

COVID-19 vaccines

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THE UNIVERSITY
OF BRITISH COLUMBIA
Faculty of Medicine



Vaccine
Evaluation
Center



Disclosures

- Salary awards
 - BC Children's Hospital Foundation
 - Michael Smith Foundation for Health Research
 - Canadian Child Health Clinician Scientist Program
- Research/Project Funding
 - Merck, VBI Vaccines, GlaxoSmithKline, Pfizer, Sanofi-Pasteur, Seqirus, Symvivo
- All funds have been paid to my institute
- Not received any personal payments



Outline

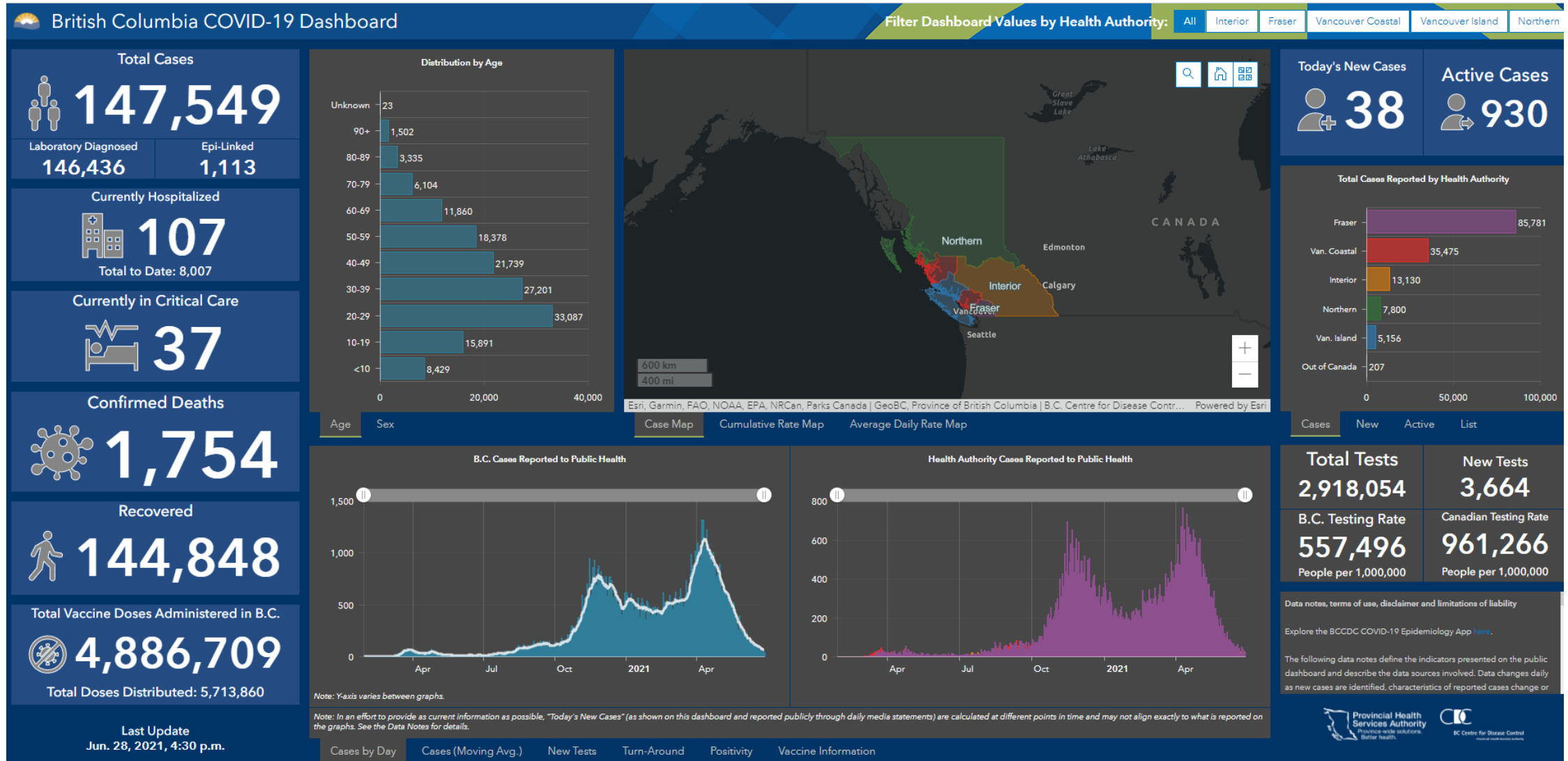
- Overview of COVID-19 vaccines and vaccine efficacy
- Variants
- Vaccine safety
- Vaccine interchangeability
- Research @VEC
- Special populations – children, pregnancy
- Vaccine hesitancy and your role



Overview of COVID-19 vaccines and vaccine efficacy



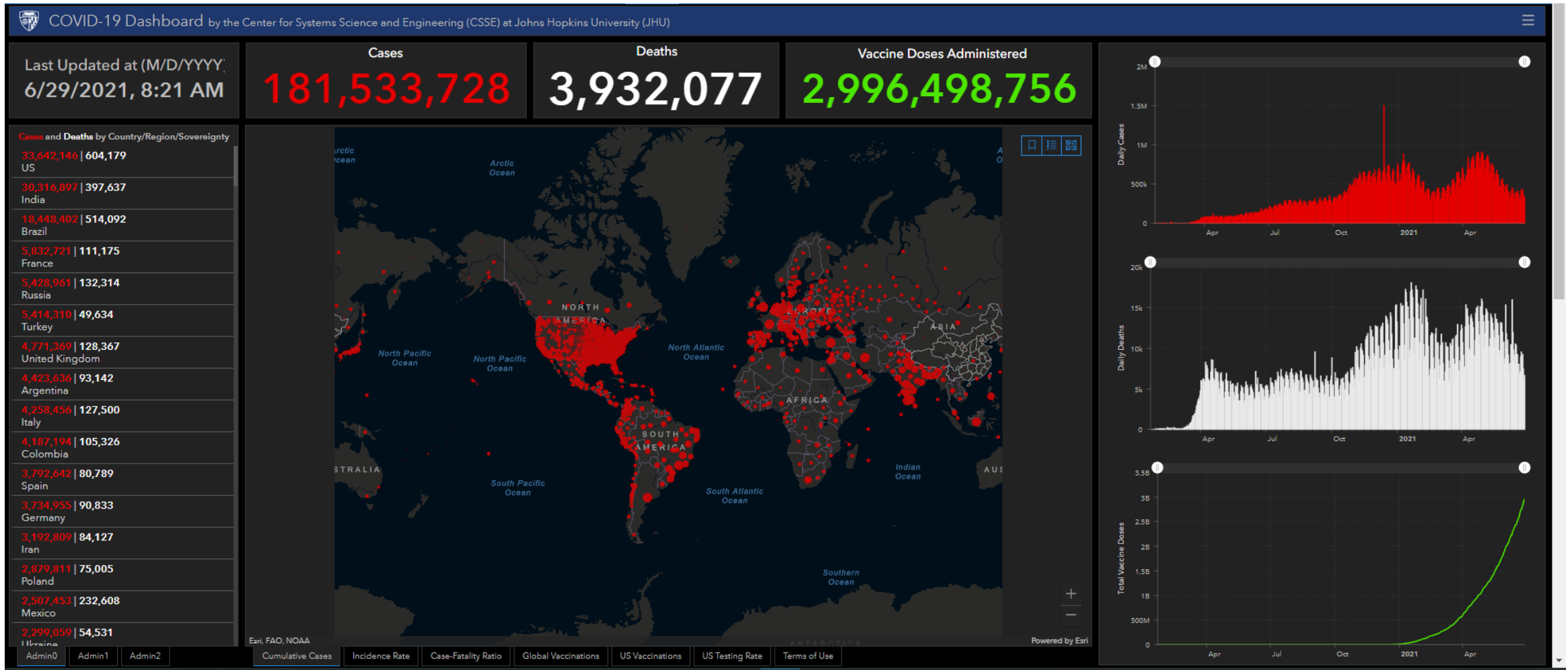
The pandemic has been devastating – in BC...



<https://experience.arcgis.com/experience/a6f23959a8b14bfa989e3cda29297ded>



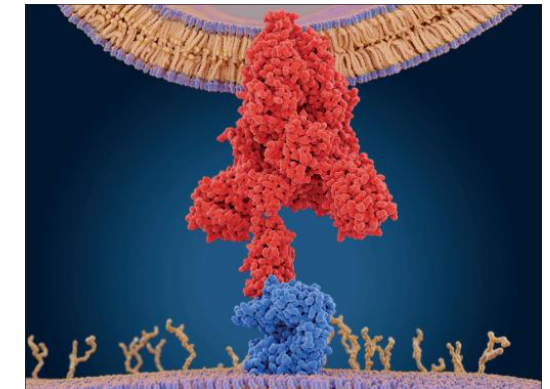
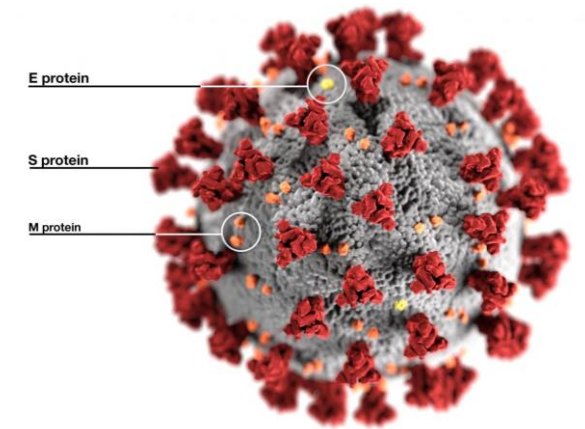
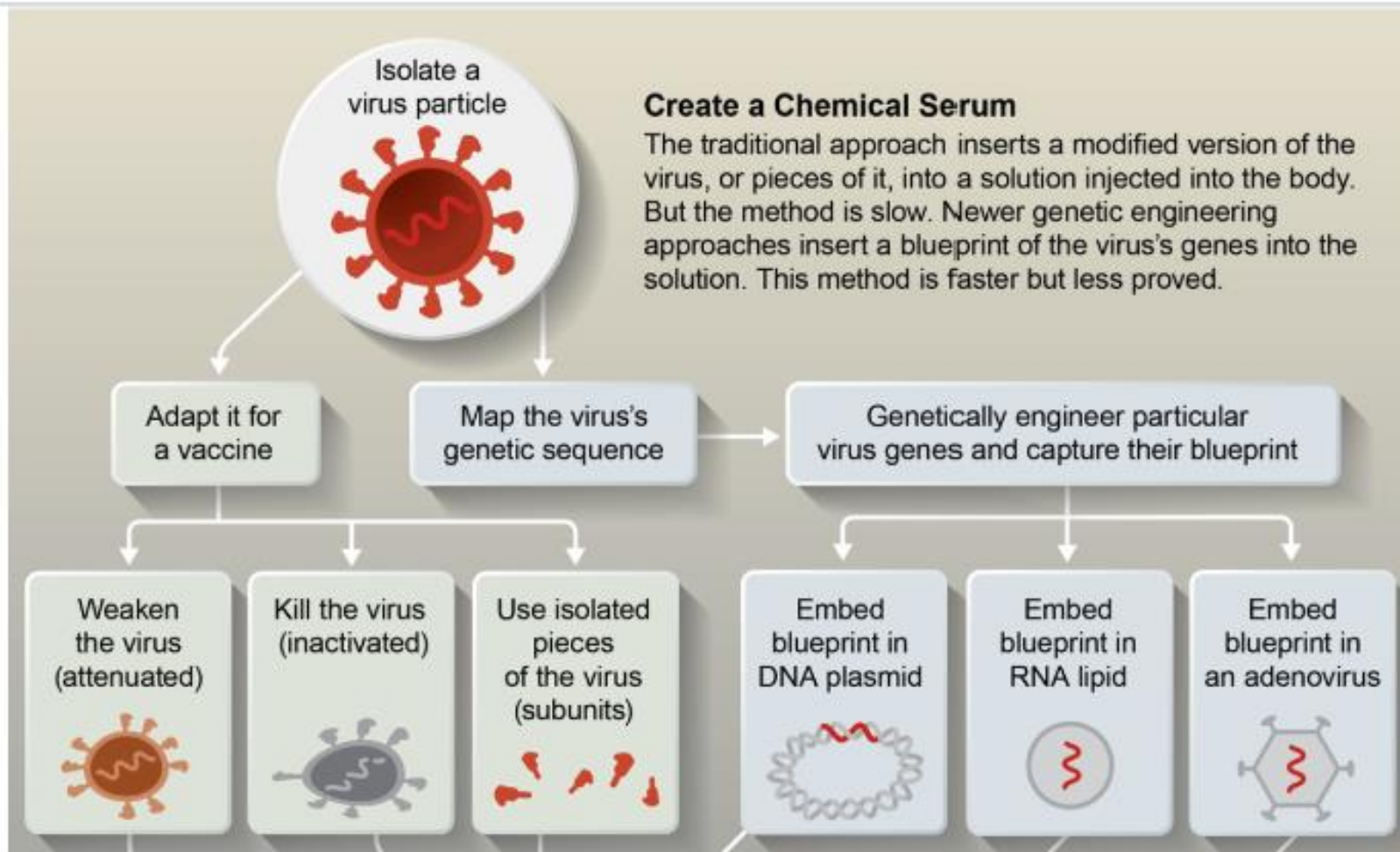
The pandemic has been devastating – in BC...and globally



<https://coronavirus.jhu.edu/map.html>



COVID-19 vaccine platforms






<https://www.scientificamerican.com/article/genetic-engineering-could-make-a-covid-19-vaccine-in-months-rather-than-years1/>

CDC; Fang et al. Lancet 2020

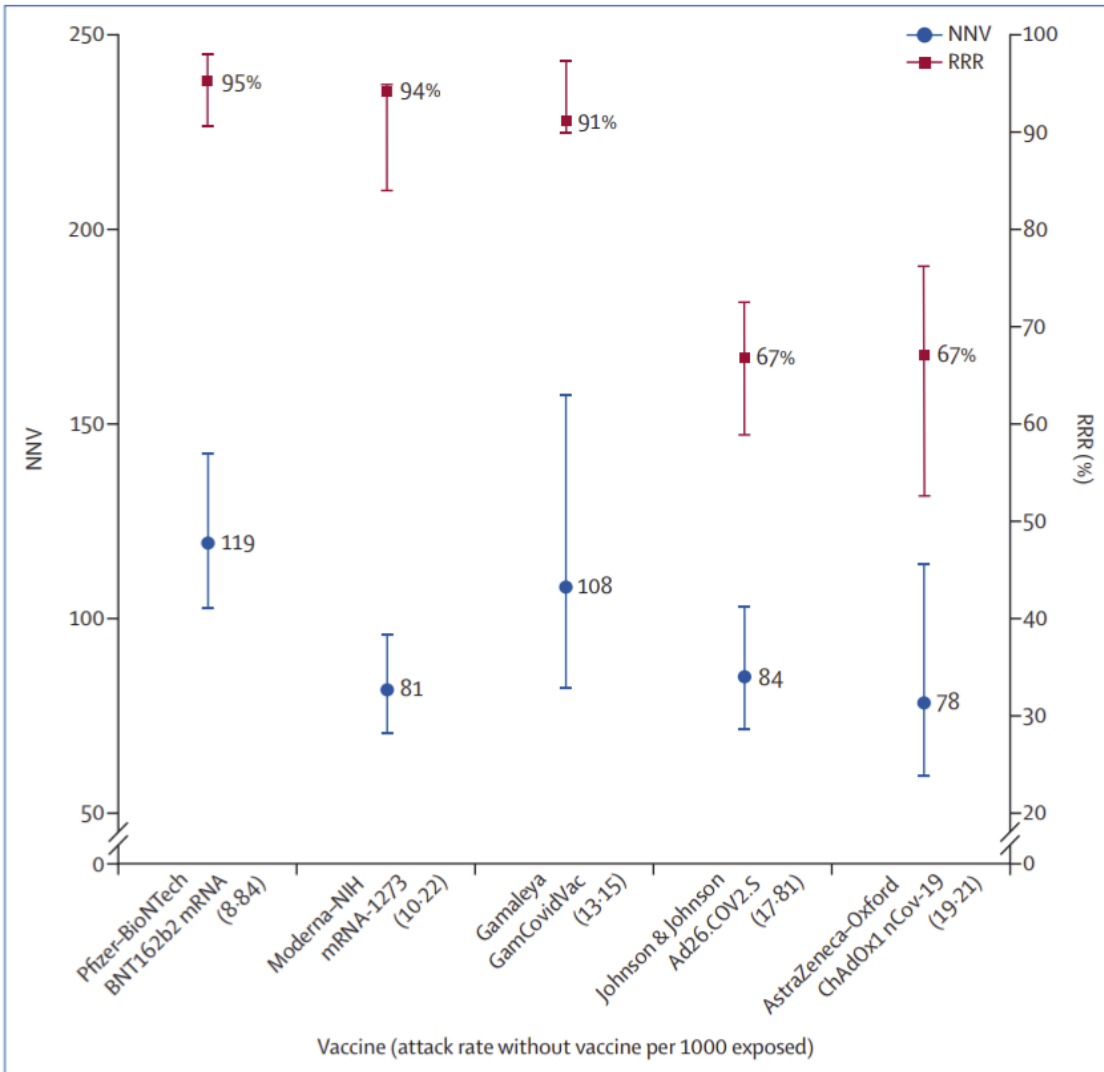


COVID-19 vaccines in Canada – clinical trials

Platform	Vaccine	Dosing regimen	Reported efficacy (vs. any symptomatic disease)
	BNT162b2 (Pfizer/BioNTech)	0, 21 days	95% (2 doses) → 91% @6 mths 93% (1 dose)
	mRNA-1273 (Moderna)	0, 28 days	95% (2 doses) 92% (1 dose)
	ChAdOx1-S (Oxford University/Astra Zeneca)	0, 28-84 days	65-75% (1 or 2 doses)
	Ad26.COVS.2.S (Janssen)	1 dose	67% (1 dose)
	NVX-CoV2373 (Novavax)	0, 21 days	90% (2 doses)
	Medicago	0,21 days	Currently in phase 3 trials
	Sanofi Pasteur/GlaxoSmithKline	0, 21 days	Completed phase 2 trials

Polack et al. NEJM 2020; Skowronski & De Serres. NEJM 2021; Baden et al. NEJM 2020; Voysey et al. Lancet 2020; Voysey et al. Lancet 2021; Sadoff et al. NEJM 2021; Logunov et al. Lancet 2021

What do the clinical trial data mean?



COVID-19

- Vaccinate ~100 people to prevent 1 case
- Vaccinate ~5,000 people to prevent 1 death
 - Vaccinate 1,000 people (60y+) to prevent 1 death

To prevent 1 death for other vaccines?

- Varicella: 34,000
- Meningococcal disease: 21,000
- Influenza (65y+): 5,000

Bottom line

- We have multiple, highly effective vaccines against a serious disease



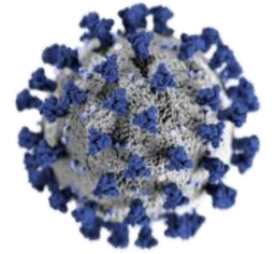
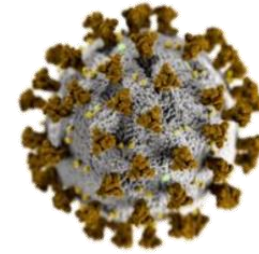
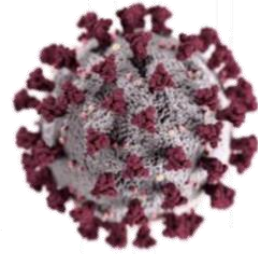
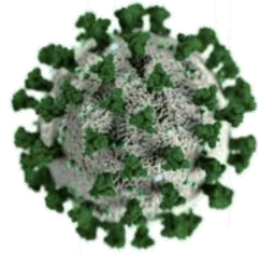
Variants



What is a Variant of Concern (VOC)?

- Evidence of one or more of:
 - Increased transmissibility
 - More severe disease
 - Significant reduction in neutralization by antibodies
 - Reduced effectiveness of treatments or vaccines
 - Diagnostic detection failures

We have variants of concern (VOCs)



Name	Alpha	Beta	Gamma	Delta
Lineage	B.1.1.7	B.1.351	P.1	B.1.617
First detected	Sep 2020	Oct 2020	Dec 2020	Dec 2020
Country of first detection	UK	South Africa	Brazil	India
Number of spike mutations	10-13	10	11	2-6
Increased transmission	✓	✓	✓	✓
Increased disease severity	✗	✓	(✓)	?
Reduced serum neutralization	(✓) minimal	✓	✓	(✓) minimal
Impact on vaccine effectiveness	(✓) minimal	(✓) variable	(✓) minimal	(✓) minimal

<https://covariants.org>; <https://www.ecdc.europa.eu/en/publications-data/covid-19-infographic-mutations-current-variants-concern>; <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/10-COVID-Scobie-508.pdf>



Impact of variants on vaccine efficacy – clinical trials

Table 1. Summary Results on SARS-CoV-2 Vaccine Trial Efficacy and Viral Neutralization of the B.1.1.7, P.1, and 501Y.V2 Variants, as Compared with Preexisting Variants.*

Vaccine (Company)	Sample Size no.	Preexisting Variants		Neutralization by Pseudovirion or Live Viral Plaque Assay			Efficacy in Settings with 501Y.V2 Variant
		Efficacy in Preventing Clinical Covid-19	Efficacy in Preventing Severe Covid-19	B.1.1.7 Variant	P.1 Variant	501Y.V2 Variant	%
		% (no. of events with vaccine vs. placebo)					
Ad26.COVS.2.S (Johnson & Johnson)	43,783	66 (NA)	85 (NA)	NA	NA	NA	57†, 85‡
BNT162b2 (Pfizer)	34,922	95 (8 vs. 162)	90 (1 vs. 9)	Decrease by 2x	Decrease by 6.7x	Decrease by ≤6.5x	NA
mRNA-1273 (Moderna)	28,207	94 (11 vs. 185)	100 (0 vs. 30)	Decrease by 1.8x	Decrease by 4.5x	Decrease by ≤8.6x	NA
Sputnik V (Gamaleya)	19,866	92 (16 vs. 62)	100 (0 vs. 20)	NA	NA	NA	NA
AZD1222 (AstraZeneca)	17,177	67 (84 vs. 248)	100 (0 vs. 3)	NA	NA	Decrease by ≤86x to complete immune escape	22§
NVX-CoV2373 (Novavax)	15,000	89 (6 vs. 56)	100 (0 vs. 1)	Decrease by 1.8x	NA	NA	49§
CoronaVac (Sinovac)¶							
Brazil	12,396	51 (NA)	100 (NA)	NA	NA	NA	NA
Turkey	7,371	91 (3 vs. 26)	NA	NA	NA	NA	NA
BBIBP-CorV (Sinopharm)	NA	79 (NA)	NA	NA	NA	Decrease by 1.6x	NA

B.1.351

* Data were available up to March 18, 2021. The definitions of mild, moderate, and severe coronavirus disease 2019 (Covid-19) vary across the vaccine trials. A list of references associated with these vaccines is provided in the Supplementary Appendix, available with the full text of this letter at NEJM.org. NA denotes not available, and SARS-CoV-2 severe acute respiratory syndrome coronavirus 2.

† Shown is the efficacy of the vaccine, as compared with placebo, against moderate-to-severe Covid-19.
 ‡ Shown is efficacy of the vaccine, as compared with placebo, against severe Covid-19 and hospitalization.
 § Shown is efficacy of the vaccine, as compared with placebo, against symptomatic Covid-19.
 ¶ Data are shown separately for the trial sites in Brazil and Turkey.

Vaccine effectiveness of BNT162b2 (Pfizer) - Qatar

Table 1. Vaccine Effectiveness against Infection and against Disease in Qatar.

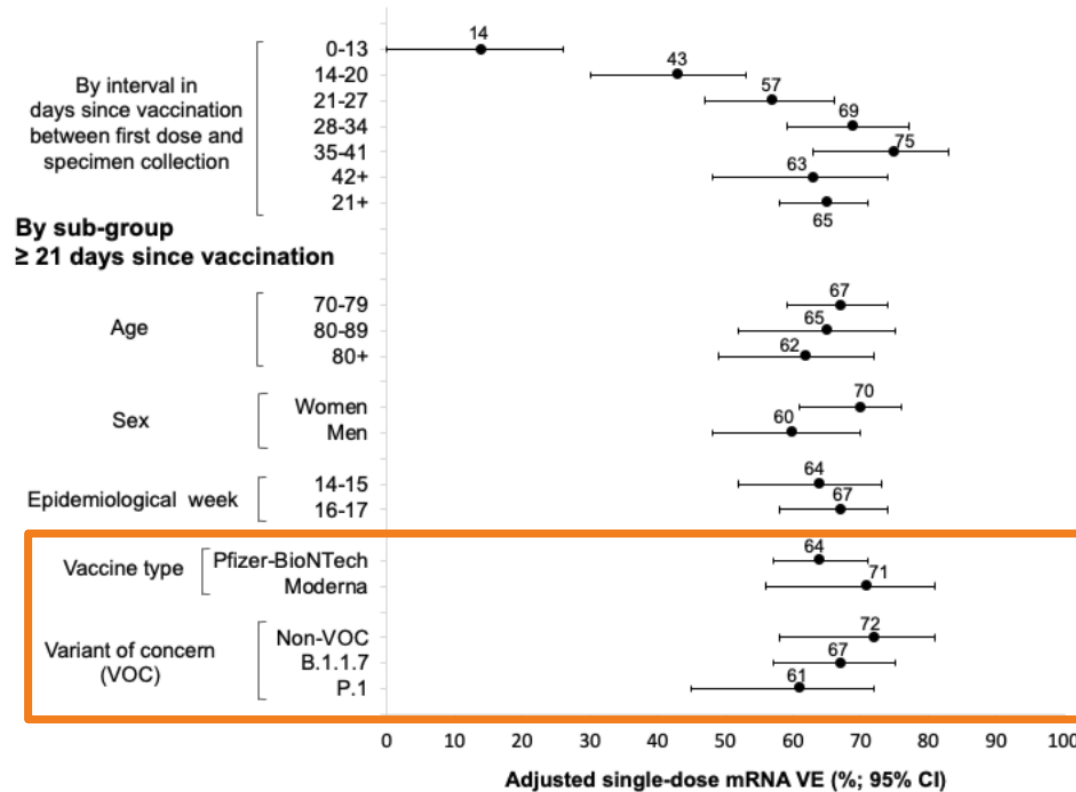
Type of Infection or Disease	PCR-Positive Persons		PCR-Negative Persons		Effectiveness (95% CI) [‡]
	Vaccinated	Unvaccinated	Vaccinated	Unvaccinated	
	<i>number of persons</i>				<i>percent</i>
Infection					
PCR-confirmed infection with the B.1.1.7 variant[†]					
After one dose	892	18,075	1241	17,726	29.5 (22.9–35.5)
≥14 days after second dose	50	16,354	465	15,939	89.5 (85.9–92.3)
PCR-confirmed infection with the B.1.351 variant[‡]					
After one dose	1329	20,177	1580	19,926	16.9 (10.4–23.0)
≥14 days after second dose	179	19,396	698	18,877	75.0 (70.5–78.9)
Disease[§]					
Severe, critical, or fatal disease caused by the B.1.1.7 variant					
After one dose	30	468	61	437	54.1 (26.1–71.9)
≥14 days after second dose	0	401	20	381	100.0 (81.7–100.0)
Severe, critical, or fatal disease caused by the B.1.351 variant					
After one dose	45	348	35	358	0.0 (0.0–19.0)
≥14 days after second dose	0	300	14	286	100.0 (73.7–100.0)
Severe, critical, or fatal disease caused by any SARS-CoV-2					
After one dose	139	1,966	220	1,885	39.4 (24.0–51.8)
≥14 days after second dose	3	1,692	109	1,586	97.4 (92.2–99.5)

Abu-Raddad et al.
NEJM 2021



Vaccine effectiveness against gamma variant - BC

Figure 2 Adjusted vaccine effectiveness estimates by interval in days since vaccination and restricted by sub-group, adults ≥ 70 years of age, British Columbia, Canada, weeks 14-17



VE = vaccine effectiveness; CI = confidence interval

All vaccine effectiveness estimates are adjusted for age group (70-79, 80-89, 90+ years); sex (men, women); epidemiological week (14, 15, 16, or 17); and health authority (HA) (Fraser HA, Interior HA, Northern HA, Vancouver Coastal HA, Vancouver Island HA). See **Supplementary Tables S2-S8** for details.

Vaccine effectiveness against delta variant - UK

Vaccination status		Alpha			Delta		
		OR vs symptomatic disease	HR vs hospitalisation	VE vs hospitalisation	OR vs symptomatic disease	HR vs hospitalisation	VE vs hospitalisation
Any vaccine							
	Dose 1	0.51 (0.48-0.55)	0.44 (0.28-0.70)	78% (65-86)	0.69 (0.64-0.75)	0.37 (0.22-0.63)	75% (57-85)
	Dose 2	0.13 (0.1-0.15)	0.64 (0.24-1.72)	92% (78-97)	0.20 (0.18-0.23)	0.29 (0.11-0.72)	94% (85-98)
Pfizer							
	Dose 1	0.53 (0.47-0.58)	0.32 (0.14-0.73)	83% (62-93)	0.64 (0.54-0.77)	0.10 (0.01-0.76)	94% (46-99)
	Dose 2	0.06 (0.05-0.08)	0.88 (0.21-3.77)	95% (78-99)	0.12 (0.1-0.15)	0.34 (0.10-1.18)	96% (86-99)
Astrazeneca							
	Dose 1	0.51 (0.48-0.55)	0.48 (0.30-0.77)	76% (61-85)	0.70 (0.65-0.76)	0.41 (0.24-0.70)	71% (51-83)
	Dose 2	0.26 (0.21-0.32)	0.53 (0.15-1.80)	86% (53-96)	0.33 (0.28-0.39)	0.25 (0.08-0.78)	92% (75-97)

Public Health England 14th June, 2021: https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZIEig/view_file/479607329?_com_liferay_document_library_web_portlet_DLPortlet_INSTANCE_v2WsRK3ZIEig_redirect=https%3A%2F%2Fkhub.net%3A443%2Fweb%2Fphe-national%2Fpublic-library%2F-document_library%2Fv2WsRK3ZIEig%2Fview%2F479607266



CoVaRR Net

Overarching Goal: Bring together all* Canadian Researchers for the common goal of understanding and stopping the SARS-CoV-2 pandemic AND anticipating what is to come

*Academic & government; basic, clinical & applied

Our vision and mission: To rapidly and efficiently act on the emergence of new SARS-CoV-2 variants of concern (VOCs) by

- 1) Functionally characterizing current VOCs' features, including the potential for vaccine resistance, breakthrough infections and immune escape,**
- 2) Predicting evolutionary trajectories and testing features of possible future VOCs, and**
- 3) Communicating new information in real-time (knowledge mobilization) to Canadian public health officials and decision-makers, as well to the broader international scientific community.**



Bottom line

- We have multiple, highly effective vaccines against a serious disease
- Vaccines are effective against variants – we need high uptake



Vaccine safety



Adverse events after vaccination - Canada

What you need to know up to and including June 18, 2021

One potential new safety signal has been identified

(one continues to be monitored)

31,400,466

Total doses administered

7,926

Total adverse event following immunization reports

(0.025% of all doses administered)

6,207

Total adverse event following immunization reports that were non-serious

(0.020% of all doses administered)

1,719

Total adverse event following immunization reports that were serious

(0.005% of all doses administered)

312

New adverse event following immunization reports since last update

(181 new non-serious and 131 new serious)

Data from US

Myocarditis/pericarditis chart confirmed rates in VSD in 21-day risk interval, 12–39-year-olds

(thru Jun 5, 2021)

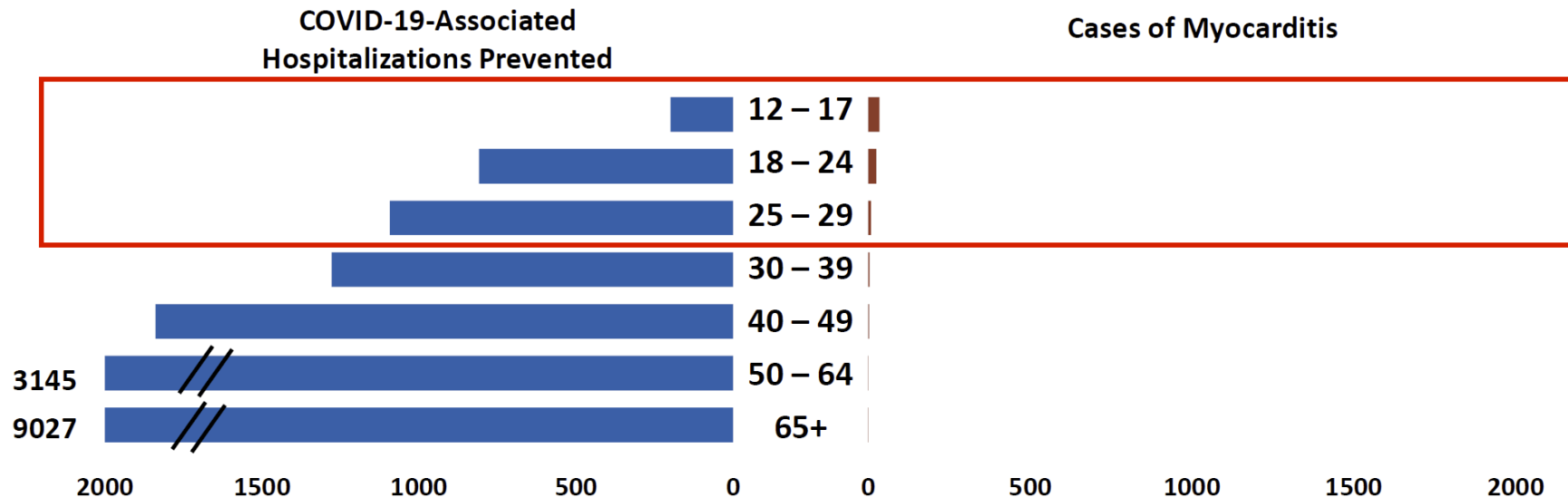
Vaccine(s) (dose #)	Cases	Doses admin	Rate per million doses (95% CI)
mRNA (both doses)	26	3,418,443	8 (5.3–11.8)
mRNA (dose 1)	8	1,879,585	4.4 (1.9–8.8)
mRNA (dose 2)	18	1,538,858	12.6 (7.5–19.9)
Pfizer-BioNTech (dose 1)	3	1,211,080	2.6 (0.5–7.7)
Pfizer-BioNTech (dose 2)	7	958,721	8.0 (3.2–16.5)
Moderna (dose 1)	5	668,505	7.5 (2.4–17.6)
Moderna (dose 2)	11	580,137	19.8 (9.9–35.5)



Data from US

Benefits and risks after dose 2, by age group

For every **million** doses of mRNA vaccine given with current US exposure risk¹



¹ Based on hospitalization rates from COVID-NET as of May 22nd. Benefit/Risk calculated over 120 days.

BC data

- 12-39yo = 1.6m in BC
- Per CDC 12.6 myocarditis cases/million 2nd doses → 20 cases in BC
- 6% ICU → 1 vaccine myocarditis ICU in BC **if all vaccinated**
- COVID-19 infection in BC in 10-39yo so far (from BCCDC situation report)
 - 200 ICU admissions
 - 17 deaths
- And that's with <5% of the population infected.....

US recommendations

Vaccine considerations in people with a history of myocarditis or pericarditis

Scenario	Recommendation
Pericarditis prior to COVID-19 vaccination	Receive any FDA-authorized COVID-19 vaccine
Pericarditis after 1 st dose of an mRNA COVID-19 vaccine but prior to 2 nd dose	Proceed with a 2 nd dose of mRNA COVID-19 vaccine after resolution of symptoms. Discuss with patient, guardian, and clinical team
Myocarditis prior to COVID-19 vaccination	Receive any FDA-authorized COVID-19 vaccine if heart has recovered
Myocarditis after 1 st dose of an mRNA COVID-19 vaccine but prior to 2 nd dose	Defer 2 nd dose of mRNA COVID-19 vaccine until more information is known However, if heart has recovered, could consider proceeding with 2 nd dose under certain circumstances. Discuss with patient, guardian, and clinical team



Safety surveillance in Canada is ongoing



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About the CANVAS-COVID Study

Why: The purpose of this study is to find out how often health events occur after a COVID-19 vaccine. The CANVAS surveillance network complements Canada's passive vaccine safety surveillance system with rapid information early in the COVID-19 vaccine campaign.

Who: You can take part in this study if you have an email address, telephone number and a device to answer online surveys. If you have been vaccinated [click here](#). If you have not been vaccinated [click here](#).

<https://canvas-covid.ca/>



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- Vaccines are effective against variants – we need high uptake
- Overall risk-benefit favours vaccination for all approved groups
 - Extremely rare serious side effects have been identified = good surveillance

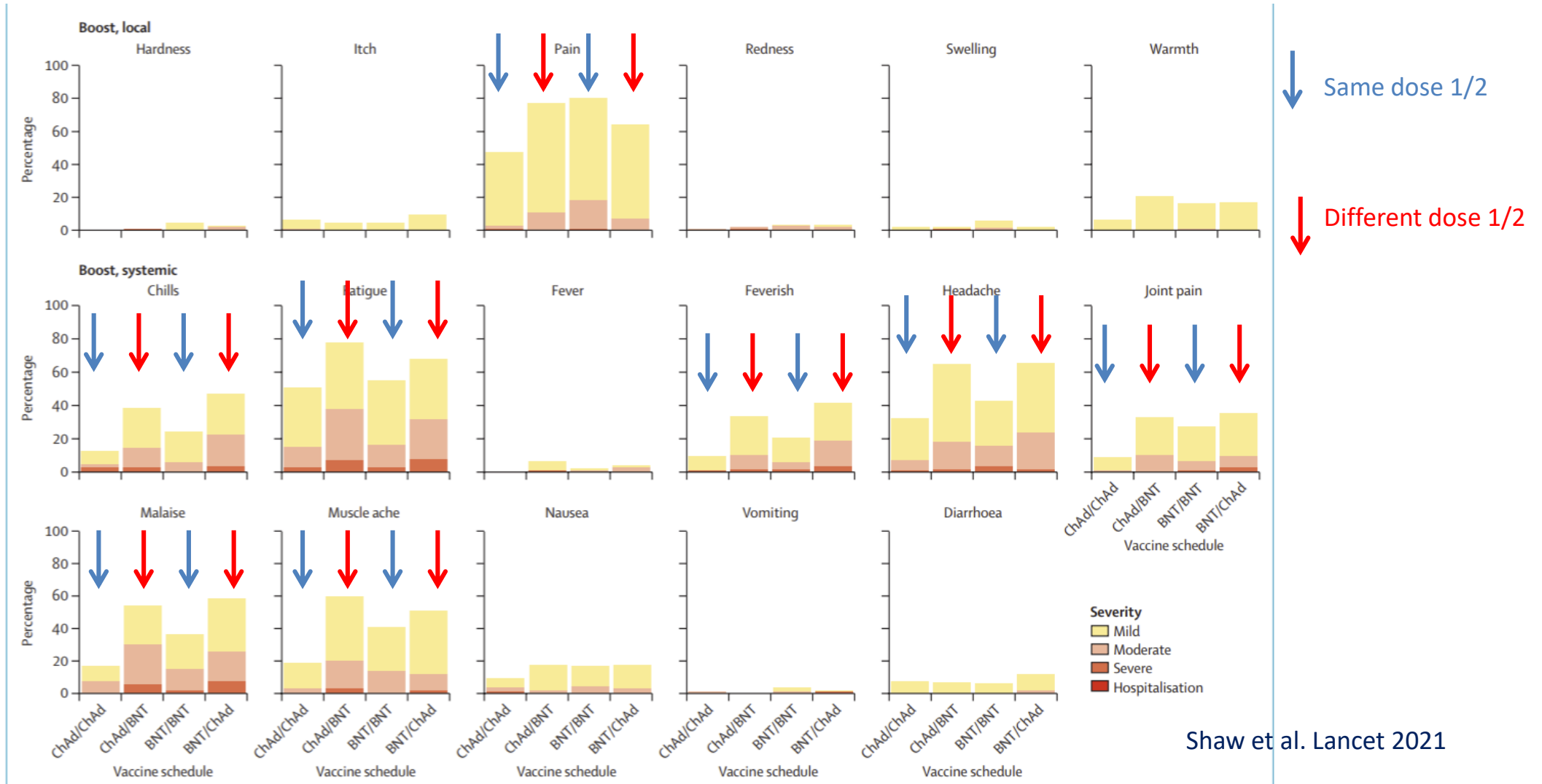


Vaccine interchangeability



Astra Zeneca – Pfizer combinations: safety

● UK



Shaw et al. Lancet 2021

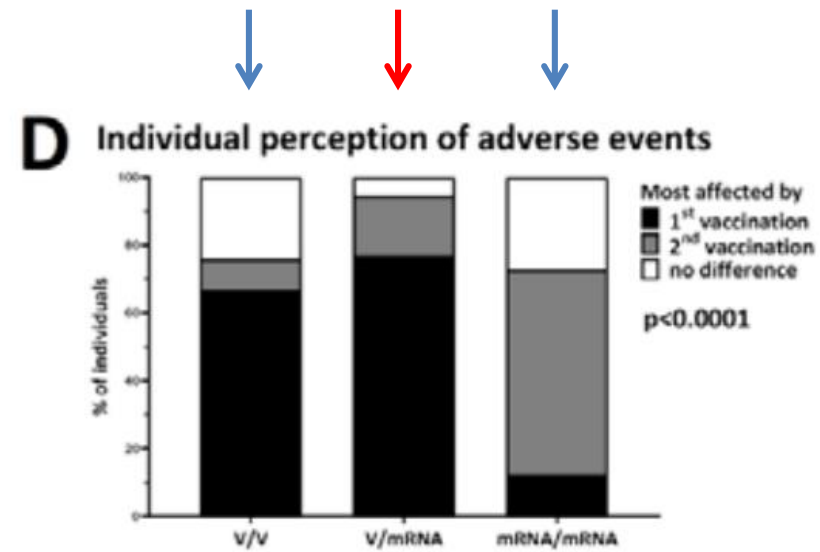
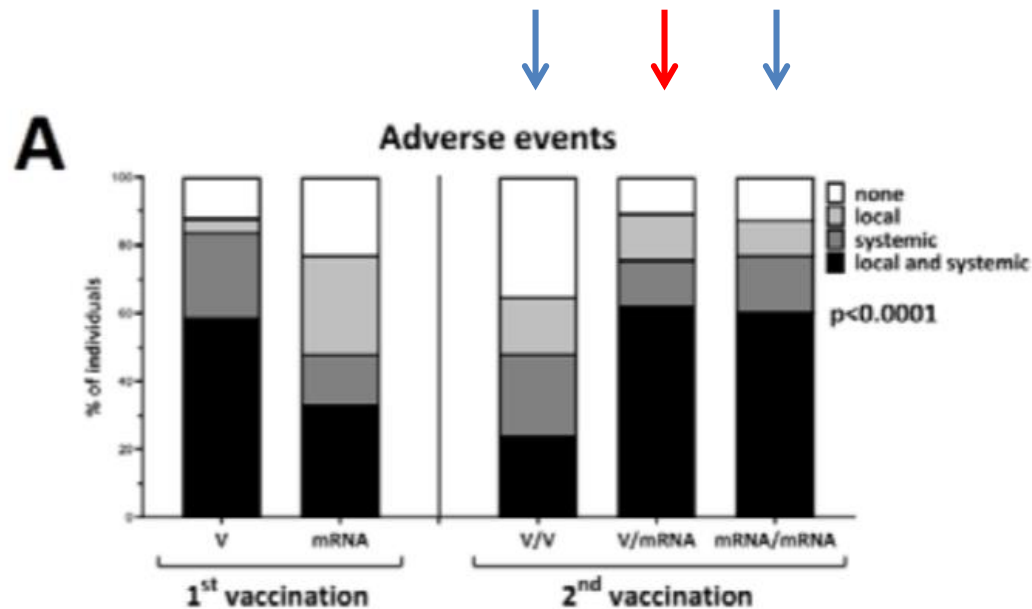


Astra Zeneca – Pfizer combinations: safety

- Germany

↓ Same dose 1/2

↓ Different dose 1/2

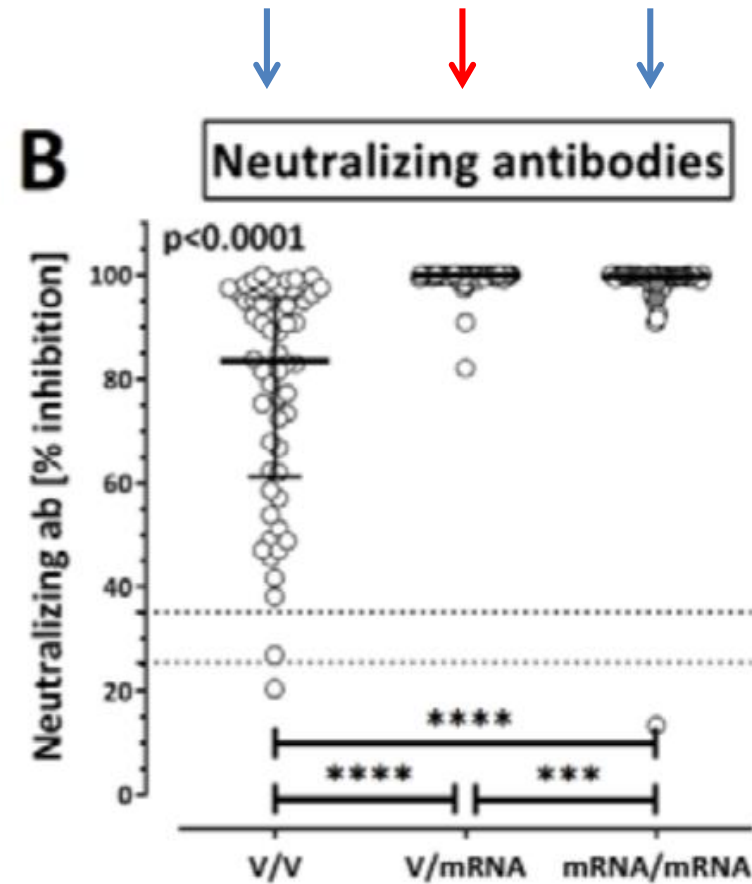
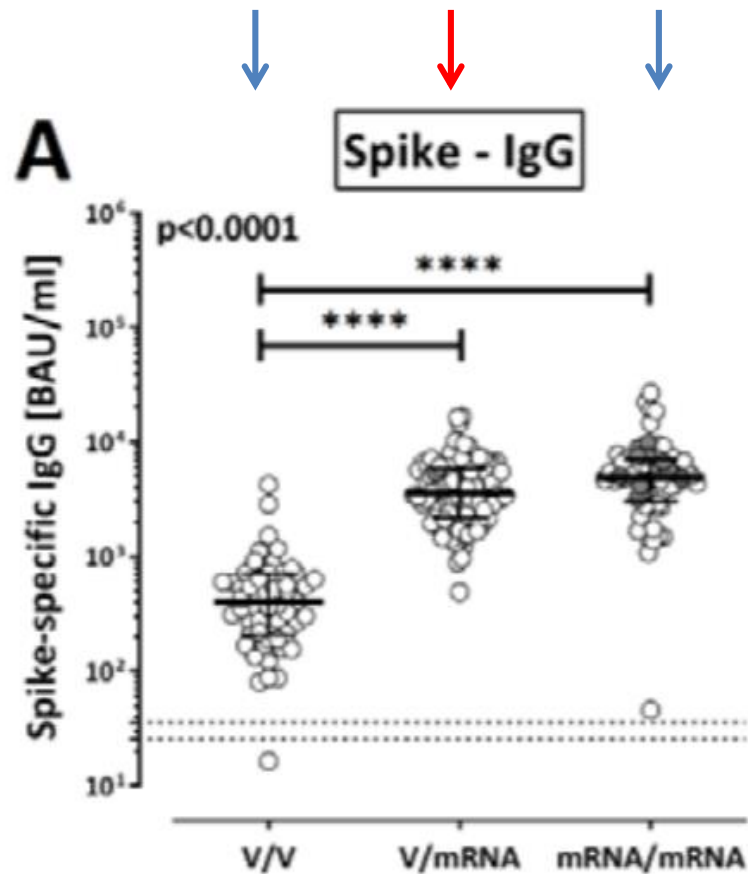


Schmidt et al. MedRxiv 2021



Astra Zeneca – Pfizer combinations: immunogenicity

- Germany



↓ Same dose 1/2

↓ Different dose 1/2

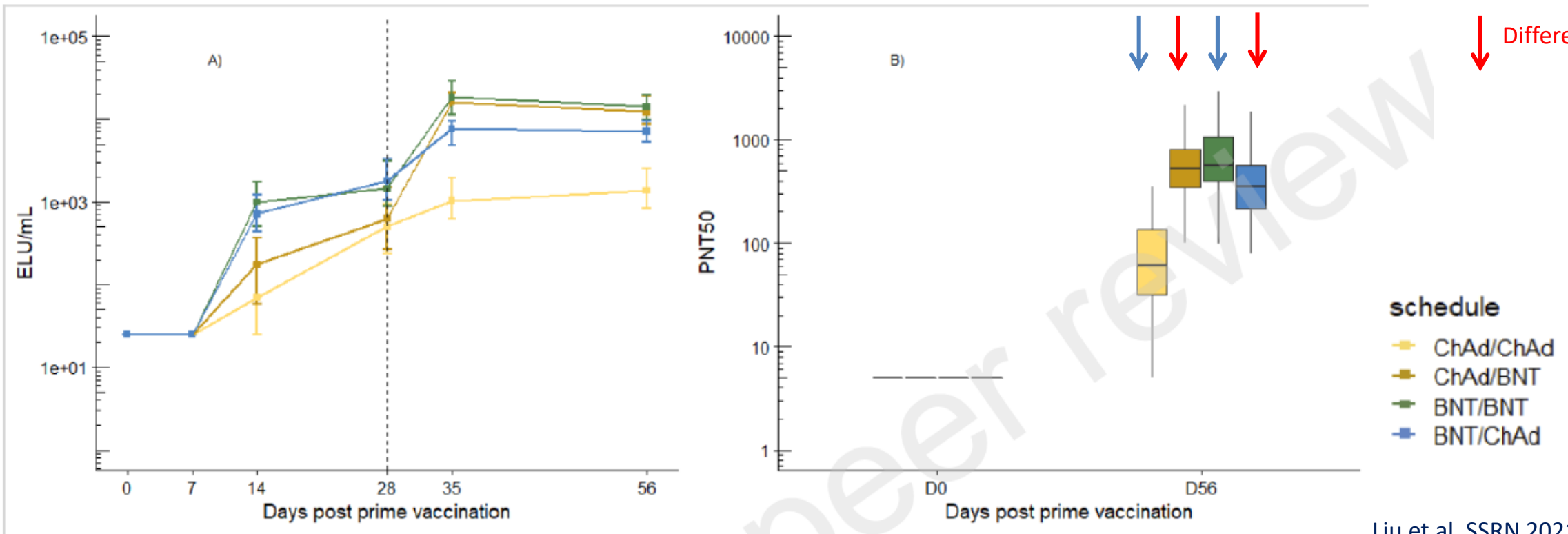
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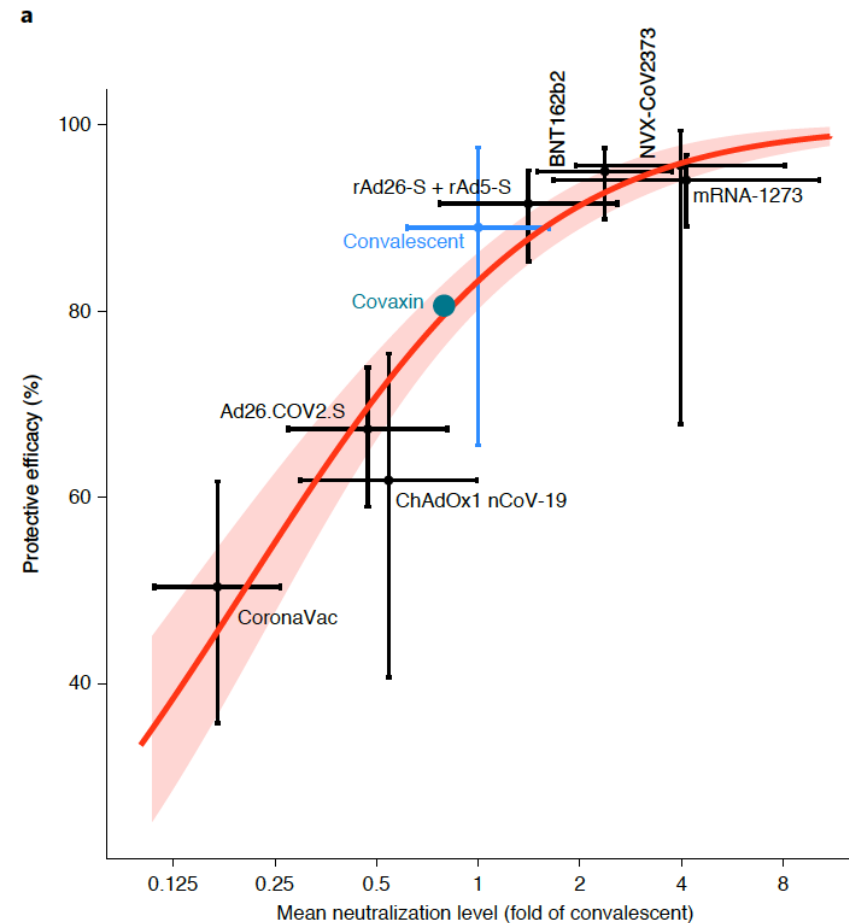


Liu et al. SSRN 2021



Does antibody matter?

- Yes, but there is more to it than that – no correlate of protection yet



Khoury et al. Nature Med 2021

MOSAIC trial: currently recruiting!



Group	1 st dose	2 nd dose	Days between doses	
1	Moderna	Moderna	28-56	
2	Moderna	Moderna		112
3	Moderna	Pfizer/BioNTech	28-56	
4	Moderna	Pfizer/BioNTech		112
5	Pfizer/BioNTech	Pfizer/BioNTech	28-56	
6	Pfizer/BioNTech	Pfizer/BioNTech		112
7	Pfizer/BioNTech	Moderna	28-56	
8	Pfizer/BioNTech	Moderna		112
9	Astra Zeneca	Moderna	28-56	
10	Astra Zeneca	Moderna		112
11	Astra Zeneca	Pfizer/BioNTech	28-56	
12	Astra Zeneca	Pfizer/BioNTech		112

Telephone: 604-875-2187

Email: mosaic.vec@bcchr.ubc.ca

Website: <https://www.bcchr.ca/vec/research/mosaic>



Bottom line

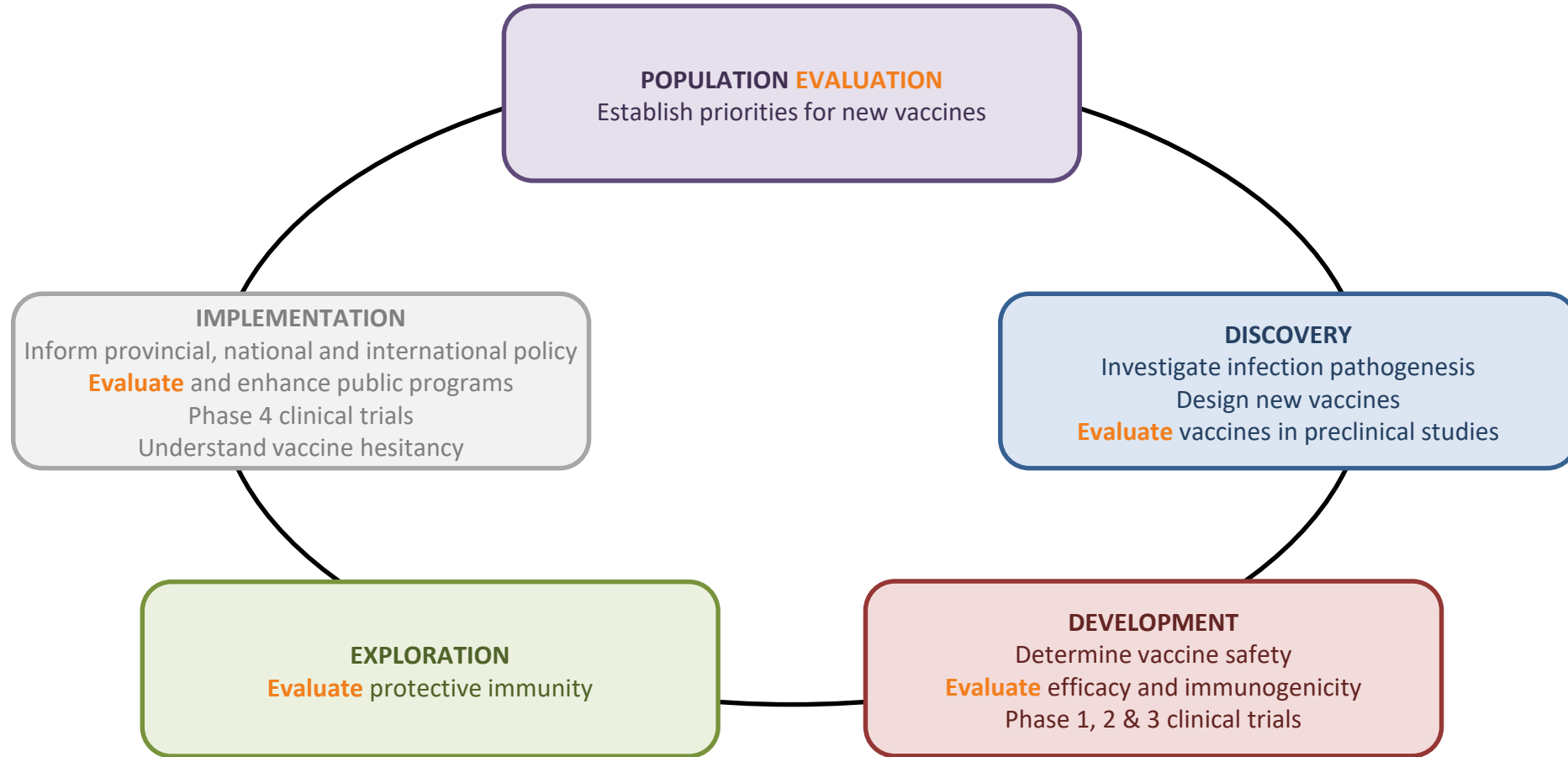
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- Current data suggest vaccines can be used interchangeably
 - But we need more data with different combinations



Research @VEC



Translational vaccinology research @VEC



Current COVID-19 Research Activities

Disease transmission and pathogenesis

- SPRING Study: SARS-CoV-2 seroPrevalence IN children and young adults in BC
- SHARE-COVID: Household transmission study (100 households in BC, 100 in Quebec)

DISCOVERY

Clinical trials, etc.

- COVID-19: PREVENT-COVID, MOSAIC
- Multiple trials in planning

DEVELOPMENT

Immunology

- BC Immunity Study: Immune responses in 50 individuals after natural infection

EXPLORATION

Phase 4 studies and vaccine safety

- Special Immunization Clinic (SIC), Canadian National Vaccine Safety (CANVAS)
- Special populations: transplant, cancer, immunocompromised, children and adults with chronic medical conditions, pregnancy, etc.

IMPLEMENTATION

Infectious Disease Epidemiology

- IMPACT: Surveillance of COVID-19 and MIS-C in 13 pediatric hospitals across Canada

POPULATION
EVALUATION

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PREVENT-COVID

- COVID-19 vaccine immunity study
 - Enable comparisons between vaccines
 - Evaluation of 1 vs. 2 dose responses
 - Antibody and T cell responses
 - Impact of prior infection with other endemic coronaviruses

Co-PIs

M Sadarangani

A Jassem

M Morshed

I Sekirov

Co-Investigators

S Bartlett

M Krajden

M Levings

D Skowronski

T Steiner

J Zlosnik



BC Centre for Disease Control



PREVENT-COVID

- Samples to be collected

- Before each vaccine dose (max. 24 hours pre-vaccination)
- 1, 3, 6, 9, 12, 18 months after completion of vaccine series
- Total 7-8 samples per person, depending on # of doses

- Sample size and sample types

- Main study: 400 per vaccine, self-collected finger prick (dried blood spots)
- **Substudy: 50 per vaccine, venous sampling**



BC Centre for Disease Control



BC
Children's
Hospital
Research Institute

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- Current data suggest vaccines can be used interchangeably
 - But we need more data with different combinations
- Lots of ongoing research generating data being used for policy in real time



Special populations – children, pregnancy



COVID-19 vaccine trials in children

Age group	Pfizer/BioNTech	Moderna	Oxford/Astra Zeneca	Janssen	Novavax
12-17 years	Approved and in use	Enrolment completed Data 2021 Q2	Recruitment ongoing	Recruitment ongoing	Recruitment ongoing
6-11 years	Recruitment ongoing USA/Europe Data 2021 Q3/4	Recruitment ongoing USA/Canada		No plans stated	Study planned
6 months – 5 years					
<6 months	No plans stated	No plans stated	Some protection expected from immunization in pregnancy		

BNT162b2 (Pfizer/BioNTech) in 12-15 years

- 12-15 years; n=2,260

- Vaccine: 1,131 → 0 cases of COVID-19; Placebo: 1,129 → 18 cases of COVID-19

- Safety

- Local reactions mostly mild to moderate, predominantly following the first dose
 - Systemic events were predominantly fatigue, headaches, chills, muscle pain, fever, and joint pain, more frequently after the second dose
 - Compared to 18-55y increased headache (65%), chills (42%) and fever (20%)

- Immunogenicity

- Neutralizing antibody geometric mean titers (GMTs) of 1,239.5 one month after the second dose; non-inferior to GMTs in participants aged 16 to 25 yrs (705.1)

Frenck et al. NEJM 2021

- Efficacy: “100% efficacy”



COVID-19 vaccines in pregnancy

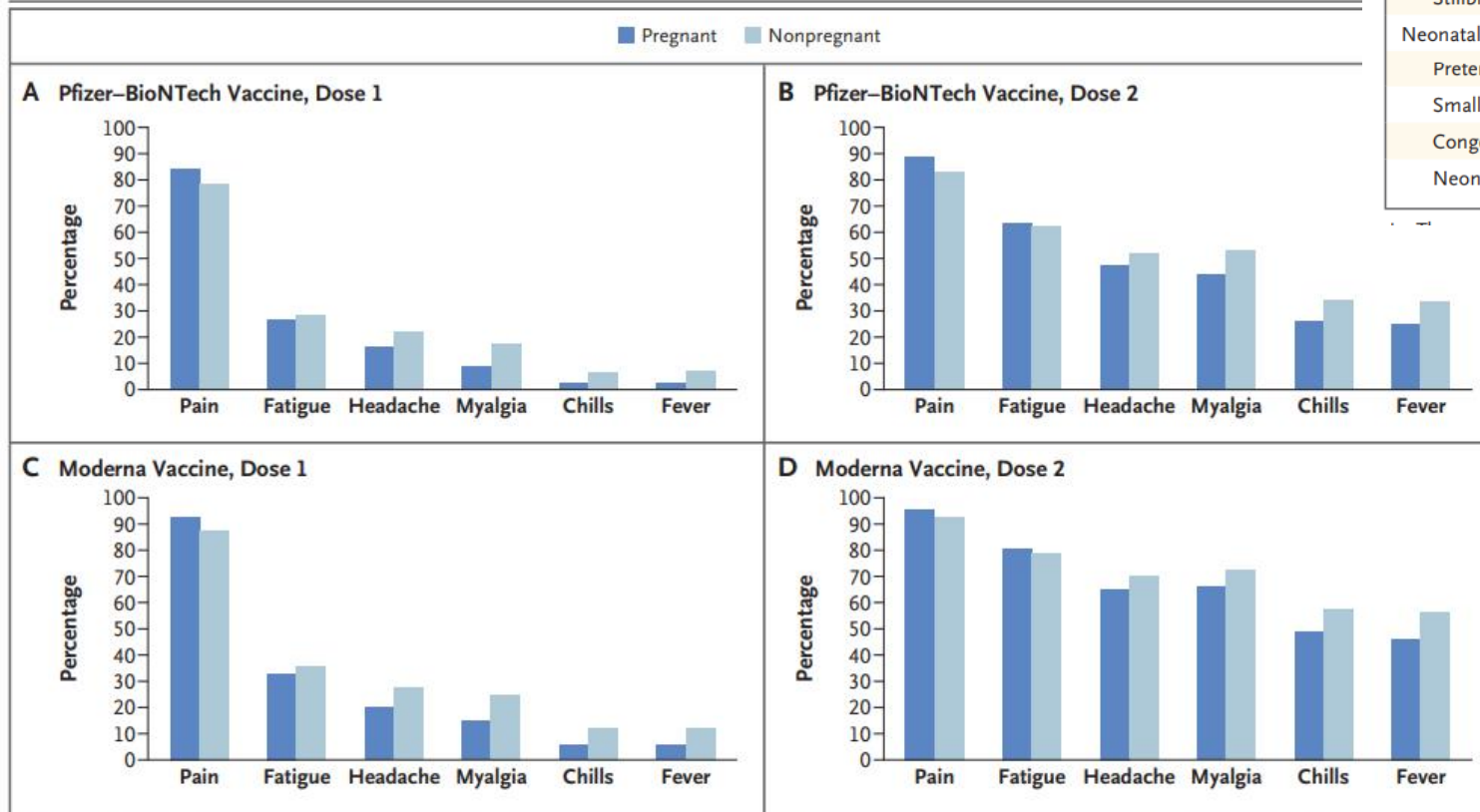


Figure 1. Most Frequent Local and Systemic Reactions Reported in the V-safe Surveillance System on the Day after mRNA Covid-19 Vaccination. Shown are solicited reactions in pregnant persons and nonpregnant women 16 to 54 years of age who received a messenger RNA (mRNA) coronavirus disease 2019 (Covid-19) vaccine — BNT162b2 (Pfizer–BioNTech) or mRNA-1273 (Moderna) — from December 14, 2020, to February 28, 2021. The percentage of respondents was calculated among those who completed a day 1 survey, with the top events shown of injection-site pain (pain), fatigue or tiredness (fatigue), headache, muscle or body aches (myalgia), chills, and fever or felt feverish (fever).

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	no./total no. (%)
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk ¹⁵⁻¹⁷	10–26	104/827 (12.6)‡
Stillbirth: ≥ 20 wk ¹⁸⁻²⁰	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk ²¹⁻²²	8–15	60/636 (9.4)¶
Small size for gestational age ^{23,24}	3.5	23/724 (3.2)
Congenital anomalies ^{25**}	3	16/724 (2.2)
Neonatal death ^{26††}	<1	0/724

>35,000 pregnant people

Shimabukuro et al. NEJM 2021



Vaccine hesitancy and your role

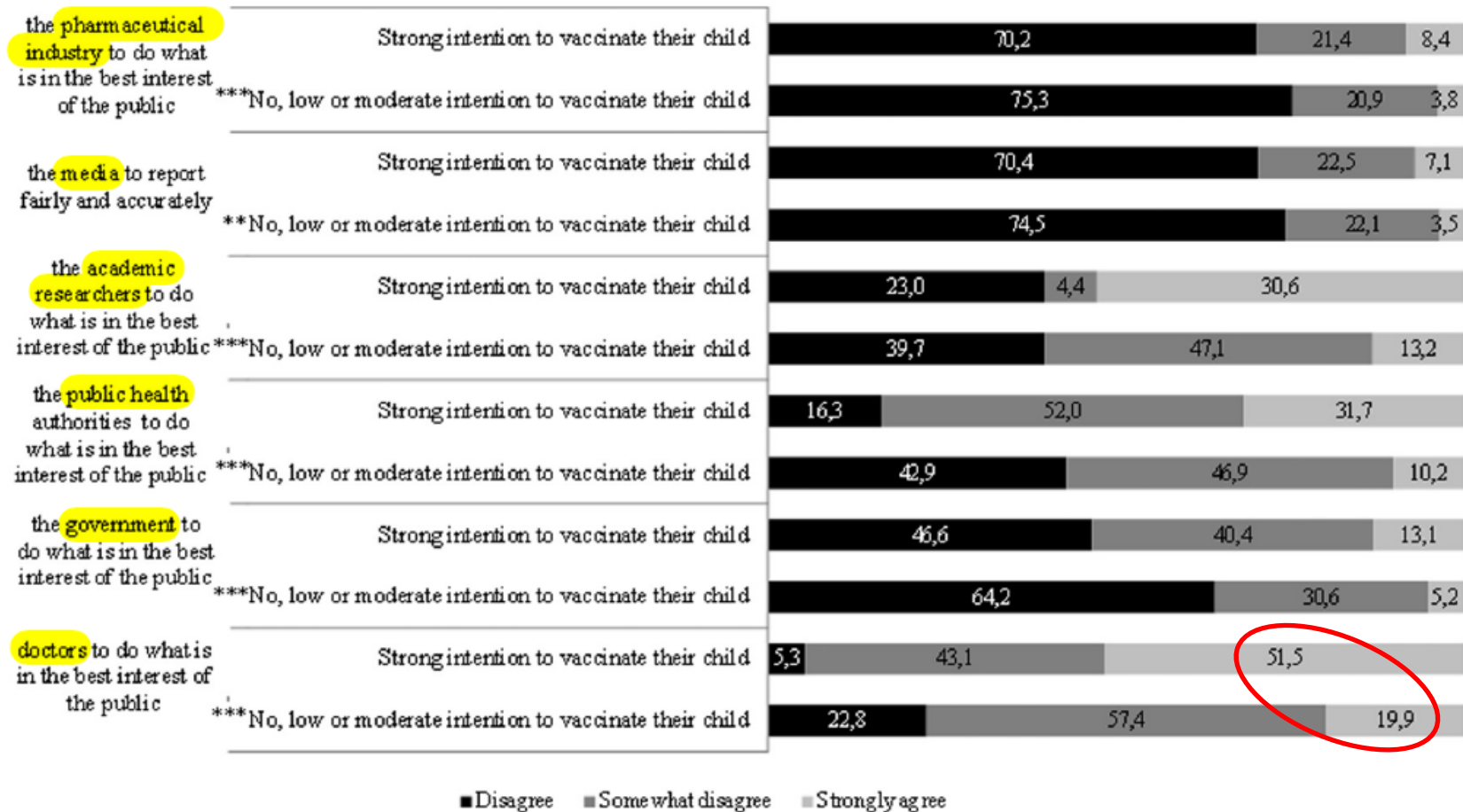


Vaccine Hesitancy - Definition

- Delay in acceptance or refusal of vaccines despite availability of vaccination services
- Complex and context specific varying across time, place and vaccines

HCWs influence others

Most of the time, we can trust...



Dubé et al. Vaccine 2018



You are the most trusted source

- Vaccinate yourselves and your co-workers
- Educate yourself about vaccines and vaccine programs
- Every health encounter is an opportunity for discussion
 - Listen to specific concerns – patients are all different
 - Use presumptive and motivational interviewing
 - “Sarah needs to be immunized today” instead of “What do you want to do about Sarah’s shots?”
 - Correct misconceptions, don’t introduce other concerns
 - Be non-judgemental and non-confrontational
 - Tell compelling stories – you have this experience!
 - Be clear in your recommendations



Specific resources

- <https://immunizebc.ca/covid-19-vaccine-frequently-asked-questions>
- <http://www.bccdc.ca/health-info/diseases-conditions/covid-19/covid-19-vaccine/bcs-plan-for-vaccine-distribution>
- <https://www.bcchr.ca/vec>

Bottom line

- We have multiple, highly effective vaccines against a serious disease
- Vaccines are effective against variants – we need high uptake
- Overall risk-benefit favours vaccination for all approved groups
 - Extremely rare serious side effects have been identified = good surveillance
- Current data suggest vaccines can be used interchangeably
 - But we need more data with different combinations
- Lots of ongoing research generating data being used for policy in real time
- You have an important role to play



Summary

- We are fortunate to have **multiple safe and effective vaccines**



- **All of us** have a duty to ensure they are used effectively

Thank you



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