COVID Talks for Docs #4

Webinar Series:
Maintaining and Optimizing Your Practice
During Times of Rapid Change

We will be starting the session promptly at 12:00 PM

COVID Talks for DOCS

January 6, 2021

Zoom technical support
(+1.888.799.9666 ext 2)

Dr. Mike Kolber
Mr. Tony Nickonchuk
Dr. Cheri Nijssen-Jordan
Dr. Cora Constantinescu
Dr. Jia Hu

Dr. Janet Craig
(Moderator)

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Land Acknowledgment

We would like to recognize that we are webcasting from, and to, many different parts of Alberta today. The province of Alberta is located on Treaty 6, Treaty 7 and Treaty 8 territory and is a traditional meeting ground and home for many Indigenous Peoples.

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Disclosure of Financial Support

This program has not received any financial or in-kind support.

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Presenter Disclosure

- Mike Kolber: ACFP, AH (Expert Committee for Drug Evaluation and Therapeutics) Alberta Society for Endoscopic Practice, U of A employee, Electronic Medical Procedures Reporting System Inc.
- Tony Nickonchuk: ACFP, AHS, AH (Expert Committee for Drug Evaluation and Therapeutics)
- Cheri Nijssen-Jordan: AHS
- Cora Constantinescu: Foundation of Canadian Women of Canada, GSK, Pfizer
- Jia Hu: Cleveland Clinic Canada - Advisory; CIHR, NSERC, Alberta Innovates and Pharmaceutical - research and operational funding; No honoraria
- Janet Craig: AMA - physician contractor, PCN Honoraria, UofA teaching, Custom Learning Solutions.

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Session Overview

This webinar will respond to common and emerging questions about the COVID-19 vaccine. Participants will have time to ask questions related to managing patient and practice needs during COVID-19, including:

- COVID-19 Vaccine safety & efficacy
- Vaccine distribution plan for Alberta
- Addressing vaccine hesitancy
- Expected post vaccination behaviours

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Learning Objectives

At the end of this session participants will be able to:

- Describe the safety & efficacy of the COVID-19 vaccine
- Summarize key messages in addressing vaccine hesitancy
- Understand some of the concerns around vaccine hesitancy
- Use a framework to hold a vaccine hesitancy conversation around COVID-19 vaccine

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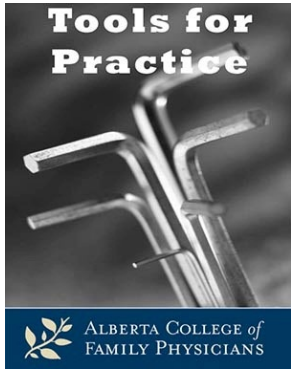
COVID-19 Vaccines

Mike Kolber MD, CCFP, MSc
Tony Nickonchuk BSc Pharm
PEER Team
University of Alberta



Status of COVID-19 Vaccines: Currently Approved (7)

SHOW/HIDE DETAILS

Show 10 entries Search:

	Name	Vaccine Type	Primary Developers	Country of Origin	Authorization/Approval
	BNT162b2	mRNA-based vaccine	Pfizer, BioNTech; Fosun Pharma	Multinational	UK, Bahrain, Canada, Mexico, US, Singapore, Oman, Saudi Arabia, Kuwait, EU
	mRNA-1273	mRNA-based vaccine	Moderna, BARDA, NIAID	US	US, Canada
	CoronaVac	Inactivated vaccine (formalin with alum adjuvant)	Sinovac	China	China
	No name announced	Inactivated vaccine	Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	China	China
	Sputnik V	Non-replicating viral vector	Gamaleya Research Institute, Acellena Contract Drug Research and Development	Russia	Russia
	BBIBP-CorV	Inactivated vaccine	Beijing Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	China	China, United Arab Emirates, Bahrain
	EpiVacCorona	Peptide vaccine	Federal Budgetary Research Institution State Research Center of Virology and Biotechnology	Russia	Russia

World Health Organization. COVID-19 vaccine tracker. https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker (Accessed Jan 2, 2021).

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Status of COVID-19 Vaccines; In Development (55)

Vaccine candidates in development

SHOW/HIDE DETAILS

Show 10 entries Search:

	Candidate	Mechanism	Sponsor	Trial Phase	Institution
	Convidicea (Ad5-nCoV)	Recombinant vaccine (adenovirus type 5 vector)	CanSino Biologics	Phase 3	Tongji Hospital; Wuhan, China
	AZD1222	Replication-deficient viral vector vaccine (adenovirus from chimpanzees)	The University of Oxford; AstraZeneca; IQVIA; Serum Institute of India	Phase 3	The University of Oxford, the Jenner Institute
	Covaxin	Inactivated vaccine	Bharat Biotech; National Institute of Virology	Phase 3	
	JNJ-78436735 (formerly Ad26.COV2.S)	Non-replicating viral vector	Johnson & Johnson	Phase 3	Johnson & Johnson
	NVX-CoV2373	Nanoparticle vaccine	Novavax	Phase 3	Novavax
	Bacillus Calmette-Guerin (BCG) vaccine	Live-attenuated vaccine	University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital	Phase 2/3	University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital
	INO-4800	DNA vaccine (plasmid)	Inovio Pharmaceuticals	Phase 2/3	Center for Pharmaceutical Research, Kansas City. Mo.; University of Pennsylvania, Philadelphia

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Canadian Vaccine Development

SHOW/HIDE DETAILS

Show 10 entries Search:

	Candidate	Mechanism	Sponsor	Trial Phase	Institution
	V591	Measles vector vaccine	University of Pittsburgh's Center for Vaccine Research	Phase 1	University of Pittsburgh; Themis Biosciences; Institut Pasteur
	VXA-CoV2-1	Recombinant vaccine (adenovirus type 5 vector)	Vaxart	Phase 1	Vaxart
	AAVCOVID	Gene-based vaccine	Massachusetts Eye and Ear; Massachusetts General Hospital; University of Pennsylvania	Pre-clinical	
	AdCOVID	Intranasal vaccine	Altimmune	Pre-clinical	University of Alabama at Birmingham
	ChAd-SARS-CoV-2-S	Adenovirus-based vaccine	Washington University School of Medicine in St. Louis	Pre-clinical	Washington University School of Medicine in St. Louis
	HaloVax	Self-assembling vaccine	Voltron Therapeutics, Inc.; Hoth Therapeutics, Inc.	Pre-clinical	MGH Vaccine and Immunotherapy Center
	LineaDNA	DNA vaccine	Takis Biotech	Pre-clinical	Takis Biotech
	MRT5500	Recombinant vaccine	Sanofi, Translate Bio	Pre-clinical	
	No name announced	Ii-Key peptide COVID-19 vaccine	Generex Biotechnology	Pre-clinical	Generex
	No name announced	Protein subunit vaccine	University of Saskatchewan Vaccine and Infectious Disease Organization-International Vaccine Centre	Pre-clinical	University of Saskatchewan Vaccine and Infectious Disease Organization-International Vaccine Centre

Showing 41 to 50 of 55 entries Previous 1 2 3 4 5 6 Next

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Evidence: Big Three

- Interim Results: ~ 2 months (from 1-2 year studies), publications/FDA reports
- Per Protocol Results provided: received 2 doses, irrespective of baseline COVID status

Pfizer BIONTECH

moderna messenger therapeutics

AstraZeneca

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Pfizer/BionTech: BNT162b2 vaccine

- Double-blind, RCT of 40,137 >16 years (X= 51 years)], 75% US
  - Also Argentina, Brazil, SA, Germany, Turkey
- Two doses 21 days apart

≥ 7 days after 2nd shot:

  - COVID cases: vaccine 9, placebo 169. Relative RR: 95%
  - Severe COVID: vaccine 1, placebo 4*
- Adverse events:
  - Unsolicited patient reports: injection pain 11%, fatigue 6%, myalgia/ headache 5%.
  - Solicited reports (patients asked daily about specific AEs): 5-10Xs more common
    - ex. solicited fatigue: vaccine 34-59%, placebo 17-33%
  - Serious AEs (~0.5%), deaths similar between groups

Pfizer-Biontech, Vaccines and Related Biological Products Advisory Committee Meeting Dec 10, 2020. FDA Briefing Document. Available at: https://www.fda.gov/media/144245/download. Accessed Dec 7, 2020. *NEJM* online Dec 10, 2020. DOI: 10.1056/NEJMoa2034577, NEJM DOI: 10.1056/NEJMoa2035389

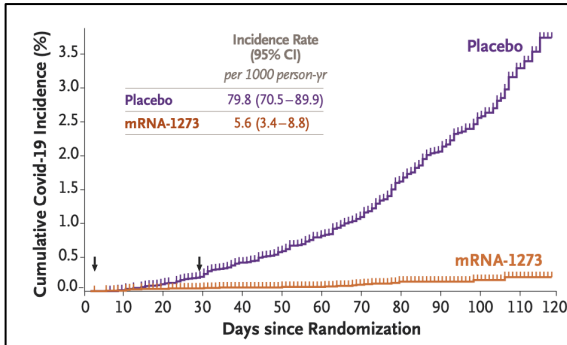
Moderna: mRNA-1273

- Double-blind RCT of 28,207 US > 18 years (median age 51)
- 2 doses given 28 days apart

≥ 14 days after 2nd shot:

  - Cases: vaccine 11, placebo 185 (RRR: 94%)
  - Severe COVID: vaccine 0, placebo 30.

- Adverse Events
  - Unsolicited: headache 3%, fatigue 2%, lymphadenopathy 1.2%, myalgia 1%.
  - Solicited: ~5-20Xs more common
    - Headache: vaccine 25-63%, placebo 18-29%
  - Serious AEs ~0.6% in both, deaths similar between groups.



	mRNA-1273 Vaccine N=14,550	Placebo N=14,598
Symptomatic Covid-19	11	185
Severe Covid-19	0	30

Vaccine efficacy of 94.1% (95% CI, 89.3–96.8%; P<0.001)

Moderna TX Inc. Vaccines and Related Biological Products Advisory Committee Meeting December 17, 2020. FDA Briefing Document. Available at: https://www.fda.gov/media/144434/download. Accessed Dec 15, 2020 NEJM Dec 30, 2020: DOI: 10.1056/NEJMoa2035389

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AstraZeneca/Oxford: AZD1222

- Multiple single-blind RCTs with multiple arms [variable 1st dose, timing (4 to >12 weeks) of second dose]. Two doses to 11,636 Brazil/UK adults.

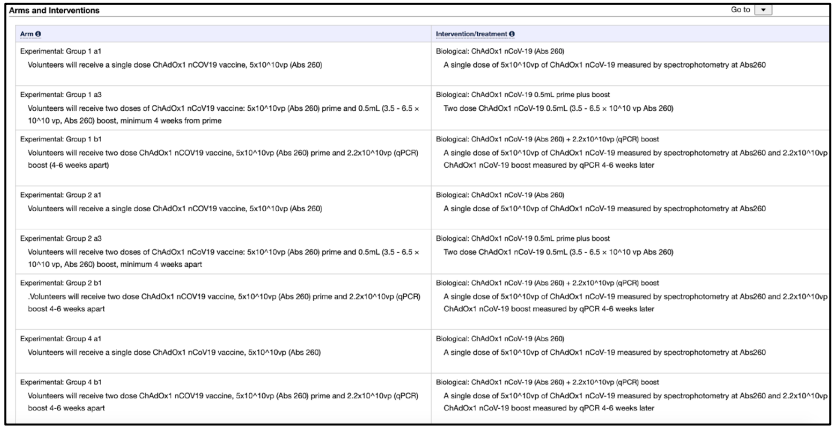
≥14 days after 2nd shot:

- COVID Overall: vaccine 30, placebo 101. RRR=70%
  - Low dose RRR=90%, Standard dose RRR=62%.
    - Low dose given to only 18-55 year-olds, ~90% health care workers.
- Severe COVID: vaccine 0, placebo 2.
- Serious AEs: vaccine 0.7%, placebo 0.8%.
  - 3 cases of transverse myelitis (2 vaccine, 1 placebo): deemed unrelated to vaccine.
  - Overall mortality similar

Lancet Dec 8, 2020. https://doi.org/10.1016/S0140-6736(20)32661-1. AstraZeneca. C Study Protocol - Amendment 2. AZD122 - D8110C00001. Sept 17, 2020. Avalable at: https://s3.amazonaws.com/ctr-med-7111/D8110C00001/52bec400-80f6-4c1b-8791-0483923d0867/c8070a4e-6a9d-46f9-8c32-cece903592b9/D8110C00001_CSP-v2.pdf. Accessed Dec 1, 2020

Issues with AZ/Oxford RCTs

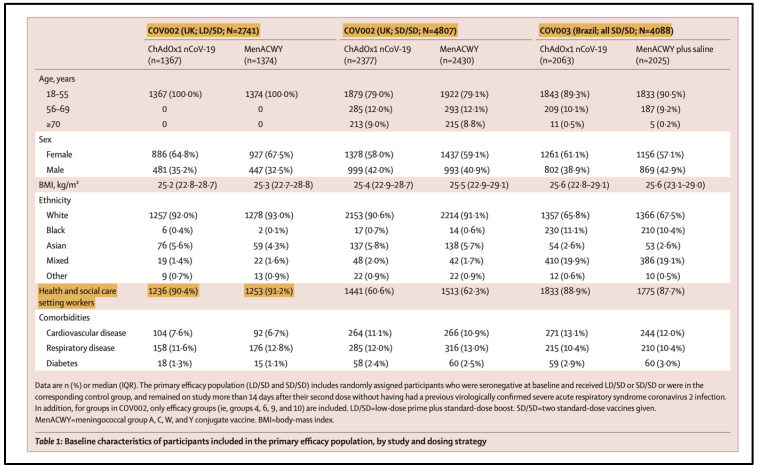
- Complex: 3 separate trials registries (NCT04400838 (UK), NCT04516746 (US), NCT04536051 (Brazil), multiple arms, multiple protocol amendments
- Low dose: given to young health care workers



Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Group 1 a1 Volunteers will receive a single dose ChAdOx1 nCOV19 vaccine, 5x10^10vp (Abs 260)	Biological: ChAdOx1 nCoV-19 (Abs 260) A single dose of 5x10^10vp of ChAdOx1 nCoV-19 measured by spectrophotometry at Abs260
Experimental: Group 1 a3 Volunteers will receive two doses of ChAdOx1 nCoV19 vaccine: 5x10^10vp (Abs 260) prime and 0.5mL (3.5 - 6.5 × 10^10 vp, Abs 260) boost, minimum 4 weeks from prime	Biological: ChAdOx1 nCoV-19 0.5mL prime plus boost Two dose ChAdOx1 nCoV-19 0.5mL (3.5 - 6.5 × 10^10 vp Abs 260)
Experimental: Group 1 b1 Volunteers will receive two dose ChAdOx1 nCOV19 vaccine, 5x10^10vp (Abs 260) prime and 2.2x10^10vp (qPCR) boost (4-6 weeks apart)	Biological: ChAdOx1 nCoV-19 (Abs 260) + 2.2x10^10vp (qPCR) boost A single dose of 5x10^10vp of ChAdOx1 nCoV-19 measured by spectrophotometry at Abs260 and 2.2x10^10vp ChAdOx1 nCoV-19 boost measured by qPCR 4-6 weeks later
Experimental: Group 2 a1 Volunteers will receive a single dose ChAdOx1 nCOV19 vaccine, 5x10^10vp (Abs 260)	Biological: ChAdOx1 nCoV-19 (Abs 260) A single dose of 5x10^10vp of ChAdOx1 nCoV-19 measured by spectrophotometry at Abs260
Experimental: Group 2 a3 Volunteers will receive two doses of ChAdOx1 nCoV19 vaccine: 5x10^10vp (Abs 260) prime and 0.5mL (3.5 - 6.5 × 10^10 vp, Abs 260) boost, minimum 4 weeks apart	Biological: ChAdOx1 nCoV-19 0.5mL prime plus boost Two dose ChAdOx1 nCoV-19 0.5mL (3.5 - 6.5 × 10^10 vp Abs 260)
Experimental: Group 2 b1 Volunteers will receive two dose ChAdOx1 nCOV19 vaccine, 5x10^10vp (Abs 260) prime and 2.2x10^10vp (qPCR) boost 4-6 weeks apart	Biological: ChAdOx1 nCoV-19 (Abs 260) + 2.2x10^10vp (qPCR) boost A single dose of 5x10^10vp of ChAdOx1 nCoV-19 measured by spectrophotometry at Abs260 and 2.2x10^10vp ChAdOx1 nCoV-19 boost measured by qPCR 4-6 weeks later
Experimental: Group 4 a1 Volunteers will receive a single dose ChAdOx1 nCoV19 vaccine, 5x10^10vp (Abs 260)	Biological: ChAdOx1 nCoV-19 (Abs 260) A single dose of 5x10^10vp of ChAdOx1 nCoV-19 measured by spectrophotometry at Abs260
Experimental: Group 4 b1 Volunteers will receive two dose ChAdOx1 nCOV19 vaccine, 5x10^10vp (Abs 260) prime and 2.2x10^10vp (qPCR) boost 4-6 weeks apart	Biological: ChAdOx1 nCoV-19 (Abs 260) + 2.2x10^10vp (qPCR) boost A single dose of 5x10^10vp of ChAdOx1 nCoV-19 measured by spectrophotometry at Abs260 and 2.2x10^10vp ChAdOx1 nCoV-19 boost measured by qPCR 4-6 weeks later



	COV002 (UK; LD/SD; N=2741)		COV002 (UK; SD/SD; N=4807)		COV003 (Brazil; all SD/SD; N=4088)	
	ChAdOx1 nCoV-19 (n=1367)	MenACWY (n=1374)	ChAdOx1 nCoV-19 (n=2377)	MenACWY (n=2430)	ChAdOx1 nCoV-19 (n=2063)	MenACWY plus saline (n=2025)
Age, years						
18–55	1367 (100·0%)	1374 (100·0%)	1879 (79·0%)	1922 (79·1%)	1843 (89·3%)	1833 (90·5%)
56–69	0	0	285 (12·0%)	293 (12·1%)	209 (10·1%)	187 (9·2%)
≥70	0	0	213 (9·0%)	215 (8·8%)	11 (0·5%)	5 (0·2%)
Sex						
Female	886 (64·8%)	927 (67·5%)	1378 (58·0%)	1437 (59·1%)	1261 (61·1%)	1156 (57·1%)
Male	481 (35·2%)	447 (32·5%)	999 (42·0%)	993 (40·9%)	802 (38·9%)	869 (42·9%)
BMI, kg/m²	25·2 (22·8–28·7)	25·3 (22·7–28·8)	25·4 (22·9–28·7)	25·5 (22·9–29·1)	25·6 (22·8–29·1)	25·6 (23·1–29·0)
Ethnicity						
White	1257 (92·0%)	1278 (93·0%)	2153 (90·6%)	2214 (91·1%)	1357 (65·8%)	1366 (67·5%)
Black	6 (0·4%)	2 (0·1%)	17 (0·7%)	14 (0·6%)	230 (11·1%)	210 (10·4%)
Asian	76 (5·6%)	59 (4·3%)	137 (5·8%)	138 (5·7%)	54 (2·6%)	53 (2·6%)
Mixed	19 (1·4%)	22 (1·6%)	48 (2·0%)	42 (1·7%)	410 (19·9%)	386 (19·1%)
Other	9 (0·7%)	13 (0·9%)	22 (0·9%)	22 (0·9%)	12 (0·6%)	10 (0·5%)
Health and social care setting workers	1236 (90·4%)	1253 (91·2%)	1441 (60·6%)	1513 (62·3%)	1833 (88·9%)	1775 (87·7%)
Comorbidities						
Cardiovascular disease	104 (7·6%)	92 (6·7%)	264 (11·1%)	266 (10·9%)	271 (13·1%)	244 (12·0%)
Respiratory disease	158 (11·6%)	176 (12·8%)	285 (12·0%)	316 (13·0%)	215 (10·4%)	210 (10·4%)
Diabetes	18 (1·3%)	15 (1·1%)	58 (2·4%)	60 (2·5%)	59 (2·9%)	60 (3·0%)

Data are n (%) or median (IQR). The primary efficacy population (LD/SD and SD/SD) includes randomly assigned participants who were seronegative at baseline and received LD/SD or SD/SD or were in the corresponding control group, and remained on study more than 14 days after their second dose without having had a previous virologically confirmed severe acute respiratory syndrome coronavirus 2 infection. In addition, for groups in COV002, only efficacy groups (ie, groups 4, 6, 9, and 10) are included. LD/SD=low-dose prime plus standard-dose boost. SD/SD=two standard-dose vaccines given. MenACWY=meningococcal group A, C, W, and Y conjugate vaccine. BMI=body-mass index.

Table 1: **Baseline characteristics of participants included in the primary efficacy population, by study and dosing strategy**

www.clinicaltrials.gov NCT04400838, Accessed Dec 15, 2020; Lancet 2020 doi.org/10.1016/ S0140-6736(20)32661-1

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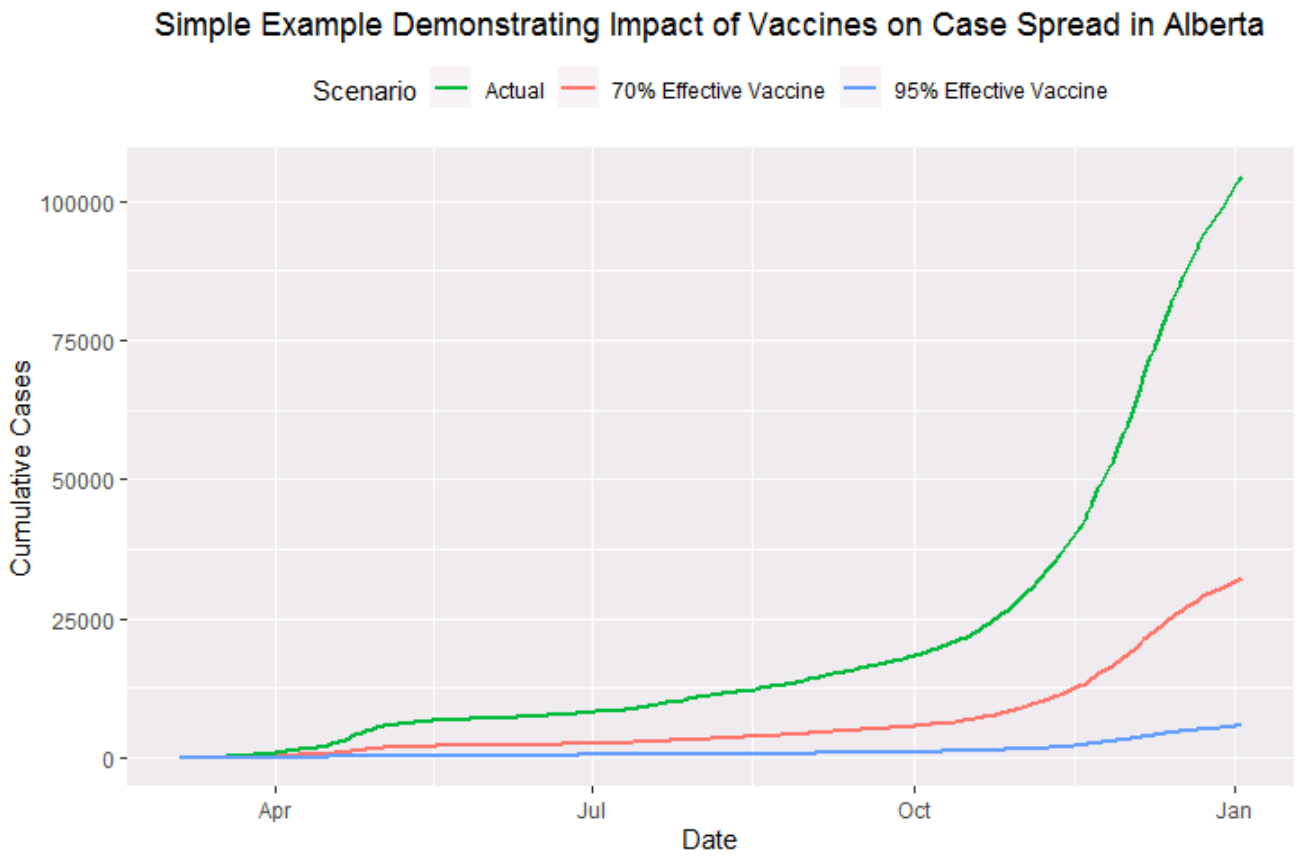
Vaccine Information

COVID-19 Vaccine (mRNA) – Pfizer ultra frozen vaccine

COVID-19 Vaccine (mRNA) – Moderna frozen vaccine

Example of Vaccine Impact



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Allergic Reactions to COVID-19 Vaccine

- 2 cases of anaphylaxis post Pfizer vaccine in UK
- HC/CDC: “if allergic to any ingredient of the vaccine → don’t get vaccine”
- Traditional Vaccine Risk Anaphylaxis: 1 per million

- Medicinal ingredient:
  - mRNA
- Non-medicinal ingredients:
  - ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
  - ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
  - 1,2-Distearoyl-sn-glycero-3-phosphocholine
  - cholesterol
  - dibasic sodium phosphate dihydrate
  - monobasic potassium phosphate
  - potassium chloride
  - sodium chloride
  - sucrose
  - water for injection

Should be available at all sites	If feasible, include at sites (not required)
Epinephrine prefilled syringe or autoinjector*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine)†	Oxygen
Blood pressure cuff	Bronchodilator (e.g., albuterol)
Stethoscope	H2 antihistamine (e.g., famotidine, cimetidine)
Timing device to assess pulse	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

https://healthycanadians.gc.ca Accessed Jan 3, 2021, NEJM Dec 30, 2020 DOI: 10.1056/NEJMra2035343
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html

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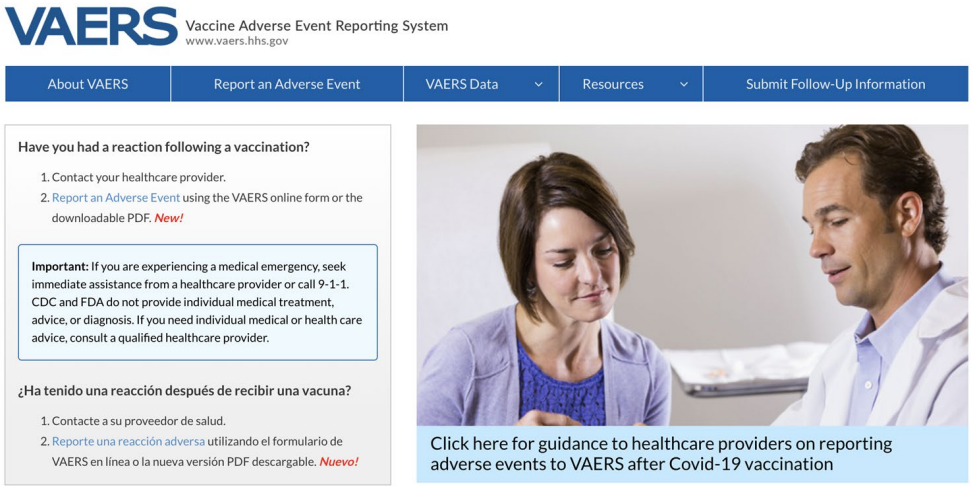
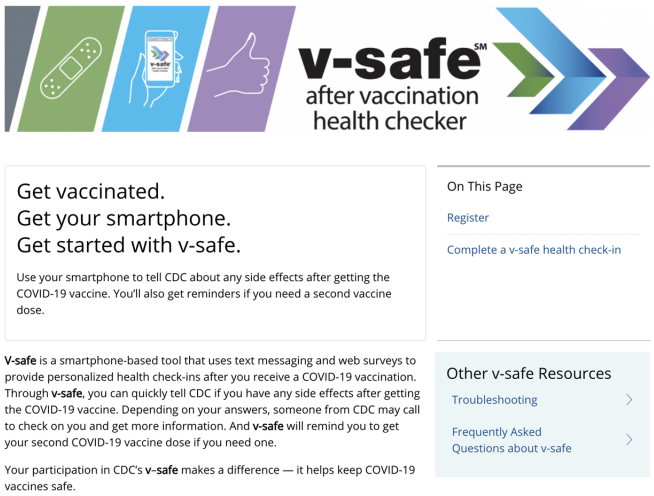
Reporting Serious AEs





- Canada: https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html

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Current Unknowns

- Efficacy of one dose
- Efficacy/Safety: children or pregnant women
  - Pfizer enrolling 12-15 year olds
- Do vaccines prevent transmission?
- How long protective? is booster needed?
  - Do those with previous COVID benefit?
- Efficacy against emerging variants

What's Next?

Roll Out Approved Vaccines, Longer Term Big Three Studies, Additional Vaccines Approved

Applications received related to the COVID-19 pandemic

Applicant	Medicinal ingredient(s)	Therapeutic area	Date application was received	Outcome of application	Date of decision/outcome
AstraZeneca Canada Inc.	Adenovirus vaccine vector (ChAdOx1)	Vaccines, for human use	2020-10-01	Under review	n/a
Janssen Inc	JNJ-78436735/Ad26.COV2.S	Vaccines, for human use	2020-11-30	Under review	n/a
Moderna Therapeutics Inc.	mRNA-1273 SARS-CoV-2	Vaccines, for human use	2020-10-12	Authorized (with terms and conditions)	2020-12-23
Pfizer Canada ULC/BioNTech SE	Tozinameran (mRNA vaccine, BNT162b2)	Vaccines, for human use	2020-10-09	Authorized (with terms and conditions)	2020-12-09

Table 1. SARS-CoV-2 Vaccines under Emergency Use Authorization (EUA) or in Late-Phase Studies.

Vaccine Platform	Type of Vaccine and Immunogen	Developer (Name of Vaccine)	Dose Schedule and Administration	Phase*	Excipients†
RNA-based vaccine	mRNA encoding spike protein (30 μg)	BioNTech–Pfizer (BNT162b2)	Two doses (day 0, day 21) Intramuscular	Post-EUA	0.43 mg {(4-hydroxybutyl)azanediyl}bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2{(**polyethylene glycol**)-**2000**}-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol, 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% sodium chloride Injection) contributes an additional 2.16 mg sodium chloride per dose
RNA-based vaccine	mRNA encoding spike protein (100 μg)	Moderna (mRNA-1273)	Two doses (day 0, day 28) Intramuscular	Post-EUA	Lipids (SM-102; 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [**PEG 2000**-DMG]; cholesterol; and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose
Adenovirus vector (nonreplicating)	ChAdOx1-Sn Cov-19 Nonreplicating chimpanzee AdV5 expressing spike protein	AstraZeneca and University of Oxford (AZD1222)	One (day 0) or two (day 0, day 28) doses Intramuscular	Phase 3	10 mM histidine, 7.5% (w/v) sucrose, 35 mM sodium chloride, 1 mM magnesium chloride, 0.1% (w/v) **polysorbate 80**, 0.1 mM edetate disodium, 0.5% (w/v) ethanol, at pH 6.6
Adenovirus vector (nonreplicating)	Ad26.COV2.S Adenovirus 26 vectored vaccine using AdVac and PER.C6 technology	Janssen	One (day 0) or two (day 0, day 56) doses Intramuscular	Phase 3	Sodium chloride, citric acid monohydrate, **polysorbate 80**, 2 hydroxypropyl-B-cyclodextrin (HBCD), ethanol (absolute), sodium hydroxide
Protein subunit	Full-length recombinant SARS-CoV-2 glycoprotein nanoparticle with Matrix M adjuvant Spike prefusion protein	Novavax	Two doses (day 0, day 21) Intramuscular	Phase 3	Matrix M1 adjuvant Full-length spike protein formulated in **polysorbate 80** detergent and Matrix M1 adjuvant
Protein subunit	SARS-CoV-2 vaccine formulation with adjuvant (S-protein) (Baculovirus production) Spike protein	Sanofi Pasteur and GSK	Two doses (day 0, day 21) Intramuscular	Phase 1–2	Sodium phosphate monobasic monohydrate, sodium phosphate dibasic, sodium chloride **polysorbate 20**, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride

* Phase information was current as of December 21, 2020. In all cases, the placebo was normal saline.
† Bold entries are excipients potentially related to vaccine reaction that may be cross-reactive to other excipients (e.g., PEG 2000 and polysorbate 80). SM-102, a component of the Moderna vaccine, is a proprietary ionizable lipid.

https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/authorization/applications.html. Accessed Jan 3, 2021
PHAC: https://www.canada.ca/content/dam/phac-aspc/documents/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-covid-19-immunization-plan-en.pdf
Accessed Jan 4, 2021
NEJM Dec 30, 2020: DOI: 10.1056/NEJMra2035343

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Summary

- Interim results of two large RCTs (Pfizer, Moderna) demonstrate ~95% relative efficacy in preventing COVID-19).
  - The AstraZeneca/Oxford vaccine has ~70% relative efficacy
  - May decrease the likelihood of severe COVID-19.
- Vaccines appear safe (SAEs < 1%), mostly local transient reactions
  - True risk of anaphylaxis: from real world evidence
- Ongoing studies to determine:
  - Adolescents and pregnant women
  - Length of benefit/booster requirement
  - Single dose efficacy

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Alberta's vaccine distribution & prioritization plan

Dr. Cheri Nijssen-Jordan

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Alberta Vaccine Rollout

- Alberta is receiving approved Health Canada vaccines and distributing through a phased immunization program
- Exact amounts and timelines are subject to change depending on vaccine supply
- Goal is to immunize Albertans as safely and effectively as possible
- Logistics complicated: multiple different vaccines/ needs

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Phases (decided by AH)

Early Phase 1 (Late Dec to Jan 4)

- Healthcare workers in ICUs
- Respiratory therapists
- Staff in long term care and designated supportive living facilities

Phase 1A (Jan 4 to Jan 25)

- All of the Early Phase
- Home care workers
- Healthcare workers in emergency departments
- All residents of long term care and designated supportive living, regardless of age

Phase 1B (Feb 1 to Mar 31)

- Seniors 75 years of age and over, no matter where they live
- First Nations, Métis and persons 65 years of age and over living in a First Nations community or Metis Settlement
- Healthcare workers in medical, surgical and COVID-19 units or operating rooms

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Future Phases

Phase 2: April to Sept 2021

- Work to identify sequencing for Phase 2 groups is underway
- Decisions will be made in 2021 by AH

Phase 3: Fall 2021

- Anticipated start of roll-out to the general public

Progress to date (as of Jan 3)

- Over 22,000 doses of COVID-19 vaccine have been administered in Alberta
- 1 adverse event has been reported to AH/AHS (adenopathy)
- Supply continues to be limited, especially for second dosing
- Eligible staff/physicians for immunization are contacted by phone initially and soon to be by online booking
- Lists being used: AHS staff, Med Affairs, Covenant Health and LTC/DSL providers, Regulator list (after acceptance by professional), Home care contractors etc.
- Contact information “validated” and sent to booking teams

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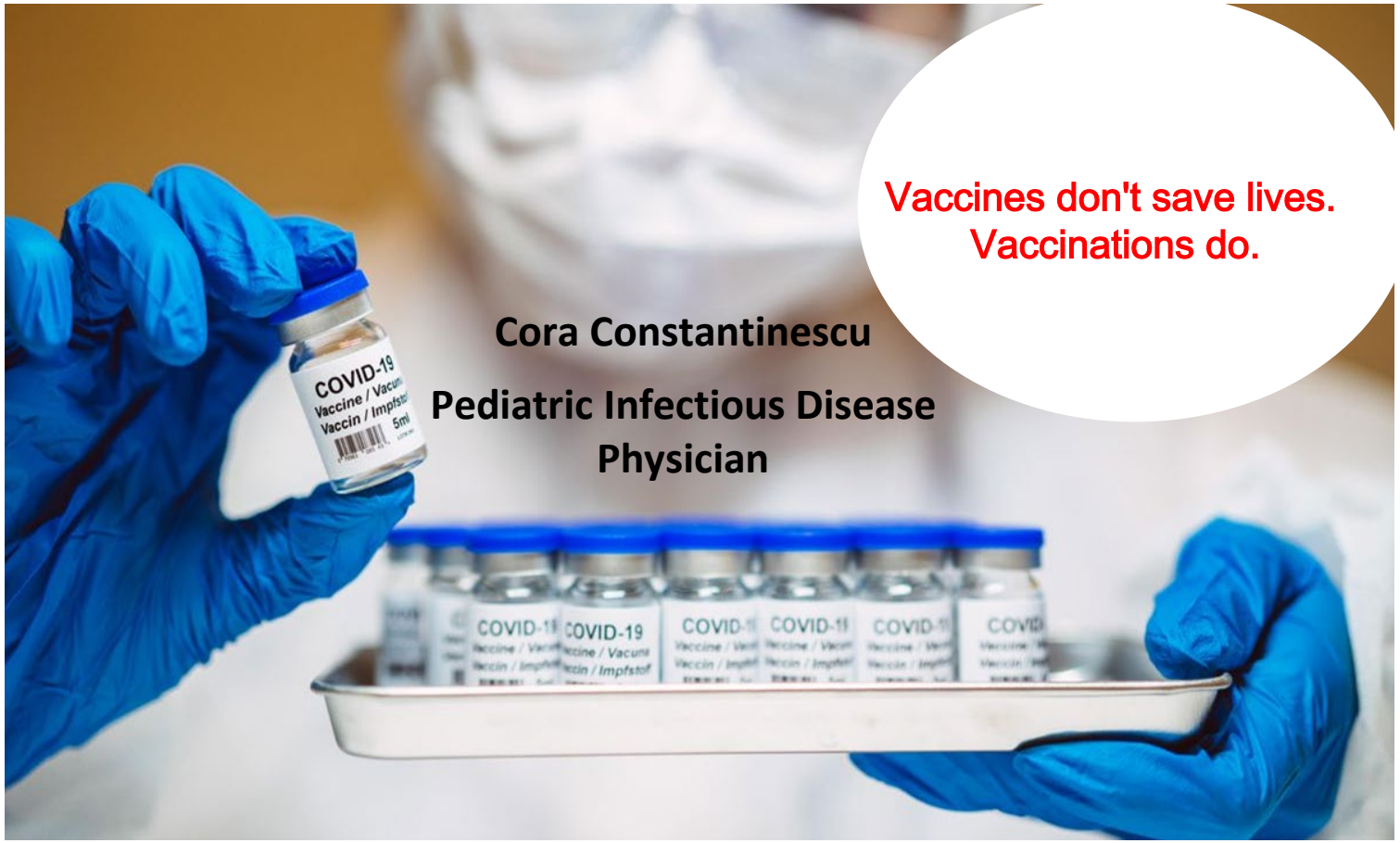
COVID-19 Vaccine Hesitancy: A Primer



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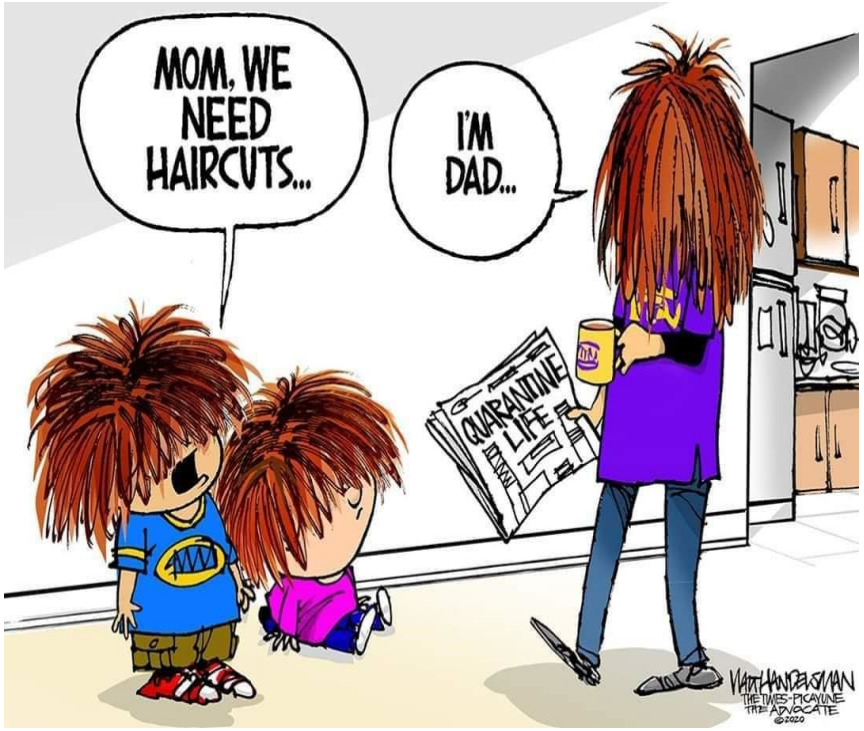
Issues with vaccine acceptance before a vaccine was even rolled out

- Pushed faster than ever seen before
- Many of the COVID-19 vaccine antigen carrying platforms (e.g. mRNA vaccine, adenovirus carrier vaccine, etc.) are new
- Production won't meet demand and scarcity may exist even among prioritized groups
- More than one type of COVID vaccine is likely to be used within a country

Dubé E, MacDonald NE. How can a global pandemic affect vaccine hesitancy? *Expert Review of Vaccines*. 2020

So how is this playing out in real life?



https://libertyonthelighterside.com/the-funniest-covid-19-memes-and-jokes/

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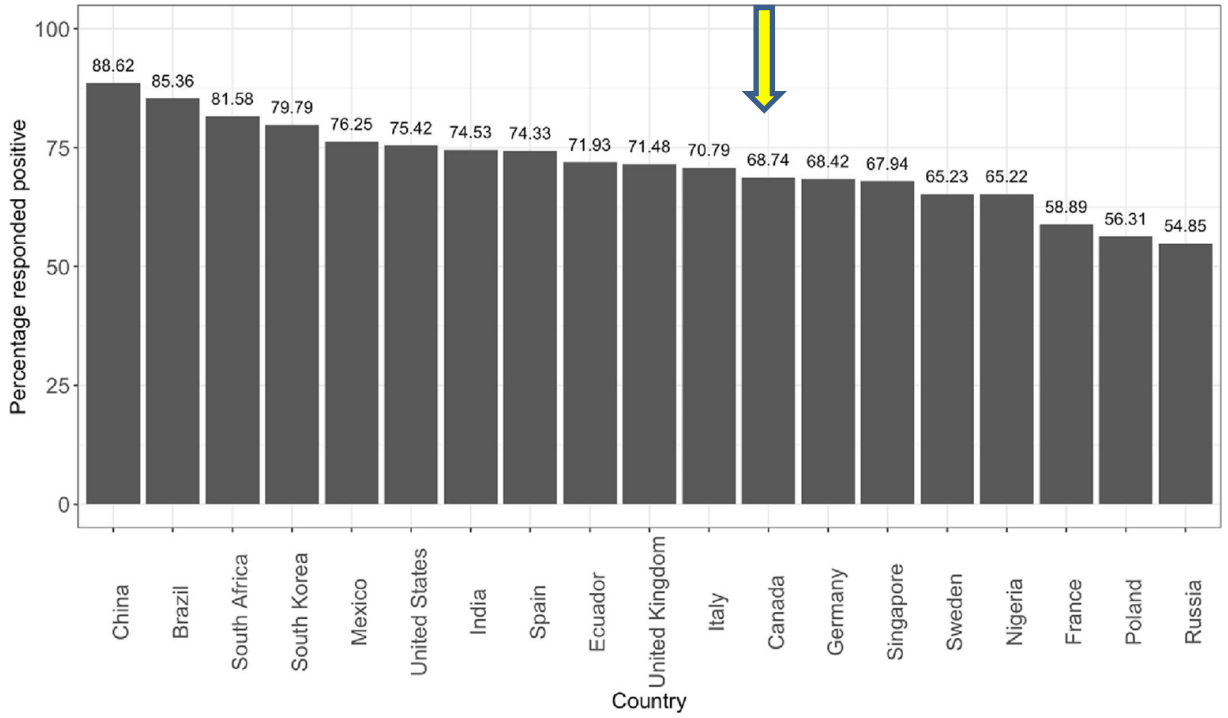
How does Canada VH compare to the world?

A global survey with around 14,000 from 19 countries



Lazarus, J.V., Ratzan, S.C., Palayew, A. *et al.* A global survey of potential acceptance of a COVID-19 vaccine. *Nat Med* (2020). https://doi.org/10.1038/s41591-020-1124-9

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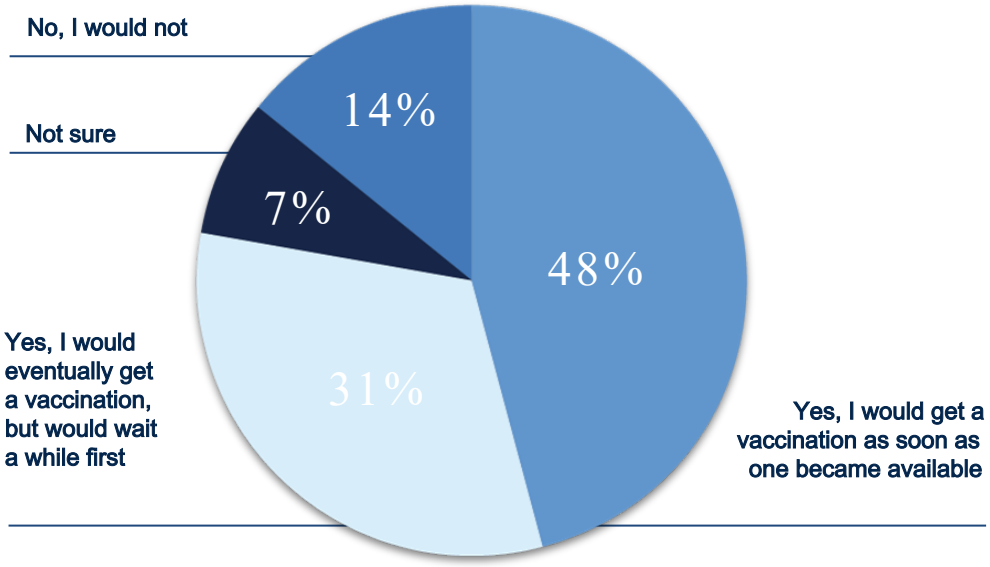
How do we quickly shift the the ~30% who would delay uptake and address those who won't take it at all?

Less than half of Canadians would get vaccinated as soon as one is available

If a vaccine against the coronavirus became available to you, would you get vaccinated, or not?



How do we quickly shift the the ~30% who would delay uptake and address those who won't take it at all?

In August:
46% would get vaccine ASAP
32% would wait
14% would not get it at all

Source: Angus Reid Institute: December 14, 2020

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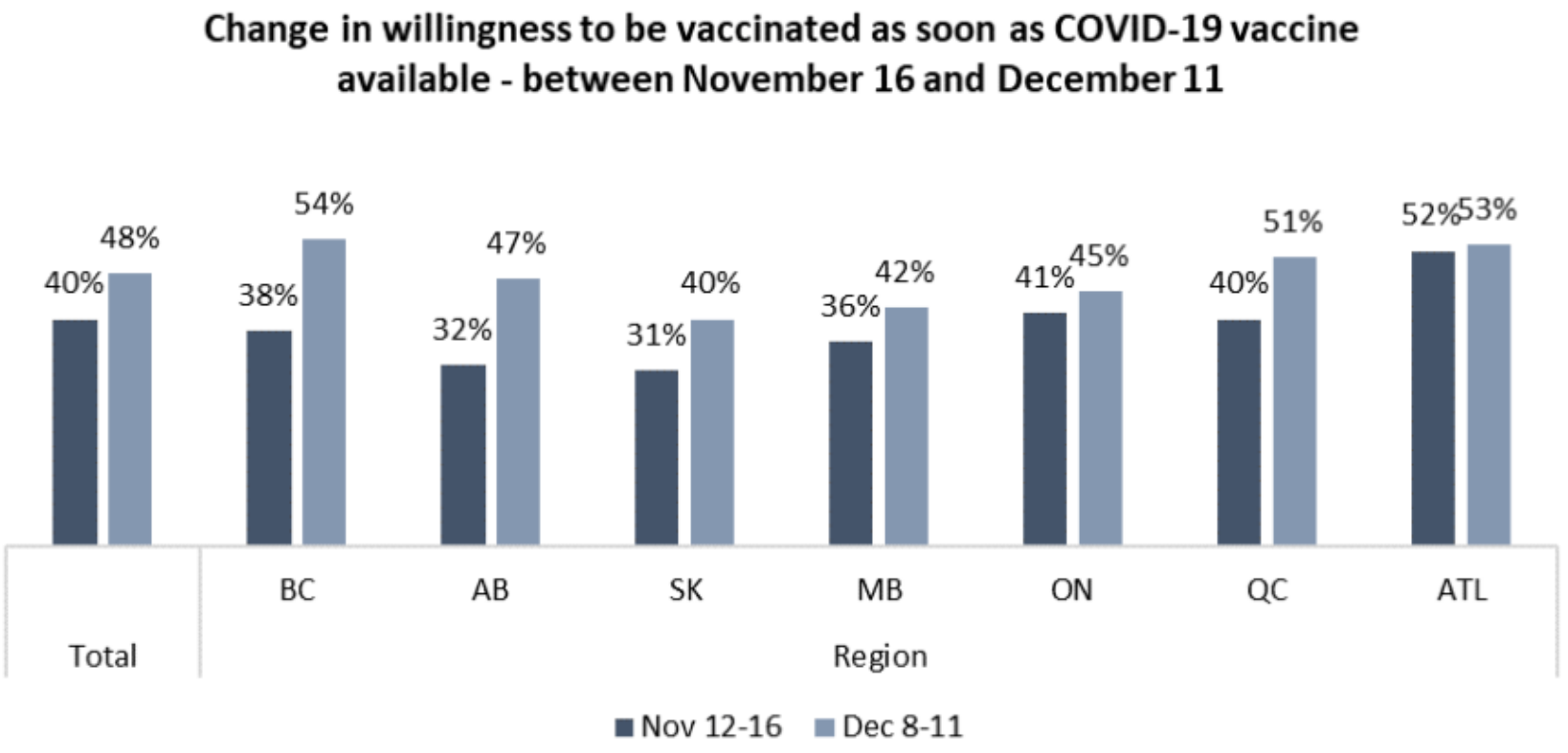
COVID-19 Vaccine Hesitancy Across Canada



Source: Angus Reid Institute: December 14, 2020

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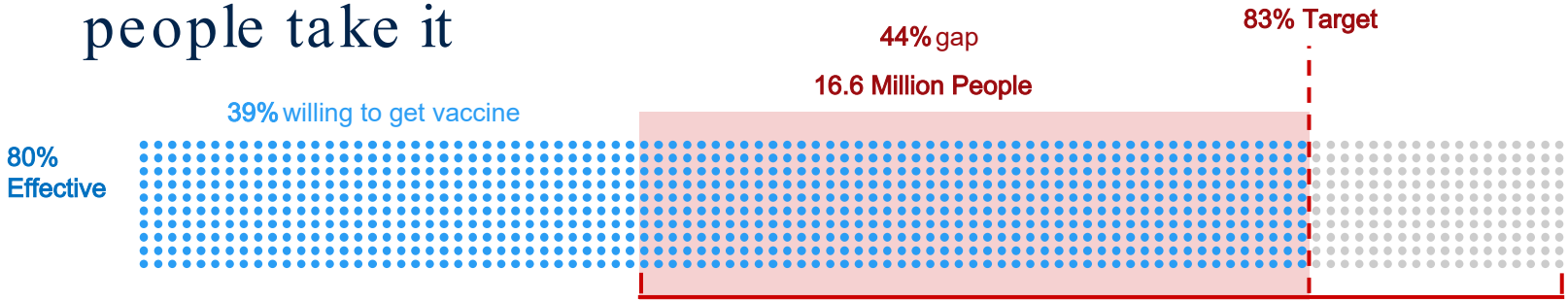
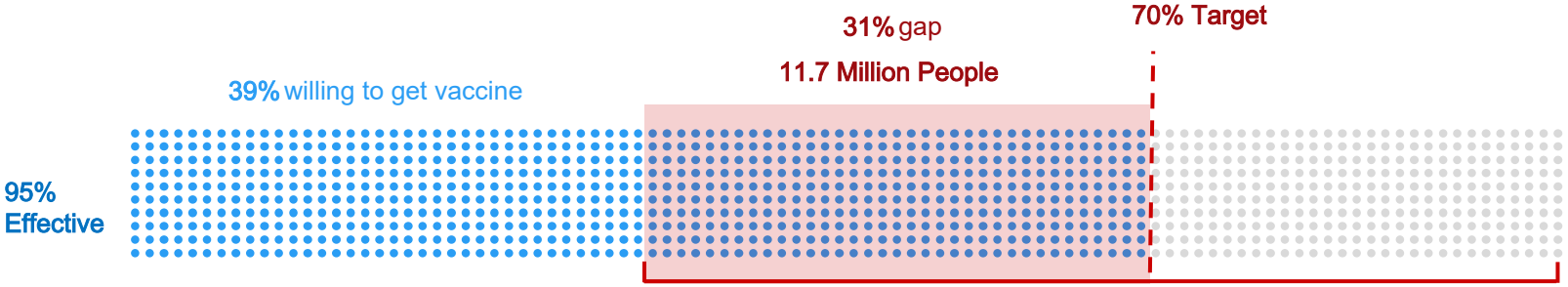
Vaccination Gap

Even the best vaccine won't solve the problem if not enough people take it



If 80% effective, need 83% uptake for community immunity



If 95% effective, need 70% uptake for community immunity

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How do Health Care Providers Fit In with VH?

- Health care professionals (HCP) are cited as the most important source for receiving vaccination information for parents.
  - They are seen as trustworthy, informative, and a reliable source for answering questions and concerns parents have about childhood vaccines.
    HCP's communication styles with parents are important.
  - Poor communication and negative relationships with HCP can heavily impact parents' vaccination decisions.
  - HCP's behavior and opinions about vaccination influence parents' acceptance of vaccination.

Olson et al. *Vaccines*. Addressing Parental Vaccine Hesitancy towards Childhood Vaccines in the US: A Systematic Literature Review of Communication Interventions and Strategies 2020.
Noni Macdonald and Eve Dube. Unpacking vaccine hesitancy among healthcare providers. 2015

Vaccine Hesitancy

If HCP refuse parents' requests to:

- delay vaccines
- be selective with vaccines
- alter the recommended childhood vaccine schedule

Parents will continue to search for other HCP or alternative health professionals

Olson et al. *Vaccines*. Addressing Parental Vaccine Hesitancy towards Childhood Vaccines in the US: A Systematic Literature Review of Communication Interventions and Strategies. 2020.

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HCP can be Vaccine Hesitant Themselves

- The nature of their hesitancy is similar to their patients'
- Knowledge about vaccines, safety, efficacy helps to build HCP confidence
- Knowledge however is NOT enough: they also need societal endorsement and support from colleagues
- Important to strengthen trust between HCP and health authorities

E. Karafillakis and H. Larson. The paradox of vaccine hesitancy among healthcare professionals. 2018
Paterson et al. Vaccine Hesitancy and healthcare providers. 2016

4 Key Groups to First Receive COVID-19 Vaccinations

4 KEY GROUPS TO FIRST RECEIVE COVID-19 VACCINATIONS

Based on the NACI's recommendation

1.

Those at risk of severe illness and death from COVID-19 (i.e. advanced age, hish risk health conditions).

2.

Individuals most likely to transmit COVID-19 to those at high risk (i.e. household contacts of those at hish risk, healthcare providers at assisted living facilities).

3.

Those who are essential to maintaining COVID-19 respnonse or contribute to essential services (first responders, healthcare workers, others who cannot work remotely).

4.

Those at high risk of infection owing to living or working conditions where infection could lead to disproportionate consequences (i.e. indigenous communities)

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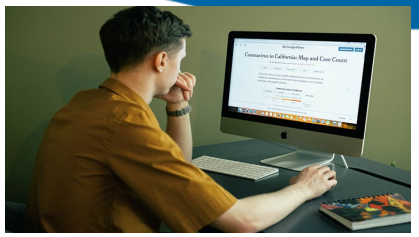
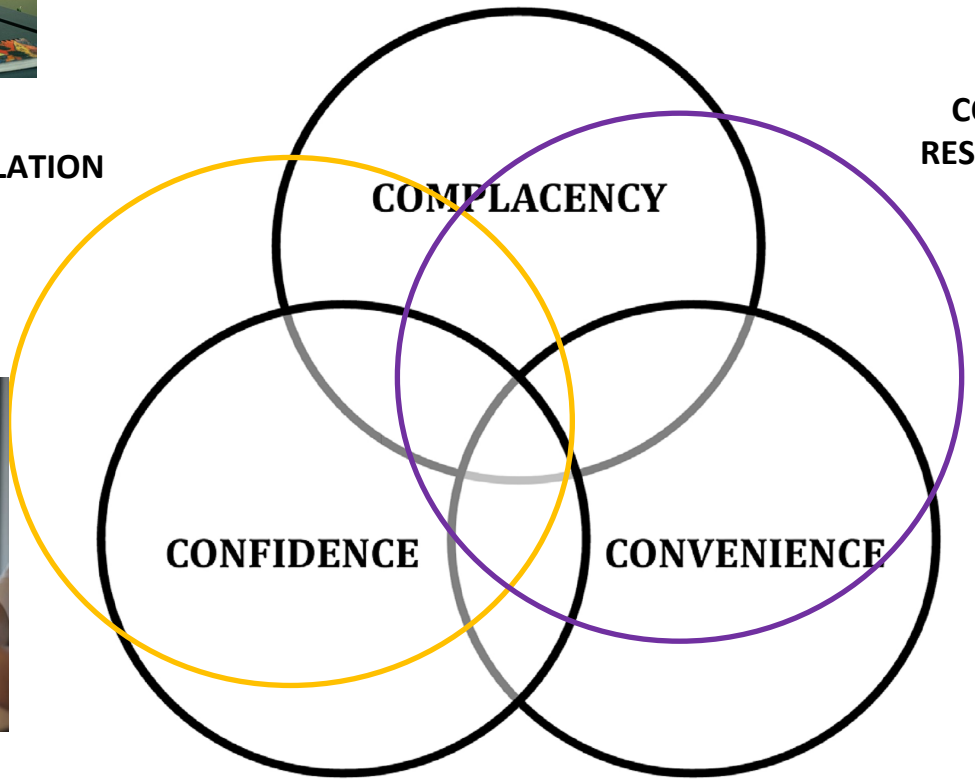
Vaccine Hesitancy



CALCULATION

COLLECTIVE RESPONSIBILITY



Macdonald et al. WHO SAGE Working Group for Vaccine Hesitancy. Vaccine 33 (2015) 4161–4164

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What do we know about vaccine hesitancy and vaccine communication?

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Humans are rational beings who sometimes feel

Humans are emotional beings who sometimes think

Here are the basics about communication around this vaccine

- You are IT
- You have to assume they will take it
- IT IS NORMAL to have doubts
- You have to build trust and be supportive WHILE correcting misinformation

https://libertyonthelighterside.com/the-funniest-covid-19-memes-and-jokes/

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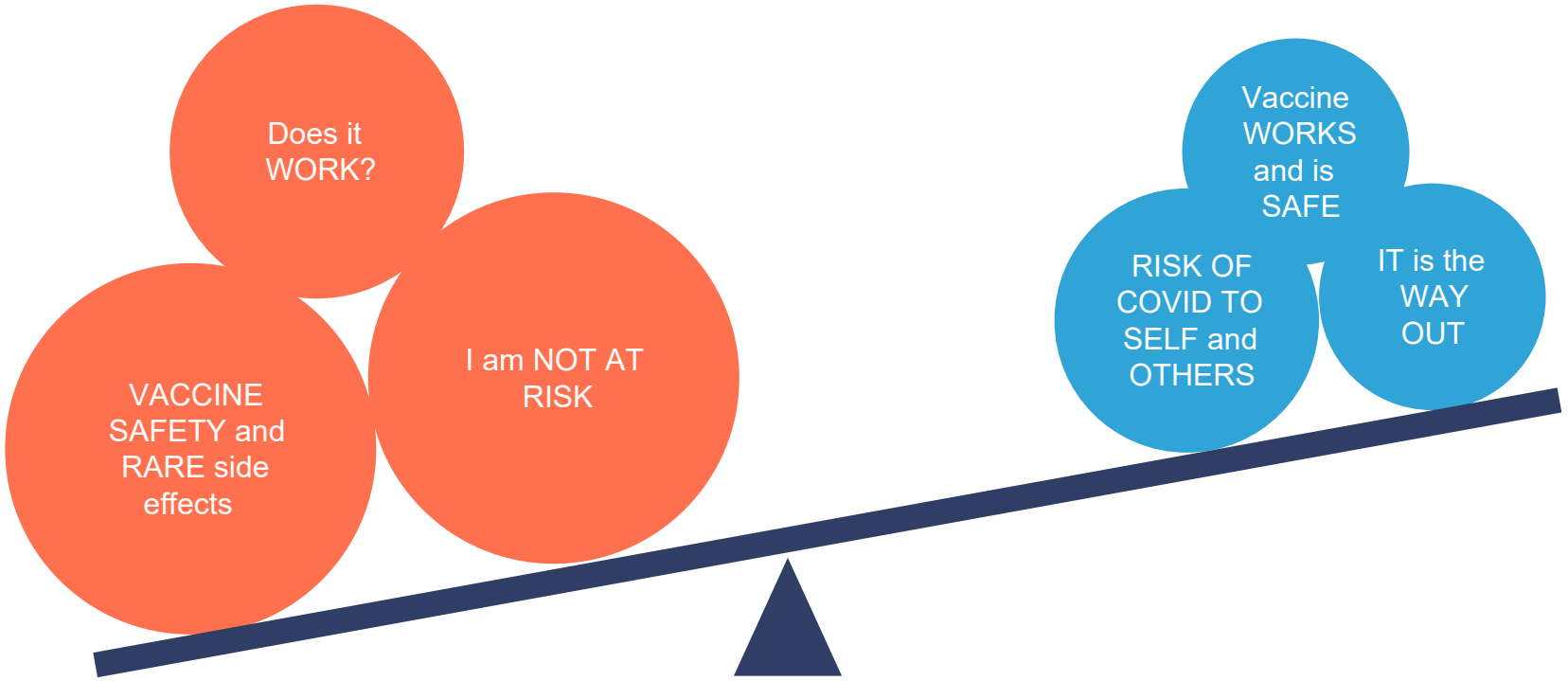
We Need to Increase the Weight of Vaccine



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COVID-19 Vaccine Communication Framework

Pr: **Pr**oactively starting the conversation with a **Pr**esumptive statement

O: **Offer** to share your knowledge about the facts and your experience with having had the vaccine

T: **Tailor** the recommendation to their specific health concerns

C: Address specific **concerns** (should not be the bulk of the conversation)

T: **Talk** through a specific plan for where and when to get the vaccine

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Vaccine Hesitancy Communication

Communication Principle	Basis for this	Example Statements
Presumptive discussion	Start assuming they will get the vaccine	I am here to support you as you make the decision to take this vaccine I had the chance to take the vaccine myself and am happy to help you make the decision too, so you can be protected
Offer/Ask to share your knowledge	You establish credibility and get a sense of how/what they want to know	I have been thinking a lot about this vaccine for my patients and educating myself on the science around it. Can I share some of what I know with you?
Tailor the recommendation to their personal health concerns	Ensure this is not a debate about philosophies	Here is why you are the right person to get this vaccine: you have high blood pressure and diabetes but have a high quality of life. Because of your conditions, whereas you are at high risk of being hospitalized with COVID, so we need to maintain the good quality of life you have right now.
Address specific concerns	Correct the mis/dis/information	I had the chance to take the vaccine myself and am happy to help you make the decision too, so you can be protected
Talk through Plan/Write it out		You can do the following the get the vaccine. Provide schedule (2 doses)

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Extra Resources

- Center for Effective Practice
  - https://cep.health/toolkit/covid-19-resource-centre
- 19tozero.ca

https://libertyonthelighterside.com/the-funniest-covid-19-memes-and-jokes/

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Expected post vaccination behaviours

Dr. Jia Hu

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Post vaccination Behaviour

- Does being vaccinated mean I can't get sick, or just less sick?
- Can I still transmit the virus after being immunized?
- Do I still need to follow public health recommendations post-immunization?
- How many Albertans need to be vaccinated for us to get back to normal?

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Contact Information for Patients with Red Flags

RAAPID phone numbers:

- North of Red Deer: 1-800-282-9911.
- Red Deer & South: 1-800-661-1700

Connect MD: 1-844-633-2263

Specialist Link: 1-844-962-5465

Timely COVID Advice: phc@ahs.ca

Dr. Jia Hu - Urgent Help: 587-596-2294

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Questions and Answers

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Upcoming Webinars

Wednesday, January 20th (12:00 - 1:00pm)

- TBD

Thursday, January 21st (5:00 - 6:00pm)

- Building blocks to successful transitions of care

- For upcoming & recorded AMA Webinars, visit: https://www.albertadoctors.org/services/media-publications/webinars-online-learning

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Evaluation Link & CME Credits

Evaluation Link:
https://interceptum.com/s/en/RC010621

CME Credits:

- Specialist physicians can only claim their credits *once* at the end of the webinar series
- Family physicians can claim their credits individually after each webinar using the following session IDs. Please note that it may take two weeks or more to show in your member portal.

Date of webinar	Session ID
November 18, 2020	192413-012
December 2, 2020	192413-013
December 16, 2020	192413-014
January 6, 2021	192413-011

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