COVID-19 Vaccine Update

Shelly A McNeil, MD, FRCPC
Professor of Medicine, Chief, Division of Infectious Diseases
Senior Medical Director, COVID Planning and Implementation, NS Health
Clinician Scientist, Canadian Center for Vaccinology

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Canadian Center for Vaccinology
Dalhousie University
IWK Health Centre
NS Health Authority

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CANADIAN IMMUNIZATION RESEARCH NETWORK

Disclosures

- **Research Funding**
  - Government
    - CIHR
    - Public Health Agency of Canada
    - Public Works Canada
  - Industry
    - GlaxoSmithKline
    - Sanofi Pasteur
    - Pfizer
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- **Consultant/Advisory Board/Committee**
  - Government
    - NS Dept of Health Experts Group
    - C19 Vaccine Expert Panel
    - DHW COVID-19 Key Populations Task Group
  - Industry
    - GlaxoSmithKline
    - Sanofi Pasteur
    - Merck
    - Pfizer
    - Medicago

Learning Objectives

- To review current data on authorized and anticipated vaccinations for COVID-19
- To review NACI recommendations for COVID-19 vaccination
- To discuss use of COVID-19 vaccines in those who are pregnant or breastfeeding, immunocompromised or have underlying autoimmune conditions
- To review process for AEFI reporting following COVID vaccines.
- To review diagnosis and treatment of Vaccine Induced Prothrombotic Immune Thrombocytopenia (VIPIT) associated with AztraZeneca vaccine

SARS-CoV-2 virion

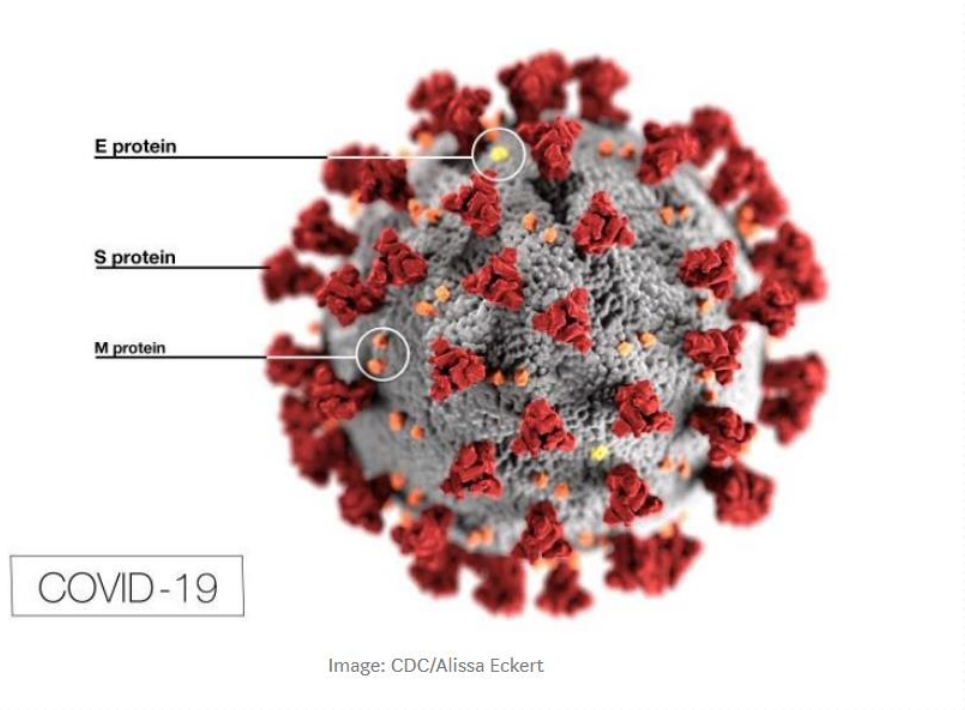
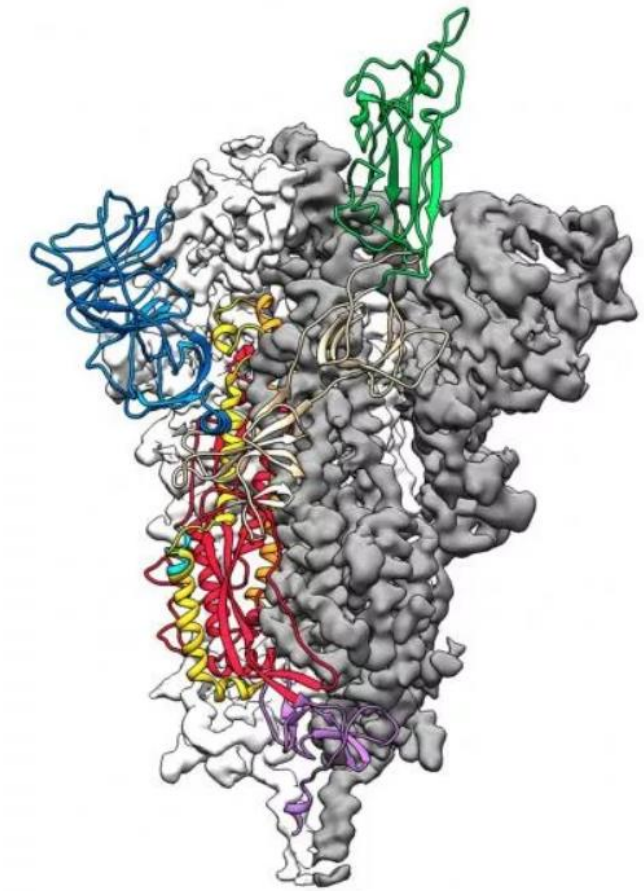


Image: CDC/Alissa Eckert

SARS-CoV-2 spike protein



This is the 3D atomic scale map or molecular structure of the SARS-2-CoV protein "spike" which the virus uses to invade human cells.
(Image: © Jason McLellan/Univ. of Texas at Austin)

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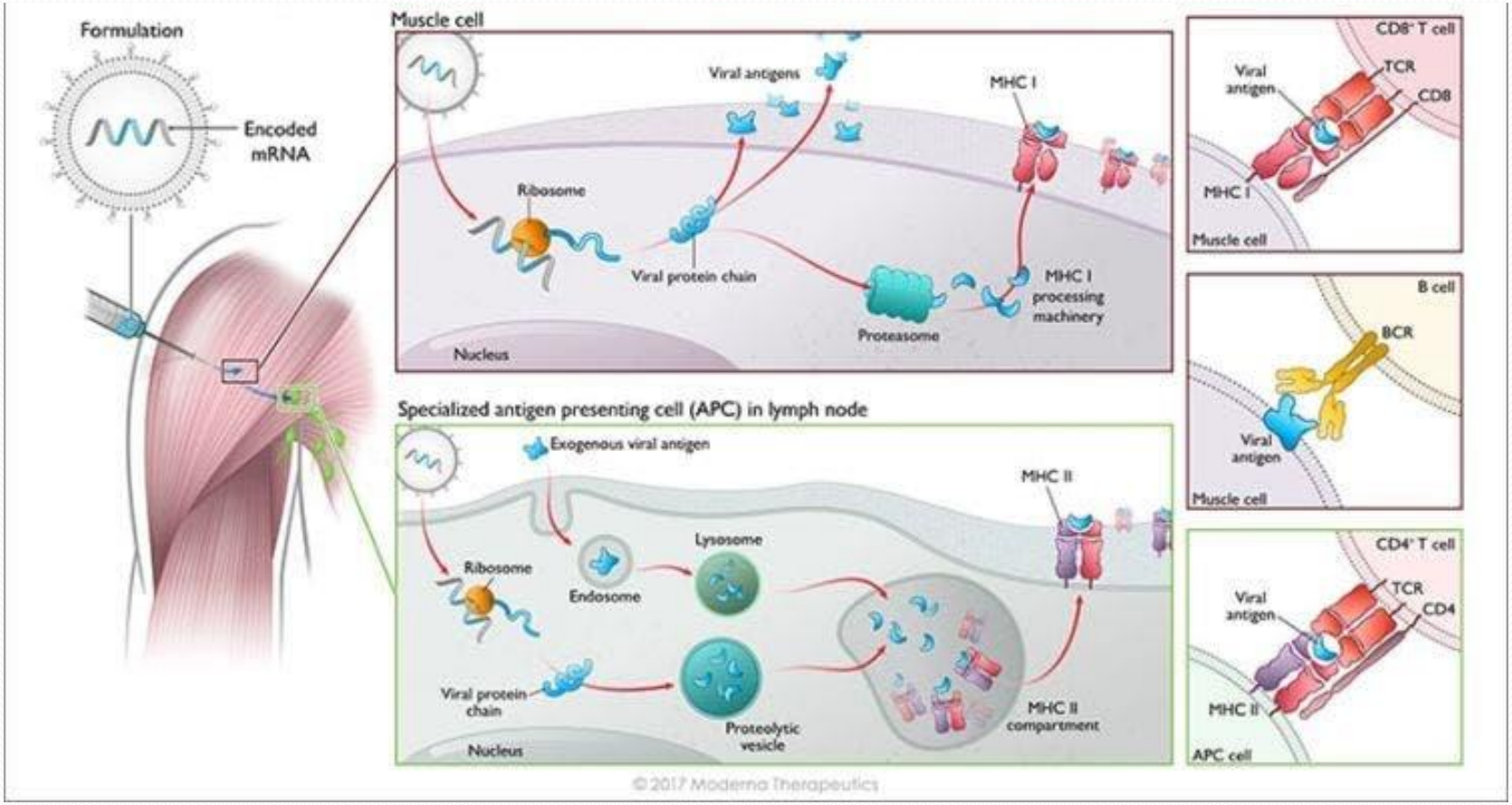
mRNA Vaccines: Mechanism of Action



Vaccine characteristics

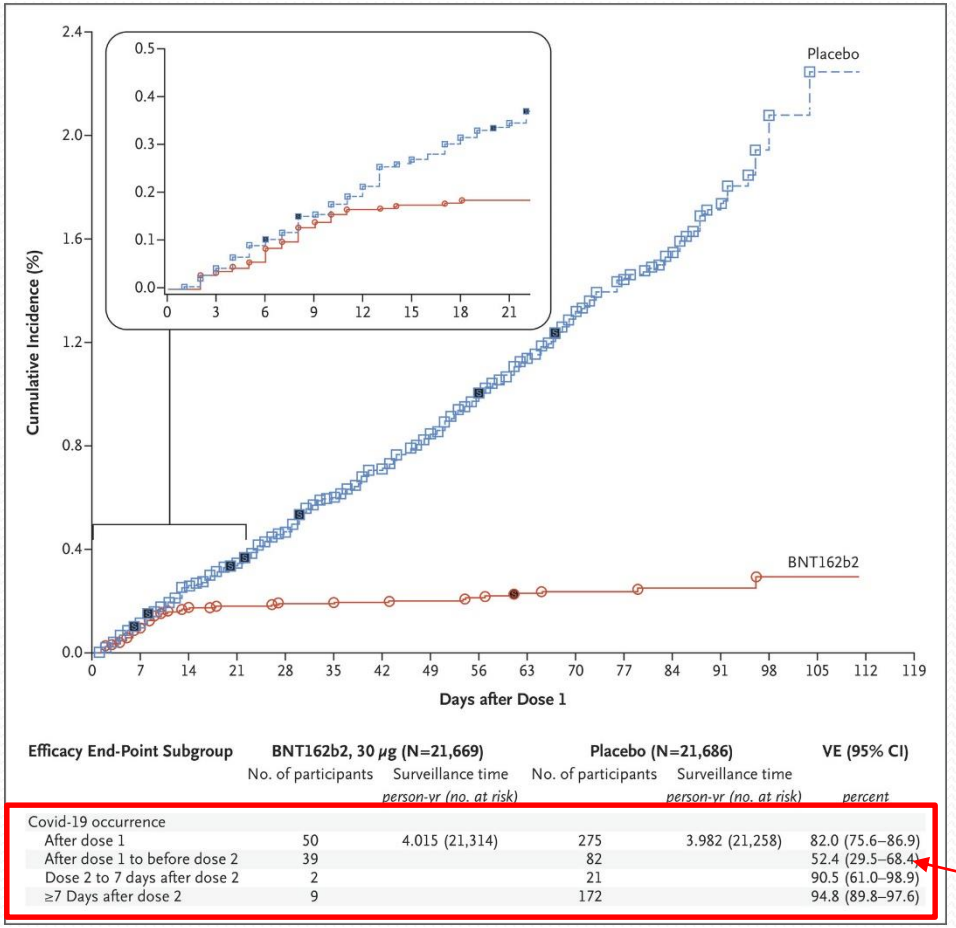
	Moderna (mRNA-1273)	Pfizer/BioNTech (BNT162b2)
Vaccine components	mRNA formulated into a lipid nanoparticle (LNP)	mRNA formulated into a lipid nanoparticle (LNP)
Authorized population	18y +	16y +
Vial size	10 dose multi-vial	5 (6) dose multi-vial
Reconstitution	None needed	Normal saline
Administration and dosing	2 x 0.5ml IM; 28d apart	2 x 0.3ml IM; 21d apart (alt 28d schedule OK per NACI)
Freezer storage	-20°C	-75°C
Transport	Frozen only (-20°C)	Ultrafrozen only (-75°C)
Fridge storage	30d	5d
Room temperature (unpunctured)	12h	2h
Once punctured	6h	6h

mRNA Vaccines: Summary Results (Efficacy)

	Moderna (mRNA-1273)[1]	Pfizer/BioNTech (BNT162b2)[2]
	Phase 3 - Age: 18+ - No LTCF residents - Size: 30,413 in US - dosing: 2xIM, 28d	Phase 3 - Age: **12-15y, 18-55y, 65-85y** - No LTCF residents - Size: 44,000 in US - Dosing: 2xIM, 21d
Efficacy Data	*Final Analysis* 185 Placebo/ 11 vaccine Data from 2 months post dose 2 **Primary endpoint: 94.1% vaccine efficacy (89.3- 96.8%)** **Efficacy in 65+: 86.4% (61.4-95.2)** **Secondary endpoint**: 30 severe cases and 1 death- all in Placebo group	Final analysis at 170 cases (162 Placebo/ 8 vaccine) Data from 1 week after dose 2 **Primary endpoint**: **95% vaccine efficacy (90.3-97.6%)** **Efficacy in 65y+: 94.7% (66.7-99.9)** **Secondary endpoint:** 10 severe cases- 9 in Placebo group.
Safety Data	Median follow up only approx. ≤ 14 weeks; quite reactogenic; no serious safety concerns	Median follow up only approx. ≤14 weeks; quite reactogenic; no serious safety concerns

[1]NEJM 2020:Dec 30 [2]NEJM 2020:Dec 10

Pfizer/BioNTech: Single dose efficacy

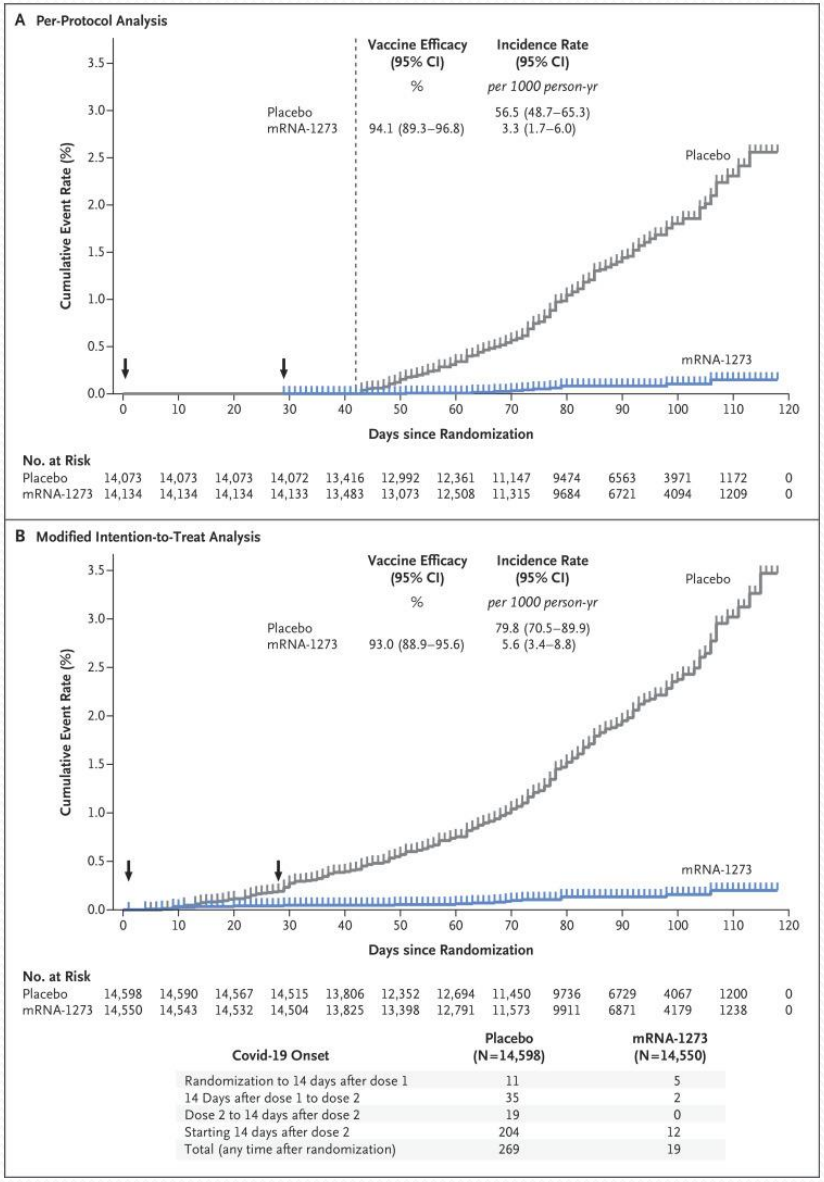


Efficacy End-Point Subgroup	BNT162b2, 30 μg (N=21,669) No. of participants	BNT162b2, 30 μg (N=21,669) Surveillance time *person-yr (no. at risk)*	Placebo (N=21,686) No. of participants	Placebo (N=21,686) Surveillance time *person-yr (no. at risk)*	VE (95% CI) *percent*
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

VE 14d after dose 1 to before dose 2 = **92.3% (69-98%)**

NB- Median duration of follow-up = 28d

Moderna: Single dose efficacy



Covid-19 Onset	Placebo (N=14,598)	mRNA-1273 (N=14,550)
Randomization to 14 days after dose 1	11	5
14 Days after dose 1 to dose 2	35	2
Dose 2 to 14 days after dose 2	19	0
Starting 14 days after dose 2	204	12
Total (any time after randomization)	269	19

Single dose efficacy:
After Dose 1 to before Dose 2: **80.2%** (55.2- 92.5%)
14d after dose 1 to before dose 2: **92.1%** (68.8- 99.1%)

NB: Median duration of follow-up= 28d

Asymptomatic transmission

- Pfizer VE: US – 40K asymptomatic pre-op patients
  - 72% decrease ≥10d post dose 1; 80% post dose 2
- Pfizer VE: UK HCW- 75% decrease post dose 1
- Pfizer VE: Israel- 75% decrease post dose 1; 94% post dose 2
- mRNA: US CDC (3h ago!)- 4000 HCW- 80% decrease post dose 1; 90% post dose 2 (MMWR March 29, 2021)
- Moderna in clinical trials: asymptomatic infn in 15/14,000 (0.1%) in vaccine arm vs 39/14,000 (0.3%) in placebo arm suggesting reduction in asymptomatic infection of about 2/3
- J&J (clinical trials): 74% decrease
- AstraZeneca: no impact on asymptomatic infection

Local injection site reactions

VACCINE	Any reaction	Pain/tenderness	Swelling	Redness	Swollen lymph nodes
Moderna					
Dose 1	85%	80%	5%	2%	10%
Dose 2	90%	90%	10%	8%	15%
Pfizer					
Dose 1	85%	83%	6%	5%	-
Dose 2	85%	78%	6%	6%	-
AstraZeneca					
Dose 1	75%	54%/ 64%	10%	14%	NA
Dose 2	less				

General reactions

VACCINE	Any reaction	Fever	Headache	Fatigue	Sore muscles	Chills	Nausea /vomiting
Moderna							
Dose 1	60%	1%	30%	35%	20%	5%	5%
Dose 2	80%	15%	60%	65%	60%	50%	20%
Pfizer							
Dose 1		1%	25%	34%	14%	6%	0%
Dose 2		11%	39%	51%	29%	23%	1%
AstraZeneca							
Dose 1	73%	8%	53%	53%	44%	32%	22%
Dose 2	less						

Implications for Occupational Health

- Local and systemic AEs common, particularly after Dose 2
- ~15% will experience fever post-dose 2; fatigue, headache and chills common (worse post dose 2)
- No role for prophylactic acetaminophen/ibuprophen but can be used to treat symptoms
- HCW meeting COVID case definition (fever OR 2 or more of sore throat, runny nose, headache or SOB) should NOT REPORT TO WORK and should arrange a COVID test
- Attempt to avoid many people from same clinical area being vaccinated on same day to avoid service implications of AEs

Allergic reactions and anaphylaxis post dose 1 Pfizer/BioNTech vaccine (CDC, MMWR Jan 15)

- Vaccine contraindicated in persons with allergy to polyethylene glycol (PEG) or prior dose of vaccine
- Caution in patients with hx of anaphylaxis to another vaccine or injectable product- proceed but observe x 30 min
- No special precautions in patients with anaphylaxis to foods, oral medications, insect stings

Allergy cont.

- 21 cases anaphylaxis reported in US in Dec following Dose 1 Pfizer- rate **11.1/mil** doses administered (vs 1.35/mil for influenza vaccine)
- Median onset 13 minutes (range 2-150 min); 71% occurred within 15min
- 4 patients hospitalized (3 in ICU)
- 81% had hx of allergies (1/3 hx of anaphylaxis)
- Early tx with IM epi critical
- Given timing, should we extend observation period in people with Hz of anaphylaxis or multiple allergies?

Rationale for delayed dosing (or single dose)

- mRNA vaccines authorized on a 2 dose 0, 21d (Pfizer) or 0, 28d (Moderna) schedule
- In some jurisdictions with significant community transmission and deaths, consideration of immunizing as many people as possible with 1st dose to achieve early, broad population protection being recommended
- Given anticipated vaccine supply, this will mean delaying (or omitting) Dose 2
- **Pros:**
  - Short term efficacy of first dose appears high
  - Maximizes number of people protected quickly
  - In general, increased interval between doses in a series not detrimental and potentially improves immunogenicity
- **Cons:**
  - Establishing large cohorts of partially immune people in the face of a highly prevalent infection could lead to development or selection for viral variants
  - Peak humoral and CMI responses occur after dose 2
  - Infections between dose 1 and delayed dose 2 could erode confidence in vaccine leading to lower overall 2-dose completion

Why has NACI recommended a 0, 4 month interval for COVID-19 vaccines?

- While studies have not yet collected 4 months of data on VE following first dose, first 2 months of real world data (3 in UK- no exceptions to intervals) show sustained high level of protection (70-80%; UK, Israel;Quebec;BC)
- Immunologic principles and vaccine science do not predict rapid waning in adults over a short time
- Modelling by PHAC demonstrated higher overall population level protection even with a 6 month interval
- Given limited vaccine supply, extending interval establishes population immunity faster, thereby protecting the vulnerable
- No evidence that extending interval will impact VOC

Are there populations that should be vaccinated on schedule?

- NACI has a process for ongoing review of emerging data that could influence recommendations
- Thus far, only small immunogenicity trials are available suggesting reduced response to first dose in some people
- Real-world effectiveness data from UK have not shown clinically important reductions in effectiveness in any group witn 0, 3 month interval
- Small trials of interest:
  - Cancer patients: SOAP trial (pre-print: medRxiv)
    - Pfizer vaccine; n= 151 elderly patients with ST and haem malignancy vs 54 controls
    - 39% of solid cancer and 13% of heam cancer had anti-SARS-CoV-2 Ab 2 weeks post dose 1 vs 97% controls
    - If dose 2 given at 3 weeks, 95% of solid cancer patients had anti-SARS-CoV-2 Ab 2 weeks post dose 2 vs 43% of solid cancer and 8% of haematologic cancer if dose 2 delayed (single dose)
  - Seniors: 12 LTCF residents (age 82) vs 36 HCW
    - Neutralizing Ab post dose 1 was 2-4-fold lower in LTCF than HCW controls

Are there populations that should be vaccinated on schedule?

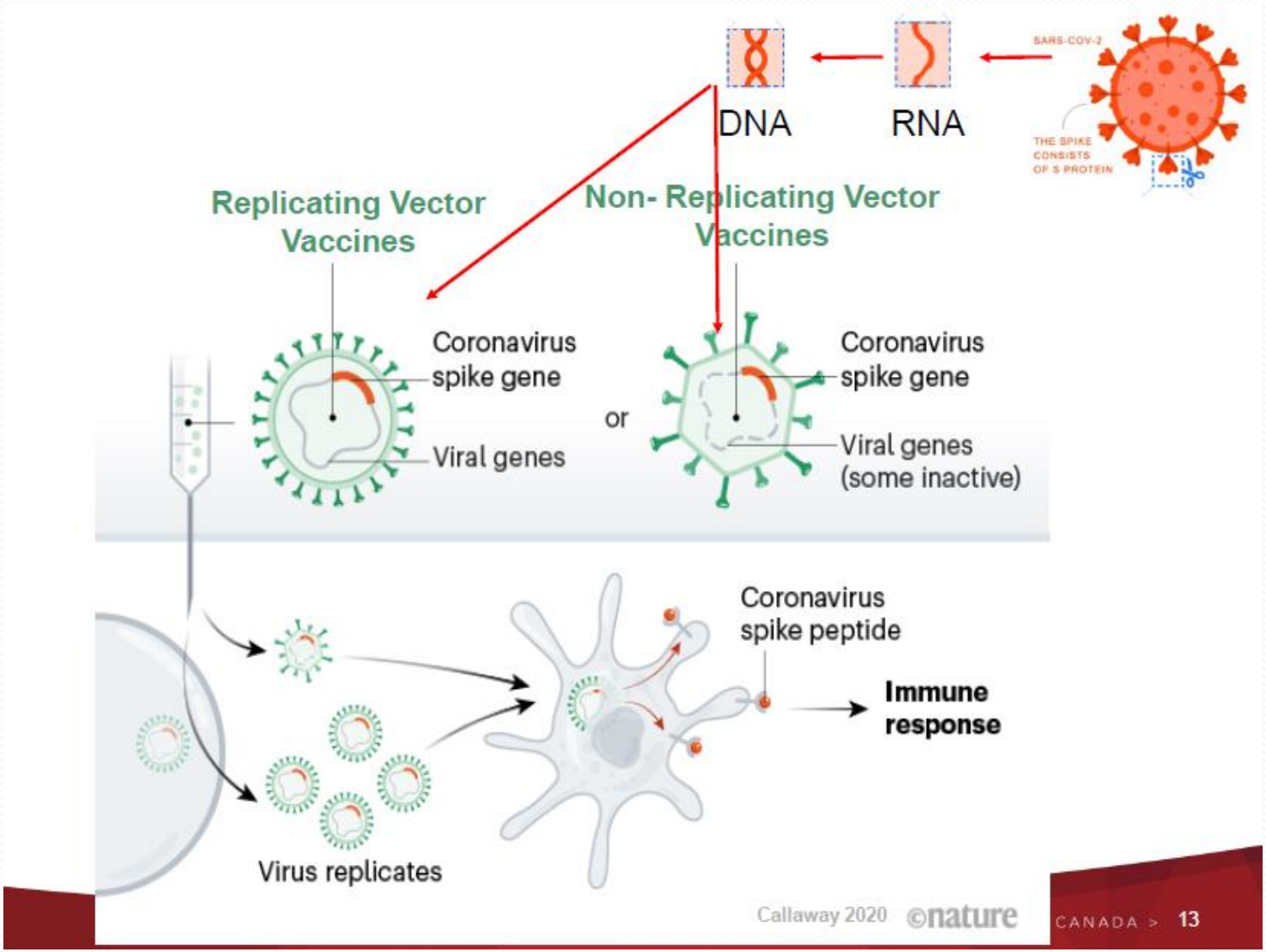
- Solid organ transplant recipients (JAMA online Mar 15)
  - 436 transplant recipients; median age 56y
  - 52% received Pfizer and 48% rec'd Moderna
  - Median time since transplant = 6.2y
  - Immunosuppression included tacrolimus, steroids, mycophenolate, azathioprine, sirolimus and everolimus
  - Ab detected in 17% 20d post dose 1
  - Recipients receiving antimetabolites, older transplant recipients and those who received Pfizer vaccine less likely to have Ab

    NOTE: no assessment of CMI; response post dose 2 not measured so not clear giving second dose rectifies response

Data limitations re available COVID vaccines

- No safety or efficacy data in:
  - Women who are pregnant or breastfeeding
  - People who are immunosuppressed
  - People with underlying autoimmune conditions
- NACI recommends that these people be offered vaccination “if risk assessment deems that the benefit outweighs potential risks and if informed consent included discussion about the absence of evidence on the use of COVID-19 in these populations”

Viral Vector Vaccines



Viral Vector Vaccines

Advantages	- Established activation of humoral and cellular responses without an adjuvant - Potential boosted immunity to vector virus - Technology authorized in 3 vaccines – 2x Ebola and a dengue/yellow fever vaccine
Disadvantages	- Potential for reduced immune responses due to vector seropositivity (increased impact with age) - Potential blunting of response to Dose 2 and to future vaccines using the same platform

AstraZeneca Vaccine Efficacy

	AstraZeneca/Oxford
	Phase 3 - Age: 18+ - Size: 12,158 SD/SD - dosing: 2xIM, 29d
Efficacy Data	**Symptomatic illness** >14d post dose 2: **62%** (51.8-71.7) ≤65y = 63% (51-72%) >65 = 51% (-66 TO 85%) **82.4%** (47- 94%) if interval **>12wks in ≤65y** No estimate >65y (n= 1375) **Asymptomatic illness** >14d post dose 2: **-4.3%** (-416- 79) Symptomatic illness >21d post **dose 1: 71%** (59-86) (x 3 mos)
Safety Data	N/A: trial paused for investigation a neurological in a participant

1Lancet 2020: Dec 8; 2NEJM 2021: Jan 14

AstraZeneca Vaccine Effectiveness

- Currently available effectiveness data for the AstraZeneca COVID-19 vaccine is for a single dose in the United Kingdom population
- In adults **≥70** years of age, effectiveness against confirmed symptomatic COVID-19 is:
  - 60% (95% CI: 41–73%) at 28–34 days post-vaccination
  - **73% (95% CI: 27–90%) at 35+ days post-vaccination**
- In adults **≥80** years of age, effectiveness against hospitalizations is **37% (95% CI: 3–59%)** at 14-28 days post-vaccination
- In adults **≥18** years of age, effectiveness against hospitalization is **94% (95% CI: 73–99%)** at 28-34 days post-vaccination
  - **Pooled** analysis of Pfizer and AstraZeneca estimated effectiveness in older adults of:
    - 65–79 years: **79%** (95% CI: 17–95%) at 28–34 days post-vaccination
    - ≥80 years: **81%** (95% CI: 65–90%) at 28–34 days post-vaccination

Local injection site reactions

VACCINE	Any reaction	Pain/tenderness	Swelling	Redness	Swollen lymph nodes
Moderna					
Dose 1	85%	80%	5%	2%	10%
Dose 2	90%	90%	10%	8%	15%
Pfizer					
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AstraZeneca					
Dose 1	75%	54%/ 64%	10%	14%	NA
Dose 2	less				

General reactions

VACCINE	Any reaction	Fever	Headache	Fatigue	Sore muscles	Chills	Nausea /vomiting
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Pfizer							
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AstraZeneca							
Dose 1	73%	8%	53%	53%	44%	32%	22%
Dose 2	less						

Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT)

Summary

- Rare, serious blood clots, including cerebral venous sinus thrombosis with thrombocytopenia
- Cases have primarily been in women <55y
- Most have occurred 4-16d after AZ vaccine
- MOA- development of antibodies that “activate” platelets leading to formation of clots and low platelets (similar to heparin-induced thrombocytopenia)
- No underlying risk factors for VIPIT have been identified
- Rate not yet known
  - March 18 EMA 1 per 800k vaccinated; CVST 8.9X increased over background rate; DIC “at least” 5X increased over background rate
  - Paul Ehrlich Institut (Germany) 1 per 100,000 vaccinated; CVST 7X higher than baseline
- Case fatality rate 40%
- No cases reported in Canada

Mechanism of action

Spontaneous heparin-induced thrombocytopenia

Heparin-induced thrombocytopenia (HIT)

- A rare syndrome
- 99% of the time occurs after heparin administration
- Heparin binds to platelet factor 4 which then bind antibodies
- The antibodies in this complex "activate" platelets, thrombosis formation and destruction of platelets (often to very low levels)
- Clots can form in venous (more common) or arterial systems

Spontaneous heparin-induced thrombocytopenia (HIT) / Autoimmune HIT

- No exposure to heparin
- Another substance serves the function of heparin (polyanionic substance that binds to platelet factor 4)
- Can be post-surgery (usually knee surgery) or infection
- Unsure what is triggering it post-vaccination – adenoviral vector; inflammation post-vaccination?
  - **Suggested new name is Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT)**

Advice to those receiving AZ vaccine

- People who have received AZ vaccine should be counselled to seek emergency assessment if they develop any of the following between 4-20 days pose vaccine:
  - Persistent and severe headache
  - Focal neurological symptoms
  - Seizures
  - Blurred vision
  - Shortness of breath
  - Chest or abdominal pain
  - Swelling and redness in a limb
  - Pallor and coldness in a limb
  - Persistent bleeding
  - Multiple small bruises, reddish or purplish spots or blood blisters

IMPORTANT INFORMATION

AstraZeneca COVID-19 Vaccine

Very rare symptoms to watch for after receiving vaccine

AstraZeneca COVID-19 vaccine is **not** associated with an increased overall risk of blood clotting disorders. However there have been very rare cases of unusual blood clots accompanied by low levels of blood platelets (which help blood to clot) after vaccination. The reported cases were almost all in women under 55 years of age. Because COVID-19 can be so serious, the benefits of the vaccine in preventing disease outweigh the risks of side effects.

However, if you get any of the following symptoms after receiving the AstraZeneca COVID-19 vaccine **please call 911 or seek medical help right away** and make sure you mention you have received the vaccine:

- breathlessness
- pain in the chest or stomach
- swelling or coldness in an arm or leg
- severe or worsening headache or blurred vision after vaccination
- persistent bleeding
- multiple small bruises, reddish or purplish spots, or blood blisters under the skin

Updated March 19, 2021

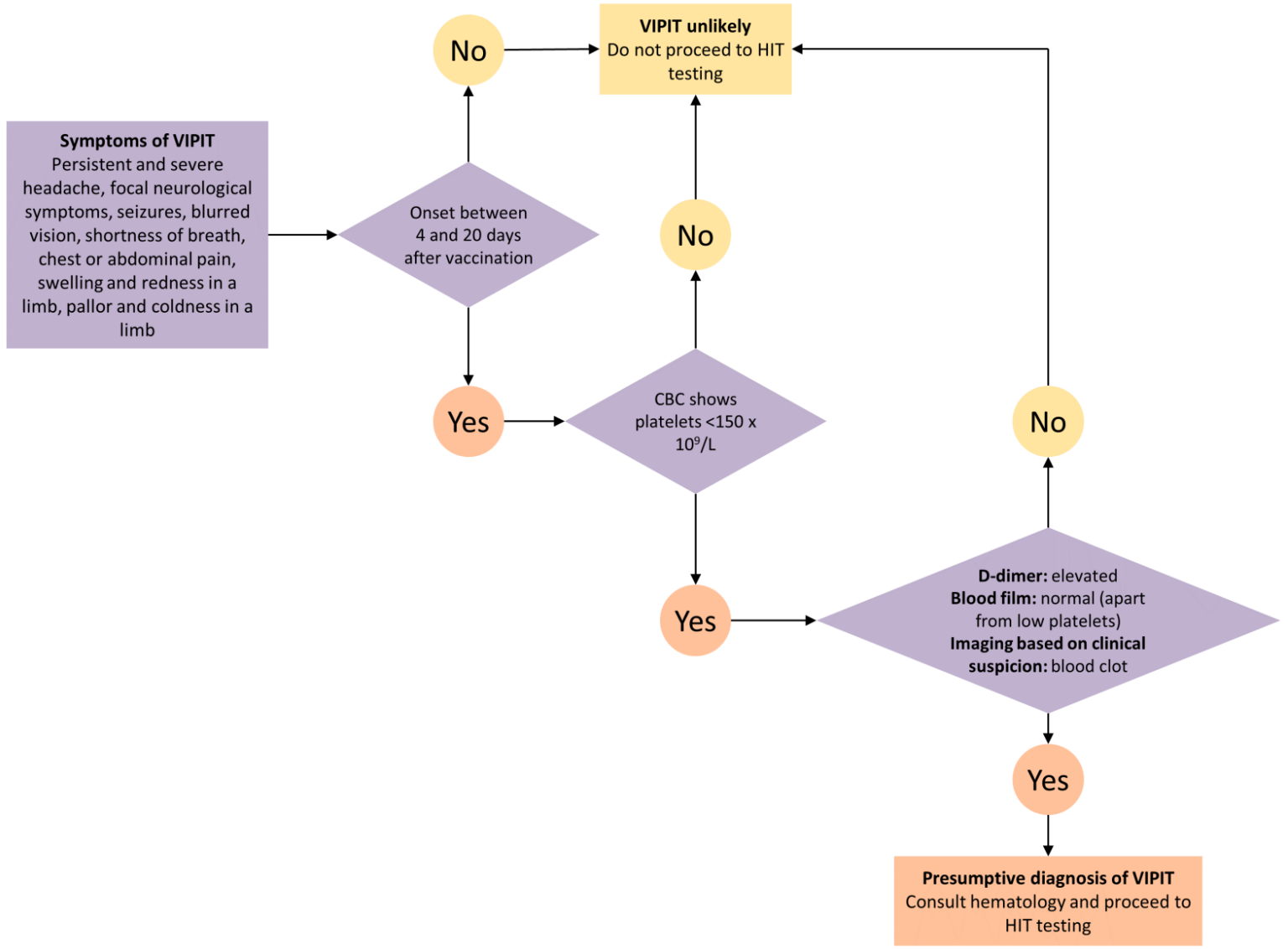
IWK Health

nova scotia health

For information visit: novascotia.ca/coronavirus

Ontario Science Table Guidance

https://covid19-sciencetable.ca/science-briefs



Treatment of presumed VIPIT

- NO heparin
- No platelet transfusions
- First line anticoagulants: direct oral anti-Xa inhibitors (e.g. rivaroxaban, apixiban)
- **Consult hematology**
- IVIG 1g/kg daily for 2 days for severe or life-threatening blood clots

NACI Recommendations

- https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html
- Updated Jan 12, 2021
- https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-extended-dose-intervals-covid-19-vaccines-early-rollout-population-protection.html
- Updated March 8, 2021

Recommendations: Summary

1) NACI recommends that a complete series should be offered to individuals in the authorized age group without contraindications

- ≥16y Pfizer
- ≥18y Moderna
- ≥ 55y AstraZeneca (60-64y in NS presently)
- NOTE: mRNA vaccines (Pfizer or Moderna) are the preferred vaccine for those at high risk of COVID complications (older adults and other priority groups)

- In order to optimize population-level protection, all COVID vaccines should be dosed at an interval of 4 months

Contraindications/Precautions

- History of anaphylaxis to previous dose of vaccine or to any component of the vaccine or its containor
- Practically speaking, this means allergy to **polyethylene glycol (PEG)**
- **Precaution:** Anaphylaxis to another vaccine or injectable medication/product: may be vaccinated with 30-60min observation period
- Note: other allergies, including anaphylaxis to foods, latex, environmental allergens, insect stings are **NOT** a contraindication to vaccination; routine observation

2) **NACI recommends that all individuals should continue to practice recommended public health measures for prevention and control of SARS-CoV-2**

- Insufficient evidence on duration of protection and effectiveness in preventing asymptomatic transmission
- Emerging data suggests mRNA vaccines reduce risk but evidence insufficient to warrant change in practice
- No evidence to support COVID-19 vaccine for post-exposure prophylaxis

3) **NACI recommends that COVID-19 vaccine may be offered to individuals with prior COVID-19 infection**

- No role for COVID testing prior to vaccination (screen for symptoms to avoid transmission in clinic)
- No evidence of increased adverse events or decreased efficacy/immunogenicity in people with prior infection
- Reinfections, though rare, have been reported

Immunosuppressed persons

4) **NACI recommends the COVID-19 vaccine may be offered to persons who are immunosuppressed by disease or treatment if a risk assessment deems that benefits outweigh potential risks and if informed consent includes discussion about absence of evidence on use of COVID-19 vaccine in this population**

- Limited evidence that immunosuppression is an independent risk factor for severe COVID-19
- Most immunosuppressed persons were excluded from the clinical trials
- In general, non-live vaccines may be safely administered to IC people; no anticipated safety concerns
- immune response may be diminished; continue all other preventive measures

Persons with Autoimmune Conditions

5) **NACI recommends that COVID-19 vaccine may be offered to persons with an autoimmune disease if a risk assessment deems that benefits outweigh potential risks and if informed consent includes discussion about absence of evidence on use of COVID-19 vaccine in this population**

- Limited evidence that having an autoimmune condition is an independent risk factor for severe COVID-19; evidence evolving
- Limited data on COVID-19 vaccine in people with AI conditions; not excluded if not IS but small sample size
- Degree of autoimmunity varies by condition, severity and progression and use of immunosuppressive meds- risk/benefit must be individualized
- Previous use of mRNA technologies were used for treatment of cancer so required immune response directed at cancer cells; raised theoretical concern that mRNA vaccines against infections would elicit similar responses, eliciting inflammation and possibly exacerbating existing autoimmune diseases; lipid vacuole technology used to reduce this risk

Autoimmune cont

- Exacerbation of AI not seen with other vaccines
- Active infection also poses theoretical risk
- Benefit of vaccination must be balanced against this theoretical risk
- Patients with stable AI disease do not require specialist consultation (including those on immunosuppressants/immunomodulators)
- Patients with active/poorly controlled AI disease should discuss with their specialist

Pregnancy and Breastfeeding

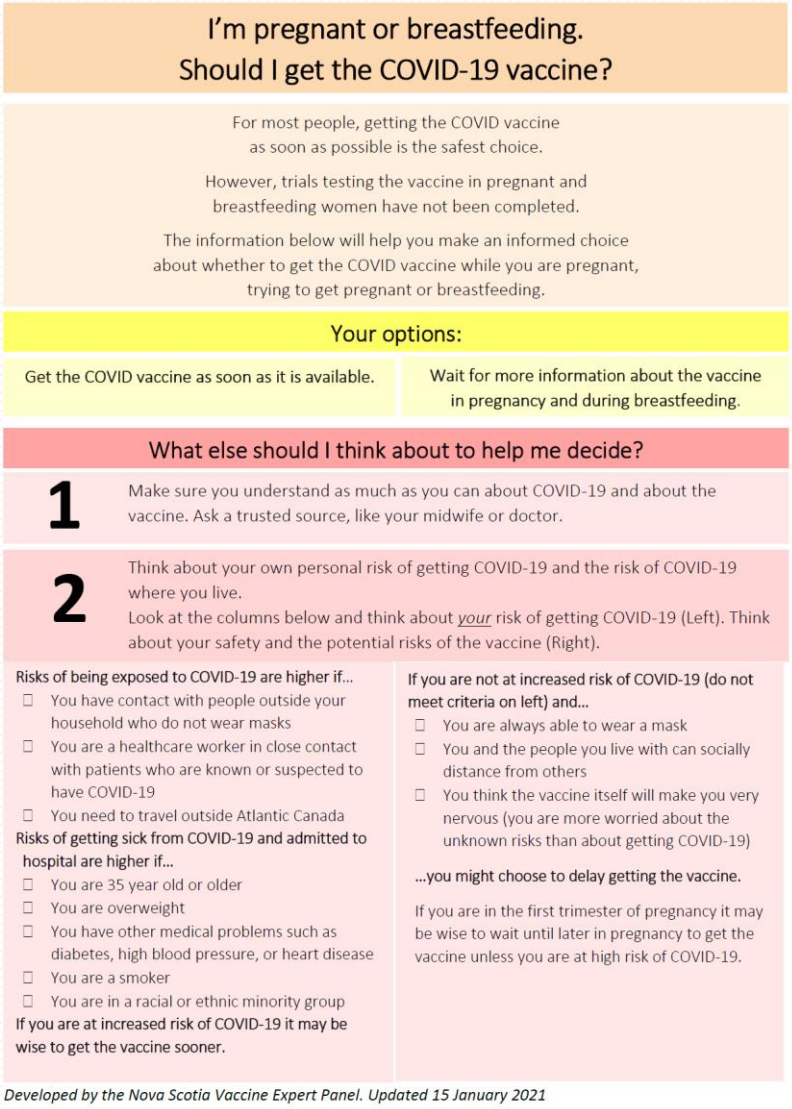
6/7) NACI recommends that COVID-19 vaccine may be offered to pregnant or breastfeeding individuals if a risk assessment deems that benefits outweigh potential risks for the individual and the fetus and if informed consent includes discussion about absence of evidence on use of COVID-19 vaccine in this population

- Evidence of pregnancy as an independent risk factor for severe COVID-19 evolving: pregnant women >35y, obese, medical comorbidities, smoking, racial or ethnic minority appear to be at increased risk of hospitalization
- Pregnant and breastfeeding individuals excluded from trials
- No theoretical concerns about these vaccines in breastfeeding woman
- Vaccine not live so not contraindicated; animal studies reassuring thus far
- Decision to receive vaccine during pregnancy requires shared decision making; SOGC recommends that pregnant women should be offered vaccine

Pregnancy cont.

- Given lack of data and risk of fever post-dose 2, may wish to consider delaying vaccination until second TM
- Those in first TM should discuss risks and benefits with their maternity care provider
- Individuals who become pregnant during vaccine series should NOT be counselled to terminate
- Consider delaying second dose until after pregnancy or beyond first TM
- No data to guide recommendation about timing between vaccination and pregnancy; NACI conservatively recommends 28d post dose 2

Available Resources



I'm pregnant or breastfeeding. Should I get the COVID-19 vaccine?

For most people, getting the COVID vaccine as soon as possible is the safest choice.

However, trials testing the vaccine in pregnant and breastfeeding women have not been completed.

The information below will help you make an informed choice about whether to get the COVID vaccine while you are pregnant, trying to get pregnant or breastfeeding.

Your options:

Get the COVID vaccine as soon as it is available.	Wait for more information about the vaccine in pregnancy and during breastfeeding.

What else should I think about to help me decide?

1 Make sure you understand as much as you can about COVID-19 and about the vaccine. Ask a trusted source, like your midwife or doctor.

2 Think about your own personal risk of getting COVID-19 and the risk of COVID-19 where you live.
Look at the columns below and think about *your* risk of getting COVID-19 (Left). Think about your safety and the potential risks of the vaccine (Right).

Risks of being exposed to COVID-19 are higher if...

- ☐ You have contact with people outside your household who do not wear masks
- ☐ You are a healthcare worker in close contact with patients who are known or suspected to have COVID-19
- ☐ You need to travel outside Atlantic Canada

Risks of getting sick from COVID-19 and admitted to hospital are higher if...

- ☐ You are 35 year old or older
- ☐ You are overweight
- ☐ You have other medical problems such as diabetes, high blood pressure, or heart disease
- ☐ You are a smoker
- ☐ You are in a racial or ethnic minority group

If you are at increased risk of COVID-19 it may be wise to get the vaccine sooner.

If you are not at increased risk of COVID-19 (do not meet criteria on left) and...

- ☐ You are always able to wear a mask
- ☐ You and the people you live with can socially distance from others
- ☐ You think the vaccine itself will make you very nervous (you are more worried about the unknown risks than about getting COVID-19)

...you might choose to delay getting the vaccine.

If you are in the first trimester of pregnancy it may be wise to wait until later in pregnancy to get the vaccine unless you are at high risk of COVID-19.

Developed by the Nova Scotia Vaccine Expert Panel. Updated 15 January 2021

Resources from Specialty care providers (samples)

- Canadian Association of Gastroenterology
- Society of Obstetricians and Gynaecologists of Canada
- Canadian Dermatology Association
- Canadian Rheumatology Association
- Canadian Association of Transplantation
- Canadian Association of Allergy and Immunology
- Canadian Association of Endocrinology and Metabolism

NS Approach to consent

- For patients with underlying conditions requiring discussion of risks/benefits in light of absence of data, discussion with a care provider- Primary care provider, specialist, vaccine expert, allergist, pharmacist
- Recommended provider to discuss consent dependent on underlying condition
- **No written documentation required** to be given to patient by provider; record discussion in your health record
- Supplemental consent/disclaimer document acknowledging consent discussion to be signed at time of vaccination

Management Pathways- UPDATED

	Pathway 1	Pathway 2	Pathway 2	Pathway 3	Pathway 4
Category	1	2	3	4	5
Education /consent discussion	Self +/- 811	Self +/- 811	Primary care provider, NP, pharmacist, clinic consult RN or specialist	Specialist or vaccine consultant (Infectious Diseases specialist)	Allergist
Consent documentation	Usual		Usual + confirmation	Usual + confirmation	Usual + confirmation

Category 1	Category 2	Category 3	Category 4	Category 5
• Splenic disorders • HIV • Chronic kidney disease • Chronic liver disease • Type 1 or 2 Diabetes mellitus • Stable anticoagulation/bleeding disorder • Radiation therapy alone • Asthma/COPD/HTN/ CAD/other medical conditions not associated with immunosuppression or autoimmunity • Anaphylaxis to another vaccine or injectable medication (observe for 30 min)	• Pregnant individuals beyond the 1st trimester • Breast-feeding individuals	• 1st TM pregnancy • Primary immune deficiency requiring IVIG or SCIG • Chronic granulomatous disease • Hyper IgE syndrome • Complement deficiency • **Any cancer not on treatment or on oral cancer treatment** • Solid organ transplant after 1 month & no acute rejection • HSCT after 3-6 months & no GVHD • Stable autoimmune condition • Stable immunomodulator therapy • History of Guillain Barre syndrome • History of Bell's palsy • On immune suppressing doses of prednisone (> 20 mg/day > 2 weeks) • **On anti-SARS-CoV-2 monoclonal antibodies**, plasma therapy , or plasmapheresis (delay 3 months)	• Active/unstable autoimmune condition • Solid organ transplant with acute rejection • **Cancer on IV chemotherapy** • Within 3 months of stem cell transplant • On check point inhibitor • Within 3 months of CAR-T procedure • Interferonopathy	• Anaphylaxis or severe reaction to prior dose of COVID-19 vaccine • Anaphylaxis to any component of the COVID-19 vaccine

Other

- Vaccination series should be completed with same product (same lot number not necessary)
- Do not give simultaneously with other vaccines- wait 14 days after another vaccine to give COVID vaccine; wait 28d after COVID vaccine to give another vaccine
- Place and read TST (or draw IGRA) before COVID-19 vaccine OR defer until 4 weeks post dose 2 (per CDC)

Summary and Conclusion

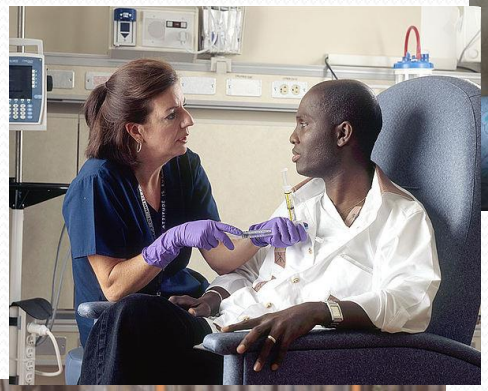
- As the NS COVID-19 immunization program ramps up, it is critical that HCP familiarize themselves with available COVID vaccines to enable discussion of risks and benefits with their patients
- Aside from allergy, there are NO CONTRAINDICATIONS for available vaccines (see age indications re AZ)
- In virtually ALL patients, benefits of vaccination outweigh theoretical risks
- Most important predictor of a patient to receive a vaccine is the recommendation of their physician
- You are the most trusted source of information on COVID vaccines for your patients and have the best info with which to help them understand risks and benefits
- Leaving discussion to the Consult RN or on-call physician in the clinic will be associated with increased (inappropriate) appointment cancellations as these providers do not know the patient's medical history or have a trust relationship
- 811 is not equipped to answer most medical questions about the vaccines or appropriateness of vaccination in an individual patient

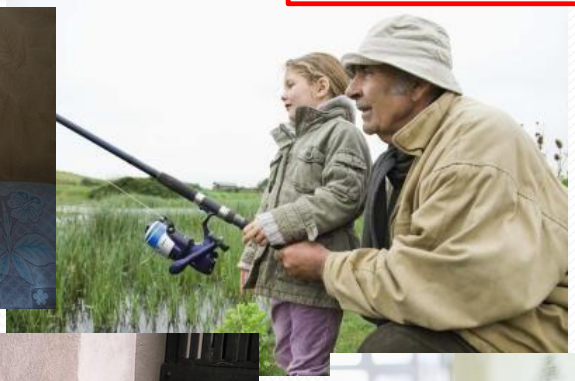
Be proactive! Discuss and recommend COVID vaccine to your patients NOW so that when their turn comes, they are ready.

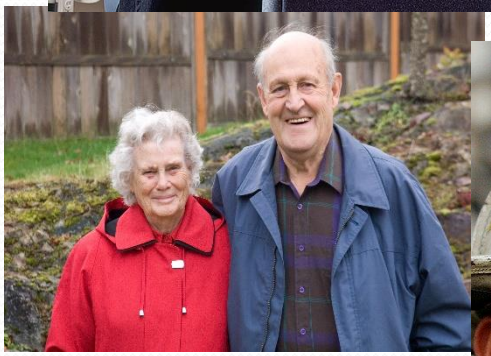
If you are vaccinating, it is your responsibility to review the consent documents with patients. The ON-CALL clinic support physician is intended to support vaccinators in the mass immunization clinic, NOT immunizing physicians and pharmacists.

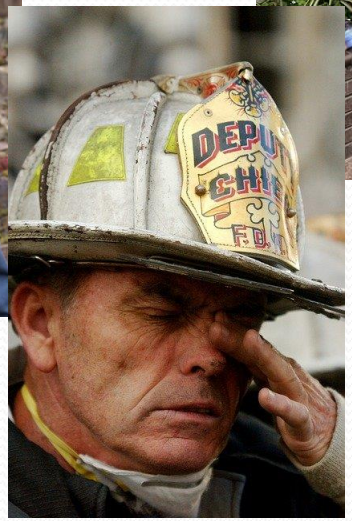
We're all in this together!

Insert your parent/grandparent here









Thanks!

Shelly.mcneil@nshealth.ca