COVID-19 Vaccination and Child Health
Symposium

February 19th, 2021

Presented by:

POLICY BENCH

Fraser Mustard Institute for Human Development

With Speakers From:

SickKids®

UNIVERSITY OF TORONTO

The Early Years
A Martin Family Initiative

Public Health Ontario | Santé publique Ontario

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Fraser Mustard Institute for Human Development Policy Bench Symposium on COVID-19 Vaccination and Child Health

COVID-19 Immunization in Children: Laying the Foundation

Dr. Shaun Morris, MD, MPH

Division of Infectious Diseases

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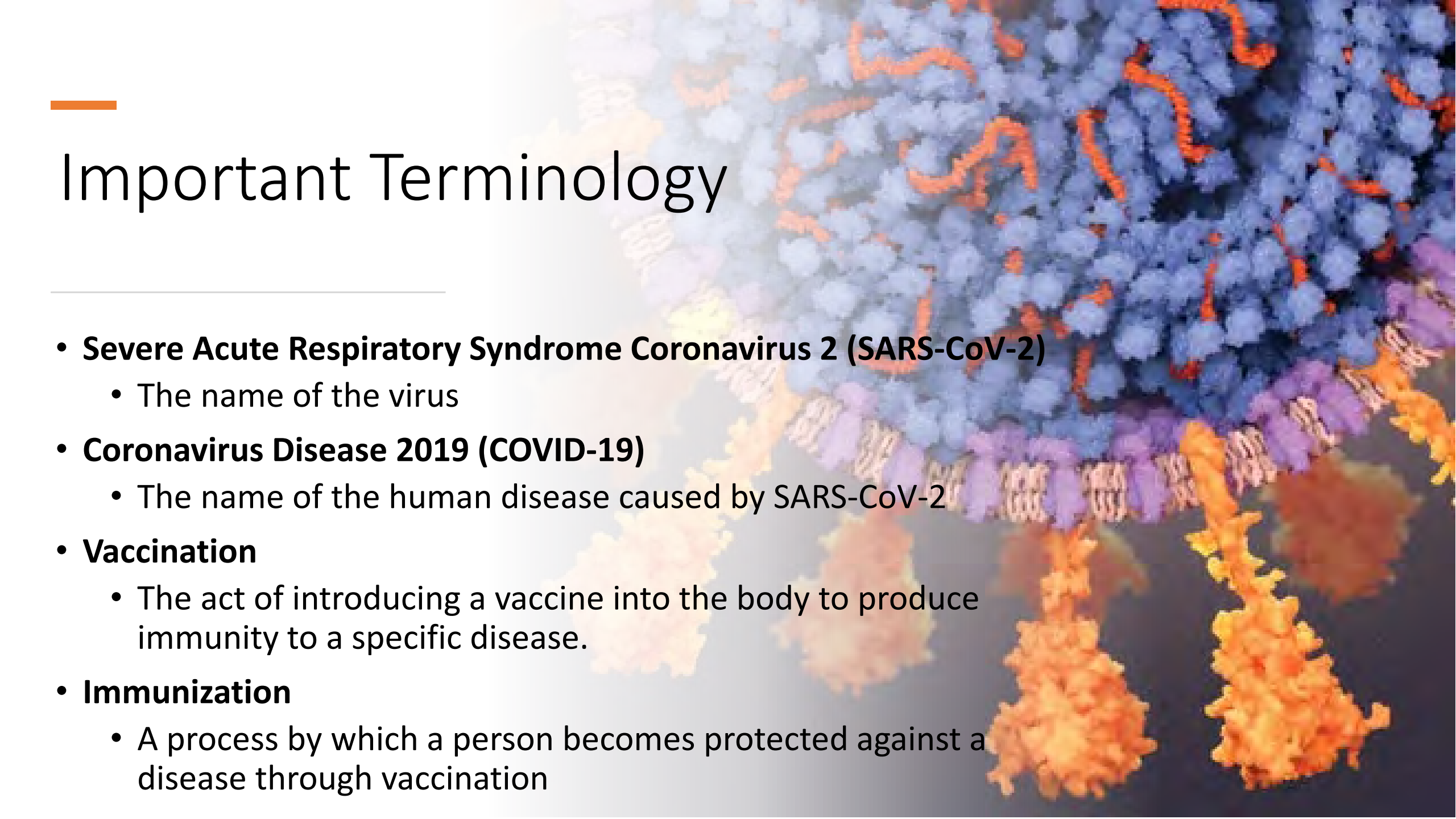
Disclosures

- I am co-PI on an investigator led grant from Pfizer related to indirect effects of COVID-19 on routine childhood immunization
- I have served on an advisory board for Pfizer for a non-SARS-CoV-2 vaccine

Objectives

- COVID-19: Key terminology and where are we now?
- Data from the Canadian Pediatric Surveillance Program (CPSP) platform
- Outlining some of the key steps in SARS-CoV-2 vaccine science, development, and approval
- Key considerations for SARS-CoV-2 immunization in children

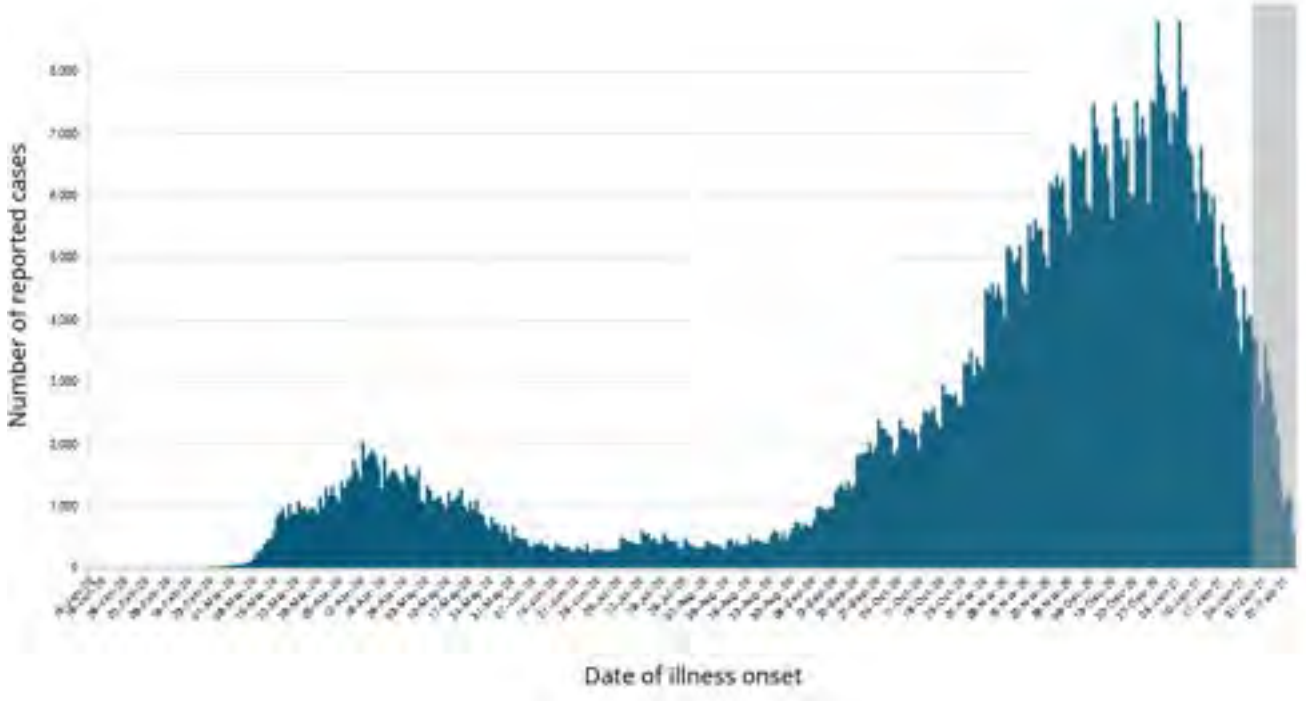
Important Terminology



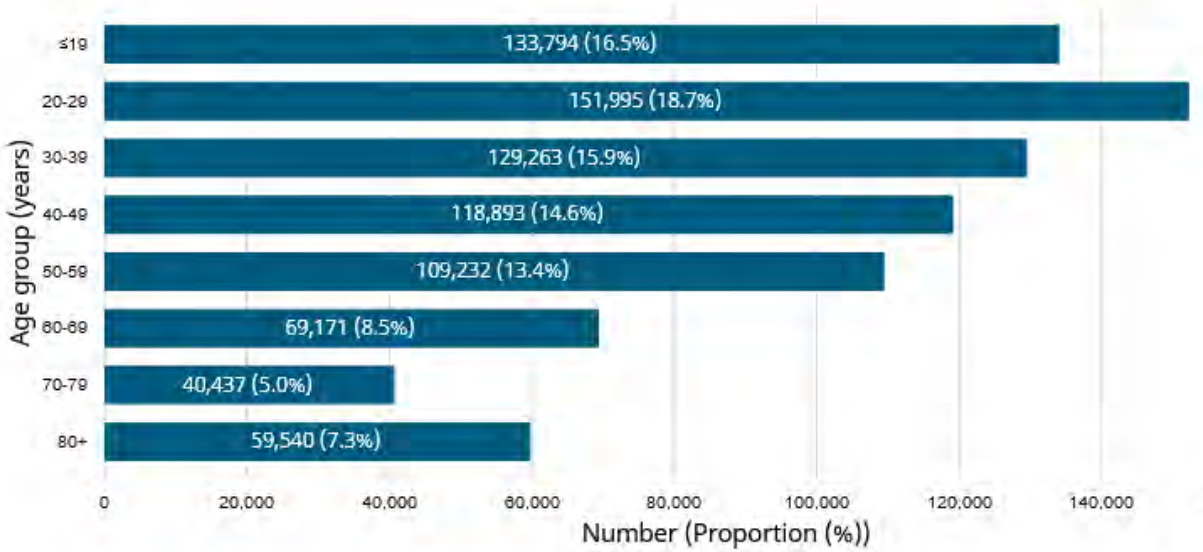
- **Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)**
  - The name of the virus
- **Coronavirus Disease 2019 (COVID-19)**
  - The name of the human disease caused by SARS-CoV-2
- **Vaccination**
  - The act of introducing a vaccine into the body to produce immunity to a specific disease.
- **Immunization**
  - A process by which a person becomes protected against a disease through vaccination

SARS-CoV-2 in Canada: Where are we now?

Public Health Agency of Canada

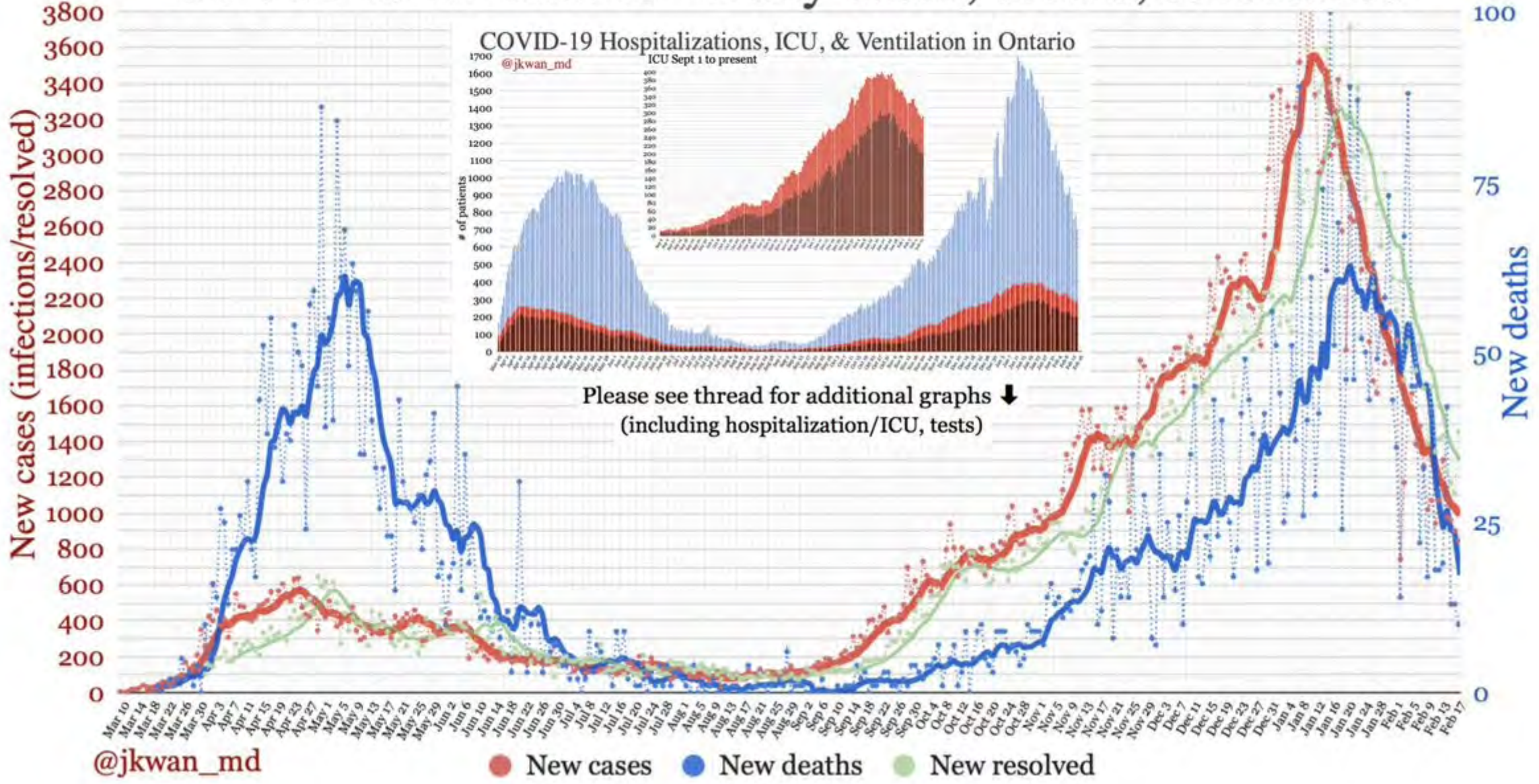


Total confirmed Cases



Age distribution of all cases

COVID-19 in Ontario - Daily cases, deaths, & resolved



SARS-CoV-2 Infection in Children in Ontario

Figure 3A. Epidemic Curve by Age Group

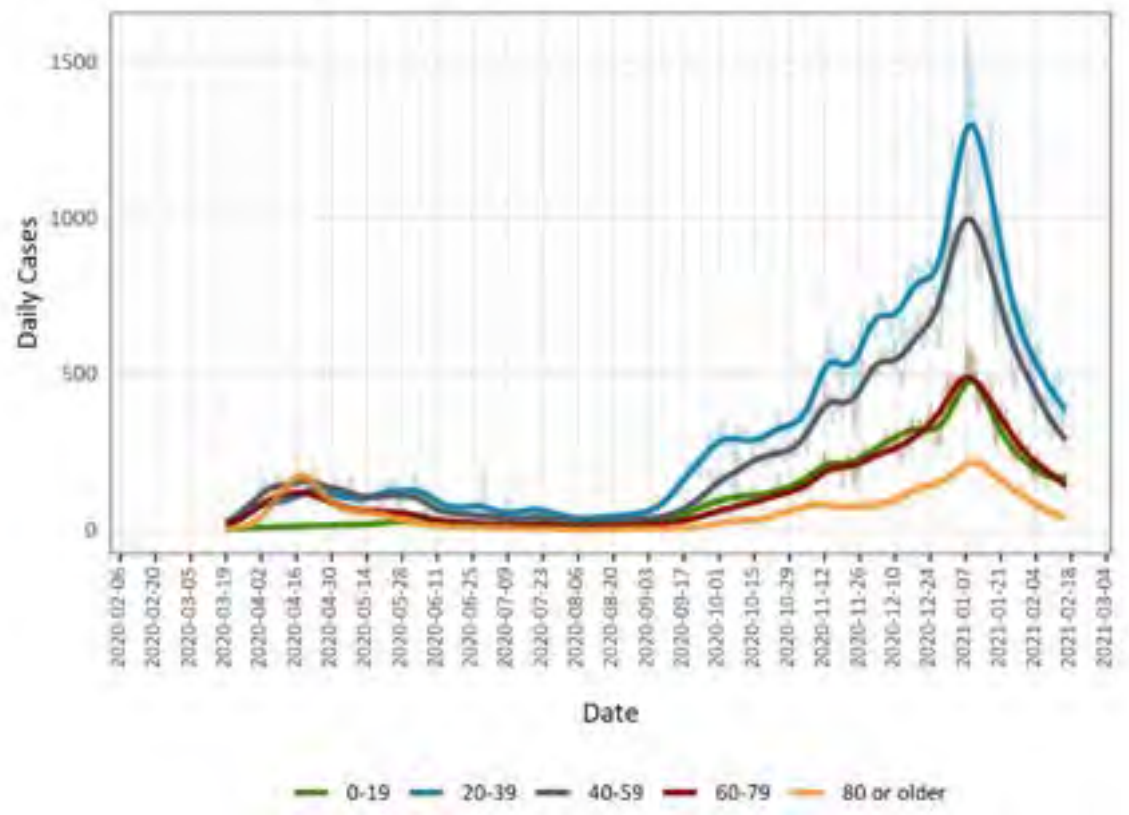
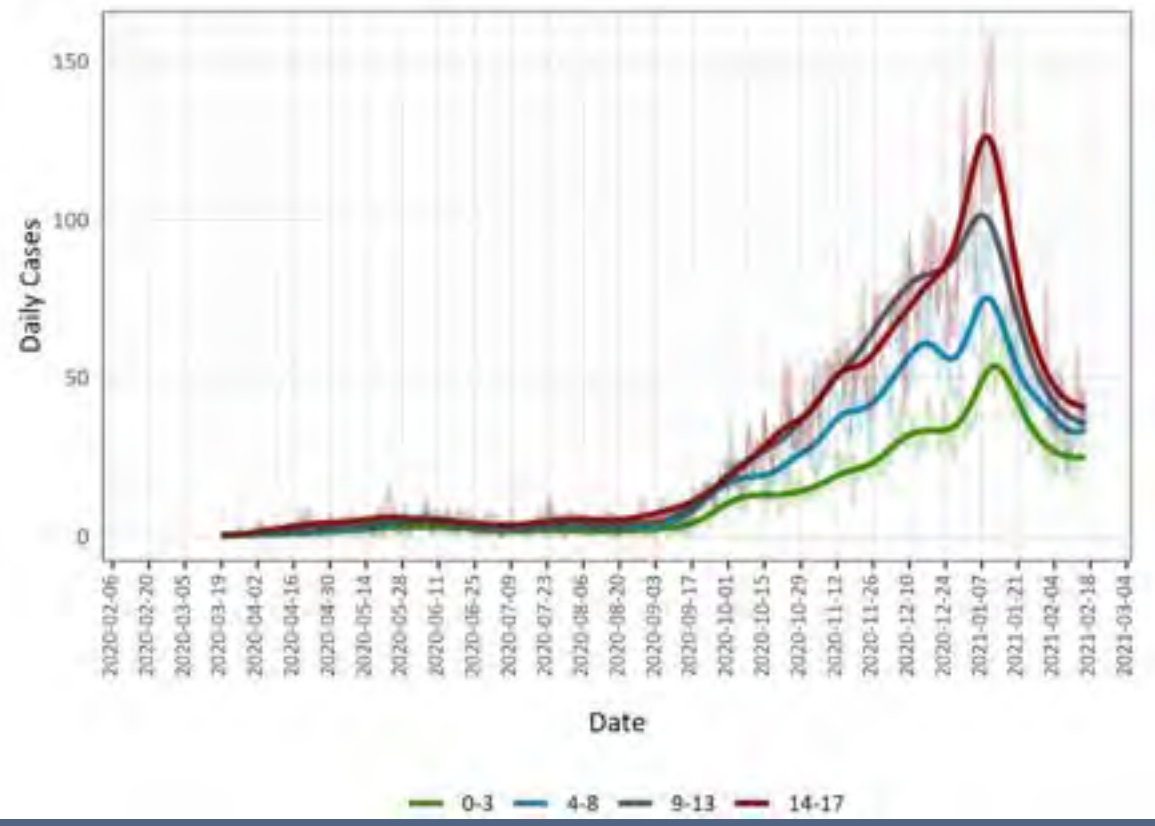


Figure 3B. Epidemic Curve in School Aged Children by Age Group



Canadian Paediatric Surveillance System

Canadian Paediatric Society / Société canadienne de pédiatrie

- The CPSP is a joint program of the **Canadian Paediatric Society** and **Public Health Agency of Canada**

- Contributes to the improvement of the health of children and youth in Canada by national surveillance into childhood disorders that are high in disability, morbidity, mortality, and economic costs to society, despite low frequency

- Provide new and necessary information on rare childhood disorders to facilitate improvements in treatment, prevention, and health-care planning.

- Respond rapidly to public health emergencies relevant to Canadian children and youth by quickly initiating one-time surveys and new studies.

CPSP COVD-19 Study: Accelerated Planning, Development, and Launch

Team of 34 investigators from across Canada including multiple disciplines, PHAC, trainees.

REB approval from HSC, PHAC, CHU SJ

Study launched April 8, 2020

Case definition

Report any new patient less than 18 years of age (up to the 18th birthday) who meets one of the following three case definitions:

1) HOSPITALIZED with acute COVID-19 (i.e., microbiologically confirmed SARS-CoV-2)

2) HOSPITALIZED with paediatric inflammatory multisystem syndrome (PIMS)/Kawasaki disease temporally associated with COVID-19, defined as:

- Persistent fever (>38 degrees Celsius for 3 or more days) and elevated inflammatory markers (CRP, ESR, or ferritin)

AND one or both of the following:

- Features of Kawasaki disease (complete or incomplete)
- Toxic shock syndrome (typical or atypical)

AND

- No alternative etiology to explain the clinical presentation

(Important note: Patients should be reported regardless of SARS-CoV-2 status)

3) NON-HOSPITALIZED with acute COVID-19 (i.e., microbiologically confirmed SARS-CoV-2) AND at least one of the following chronic comorbid conditions:

< 12 months of age	Asthma
Obesity	Chronic lung disease
Congenital heart disease	Chronic renal disease
Immunocompromising medications (high-dose steroids,* chemotherapy, biologics, immunomodulators)	Solid tumor or hematologic malignancy
Solid organ transplant	Bone marrow transplant
Primary or secondary immunodeficiency	Chronic neurologic or neurodevelopmental condition
Sickle cell disease or other chronic hematologic condition	Diabetes
Tracheostomy	Chronic rheumatologic or autoimmune disease
Inflammatory bowel disease or other chronic gastrointestinal or liver disease	Genetic/metabolic disease

* Equivalent to at least 2 mg/kg or 20 mg/day of prednisone for at least 2 weeks

PROTOCOLS

CPSP

CANADIAN PAEDIATRIC SURVEILLANCE PROGRAM

Table 1. Demographic information of acute COVID-19 hospitalizations prior to December 1, 2020 in Canada.

	All Cases	Admissions not due to COVID-19	COVID-19 admissions[1]		p-value[2]
			Non-severe	Severe	
Total cases reported, N	201	85	63	50	---
Age of child[3]					0.001*
Infants (<1 year)	73 (37.1)	23 (27.7)	37 (59.7)	12 (24.5)	---
Preschool (1-5 years)	36 (18.3)	18 (21.7)	8 (12.9)	10 (20.4)	---
School age (6-12 years)	30 (15.2)	12 (14.5)	6 (9.7)	12 (24.5)	---
Adolescents (13-17 years)	58 (29.4)	30 (36.1)	11 (17.7)	15 (30.6)	---
Sex of child[3]					0.067
Female	95 (48.0)	48 (57.8)	25 (40.3)	21 (42.0)	---
Male	103 (52.0)	35 (42.2)	37 (59.7)	29 (58.0)	---
Population group of child[4]					
White	38 (18.9)	17 (20.0)	12 (19.0)	9 (18.0)	---
Black	28 (13.9)	10 (11.8)	6 (9.5)	12 (24.0)	---
South Asian	26 (12.9)	9 (10.6)	8 (12.7)	9 (18.0)	---
Arab/West Asian	20 (10.0)	5 (5.9)	10 (15.9)	5 (10.0)	---
Indigenous	16 (8.0)	DNS	DNS	DNS	---
Other	12 (6.0)	DNS	DNS	DNS	---
Unknown	65 (32.3)	30 (35.3)	22 (34.9)	10 (20.0)	---
Region of residence					
Quebec	95 (47.3)	---	---	---	---
Ontario	68 (33.8)	---	---	---	---
Manitoba	16 (8.0)	---	---	---	---
Alberta	13 (6.5)	---	---	---	---
Rest of Canada[5]	9 (4.5)	---	---	---	---
Comorbid conditions					0.002*
None	119 (60.1)	52 (61.2)	48 (76.2)	19 (38.0)	---
One	51 (25.8)	22 (25.9)	10 (15.9)	19 (38.0)	---
≥Two	28 (14.1)	11 (12.9)	5 (7.9)	12 (24.0)	---

DNS = Data not shown due to <5 cell counts in one or both subgroups.

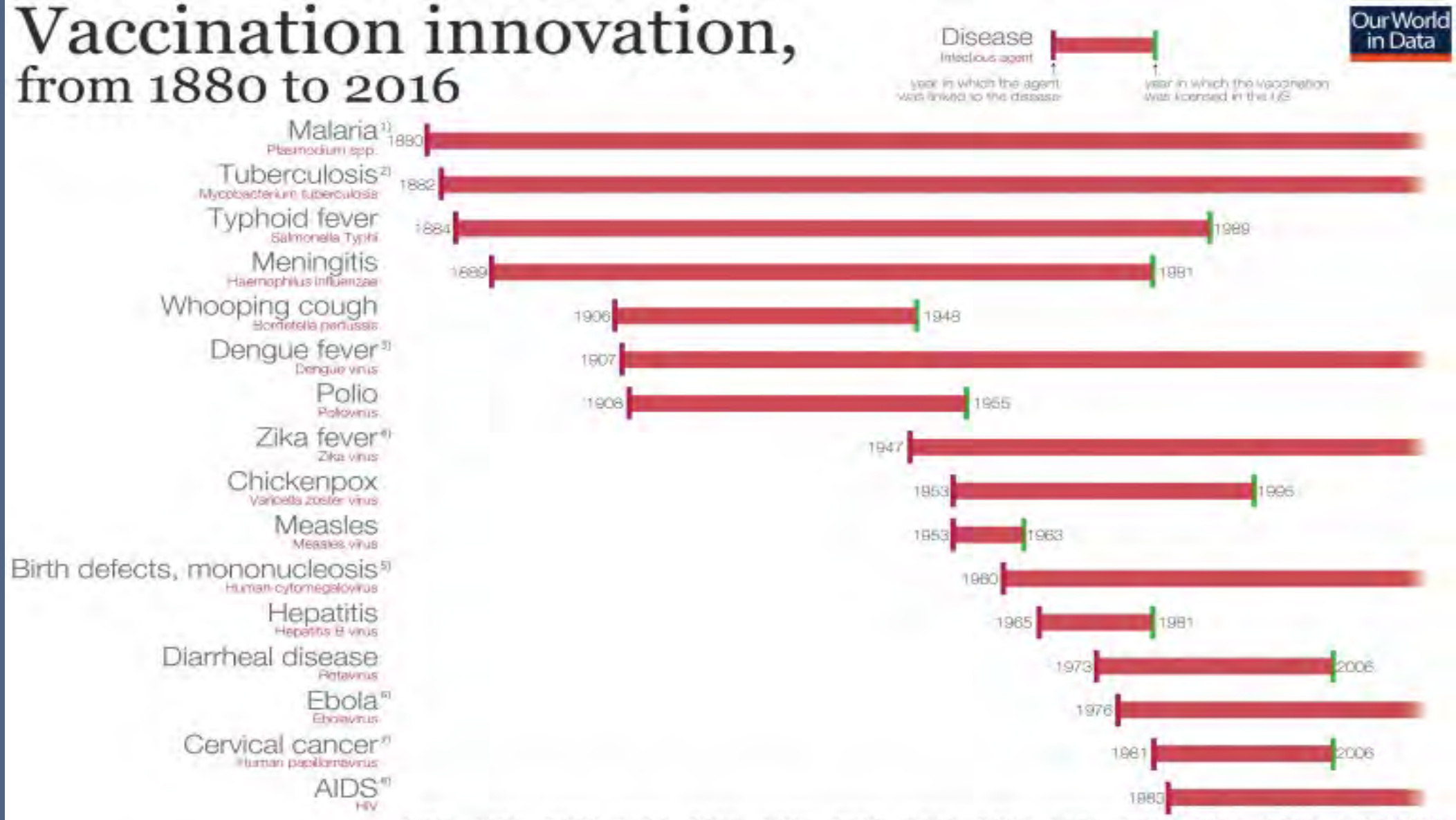
Rapid Development and Licensing of SARS-CoV-2 Vaccines

SARS-CoV-2 Vaccination in Ontario – Where are we now?

- 12,383 daily doses administered
- 501,867 total doses administered
- 205,802 people fully vaccinated

- O Children!

Vaccination innovation, from 1880 to 2016



1) – 2016 vaccine RTS,S undergoing pilot trials in select countries after being approved by European regulators in 2015.
2) – The only approved vaccine is bacilli Calmette-Guérin (BCG), developed in 1921, but its efficacy in adults is variable. Other tuberculosis vaccines are currently in development.
3) – 2016 partially effective vaccine CYD-TDV, sold under the brand name Dengvaxia.
4) – Successful first human clinical trials of a vaccine against the virus in 2016. Only in 2016 did the WHO issue statements of concern about the zika virus' links to Guillain-Barré Syndrome (GBS) and microcephaly.
5) – A number of vaccine candidates are under investigation.
6) – 2016 VSV-EBOV vaccine in human clinical trials and allowed for use in emergency through the WHO 'Emergency Use Assessment and Listing' (EUAL).
7) – Not all cervical cancers are caused by the HPV virus and the HPV vaccine can protect against other cancers caused by the HPV virus.
8) – 2009 efficacy findings for vaccine candidate RV 144 has shown some promise. In stage III human trials.

This visualization is from OurWorldinData.org. There you find research and more visualizations on vaccinations

Vaccine development and approval in Canada

Vaccine development

Scientists develop a potential vaccine

Scientists conduct lab and animal studies before testing on humans

10s of volunteers

Phase I

- Is the vaccine safe?
- What is a safe dose?
- Are there any side effects?

100s of volunteers

Phase II

- How well does the vaccine work?
- Is it safe on a larger number of people?
- Safest and most effective dose?

1000s of volunteers

Phase III

- Does the vaccine prevent disease?
- What are the side effects?

Manufacturer submits application to Health Canada for review

Exploratory → Preclinical → Clinical Trials → Application

Review and approval of vaccines

Teams of Health Canada experts conduct a thorough and independent review of all vaccine data *

Health Canada approves a vaccine if it is safe, it works, it meets manufacturing standards, and the benefits outweigh the risks

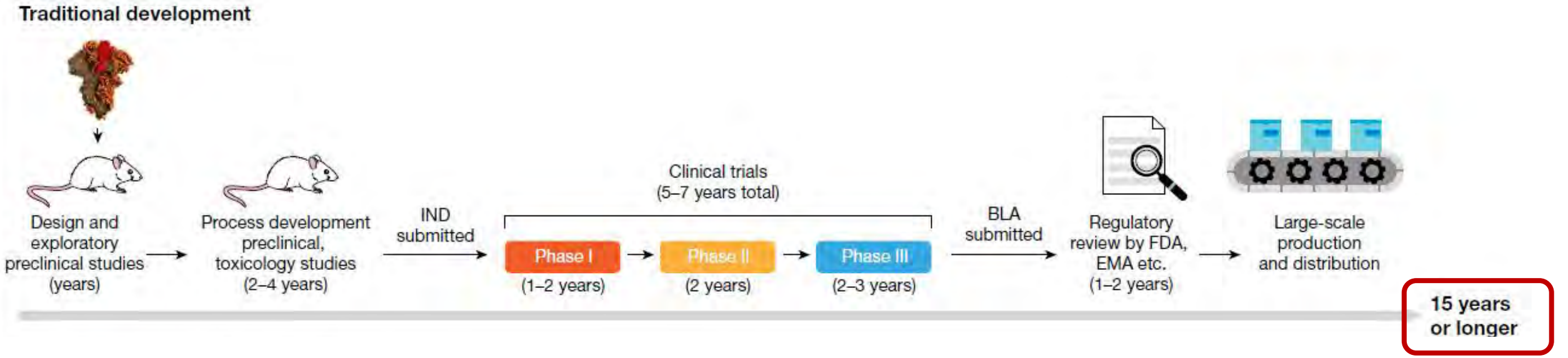
Governments coordinate the purchase, logistics and distribution of vaccines across Canada

All Canadians have access to the vaccine

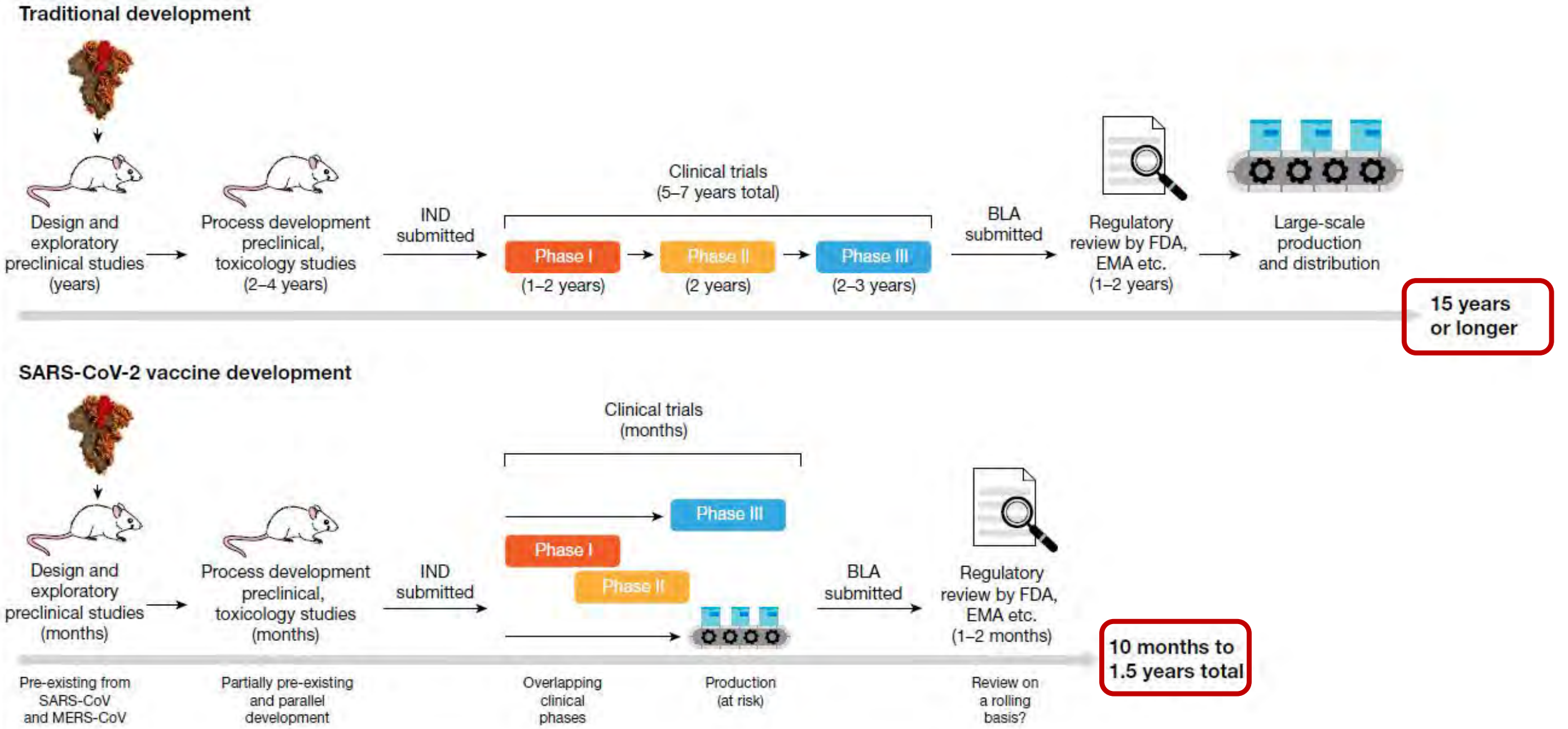
Continuous monitoring and review to confirm the safety of the vaccine, and that benefits outweigh risks

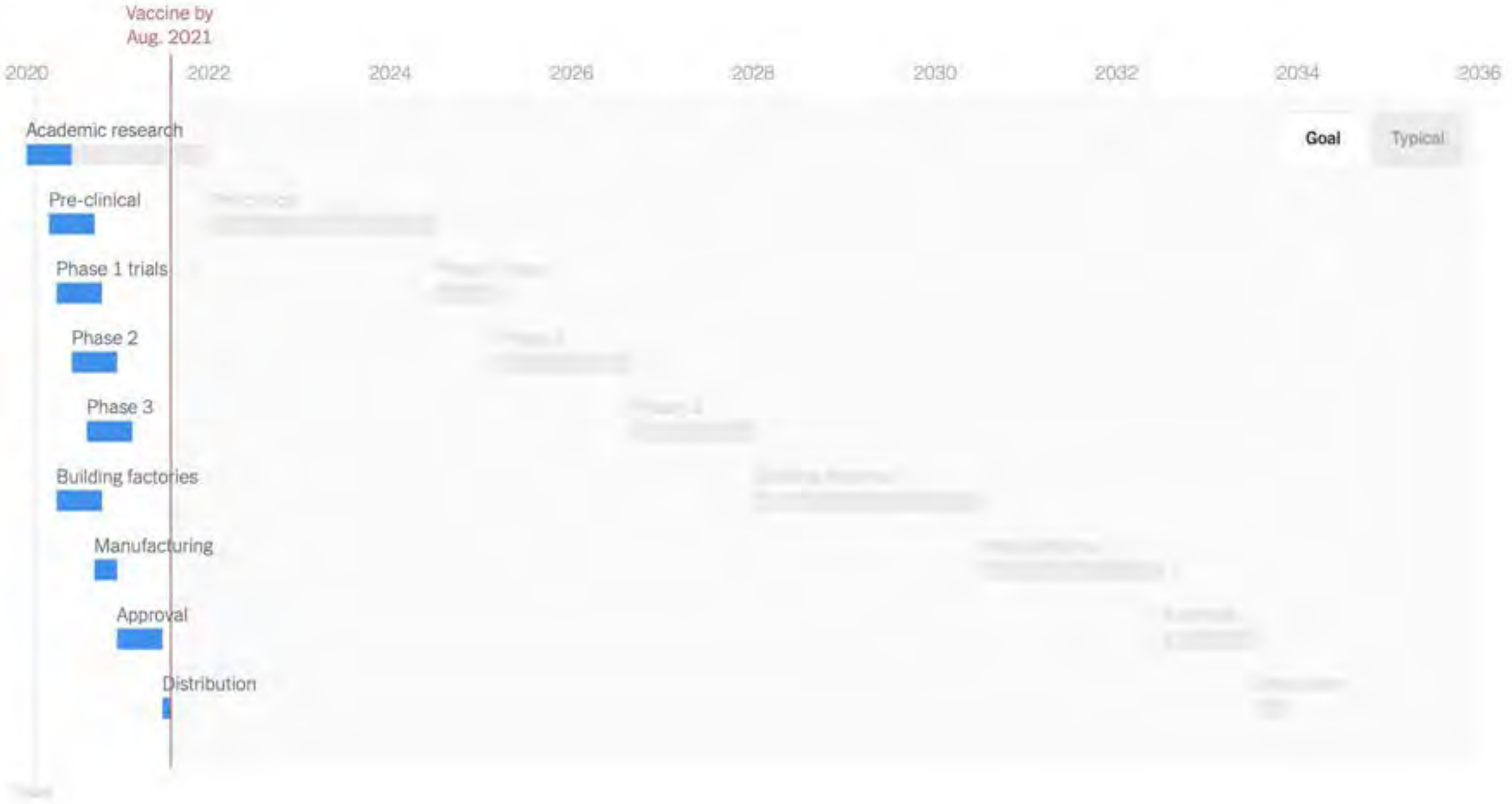
Scientific Review → Approval → Distribution → Vaccination → Ongoing Monitoring and Review

Timelines for Vaccine Development Traditional vs SARS-CoV-2



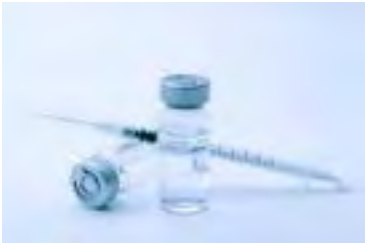
Timelines for Vaccine Development Traditional vs SARS-CoV-2

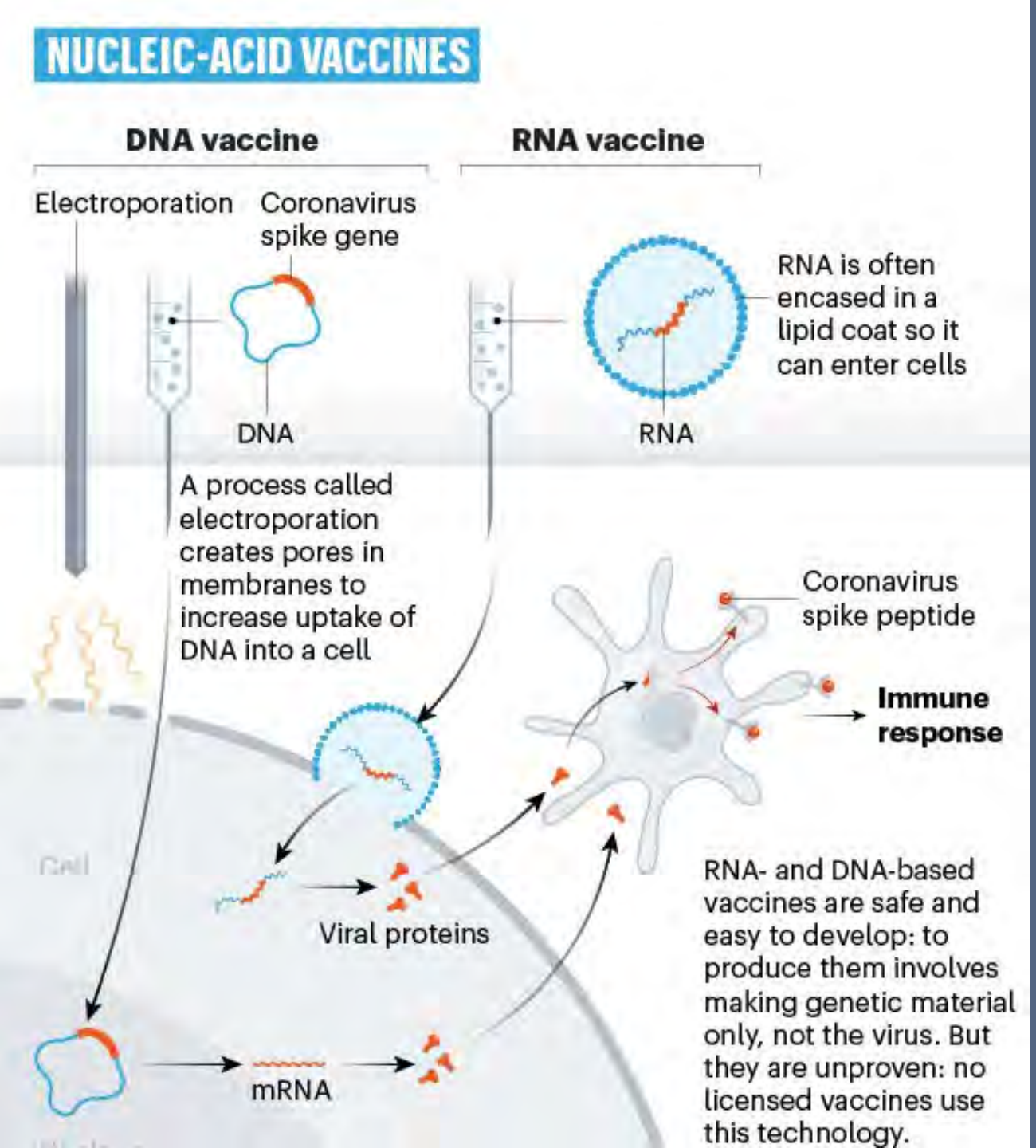



Vaccine by
Aug. 2021
2020
2022
2024
2026
2028
2030
2032
2034
2036
Goal
Typical
Academic research
Pre-clinical
Phase 1 trials
Phase 2
Phase 3
Building factories
Manufacturing
Approval
Distribution

Sars-CoV-2 Vaccine Types

- Nucleic Acid Vaccines
- Viral Vector Vaccines
- Attenuated Virus Vaccines
- Protein Based Vaccines

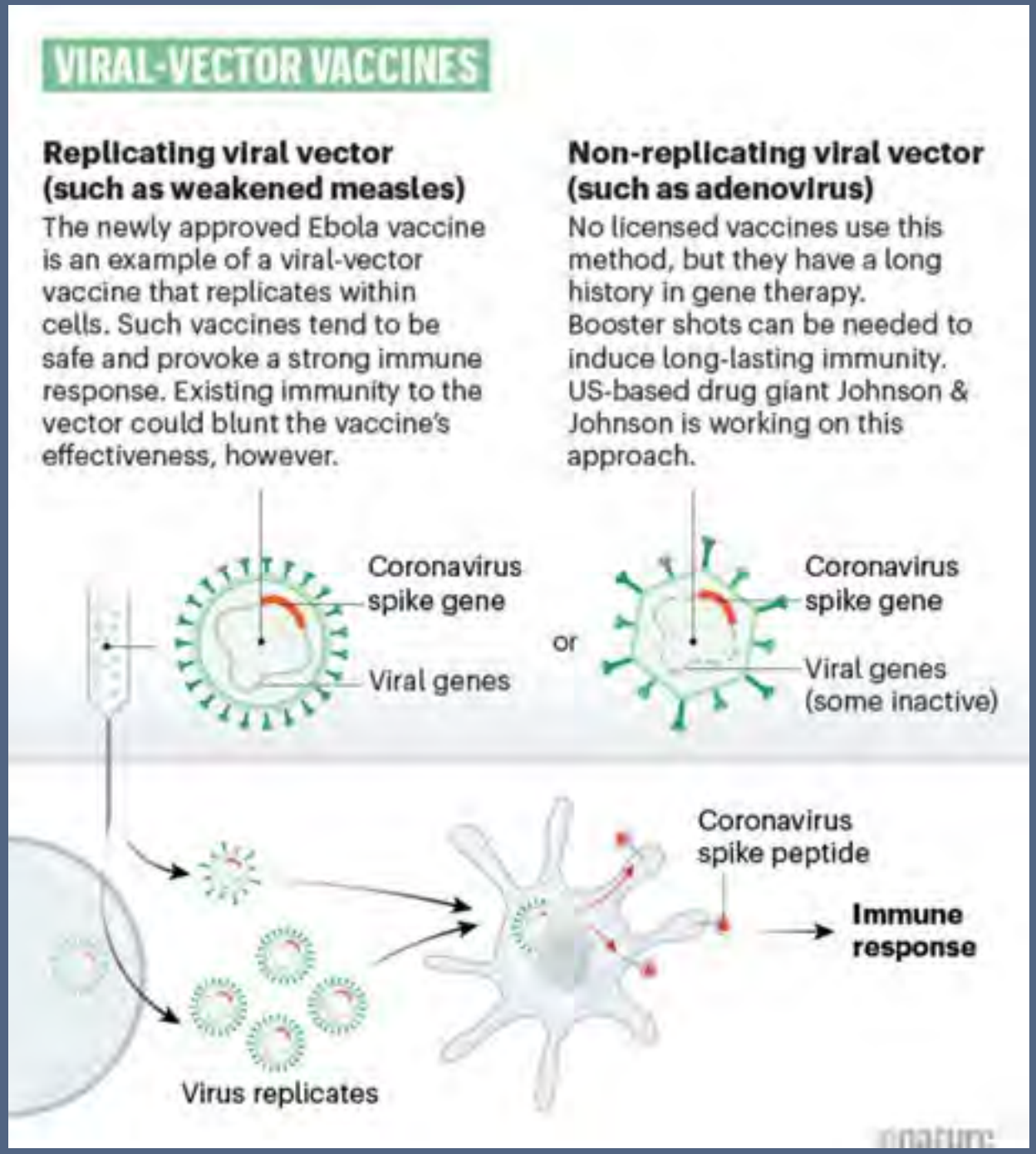




- **Pfizer/BioNTech (USA/Germany)**
- **Type:** mRNA
- **Doses reserved by Canada:** At least 20 million

- **Moderna (USA)**
- **Type:** mRNA
- **Doses reseved by Canada:** Up to 56 million

CBC



- **AstraZeneca/Oxford University (UK)**
- **Doses reserved by Canada:** 20 million

- **Janssen Pharmaceutical Companies (Johnson & Johnson, USA)**
- **Doses reserved by Canada:** Up to 38 million

CBC

The NEW ENGLAND JOURNAL of MEDICINE

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Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

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ABSTRACT

BACKGROUND

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (Covid-19) have inflicted tens of millions of people in a worldwide pandemic. Safe and effective vaccines are needed urgently.

METHODS

In an ongoing multinational, placebo-controlled, observer-blinded, pivotal efficacy trial, we randomly assigned persons 16 years of age or older in a 1:1 ratio to receive two doses, 21 days apart, of either placebo or the BNT162b2 vaccine candidate (30 μg per dose). BNT162b2 is a lipid nanoparticle–formulated, nucleoside-modified RNA vaccine that encodes a prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. The primary end points were efficacy of the vaccine against laboratory-confirmed Covid-19 and safety.

RESULTS

A total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo. There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo; BNT162b2 was 95% effective in preventing Covid-19 (95% credible interval, 90.3 to 97.6). Similar vaccine efficacy (generally 90 to 100%) was observed across subgroups defined by age, sex, race, ethnicity, baseline body-mass index, and the presence of coexisting conditions. Among 10 cases of severe Covid-19 with onset after the first dose, 9 occurred in placebo recipients and 1 in a BNT162b2 recipient. The safety profile of BNT162b2 was characterized by short-term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and was similar in the vaccine and placebo groups.

CONCLUSIONS

A two-dose regimen of BNT162b2 conferred 95% protection against Covid-19 in persons 16 years of age or older. Safety over a median of 2 months was similar to that of other viral vaccines. (Funded by BioNTech and Pfizer; ClinicalTrials.gov number, NCT04368728.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Absalon at Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965, or at judith.absalon@pfizer.com.

*A complete list of investigators in the C4591001 Clinical Trial Group is provided in the Supplementary Appendix, available at NEJM.org.

Drs. Polack and Thomas contributed equally to this article.

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ORIGINAL ARTICLE

Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine

L.R. Baden, H.M. El Sahly, B. Essink, K. Kotloff, S. Frey, R. Novak, D. Diemert, S.A. Spector, N. Rouphael, C.B. Creech, J. McGettigan, S. Khetan, N. Segall, J. Solis, A. Brosz, C. Fierro, H. Schwartz, K. Neuzil, L. Corey, P. Gilbert, H. Janes, D. Follmann, M. Marovich, J. Mascola, L. Polakowski, J. Ledgerwood, B.S. Graham, H. Bennett, R. Pajon, C. Knightly, B. Leav, W. Deng, H. Zhou, S. Han, M. Ivarsson, J. Miller, and T. Zaks, for the COVE Study Group*

ABSTRACT

BACKGROUND

Vaccines are needed to prevent coronavirus disease 2019 (Covid-19) and to protect persons who are at high risk for complications. The mRNA-1273 vaccine is a lipid nanoparticle–encapsulated mRNA-based vaccine that encodes the prefusion stabilized full-length spike protein of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes Covid-19.

METHODS

This phase 3 randomized, observer-blinded, placebo-controlled trial was conducted at 99 centers across the United States. Persons at high risk for SARS-CoV-2 infection or its complications were randomly assigned in a 1:1 ratio to receive two intramuscular injections of mRNA-1273 (100 μg) or placebo 28 days apart. The primary end point was prevention of Covid-19 illness with onset at least 14 days after the second injection in participants who had not previously been infected with SARS-CoV-2.

RESULTS

The trial enrolled 30,420 volunteers who were randomly assigned in a 1:1 ratio to receive either vaccine or placebo (15,210 participants in each group). More than 96% of participants received both injections, and 2.2% had evidence (serologic, virologic, or both) of SARS-CoV-2 infection at baseline. Symptomatic Covid-19 illness was confirmed in 185 participants in the placebo group (56.5 per 1000 person-years; 95% confidence interval [CI], 48.7 to 65.3) and in 11 participants in the mRNA-1273 group (3.3 per 1000 person-years; 95% CI, 1.7 to 6.0); vaccine efficacy was 94.1% (95% CI, 89.3 to 96.8%; P<0.001). Efficacy was similar across key secondary analyses, including assessment 14 days after the first dose, analyses that included participants who had evidence of SARS-CoV-2 infection at baseline, and analyses in participants 65 years of age or older. Severe Covid-19 occurred in 30 participants, with one fatality; all 30 were in the placebo group. Moderate, transient reactogenicity after vaccination occurred more frequently in the mRNA-1273 group. Serious adverse events were rare, and the incidence was similar in the two groups.

CONCLUSIONS

The mRNA-1273 vaccine showed 94.1% efficacy at preventing Covid-19 illness, including severe disease. Aside from transient local and systemic reactions, no safety concerns were identified. (Funded by the Biomedical Advanced Research and Development Authority and the National Institute of Allergy and Infectious Diseases; COVE ClinicalTrials.gov number, NCT04470427.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. El Sahly at the Departments of Medicine, Virology, and Microbiology and Medicine, Baylor Plaza, BCM-MS260, Houston, TX 77030, or at hana.elsahly@bcm.edu; or to Dr. Baden at the Division of Infectious Diseases, Brigham and Women's Hospital, 15 Francis St., HNB-6A, Boston, MA 02115, or at lbaden@bwh.harvard.edu.

*A complete list of members of the COVE Study Group is provided in the Supplementary Appendix, available at NEJM.org.

Drs. Baden and El Sahly contributed equally to this article.

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The NEW ENGLAND JOURNAL of MEDICINE

DECEMBER 31, 2020

Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Dose 1 All-Available Efficacy Population

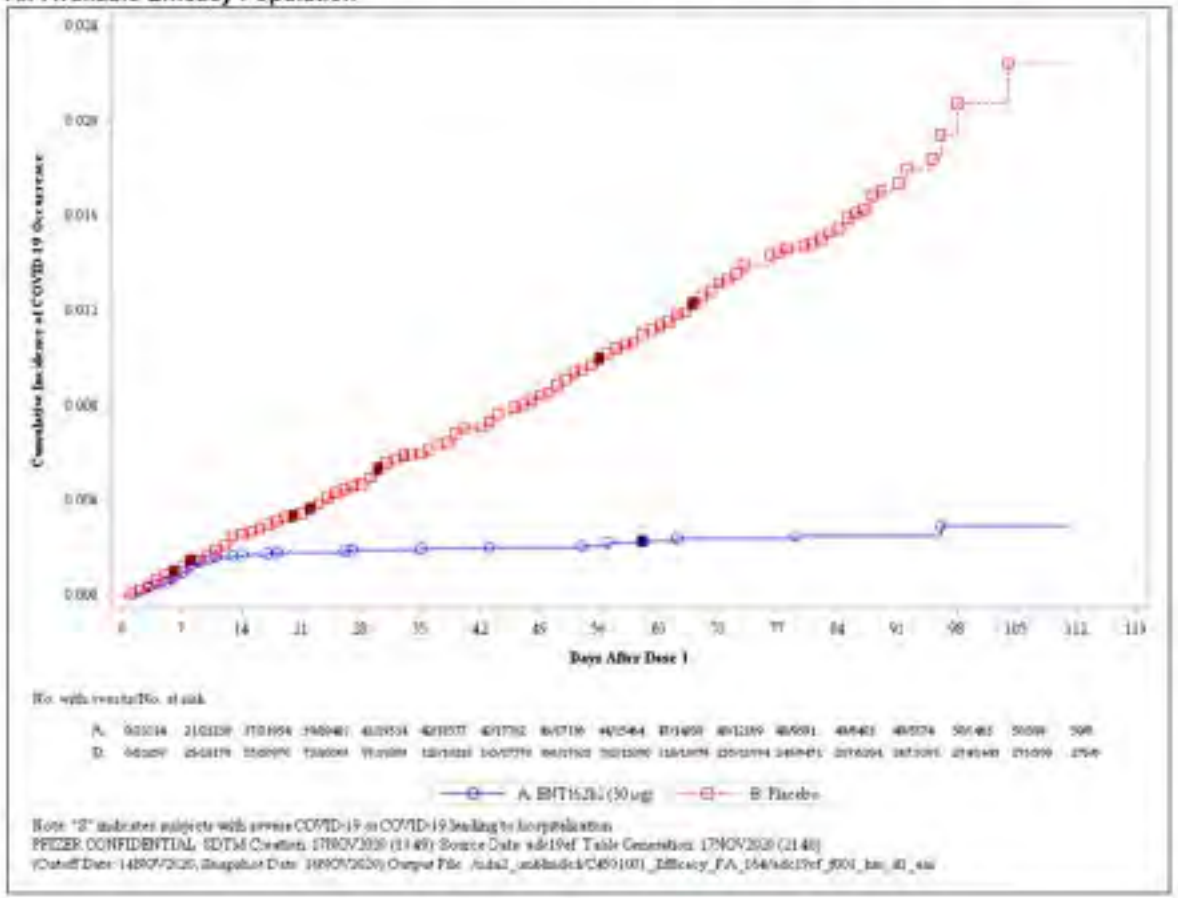

Table 3. Vaccine Efficacy Overall and by Subgroup in Participants without Evidence of Infection before 7 Days after Dose 2.

Efficacy End-Point Subgroup	BNT162b2 (N=18,198) No. of Cases	BNT162b2 (N=18,198) Surveillance Time (No. at Risk)*	Placebo (N=18,325) No. of Cases	Placebo (N=18,325) Surveillance Time (No. at Risk)*	Vaccine Efficacy, % (95% CI)†
Overall	8	2.214 (17,411)	162	2.222 (17,511)	95.0 (90.0–97.9)
Age group					
16 to 55 yr	5	1.234 (9,897)	114	1.239 (9,955)	95.6 (89.4–98.6)
>55 yr	3	0.980 (7,500)	48	0.983 (7,543)	93.7 (80.6–98.8)
≥65 yr	1	0.508 (3,848)	19	0.511 (3,880)	94.7 (66.7–99.9)
≥75 yr	0	0.102 (774)	5	0.106 (785)	100.0 (-13.1–100.0)
Sex					
Male	3	1.124 (8,875)	83	1.108 (8,762)	96.4 (88.9–99.3)
Female	5	1.090 (8,536)	83	1.114 (8,749)	93.7 (84.7–98.0)
Race or ethnic group‡					
White	7	1.839 (14,504)	146	1.903 (14,670)	95.2 (89.8–98.1)
Black or African American	0	0.165 (1,502)	7	0.164 (1,486)	100.0 (31.2–100.0)
All others	1	0.160 (1,405)	9	0.155 (1,355)	89.3 (22.6–99.8)
Hispanic or Latinx	3	0.605 (4,764)	53	0.600 (4,746)	94.4 (82.7–98.9)
Non-Hispanic, non-Latinx	5	1.596 (12,548)	109	1.608 (12,661)	95.4 (88.9–98.5)
Country					
Argentina	1	0.351 (2,545)	35	0.346 (2,521)	97.2 (83.3–99.9)
Brazil	1	0.119 (1,129)	8	0.117 (1,121)	87.7 (8.1–99.7)
United States	6	1.732 (13,359)	119	1.747 (13,506)	94.9 (88.6–98.2)

* Surveillance time is the total time in 1000 person-years for the given end point across all participants within each group at risk for the end point. The time period for Covid-19 case accrual is from 7 days after the second dose to the end of the surveillance period.
† The confidence interval (CI) for vaccine efficacy is derived according to the Clopper–Pearson method, adjusted for surveillance time.
‡ Race or ethnic group was reported by the participants. "All others" included the following categories: American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported.

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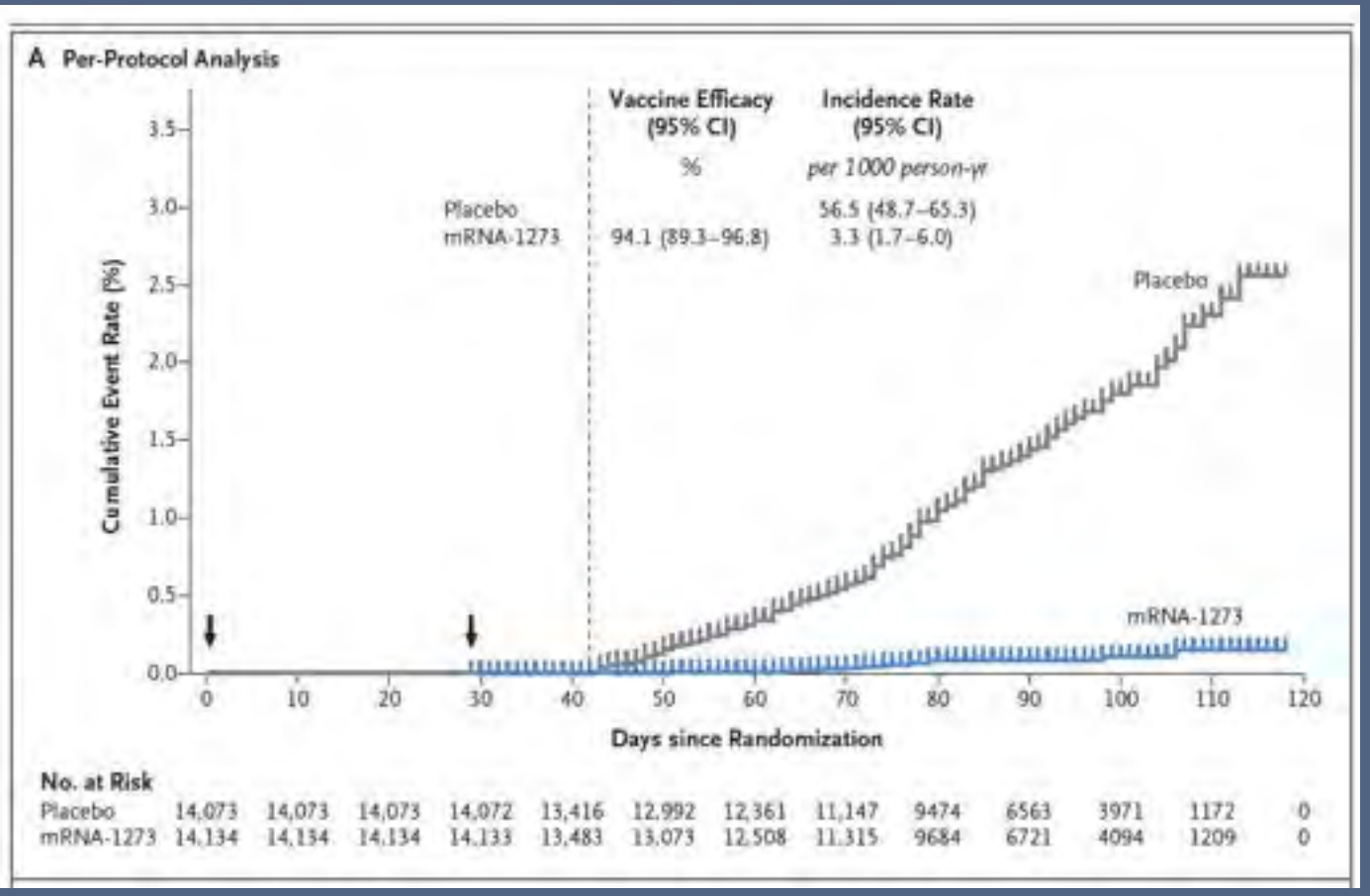
ORIGINAL ARTICLE

Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine



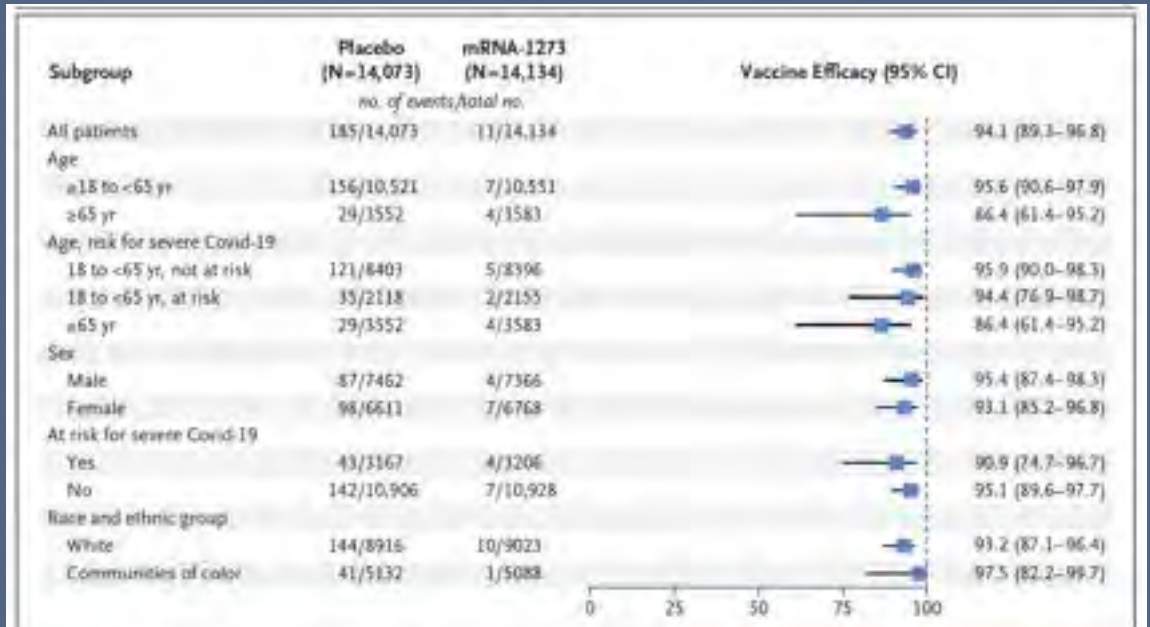


Figure 4. Vaccine Efficacy of mRNA-1273 to Prevent Covid-19 in Subgroups.

The efficacy of the RNA-1273 vaccine in preventing Covid-19 in various subgroups in the per-protocol population was based on adjudicated assessments starting 14 days after the second injection. Vaccine efficacy, defined as 1 minus the hazard ratio (mRNA-1273 vs. placebo), and 95% confidence intervals were estimated with the use of a stratified Cox proportional hazards model, with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable. Race and ethnic group categories shown are White (non-Hispanic) and communities of color (all others, including those whose race and ethnicity were both reported as unknown, were not reported, or were both missing at screening). Data for communities of color were pooled owing to limited numbers of participants in each racial or ethnic group, to ensure that the subpopulations would be large enough for meaningful analyses.

Many Important Questions & Considerations Regarding Children

- Vaccine effectiveness and safety
- Duration of immunity and impact on transmission
- Risk benefit for the child vs community
- Virus evolution and new variants
- Logistics of distribution – potentially unique settings for child immunization
- Risk group prioritization within children
- Hesitancy
- Global use

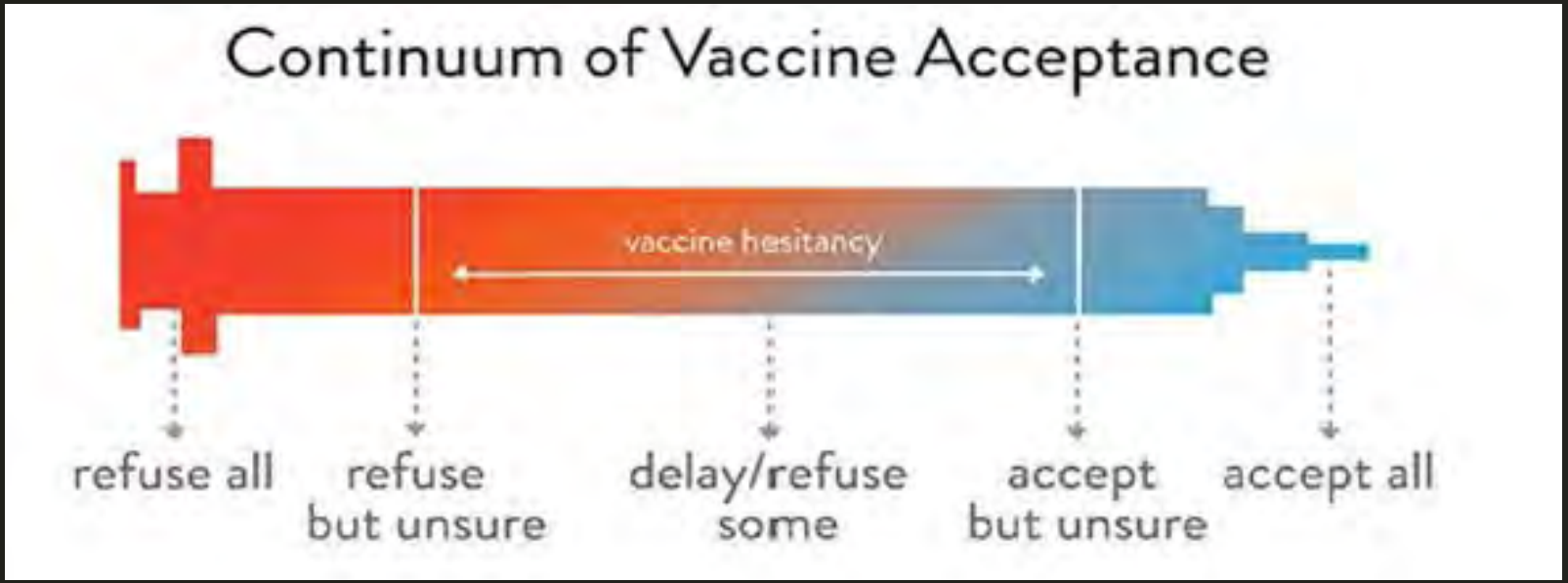

Thank You

Getting A Head Start:
What Decades of Vaccine Hesitancy Research Can Teach Us About Parents, Kids, and the COVID-19 Vaccine

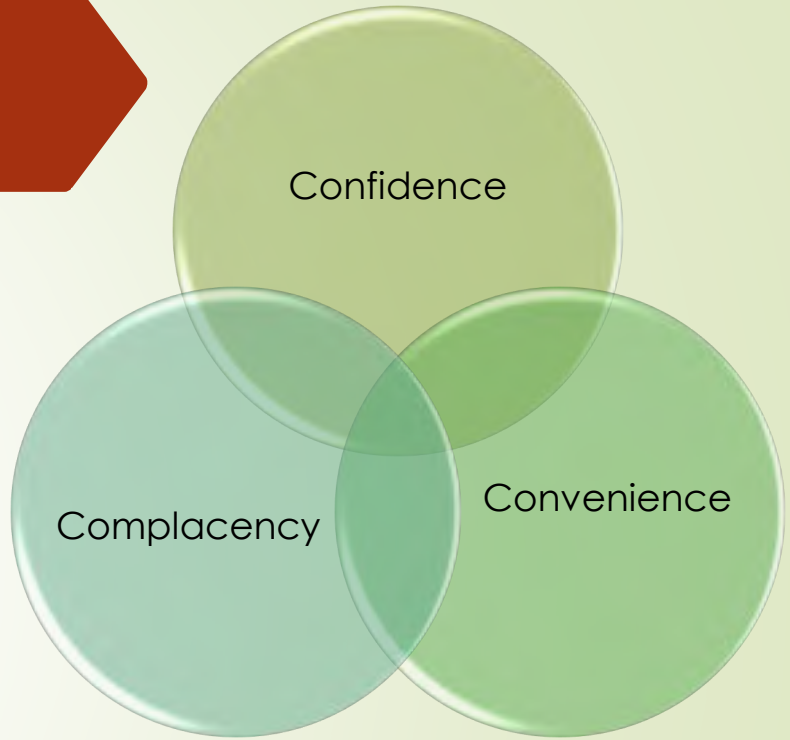
Kate Allan
PhD Candidate, Factor-Inwentash Faculty of Social Work, University of Toronto
Postdoctoral Fellow, Centre for Vaccine-Preventable Diseases

What does vaccine hesitancy look like?

What is vaccine hesitancy?



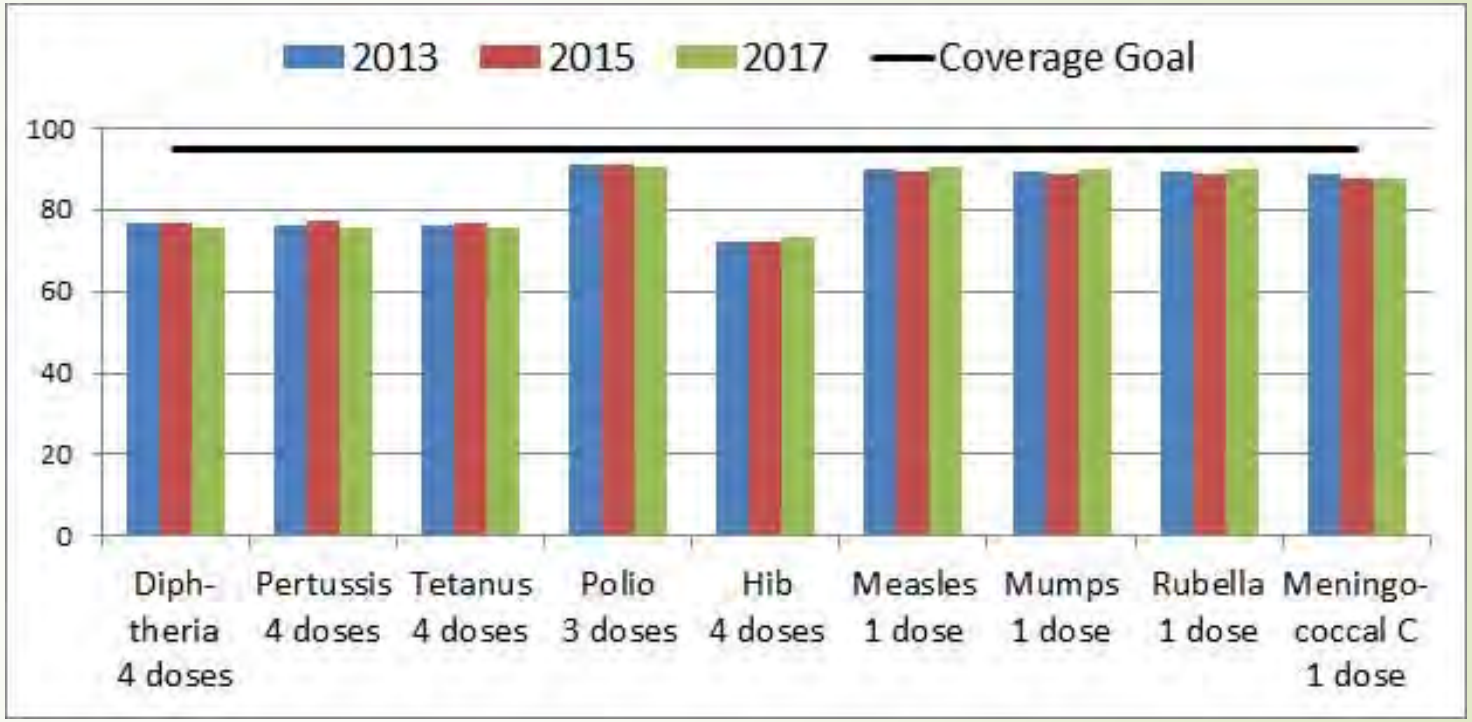
Kaith & Scotto, 2020; based on MacDonald, 2015



+ calculation
+ constraints
+collective responsibility

The Canadian Picture

- 89% had encountered parents with concerns about vaccines (Allan, 2021)
- 23% of parents with concerns had their child fully immunized (PHAC, 2011)



PHAC, 2020 https://www.canada.ca/en/public-health/services/publications/healthy-living/2015-vaccine-uptake-canadian-children-survey.html

The Dangers of Hesitancy

- Children with vaccine exemption 22x and 6x more likely to acquire measles and pertussis, respectively (Feikin et al., 2000)

- For each 1% increase in children with exemptions in a school, risk of pertussis outbreak increased by 12% (Feikin et al., 2000)

Reasons for Hesitancy

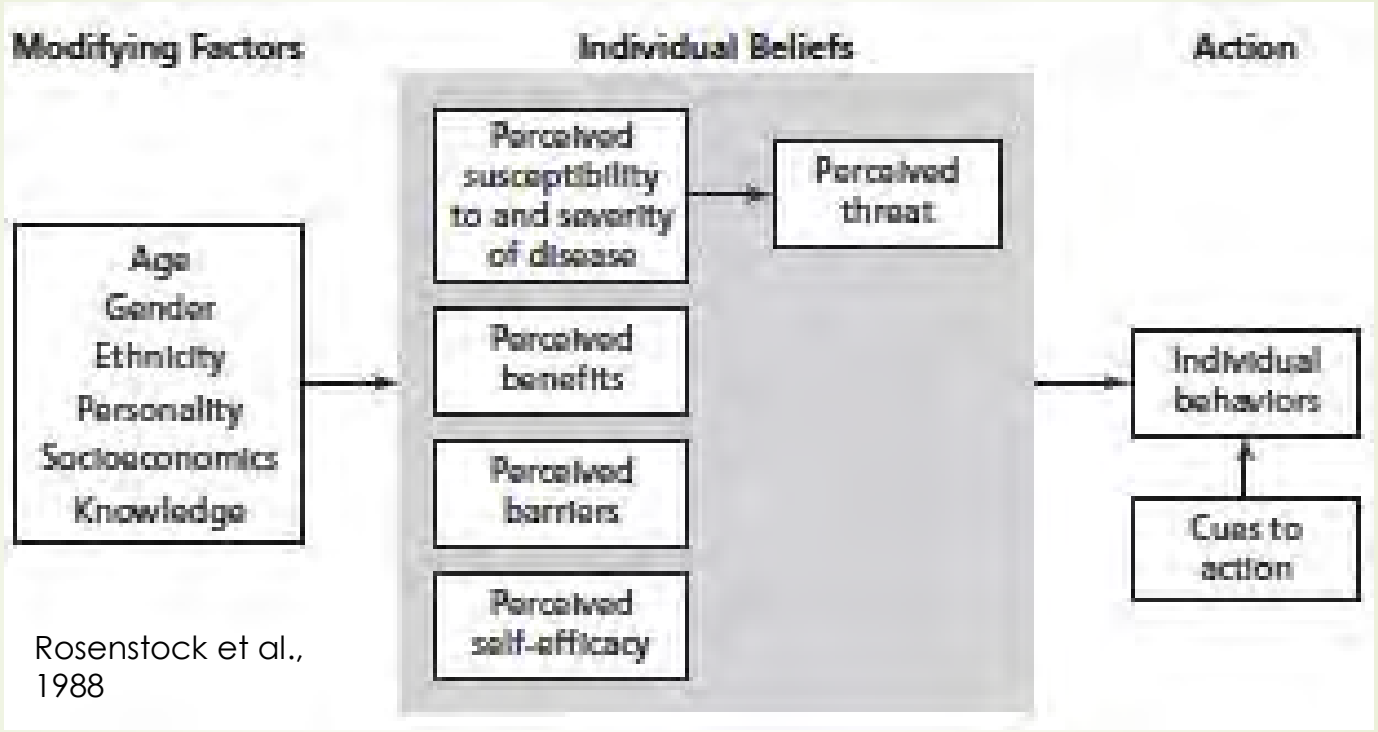
- Pain
- Not natural/organic
- Weaken immune system
- Autism
- Difficulty attending appointments
- Short track record of safety data
- Previous adverse reaction
- Vaccine additives
- Too many vaccines
- Risk of vaccination greater than disease

(Allan, 2021)

Factors Associated with Hesitancy

- Lower income family
- Higher income family
- Higher parental education level
- Lower parental education level
- Autism diagnosis in family
- Later birth order
- Alternative school attendance
- No regular care provider
- Use of complementary/alternative medicine
- Multiparous mother
- Single parenthood
- Younger parental age
- Child chronic illness
- Internet as primary information source

Health Belief Model



Rosenstock et al., 1988

How do parents make decisions about vaccination?

Cognitive Heuristics

- Omission bias
- Availability bias
- Affect heuristic
- Confirmation bias
- Bandwagon effect
- Illusions of causality

Profiles of Hesitancy

- The Dogmatic Non-Believers
- The Rational Free-Riders
- The Under-Informed
- The Under-Resourced
- The Systemically Alienated

The Dogmatic Non-Believers

"…when you look at sky rocketing auto immune diseases, autism, et cetera. Yes, there are all these studies that there's no link [between poor health and vaccination] but …. what has changed that dramatically? Vaccination is possibly one of the major things."

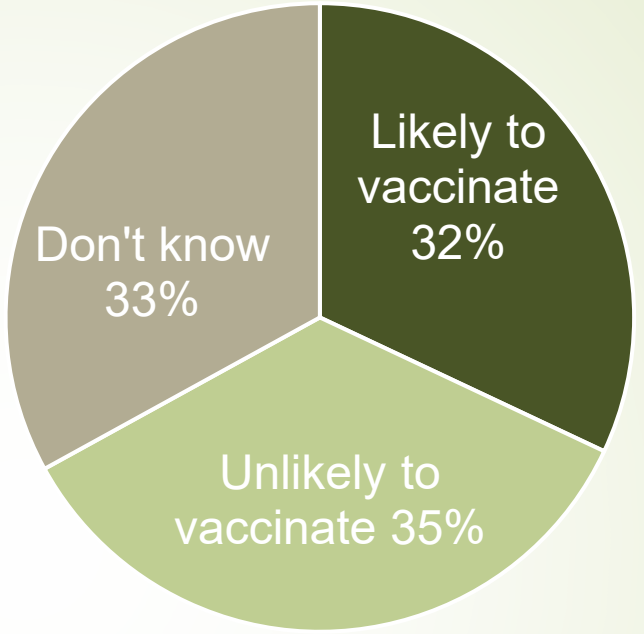
-Helps et al. (2019)

Intent to Vaccinate Following a VPD

- 32% admitted to hospital
- 15% cared for in ICU
- 89% under age 8

- Pertussis (47%)
- Varicella (33%)
- Pneumococcal disease (22%)

Allan, 2021



Only predictor of intention to vaccinate after VPD:
Having received other vaccines

The Rational Free-Riders

"…we recognize that social dilemma…[that] you're riding off the shirttails of everybody else, so everybody else is—if you believe that there is a potential adverse effect of vaccinations—then you're riding off the fact that everybody else is exposing their kid to those potential adverse effects."

-Reich, 2014

The Under-Informed

"…I know the myth has been debunked many times but the whole autism link. I didn't delay it, but I was very nervous about everything surrounding it."

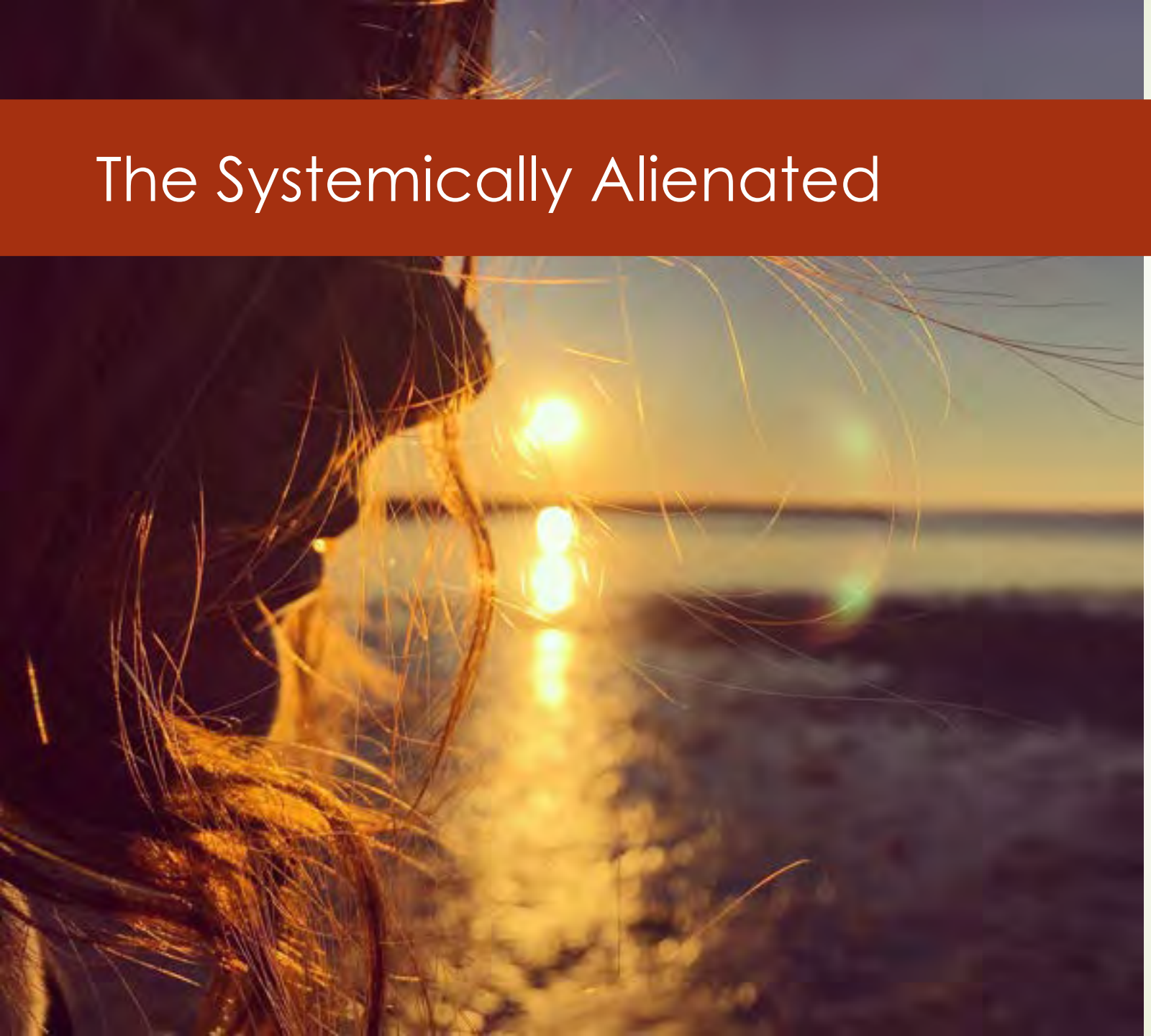
-Enkel et al., 2018

The Under-Resourced

"It's hard to commit to child health appointments six weeks in advance when we're not even sure where we'll be living. "

-Lannon et al., 1995

The Systemically Alienated



"…the first visits [after the baby was born] they come in to you, with quite heavy immunisation agendas… I felt like they were trying to manipulate me, without giving me a chance to think about it. It isn't about choice anymore, it's about an agenda."

-Helps et al., 2019

Healthcare Providers are Central

- Information/assurance from healthcare provider main factor in parents changing mind about vaccination (Gust et al., 2008)
- Among both vaccine-hesitant parents and vaccine-compliant parents, healthcare provider is most trusted source of information (Chung et al., 2017)

So…what works?

- Motivational Interviewing
- Personal Recommendations
- Presumptive Approach
- Community-based interventions

Motivational Interviewing

- Maternal education intervention (Gagneur et al., 2020)
- 15% increase in maternal intention to vaccinate
- 7% increase vaccine coverage at 7months, 9% increase at 2yrs
- 40% reduction in VH scores

Personal Recommendation

- Strong recommendations (active voice) and personal pronouns associated with higher rates of vaccination (Shay et al., 2018)
- "I vaccinate my own children."
- Personal recommendation associated with 5x greater vaccine compliance in practice (Allan, 2021)

Presumptive Approach

- "Well, we have to do some shots." (Presumptive)
- "What do you want to do about shots?" (Participatory)
- Participatory: 17x more likely to resist vaccination (Opel et al., 2013)
- 47% who were initially resistant, agreed with repeated recommendation (Opel et al., 2013)

Community-based Interventions

"People had always assumed [they] were just anti-vax, but in reality, in turns out issues were often around access."- Dr. Bonnie Henry

"This would be a dream come true." (Lannon, 1995)

- School-based clinics
- After-hours clinics
- Non-compliance fell by 50% (Simcoe-Muskoka) (Hapuhennedige, 2020)
- Wrap-around interventions (e.g. Early Years)

What does this mean for COVID-19?

- Vaccination history related to paediatric trial acceptance (Goldman, 2020)
- UK data related to parent acceptance indicates need to target specific cultural populations (Bell et al., 2020)
- 31% Canadian parents unsure, 9% would not vaccinate (Hetherington et al., 2021)

Thank you

- Questions?

- kate.allan@mail.utoronto.ca

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The Early Years
A Martin Family Initiative

THE EARLY YEARS

February 19th, 2020

Presented by: Charlene Rattlesnake & Chloe Ferguson

The Early Years
A Martin Family Initiative

Samson Cree Nation, Maskwacis AB

ABOUT THE EARLY YEARS

The Early Years (EY) takes a unique approach to supporting child well-being and strengthening families in the home and community.

The program staff and resources support the whole child in the context of their family by targeting the social factors that affect overall well-being—early learning, health and social services.

The Early Years honours Indigenous parents as their children's first and best teachers.

The Early Years
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Within the next five years, I can see the program having an impact on the whole community. Early Years will be known as the program that supports your success and makes your children successful too."

Early Years Visitor, Maskwacis AB

Szt'uminus First Nation, Vancouver Island, BC

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OUR GOALS

1. Support healthy pregnancies

2. Enrich children's pride in identity and culture

3. Enhance children's language development and overall school readiness

4. Provide play-based learning opportunities for children

5. Strengthen parenting capacity and family well-being

Pond Inlet, Nunavut

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PROGRAM MODEL

Prenatal – 24 months
Pregnant women and primary caregivers are supported by EY Visitors from the community

Group gatherings support participants in strengthening and expanding their social networks

Community Elders and relevant experts provide input on child-rearing and traditional care practices

Louis Bull Tribe, Maskwacis AB

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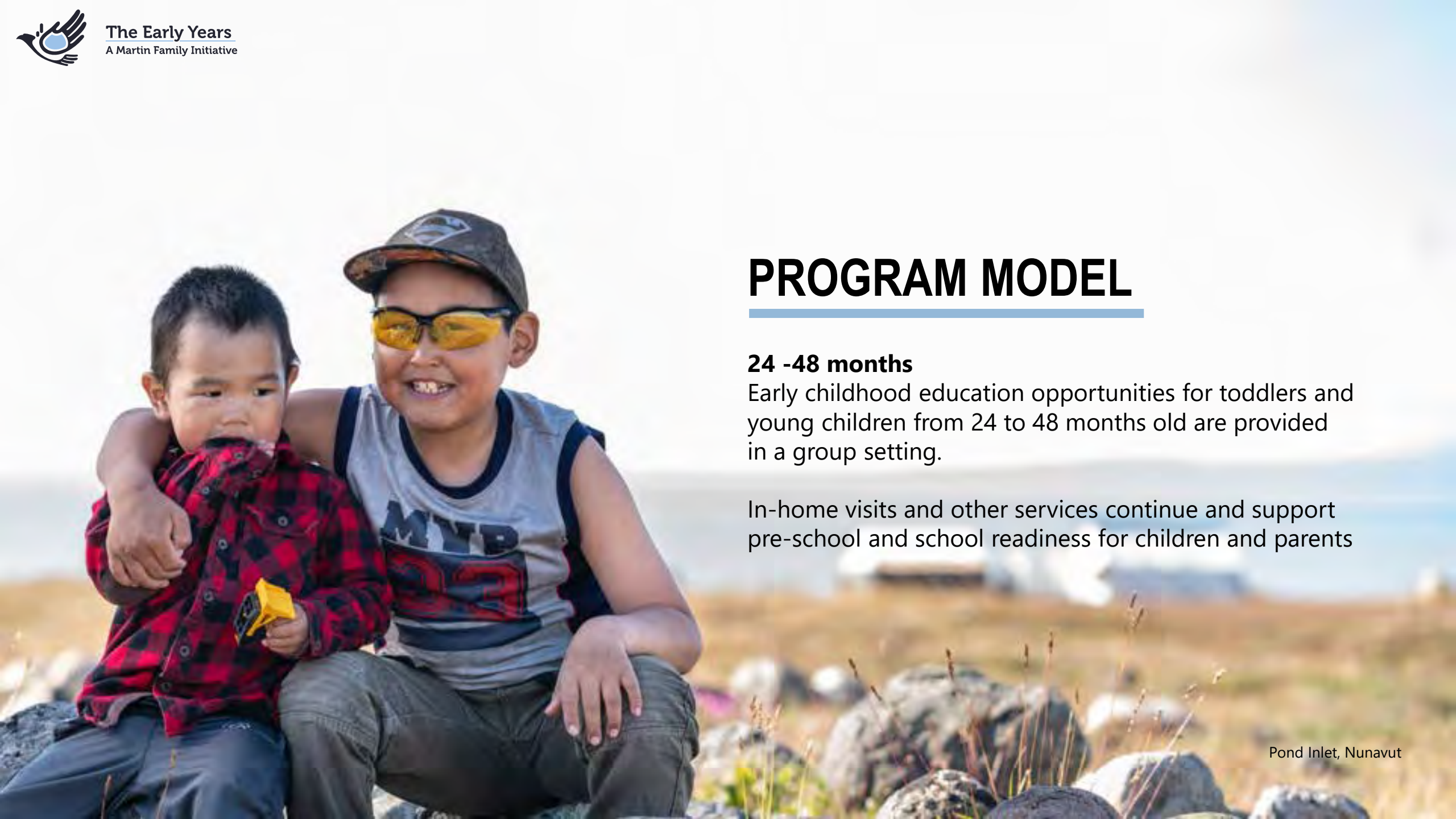

PROGRAM MODEL

24 -48 months
Early childhood education opportunities for toddlers and young children from 24 to 48 months old are provided in a group setting.

In-home visits and other services continue and support pre-school and school readiness for children and parents

Pond Inlet, Nunavut

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PROGRAM ADAPTATION

The program was created so that it could be adapted to suit the needs of individual communities, respond to specific cultural contexts, and work hand in hand with strong programs already being offered in community.

The content, implementation, and evaluation of the EY program is grounded in Indigenous culture and the lived experiences of children and families.

Ermineskin Cree Nation, Maskwacis AB

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PROGRAM LOCATIONS

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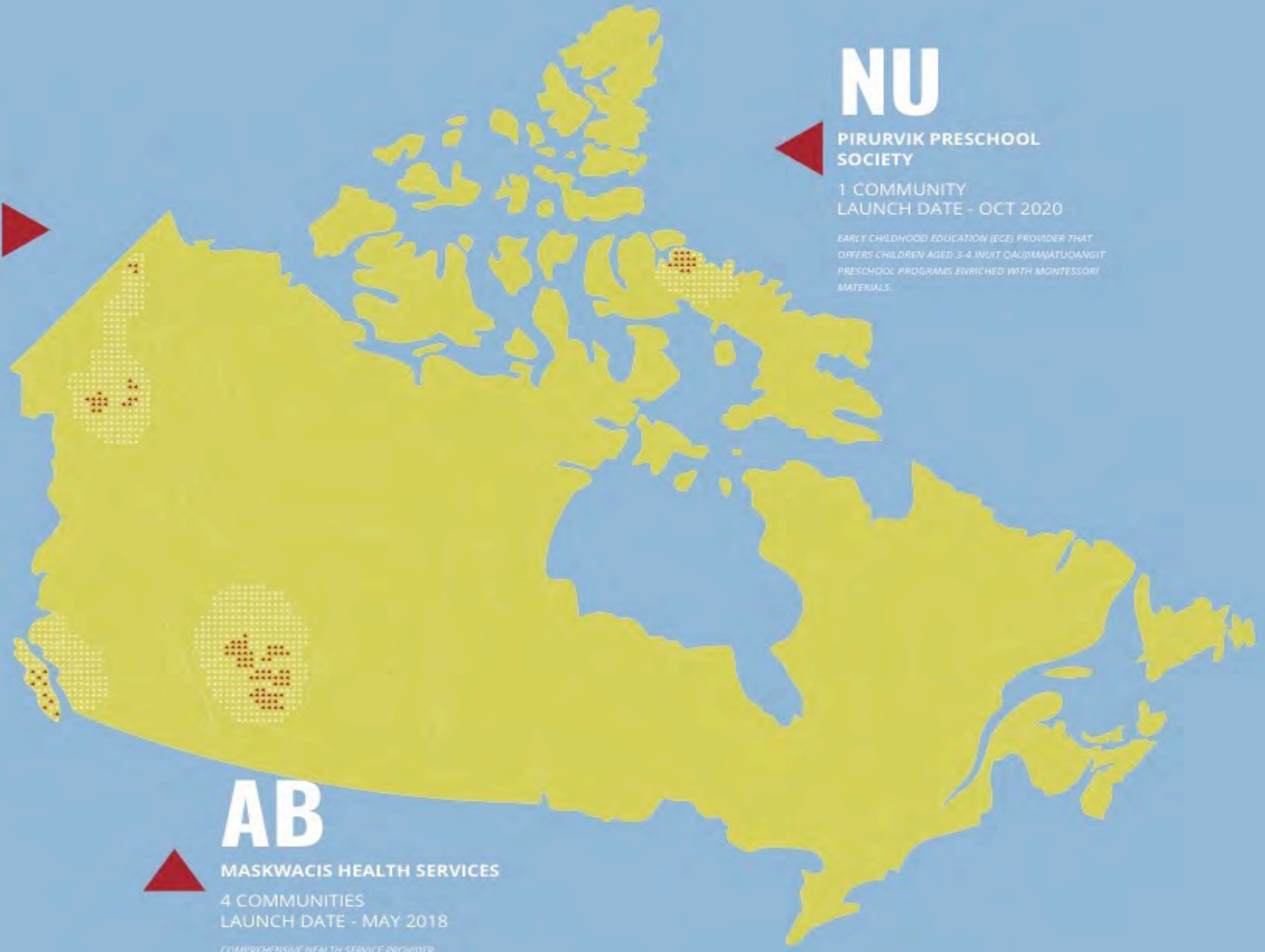

YT

YUKON FIRST NATION EDUCATION DIRECTORATE

4 COMMUNITIES
LAUNCH DATE - APR 2021

INDIGENOUS-LED EDUCATION ORGANIZATION THAT PROVIDES WRAP-AROUND SERVICE DELIVERY FOR STUDENTS, INCLUDING MOBILE COUNSELLING, SCHOOL ADVOCATES, FOOD PROGRAMMING, MATERNAL HEALTH AND EARLY CHILDHOOD EDUCATION SUPPORT.

NU

PIRURVIK PRESCHOOL SOCIETY

1 COMMUNITY
LAUNCH DATE - OCT 2020

EARLY CHILDHOOD EDUCATION (ECE) PROVIDER THAT OFFERS CHILDREN AGED 3-4 INUIT QAUJIMAJATUQANGIT PRESCHOOL PROGRAMS ENRICHED WITH MONTESSORI MATERIALS.

BC

KW'UMUT LELUM CHILD AND FAMILY SERVICES

9 COMMUNITIES
LAUNCH DATE - FEB 2021

FIRST NATION CHILD AND FAMILY SERVICES AGENCY THAT PROVIDES QUALITY CARE, PROTECTION, AND PREVENTION SERVICES FOR CHILDREN AND YOUTH AGED 0-19.

AB

MASKWACIS HEALTH SERVICES

4 COMMUNITIES
LAUNCH DATE - MAY 2018

COMPREHENSIVE HEALTH SERVICE PROVIDER FOR THE FOUR NATIONS OF MASKWACIS

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PROGRAM RESOURCES + CURRICULUM DEVELOPMENT

Ermineskin Cree Nation, Maskwacis AB

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UNDERSTANDING THE EARLY YEARS (EY-1)

- 40-hour training course for all EY program staff that weaves together Indigenous and non-Indigenous knowledge about early childhood development.
- Supports EY Visitors and staff members in their work with children and families by building upon their existing early childhood development knowledge in a culturally relevant setting.
- Facilitates the co-development of course content and employ an intentional co-instruction model throughout course delivery.
- Original course was developed in collaboration with Red River College, and recently revised and expanded. The revision was led by **Dr. Margo Greenwood**, Indigenous scholar, and early childhood educator.

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PROGRAM RESOURCES

EARLY YEARS TOOLBOX

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EARLY YEARS TOOLBOX

- Evidence informed resource which supports EY Visitors in their day-to-day work of home visiting.

- Consists of over 170 illustrated cards divided into five topic areas including healthy pregnancies, nurturing caregiving, play based interactions, language development and family well-being.

- The Toolbox has been translated into 6 FNIM languages including:
Cree, Inuktitut, Hul'q'umi'num, Gw'ichin, Kaska, and **Northern Tutchone.**

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EARLY YEARS TOOLBOX

Maskwacis Toolbox

Pirurvik Toolbox

YFNED Toolbox

Kw’umut Lelum Toolbox

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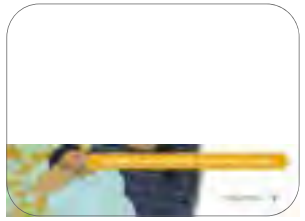
PROGRAM RESOURCES

TOOLBOX APP



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MEASURING IMPACTS

Maskwacis 2020

Evaluation is a cornerstone of the EY program as it is foundational to MFI's ability to track the progress of the program and to adjust and adapt as needed.

The Early Years Impact site is a program-specific data collection and case management tool developed by MFI. The EY Impact allows EY Visitors to view their participants' profiles, add Visit notes and evaluation questionnaires and track deadlines.

The data tool also supports EY Program Managers in community to evaluate the impact of the program on the community and refine the program delivery.

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MASKWACIS EARLY YEARS

- First Early Years program pilot began at the Ermineskin Cree Nation in 2018, and has since expanded to all four Nations in Maskwacis
- Collaboration with Maskwacis Health Services, Maskwacis Education Schools Commission and led by Charlene Rattlesnake and Heather Downie
- 13 Early years visitors from the four Nations of Maskwacis who are all mothers themselves support over 140 participants.

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Age of participants

Many moms are

18-23

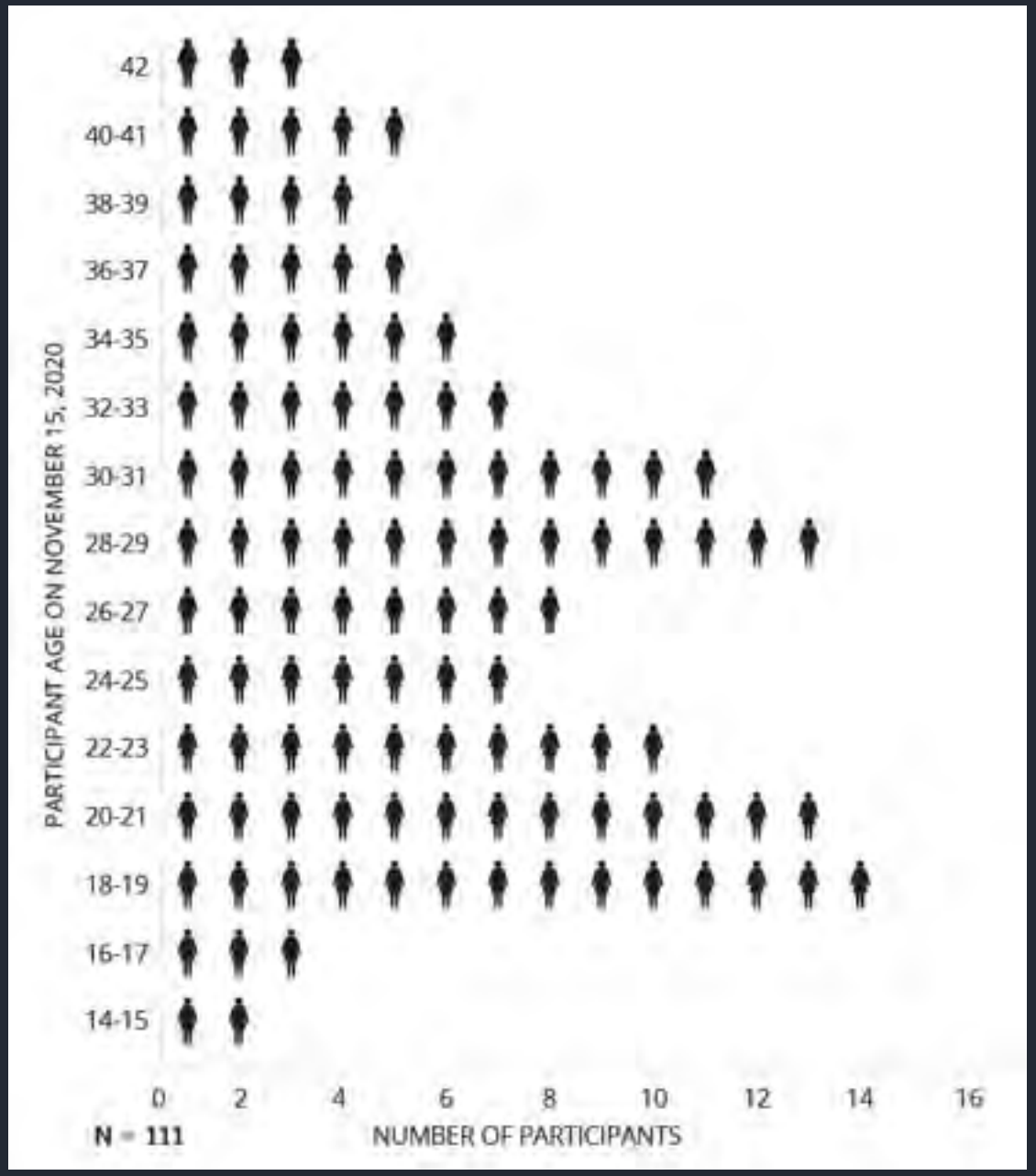
and

28-31

Average age is

27

years old



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Location of visits

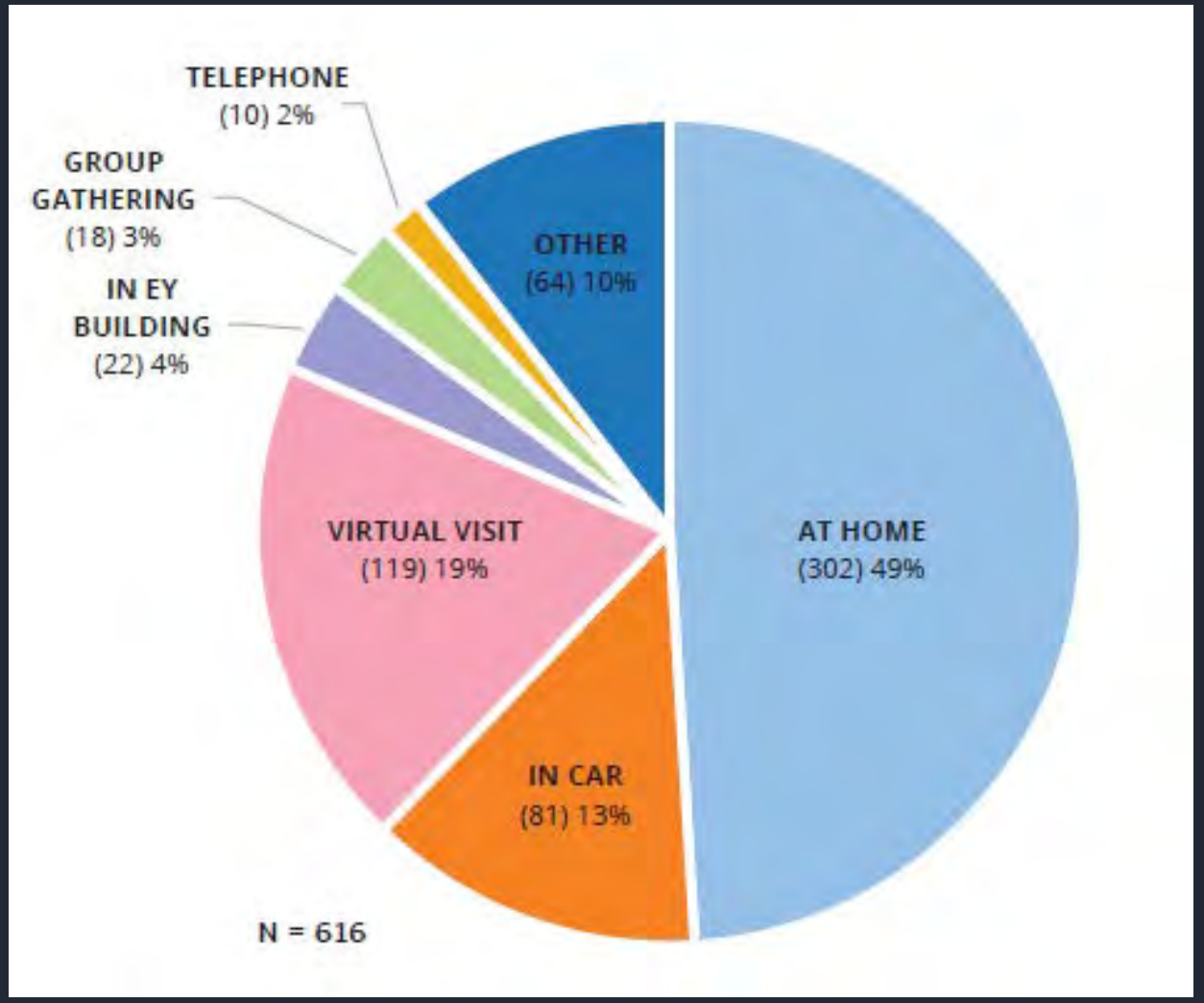
Most visits happened

at home

(especially before COVID-19)

Virtual visits

were second most common
(especially after COVID-19)



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Who was at visits?

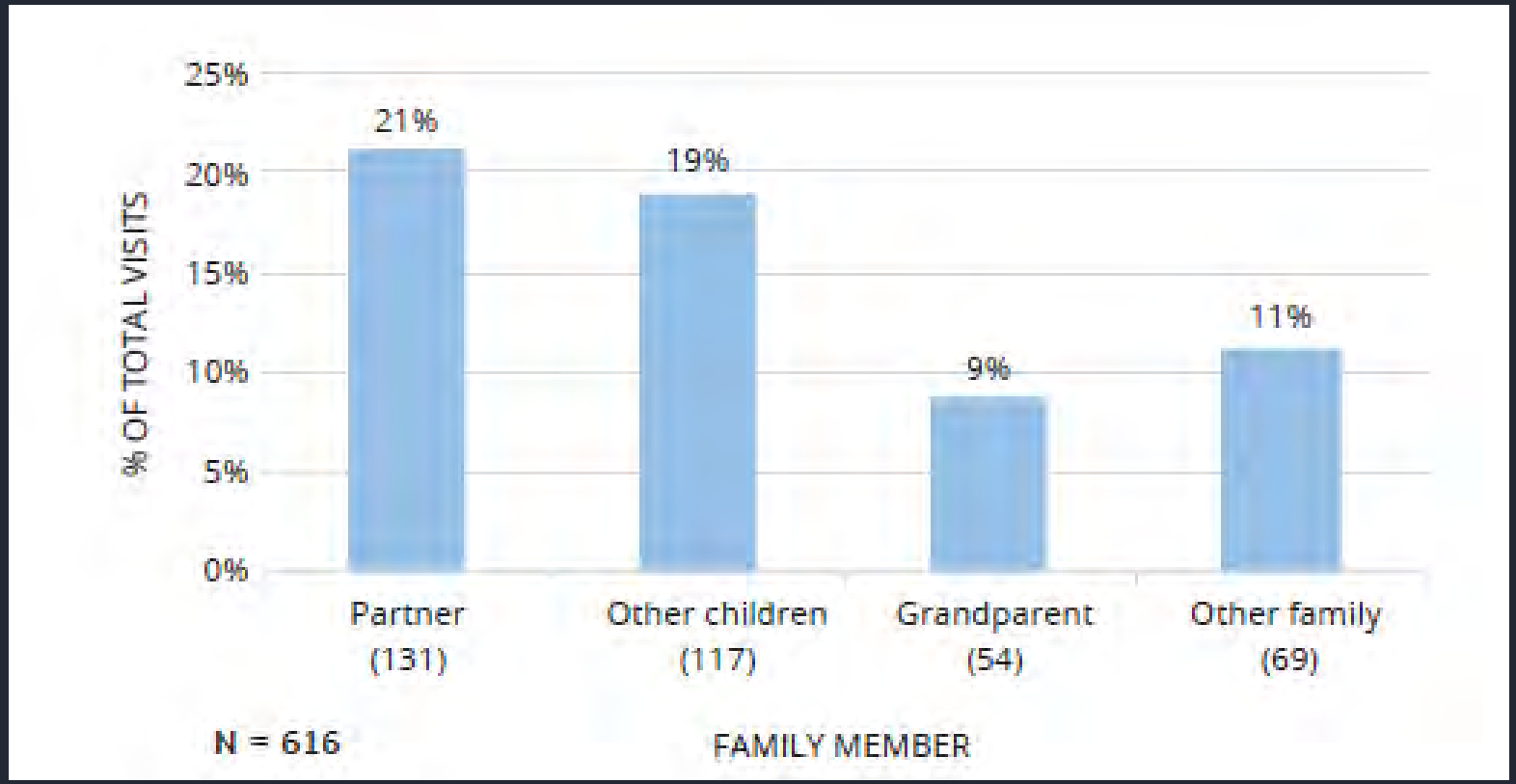
Another family member was present at

more than half

of visits

Including:

Partner
Other children
Grandparent



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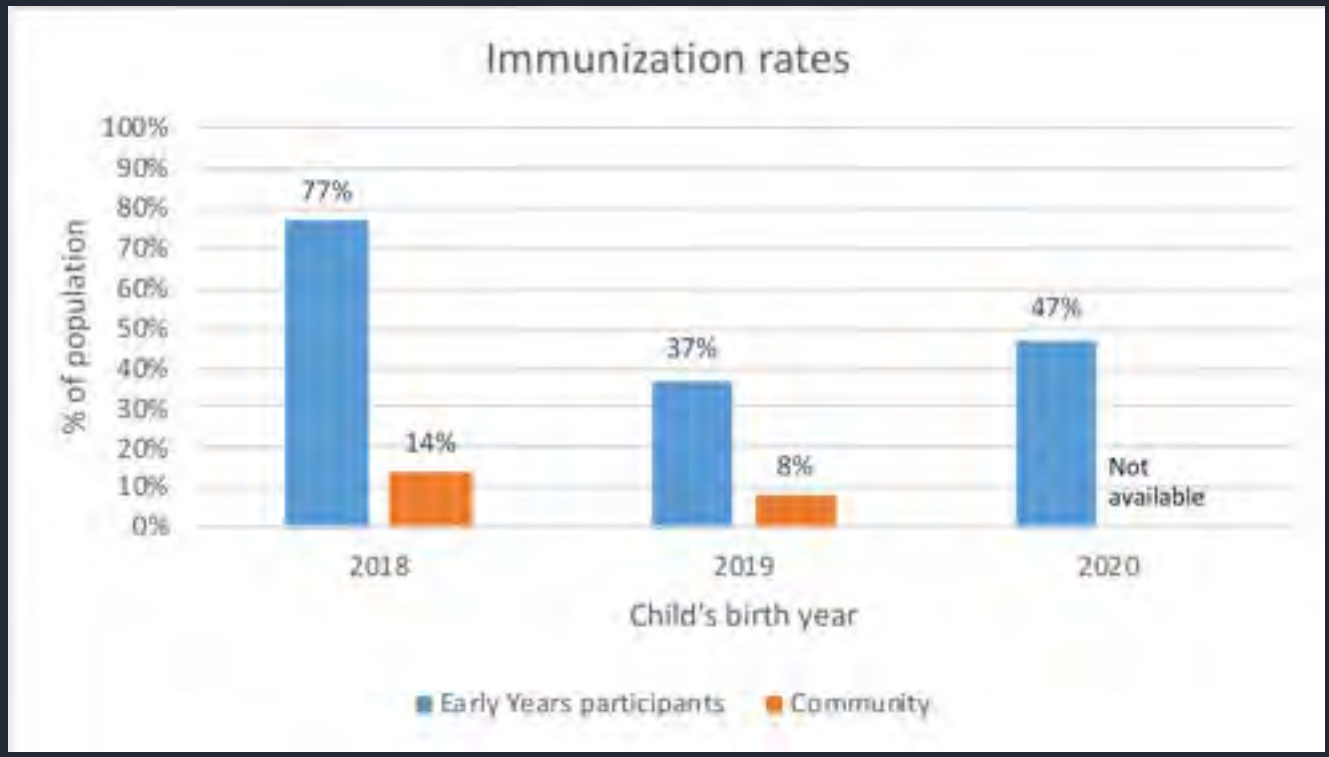
Immunizations

51%

of EY children are up to date with immunizations

Early Years participants are immunized at a much higher rate than the broader community.



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Immunizations

- Information about immunizations provided by an Early Years Visitor once a relationship with family has been well established.
- Frequent immunization clinics offered in a safe and familiar setting with resources such as snacks, books, and toys provided.
- Transportation provided as needed

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Public Health Ontario | Santé publique Ontario

COVID-19 Immunization in Children: Looking Towards the Future

Dr. Sarah Wilson

COVID-19 Vaccination and Child Health

February 19, 2021

Disclosures

- No relationships with private industry or vaccine manufacturers
- Mom of two children who keep asking me when COVID will end

Background

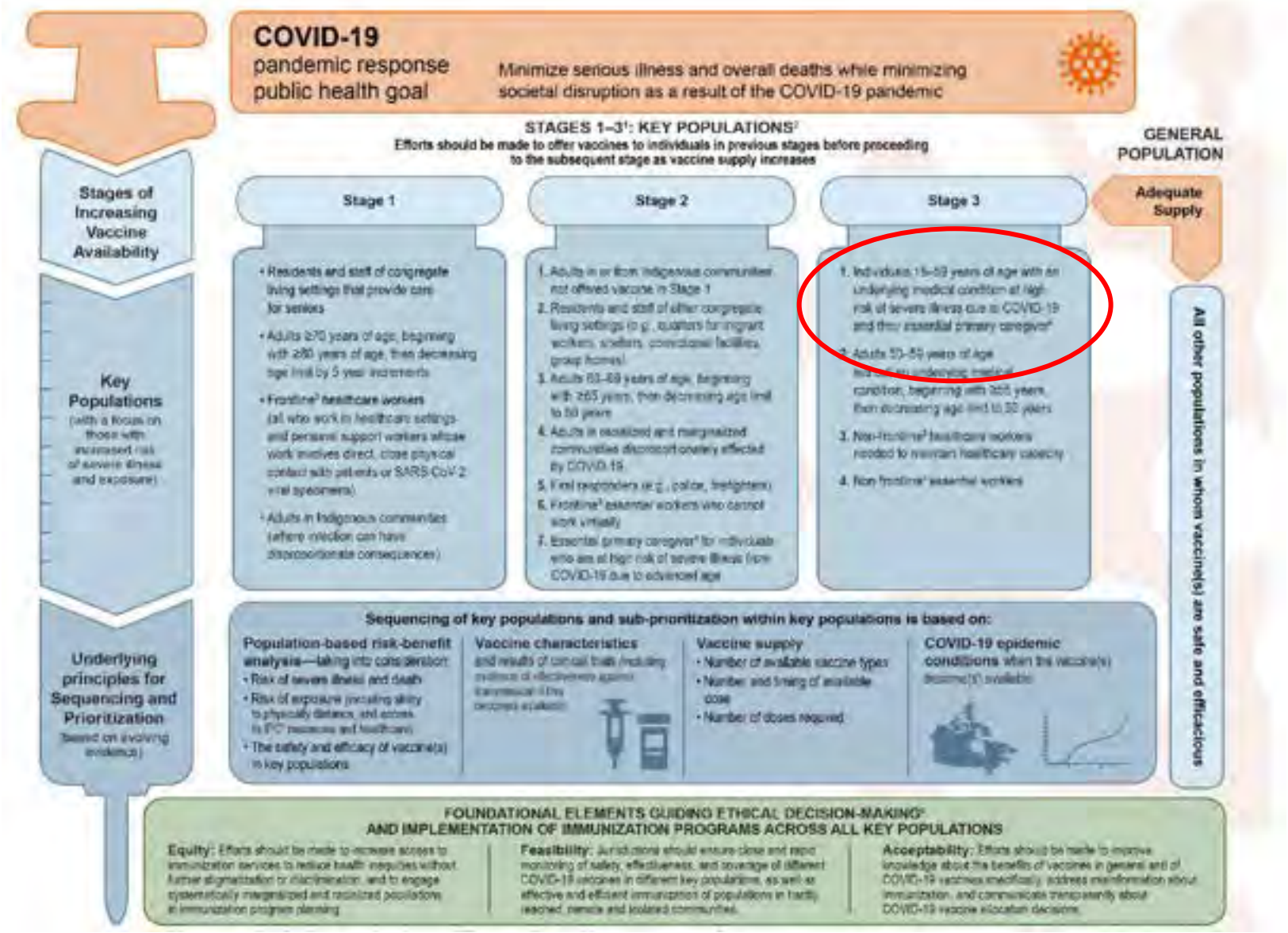
- Overview of the National Advisory Committee on Immunization (NACI) Prioritization Guidance
- Approved COVID-19 vaccines and candidates: current age indications and clinical trial enrollment
- Vaccine program decision-making: considerations

National Advisory Committee on Immunization (NACI) Prioritization Guidance: Underlying principles

- Population-based risk-benefit analysis, taking into consideration:
  - Risk of severe illness and death from COVID-19
  - Risk of exposure to SARS-CoV-2 (including ability to physically distance, as well as access to other infection prevention and control measures and healthcare)
  - Safety and efficacy of authorized vaccines in key populations
- Vaccine characteristics and results of clinical trials
- Vaccine supply
- COVID-19 epidemiology

NACI. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7

NACI Prioritization Guidance



Stage 3: Individuals **16-59** years of age with an underlying medical condition at high risk of severe due to COVID-19 and their essential primary care giver

NACI. Available at: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-prioritization-key-populations-covid-19-vaccination.html

COVID-19 vaccines: Platforms, age indications and NACI recommendations for use

	Pfizer-BioNTech vaccine	Moderna vaccine	AstraZeneca vaccine (not yet approved for use in Canada)
Vaccine platform	mRNA	mRNA	Non-replicating viral vector (adenovirus)
Current age indication	16+ years	18+ years	EMA: 18+ years[1] WHO: 18+ years[2]
NACI guidance on use in adolescents	Discretionary recommendation in those 12-15	No recommendation	No recommendation

1. https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf
2. https://www.who.int/news/item/15-02-2021-who-lists-two-additional-covid-19-vaccines-for-emergency-use-and-covax-roll-out

NACI recommendations

- A **strong recommendation** applies to most populations/individuals and should be followed unless a clear and compelling rationale for an alternative approach is present

- A **discretionary recommendation** may be offered for some populations/individuals in some circumstances. Alternative approaches may be reasonable

NACI. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7

NACI recommendations for use of COVID-19 vaccines in adolescents

- NACI recommends that COVID-19 vaccine(s) should not be offered to individuals who are not in the authorized age group. (**Strong NACI Recommendation**)

- However, a complete vaccine series with a Pfizer-BioNTech may be offered to individuals 12-15 years of age who are:
  - at **very high risk of severe outcomes of COVID-19** (e.g., due to a pre-existing medical condition known to be associated with increased risk of hospitalization or mortality) and
  - are at **increased risk of exposure** (e.g., due to living in a congregate care facility),
  - if a **risk assessment deems that the benefits outweigh the potential risks** for the individual, and if informed consent with the individual and the parent or guardian includes discussion about the insufficiency of evidence on the use of COVID-19 vaccines in this population. (**Discretionary NACI Recommendation**)

NACI. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html#a7

COVID-19 vaccines: Clinical trial enrollment of children/adolescents

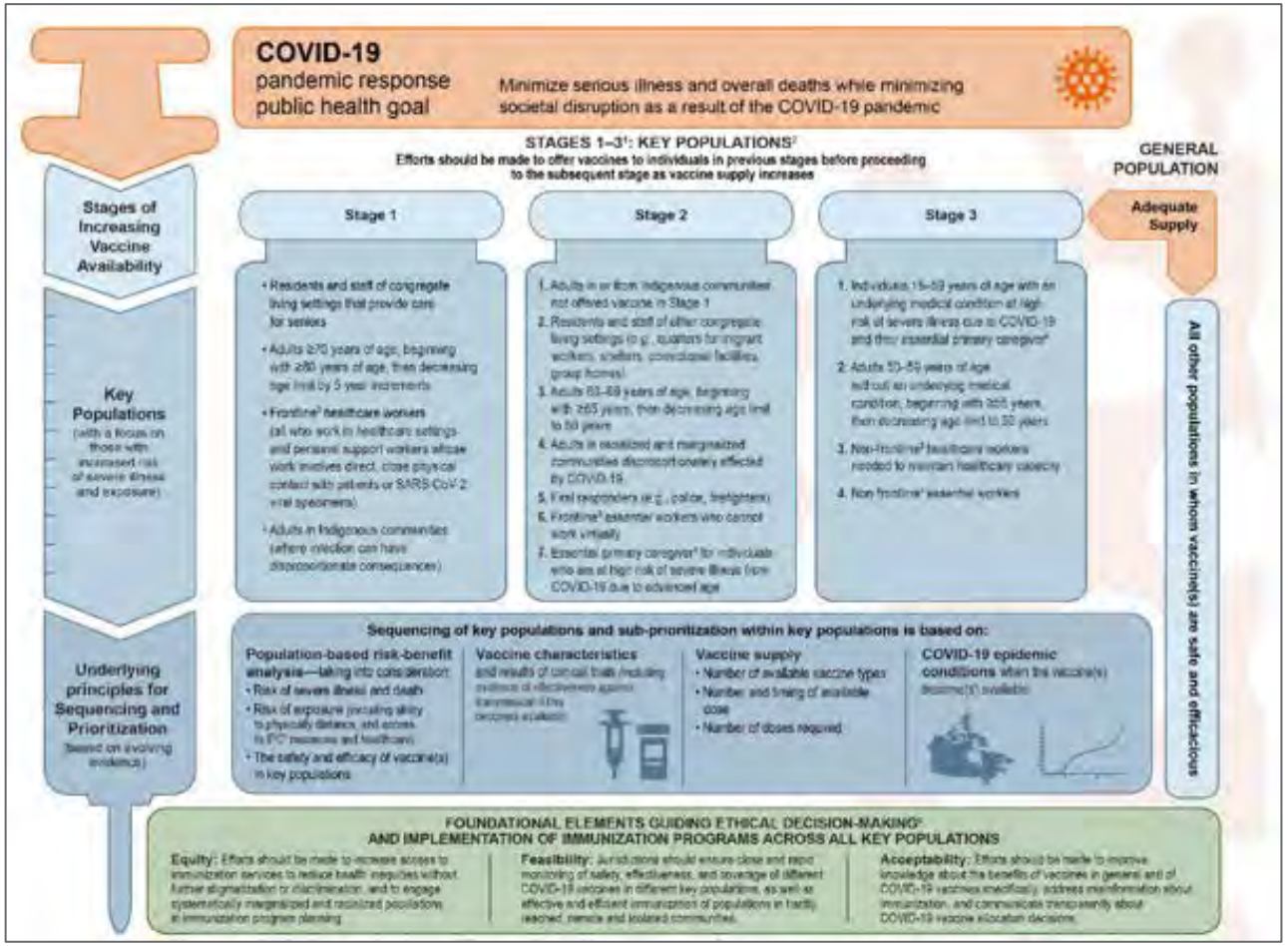
	Pfizer-BioNTech vaccine	Moderna vaccine	Astra Zeneca vaccine	Janssen vaccine
Current age indication (Health Canada)	16+	18+	n/a	n/a
Enrollment	n=2,259 enrolled (Phase 3)	Goal: 3,000 (Phase 3)	Goal: 300 COVID-vaccine arm n=240; placebo n=60[4] (Phase unspecified)	1,200 subjects (all ages) for Phase 2 dosing/schedule study[5]
Ages	12 to 15 years	12 to 17 years	6 to 17 years	12 to 17 years
Enrollment status	Complete[1]	Ongoing	Enrolling this month	Ongoing
Start date	April 2020	December 2020	February 2021	August 2020
Estimated study completion	"First half of 2021"[2]	June 2022	Unstated	December 2021

1. https://www.reuters.com/article/health-coronavirus-pfizer-int-idUSKBN29R26A 2. https://www.aappublications.org/news/2021/01/27/acip-covid-vaccine-pediatric-trials-012721
3. https://www.clinicaltrials.gov/ct2/show/NCT04649151?term=vaccine&cond=covid-19&age=0&draw=2&rank=3
4. https://www.theguardian.com/world/2021/feb/13/oxford-astrazeneca-covid-vaccine-to-be-tested-on-children-as-young-as-six 5. https://clinicaltrials.gov/ct2/show/NCT04535453

Stages of increasing vaccine availability

- Key populations are sequenced in three stages corresponding to increasing vaccine availability in each quarter of 2021

- By the end of the third quarter of 2021, it is anticipated that sufficient vaccine supply will be available to offer vaccines to the general Canadian population



Vaccine program considerations once vaccines are available for children/adolescents

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Vaccine

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An analytical framework for immunization programs in Canada

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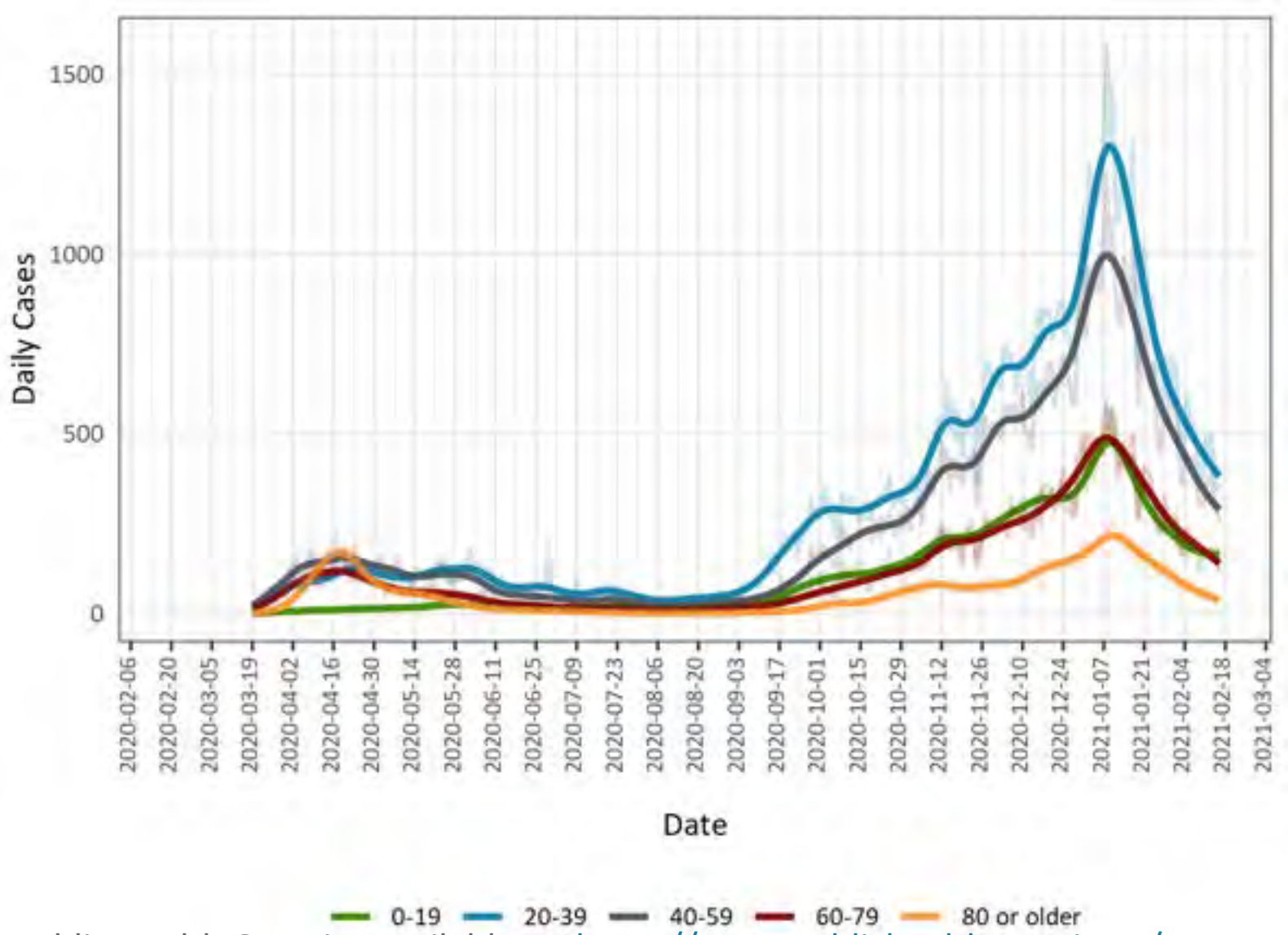
Analytic Framework for Vaccine Decision Making:
Ericson and De Wals

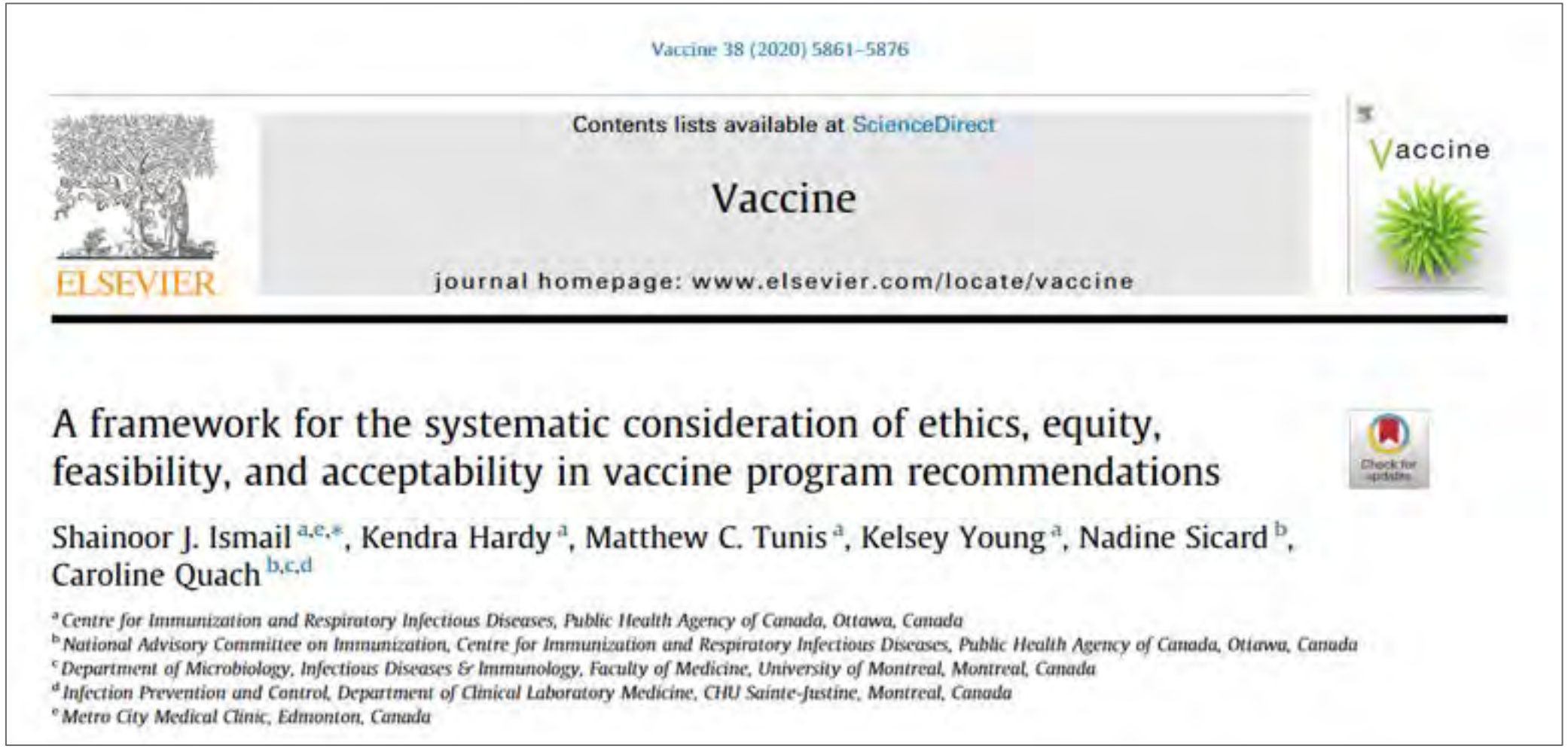
Disease Characteristics and Burden	• Disease (infectious agent, mode of transmission etc.) • Epidemiology
Vaccine Characteristics	• Efficacy, effectiveness (short and long-term) • Safety: short-term, long-term
Alternative Immunization Strategies	• Schedules • Age group / Risk group • Modes of delivery (physician, public health, school-based)
Social and Economic Costs and Benefits	• Vaccine related • Disease related • Perspective (societal /individual)
Feasibility and Acceptability	• Public • Professionals • Political
Ability to Evaluate Programs	• Vaccine effectiveness • Adverse events • Vaccine coverage • Disease • Screening programs
Research Questions	• Fundamental • Intervention • Program Delivery
Other Considerations	• Equity • Ethical • Legal • Political
Overall Recommendation	• Who should receive vaccine? • Should this vaccine be publicly funded?

Ontario COVID-19 epidemic curve: Case counts by age



Public Health Ontario: Available at: https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-epi-trends-incidence-ontario.pdf?la=en

Vaccine program considerations once vaccines are available for children/adolescents: ethics, equity, feasibility, acceptability



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A framework for the systematic consideration of ethics, equity, feasibility, and acceptability in vaccine program recommendations

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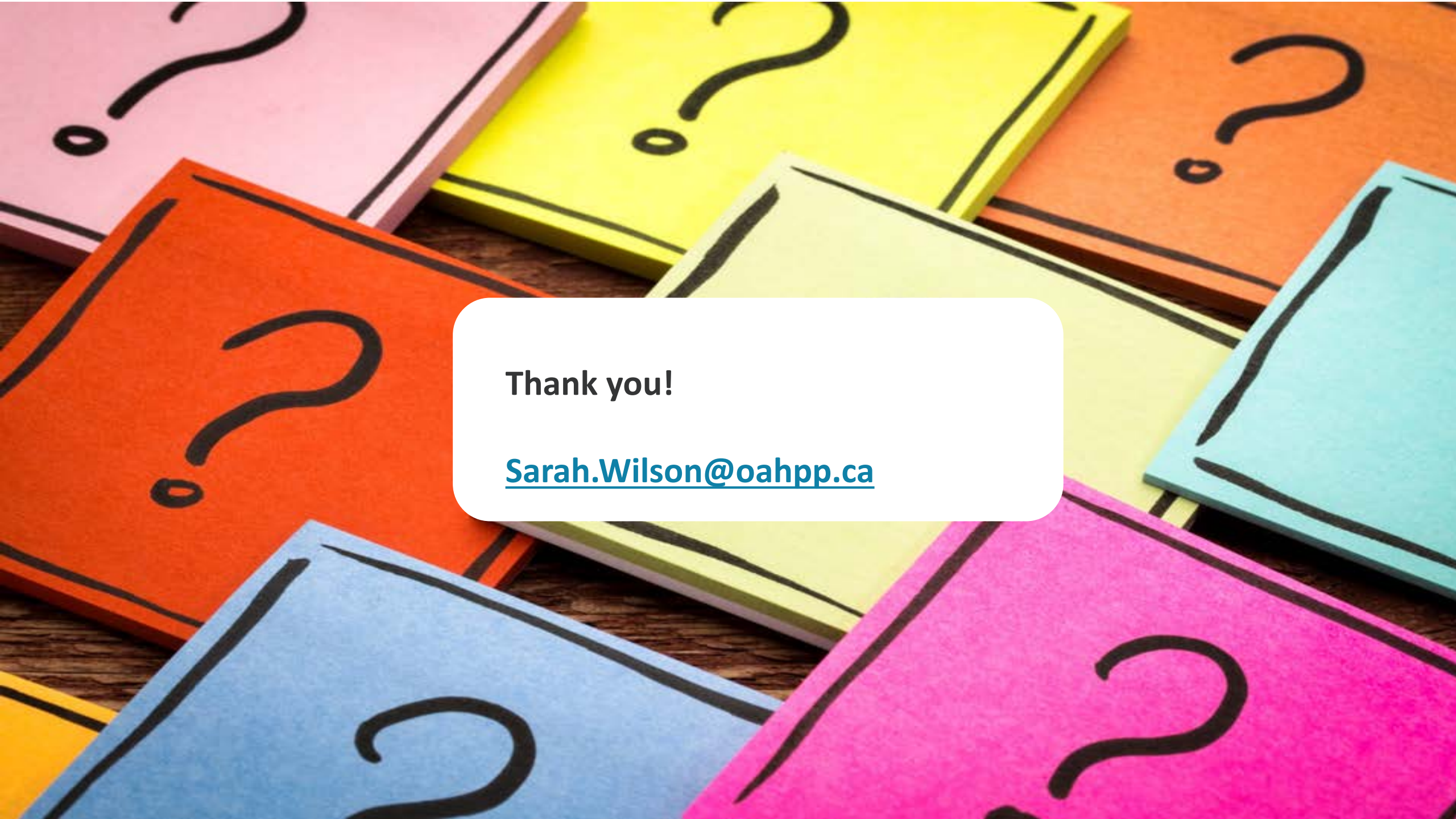
Questions to inform vaccine program decision-making

- Impact of vaccines on asymptomatic infection and transmission
- Impact of variants of concern on vaccine effectiveness
- Coverage among high risk adults and general adult population
- Safety of COVID-19 vaccines in children/adolescents based on clinical trials with relatively small numbers
- Acceptability of COVID-19 vaccines among parents/guardians and children/adolescents
- Impact of COVID-19 vaccines on community epidemiology and their impact in reducing risk of clinical severity among those vaccinated
- Vaccine program goal for children: reducing serious illness/death (direct protection) or reducing societal disruption (indirect protection of others) or both



Thank you!

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