



COVID-19
IMMUNITY
TASK FORCE

GRUPE DE TRAVAIL
SUR L'IMMUNITÉ
FACE À LA COVID-19



CanCOVID



Seminar Series | Research Results & Implications

COVID-19 vaccine safety



May 5, 2022 | 11:30 a.m. to 1:00 p.m. EDT

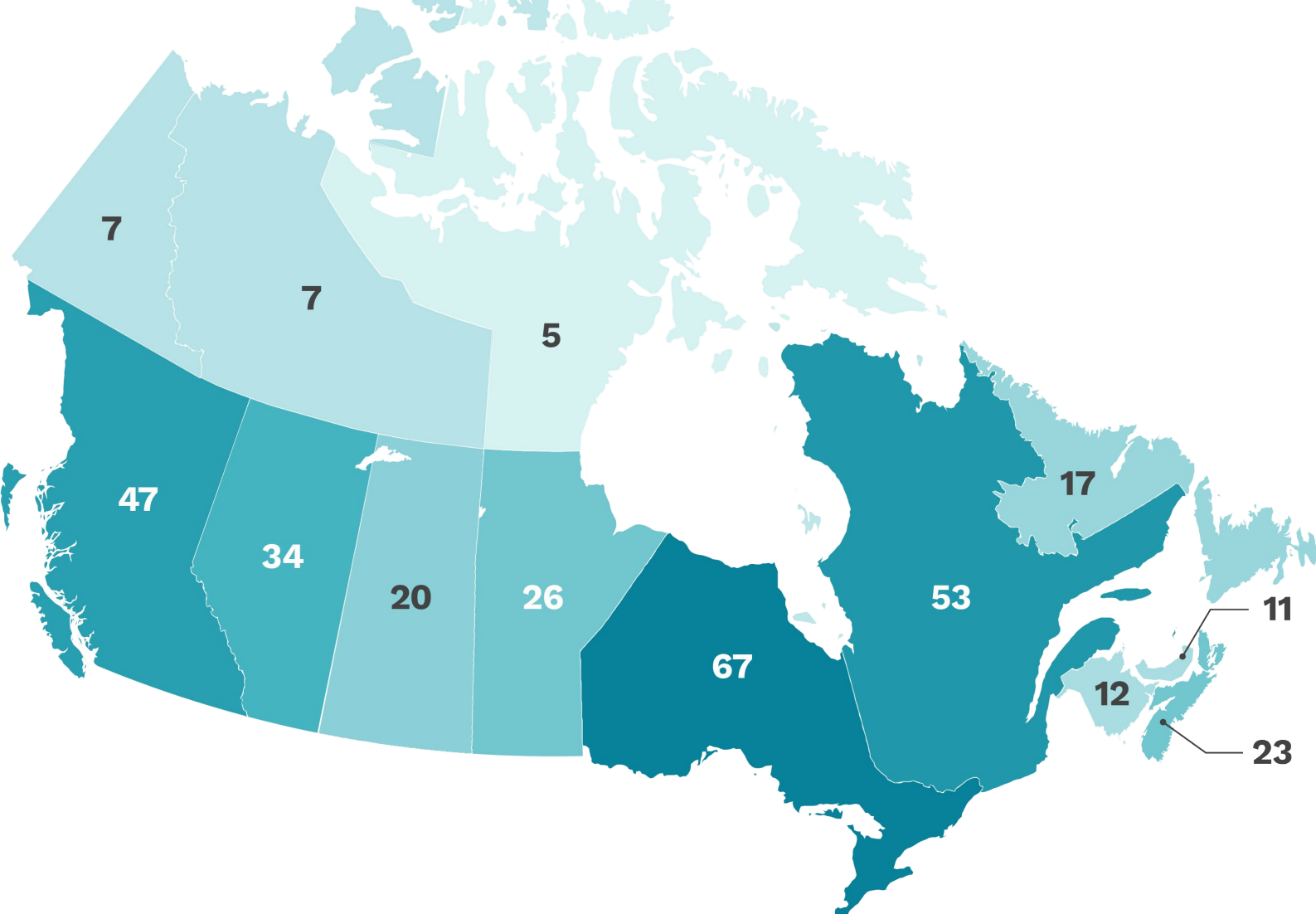
Moderator

Dr. Tim Evans

Executive Director, COVID-19 Immunity Task Force



CITF supports studies active across Canada

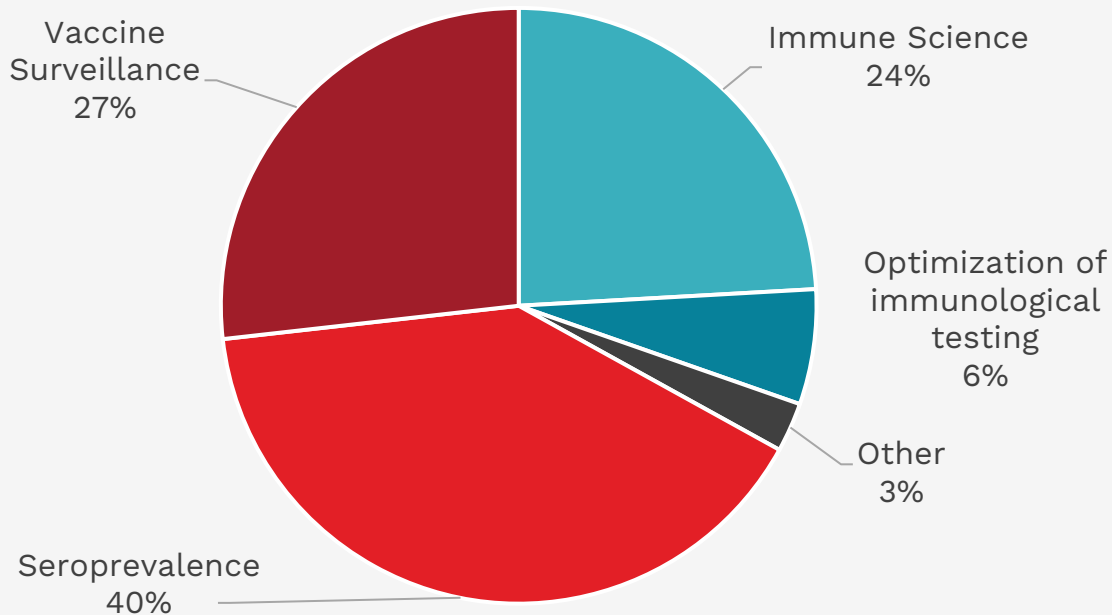


113 studies



Vaccine safety: a critical component of vaccine surveillance

Over a quarter of CITF's funded studies focus on vaccine surveillance



- All vaccines approved in Canada go through rigorous testing during clinical trials and must pass a stringent approval process by Health Canada.
- This has been the case for all COVID-19 vaccines approved over the last 2 years.
- The CITF and its Vaccine Surveillance Working Party support vaccine safety and effectiveness studies of Health Canada approved COVID-19 vaccines in collaboration with:
 - ▶ Public Health Agency of Canada (PHAC)
 - ▶ Canadian Immunization Research Network (CIRN)
 - ▶ National Advisory Committee on Immunization (NACI)

Adverse events due to COVID-19 vaccines are very rare

- # vaccine doses administered in Canada: 82,185,545
- Total adverse events following immunization: **0.054%** (44,154 events)
 - ▶ Non-serious – **0.043%** (35,035 events)
 - ▶ Serious – **0.011%** (9,119 events)
 - ▶ Deaths – **0.00000273%** (224*)
*includes 56 still under investigation

- The adverse event may be any:
 - ▶ unfavourable or unintended sign (e.g., skin rash)
 - ▶ abnormal laboratory finding
 - ▶ symptom
 - ▶ disease
- An event is considered serious if it:
 - ▶ is life-threatening (patient was at risk of death at the time of the event/reaction)
 - ▶ requires in-patient hospitalization or prolongation of existing hospitalization
 - ▶ results in persistent or significant disability/incapacity, or
 - ▶ results in a congenital anomaly/birth defect
 - ▶ results in death

Speakers

Scott Halperin, MD, Professor, Dalhousie University; Principal Investigator, CIRN; member of the CITF Leadership Group and Chair of the CITF Vaccine Surveillance Working Party.

Julie Bettinger, MPH, PhD, Professor, University of British Columbia; Principal Investigator, Canadian National Vaccine Safety (CANVAS), Canadian Immunization Research Network (CIRN); CITF-funded researcher.

Karina Top, MD, MSc, FRCPC, Associate Professor, Dalhousie University; Principal Investigator, Special Immunization Clinic (SIC) Network at CIRN; and co-PI, Canadian Immunization Monitoring Program, ACTive (IMPACT) Project; CITF-funded researcher.

Jeff Kwong, MD, MSc, CCFP, FRCPC, Senior Scientist, ICES; Scientist, Public Health Ontario; Professor, Department of Family & Community Medicine and Dalla Lana School of Public Health, University of Toronto; CITF-funded researcher.

COVID-19
Vaccine Safety:
An Introduction

Dr. Scott A. Halperin

Professor, Department of Pediatrics and Microbiology
& Immunology, Division of Infectious Diseases,
Dalhousie University, IWK Health Centre

Principal Investigator, CIRN

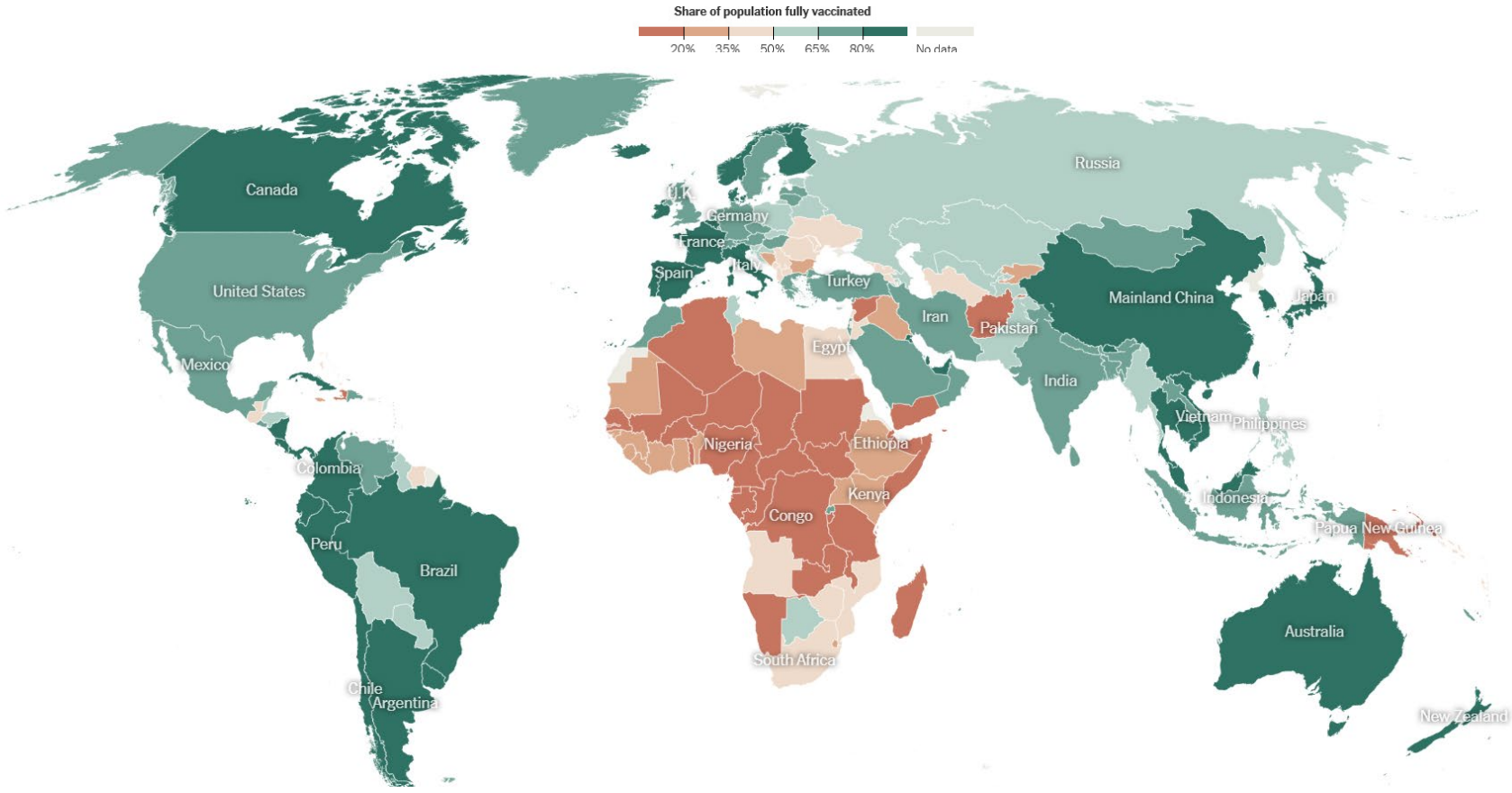
Member of the CITF Leadership Group and Chair of
the CITF Vaccine Surveillance Working Party



Disclaimer

I have received research funding from various COVID-19 vaccine manufacturers, including approved vaccines (Pfizer, Moderna, CanSino, Medicago). I have also served on ad hoc advisory boards for various COVID vaccine manufacturers including Astra Zeneca, Pfizer, Medicago, Novavax, and Moderna.

Status report: Global COVID-19 vaccine usage



>5.6 billion people have received a dose worldwide

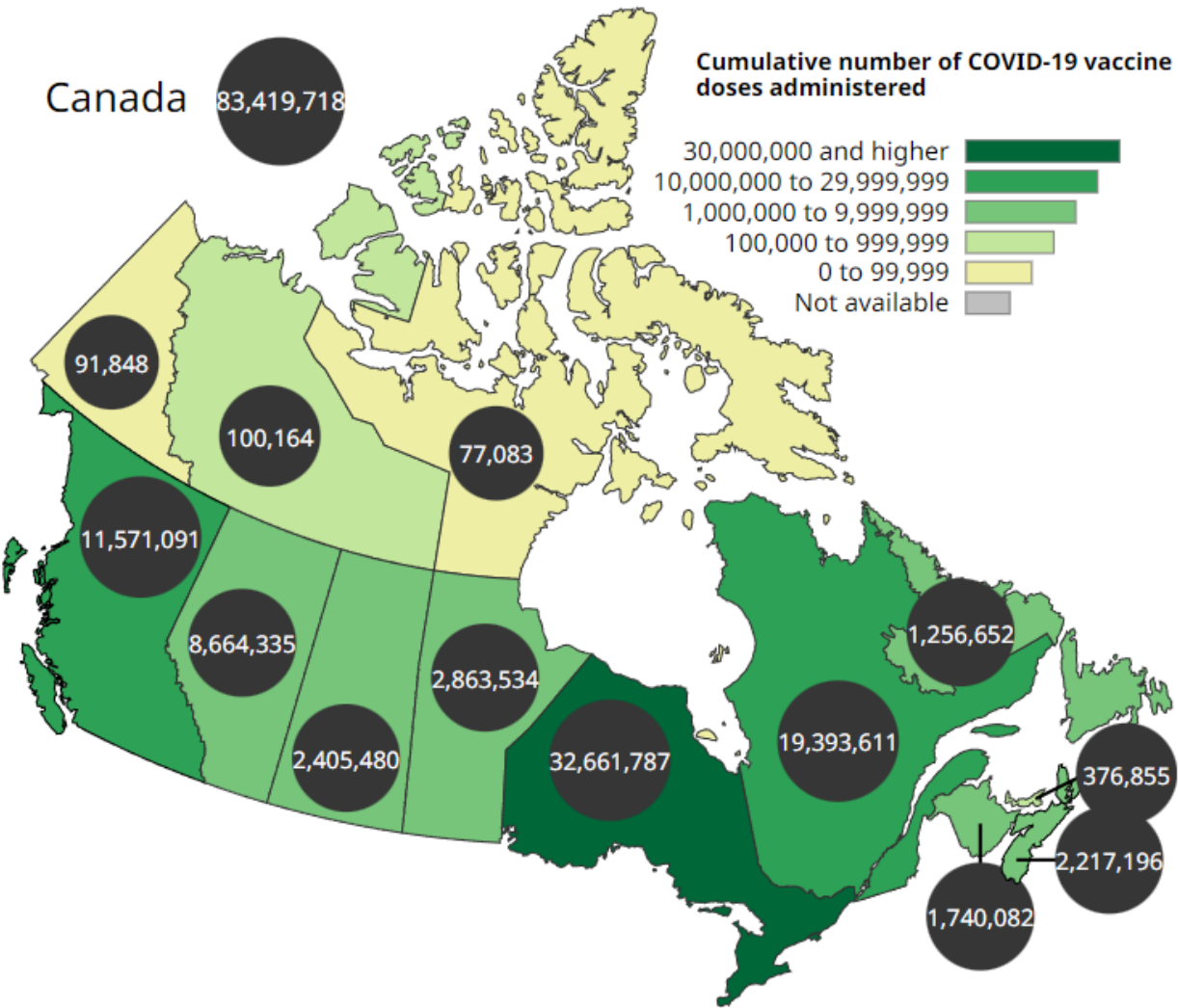
- ▶ 66.7% of global population

11.5 billion doses given

<https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/> as of April 2022

<https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> as of 16 April 2022

Status report: COVID-19 vaccine use in Canada



- >83.4 million doses administered in Canada
 - ▶ 32.5 million 1st doses
 - ▶ 31.1 million 2nd doses
 - ▶ 18.0 million 3rd doses
- 84.8% of total population received at least 1 dose
 - ▶ 81.4% fully vaccinated
- 89.1% of population over 5 years received at least 1 dose
 - ▶ 85.6% fully vaccinated

<https://health-infobase.canada.ca/covid-19/vaccine-administration/> as of 14 April 2022

Vaccine (mis)perceptions: What's driving vaccine hesitancy

Perceptions

- New virus, new vaccine
- New technology
 - ▶ mRNA
- Rushed approvals, short-cuts
 - ▶ Emergency use authorization
- Politicization of vaccines/vaccination
 - ▶ Freedom to choose
 - ▶ Mandates



Reality

- Lessons learned from SARS-CoV-1
- mRNA vaccines previously in clinical trials for over 10 years
- Approval of vaccines in under 10 months compared to 5-10 years
 - ▶ Moon shot strategy
 - ▶ Regulatory efficiencies
 - ▶ Adaptive designs
- Spillover from the US
 - ▶ Polarization following mandates
 - ▶ Breakdown of unified approach

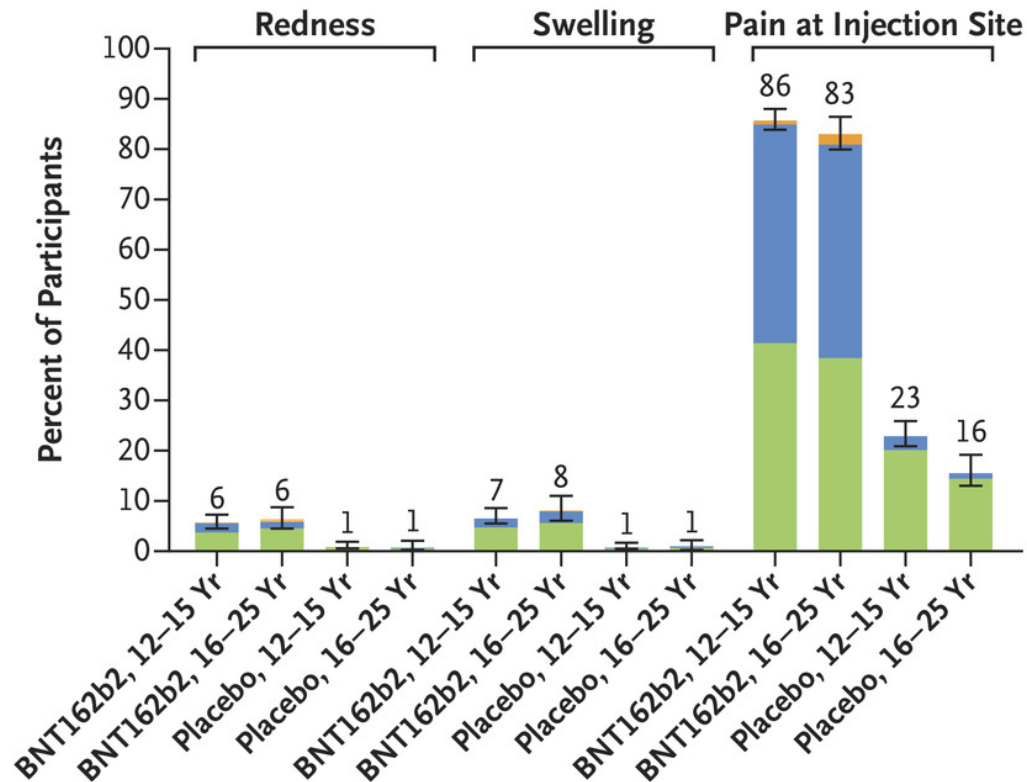
Vaccine safety reality: Adverse events following immunization (AEFI)

- Mild AEFI are frequent, moderate AEFI are common
 - ▶ Adverse events more common after mRNA vaccines than after vectored or inactivated virus vaccines
- Most AEFI are mild or moderate severity
- No clear pattern between first and second doses
- Serious adverse events are rare
 - ▶ Vary by vaccine type
 - Anaphylaxis
 - Adenovirus vectored vaccines and venous thrombotic events and thrombocytopenia
 - Myocarditis/pericarditis and mRNA vaccines
- More active vaccine safety surveillance in place in Canada (and globally) than for any previous vaccine

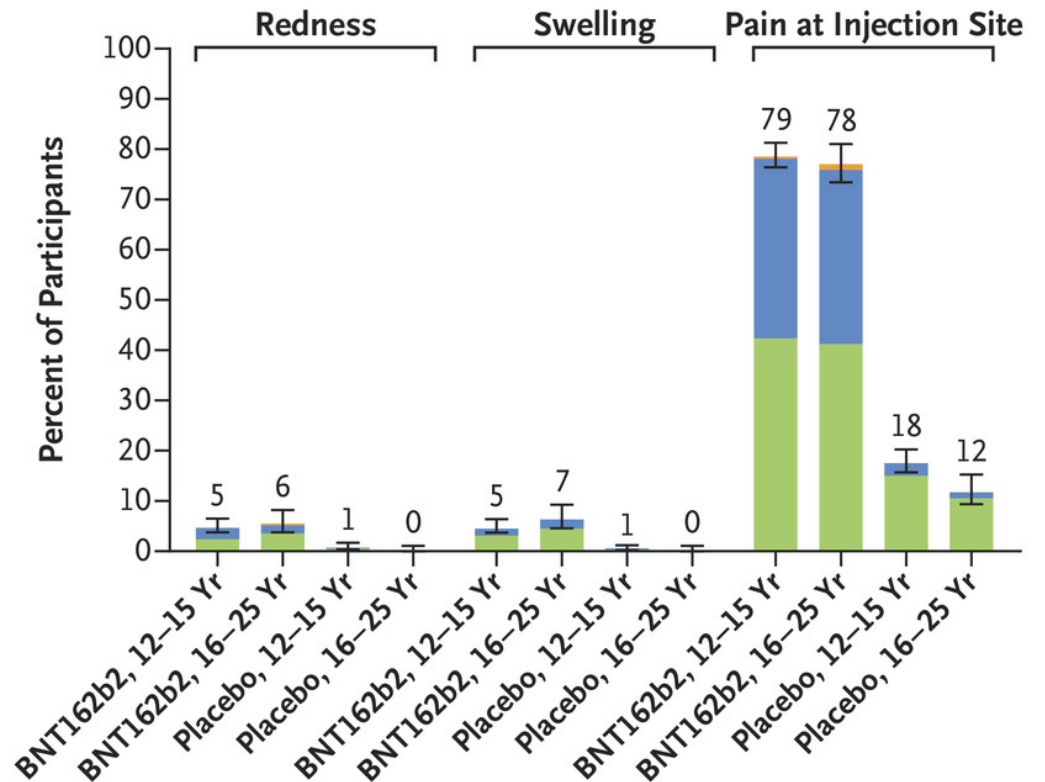
Injection-site reactions (pain) were frequent, most mild to moderate in ages 12-15

■ Mild; temperature 38.0 to 38.4°C
 ■ Moderate; temperature >38.4 to 38.9°C
 ■ Severe; temperature >38.9 to 40.0°C
 ■ Grade 4; temperature >40.0°C

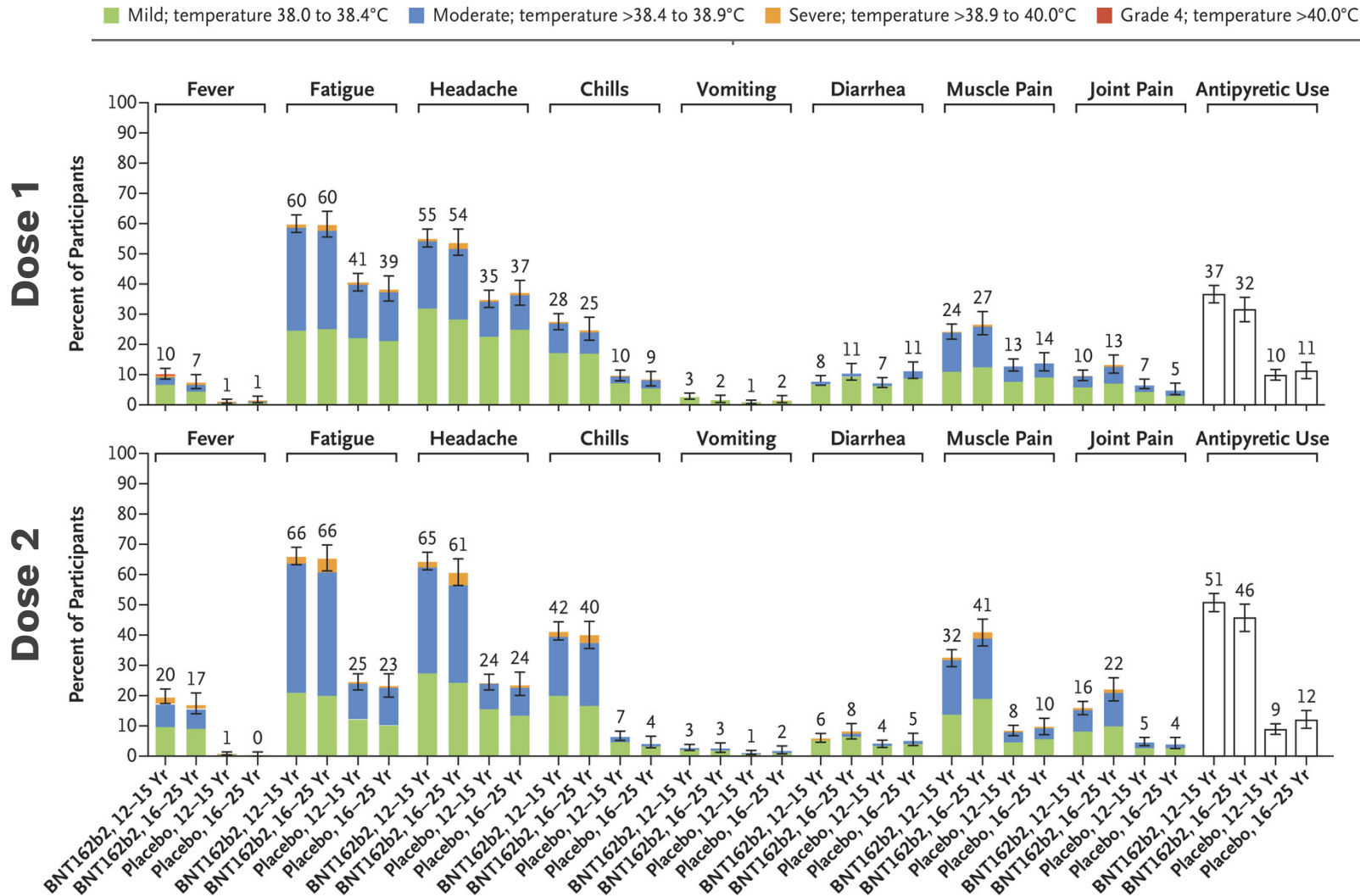
A Local Events, Dose 1



B Local Events, Dose 2



Systemic adverse events reported frequently, but mild to moderate in ages 12-15

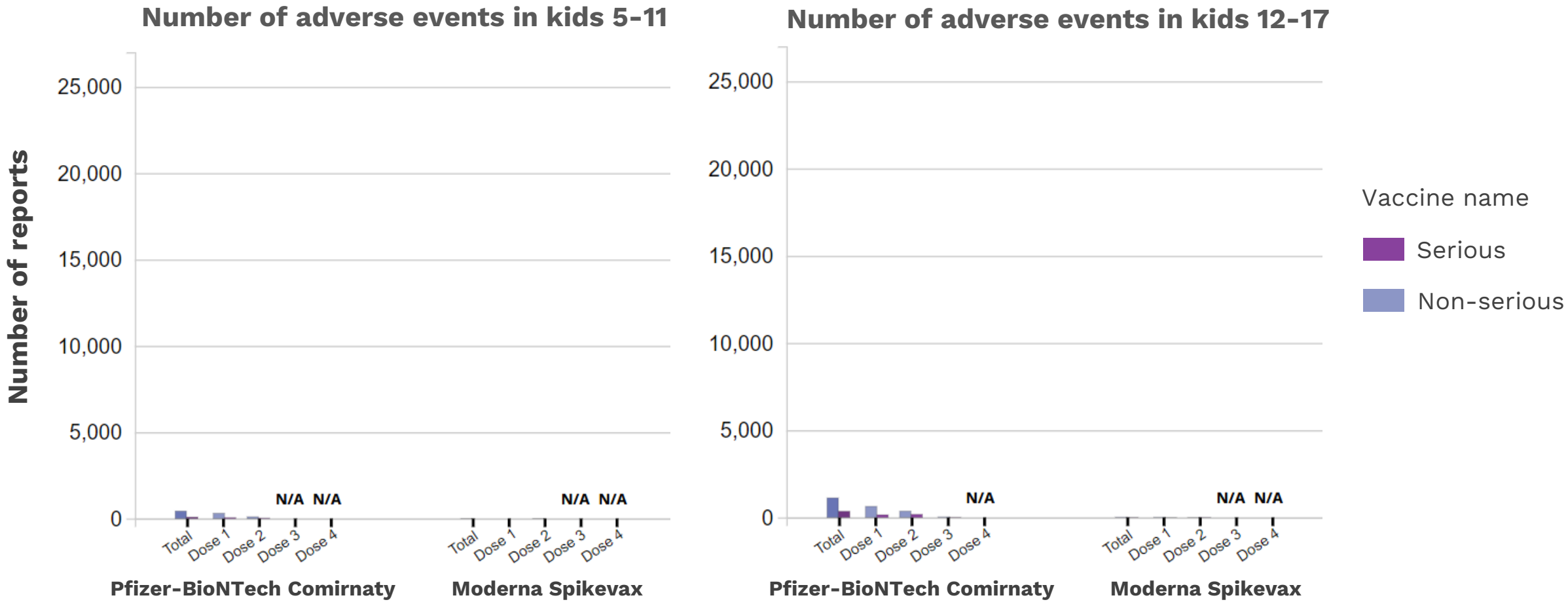


SAE: <0.4%

- ▶ None assessed as related to vaccine
- ▶ No thrombosis
- ▶ No hypersensitivity reactions

Frenck RW Jr, et al. Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents. N Engl J Med. 2021 May 27.

Number of adverse events in children & teens due to COVID-19 vaccines in Canada extremely low



<https://health-infobase.canada.ca/covid-19/vaccine-safety/>

Canadian National
Vaccine Safety
(CANVAS) Network:
Active Safety
Surveillance on
COVID-19 Vaccines

Across Canada

Dr. Julie Bettinger

Professor, Pediatrics
Vaccine Evaluation Center
BC Children's Hospital Research Institute
University of British Columbia

CITF-funded researcher



Disclaimer

I have no COIs to declare related to this study



CANVAS-COVID: Surveillance

- Over 1 million participants enrolled
 - ▶ BC, YT, AB, QC, ON, NS, PEI participating
 - ▶ Age group, vaccine type, health status, previous COVID Infection
- Online survey captures **8 days after dose 1, 8 days after dose 2** and **~7 months after dose 1**
- Survey captures **severe health events** that:
 - ▶ Cause work/school absenteeism
 - ▶ Prevent daily activities
 - ▶ Require a medical visit
- Control survey of unvaccinated controls captures health events over 7-day period
- Telephone follow up for medically attended events

Pediatric results: April 20, 2022

CANVAS-COVID Kids:

Monitoring the safety of COVID-19 vaccines in Canada

Vaccination
dose
received
and survey
completed:

DOSE 1

survey completed

246,977

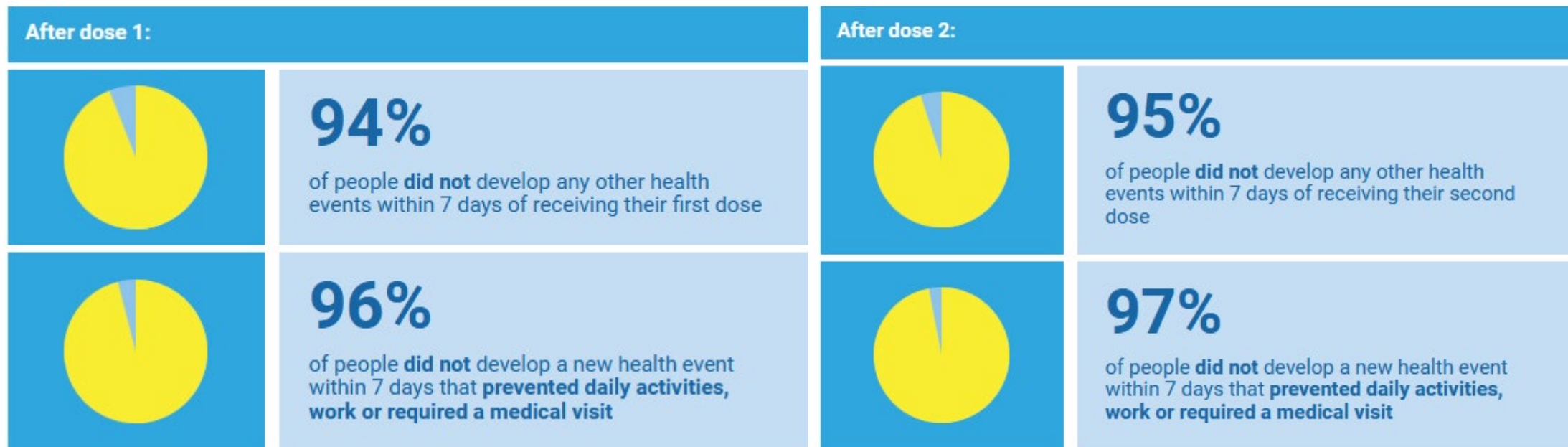
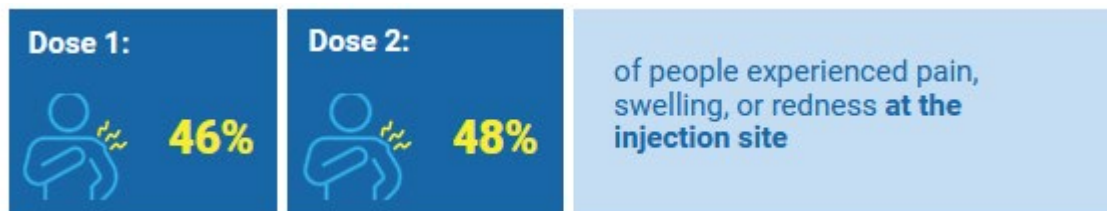
DOSE 2

survey completed









123,633

See www.CANVAS-COVID.ca
for weekly updates

Pediatric results with Pfizer: April 20, 2022



Pediatric results with Pfizer: April 20, 2022

Dose 1:	Dose 2:	
 2.7%	 2.7%	Flu-like symptoms (such as fatigue, muscle ache, feeling unwell)
 1.9%	 2.2%	Headache or migraine
 1.5%	 1.3%	Nausea, vomiting, diarrhea
 1.3%	 1.5%	Fever

See www.CANVAS-COVID.ca for weekly updates

Conclusion

Pfizer vaccine **well tolerated**
in children



Assessment of
children & teens
with adverse events
following COVID-19
vaccination

Across Canada

Dr. Karina Top

Associate Professor, Dalhousie University

Principal Investigator, Special Immunization Clinic (SIC)
Network at CIRN

Co-PI, Canadian Immunization Monitoring Program,
ACTive (IMPACT) Project

CITF-funded researcher

IMPACT



Disclaimer

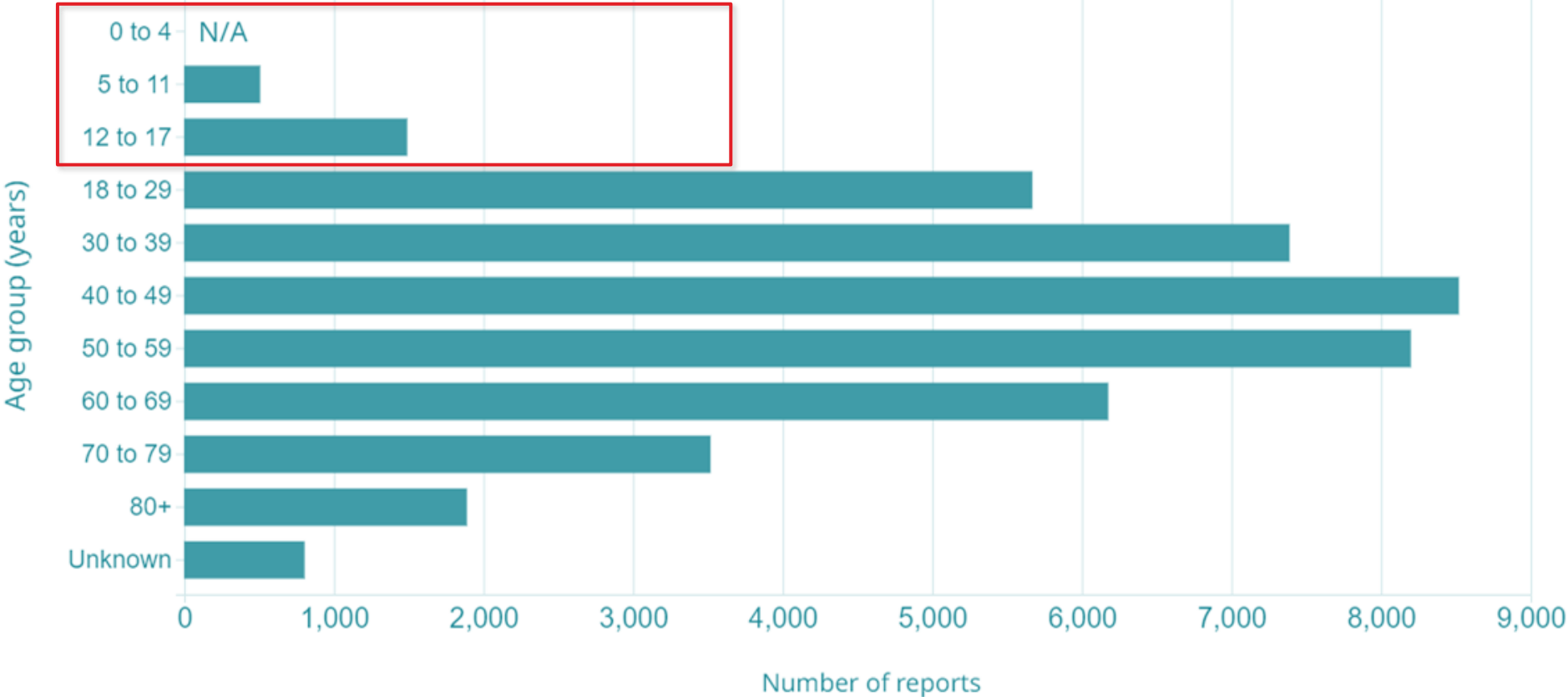
I have no conflicts of interest to declare related to this study.



COVID-19 vaccine safety and effectiveness in children: Canadian Immunization Monitoring Program Active

- Conducting active sentinel surveillance for serious AEFIs in children 0-16 years since 1991 at pediatric tertiary care centres
- Objectives:
 - ▶ To determine safety of COVID-19 vaccination among children ages 0-16 assessed at an IMPACT centre, with respect to:
 - myocarditis, multisystem inflammatory syndrome in children (MIS-C), febrile seizure
 - ▶ To evaluate trends in SARS-CoV-2 infection, COVID-19, and MIS-C among hospitalized children ages 0-16 pre- and post-introduction of vaccination programs
- Approach:
 - ▶ Nurses monitor screens admission lists, ED discharge diagnoses (Jun 2021 to Dec 2022)
 - ▶ Data collection on all cases, including immunization status, SARS-CoV-2 infection, 6-week outcomes
 - ▶ Descriptive and self-controlled case series analysis
 - ▶ AEFIs are reported to passive surveillance system

AEFIs are rarer in children than in adults



Number of adverse event reports by age up to April 8, 2022
(n=44,154)

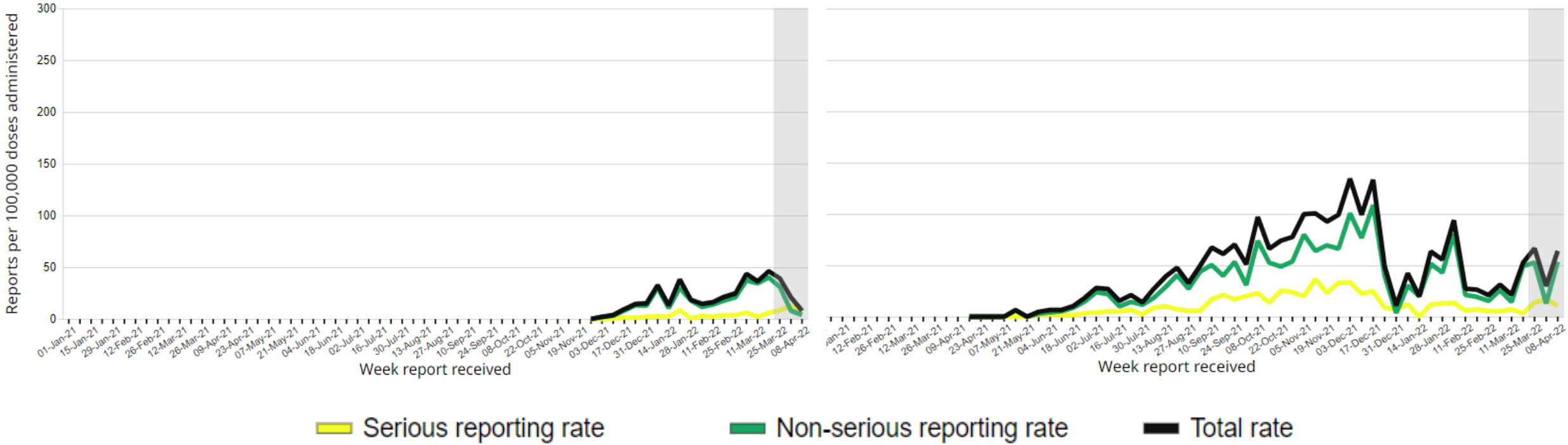
Total COVID-19 vaccine doses administered:
82,185,545

<https://health-infobase.canada.ca/covid-19/vaccine-safety/>

Serious and non-serious AEFI reporting to PHAC until April 8, 2022

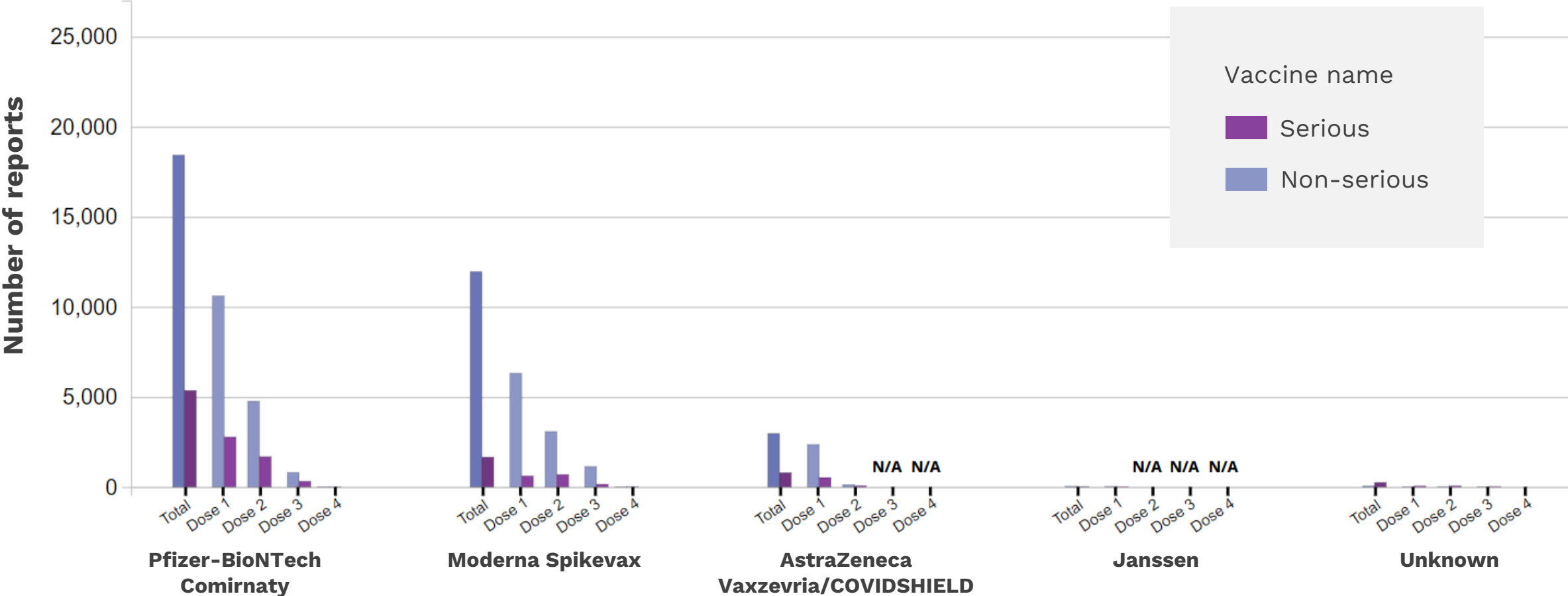
AEFIs among 5- to 11-year-olds (n=506)

AEFIs among 12- to 17-year-olds (n=1489)

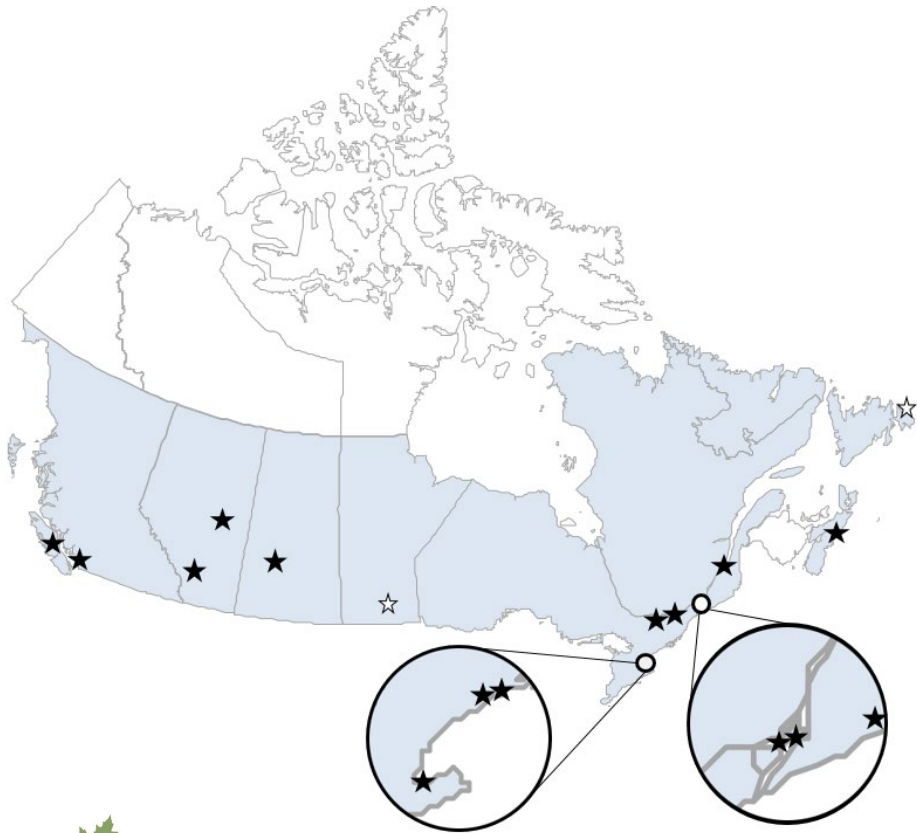


<https://health-infobase.canada.ca/covid-19/vaccine-safety/>

Number of adverse events in people over 18 is higher than in children, but relatively low



Special Immunization Clinic Network



Objectives:

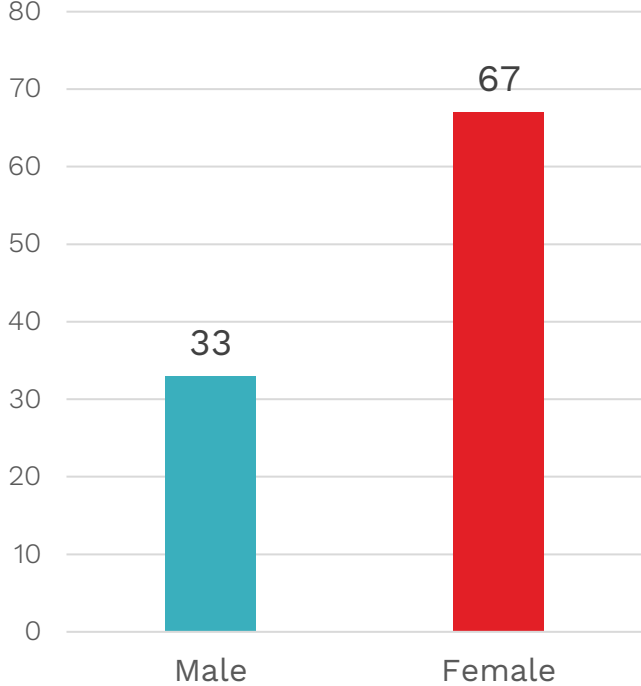
- ▶ Standardize clinical care of patients after an adverse event following COVID-19 vaccination
- ▶ Determine the rate of adverse event recurrence

SIC Network approach:

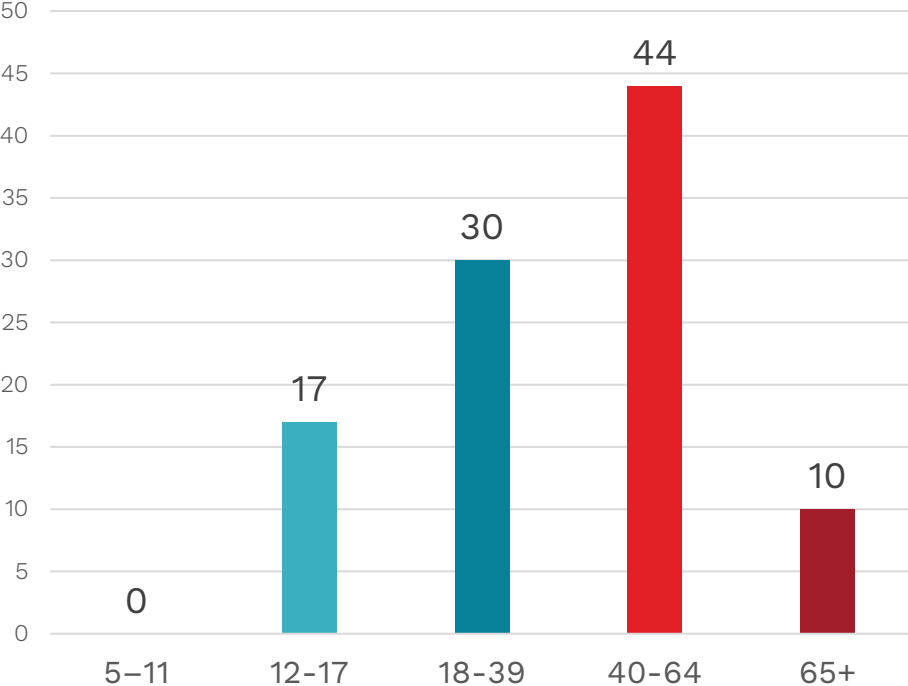
- ▶ Patients with AEs are referred to one of the 15 SICs for assessment regarding safety of future vaccinations
- ▶ Standard protocols for evaluation of specific AEs of interest
 - Hypersensitivity reaction – e.g., Anaphylaxis
 - Cardiac event – e.g., Myocarditis
 - Neurologic event - e.g., Bells Palsy
 - Hematologic disorder – e.g., Blood clots
 - Other Symptoms – e.g., Multisystem inflammation
- ▶ 318 patients enrolled (to Jan 2022)
- ▶ Followed up after revaccination to capture AE recurrences
- ▶ Data are collected centrally

More participants assessed for AEFIs were women and people 40 to 64 years old

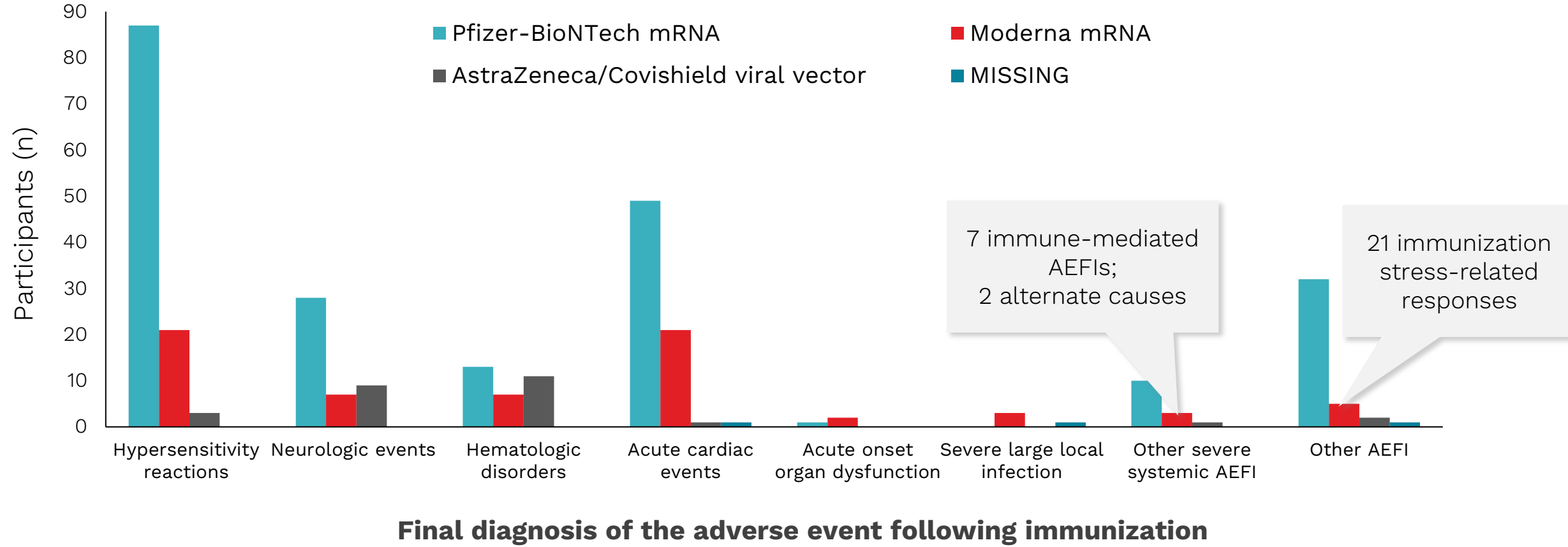
Percentage of AEFIs reported by sex



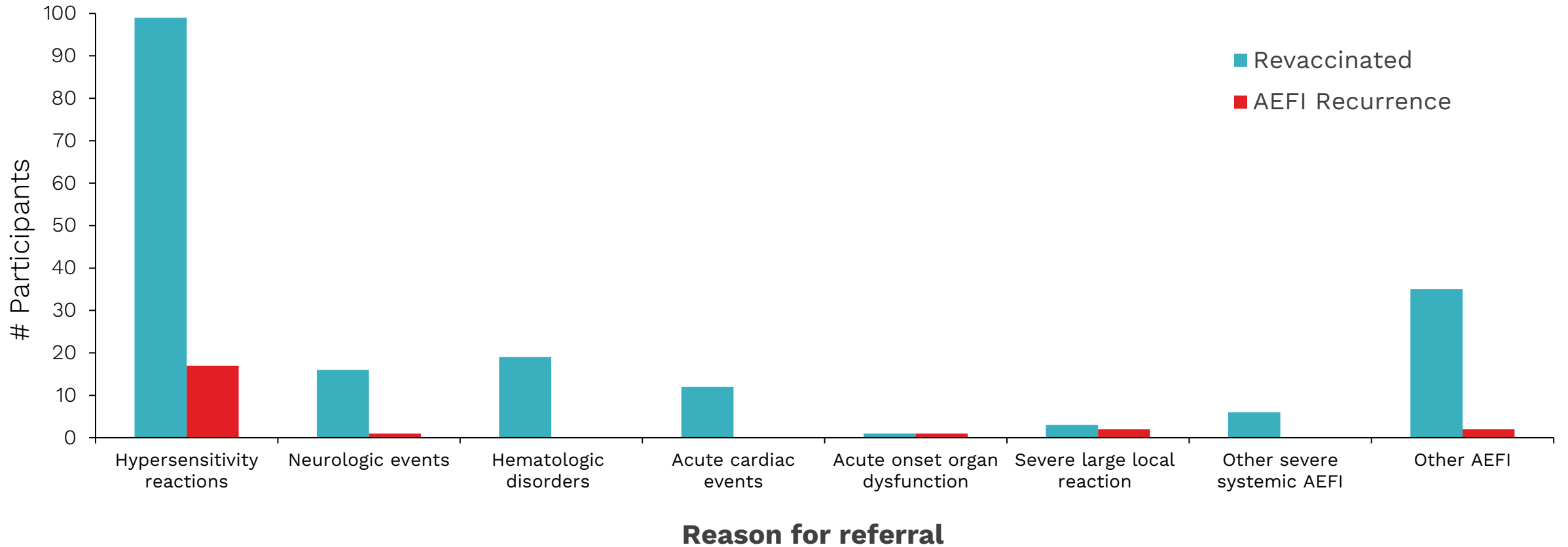
Percentage of AEFIs reported by age group



More participants had AEFIs following Pfizer vaccine



Most patients seen for AEFIs were safely revaccinated



Discussion and future plans

- **Limitations:** referral and selection bias, despite assessment protocol, there is variation in work-up and recommendations by site/physician
- Most patients with adverse events following COVID-19 vaccination were safely revaccinated, including those with suspected hypersensitivity
- **Future plans:** Detailed analyses of specific AEFIs planned in 2022:
 - ▶ Patients assessed for PEG allergy and suspected allergic reactions post-vaccination
 - ▶ Myocarditis/pericarditis
 - ▶ Neurologic events
 - ▶ Hematologic events
 - ▶ Partnering with international studies into causes of specific AEFIs

On-going safety concerns - PHAC and Health Canada are actively monitoring 3 safety signals

- 1. Thrombosis with thrombocytopenia syndrome** following vaccination with the AstraZeneca vaccine
 - ▶ 269 cases in total in Canada, 85 from AstraZeneca
- 2. Guillain-Barré Syndrome (GBS)** following AstraZeneca
 - ▶ 39 cases in Canada
- 3. Myocarditis** (inflammation of the heart muscle) **and pericarditis** (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines
 - ▶ 1971 cases in Canada



Myocarditis/
pericarditis after
mRNA vaccination
or SARS-CoV-2
infection

Ontario, Quebec, BC

Dr. Jeff Kwong

Senior Scientist, ICES
Scientist, Public Health Ontario

Professor, University of Toronto

CITF-funded researcher



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TORONTO

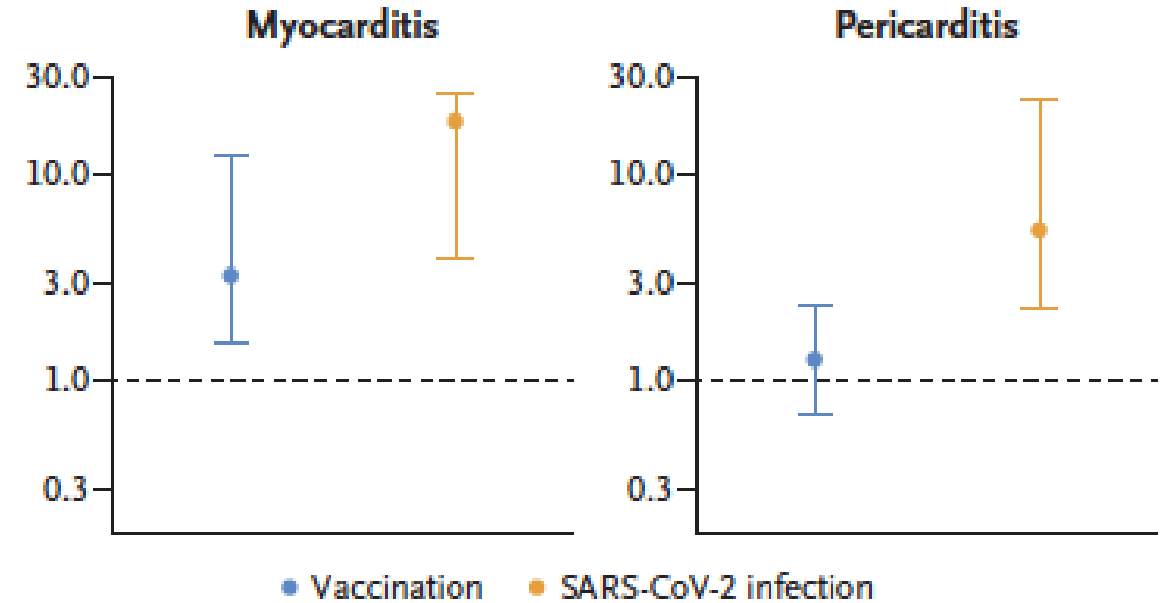
Disclaimer

I have no conflicts of interest to declare related to this study.



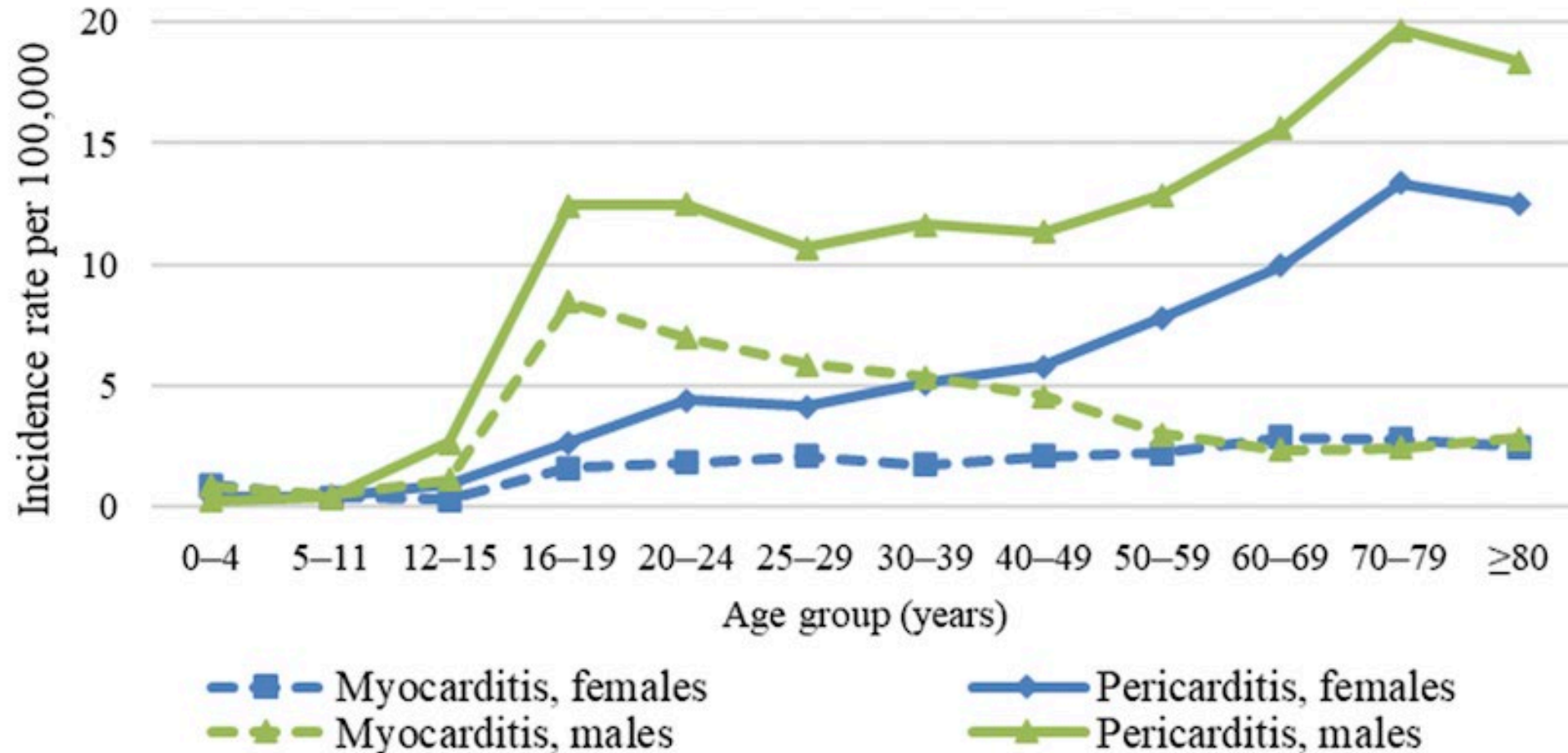
Background

- Multiple countries have reported increased myocarditis/pericarditis risk after mRNA vaccines, especially for adolescent and young adult males, after second dose, and with Moderna vaccine
- Limited data comparing risk of myocarditis/pericarditis after vaccination vs. SARS-CoV-2 infection, or by dosing interval



Barda N, et al. Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting. *NEJM*. 2021;385(12):1078-90. <https://www.nejm.org/doi/10.1056/NEJMoa2110475>

Background rates of myocarditis and pericarditis are higher for males than females and vary by age group



Nasreen S, et al. Background incidence rates of adverse events of special interest related to COVID-19 vaccines in Ontario, Canada, 2015 to 2020, to inform COVID-19 vaccine safety surveillance. *Vaccine*. 2022; in press.

Objective

To evaluate whether the incidence of **myocarditis/pericarditis** after receiving an mRNA vaccine as the second dose varies by dosing interval, and to compare with the incidence after SARS-CoV-2 infection.



Methods

- Study population
 - ▶ Community-dwelling residents of BC, Ontario, or Quebec aged ≥ 12 years
 - ▶ Exclusions: history of myocarditis/pericarditis in the past year
- Exposures
 - ▶ Receipt of mRNA vaccine as second dose (Dec 14, 2020 to Sep 9, 2021), by dosing interval (15-30 days, 31-55 days, ≥ 56 days)
 - ▶ RT-PCR-confirmed SARS-CoV-2 infection (Jan 26, 2020 to Sep 9, 2021)
- Outcomes
 - ▶ Emergency department visit or hospitalization coded as myocarditis (ICD-10: I40, I41, I51.4) or pericarditis (ICD-10: I30, I32) within 21 days after an exposure

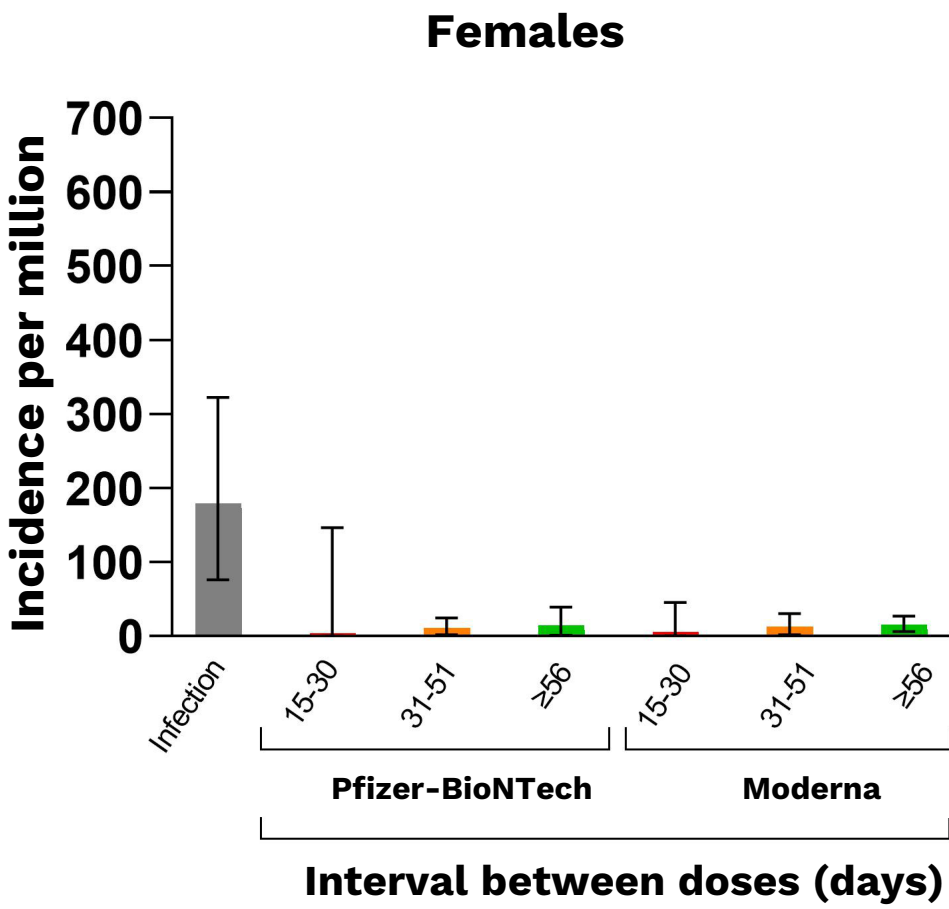
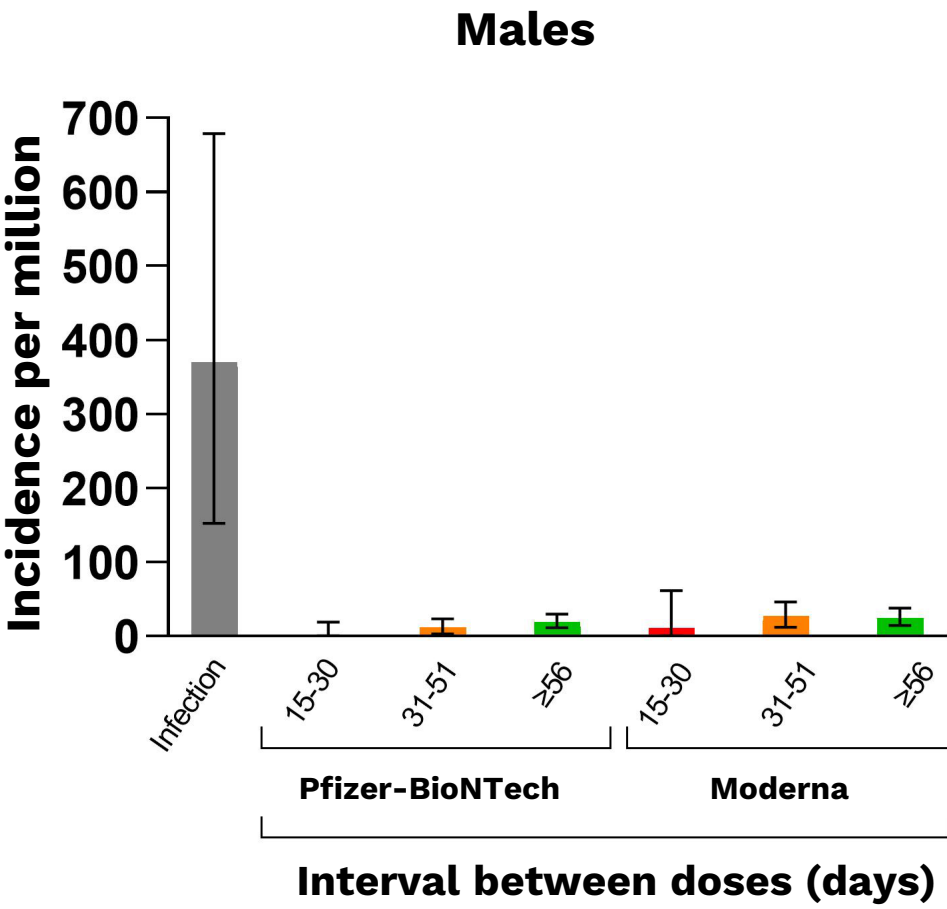
Number of vaccinated and infected individuals, by selected characteristics

	Pfizer-BioNTech, n (%)	Moderna, n (%)	SARS-CoV-2 infection, n (%)
Total exposed	13,106,504	5,754,313	860,335
Male sex	6,133,792 (47)	2,881,279 (50)	418,417 (49)
Age (years)			
12-17	1,260,444 (10)	4,188 (0.1)	64,870 (8)
18-29	1,849,440 (14)	989,185 (17)	202,410 (24)
30-39	1,795,090 (14)	950,195 (17)	153,809 (18)
≥40	8,201,530 (63)	3,810,745 (66)	439,246 (51)
Dosing interval			
15-30 days	704,166 (5)	343,145 (6)	N/A
31-55 days	3,119,068 (24)	1,826,722 (32)	N/A
≥56 days	9,283,270 (71)	3,584,446 (62)	N/A

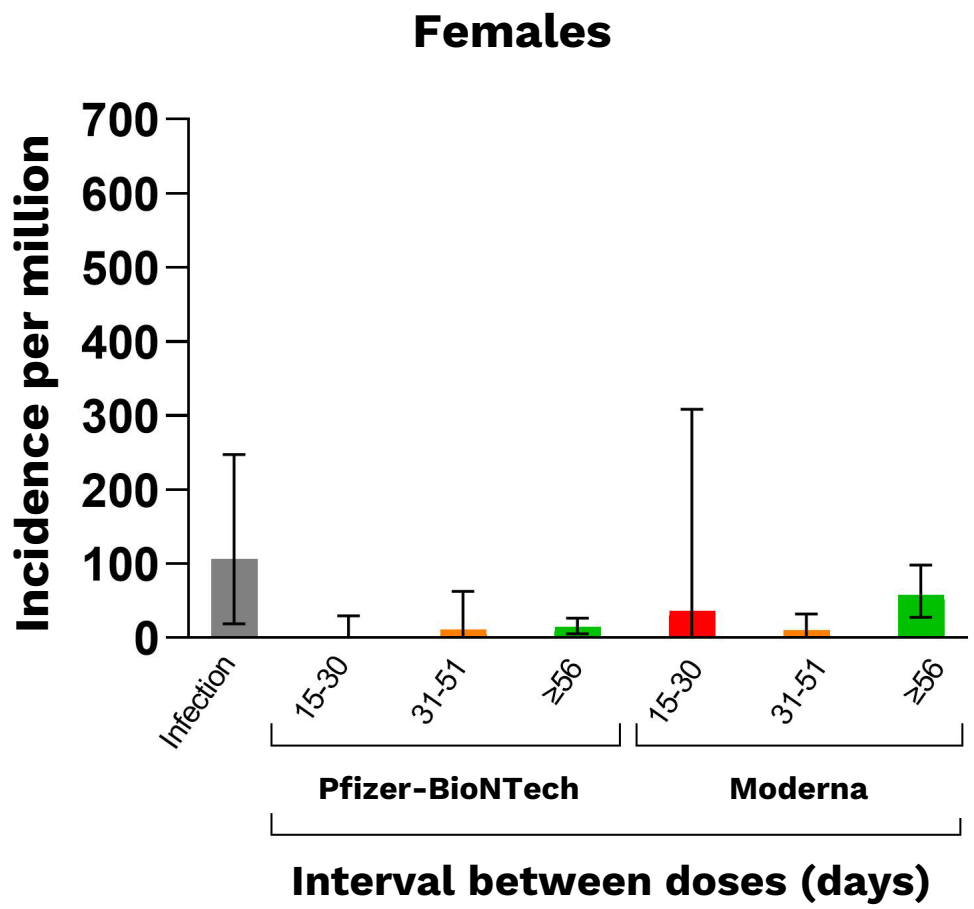
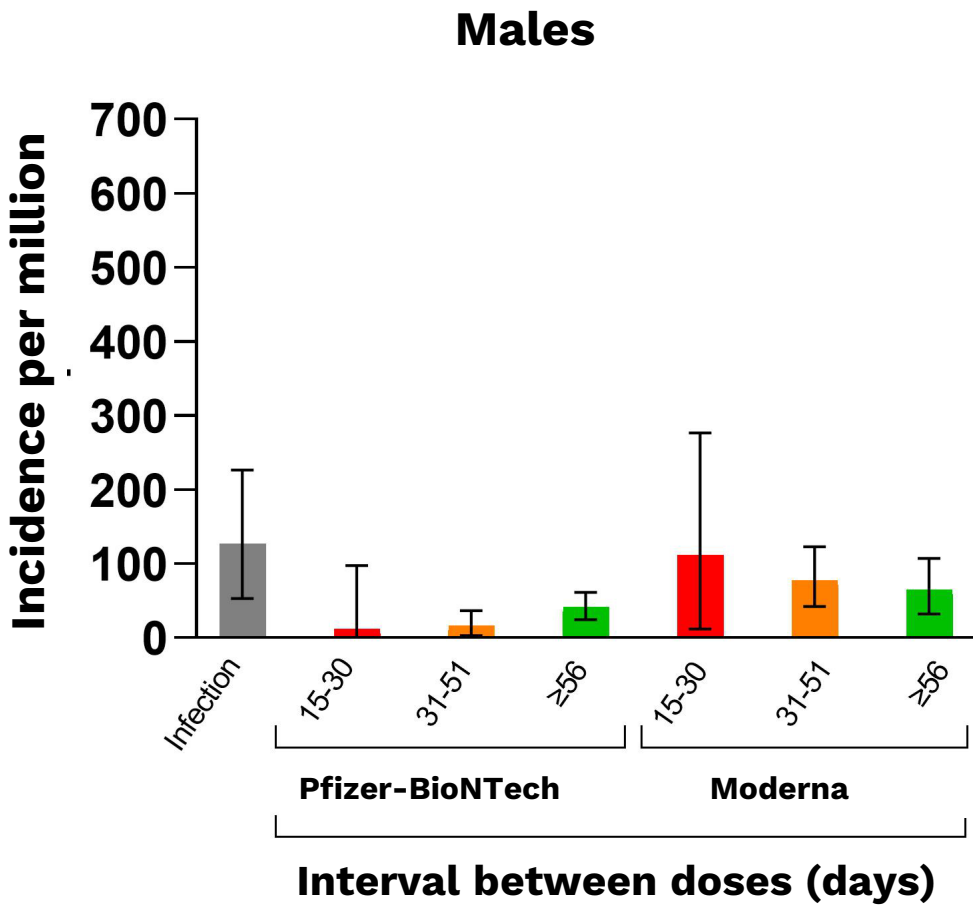
Number of myo/pericarditis cases after mRNA vaccination and after SARS-CoV-2 infection, by selected characteristics

	After mRNA vaccination, n (%)	After SARS-CoV-2 infection, n (%)
Total outcomes	686 (100)	160 (100)
Male sex	479 (70)	102 (64)
Age (years)		
12-17	98 (14)	1-5 (1-3)
18-29	261 (38)	26 (16)
30-39	106 (16)	19-23 (12-14)
≥40	221 (32)	110 (69)
Dosing interval		
15-30 days	80 (13)	N/A
31-55 days	203 (33)	N/A
≥56 days	340 (55)	N/A

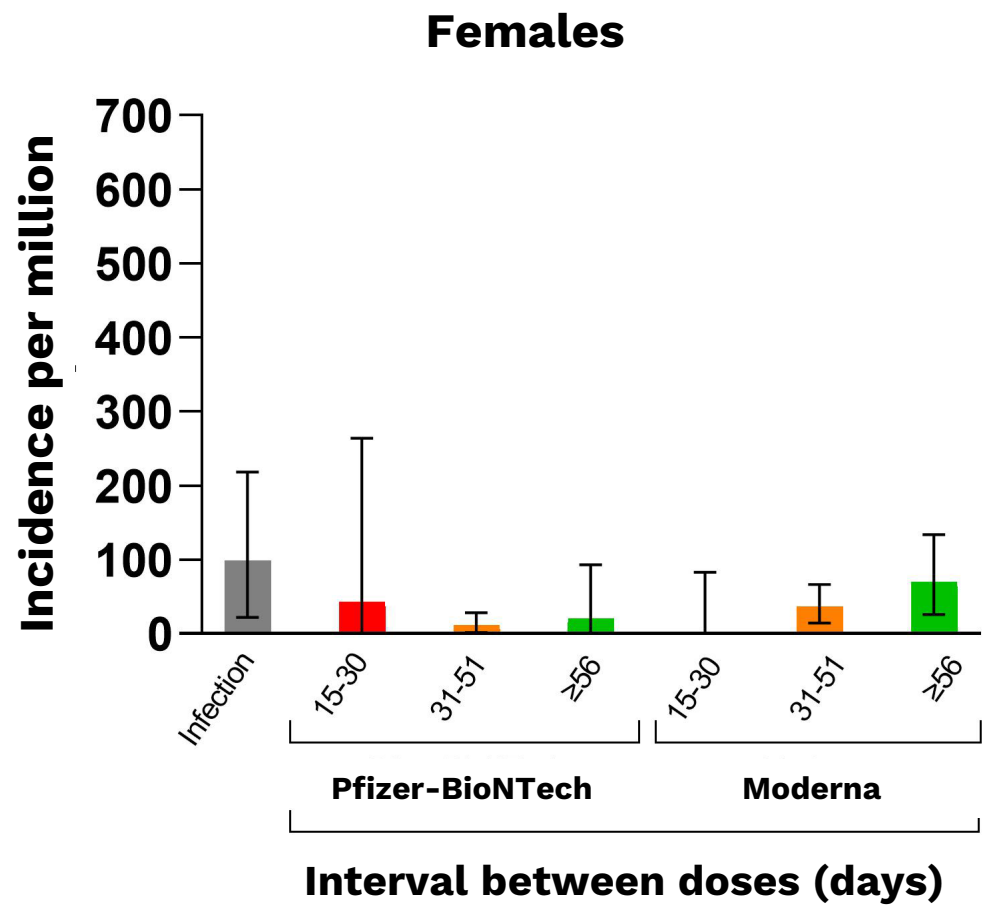
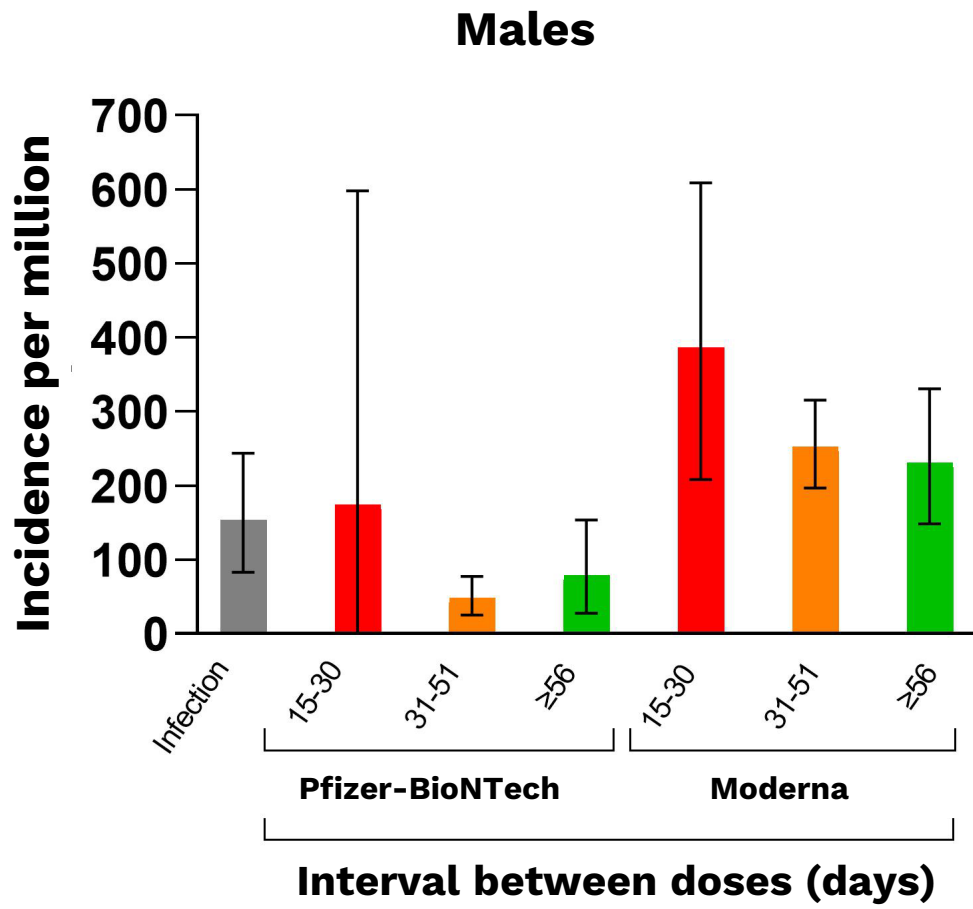
For those ≥ 40 years, myo/pericarditis incidence higher after SARS-CoV-2 infection than mRNA vaccination, especially males



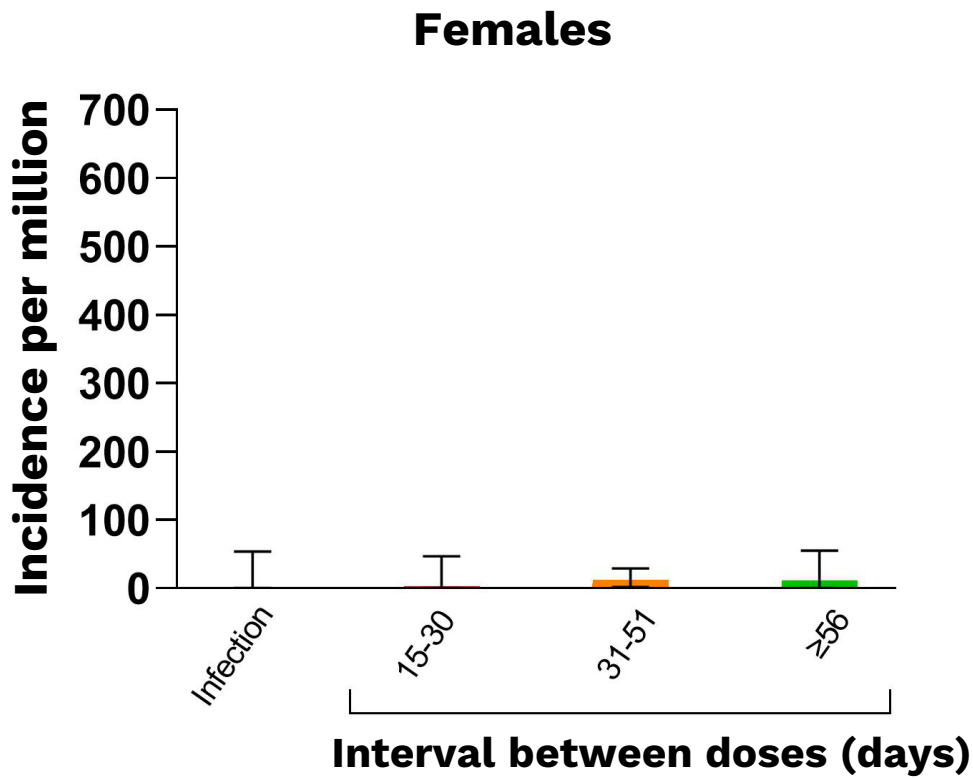
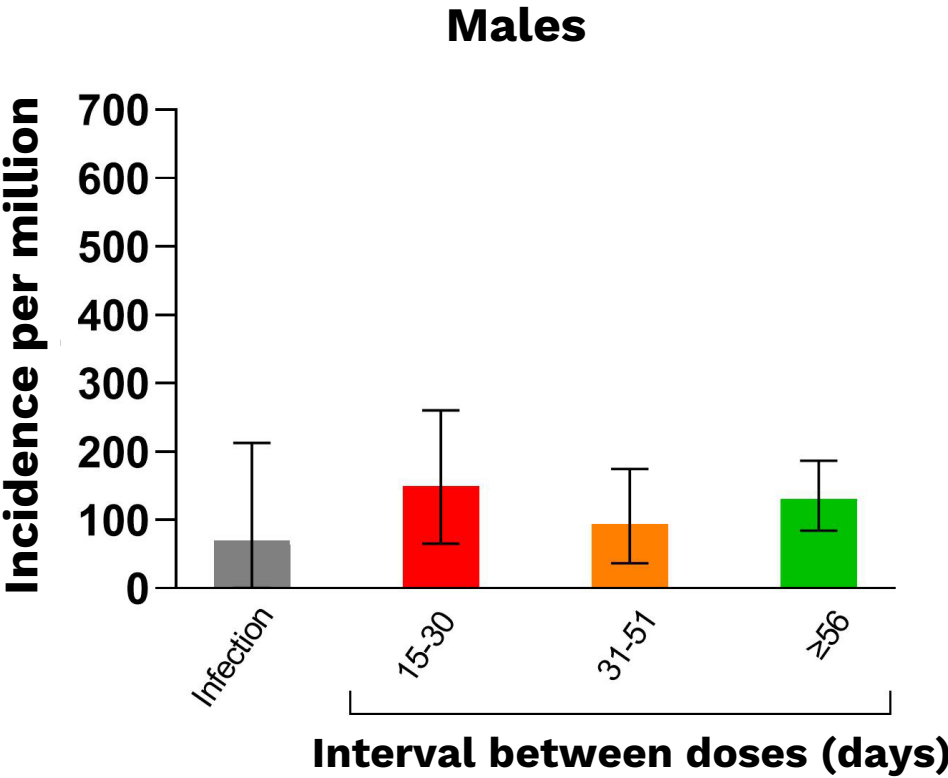
For those 30-39 years, myocarditis/pericarditis incidence higher after infection than vaccination for females, Pfizer recipients



For those 18-29 years, myocarditis/pericarditis incidence higher after Moderna vaccine than infection for males



For those 12-17 years, myocarditis/pericarditis incidence comparable after SARS-CoV-2 infection and Pfizer vaccine



Limitations

- Outcomes obtained from health administrative data using ICD-10 diagnostic codes (uncertain validity); no review of clinical charts to confirm diagnoses
- Missing cases of myocarditis/pericarditis who don't seek medical attention and those following SARS-CoV-2 infection that aren't confirmed by laboratory testing
- Rare events, leading to wide confidence intervals



Conclusions

- Incidence of myocarditis/pericarditis is higher:
 - ▶ For males than females, after Moderna compared to after Pfizer
 - ▶ With shorter dosing intervals compared to longer dosing intervals for those aged ≥ 18 years
 - ▶ After SARS-CoV-2 infection compared to after mRNA vaccination for adults ≥ 40 years, but opposite seen for males aged 18-29 years who received Moderna
- Programmatic strategies could reduce myocarditis/pericarditis risk following mRNA vaccines (avoid Moderna for adolescents and young adults, use longer dosing interval).
- Risk/benefit decisions regarding COVID-19 vaccination should account for outcomes beyond myocarditis/pericarditis.

Pregnant people had a greater chance of severe outcomes from COVID

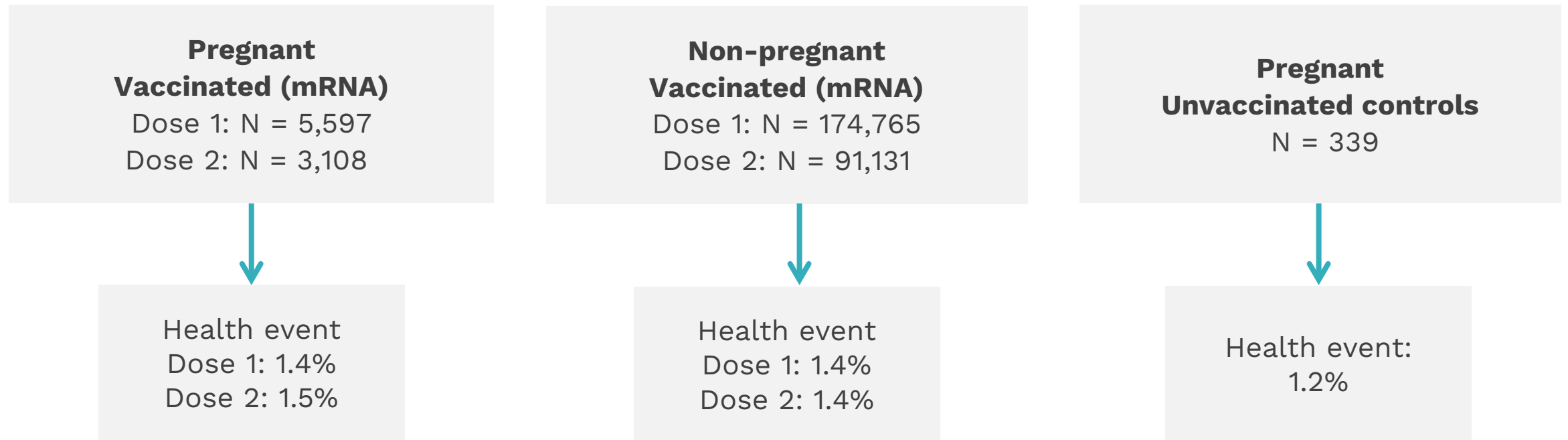


	Pregnant positive SARS-CoV-2 cases in BC, AB, MB, ON, NS, and QC to October 31 st , 2021 (n=6012)	Positive SARS-CoV-2 females aged 20-49 in Canada to October 31 st , 2021 (n=313,982)	Relative Risk	95% CI
Number and percent hospitalized	466 (7.75%)	9196 (2.93%)	2.65	2.4-2.9
Number and percent admitted to ICU	121 (2.01%)	1157 (0.37%)	5.46	4.5-6.5

98.7% of hospitalized were unvaccinated or incompletely vaccinated

(Information from early analysis to end of September)

COVID-19 vaccine in pregnant people

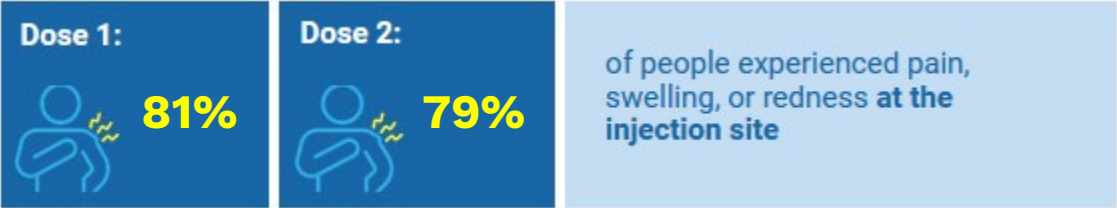




Vaccinations did not increase the risk of miscarriages or other pregnancy complications

Health events in pregnant people	Vaccinated	Unvaccinated
Miscarriage	1.5%	2.1%
Preterm labour	0.1%	0%
High blood pressure	0.1%	0%
Vaginal spotting or vaginal bleeding	0.4%	0.3%
Other pregnancy complications*	0.5%	0.3%

*included lower abdominal pain, reduce fetal movement, cramp, vomiting etc.

Systemic symptoms most frequently reported and at higher rates in vaccinated pregnant people



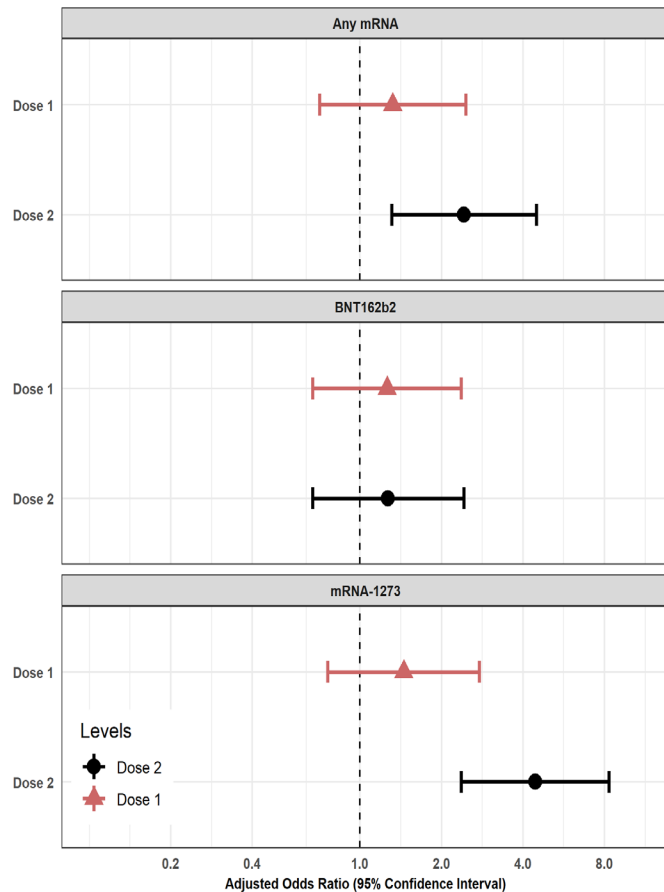
SYMPTOM	Any mRNA		Unvaccinated Pregnant People
	Dose 1	Dose 2	
 Fatigue, muscle ache, feeling unwell	2.9%	6.6%	0.9%
 Headache/Migraine	2.3%	4.6%	0.6%

Sadarangani et. al.
<https://www.medrxiv.org/content/10.1101/2022.02.22.22271358v1>

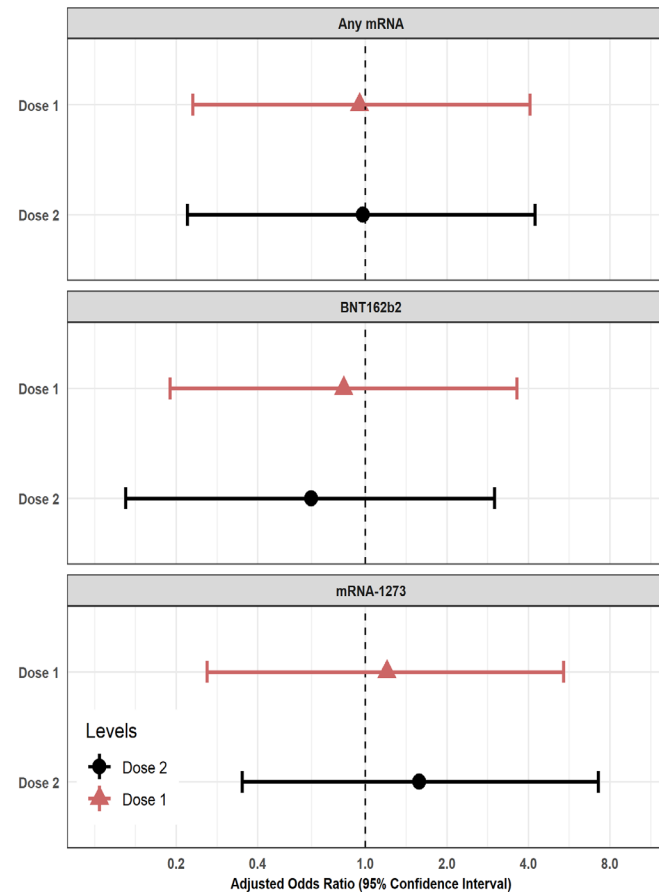
Vaccinated pregnant people had more symptoms after 2nd dose of Moderna vaccine compared to unvaccinated pregnant people

Association of vaccination with health events in pregnant people, comparing vaccinated with unvaccinated pregnant individuals

Association of health event



Association of ED Visit/Hospitalization



- No difference in ED visits or hospitalization
- No difference in health events dose 1
- Vaccinated pregnant people higher rate of symptoms after dose 2 Moderna

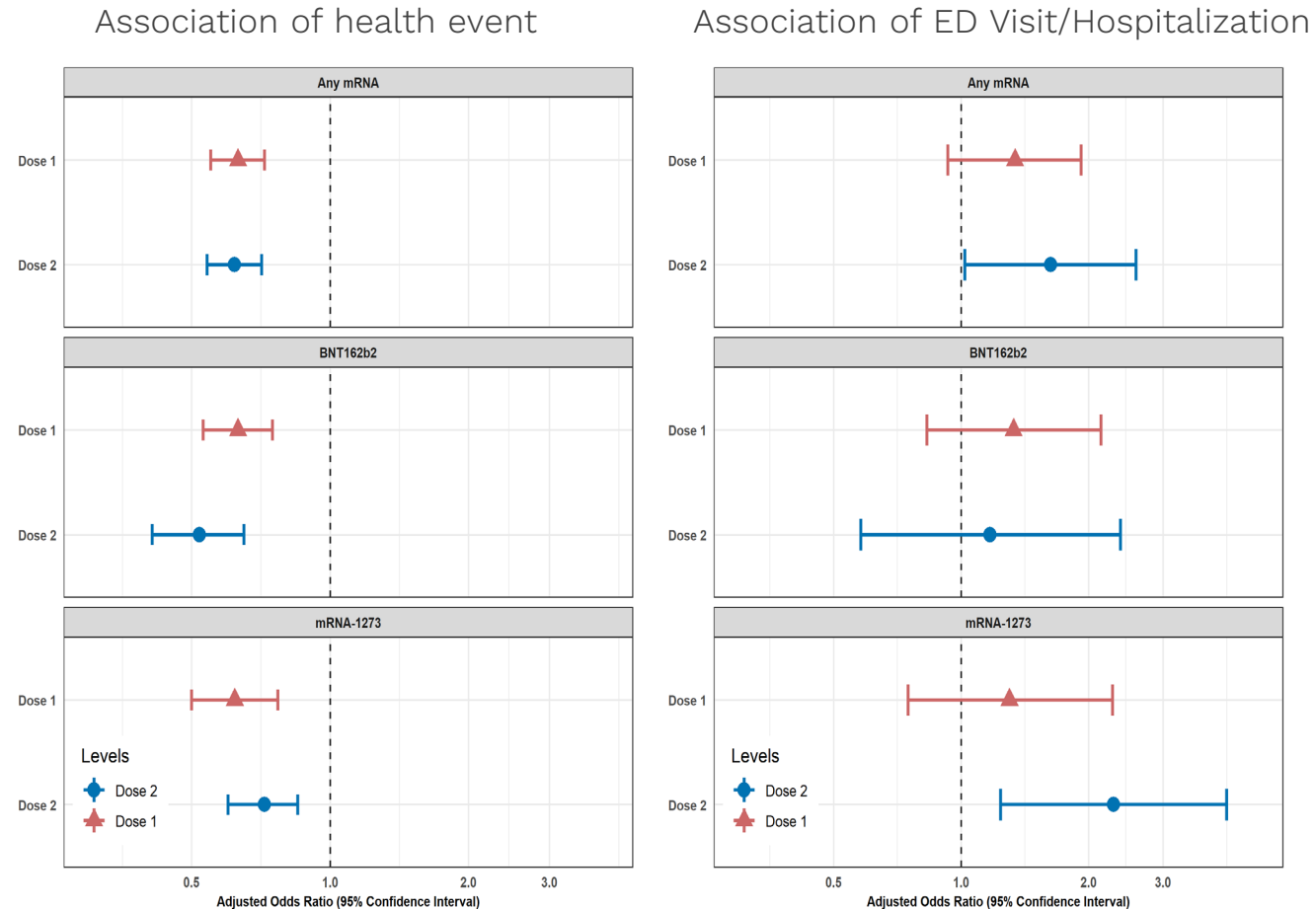
Adjusted for Age group, trimester and previous COVID infection

Sadarangani et. al.

<https://www.medrxiv.org/content/10.1101/2022.02.22.22271358v1>

No differences in symptoms between vaccinated pregnant people and vaccinated females but pregnant vaccinated people were more likely to seek care for symptoms than non-pregnant people

Association of pregnancy with health events in vaccinated people, comparing pregnant with non-pregnant females



- No difference in health events
- No difference in ED visits or hospitalization for Pfizer vaccine
- After dose 2 Moderna, pregnant individuals were more likely to seek emergency care

Adjusted for age group and previous COVID infection

Sadarangani et. al.

<https://www.medrxiv.org/content/10.1101/2022.02.22.22271358v1>

Conclusions

- mRNA vaccines **safe in pregnancy**
 - ▶ No differences in AEFI among vaccinated individuals
 - ▶ No differences in ED/hospitalization between vaccinated/unvaccinated pregnant people
 - ▶ No differences detected for pregnancy related events between vaccinated/unvaccinated pregnant people
- Pregnant people more likely to seek care for vaccine-related symptoms (increase in ED/hospitalization) after dose 2 Moderna
- Counseling of expected AEFI important: both for providers and pregnant people

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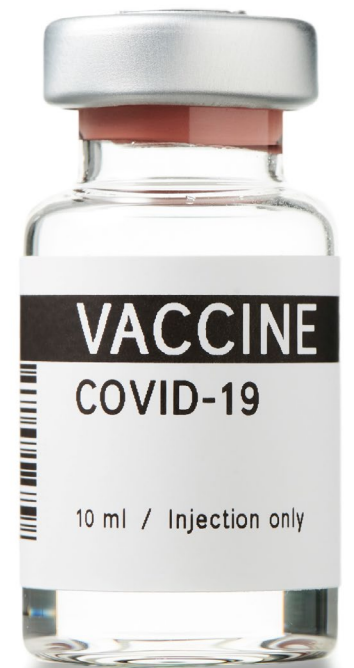
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Serious adverse effects in children are low

- ▶ Pediatric Pfizer vaccine **well tolerated** in children
- ▶ **Under 3%** experience systemic events (headache and nausea/vomiting) after a vaccine (CANVAS, Dr. Bettinger)
- ▶ After dose 1: **96% did not develop any health event** that impacted daily activity or required a hospital visit (CANVAS, Dr. Bettinger)
- ▶ After dose 2: **97% did not develop any health event** that impacted daily activity or required a hospital visit (CANVAS, Dr. Bettinger)
- ▶ Adverse effects have been even **rarer in children than in adults** (IMPACT, Dr. Top)

Mild adverse events frequent, serious events extremely rare among adults

- Over **82 million doses** of COVID-19 vaccines administered in Canada:
 - ▶ Total adverse events following immunization: **0.054%** (44,154)
 - ▶ Serious adverse events – **0.011%** (9,119)
 - ▶ Deaths – **0.00000273%** (224*) *includes those still under investigation
- The vast majority of adults who had an adverse reaction to dose 1 were recommended to receive dose 2 (SIC, Dr. Top)
 - ▶ The reoccurrence of adverse events was even more rare after dose 2
- The number of adverse events reported in Canada after the second, third and fourth doses are low





Strategies to mitigate myocarditis/pericarditis

- Adults over 40 have a higher risk of myocarditis/pericarditis from COVID-19 than from mRNA vaccine
- Recommend Pfizer for males under 30 (some would suggest under 40) as done in other countries (Dr. Kwong)
- Recommend longer dosing intervals for adults over 18 (Dr. Kwong)

Pregnant people: vaccination best option

- mRNA vaccines are **safe in pregnancy**
- Health risks for pregnant people due to getting COVID are more severe than the risk of vaccination
- Pain, swelling, and redness at the injection site were the most common adverse events among pregnant people
- Increase in systemic symptoms after dose 2 of Moderna
- Important to discuss and offer counseling to pregnant people relating to expected adverse events





Questions?



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