels comparable to young adults.
- The vaccine was well-tolerated. AE were mild to moderate.
- Most common AE were fatigue, headache, fever and injection site pain.
- Moderna plans to submit results to the US FDA and other regulatory agencies in the near term.

Moderna Announces Positive Top Line Data from Phase 2/3 Study of COVID-19 Vaccine in Children 6 to 11 Years of Age. October 25, 2021

PFIZER vaccine in 6m-5 years of age - early press release information

- Pfizer announced the vaccine was safe for children 6m-5y administered as a two dose series of 3µg
- The study will be amended to include a third dose of 3µg at least two months after the second dose as younger children's immune system may not respond as robustly to two doses compared to older children and adults
- If the three-dose study is successful, Pfizer-BioNTech expect to submit data to the US FDA in the first half of 2022

Pfizer and BioNTech Provide Update on Ongoing Studies of COVID-19 Vaccine. December 17, 2021

Vaccine Trials in Younger (6 months to 5 years of age) Children - expected soon

Vaccine Clinical Trial	Trial Details	Results Timeline
Pfizer NCT04816643	• Recruiting; 6 mos - 11 y/o in 3 age groups (5-11y; 2-4y; 6-23m, in sequence); n=4644 • Phase 1 is dose finding (10/20/30 mcg mRNA) • Phase 2/3 is safety, immunogenicity, clinical efficacy - bridging trial	Results for 6 mo - 5 year olds expected in early 2022
Moderna NCT04796896	• Recruiting; 6 mos - 11 y/o in 3 age groups (6-11y; 2-5y; 6-23m, in sequence); n=13275 • Phase 1 is dose finding (25/50/100 mcg mRNA) • Phase 2/3 is safety immunogenicity, clinical efficacy - bridging trial	Results for 6-11y released Oct 2021 (press release); results for 5 and under expected later

Considerations for Vulnerable Populations

Study led by Health Commons Solutions Lab

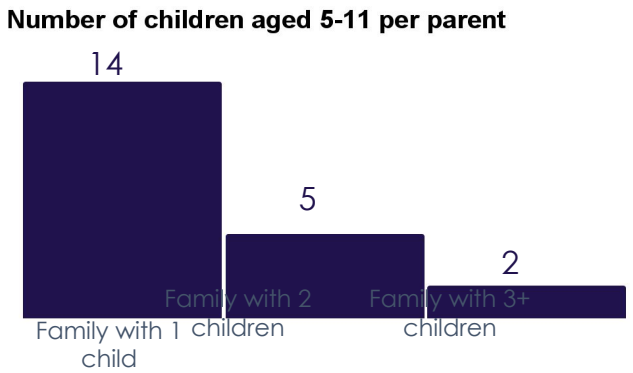
The voices we heard from

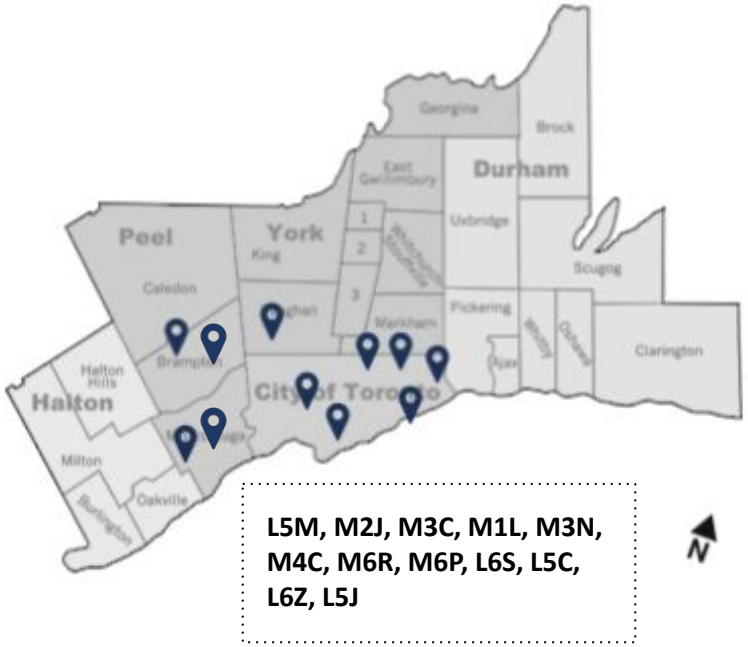
29 community members between the ages of 28-46 (96% female, 4% male) from multiple neighbourhoods across the **High Priority Communities** **in Ontario** shared their perspectives with us

- 22 participants provided voluntary socio-demographic information including the following self-identified ethnicities:
  - → African, African/indigenous, Arab, Black, Black Canadian (Jamaican), Caribbean, Caucasian, Hispanic, Indian, Karen (Myanmar/Burma), Middle Eastern, Lebanese, South Indian

Approximately **40 community ambassadors** from the High Priority Communities Strategy in Ontario also informed this work through a group discussion on vaccines in children

While the intention of this engagement was to capture the voices of marginalized groups we did have some gaps (Indigenous parents and children, and parents and children with physical and intellectual disabilities)





Community members represented postal codes from Peel, Toronto, and York region

Parents' experiences during the pandemic are influencing their decision making

- There remain communities, families and children who have been differentially impacted by the pandemic, specifically low income and racialized communities. This is the context that "primes" the conversation for many of the parents we spoke to

- Parents who have questions or concerns about the vaccine feel coerced by the mandates and public messaging and this is eroding trust - **running the risk of entrenching a "no"**

- Many do not trust the motivations behind the public health messaging for vaccines for children under 12

- Wholistically support parents with more than vaccine information
  - Support schools and children's programming with **policies that ensure inclusion of unvaccinated children, maintain their safety, and leave the door open for vaccination**

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Provide factual, accessible, clear information to answer parents questions about COVID, vaccines, and safety measures now and in the future

- In the context of an "emerging picture" parents see themselves as capable of making an informed choice if they have the right information
  - Transparently and neutrally relay scientific advice and updated guidance in real time
  - Normalize changes in advice as a part of the process so that they are not seen as inconsistencies or mistakes
  - Convey information about the benefits and risks of the vaccine vs. COVID for children in a balanced way
- Provide data showcasing the local impact of participating in vaccination and celebrate the progress of increasing community safety
- Be transparent about the rationale behind new phases of safety protocols and vaccination rolls out. Offer detailed information about the factors being considered (public health, economic recovery, vulnerable populations, pediatric consent laws)

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Tips

How to have productive conversations

Recruit their sense of agency and their individual motivations

- Providing information in neutral way and then shifting to motivational interviewing strategies will help people explore their own reasons for choosing to have their children vaccinated
- Common approaches such as: using the “all in this together” positioning, challenging or interrogating assumptions or attempting to sway in the conversation; **are more likely to increase resistance and entrench an individual's beliefs**

Motivational interviewing approach (Adapted from NYT Article):

- **Be curious** and establish a friendly tone in the conversation
- **Acknowledge that there is a lot of conflicting information** out there and that **people start out with different levels of trust** in governments, pharma and institutions
- Decide that the goal is to **open** the conversation and create a space where parent’s can explore their beliefs without challenging their identities. Assume that the first conversation may not be the last

Messages for parents at public health level

An indication from barriers and facilitators to COVID-19 vaccine uptake, that:

- That not all kids are at low risk of COVID
- As a vaccine preventable disease, COVID-19 has had a significant toll in children
- As our understanding in children of this disease progresses, more long term effects of COVID-19 in kids are identified
- Cannot predict with high accuracy which children will have mild vs severe COVID-19
- Even in people who have complied as much as possible with public health measures have been infected (even very careful isolation is not immune to infection)
- Other groups (by age, region) who have been successfully vaccinated already

Messages for parents in one on one interactions

Explore past history with regards to:

- Cultural trauma and how that impacts the vaccination decision
- Negative or positive interactions with healthcare workers
- Perceived personal contraindications to immunization

Focus messaging on:

- Personal health benefits of vaccine
- Children's mental health & socialization are impacted by the pandemic
- Outline how you as health care provider have vaccinated your children, how other parents in your social circle have (Peer pressure to vaccinate)
- If available/applicable, offer parents choice between vaccines

Mitigating Pain & Anxiety During Vaccination

Pain is an important factor in vaccine uptake.

- Meta-analysis, 35 studies included in the final analysis.
- Avoidance of influenza vaccines related to needle fear in influenza vaccine occurred in:
- 16% of adult patients.
- 27% of hospital employees.
- 18% of workers at long term care facilities.
    - Important factor in COVID-19 vaccines as they are reported to have more pain and injection site reactions than influenza vaccines.

5 Commitments to Comfort Principles

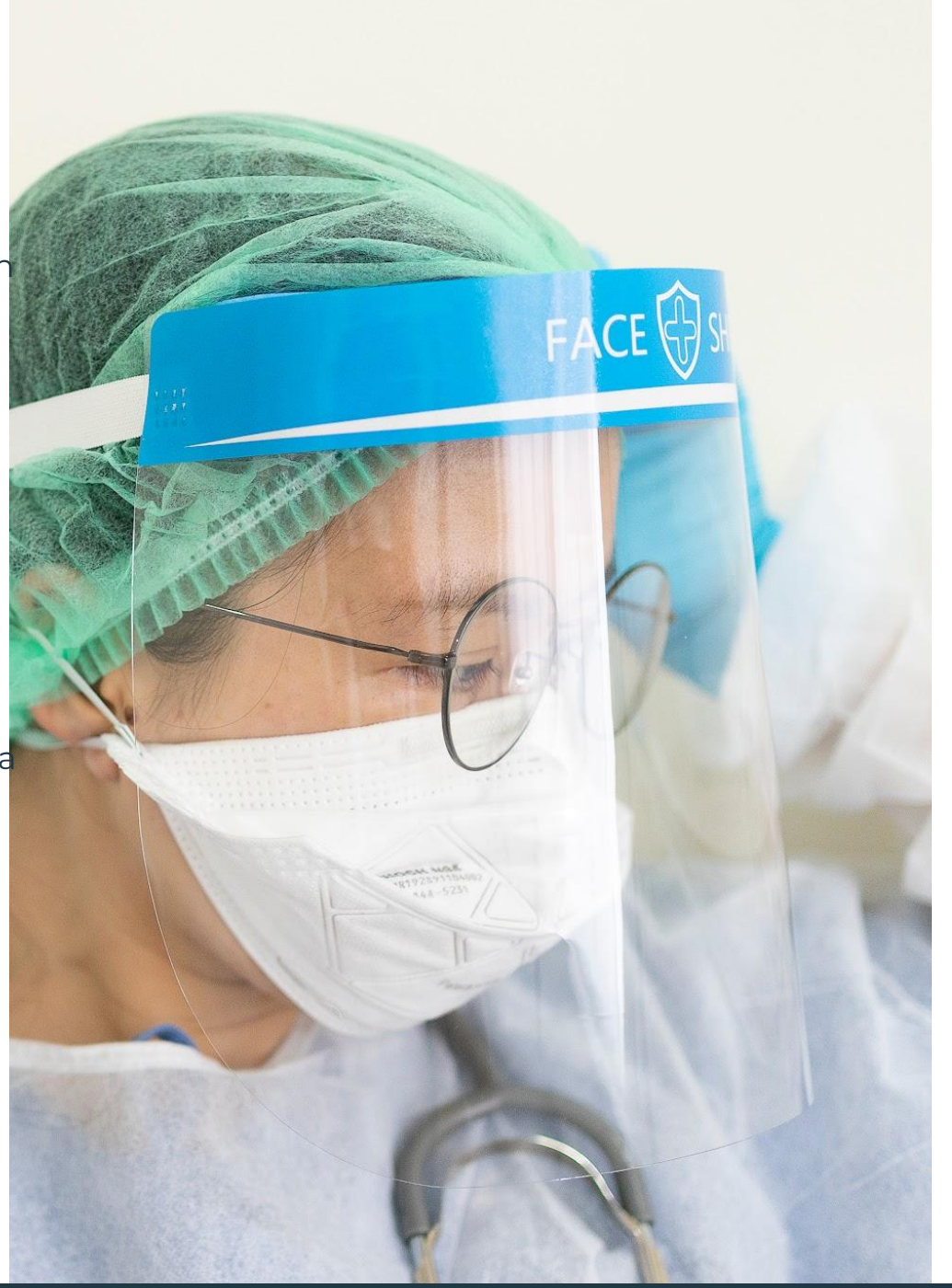
1. **Create a Comfort Plan**
   a. Ask if the person being vaccinated has preferences or concerns with their comfort management and offer choice when able (e.g., preferred pain management strategies, comfort positions).

2. **Use Numbing Cream**

3. **Use Simple, Positive Language**
   a. This makes it more likely a person will return for vaccinations in the future.
   b. Communicate in a way that reduces fear and distress prior, during, and after the immunization.
      i. Avoid saying “it will be over soon” or “it will be OK” or words that amplify fear or pain, for example “this is a really painful shot”.
      ii. Talk about what is going well/went well, for example “you did a great job relaxing your arm”
      iii. After the immunization is over tell the individual “they did well”, or “by doing this today you are saving lives/keeping yourself and others safe.

4. **Use Comfort Positions: Upright comfortable position**
   a. If they feel faint or has a history of fainting with needles:
      i. encourage alternating muscle tension and relaxation (for 15 seconds increments), or have them lie down.

5. **Shift Attention**
   a. Examples: using electronics (music/games), slow deep breathing, asking ‘small talk’ friendly questions, or focusing on a picture or poster on the wall.



Boosters for 18+ population

Third Dose vs. Booster Dose

Third or additional dose after primary vaccine series:
Administration of an initial vaccine dose when the initial immune response following the first and second doses (series) is likely to be insufficient.

Booster:
Administration of a vaccine dose when the initial **sufficient** immune response to the primary series (dose 1 and 2) has likely to have waned over time. Whether we will need a booster has not yet been determined.

Booster Dose

US: As of September 23rd, the FDA has authorized booster shots of the Pfizer vaccine for **people over 65 and those who are in high risk of developing COVID-19**

The CDC ACIP is currently recommending boosters for older adults and younger people at high risk for the disease

Israel: A booster dose was found to be 93% effective in preventing hospitalization, 92% in preventing severe disease and 81% in preventing death compared to receiving two doses at least 5 months ago.

Health Canada:
Authorized the use of Pfizer-BioNTech Comirnaty 30 mcg (Nov 9, 2021) and Moderna Spikevax 50 mcg (Nov 12, 2021) as booster doses in those 18 years of age and older at least 6 months after completion of the primary series

Barda et al. 2021 Effectiveness of a third dose of the BNT162b2 mRNA COVID-19 vaccine for preventing severe outcomes in Israel: an observational study. The Lancet.

Why boost?

- New variants such as Omicron
- Decrease in vaccine effectiveness with time from second dose
  - A differential in decrease between symptomatic infection and severe disease

Percentage point decline in VE from 1 to 6 months	Disease severity
18.5% (95% CI: 8.4 to 33.4)	SARS-CoV-2 infection
25.4% (95% CI: 13.7 to 42.5)	Symptomatic COVID-18
8.0% (95% CI: 3.6 to 15.2)	Severe disease

Safety of boosters

Safety profile comparable to that observed after the second dose of the vaccine

Israel: rates of myocarditis/pericarditis following the booster dose of Pfizer-BioNTech Comirnaty (30mcg) (given at least five months after the primary series and primary series 3 weeks apart in 12 yo and older)

- Lower than the elevated rates seen after the second dose, but higher than the rates seen after the first dose

NACI Recommendation on COVID-19 Vaccine Boosters

Boosters can offer enhanced protection and are safe, with a similar safety profile as primary series.

NACI **strongly** recommends an mRNA booster ≥6 months after a primary series for populations at high risk:

- 50+, long term care residents, recipients of viral vector vaccine series, First Nations, Inuit & Métis and frontline HCW

NACI also recommends an mRNA booster may be offered to adults 18-49 years of age ≥6 months after a primary vaccine series

National Advisory Committee on Immunization (NACI) statement: Guidance on booster COVID-19 vaccine doses in Canada. December 3, 2021

What vaccine to use as booster?

Population	Vaccine type and dose for booster doses
18-29 year olds	Pfizer-BioNTech Comirnaty (30 mcg)
≥70 year olds Adults living in long-term care homes for seniors or other congregate living settings that provide care for seniors Moderately to severely immunocompromised adultsb (after the recommended 3-dose primary series)	Either Moderna Spikevax or Pfizer Comirnaty (30mcg) may be considered. If Moderna Spikevax vaccine is being used as the booster product, a 100 mcg dose may be preferred, based on clinical discretion.
For all other populations in whom booster doses are recommended that have not been specified above.	Either Moderna Spikevax (50 mcg) or Pfizer-BioNTech Comirnaty (30 mcg) are suitable products as a booster dose

National Advisory Committee on Immunization (NACI) statement: Guidance on booster COVID-19 vaccine doses in Canada. December 3, 2021