COVID-19 Vaccination: Anaphylaxis Clinical Signs and Symptoms Documentation

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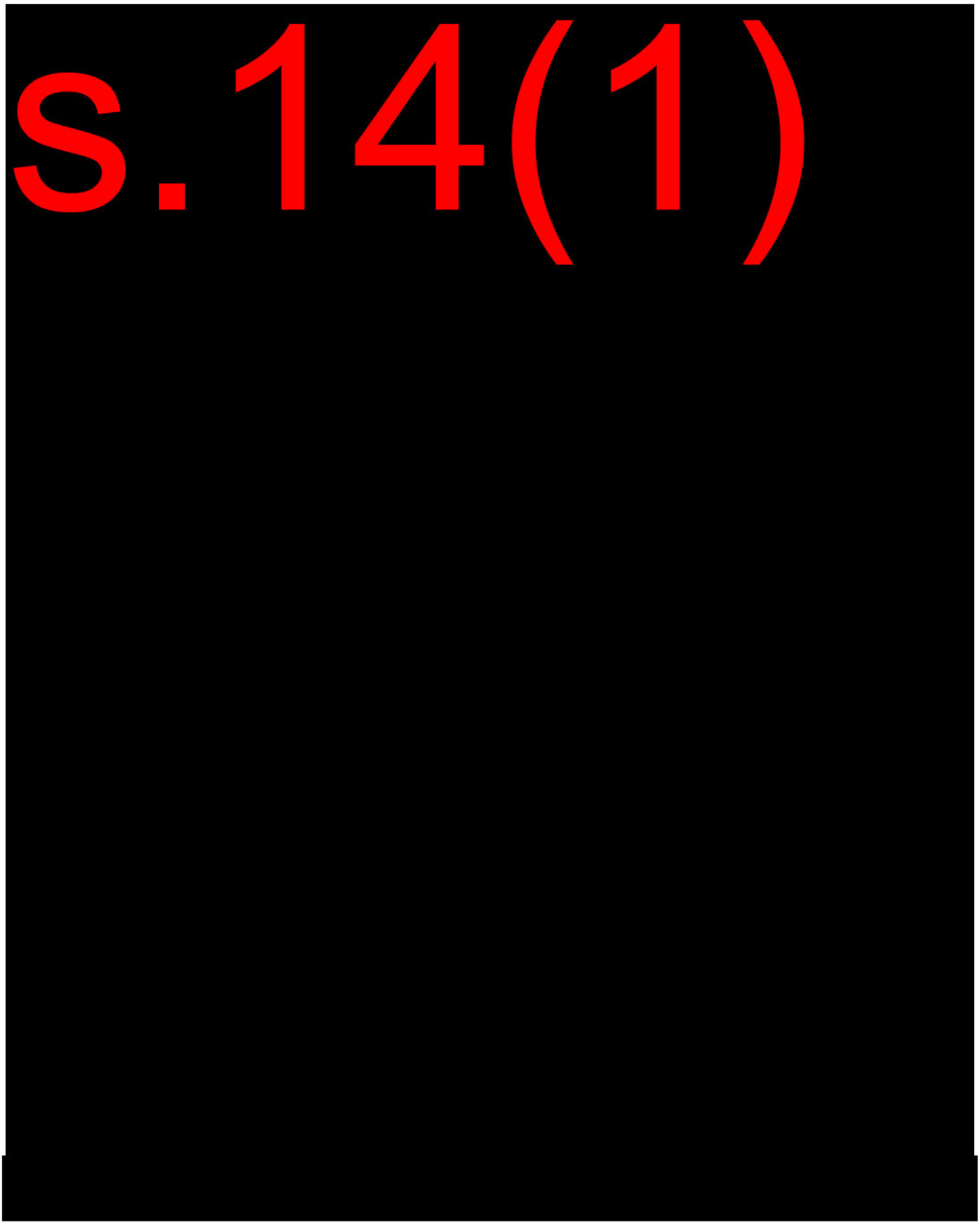
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NOVA SCOTIA
Seniors and Long-Term Care

PO Box 488
Halifax, Nova Scotia
Canada B3J 2R8

CCIR#21-216.0

CONTINUING CARE
INFORMATION RELEASE

TO: Long-Term Care Facilities, Home Care Agencies, Home Oxygen Providers

FROM: Shelley Jones, Project Executive, Continuing Care

CC: Tracey Barbrick, ADM, DSLTC
Katelyn Randell, Director, LTC
Kim Silver, Director, Home and Community, Continuing Care, DSLTC
Robert Lafferty, Director, Investigation and Compliance, DHW
Susan Stevens, Senior Director, Continuing Care, NSHA
Melissa Boland, CDPC consultant, DHW
Maria Medioli, Executive Director, DSP, DCS
Nancy Neil, Coordinator, Community Residential Programs, DCS

DATE: December 17, 2021

RE: COVID-19 Vaccine Program – Information for Health Care Professionals – December 17, 2021.

Please distribute this important information to individuals/teams as appropriate within your organization.

Please find attached the following **updated** document, *Nova Scotia COVID-19 Vaccine Program – Information for Health Care Professionals* – December 17, 2021. This evergreen document is also available at: https://novascotia.ca/dhw/cdpc/info-for-professionals.asp (Immunization tab).

New information/notable updates include:

- Booster doses of COVID-19 vaccine (question 4) ***update***
  - Eligible group information now found here: https://novascotia.ca/coronavirus/vaccine/#booster-doses
  - Booster dose guidance for individuals 18 to 29 years of age
- Interchangeability of adult/adolescent COVID-19 vaccines (question 5) ***update***
  - Myocarditis and pericarditis information for individuals under 30 years of age
  - Moderna Spikevax (100 mcg) antibody levels compared to Pfizer Comirnaty (30 mcg) and Moderna protection durability
- Safety in adolescents and children (question 9) ***update***
- Immunization Stress-Related Responses (question 11) ***update***
  - Interactive CARD (Comfort, Ask, Relax, Distract) game

- COVID-19 vaccine AEFIs in Nova Scotia (question 12) ***update***
- Myocarditis and pericarditis (question 13) ***update***
- Table 4: Pfizer BioNTech Comirnaty Summary of Use ***update***
- Table 5: Moderna Spikevax Summary of Use ***update***
- Equalizing pressure in Pfizer pediatric vaccine (10 mcg) vials (question 30) ***update***
- Pooling of Pfizer pediatric vaccine (10 mcg) (question 32) ***new***
- MIS-C in children and COVID-19 vaccination (question 40) ***new***
- COVID-19 vaccines received out of Canada (question 41) ***update***
    - Links to vaccine specific information for non-Health Canada, WHO authorized COVID-19 vaccines
- Allergens (question 43) ***update***
    - Inclusion of tromethamine related to Pfizer Comirnaty pediatric (10 mcg) vaccine

The *Moderna Spikevax/Pfizer BioNtech Comirnaty COVID-19 Vaccine Consent Form* (for downtime procedures) is available here:
http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=84478

The *COVID-19 Vaccine Booster Dose Information Sheet* is available here:
http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=91481

The *Pediatric 5 to 11 Years Old – Pfizer BioNTech Comirnaty COVID-19 Vaccine Consent Form* (for downtime procedures) is available here:
http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=91558

The *Pediatric Vaccine Information and Aftercare Sheet* is available here:
http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=91444

For immunization providers who are administering the small supply of Janssen COVID-19 vaccine for limited use:

The *Janssen COVID-19 Vaccine Consent Form* is available here:
http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=91606

The *Janssen COVID-19 Vaccine Information and Aftercare Sheet* is available here:
http://policy.nshealth.ca/Site_Published/covid19/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=91594.

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From:	Bailey, Darla
To:	Alexiadis, Maria; Boutilier, Nicole; Burgess, Stacy; Burris, Debbie; Croft, Julianne; Davidson, Angie; Dennis, Lori; DeSantis, Marcia; Dobson, Jaimee; Flinn, Jill; Hawkesworth, Theresa; Heather, Kerry; Howlett, Todd; Johnston, Lynn; Katelyn Randell; Kay, Janis; Keenan, Angela; Lamb, Alyson; MacDonald, Madonna; MacDonald, Tammy; MacDougall, Brett; MacGillivary, Kerri; MacNeil, Cheryl; MacQuarrie, Cindy; McCormick, Bethany; McGill, Kim; McNeil, Shelly; Miller, Dale Dr.; Nixon, Tanya L; Parker, Valerie; Pettipas, Janice; Piek, Krista; Pugh, Cheryl; Robinson, Nancy; Sandall-Holt, Alice; Sommers, Ryan; Stairs, Angela; Steeves, Anne; Stevenson, Colin; Sullivan, Vickie; Trottier, Anne; Wells, Tarin; Whelan, Noella; White, Heather
Cc:	DePodesta, Michelle; Jenkins, Bob; Keenan, Glenda; McVeigh, Wendy; Scales, Mark; Stevens, Susan
Subject:	CCIR 21-216.0 COVID-19 Vaccine Program Information for Health Care Professionals
Date:	Monday, December 20, 2021 10:01:09 AM
Attachments:	CCIR 21-216.0 COVID-19 Vaccine Program Information for Health Care Professionals.pdf CCIR 21-216.0 Attachment Nova Scotia COVID-19 Vaccine Program - Info for HCPs 20211217.pdf

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~Sending on behalf of Glenda Keenan~

For your information: The attached CCIR 21-216.0 was distributed by DSLTC to Long Term Care Facilities, Home Care Agencies and Home Oxygen Providers on December 17th.

Darla Bailey
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Glenda Keenan, Director
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Nova Scotia COVID-19 Vaccine Program

Information for Health Care Professionals

Updated December 17, 2021

Electronic copy can be found here: https://novascotia.ca/dhw/cdpc/info-for-professionals.asp; Immunization Tab; COVID-19 Immunization.

This evergreen document will be updated as evidence on COVID-19 and COVID-19 vaccines evolves.

The Public Health Agency of Canada (PHAC) has developed the COVID-19 Vaccination Tool Kit for Health Care Providers. Within the tool kit, there are links to general information about COVID-19, an overview of authorized vaccines, guidance for managing COVID-19 vaccination clinics, an overview of vaccine safety, as well as a number of additional resources such as digital tools and communication materials.

The Nova Scotia Health Authority (NSHA) has developed a Pandemic Immunizer Education site as an educational resource designed for health care providers who will be supporting community immunization clinics.

COVID-19 vaccine information and resources may also be found on the NSHA COVID-19 Hub.

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COVID-19 Vaccines in Canada – Eligibility, Interchangeability, Efficacy and Immunity

1. Which COVID-19 vaccines are currently available for use in Nova Scotia?

There are two COVID-19 mRNA vaccines available for use in Nova Scotia:

- Pfizer-BioNTech Comirnaty COVID-19 vaccine was authorized on December 9, 2020. Pfizer BioNTech Comirnaty pediatric formulation (age 5 -11) received Health Canada approval on November 19, 2021. Pfizer Comirnaty vaccine information including the product monograph is available from: https://www.cvdvaccine.ca/.
- Moderna Spikevax COVID-19 vaccine was authorized on December 23, 2020. Moderna Spikevax information including product monograph is available from: https://www.modernacovid19global.com/ca/.

There is a small supply of Janssen COVID-19 vaccine (non-replicating viral vector vaccine) available for use in Nova Scotia.

- Janssen COVID-19 vaccine was authorized on March 5, 2021. The Janssen COVID-19 product monograph is available from: https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf.

AstraZeneca Vaxzevria (non-replicating viral vector vaccine) is expected to be made available in early 2022.

- AstraZeneca Vaxzevria COVID-19 vaccine was authorized on February 26, 2021. The AstraZeneca Vaxzevria product monograph is available from: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf

Additional information specific to the COVID-19 vaccines currently authorized for use in Canada can be found in the NACI Statement Recommendations on the use of COVID-19 Vaccines.

2. Who is eligible to receive COVID-19 vaccine?

Any person living in Nova Scotia who is 5 years of age or older is eligible to receive COVID-19 vaccine for free. On November 19, 2021,the National Advisory Committee on Immunization (NACI) released its *Recommendation on the use of Pfizer BioNTech COVID-19 vaccine (10 mcg) in children 5 to 11 years of age.*

Nova Scotia adopted a predominantly age-based roll out of COVID-19 vaccine, however healthcare workers, and those living in large congregate settings (public and private) were the first groups eligible to receive COVID-19 vaccine.
The province also has ensured equitability and accessibility into its COVID-19 vaccine program by working with First Nations and African Nova Scotian stakeholders, to develop culturally sensitive vaccination clinics. For the First Nations approach, vaccine eligibility initially focussed on Elders, Knowledge and Language keepers, along with those that were > 55 years of age. For the African Nova Scotian community, eligible vaccine recipients began with those who were > 55 years of age. Outreach vaccine clinics with urban indigenous, shelters, persons with disabilities, community day programs and some large, specialized homes have also occurred.

Many factors are involved in the development of Nova Scotia's vaccine plan and are continually assessed as circumstances change.

3. Is Nova Scotia offering additional doses of COVID-19 vaccine for immunocompromised individuals?

Immunocompromised individuals are at higher risk of severe outcomes from COVID-19. Immunocompromised individuals have a weakened immune system due to disease or treatment. Evidence to date shows that some immunocompromised individuals have a lower immune response to COVID-19 vaccines compared to the general population. Some individuals who are moderately to severely immunocompromised that either did not respond or had a reduced response after two doses of an mRNA vaccine can have an increased immune response after a third dose. The National Advisory Committee on Immunization (NACI) has reviewed evidence from studies on the effectiveness, immunogenicity and safety of an additional dose of a COVID-19 vaccine in immunocompromised individuals who had previously received a 1- or 2-dose primary COVID-19 vaccine series and have updated recommendations for this population. The effectiveness of a third dose in immunocompromised individuals is not known at this time, and some people may not respond to a third dose. The safety profile of mRNA vaccines in observational studies in this population has been comparable to what has been observed in the general population, with no unexpected safety signals to date, including no worsening of an immunocompromising condition that has been attributed to the vaccine. However, the impact of additional doses on rare adverse are unknown at this time, this includes the risk of myocarditis and/or pericarditis associated with a third dose of an mRNA vaccine, including when given to immunocompromised individuals. Despite limited evidence, NACI has noted that although waiting for vaccine effectiveness data for this population would increase the certainty of the updated recommendations, an assessment of the benefits and harms given the available evidence on immunogenicity and safety, supports offering an additional dose to this population in order to optimize direct protection from vaccine if possible.

In alignment with NACI's strong recommendations, the following is recommended for Nova Scotians who are moderately to severely immunocompromised and within the authorized age group:

- Individuals meeting the moderately to severely immunocompromised criteria who have previously received a primary COVID-19 vaccine series (with a homologous or heterologous schedule using mRNA or viral vector vaccines) are recommended to receive, and are eligible for, an additional dose of mRNA COVID-19 vaccine [(i.e., 2 doses of mRNA and AstraZeneca COVID-19 vaccine (homologous or heterologous series), or 1 dose of Janssen (Johnson & Johnson) vaccine].
- Individuals meeting moderately to severely immunocompromised criteria who have not yet been immunized with a primary series of COVID-19 vaccine are recommended to receive, and are eligible for, a primary series of three doses of an mRNA COVID-19 vaccine at a minimal interval of 28 days between each dose, however the preferred schedule is 28 days between dose 1 and 2, and 8 weeks between dose 2 and 3.

To meet eligibility criteria for additional COVID-19 doses, moderately to severely immunocompromised is defined by specific criteria which may be found at:

- https://novascotia.ca/dhw/cdpc/documents/third-doses-Covid-19-vaccine-immunocompromise.pdf (eligibility criteria)
- https://novascotia.ca/dhw/cdpc/documents/immunosuppressive-medication-list.pdf (immunosuppressive medications), and
- https://novascotia.ca/dhw/cdpc/documents/primary-immunodeficiency-list.pdf (primary immunodeficiencies)

If immunization providers have questions regarding primary immunodeficiencies, they may contact Dr. Gina Lacuesta at 902-425-3927 (office) or via the QEII switchboard at 902-473-2220. After reviewing the list of immunosuppressive medications, if providers have questions regarding medication eligibility, they may contact the Nova Scotia Health COVID-19 Vaccine Pharmacist Consult Service by calling 1-833-768-1151. **The contact information for immunization provider support is not to be given to individuals presenting for immunization**.

Informed consent should include discussion about the current limited evidence for the use of an additional dose of any of the authorized COVID-19 vaccines. Informed consent for additional doses of COVID-19 vaccine should also include a discussion of the potential for increased risk of myocarditis and pericarditis following receipt of mRNA COVID-19 vaccine, which is currently reported more commonly after second doses compared to first doses. The risk of myocarditis and/or pericarditis associated with a third dose of an mRNA vaccine, including when given to immunocompromised individuals, is unknown at this time. Recipients of mRNA vaccine should be advised to seek medical attention if they develop symptoms including chest pain or pressure, shortness of breath, or palpitations. As a precaution, NACI advises that individuals who experienced myocarditis and/or pericarditis after a first or second dose of an mRNA vaccine should wait to get an additional dose until more information is available.

4. Who is eligible for booster doses of COVID-19 vaccine in Nova Scotia?

To date, COVID-19 vaccines have been shown to provide strong protection against serious illness, hospitalization, and death from COVID-19. There is currently no evidence of widespread waning of protection against severe disease in the general population who have been vaccinated against COVID-19. Current emerging evidence suggests some decrease in protection against severe disease with time since vaccination in elderly adults, particularly those 80 years of age and over and residents in long term care facilities. Evidence also suggests that vaccine effectiveness against asymptomatic infection and mild COVID-19 disease decreases with time, which could contribute to increased transmission of infection, particularly with the highly transmissible Delta or Omicron variant. Data also show that shorter intervals between doses in a primary series may result in lower immune responses and more rapid waning of protection. Studies have shown that people who received a complete vaccine series of a viral vector vaccine (two doses of AstraZeneca/COVISHIELD or one dose of Janssen COVID-19 vaccine) have somewhat lower initial vaccine effectiveness and may become susceptible to infection sooner than people who received a primary series that included at least one dose of an mRNA vaccine. Therefore, a booster dose of an mRNA COVID-19 vaccine in certain populations could help restore and maintain protection against disease. Studies suggest that a booster dose of an mRNA COVID-19 vaccine produces a good immune response that is generally higher than the immune response after the primary series, has a favourable safety profile, and provides good short-term protection against infection.

In alignment with NACI recommendations, certain groups are eligible to receive a booster dose of COVID-19 vaccine **6 months (no sooner than 168 days) following completion of the primary COVID-19 vaccine series**. These groups may be found at: https://novascotia.ca/coronavirus/vaccine/#booster-doses.

Booster doses of an mRNA COVID-19 vaccine will be offered to eligible individuals who have had previous COVID-19 infection. NACI continues to monitor evidence regarding the need for a booster dose in people who have previously been infected with COVID-19 disease.

As per NACI's guidance, for booster doses, the use of the Pfizer-BioNTech 30 mcg booster dose may be preferred to the Moderna 50 mcg booster dose among eligible 18 to 29 year olds. This is a precautionary approach due to the lower reported rate of myocarditis/pericarditis following the Pfizer COVID-19 vaccine compared to the Moderna 100 mcg vaccine. Data specific to the lower Moderna 50 mcg booster dose are limited and will be assessed as it emerges.

To assist in informed decision-making, information regarding booster doses is available for the general public via the *Pfizer-BioNTech Comirnaty and Moderna Spikevax Vaccines Information about COVID-19 Vaccine Booster Doses* Information Sheet.

For information on dosing related to boosters, please see Table 4 (Pfizer BioNTech Comirnaty Summary of Use) and Table 5 (Moderna Spikevax Summary of Use).

5. With the information regarding interchangeability of authorized adult/adolescent COVID-19 vaccines, how can health care professionals support patients in making an informed choice about receiving a specific type of COVID-19 vaccine?

NACI has provided advice on the interchangeability of authorized adult COVID-19 vaccines in a two-dose primary series schedule for COVID-19 immunization. NACI recommends that:

- COVID-19 mRNA vaccines should be considered interchangeable, however NACI also recommends that individuals aged 12 to 29 years of age preferentially receive the Pfizer Comirnaty COVID-19 vaccine to start or continue the mRNA primary vaccine series.
- Adults who received a first dose of AstraZeneca/COVISHIELD vaccine (viral vector vaccine), may be offered either AstraZeneca/COVISHIELD or an mRNA vaccine for the second dose, unless contraindicated. An mRNA vaccine is preferred as a subsequent dose due to emerging evidence including the possibility of better immune response, and the safety of mixed schedules.

There is evidence that Moderna Spikevax (100 mcg) induces somewhat higher antibody levels and provides longer-lasting protection against disease compared to Pfizer Comirnaty (30 mcg). This may be particularly noteworthy for populations who may have less robust immune function (elderly) or a diminished immune response to the vaccine (some immunocompromised individuals)

Vaccine safety surveillance data indicate a higher number of myocarditis and/or pericarditis cases in individuals under 30 years of age following vaccination with mRNA COVID-19 vaccines than would normally be expected, particularly among males, with data indicating that this occurs more frequently following Moderna (100 mcg) compared to the Pfizer-BioNTech COVID-19 vaccine. NACI recommends that for individuals 12 to 29 years of age, the use of Pfizer Comirnaty (30 mcg dose) is preferred to Moderna Spikevax (100 mcg dose) to start or continue the mRNA primary vaccine series.

A COVID-19 mRNA vaccine series completed with a different mRNA vaccine product is considered valid and does not need to be repeated. Similar vaccines from different manufacturers are routinely used interchangeably, including vaccines for Hepatitis A, Hepatitis B, Influenza, and Measles, Mumps, Rubella (MMR). General vaccine principles indicate that to be considered interchangeable, vaccines should be authorized with the same indications and with similar

schedules, for the same population, contain or produce comparable type(s) of antigen, and be similar in terms of safety, reactogenicity, immunogenicity and efficacy. All currently authorized COVID-19 vaccines in Canada use the spike protein of the SARS-CoV-2 virus as the antigen.

Emerging evidence indicates that mixed COVID-19 vaccine schedules (e.g., viral vector vaccine followed by an mRNA vaccine) have an acceptable safety profile, may be associated with short-term increased systemic reactogenicity (i.e. headache, fatigue and feeling generally ill) and are immunogenic.

Based on NACI recommendations, emerging evidence, including a small study which demonstrated that AstraZeneca followed by Pfizer COVID-19 vaccine resulted in an increased immune response compared to AstraZeneca followed by AstraZeneca, and the fact that vaccine-induced immune thrombotic thrombocytopenia (VITT) is not a risk with mRNA vaccines, Nova Scotia recommends that **mRNA vaccine should be used for second doses among individuals who received AstraZeneca for their first dose of COVID-19 vaccine**.

Completing the two-dose COVID-19 vaccination schedule remains essential. The first dose offers very good protection against COVID-19 infection, hospitalization and death. The second dose enhances and strengthens that protection over the longer term and may improve protection against emerging variants of concern.

6. What is the efficacy of the COVID-19 vaccines?

The currently authorized mRNA COVID-19 vaccines (Pfizer Comirnaty and Moderna Spikevax) have been shown to be highly efficacious in the short term against confirmed symptomatic COVID-19 disease. For mRNA vaccines, the highest efficacy is seen after the second dose is administered. In clinical trials, the viral vector COVID-19 vaccines (AstraZeneca Vaxzevria and Janssen) have shown moderate short-term efficacy against symptomatic COVID-19 disease.

For the most current information regarding efficacy of Health Canada authorized COVID-19 vaccines, please consult NACI's Recommendations on the Use of COVID-19 Vaccines statement.

7. How long does it take for immunity to develop following vaccination?

All authorized COVID-19 vaccines induce both humoral and cellular immune response. Humoral immune responses were demonstrated approximately 2 weeks after the first dose and boosted by the second dose of the vaccine. Emerging population-based data suggest that in older individuals it may take up to 3 weeks to mount a response. In clinical trials, maximal humoral immune response was seen after the second dose for each mRNA vaccine and for the AstraZeneca COVID-19 vaccine. The humoral immune response following the second dose of a complete two-dose vaccination schedule with mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna) was non-inferior in adolescents compared to young adults. Cellular immune responses increased after the second dose of mRNA vaccine, while responses for AstraZeneca COVID-19 vaccine did not appear to increase after the second dose. Cellular immune responses do not appear to differ between age groups. The duration of protection after a two-dose series is currently unknown.

COVID-19 Vaccine Safety and Adverse Events Following Immunization (AEFI)

8. How do we reassure the public that COVID-19 vaccines are safe and effective?

Like all vaccines authorized for use in Canada, COVID-19 vaccines are held to the same high safety, effectiveness, and quality standards. Only COVID-19 vaccines that meet those standards will be approved. Once a COVID-19 vaccine has been authorized for use in Canada, both Health Canada (the regulator) and the Public Health Agency of Canada (PHAC) monitor its safety and effectiveness in individuals. Manufacturers are legally required to report specific adverse events to Health Canada. In addition, there is surveillance of vaccine safety within each province and continuous monitoring of vaccine safety reports received across the country at PHAC as part of Canada's post-marketing surveillance program.

Patients consistently rank healthcare providers as their most trusted source for vaccine information. A healthcare provider's recommendation to get the COVID-19 vaccine has a positive impact on individuals' intentions to be immunized. Be transparent about the latest vaccine information, reassure that there is a robust vaccine safety surveillance system in Canada, and emphasize vaccines' roles to protect recipients and the people around them.

Providers can use the PHAC's COVID-19 Vaccination Tool Kit for Health Care Providers as a resource to help clients and colleagues make informed decisions about COVID-19 vaccination by sharing credible information and resources with them.

Safety in Adolescents and Children

9. What new evidence has emerged to demonstrate that the mRNA COVID-19 vaccines are safe for adolescents and children?

Advice from NACI recommends that a complete series with an mRNA COVID-19 vaccine should be offered to individuals 12 years of age and older who do not have contraindications to vaccine. In addition, NACI recommends that for individuals aged 12 to 29 years of age, the use of Pfizer Cominrnaty (30 mcg dose) is preferred to Moderna Spikevax (100 mcg dose) to start or continue the mRNA primary COVID-19 vaccine series. In individuals under 30 years of age, the rare risk of myocarditis and pericarditis associated with mRNA vaccines appears more common after Moderna than Pfizer vaccine. NACI recommends that the second dose of mRNA COVID-19 vaccine should be provided 8 weeks after the first dose as a longer interval between doses is associated with higher vaccine effectiveness and potentially lower risk of myocarditis/pericarditis. NACI advises that for individuals aged 18 to 29 years of age who are eligible to receive a booster dose of COVID-19 vaccine, the use of Pfizer Comirnaty (30 mcg dose) may be preferred to Moderna Spikevax booster dose (50 mcg dose).

Informed consent should include discussion about rare reports of myocarditis and/or pericarditis in the week following an mRNA vaccine dose and that there are many potential causes beyond receiving a COVID-19 mRNA vaccine for myocarditis and pericarditis. Myocarditis can also occur as a complication in people who are infected with COVID-19. Vaccine recipients should be advised of the symptoms of myocarditis/pericarditis and to seek immediate medical attention should symptoms develop. Important information for vaccine recipients about myocarditis and pericarditis for Pfizer and Moderna COVID-19 vaccines is available as a one-page handout.

On November 19, 2021, Health Canada authorized the use of Pfizer-BioNTech Comirnaty COVID-19 vaccine in children 5 – 11 years of age. On this same date, NACI provided its recommendations on the use of Pfizer-BioNTech COVID-19 vaccine (10 mcg) in children 5 to 11 years of age. Overall, clinical trial data shows that the Pfizer Comirnaty COVID-19 vaccine was well tolerated in children 5-11 years of age. No serious adverse events related to the Pfizer Comirnaty (age 5 – 11) vaccine, no cases of multisystem inflammatory syndrome in children (MIS-C), myocarditis/pericarditis or deaths were reported in the clinical trial. Given the trial size, it is unlikely that any adverse event occurring at a frequency less often than 1 in 1,000 would be detected.

Mature Minor Consent

10. Is parental/guardian consent required for a provider to proceed with COVID-19 vaccination in adolescents?

There is no minimum age for giving consent for any health care decisions in Nova Scotia, including immunization. In Nova Scotia, like in other provinces and territories across Canada, the capacity to make a decision is not tied strictly to age. If, in the judgment of the health care professional, an individual has the capacity to consent (e.g. is mature enough to understand the nature and consequences of the decision to be immunized or not be immunized), the individual can give her/his own consent. Adolescents who are able to understand the benefits and possible reactions of the vaccine and the risk of not getting immunized, can legally consent to or refuse to proceed with COVID-19 vaccination. Parental/legal guardian consent is not required. Mature minor authority to provide consent takes precedence over parental/guardian authority. Parents/guardians may provide consent for an adolescent to be immunized—it is preferable that the parent/guardian provides consent after discussing immunization with their child. However, before the immunization is given, every adolescent must be asked by the immunization provider if they understand, have any questions, and consent to be immunized. If the parent wishes the adolescent to be immunized and the adolescent refuses, the immunization should not be given. Providers must assess the adolescent's ability to consent. To assess consent, providers must consider the adolescent's ability to understand the:

- condition for which the vaccine is being offered,
- nature and purpose of the vaccine,
- risks and benefits of receiving the vaccine, and
- risks and benefits of not receiving the vaccine.

During the assessment, consider:

- the adolescent's ability to think and make choices
- the adolescent's ability to understand and communicate information relevant to the situation.

If the adolescent is assessed as being unable to give informed consent, a substitute decision maker must be involved, for example, a parent or guardian.

Clinical guidance regarding mature minor consent has been developed by the NSHA/IWK and is available on the COVID-19 Hub. Information regarding *Mature Minor Consent for COVID-19 Immunization* for the general public may be found on the Province of Nova Scotia's Coronavirus website.

Immunization Stress-Related Responses (ISRR)

11. What resources are available for health care providers to support patients who experience stress and anxiety related to immunizations?

Immunizations can cause unnecessary stress and anxiety which could lead to non-adherence to schedules or missed second doses of the COVID-19 vaccine. Immunization stress-related response (ISRR) is a response to the stress some individuals may feel when receiving an injection and can range from mild feelings of worry to symptoms such as increased heart rate, palpitations, difficulty breathing, fainting, nausea and/or vomiting. *Immunization Stress-Related Responses: A synopsis of the manual for program managers and health professionals to prevent, identify and respond to stress-related responses following immunization* has been produced by the World Health Organization.

Health care providers can offer a more positive experience for individuals through a patient-centred approach which promotes coping. Resources for health care providers, parents and caregivers include:

- Immunize Canada- reducing pain and fear in both adults and children during vaccination.
- The CARD system - promotes activities for vaccine recipients in order to have a more positive immunization experience. The interactive CARD game for children is available here: https://immunize.ca/card-game-kids.
- *Nervous about needles? 7 tips for making vaccinations more comfortable* – vaccination tip sheet for youth developed by the IWK/NSH
- IWK Health Comfort Promise COVID-19 Vaccine Toolkit - resources for parents and caregivers of children aged 5 to 11 years who will be receiving the COVID-19 vaccine
- Vaccination resources for children, youth and families – Comfort Promise: IWK Health; COVID-19 Vaccine Safety for Youth; Needle Phobias; How to talk about Vaccination

Side Effects and Adverse Events

12. What are the side effects and adverse events related to COVID-19 vaccines?

Monthly reports of AEFIs with COVID-19 vaccines in Nova Scotia are available here: https://novascotia.ca/coronavirus/alerts-notices/#adverse-events-following-immunization. Please see NACI Statement Recommendations on the use of COVID-19 Vaccines for a summary of adverse events identified in clinical trials of authorized COVID-19 vaccines. The COVID-19 Vaccine Information and Aftercare Sheets (Pfizer and Moderna; AstraZeneca/COVISHIELD, Janssen), provide information for vaccine recipients regarding side effects.

Very common and common adverse events

Common adverse events are defined as those that occur in 1% to less than 10% of vaccine recipients; very common adverse events occur in 10% or more of vaccine recipients.

Local

Pain at the injection site is very common after administration of the currently authorized COVID-19 vaccines. Redness/erythema and swelling are common or very common after administration. Clinical findings to date have indicated that the Pfizer COVID-19 vaccine is well tolerated in adolescents 12 to 15 years of age and children 5-11 years of age. Local reactions have been mostly mild to moderate in severity and occurred predominantly following the first dose. Compared to clinical trial participants ≥12 years of age (who received a 30 mcg dose), children 5-11 years of age

that received a 10 mcg dose had similar frequencies of pain at the injection site and higher frequencies of swelling and redness. Localized axillary lymph node swelling and tenderness was a solicited adverse event in the Moderna COVID-19 clinical trial and was very common after administration with that vaccine. Local adverse events are usually mild or moderate and resolve within a few days of vaccination. Vaccine recipients who have experienced these local reactions can receive the second dose. For the authorized mRNA COVID-19 vaccines, pain at the injection site was slightly more frequent in younger authorized age groups including adolescents 12-15 years of age (Pfizer COVID-19 vaccine) compared to older adults. For AstraZeneca COVID-19 vaccine, local reactions were milder and reported less frequently after the second vaccine dose in all age groups.

Delayed reactions with pain, redness, swelling, and occasionally pruritus, at the injection site have been noted in those individuals who have received Moderna vaccine. Such reactions were observed in the Moderna clinical trials with onset on or after day 8 following vaccination and were more likely to occur following the first dose than the second dose. Vaccine recipients who have experienced these delayed local reactions can safely receive the second dose.

Table 1: Frequency of solicited local adverse events in authorized populations[a]

AEFI	Pfizer-BioNTech		Moderna		AstraZeneca	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Pain at injection site	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Tenderness	NS	NS	NS	NS	Very Common	Very Common
Redness/erythema	Common	Common	Common	Common	Very Common	Common
Swelling	Common	Common	Common	Very Common	Common	Common
Lymphadenopathy/ Axillary swelling and Tenderness	NS	NS	Very Common	Very Common	NS	NS
Warmth	NS	NS	NS	NS	Very Common	Common
Pruritis	NS	NS	NS	NS	Very Common	Common
Induration	NS	NS	NS	NS	Common	Common

Abbreviations: AEFI: adverse event following immunization; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients.

Systemic

Fatigue, headache, muscle pain, chills, and joint pain are all either common or very common after the administration of the currently authorized COVID-19 vaccines. Fever was very common after administration of the second dose of the currently authorized mRNA COVID-19 vaccines and common after any dose of the AstraZeneca COVID-19 vaccines. Oral analgesics or antipyretics may be considered for the management of adverse events (e.g., pain or fever, respectively), if they occur after vaccination. Systemic adverse events are usually mild or moderate intensity and resolve within a few days of vaccination. Vaccine recipients who have experienced these systemic reactions can receive the second dose. For the mRNA COVID-19 vaccines, systemic reactions are more frequent after the second vaccine dose and in younger authorized age groups including adolescents 12-15 years of age (Pfizer COVID-19 vaccine). Compared to individuals 18 to 55 years of age, adolescents 12 to 15 years of age demonstrated increased frequency of headache, chills, and fever. For AstraZeneca COVID-19 vaccine, systemic reactions are milder and reported less frequently after the second vaccine dose than the first in all age groups.

Table 2: Frequency of solicited systemic adverse events in authorized populations[a]

AEFI	Pfizer-BioNTech		Moderna		AstraZeneca	
	Dose 1	Dose 2	Dose 1	Dose 2	Dose 1	Dose 2
Fatigue	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Headache	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Muscle pain	Very Common	Very Common	Very Common	Very Common	Very Common	Very Common
Chills	Very Common	Very Common	Common	Very Common	Very Common	Common
Joint Pain	Common	Very Common	Very Common	Very Common	Very Common	Very Common
Fever[b]	Common	Very Common	Uncommon	Very Common	Common	Common
Feverishness[b]	NS	NS	NS	NS	Very Common	Common
Diarrhea	Common	Common	NS	NS	NS	NS
Nausea and/or Vomiting Vomiting[c]	Uncommon	Common	Common	Very Common	Very Common/ Common	Common/ Uncommon

Abbreviations: AEFI: adverse event following immunization; NS: not solicited

[a] Very common = occur in 10% or more of vaccine recipients, common = occur in 1 to less than 10% of vaccine recipients, uncommon= occur in 0.1% to less than 1% of vaccine recipients.

[b] Fever was objectively reported as having a temperature ≥38°C/100.4°F. Feverishness was a subjective, self-reported feeling of having fever.

[c] If two frequencies are reported the first reflects frequency of nausea and the second reflects the frequency of vomiting.

Uncommon, Rare and Very Rare Adverse Events

Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. While not solicited, lymphadenopathy was uncommonly reported after administration of the Pfizer-BioNTech and AstraZeneca COVID-19 vaccine. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. No rare or very rare solicited adverse events were reported among vaccinated participants in any COVID-19 vaccine clinical trial to date.

The probability of detection of very rare adverse events in clinical trials is low given clinical trial population sizes; therefore, ongoing post-marketing vaccine safety surveillance is essential.

Myocarditis and Pericarditis

13. Is there an established association between COVID-19 mRNA vaccines and myocarditis or pericarditis?

There have been rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with mRNA COVID-19 vaccines including Pfizer and Moderna reported in Canada and internationally. The Public Health Agency of Canada and Health Canada are monitoring reports of myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines internationally and in Canada through passive and active Canadian safety surveillance systems. The Canadian weekly online adverse events report provides updates on the latest numbers. Nova Scotia specific data is available here: https://novascotia.ca/coronavirus/alerts-notices/#adverse-events-following-immunization. Available information indicates that these cases occur:

- more commonly after the second dose,
- typically, within several days after vaccination, and most are reported within a week after vaccination,
- mainly in adolescents and adults under 30 years of age, and
- more often in males than females.

Data suggests that this occurs more frequently following the Moderna COVID-19 vaccine compared to the Pfizer-BioNTech vaccine. There are no data and limited data on myocarditis/pericarditis following a third dose of mRNA vaccine and following heterologous schedules, respectively. NACI has advised that the second dose of an mRNA COVID-19 vaccine series should be provided 8 weeks after the first dose as a longer interval between doses appears to be associated with a lower risk of myocarditis/pericarditis.

Myocarditis and pericarditis both involve inflammation of the heart in response to an infection or some other trigger. Immunization providers should inform those individuals receiving mRNA COVID-19 vaccines of the rare risk of myocarditis and/or pericarditis following immunization. Individuals should be advised to seek immediate medical attention if they develop symptoms. Symptoms can include:

- shortness of breath,
- chest pain or pressure,
- unexplained sweating,
- cough,
- the feeling of a fast, pounding or fluttering heartbeat,
- swelling in the ankles and feet.

While myocarditis can be serious, cases reported after receipt of COVID-19 mRNA vaccines appear to be generally mild and have responded well to conservative treatment and rest, with quick symptom improvement. **Healthcare providers should consider myocarditis and pericarditis in the evaluation of acute chest pain or pressure, arrhythmias, shortness of breath or other clinically compatible symptoms after vaccination.** Providers should consider doing an electrocardiogram (ECG), troponins, and an echocardiogram, in consultation with a cardiologist. It would also be important to rule out other potential causes of myocarditis and pericarditis. As such, consultation with infectious diseases and/or rheumatology is recommended to assist in this evaluation, particularly for acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing). **All cases of myocarditis or pericarditis following vaccination should be reported to local public health.**

As a precaution and in alignment with NACI, individuals in Nova Scotia who experienced myocarditis and/or pericarditis following their first dose of an mRNA vaccine **should defer** their second dose until more information is available. If individuals who experienced myocarditis and/or pericarditis following their last dose of an mRNA COVID-19 vaccine wish to proceed with their next dose, they may choose to do so following an informed consent discussion with a health care provider. Individuals with a medical history of myocarditis not related to mRNA COVID-19 vaccination should consult their health care provider for individual considerations and recommendations. Individuals previously diagnosed with myocarditis but who are no longer being followed by a medical professional for heart issues should receive the vaccine.

Vaccine recipients should be encouraged to review the Important Information about Myocarditis and Pericarditis for Pfizer and Moderna COVID-19 Vaccines handout and have a discussion with their provider if they have questions about symptoms after vaccination or when to seek medical care if symptoms develop. Informed consent should also include discussion about the individual's personal risk of severe COVID-19 disease, risk of infection and local epidemiology (including circulation of variants of concern), complications of COVID-19 (which may include myocarditis and pericarditis), and protection offered by COVID-19 vaccination. The benefits of receiving COVID-19 vaccine outweigh the rare risk of myocarditis/pericarditis in people of all ages.

Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)

14. Are viral vector COVID-19 vaccines safe with the recent information regarding Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT)?

Very rare cases of thrombosis associated with thrombocytopenia [called Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT)], some presenting as mesenteric vein or cerebral vein/cerebral venous sinus thrombosis, have been reported globally in persons who had recently received AstraZeneca COVID-19 vaccine usually occurring between 4 and 28 days after vaccination. This adverse event has not been reported in those who receive an mRNA vaccine. VITT is associated with the development of antibodies that "activate" platelets, which stimulate the formation of clots and result in thrombocytopenia. The mechanism of action is similar to Heparin-induced Thrombocytopenia (HIT). The exact mechanism by which viral vector COVID-19 vaccines may trigger VITT is still under investigation. Many VITT cases have been reported to have serious long-term illness, including neurologic injury. Cases have occurred in vaccine recipients of all ages and there do not appear to be any risk factors. Updated case numbers of VITT in Canada, may be found in the "Serious and non-serious adverse events reported" section of Reported side effects following COVID-19 vaccination in Canada. The case fatality rate of VITT varies between countries, and ranges between 20 and 50%. This rate may be

modified with early diagnosis and treatment so it is very important that individuals are made aware of signs and symptoms of concern and instructed to seek immediate medical attention should they occur. The majority of VITT cases which occurred following administration of Janssen COVID-19 vaccine occurred within three weeks following vaccination. Individuals should monitor for symptoms up to 42 days after receiving AstraZeneca/COVISHIELD COVID-19 vaccine.

Health Canada has advised that if individuals experience rare blood clots with low platelets following their first dose of the AstraZeneca or COVISHIELD COVID-19 vaccine, it is not recommended that they receive a second dose of any version of the AstraZeneca vaccine. Healthcare professionals are urged to be alert for symptoms of VITT, possible cases of thromboembolism, disseminated intravascular coagulation (DIC) or cerebral venous sinus thrombosis (CVST) occurring in vaccinated individuals. **Symptoms to be vigilant for include**: sudden onset of severe or persistent worsening headaches, shortness of breath, chest pain, leg pain, swelling and redness in a limb, pallor and coldness in a limb, persistent abdominal pain; visual changes, including blurred or double vision, confusion, episodes suspicious for seizure; or unusual bleeding, multiple small bruises, or reddish or purplish spots or blood blisters under the skin (other than at the site of vaccination). Providers should ensure that individuals who receive the AstraZeneca or Janssen COVID-19 vaccine are informed of the potential risk of these rare thromboembolic side effects and instructed to seek immediate medical attention should they develop any of the signs or symptoms described following receipt of the vaccine. **All cases of VITT should be reported to local public health.** Individuals should monitor for symptoms up to 42 days after receiving a viral vector COVID-19 vaccine. More information regarding abnormal blood clotting, thrombocytopenia, and unusual bleeding following vaccination with viral vector vaccines may be found in the Janssen Information and Aftercare Sheet and the AstraZeneca Important Information sheet.

Individuals who have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should only receive the Janssen COVID-19 vaccine if the potential benefits outweigh the potential risks.

More information regarding VITT may be found in NACI's Recommendations on the use of COVID-19 vaccines statement.

15. What clinical guidance regarding Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT) is available for health care providers?

Thrombosis Canada's Clinical Guide: Vaccine-Induced Prothrombotic Immune Thrombocytopenia (VIPIT) provides information for health care professionals to assist in the diagnosis and management of VIPIT, also known as VITT. Thrombosis Canada provides resources regarding COVID-19 vaccines and blood clots in the form of an FAQ, infographic, and webinars. These resources may be found here: https://thrombosiscanada.ca/covid-19-vaccines-and-blood-clots-faqs/. To support clinicians, Thrombosis Canada has identified key contacts in provinces and territories across Canada as provincial thrombosis champions. Dr. Sudeep Shivakumar is available to assist Nova Scotia clinicians with possible cases of VITT and to direct in diagnosing/ruling out and managing cases of VITT. Dr. Shivakumar may be reached via email at sudeep.shivakumar@nshealth.ca or cell at 902-789-7558.

Capillary Leak Syndrome (CLS)

16. What information is available regarding capillary leak syndrome (CLS) and viral vector COVID-19 vaccines?

On June 29, 2021, Health Canada updated the AstraZeneca and COVISHIELD Product Monographs and issued a Health Product Risk Communication. These updates highlight that capillary leak syndrome (CLS) has been observed very rarely following vaccination with the AstraZeneca COVID-19 vaccine and provide further guidance for healthcare professionals and vaccine recipients. Janssen COVID-19 vaccine is contraindicated in individuals with a history of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (due to low blood pressure) leading to organ damage. Individuals should seek medical attention immediately if they develop these symptoms following vaccination. CLS is a life-threatening condition characterized by acute episodes of limb edema, hemoconcentration, hypoalbuminemia and hypotension leading to organ damage. Patients with an acute episode of CLS following vaccination require an urgent medical assessment. Intensive supportive therapy is usually warranted for this life-threatening condition. Individuals who have previously experienced episodes of CLS should not be vaccinated with AstraZeneca COVID-19 Vaccine or COVISHIELD and should discuss options for COVID-19 vaccines with their healthcare professional. **All cases of CLS following vaccination should be reported to local public health.**

Guillain-Barre Syndrome (GBS)

17. What information is available regarding Guillain-Barre Syndrome following vaccination with authorized COVID-19 vaccines?

Guillain-Barre syndrome (GBS) is a rare but potentially serious immune-mediated neurologic disorder that results in pain or numbness, muscle weakness, and paralysis in severe cases. Most people fully recover from GBS but some have lasting deficits or symptoms and rarely, fatal cases can occur. GBS can result from different causes, including infections, and occurs more frequently in males and persons aged 50 years or more. Symptoms of GBS may include:

- weakness or tingling sensations, especially in the upper or lower limbs, that worsens and spreads to other parts of the body
- coordination problems and unsteadiness
- difficulty walking
- weakness in the limbs, chest or face
- difficulty with bladder control and bowel function
- double vision or difficulty moving eyes
- difficulty with facial movements, including swallowing, speaking, or chewing

GBS has been reported very rarely following COVID-19 vaccination. To date, no increased risk of GBS has been identified following vaccination with the authorized mRNA COVID-19 vaccines (Pfizer and Moderna). There have been reports of an increased risk of GBS following vaccination with the authorized viral vector COVID-19 vaccines (AstraZeneca and Janssen).

The risk of GBS recurrence after COVID-19 vaccination amongst those with a past history of GBS appears to be very low. A causal association between GBS recurrence and COVID-19 vaccination has not been established. More information regarding the number of cases of GBS reported in Canada is available through the PHAC weekly AEFI report.

Individuals with past history of GBS should receive an authorized mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of an authorized COVID-19 vaccine may receive a second dose of an mRNA COVID-19 vaccine following specialist consultation, a risk-benefit discussion and following informed consent.

Reporting Adverse Events

18. When should I report an adverse event following immunization (AEFI)?

An AEFI is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of a vaccine. All adverse events not normally expected (i.e. listed in the product monograph) that are temporally related to the administration of the vaccine need to be reported to local public health in accordance with It's the Law: Reporting of Adverse Events Following Immunization. These reports are reviewed as they are received and are summarized at the provincial and national level as part of Canada's post-marketing surveillance program.

19. How do I report an adverse event following immunization (AEFI)?

Providers reporting an AEFI to public health can obtain the AEFI form and the User Guide from the Public Health Agency of Canada. Serious adverse events must be reported within **one** working day. Other adverse events must be reported within **five** working days. Information regarding serious and other adverse events may be found here: https://novascotia.ca/dhw/cdpc/documents/Reporting-Adverse-Events-Following-Immunization.pdf

Adverse Events of Special Interest (AESI)

20. What is an Adverse Event of Special Interest (AESI)?

An AESI is a specific adverse event that has been identified by international health authorities to be monitored as part of COVID-19 vaccine safety surveillance. The conditions have been included because they have been associated with COVID-19 disease or there is a theoretical/proven association with vaccines in general or a vaccine platform. Further information regarding AESIs is available via the Brighton Collaboration. The Brighton Collaboration AESI list may be found here: https://brightoncollaboration.us/wp-content/uploads/2021/01/COVID-19-updated-AESI-list.pdf. Examples of AESIs include but are not limited to acute cardiovascular injury, coagulation disorders, acute kidney or liver injury, acute pancreatitis, and rhabdomyolysis. These events should also be reported to public health by providers.

Storage, Dosing, Scheduling and Administration

21. What are the differences in the storage requirements, authorized schedules, doses, and administration between the COVID-19 vaccines approved for use in Canada?

Table 3: mRNA COVID-19 Vaccines authorized for use in Canada

Product Brand Name	Pfizer BioNTech Comirnaty adult/adolescent COVID-19 vaccine	Pfizer BioNTech Comirnaty pediatric COVID-19 vaccine	Moderna Spikevax COVID-19 vaccine
Type of vaccine	mRNA	mRNA	mRNA
Ages for use	HC: 12 years of age and older	HC: 5 – 11 years of age	**NS: 18 years of age and older** HC: 12 years of age and older
Dose	0.3 mL (30 mcg of mRNA)	0.2 mL (10 mcg of mRNA)	See Table 5
Schedule	See Table 4	See Table 4	See Table 5
Route of administration	IM	IM	IM
Diluent	Yes (1.8 ml per vial)	Yes (1.3 ml per vial)	No
Primary storage requirements pre-puncture	-90°C to -60°C	-90°C to -60°C	-25°C to -15°C
Additional storage requirements pre-puncture [1]	Frozen vials: -25°C to -15°C for up to 2 weeks [2] Thawed under refrigeration: 1 month at +2°C to +8°C Thawed at room temperature: 2 hours up to +25°C	Up to 10 weeks at +2°C to +8°C AND/OR 12 hours prior to dilution	30 days at +2°C to +8°C **and/or** 24 hours at +8°C to +25°C
Usage limit post-puncture	6 hours at +2°C to +25°C [3]	12 hours at +2°C to +25°C [4]	24 hours at +2°C to +25°C
Formats available	Multi-dose vial (6 doses) [5], preservative-free	Multi-dose vial (10 doses), preservative-free	Multi-dose vial (10 doses), preservative-free; US label multi-dose vial (14 – 15 doses), preservative-free

Abbreviations: mRNA: Messenger ribonucleic acid; HC: Health Canada; IM: intramuscular

1 Protected from light during storage.

2 Vials stored at -25°C to -15°C for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C. Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks.

3 After dilution, vaccine must be used within 6 hours.

4 Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in this Product Monograph supersedes the number of hours printed on vial labels and cartons.

5 After dilution, one vial contains 6 doses of 0.3 mL each. However, vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. Information in the product monograph supersedes the number of doses stated on vial labels and cartons. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial. Refer to the product monograph for choice of diluent, dilution instructions and type of syringes which can be used to extract 6 doses from a single vial.

US labeled Moderna COVID-19 vaccine is similar to the Health Canada authorized Moderna COVID-19 vaccine in aspects such as formulation, strength and route of administration. Providers should continue to reference the Canadian Product Monograph for all product use in Canada. A Health Product Risk Communication regarding US labeled Moderna COVID-19 vaccine supply, labelling and packaging is available here: http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75807a-eng.php.

Interim national guidelines on vaccine storage, handling and transportation for ultra-low temperature and frozen temperature COVID-19 vaccines is available from the Public Health Agency of Canada: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/vaccine-storage-handling-transportation-ultra-low-temperature-frozen.html#a1.1 Information on the specific vaccine storage and handling requirements for the mRNA COVID-19 vaccines is available from: Pfizer BioNTech: https://www.cvdvaccine.ca/ and Moderna: https://www.modernacovid19global.com/ca/.

Table 4: Pfizer-BioNTech Comirnaty Summary of Use

Population	Formulation Diluent Volume	Dose	Schedule
Primary series for 12 years of age and over* *Not moderately to severely Immunocompromised*	**Adult/adolescent** 1.8 ml of diluent	**0.3 ml** (30 mcg)	**Two doses** • 8-week interval between first and second dose
Primary series for 12 years of age and over for moderately to severely immunocompromised	**Adult/adolescent** 1.8 ml of diluent	**0.3 ml** (30 mcg)	**Three doses** • May book a 28-day interval between dose 1 and 2 • May book a 28-day interval between dose 2 and 3, however 8-week interval is preferred • Longer intervals may result in a better immune response but may result in being susceptible for longer between doses • Moderna may be associated with higher antibody response and longer-lasting protection compared to Pfizer
Booster dose for eligible populations**	**Adult/adolescent** 1.8 ml of diluent	**0.3 ml** (30 mcg)	**One dose** • 6 months (at least 168 days) from completion of primary series
Primary series for children 5 to 11 years of age	**Pediatric**	**0.2 ml** (10 mcg)	**Two doses** • At least 8 weeks between first and second

Population	Formulation Diluent Volume	Dose	Schedule
	1.3 ml of diluent		dose • Avoid routine concomitant vaccination at this time

* In individuals 12 – 29 years of age: NACI recommends the use of Pfizer Comirnaty vaccine.

** In individuals 18 – 29 years of age: NACI advises that that use of Pfizer Comirnaty may be preferred to the use of Moderna Spikevax as a booster dose.

Table 5: Moderna Spikevax Summary of Use

Population	Dose	Schedule
Primary series for 18 years of age and over* *Not moderately to severely Immunocompromised*	**0.5 ml** (100 mcg)	**Two doses** • 8-week interval between first and second dose
Primary series for 18 years of age and over for moderately to severely immunocompromised	**0.5 ml** (100 mcg)	**Three doses** • May book a 28-day interval between dose 1 and 2 • May book a 28-day interval between dose 2 and 3, however, 8-week interval preferred • Longer intervals may result in a better immune response but may result in being susceptible for longer between doses • NACI recommends that individuals under age 30 receive Pfizer Comirnaty vaccine
Booster dose for long-term care residents and seniors in congregate living settings	**0.5 ml** (100 mcg)	**One dose** • 6 months (at least 168 days) from completion of primary series
Booster dose for eligible populations living in community	**0.25 ml** (50 mcg)**	**One dose** • 6 months (at least 168 days) from completion of primary series

* Evidence is showing that Moderna Spikevax (100 mcg) induces somewhat higher antibody levels compared to Pfizer Comirnaty (30 mcg). Additionally, a primary series of Moderna Spikevax (100 mcg) has been shown to provide longer-lasting protection against infection and severe disease. NACI also recommends that people under age 30 receive the Pfizer vaccine because the rare risk of myocarditis and pericarditis associated with mRNA vaccines appears more common after Moderna than Pfizer vaccine.

****Moderna Vial Puncture Limit**

Do not puncture the vial more than 20 times.

US labelled Moderna 15 full dose vials remain within Nova Scotia's vaccine inventory. Moderna has sufficient data to support that their product remains sterile and stable with 20 punctures. Moderna has indicated that the rationale for the 20-puncture limit is a limitation of the rubber stopper. As with any immunization from a vial, it is preferable to pierce the stopper at a different site with each puncture. At 20 punctures, there could be a physical limitation of achieving different entry points into the rubber stopper. For half-doses of boosters, greater than 20 punctures would be required to enable administration of all of the US labelled Modernal vial presentation. Due to Moderna's direction on vial puncture limit, it is expected that there will be wastage of US labelled Moderna vaccine with fractional dosing.

Table 6: Viral Vector COVID-19 Vaccines authorized for use in Canada

Product Brand Name	AstraZeneca COVID-19 vaccine	Janssen COVID-19 vaccine
Type of vaccine	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)
Ages for use	18 years of age and older	18 years of age and older
Dose	0.5 mL (5×10^{10} viral particles)	0.5 mL (5×10^{10} viral particles)
Route of administration	IM	IM
Authorized Schedule	2 doses, 4 weeks – 12 weeks apart	1 dose
Diluent	No	No
Primary storage requirements pre-puncture	+2°C to +8°C	+2°C to +8°C[1]
Additional storage requirements pre-puncture [2]	+2°C to +8°C	+2°C to +8°C
Usage limit post-puncture	6 hours at room temperature (up to +30°C) OR 48 hours at +2°C to 8°C	3 hours at room temperature (up to +25°C) or 6 hours at +2°C to +8°C[3]
Formats available	Multi-dose vial (8-and 10-dose presentations), preservative-free	Multi-dose vial (5 doses), preservative-free

Abbreviations: ChAd: Chimpanzee adenovirus; IM: intramuscular

1 If Janssen COVID-19 vaccine is received frozen (-25°C to -15°C), the expiry date for frozen storage is printed on the vial and carton after "EXP". The vaccine can be stored at +2°C to +8°C for a single period of up to 6 months, not exceeding the original expiry date. Upon moving the product to a +2°C to +8°C state, the updated expiry date must be written on the carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable. **DO NOT RE-FREEZE ONCE THAWED.**

2 Protected from light during storage
3 Maximum hold times for these two temperature ranges post-puncture are not cumulative (i.e. the vaccine cannot be held at room temperature for 3 hours and then held refrigerated for another 6 hours). If the 3-hour time limit at room temperature is not met, the punctured vial may be transferred to a refrigerated storage unit between 2°C to 8°C for the remaining time, up to the 3 hour time limit. For example, a vial held at room temperature for 1 hour after first puncture can be stored in the refrigerator (between 2°C to 8°C) for no more than 2 hours before using or discarding. If the 3-hour time limit at room temperature has been met, the vial must be discarded and cannot be transferred to the refrigerator. If stored refrigerated after the first puncture, the vaccine can be moved to room temperature for brief periods of time for dose withdrawal. This does not impact the maximum 6-hour hold period in the refrigerator.

Information on the specific vaccine storage and handling requirements for the viral vector COVID-19 vaccines is available from:

- AstraZeneca: https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf a
- Janssen: https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf

Valid Intervals

22. What if a client presents later than the recommended interval for the COVID-19 vaccines?

Currently, no data on a maximum interval between doses or on long-term efficacy of COVID-19 vaccines are available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series as delays between doses do not result in a reduction in final antibody concentrations for most other vaccines requiring more than one dose for a series. Maximum protection may not be attained until the complete vaccine series has been administered.

23. When is a dose of a Health Canada authorized COVID-19 vaccine considered valid?

Although not the recommended schedule, a dose of COVID-19 vaccine would be considered valid if the interval between first and second doses are as follows:

- Pfizer-BioNTech Comirnaty adult formulation (30 mcg) (≥ 12 years): 19 days
- Pfizer-BioNTech Comirnaty pediatric formulation (10 mcg) (5 -11 years): 19 days
- Moderna Spikevax: 21 days
- AstraZeneca Vaxzevria: 28 days

For mixed COVID-19 vaccine schedules, the valid interval between doses should be based on the interval of the product used for the first dose (e.g., Pfizer COVID-19 vaccine should be offered a minimum of 21 days after Moderna COVID-19 vaccine; Moderna COVID-19 vaccine should be offered a minimum of 19 days after Pfizer COVID-19 vaccine).

Providers' Responsibilities in Ensuring Proper Storage of Vaccines

24. Why is it a provider's responsibility to ensure vaccine storage conditions are maintained?

Vaccines are sensitive biological products that may be less effective, or even destroyed, when exposed to temperatures outside the recommended range. There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine-preventable disease. Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccine may result in the cancellation of immunization clinics, resulting in lost opportunities to immunize. Revaccination of clients who received an ineffective vaccine may also cause loss of public confidence in vaccines and/or the health-care system.

25. What should I do if the storage conditions of vaccines have been compromised?

All cold chain breaks must be reported to the local Public Health office. Vaccine that is exposed to a cold chain break must be bagged, dated, labelled "Do not use" and refrigerated while waiting to receive direction from Public Health on the use of affected vaccines.

Pre-filling Syringes for Onward Transport

26. Are providers able to pre-fill syringes with COVID-19 vaccine doses and transport syringes to clients?
Pre-filling syringes for onward transportation of COVID-19 vaccine doses may be warranted in exceptional situations and is permissible if specific criteria are followed as outlined in the OCMOH document *Pre-filling syringes for onward transportation of COVID-19 vaccine doses in exceptional situations*.

Exceptional situations where pre-filling syringes for onward transportation of COVID-19 vaccine doses may be warranted include:

- where the risk assessment demonstrates that movement of the vaccine would be a safer alternative for the person being immunized
- home visits for individuals who are unable to leave their home
- congregate living settings for a small number of residents who are unable to access the immunization clinic

Pre-filling syringes with COVID-19 vaccine doses for onward transportation is not to be implemented as part of routine practice.

Simultaneous Administration of COVID-19 Vaccines with Other Vaccines

27. Can individuals receive COVID-19 vaccines simultaneously with non-COVID-19 vaccines?

As a precaution, NACI recommends that **COVID-19 vaccines for children 5-11 years old** should not routinely be given concomitantly with other vaccines. **It is prudent to wait for a period of at least 14 days before or after** the administration of another vaccine before administering a COVID-19 vaccine for children 5 – 11 years old.

Administering the COVID-19 vaccine alone in this age group assists with the assessment of any adverse event following immunization.

There may be circumstances in which a dose of COVID-19 vaccine and a non-COVID-19 vaccine needs to be administered simultaneously, or a shortened interval between these vaccines may be necessary on an individual basis in children. These circumstances may include:

- when another vaccine is required for post-exposure prophylaxis;
- when individuals require accelerated vaccination schedules prior to immunosuppressive therapy or transplant;
- when there is a risk of the individual being unable to complete an immunization series due to limited access to health services or being unlikely to return at a later date; and
- at the clinical discretion of the healthcare provider.

NACI recommends that COVID-19 vaccines for adolescents/adults may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines. Informed consent should include a discussion of the benefits and risks given the limited data available on concomitant administration of COVID-19 vaccines with other vaccines. Studies to assess the safety and immunogenicity of simultaneous administration of COVID-19 vaccines with other vaccines are ongoing.

It is currently not known if the reactogenicity of COVID-19 vaccines is increased with concomitant administration of other vaccines. While no specific safety concerns have been identified for various other vaccines with co-administration, there is potential for increased reactogenicity with concomitant administration of COVID-19 vaccines with other vaccines, particularly those known to be more reactogenic, such as newer adjuvanted vaccines. If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment.

NACI continues to recommend that COVID-19 vaccines should not be given simultaneously with anti-SARS-CoV-2 monoclonal antibodies (i.e. bamlanivimab, casirivimab/imdevimab, sotrovima) or convalescent plasma. The interval between receipt of these products and COVID-19 vaccine is under review.

28. Can a client receive COVID-19 vaccine following tuberculin skin testing (TST) or Interferon Gamma Release Assay (IGRA)?

There is a theoretical risk that mRNA vaccines or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If a TST or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks after vaccination. Vaccination with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing have been completed. In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of TB infection may be prudent to avoid missing cases due to potentially false negative results.

Vaccine Preparation and Administration Techniques to Minimize Vaccine Waste

29. Is there a recommendation on the size of needle to be used to dilute the Pfizer-BioNTech vaccine?

Yes. A 21-gauge needle or narrower is recommended to prevent a larger opening in the vial stopper that may allow vaccine to leak.

30. When diluting the Pfizer-BioNTech COVID-19 vaccine, is there a need to expel air from the vial to equalize the pressure?

Yes. After adding the diluent into the adult formulation vaccine vial, withdraw 1.8 mL of air from the vaccine vial into the empty diluent syringe prior to removing the needle and attached syringe from the vial. After adding diluent and before removing the needle from the pediatric vaccine vial, withdraw 1.3 ml of air into the empty diluent syringe. This will prevent loss of vaccine from the vial through forceful expulsion under pressure.

31. Is there a recommendation on the size of the syringe to be used to withdraw and administer the Pfizer BioNTech vaccine?

Yes. A 1ml low dead-volume syringe is recommended to maximize doses. Information regarding low-dead volume syringes may be found here: https://www.cvdvaccine.ca/files/PfizerCovid_6doseWithdrawalGuide-EN.pdf. An instructional video on 6th dose extraction of Pfizer vaccine (30 mcg dose) may be found here: https://www.youtube.com/watch?v=k_IxCPcbRGk.

32. What steps can immunization providers take to ensure all ten doses of the Pfizer Comirnaty pediatric formulation (10 mcg dose) can be obtained from the multi-dose vial (MDV)? Is pooling of the Pfizer Comirnaty pediatric vaccine a supported practice?

Pfizer Comirnaty's product monograph indicates that each MDV contains a volume of 1.3 mL to which 1.3 mL of diluent is added. After dilution, each vial of the pediatric formulation contains 10 doses of 0.2 mL. Low dead-volume syringes and/or needles (e.g., low dead-volume luer lock syringes) are recommended for use to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial. Immunization providers are encouraged to review Pfizer's dose preparation guide which includes information regarding dilution, equalizing vial pressure and administration. **In order to ensure consistent withdrawal of 10 doses of 0.2 mL, it is important to adhere to minimizing volume loss during dose extraction.**

In response to provider reports of obtaining 9 doses of Pfizer Comirnaty (10 mcg) per vial and to mitigate the risk of pediatric vaccine appointment cancellations, pooling of Pfizer pediatric vaccine (10 mcg), the process of drawing-up vaccine from a maximum of **two** vials, is a supported practice in Nova Scotia provided adherence to the following steps are taken to mitigate any theoretical contamination risk:

1) Pooling is done using volume from only **two** vials and the vials **must be the same product and lot number**.
2) The date and time of first puncture or dilution are written on each vial.
3) Immunizers must ensure that vaccine used for pooling is administered within 12 hours of the first vial punctured.
4) Strict aseptic technique must be followed in diluting and/or drawing up the vials (e.g., hand hygiene before process; use of a new alcohol swab for the stopper for each puncture of all vials; and allow the stopper to dry before puncture).
5) Only residual amounts from a vial should be used to pool (i.e., do not top up a partial dose with vaccine from a vial that has one or more full doses remaining in it; pool only with residuals that will not alone allow a full dose to be obtained).
6) The pooling should be from vials that have been used as close to each other as possible (e.g., do not reserve vials with residual volume until the end of the day).
7) Administer syringes that have pooled vaccine in them as soon as feasible.

Pooling is not recommended by manufacturers due to concerns that this process increases the risk of contamination of the vaccines, which have no preservatives, due to the cumulative multiple punctures from each vial. However, this risk is a **theoretical concern** that can be **mitigated with good infection prevention and control practices**. **The risk of contamination of pooled vaccines is very small relative to losing doses of the vaccines which are important to prevent morbidity and mortality from COVID-19.**

33. How do providers maximize doses and minimize waste when withdrawing Moderna COVID-19 vaccine from the US labeled Moderna 14 dose vials?

The U.S. Pharmacopeia provides guidance for maximizing doses from the Moderna COVID-19 14 dose vials. This guidance may be retrieved by accessing: https://www.usp.org/covid-19/vaccine-handling-toolkit and completing the form to download an instructional fact sheet.

34. How do providers balance minimizing COVID-19 vaccine wastage with opportunities to vaccinate all eligible individuals?

Given that only multi-dose vials of COVID-19 vaccine are available in Canada, some wastage is inevitable as efforts are made to immunize remaining unvaccinated or partially vaccinated people, particularly when vaccines are offered outside of larger immunization clinics (e.g., when vaccines are offered in pharmacies, health care providers' offices, and remote and isolated communities). All efforts should be made to minimize wastage including:

- Having plans to immunize as many people as possible when a vial is opened/reconstituted (e.g. preparing a waitlist of clients that providers can call at the end of the day; utilizing social media to advertise extra available COVID-19 vaccines);
- If it is anticipated that a full vial may not be used in a particular location, attempting to use an alternative product with less doses per vial thereby incurring less wastage (i.e., use the Pfizer-BioNTech product if it is available, which has fewer doses per vial than the Moderna product).

Vaccinating individuals should be prioritized over minimizing open-vial wastage of COVID-19 vaccines. There may be circumstances where a new COVID-19 vial must be opened to vaccinate only one or a few people, and plans cannot be implemented to use the remaining doses in the vial. In these cases, **providers should take every opportunity to vaccinate every eligible person who presents for vaccination,** even if it requires puncturing a multi-dose vial and results in the remainder of the vial being discarded in accordance with the product monograph or best practices**.**

35. How do providers use the Sol-Guard safety syringe to activate the safety mechanism with cap protection?

Please view the video which provides a demonstration of the Sol-Guard safety syringe: https://www.youtube.com/watch?v=jHH_xtgkJEk

36. How do providers ensure successful auto-retraction of the Wealy SSFNO1-25-02 needle/syringe combination product when in use?

Please view the video which provides a demonstration of the Wealy needle/syringe product: https://www.youtube.com/watch?v=YQB9W7Kt8b4. Providers must inject slowly. Injecting too fast may unseat the "O" ring or cause needle non-retraction.

Administration Errors and Deviations

37. What approach can immunization providers take after recognizing a COVID-19 vaccine has been administered in a manner that differs from a manufacturer's and/or NACI's recommendations?

There is limited evidence to guide the management of COVID-19 vaccine administration errors and deviations. PHAC's Quick Reference Guide on Use of COVID-19 Vaccines provides guidance for these situations. This guidance is to be used only to manage errors or deviations that have already occurred. Immunization providers should follow vaccine product monographs and recommendations from NACI when administering COVID-19 vaccines.

Special Considerations

Pregnancy, Breastfeeding, Immunosuppression and Autoimmune Conditions

38. Are there groups in which the approved vaccines have not been specifically studied?

NACI has provided recommendations for COVID-19 immunization in some specific populations who were either excluded from or were represented by small numbers of participants in the clinical trials as there was no or limited evidence of safety or efficacy in these populations. However, considerable real-world data from the use of COVID-19 vaccines in these populations continued to accumulate. These recommendations may change as more evidence becomes available.

NACI preferentially recommends that a complete mRNA COVID-19 vaccine series (Pfizer or Moderna) should be offered to individuals in the authorized age group who are pregnant. NACI recommends that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are breastfeeding. Informed

consent should include discussion about the emerging evidence on the safety of mRNA COVID-19 vaccines in pregnant and breastfeeding individuals. There have not been any unique safety concerns raised about negative health effects from mRNA COVID-19 vaccine for pregnant individual or their babies. There are concerns about the treatment of the rare side effect of blood clotting with low blood platelets during pregnancy, should it occur following the administration of the AstraZeneca/COVISHIELD or Janssen COVID-19 vaccine. Evidence is showing that pregnant individuals develop immunity from COVID-19 vaccines in the same way as non-pregnant individuals and that vaccination in pregnancy may provide some protection for babies after they are born. Evidence is also showing that antibodies from mRNA COVID-19 vaccines are present in breast milk after maternal vaccination with mRNA vaccines which may provide some protection for breastfed babies. Information to assist in informed decision-making about whether to receive a COVID-19 vaccine for those who are pregnant, planning a pregnancy or breastfeeding is available via the Know the Facts. Get the Vax. Video series: COVID-19 Vaccine and Pregnancy and Fertility.

NACI preferentially recommends that a complete COVID-19 vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are immunosuppressed due to disease or treatment and to individuals in the authorized age group with an autoimmune condition. In addition, individuals with moderate to severe immunosuppression should have an additional dose of a COVID-19 mRNA vaccine. Informed consent should include discussion about the possibility that individuals who are immunosuppressed may have a diminished immune response to any of the authorized COVID-19 vaccines and that evidence is emerging on the safety of mRNA COVID-19 vaccines in individuals with an autoimmune condition. Individuals who are immunocompromised were not included in the trials testing COVID-19 vaccines, however many immunocompromised individuals have received Pfizer and Moderna mRNA vaccines during the pandemic. There have not been any unique safety concerns raised about negative health effects from vaccine for immunocompromised individuals. Few individuals who have an autoimmune condition were included in the trials testing COVID-19 vaccines, however numerous individuals with autoimmune conditions have received Pfizer and Moderna mRNA COVID-19 vaccines during the pandemic. There have not been any unique safety concerns raised about negative health effects from the mRNA COVID-19 vaccines for autoimmune individuals at this time.

Summary of evidence and rationale for recommendations in special populations is available in NACI's Recommendations on the use of COVID-19 vaccines statement. Information regarding NACI's recommendation for an additional dose of COVID-19 vaccine in immunocompromised individuals following a primary series is available in NACI's Rapid Response.

Previous lab-confirmed SARS-CoV-2 Infection in Individuals and MIS-C in children

39. Can an individual who has previous lab-confirmed SARS-CoV-2 infection receive the COVID-19 vaccine?

Yes. NACI currently recommends that a complete series with a COVID-19 vaccine should be offered to individuals with prior PCR-confirmed SARS-CoV-2 infection. Individuals may receive COVID-19 vaccine following SARS-CoV-2 infection once they are past their infectious stage from COVID-19 and no longer under the requirement from Public Health to be self-isolating. This recommendation may be modified as further evidence emerges.

40. Can a child with a previous history of MIS-C vaccination receive the COVID-19 vaccine?

For children with a previous history of MIS-C, COVID-19 vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.

COVID-19 Vaccines Received out of Canada

41. Are individuals who received non-Health Canada authorized COVID-19 vaccines eligible to receive a COVID-19 vaccine in Nova Scotia?

The immunogenicity, efficacy and effectiveness of authorized COVID-19 vaccines vary. The World Health Organization's (WHO) Emergency Use Listing (EUL) assesses the quality, safety and efficacy of COVID-19 vaccines for use during public health emergencies. The authorization status of COVID-19 vaccines within the WHO EUL process may be found here: https://extranet.who.int/pqweb/vaccines/covid-19-vaccines (under EUL Submissions, Status of COVID-19 vaccines within the WHO EUL/prequalification evaluation process). Vaccines which have been authorized through the WHO EUL process have a "finalized" status of assessment

Individuals who have received one dose of a COVID-19 vaccine not approved by Health Canada that is authorized by the WHO and are within the WHO authorized age group are recommended to receive and are eligible for one dose of an mRNA COVID-19 vaccine (Pfizer or Moderna) to be considered fully vaccinated.

Individuals who have received a full series of a COVID-19 vaccine not approved by Health Canada that is authorized by the WHO and are within the WHO authorized age group are considered fully vaccinated. It is recommended that these individuals receive one dose of an mRNA vaccine to achieve optimal protection against COVID-19 disease.

Individuals who have received a COVID-19 vaccine that is not authorized by the WHO and not approved by Health Canada are eligible to receive two doses of mRNA COVID-19 vaccine to be considered fully vaccinated and optimally protected against COVID-19 disease.

For vaccine-specific information regarding non-Health Canada approved, WHO authorized COVID-19 vaccines (including age recommendations, please review:

- Sinopharm [Beijing Institute of Biological Products co., Ltd. (BIBP)] (18 years and above): https://www.who.int/news/item/07-05-2021-who-lists-additional-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations#:~:text=WHO%20today%20listed%20the%20Sinopharm%20COVID-19%20vaccine%20for,Ltd%2C%20subsidiary%20of%20China%20National%20Biotec%20Group%20%28CNBG%29.
- Sinovac-CoronaVac (Sinovac Life Sciences Co., Ltd.) (18 years and above): https://www.who.int/news/item/01-06-2021-who-validates-sinovac-covid-19-vaccine-for-emergency-use-and-issues-interim-policy-recommendations

- Covaxin (Bharat Biotech, India) (18 years and above): https://www.who.int/news/item/03-11-2021-who-issues-emergency-use-listing-for-eighth-covid-19-vaccine

Healthcare professionals caring for individuals that received non-Health Canada, WHO authorized approved vaccines outside of the WHO authorized age group should call the COVID-19 Vaccine Pharmacist Consult Service at 1-833-768-1151 for recommendations to provide one or two doses of mRNA COVID-19 vaccine.

Medical Exemptions

42. What are the criteria in Nova Scotia for a medical exemption against COVID-19 vaccination?

Medical contraindications against receiving a COVID-19 vaccine which would permit an individual to be considered exempt from Nova Scotia's Proof of Vaccine Policy are limited in number and include:

- a history of severe allergic reaction (e.g. anaphylaxis) after previous administration of a COVID-19 vaccine using a similar platform (mRNA or viral vector)
- an allergy to any component of the specific COVID-19 vaccine or its container [polyethylene glycol (PEG) for Pfizer and Moderna COVID-19 vaccines; tromethamine (trometamol or Tris) for Moderna COVID-19 vaccine; polysorbate 80 for viral vector vaccines (AstraZeneca and Janssen/Johnson & Johnson COVID-19 vaccines)]
- a history of major venous and/or arterial thrombosis with thrombocytopenia following vaccination with AstraZeneca COVID-19 vaccine
- a history of capillary leak syndrome (CLS) following vaccination with AstraZeneca COVID-19 vaccine
- a history of myocarditis and/or pericarditis after a first dose of an mRNA COVID-19 vaccine
- a history of a serious adverse event following immunization (AEFI) after the first dose of a COVID-19 vaccine, with "serious" defined using the WHO standard definition: *an AEFI that results in death, is life-threatening, requires in-patient hospitalization or prolongs an existing hospitalization, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth defect.*

For a list of components in the vaccine and packaging consult the respective COVID-19 vaccine product monographs found at:

- Pfizer BioNTech: https://www.cvdvaccine.ca/
- Moderna: https://www.modernacovid19global.com/ca/
- AstraZeneca Vaxzevira : https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf
- Janssen : https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf

Studies have shown that individuals with a severe immediate allergic reaction after a previous dose of mRNA COVID-19 vaccine can be re-vaccinated with the same vaccine or another mRNA COVID-19 vaccine following an appropriate allergist assessment. In these studies, re-vaccination was safe and well tolerated with predominantly no, or mild, reactions after re-vaccination when provided in a controlled environment.

NACI now recommends that:

- It is possible for people who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine to safely receive future doses of the same or another mRNA COVID-19 vaccine in a controlled setting after consulting with an allergist or another appropriate physician.
- People with a history of a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine should:
    - Consult with an allergist or another appropriate physician before receiving future doses of an mRNA COVID-19 vaccine;
    - Receive future doses of an mRNA COVID-19 vaccine in a controlled setting with someone who is experienced in managing anaphylaxis and
    - Be observed for at least 30 minutes after vaccination (the normal observation period for people who have not experienced a severe immediate allergic reaction after vaccination is 15 minutes).

Note: None of the authorized COVID-19 vaccines, including the mRNA vaccines nor the viral vector vaccine, are contraindicated in people who are immunosuppressed. As such, people who are immunosuppressed and people with autoimmune diseases should be vaccinated with COVID-19 vaccines. Ideally, the COVID-19 vaccine series should be completed 2 weeks before starting immunosuppressive therapy or when immunosuppressive therapy is the lowest but can be given when needed. This ensures that COVID-19 protection is provided sooner. People who are pregnant and breastfeeding should also be vaccinated with COVID-19 vaccines.

Allergens

43. What are the potential allergens in the COVID-19 vaccines that are known to cause type 1 hypersensitivity reactions?

The authorized COVID-19 mRNA vaccines in Canada contain polyethylene glycol (PEG) which can be found in various products such as: over the counter (e.g., cough syrup, laxatives), and prescription medications, medical bowel preparation products for colonoscopy, skin care products, dermal fillers, cosmetics, contact lens care solutions, products such as ultrasound gel.

The Moderna COVID-19 vaccine and Pfizer Comirnaty pediatric formulation (10 mcg) also contains tromethamine (trometamol or Tris) which is a component in contrast media, and oral and parenteral medications. In the literature, one case report of anaphylaxis to tromethamine has been described. The Canadian Society of Allergy and Clinical Immunology provides guidance for health care professionals regarding vaccination in individuals with confirmed or suspected allergic conditions.

The authorized COVID-19 viral vector vaccines in Canada contain polysorbate 80. Polysorbates may be found in medical preparations such as vitamin oils, tablets, and anticancer agents and cosmetics.

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. Most instances of anaphylaxis to a vaccine begin within 30 minutes after administration of vaccine. Therefore, if there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being

administered, or if an individual has a history of anaphylaxis to another vaccine or to an injectable medication or product, an extended period of observation post-vaccination of 30 minutes may be warranted.

For current information regarding anaphylaxis management please refer to the Canadian Immunization Guide: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-4-early-vaccine-reactions-including-anaphylaxis.html#a16

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From: Ramsey, Tasha
To: Whelan, Noella
Cc: Nodwell, Lisa
Subject: COVID-19 Vaccination: Anaphylaxis Clinical Signs and Symptoms Documentation Advice
Date: Wednesday, June 2, 2021 8:00:54 AM
Attachments: Anaphylaxis Clinical Signs and Symptoms Documentation.docx

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Hi Noella,

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[redacted]

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Vaccine Efficacy and Effectiveness against Variants of Concern
Rapid Review – April 20, 2021

Key Review Question: What is the efficacy/effectiveness of each of the available vaccines (Pfizer, Moderna, AstraZenca, Johnson & Johnson) against variants of concern (B.1.1.7, B.1.351, P1, other?)

Summary:

- There is an increasing concern that the mutations in emerging SARS-CoV-2 variants could reduce the efficacy of current vaccines.
- This is because many of the variant mutations reside in the antigenic supersite in NTD16,17 or in the ACE2-binding site (also known as the receptor-binding motif—RBM) that is the main target of potent virus-neutralizing antibodies (Wang et al., 2021)
- This review looked at four different variants of concern: B.1.1.7, B.1.351, P.1 and P.2 and current authorized COVID-19 vaccines (Pfizer-BioTech, Moderna, AstraZeneca and Johnson & Johnson) to determine vaccine efficacy/effectiveness against these variants of concern

B.1.1.7 variant:

- Generally, current COVID-19 vaccines are able to neutralize the B.1.1.7 variant effectively. B.1.1.7 is unlikely to be a major concern for current vaccines and is unlikely to increase the risk of SARS-CoV-2 reinfection (Shen et al., 2021)
- A 2x reduction in neutralization is seen for the B.1.1.7 variant compared to the original SARS-CoV-2 through individuals vaccinated by the Pfizer-BioTech/BNT162b2 vaccine.
- Interestingly, effects may also be age-dependent, as one study on 40 adult participants found that though the Pfizer vaccine remained effective against B.1.1.7 with a slight but significant decrease in neutralization that was more apparent in participants under 55 years of age (Muik et al., 2021)
- A 1.8x reduction in neutralization is seen for the B.1.1.7 variant with the Moderna/mRNA-1273 vaccine (Karim & Oliviera, 2021)
- AstraZeneca vaccine protects against B.1.1.7 Variant. The point estimate suggests the efficacy may be lower than against the original virus strain but the difference is not significant with the current data (Emary et al., 2021)
- B.1.1.7 is seen to be resistant to neutralization by most antibodies to the N-terminal domain of spike and relatively resistant to antibodies to the receptor-binding domain. It is also more resistant to the sera of convalescent (~3 fold) and fully vaccinated individuals (~2 fold) (Wang et al., 2021)

B.1.1.351 variant:

- B.1.351 is not only resistant to neutralization by most antibodies to the N-terminal domain, but also by multiple individual antibodies to the receptor-binding motif on RBD, mostly due to an E484K mutation (Wang et al., 2021)
- The B.1.351 variant showed reduced neutralization according to Moderna/mRNA-1273 vaccinated human and NHP sera. (Wu et al., 2021)
- Clinical trials show an efficacy of the Johnson and Johnson vaccine of 57% against the B.1.351 strain (Karim & Oliviera, 2021) where another study found that Johnson & Johnson vaccine efficacy was 52% (30.3-67,4%) 28 days post-vaccination (CDC, 2021)
- A multi-site double blind study examining 18-65 year old adults in South Africa found that the AstraZeneca vaccine was not efficacious against the B 1.351 vaccine group (Lundstrom, 2021)

P.1 variant:

- Data on antibody evasion by the P.1. strain of SARS-CoV-2 show nearly a three-fold reduction in the level of the virus neutralization by the antibodies generated by the AstraZeneca and Pfizer-BioNTech vaccines for the P.1 variants when compared to the original strain, and a 9-fold and 7.6 fold reduction respectively against the B.1.351 strain (Dejnirattisai et al., 2021)

P.2 variant:

- Johnson and Johnson Vaccine efficacy was 64.7% (54.1-73.0) in settings with P2 variant (Latin America) 28 days post-vaccination (CDC, 2021)

Considerations for Interventions:

- Sera from COVID-19 mRNA vaccine recipients cross-neutralize some, but not all, SARS-CoV-2 variants of concern. COVID-vaccines promote potent, dose-dependent neutralizing responses against SARS-CoV-2, which remains true regardless of age or sex. (Garcia-Beltran et al., 2021)
- Prior infection, combined with vaccination, may result in the greatest breadth of cross-reactive neutralizing antibody responses, even against distantly related coronaviruses.(Garcia-Beltran et al., 2021)
- Strain-matched vaccines can be developed in response to variants. Variants should be monitored and assessed either to understand how we may use boosting to evolve the vaccine-induced immune response, or to examine the cross-protection provided by a primary series (Wu et al., 2021)

Table of Contents

Disclaimer: Due to the rapidly emerging evidence around COVID-19, key messages and summaries included in our rapid synthesis have been retrieved from diverse sources including systematic reviews, commentaries, rapid reviews, credible and trustworthy websites (JAMA, WHO, CDC, IPAC, BMJ, CMAJ), and credible media sites. The information in the document reflects what is known as April 20, 2021, and may change as new information becomes available.

Summary Table of Vaccine Efficacy against Variants

Table 1: AstraZeneca, Pfizer-BioTech, Johnson and Johnson, and Moderna Vaccine Efficacy against B.1.1.7, B.1.357, P.1, and P.2 variants of SARS-CoV-2

	B.1.1.7	B.1.351	P.1	P.2
Population based research				
AstraZeneca				
Emary et al, 2021	Efficacy = 61.7 (36.7-76.9)	-	-	-
Madhi et al, 2021		Efficacy = 10.7 (-76.8-54.8)	-	-
Pfizer Biotech				
Lopez Bernal et al, 2021	OR_1= 0.32 – 0.74[1] OR_2 = 0.10-0.50[2]		-	-
Kustin et al, 2021	OR_1= 0.64[3] p=0.4 OR_2 = 26.1[4] p<0.001	OR_1= 0.81[3] p=0.02 OR_2 = not defined[4]	-	-
Johnson and Johnson				
MMWR, 2021	-	Efficacy = 52.0 (30.3-67.4)	-	Efficacy = 64.7 (54.1-73.0)
Moderna				
-No specific data on efficacy % or OR was provided				

[1] OR ranges for older adults who received their first dose of vaccine at least 21 days prior. Comparison is odds of a positive COVID-19 test in vaccinated vs unvaccinated individuals.

[2] OR ranges for older adults who received their second dose of vaccine. Comparison is odds of a positive COVID-19 test in vaccinated vs unvaccinated individuals.

[3] Comparison is odds of a positive COVID-19 test in fully vaccinated vs unvaccinated individuals

[4] Comparison is odds of a positive COVID-19 test in partially vaccinated vs unvaccinated individuals

Evidence Summaries from Clinical and Lab-Based Research

Article 1: New SARS-CoV-2 Variants — Clinical, Public Health, and Vaccine Implications (Karim & Oliveira, 2021)

- This is a letter to the editor published in the NEJM written by two researchers in South Africa.
- The letter highlights some of the current research about COVID-19 and its variants (based on data as of March 18, 2021).
- Summary table below highlights the available evidence on vaccine efficacy against the B.1.1.7, P.1 and B.1351 variant.
    - Neutralization studies have been conducted with the BNT162b2, mRNA-1273, AZD1222 and Novavax vaccines on the variants of concern. Generally the vaccines are able to neutralize the variants. Clinical trials show an efficacy of the Johnson and Johnson vaccine of 57% against the B.1.357 strain.

Table 2: 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 Pre-Existing Variants

Vaccine (Company)	Preexisting Variants			Neutralization by Pseudovirion or Live Viral Plaque Assay			Efficacy in Settings with 501Y.V2 Variant
	Sample Size	Efficacy in Preventing Clinical Covid-19	Efficacy in Preventing Severe Covid-19	B.1.1.7 Variant	P.1 Variant	501Y.V2 Variant	
	no.	*% (no. of events with vaccine vs. placebo)*					%
Ad26.COV2.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 2×	Decrease by 6.7×	Decrease by ≤6.5×	NA
mRNA-1273 (Moderna)	28,207	94 (11 vs. 185)	100 (0 vs. 30)	Decrease by 1.8×	Decrease by 4.5×	Decrease by ≤8.6×	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 ≤86× to complete immune escape	22§
NVX-CoV2373 (Novavax)	15,000	89 (6 vs. 56)	100 (0 vs. 1)	Decrease by 1.8×	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 1.6×	NA

* 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.

Population-based clinical research

AstraZeneca (AZD122 or ChAdOx1)

Article 2: Efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine against SARS-CoV-2 variant of concern 202012/01 (B.1.1.7): an exploratory analysis of a randomised controlled trial (Emary et al., 2021)

- *Objective*: To provide an analysis of the efficacy of AsraZeneca Vaccine (chAdOx1 nCoV-19) against the B1.1.1.7 variant as well as an in vitro analysis of vaccine inducted neutralizing antibody responses.
- *Methods*: Single blind, multi-centre RCT trial. Participants were aged 18 and older and lived in the UK. Participants were enrolled from occupations with high SARs-COV-2 exposure.
    - Experimental arm was a standard-dose of ChAdOPx1 NCoV-19 vaccine and the control arm was an Meningococcal vaccine. There was also a group of participants who received a low dose vaccine
    - Participants sent weekly nose and throat swabs for NAAT testing from 1 week after first vaccination. Anyone who was symptomatic (fever, cough) went under clinical assessment at local clinical site.
    - Outcomes of interest were: 1. Symptomatic COVID-19 disease (defined as positive NNAT result on an upper airway swab and at least one symptom: cough, fever, shortness of breath, anosmia, ageusia; 2. Asymptomatic infections
- *Results* :There were 8534 participants in the cohort
    - 520 developed SARS-CoV-2 infection; 269 had primary symptomatic COVID-19; 209 had asymptomatic COVID-19 infection
    - 35% of infections were due to 1.17 variant and 65% were non-B1.1.7 lineage. The majority were caused by B.1.177 lineage
    - All symptomatic cases were NAAT positive for longer; but those who received the vaccine were positive for shorter time than those who received control
    - There was not difference in duration of positive tests in B.1.1.7 variant cases vs. other cases
    - In-vitro: neutralizing titers were nine times lower again that B.1.1.7 lineage than against Victoria lineage

	Cases	Vaccine (n=4244)	Control (n=4290)	Efficacy
B.1.1.7				
Symptomatic	52	12	40	70.4 (43.6-84.5)
Asymptomatic	19	8	11	28.9 (-77.1-71.4)
Any infection	75	21	54	61.7 (36.7-76.9)
Other variants				
Symptomatic	95	15	80	81.5 (67.9-89.4)
Asymptomatic	34	8	26	69.7 (33.0-86.3)
Any infection	144	27	117	77.3 (65.4-85.0)
All cases				
Symptomatic	269	59	210	72.3 (63.1-79.3)
Asymptomatic	209	97	112	14.3 (-12.1-34.9)
Combined	520	173	347	50.9 (41.0-59.0)

- *Conclusions*: AstraZeneca vaccine does protect against B.1.1.7 Variant. The point estimate suggests the efficacy may be lower than against the original virus strain but the difference is not significant with the current data

Article 3: Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant (Lundstrom, 2021)

- *Objective*: To evaluate safety of ChAdOx1 vaccine; to determine the efficacy of vaccine in preventing any Covid-19 infection and infection from the B 1.351 variant; to evaluate the ability of the vaccine to neutralize the original virus and the B.1.351 variant
- *Methods*: A multi-site double blind RCT in South Africa. Treatment arm was the ChAdOx1 nCoV-19 vaccine and control arm was a saline placebo. Adults aged 18-65 with no or with controlled medical conditions were included
    - Symptomatic individuals were given a clinical assessment and swabbed for a NAAT test. Detection of asymptomatic cases was done at routine clinical visits
    - Neutralization assays were performed
    - Incidence of infection was recorded. Infection was defined as NAAT-confirmed symptomatic COVID-19 infection more than 14 days after the second dose.
- *Results*: 2026 participants randomized: 951 received placebo and 865 of these were included in these analysis; 961 received vaccine and 884 were included in these analysis
    - There were 42 cases of COVID-19 (19 in vaccinated and 23 in placebo arm).
    - Almost all the infections were of the B.1.351 variant
    - The vaccine was not efficacious against the B 1.351 vaccine group
    - The live virus neutralization assay as suggest there is a greater cellular resistance to B 1.351 samples

	Cases (Total)	Vaccine	Control	Efficacy
Any COVID-19 after second injection	42	19/750	23/717	21.9 (-49.9-59.8)
Infection with B.1.351 variant after second injection	39	19/750	20/714	10.4 (-76.8-54.8)
Infection with illness after first injection (proxy for original variant)	15	3/944	12/938	75.4 (8.9-95.5)

Pfizer Biotech (BNT162b2)

Article 4: Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England (Bernal et al., 2021)

***note: this summary only includes results relevant to variant effectiveness**

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Article 5: Two doses of SARS-CoV-2 vaccination induce more robust immune responses to emerging SARS-CoV-2 variants of concern than does natural infection (Skelly et al., 2021)

- Aim: **To understand and address the potential threat posed by variants of concern (VOC)**

- Methods: Sampling of uninfected UK cohort recently vaccinated with Pfizer-BioNTech (BNT162b2, two doses delivered 18-28 days apart), along with a cohort sampled in the early stages after natural infection in wave 1 of the COVID-19 pandemic in Spring 2020
    - Tested antibody and T-cell responses against a reference isolate of the original circulating lineage, B, and the impact of sequence variation in two variants of concern: B.1.1.7 and B.1.351
- Results: Neutralization of the variants of concern compared to the B isolate was reduced. Reduction of neutralization was most prevalent for the B.1.351 isolate. Reduction of antibody neutralization was less evident in post-boost vaccine-induced responses compared to naturally induced immune responses, and could likely be attributed to the potency of the homotypic antibody response
    - Neutralization was most notably reduced after a single vaccine dose, especially in variants of concern.
    - In contrast, high magnitude T cell responses were generated after two vaccine doses, with the majority of the T cell response directed against epitopes that are conserved between the VOC and the prototype isolate B.
    - Neutralizing potency of sera from those recovering from mild SARS-CoV-2 infection were higher than those recovering from asymptomatic SARS-CoV-2 infection.
        - After a single dose of vaccine, homotypic neutralization potency was on average comparable to that of the asymptomatically infected cohort.
- Conclusion: VOC may evade the protective neutralization responses provided by prior infection, and to a lesser extent by vaccination, particularly after a single vaccine dose, but the impact of the VOC on T cell responses appears less pronounced. There is a need to generate high potency immune responses by immunization to protect the population against the B.1.1.7 and B.1.351 variants as well as other emerging variants.

Johnson and Johnson (Ad26.CoV2.S)

Article 6: The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine (CDC, 2021)

- A randomized double-blind, placebo-controlled phase 3 study to assess the efficacy and safety of Ad26.COV2.S for the prevention of SARS-CoV-2-mediated COVID-19 in adults aged 18 years and Older. Clinical protocol.
- This guidance document released by the US Advisory Committee on Immunization Practices describes the results of the interim analysis of a phase 3 RCT trial of the Johnson and Johnson vaccine.

- The reference for the phase 3 study protocol is also provided here as methodological details were scant in the CDC report
- *Objective*: to determine the efficacy of the Ad26.COV2.S vaccine as compared with placebo in sero negative adults.
- *Methods:* 40,000 participants were randomized to receive the Ad26.COV2.S vaccine or saline placebo (20k in each arm). Participants were aged 18-60 and were healthy and free of any COVID-19 at baseline. Enrollment began September 2020
    - COVID-19 diagnsoses were based on positive RT-PCR test and one of a list of symptoms (including but not limited to: fever, cough, headache, muscle pain)
    - Primary endpoints were occurrence of infection 14 days post vaccination and 28 days post vaccination. Samples were from the US, Latin America and South Africa
- Results:
    - Vaccine efficacy was 64.7% (54.1-73.0) in settings with P2 variant (Latin America) 28 days post-vaccination
    - Vaccine efficacy was 52% (30.3-67,4%) in settings with B.1.351 variant (South Africa) 28 days post-vaccination
    - In Latin America: 70% of the strains were the P2 variant
    - In South Africa, 94.5% of viruses were the B.1.351 variant

Lab-based research

AstraZeneca (AZD122 or ChAdOx1)

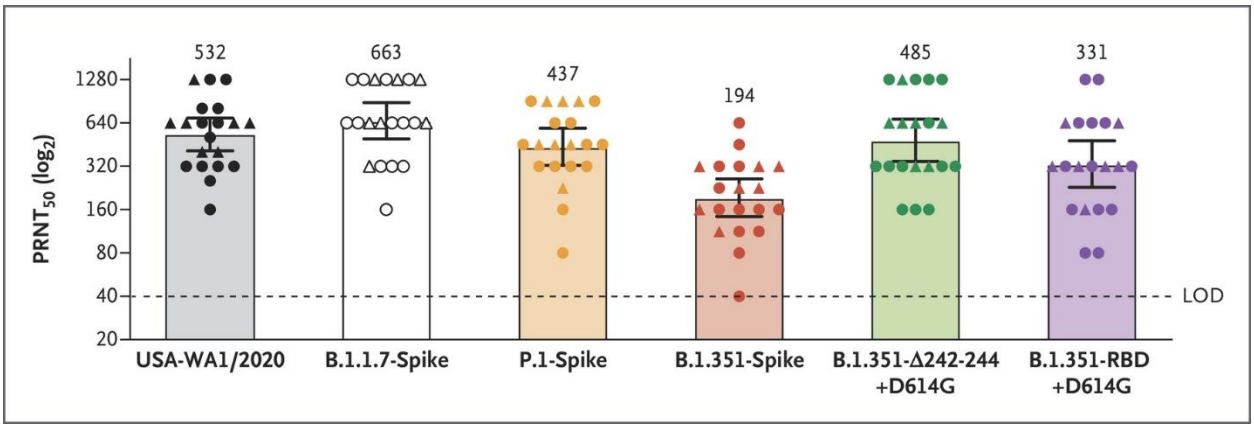
Article 7: Antibody evasion by the Brazilian P.1 strain of SARS-CoV-2

- These data show nearly a three-fold reduction in the level of the virus neutralization by the antibodies generated by the ChAdOx1 nCoV-19 and BNT162b2 vaccines for the B.1.1.7 (Kent) and P.1. (Brazil) variants when compared to the original 'Victoria' strain, and a 9-fold and 7.6 fold reduction respectively against the B.1.351 'South Africa' strain

Pfzier Biotech (BNT162b2)

Article 8: Neutralizing Activity of BNT162b2-Elicited Serum (Liu et al., 2021)

- *Objectives***:** this is a brief letter to the editor describing the contributor's study to determine neutralization by BNT162b2 on five engineered viruses: B.1.351, B.1.1.7, P.1 and two additional B.1.351 mutations
- *Methods*: Researchers performed a 50% plaque reduction neutralization test ($PRNT_{50}$) using serum from 15 participants in the 2-4 weeks after administration of the vaccine
- *Results*: Neutralization of B1.1.7 and P.1 spike viruses was roughly equal, and B.1.351 was robust but lower. Results are shown below.



Article 9: [Neutralization of SARS-CoV-2 lineage B.1.1.7 pseudovirus by BNT162b2 vaccine-elicited human sera (Muik et al., 2021)]

- *Objectives*: To determine the neutralization of SARS-COV-2 in the Wuhan reference strain and the B.1.1.7 strain among serum samples of those vaccinated with BNT162b2
- *Methods*: Serum was drawn from 40 participants: 26 younger (23-55) and 15 older (57 to 73) at 7 or 21 days after immunization
- *Results*: vaccine remained effective against B.1.1.7 with a slight but significant decrease in neutralization that was more apparent in participants under 55 years of age.

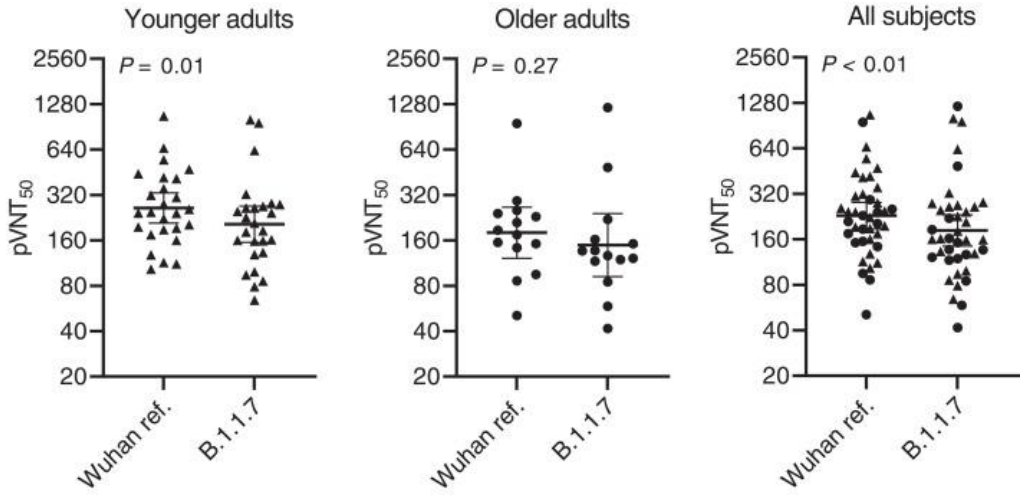


Figure 2: 50% pseudovirus neutralization titers (pVNT50) of 40 sera from BNT162b2 vaccine recipients against VSV-SARS-CoV-2-S pseudovirus bearing the Wuhan reference strain or lineage B.1.1.7 spike protein.

Moderna

Article 10: mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants (Wu et al., 2021)

- *Background*: The Moderna mRNA-1273 vaccine has demonstrated ~94% efficacy in a Phase 3 study and has been approved under emergency use authorization. SARS-CoV-2 variants with mutations in the spike protein recently circulating from the UK (B.1.1.7) and South Africa (B.1.351) has led to lower neutralization from convalescent serum by neutralization assays and resistance to certain monoclonal antibodies
- *Aim*: To assess the neutralizing capacity of sera from human subjects or non-human primates (NHPs) that received mRNA-1273 against the mutations present in the B.1.1.7 and B.1.351 variants
- *Methods*: Assessment of sera from mRNA-1273 vaccinated Phase 1 clinical trial participants against recombinant VSV-based SARS-CoV-2 PsVN assay wit hS protein from the original Wuhan-Hu-1 isolate, D614G variant, the B.1.1.7 and B1.351 variants, and variants that have formerly emerged.
    - Also assessed the effect of both single
    - mutations, and combinations of mutations. Present in the RBD region of the S protein.
    - Two orthogonal VSV and lentivirus PsVN assays were performed on sera from NHPs that received the mRNA-1273 vaccine at two different dose levels- this has been useful as a pre-clinical model for vaccine induced immunogenicity and protection
- *Results*: There was a 2.7-fold reduction in neutralization from sera collected from participants vaccinated with mRNA-1273 when the 3 mutations found in the RBD were present in the VSV-based pseudovirus assay. Additionally, a 6.4-fold reduction was seen when the full set of mutations, including those in the N-terminal domain (NTD), were included. All samples from both the clinical trial participants and NHPs fully neutralized the variants in the VSV PsVN assay, though at lower dilutions of sera, and the neutralizing titers remained at ~ 1/300.
- *Conclusion*: No significant impact on neutralization against the B.1.1.7 variant was detected. Data from this set shows that mRNA-1273 maintained activity against all circulating strain variants tested to date, and only the B.1.351 variant showed reduced neutralization according to vaccinated human and NHP sera. New variants should be monitored and strain-matched vaccines can be developed in response to variants, either to understand how we may use boosting to evolve the vaccine-induced immune response, or to assess the cross-protection provided by a primary series.

Article 11: Increased resistance of SARS-CoV-2 variants B1.351 and B.1.17 to antibody neutralization (Wang, 2021)

- Context: Considerable viral evolution has occurred since the vaccine constructs were developed for the initial SARS-CoV-2 that emerged in 2019, including variants with a D614G mutation that have become dominant
    - Recent strains of B.1.1.7 in the UK and B.1.351 in South Africa are of concern because of their seemingly extensive mutations in the spike protein and their ease of transmission
- Methods: Developed VSV-based SARS-CoV-2 pseudoviruses that contain each of the individual mutations as well as one with all 8 mutations of the B.1.1.7 variant (UKΔ8) and another with all 9 mutations of the B.1.351 variant (SAΔ9).
    - A total of 18 mutant pseudoviruses were developed and each was found to have a robust titer acceptable to measure its susceptibility to neutralization by 30 monoclonal antibodies, 20 convalescent plasma, and 22 vaccinee sera.
- Results: B.1.1.7 is seen to be refractory to neutralization by most antibodies to the N-terminal domain of spike and relatively resistant to antibodies to the receptor-binding domain. It is also more resistant to the sera of convalescent (~3 fold) and fully vaccinated individuals (~2 fold)
- B.1.351 is not only refractory to neutralization by most antibodies to the N-terminal domain, but also by multiple individual antibodies to the receptor-binding motif on RBD, mostly due to an E484K mutation

Article 12: SARS-CoV-2 variant B.1.1.7 is susceptible to neutralizing antibodies elicited by ancestral spike vaccines (Shen et al., 2021)

- Aim: To assess whether the B.1.1.7 variant will evade current vaccines, all of which are based on ancestral spike
- Methods: The neutralization phenotype of the B.1.1.7 variant was assessed using convalescent sera, monoclonal antibodies (mAbs), and serum samples from phase 1 trials of mRNA-1273/Moderna and a protein nanoparticle vaccine (NVX-CoV2373, Novavax).
- *Results:* B.1.1.7 remains sensitive to neutralization at moderately reduced levels (~2-fold), by serum samples from convalescent individuals and recipients of an mRNA vaccine (mRNA-1273, Moderna) and a protein nanoparticle vaccine (NVX-CoV2373, novavax). Thus B.1.17 does not escape neutralization by antibodies elicited through COVID-19 vaccination.B.1.1.7 escapes a subset of RBD-specific antibodies but overall monoclonal antibodies to receptor binding domain of spike are unaffected.

Table 3: Neutralization of variants by mAbs (Shen et al., 2021)

Virus	Value[a]	mAbs									
		B38	COVA1-18	COVA2-15	DH1041	DH1042	DH1043	DH1047	H4	P2B-2F6	S309
D614G	IC50	2.10	0.0060	0.0058	0.0094	0.011	0.0081	0.14	2.10	0.071	0.048
	IC80	12.00	0.031	0.028	0.036	0.068	0.040	0.54	18.00	1.20	0.69
D614G.B117	IC50	30 (14.2x)	0.011 (1.8x)	0.05 (8.7x)	0.015 (1.6x)	0.052 (4.7x)	0.01 (1.3x)	0.17 (1.2x)	9.9 (4.7x)	0.075 (1.1x)	9.2 (191.4x)
	IC80	>50 (> 4x)	0.16 (5.1x)	0.95 (34.5x)	0.039 (1.1x)	0.13 (1.9x)	0.05 (1.3x)	0.64 (1.2x)	>50 (> 3x)	2.2 (1.8x)	>50 (> 72x)
D614G.N501Y	IC50	4.7 (2.2x)	0.032 (5.2x)	0.084 (14.6x)	0.01 (1.1x)	0.012 (1.1x)	0.015 (1.8x)	0.072 (0.5x)	3.7 (1.7x)	0.043 (0.6x)	0.15 (3.1x)
	IC80	>50 (> 4x)	0.19 (6.1x)	0.93 (33.8x)	0.034 (1x)	0.06 (0.9x)	0.058 (1.5x)	0.43 (0.8x)	46 (2.5x)	0.93 (0.8x)	>50 (> 72x)
D614G.del69-70	IC50	1.5 (0.7x)	0.0042 (0.7x)	0.0051 (0.9x)	0.007 (0.8x)	0.0095 (0.9x)	0.0077 (0.9x)	0.1 (0.7x)	2.5 (1.2x)	0.1 (1.4x)	0.018 (0.4x)
	IC80	9.9 (0.8x)	0.026 (0.8x)	0.026 (0.9x)	0.029 (0.8x)	0.053 (0.8x)	0.033 (0.8x)	0.5 (0.9x)	26 (1.4x)	1.1 (0.8x)	18 (26.8x)
D614G.del69-70.N501Y	IC50	2.5 (1.2x)	0.026 (4.3x)	0.051 (8.8x)	0.0044 (0.5x)	0.0061 (0.6x)	0.0074 (0.9x)	0.049 (0.4x)	3.1 (1.5x)	0.033 (0.5x)	0.11 (2.2x)
	IC80	40 (3.3x)	0.18 (5.8x)	11.6 (56.4x)	0.025 (0.7x)	0.039 (0.6x)	0.035 (0.9x)	0.28 (0.5x)	30 (1.6x)	1.0 (0.8x)	>50 (> 72x)
D614G.del69-70.Y453F	IC50	1.2 (0.5x)	0.0083 (1.4x)	0.0055 (0.9x)	0.0046 (0.5x)	0.004 (0.4x)	0.011 (1.4x)	0.048 (0.3x)	0.64 (0.3x)	0.094 (1.3x)	0.098 (2x)
	IC80	15 (1.3x)	0.043 (1.4x)	0.03 (1.1x)	0.027 (0.8x)	0.03 (0.5x)	0.05 (1.3x)	0.24 (0.4x)	5.7 (0.3x)	1.3 (1x)	11 (15.5x)
D614G.N439K	IC50	1.3 (0.6x)	0.0061 (1x)	0.011 (1.9x)	0.0075 (0.8x)	0.0063 (0.6x)	0.017 (2.1x)	0.016 (0.1x)	3.6 (1.7x)	0.15 (2.2x)	0.046 (0.9x)
	IC80	19 (1.6x)	0.049 (1.6x)	0.1 (3.8x)	0.035 (1x)	0.07 (1x)	0.059 (1.5x)	0.33 (0.6x)	42 (2.3x)	1.6 (1.3x)	0.38 (0.6x)

- *Conclusions:* B.1.1.7 is unlikely to be a major concern for current vaccines and is unlikely to increase the risk of SARS-CoV-2 reinfection

Article 13: Multiple SARS-CoV-2 variants escape neutralization by vaccine-induced humoral immunity (Garcia-Beltran et al., 2021)

- *Aim*: To understand the impact of the emergence of SARS-CoV-2 variants with spike mutations on immune responses and neutralization by antibodies through immunization
- *Methods*: Evaluated the neutralization potency of 99 individuals that obtained one or two doses of either Pfizer (BNT162b2) or mRNA-1273 (Moderna) vaccines against pseudoviruses representing 10 globally circulating strains of SARS-CoV-2
- *Results*: Five of the 10 pseudoviruses with receptor-binding domain (RBD) mutaitons, including K417N/T, E484K, and N501Y, were highly resistant to neutralization. Findings indicate that a relatively minor percentage of mutations can potentially escape from vaccine responses due to cross-neutralization of B.1.351 variants that was comparable to SARS-CoV and bat-derived WIV1-CoV. Prior infection, combined with vaccination, may result in the greatest breadth of cross-reactive neutralizing antibody responses, even against distantly related coronaviruses.
- *Conclusion*: Further research is necessary to determine the clinical impact of neutralization resistance, however, these results indicate that there is a potential for variants to escape neutralization by humoral immunity and emphasize the need to develop broadly protective interventions against the evolving COVID-19 pandemic.

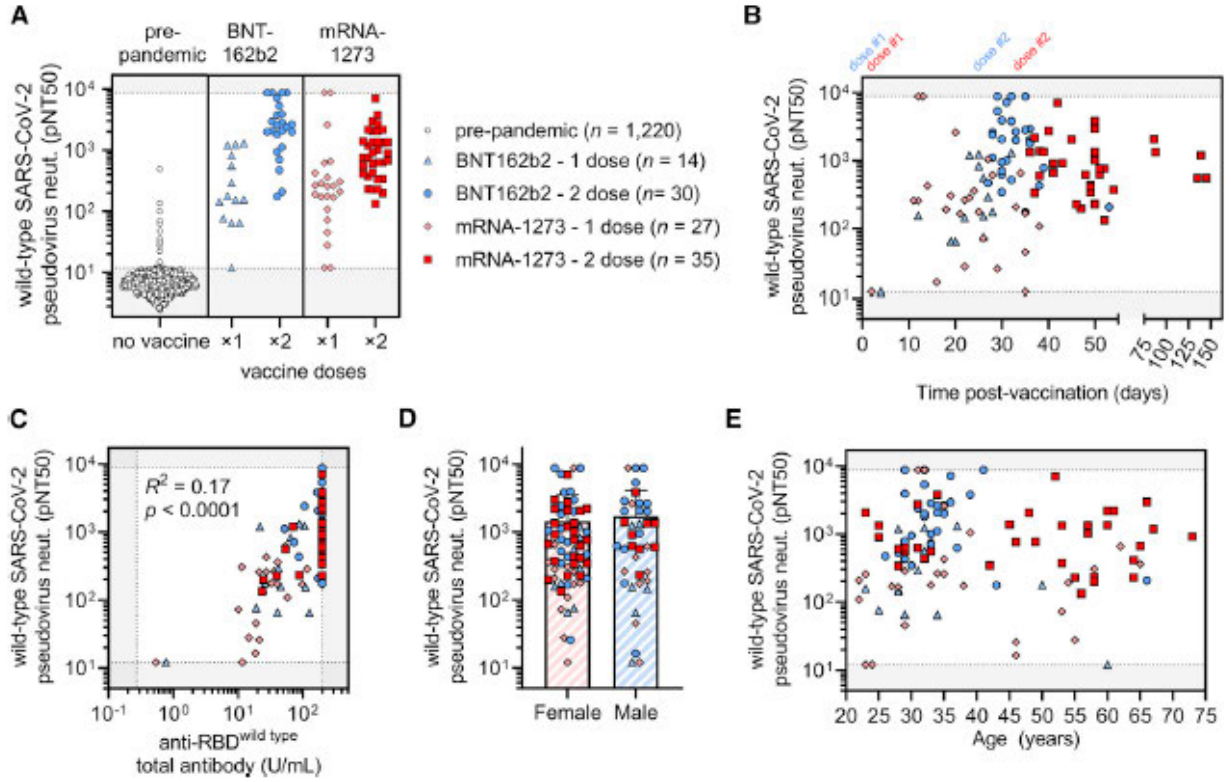


Figure 3: COVID-vaccines promote potent but dose-dependent neutralizing responses against SARS-CoV-2, regardless of age or sex.

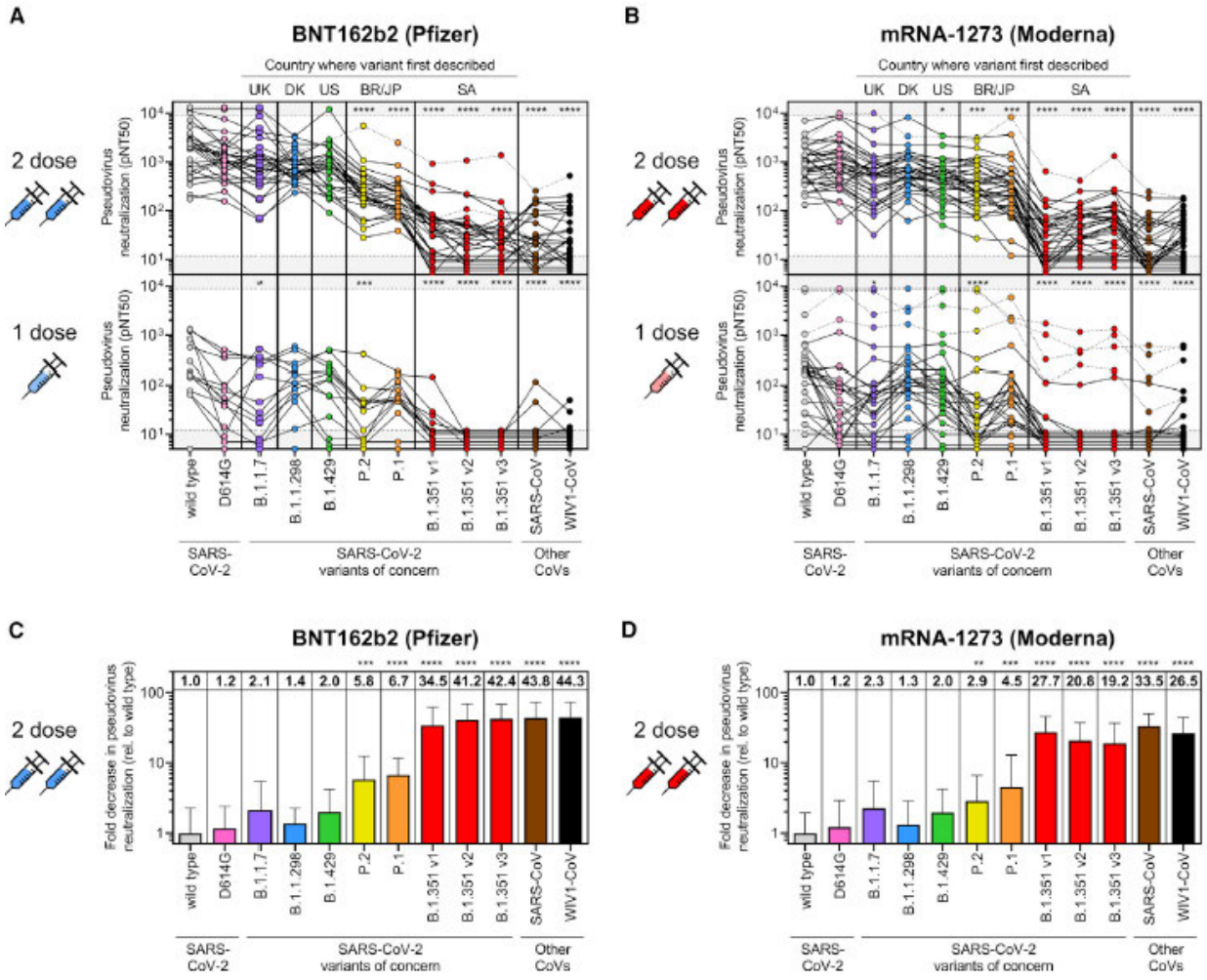


Figure 4: Sera from COVID-19 vaccine recipients cross-neutralize some, but not all, SARS-CoV-2 variants of concern.

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COVID-19 vaccine safety update

Advisory Committee on Immunization Practices (ACIP)
January 27, 2021

Tom Shimabukuro, MD, MPH, MBA
CDC COVID-19 Vaccine Task Force
Vaccine Safety Team

Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the U.S. Food and Drug Administration (FDA)
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by the CDC or FDA

Topics

- V-safe update
- Vaccine Adverse Event Reporting System (VAERS) surveillance update
- Clinical Immunization Safety Assessment (CISA) Project update
- Vaccine Safety Datalink (VSD) surveillance update
- Update on anaphylaxis following COVID-19 vaccination
- Reports of deaths and mortality following COVID-19 vaccination

v-safe℠ after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

1. Text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

   Vaccine recipient completes web survey

Vaccine recipient

v-safe
after vaccination health checker

2. Clinically important event(s) reported

✓ **Received medical care**

Call center

3. A VAERS customer service representative conducts active telephone follow-up on a medically attended health impact event and takes a report if appropriate

CDC ↔ FDA

Summary of v-safe data

	Pfizer-BioNTech	Moderna	All COVID-19 vaccines
People receiving 1 or more doses in the United States*	12,153,536	9,689,497	21,843,033
Registrants completing at least 1 v-safe health check-in†	997,042	1,083,174	2,080,216
Pregnancies reported to v-safe	8,633	6,498	15,131

* COVID Data Tracker data as of 1/24/2021
† v-safe data as of 1/20/2021, 5:00 AM ET

Reactogenicity reported to v-safe

Local and systemic reactions, day 0-7*,†	All vaccines %	Pfizer- BioNTech dose 1 %	Pfizer-BioNtech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

* v-safe data lock point 1/14/2021, 5:00 AM ET

† Reported on at least one health check-in completed on days 0-7 after receipt of vaccine

Reactogenicity reported to v-safe

Local and systemic reactions, day 0-7*,†	All vaccines %	Pfizer-BioNTech dose 1 %	Pfizer-BioNtech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

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Nausea	8.9	7.0	13.9	7.7

* v-safe data lock point 1/14/2021, 5 AM ET

† Reported on at least one health check-in completed on days 0-7 after receipt of vaccine

Active COVID-19 vaccine safety surveillance in v-safe

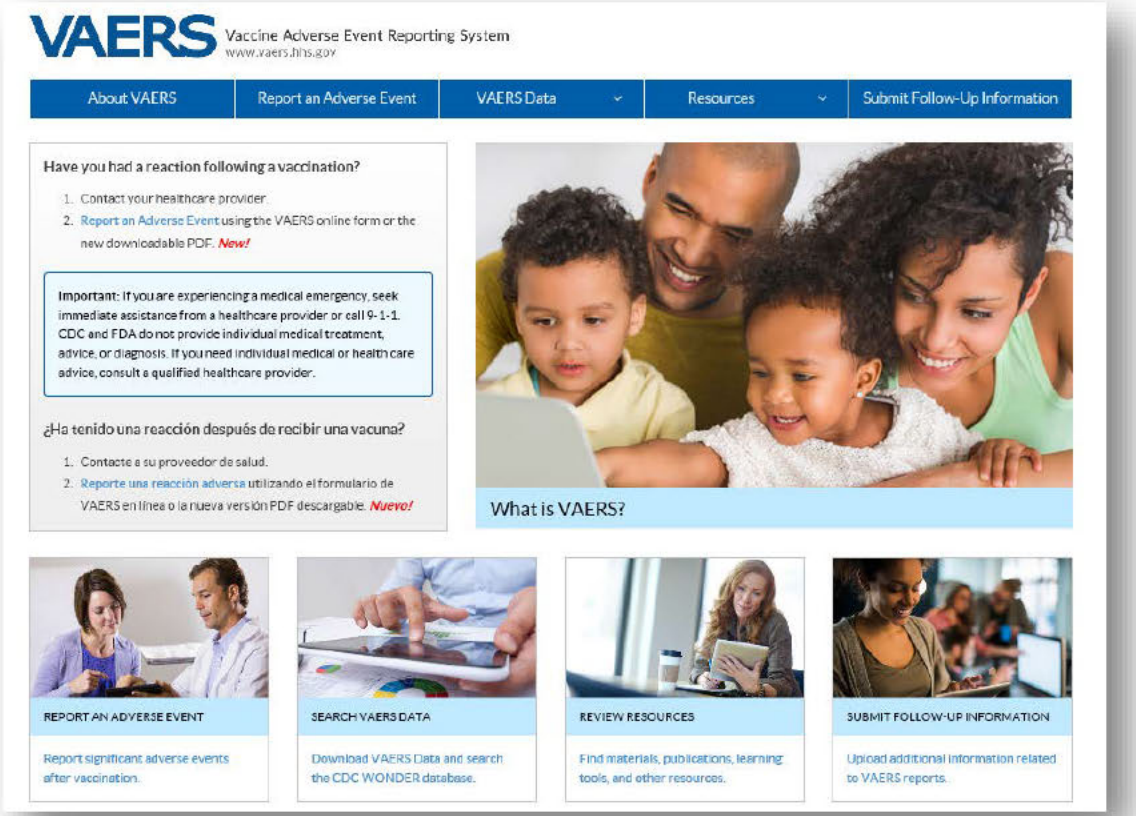
- Follow-up phone calls ongoing to v-safe participants who report medically attended health impact events
- Pregnancy registry
  - 227 pregnancies enrolled as of January 22, 2021

VAERS is the nation's early warning system for vaccine safety

Vaccine Adverse Event Reporting System

co-managed by CDC and FDA

http://vaers.hhs.gov



Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

Limitations

- Reporting bias
- Inconsistent data quality and completeness of information
- Lack of unvaccinated comparison group
- Not designed to assess causality

- VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

Reports to VAERS after COVID-19 vaccines*

Vaccine	N	Non-serious AEs (%)	Serious AEs† (%)	Median age in years (range)	Female (%)
Moderna	1,786	1,396 (78)	390 (22)	43 (15–102)	1,361 (76)
Pfizer-BioNTech	7,307	6,719 (92)	588 (8)	43 (17–104)	5,628 (77)
Unknown vaccine	3	2 (67)	1 (33)	58 (49–93)	3 (100)
Total	**9,096**	**8,117 (89)**	**979 (11)**	**43 (15–104)**	**6,992 (77)**

- Reporting rates: Non-serious AEs 372 reports per million doses administered
  Serious AEs 45 reports per million doses administered

* Reports received through January 18, 2021

† Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect

Most commonly reported adverse events to VAERS after COVID-19 vaccines*

Pfizer-BioNTech COVID-19 vaccine (N = 7,307)

Adverse event†	N (%)
Headache	1,550 (21.2)
Fatigue	1,192 (16.3)
Dizziness	1,113 (15.2)
Nausea	1,014 (13.9)
Chills	983 (13.5)
Pyrexia	962 (13.2)
Pain	958 (13.1)
Injection Site Pain	716 (9.8)
Pain In Extremity	610 (8.4)
Dyspnoea	536 (7.3)

Moderna COVID-19 vaccine (N = 1,786)

Adverse event†	N (%)
Headache	430 (24.1)
Pyrexia	333 (18.6)
Chills	315 (17.6)
Pain	290 (16.2)
Dizziness	289 (16.2)
Fatigue	287 (16.1)
Nausea	281 (15.7)
Injection Site Pain	208 (11.6)
Pain In Extremity	189 (10.6)
Dyspnoea	172 (9.6)

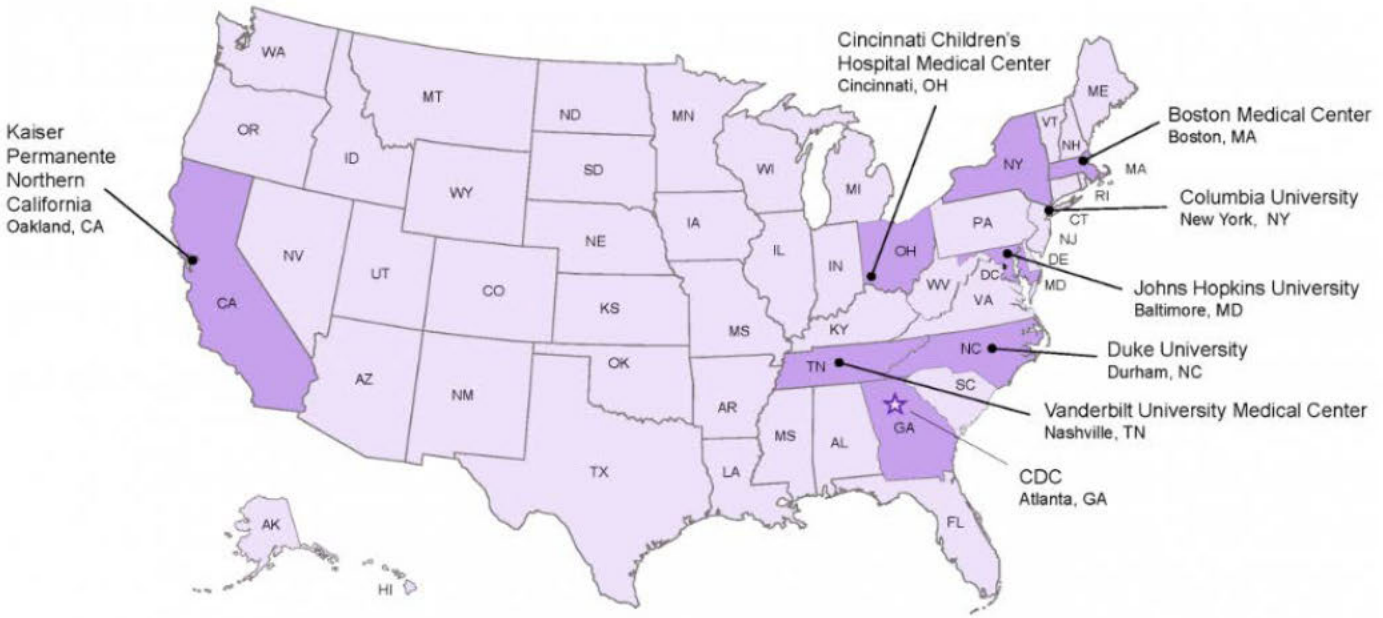
* Reports received through January 18, 2021; †Adverse events are not mutually exclusive

Empirical Bayesian data mining in VAERS

- FDA uses data mining to identify disproportional adverse event reporting for vaccines, including COVID-19 vaccines
  - Identifies, with a high degree of confidence, adverse event-vaccine pairs reported at least twice as frequently as expected for a COVID-19 vaccine compared to the VAERS database
  - i.e., lower bound of the 90% confidence interval surrounding the empirical Bayesian geometric mean (EB05 ≥2) compared to all other U.S.-licensed vaccines
- No empirical Bayesian data mining alerts (EB05 ≥2) detected for any adverse event-COVID-19 vaccine pairs (most recent [January 22, 2021] weekly results)

CISA

Clinical Immunization Safety Assessment (CISA) Project



7 participating medical research centers with vaccine safety experts

- clinical consult services†
- clinical research

†More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

CISA Project COVIDvax

- Extension of CDC's CISA* Project's clinical consultation service for U.S. healthcare providers and health departments for complex COVID-19 vaccine safety questions/issues that are**
  - (1) about an individual patient(s) residing in the United States
  - (2) not readily addressed by CDC or ACIP guidelines
- Vaccine safety subject matter expertise in multiple specialties (e.g., infectious diseases, allergy/immunology, neurology, OB/GYN, pediatrics, geriatrics)
- Requests for a CISA consult about COVID-19 vaccine safety:
  - Contact CDC-INFO: 800-CDC-INFO (800-232-4636) or webform
  - Indicate the request is for a "CDC CISA"* consult (no patient identifiers)

* https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
**Advice from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management

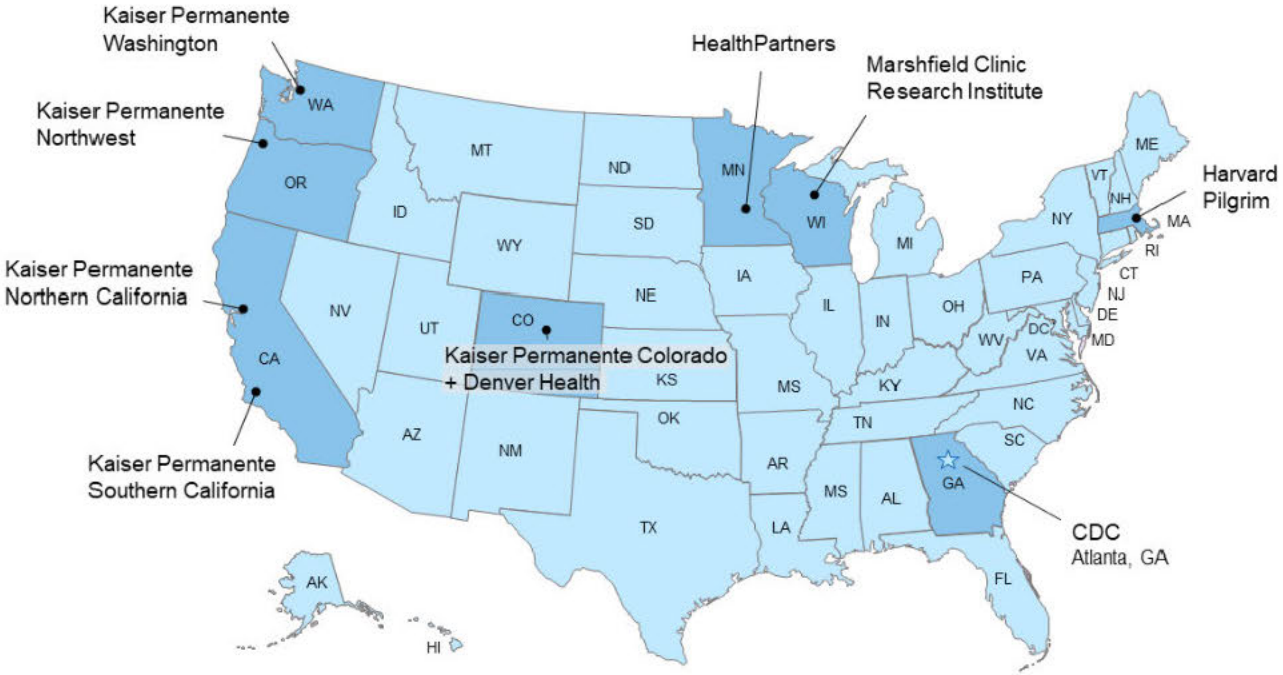
CISA Project contributions

- Responded to 143 clinical inquiries or consultation requests about COVID-19 vaccine safety*
- Assisted state health departments with evaluation of complex medical issues pertaining to COVID-19 vaccines safety
- Convened CISA Project workgroup with allergy/immunology specialists
  - Provided input for CDC's guidance on clinical considerations for use of the mRNA COVID-19 vaccines and how to prepare for managing anaphylaxis after vaccination
  - Contributed to MMWRs on anaphylaxis/allergic reactions after 1st dose of Pfizer-BioNTech and Moderna COVID-19 vaccines
  - Ongoing work to investigate possible mechanism for anaphylaxis, in collaboration with FDA, NIH and other partners

*Since December 14, 2020 – January 24, 2021

VSD

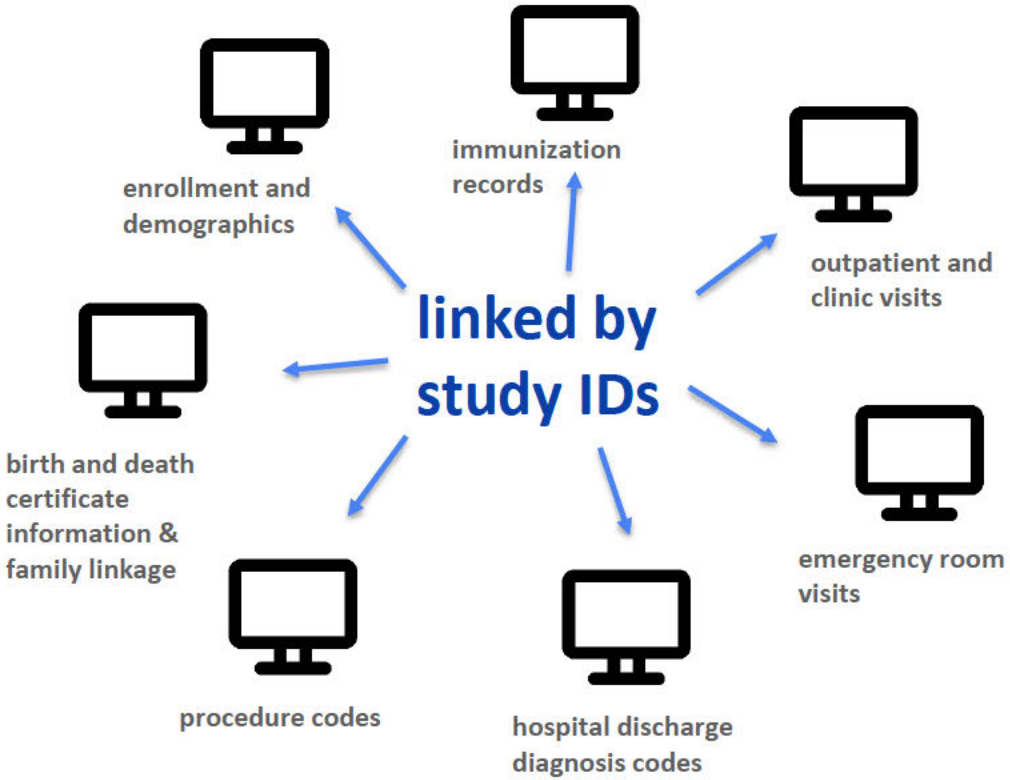
Vaccine Safety Datalink

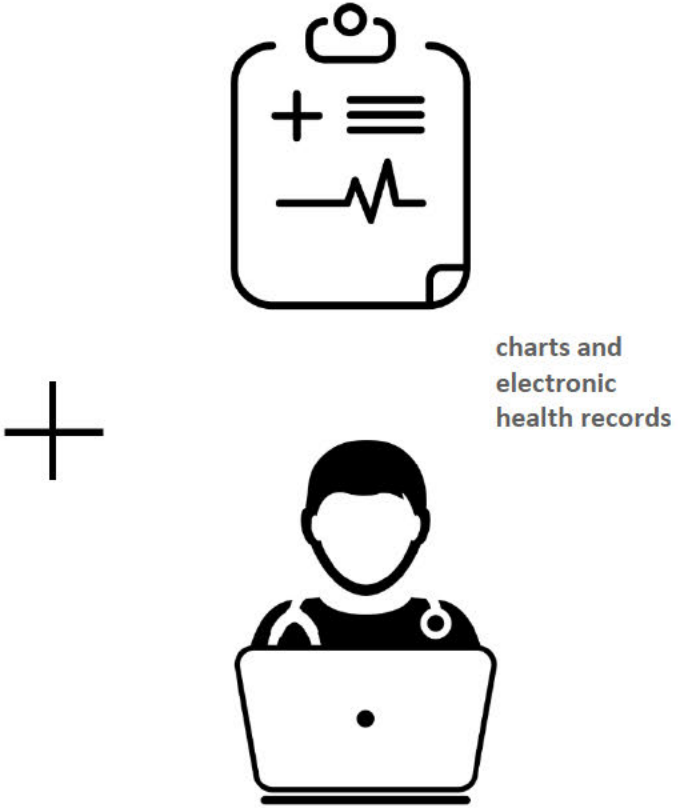


9 participating integrated healthcare organizations

data on over **12 million** persons per year

Types of information in VSD



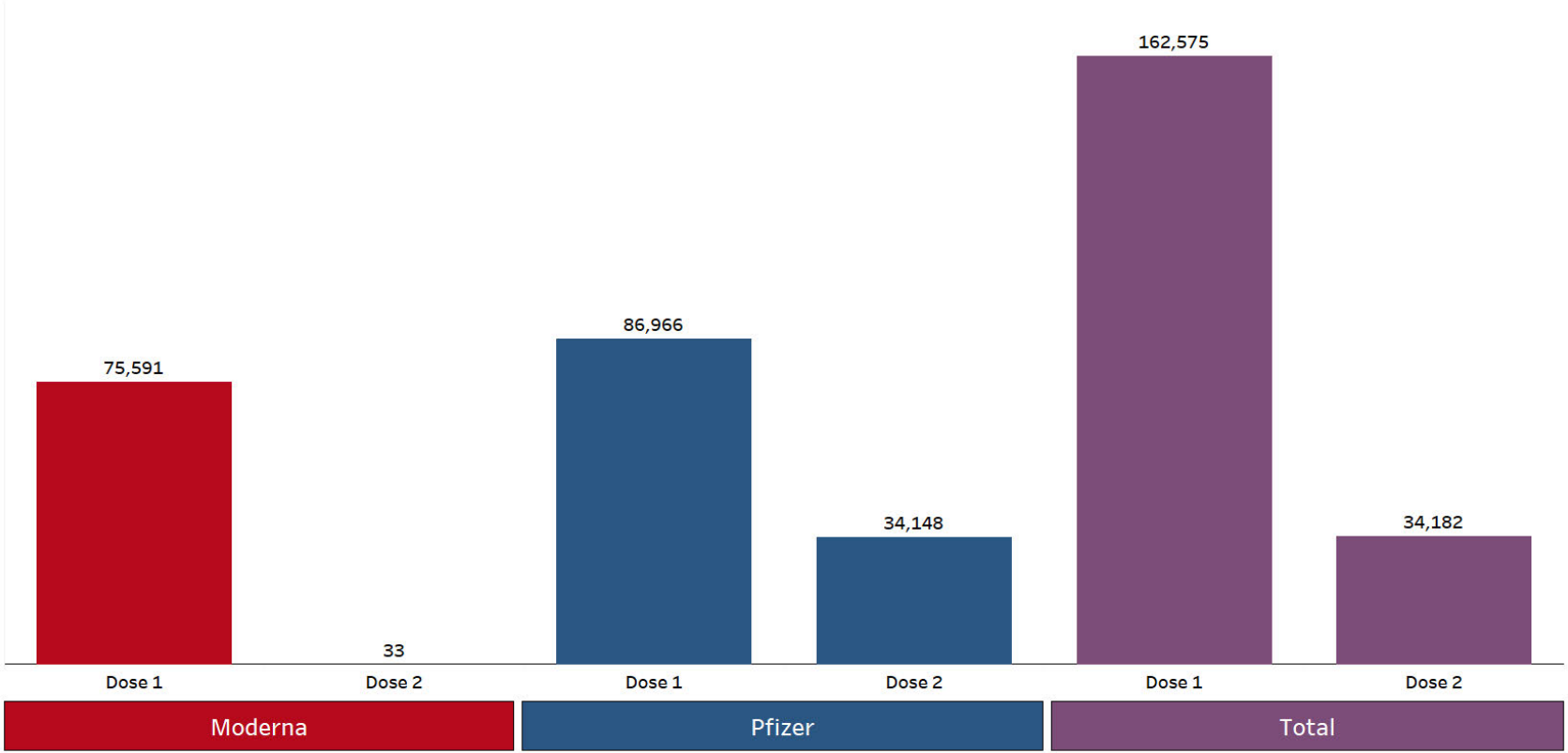


Images created by Wilson Joseph, Megan Mitchell, Ananth, and Iga from the noun project

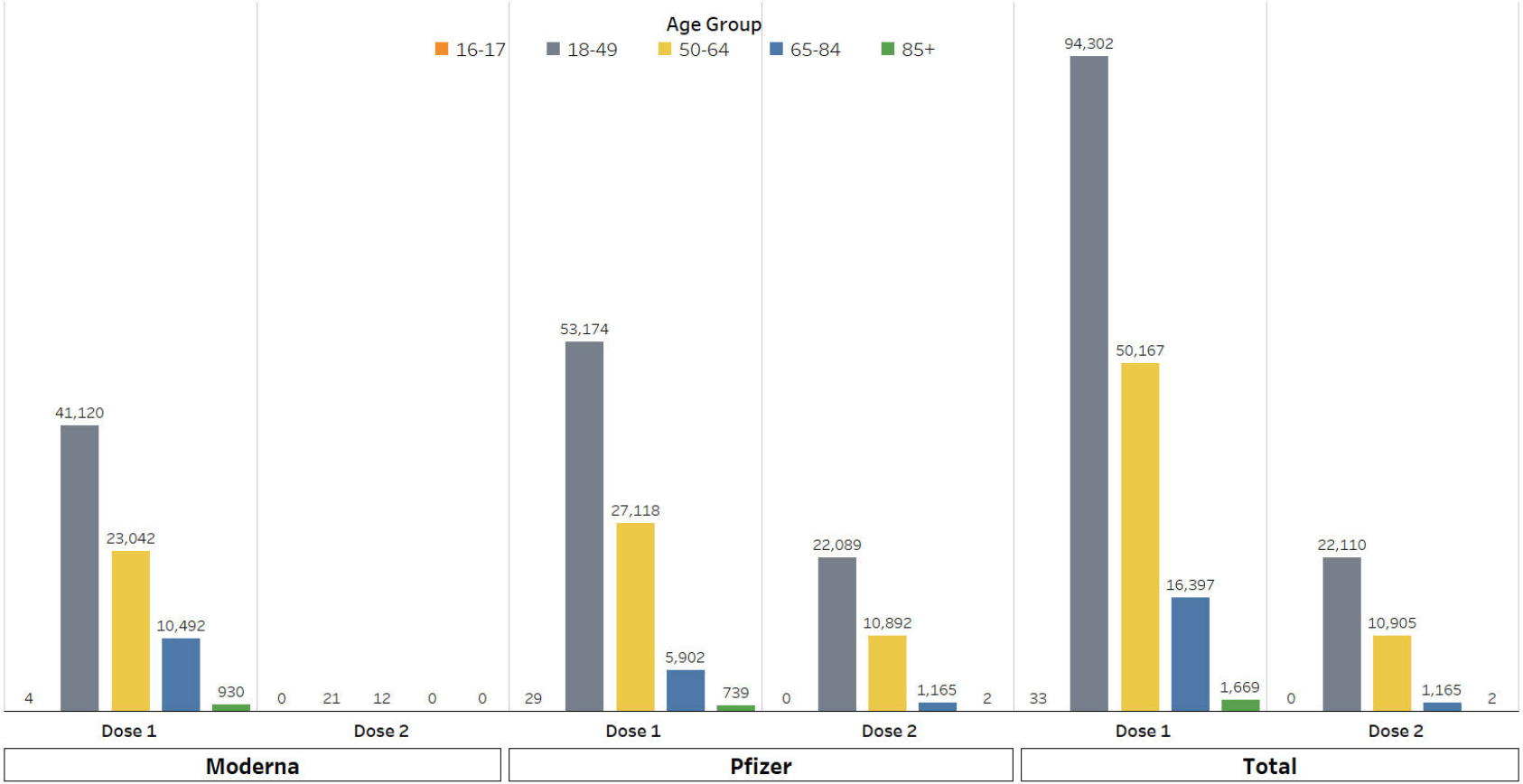
VSD Rapid Cycle Analysis (RCA) aims

- Monitor the safety of COVID-19 vaccines weekly using pre-specified outcomes of interest among VSD members
- Assess each pre-specified outcome for a 1-21 and 1-42 day risk interval
- Describe the uptake of COVID-19 vaccines over time among eligible VSD members

VSD COVID-19 vaccine totals through Jan 16, 2021



VSD COVID-19 vaccine totals through Jan 16, 2021



VSD RCA outcomes for COVID-19 vaccines	Concurrent comparator	Risk interval	Events in vaccinated	Events in unvaccinated	Signal (Y/N)
Acute disseminated encephalomyelitis	Unvaccinated	1-21 days	0	0	N
Acute myocardial infarction	Unvaccinated	1-21 days	1	179	N
Acute respiratory distress syndrome	Unvaccinated	1-21 days	0	4	N
Anaphylaxis	Unvaccinated	0-1 days	0	8	N
Appendicitis	Unvaccinated	1-21 days	5	267	N
Bell's palsy	Unvaccinated	1-21 days	4	358	N
Convulsions / seizures	Unvaccinated	1-21 days	0	39	N
Disseminated intravascular coagulation	Unvaccinated	1-21 days	0	14	N
Encephalitis / myelitis / encephalomyelitis	Unvaccinated	1-21 days	0	6	N
Guillain-Barré syndrome	Unvaccinated	1-21 days	0	4	N
Thrombotic thrombocytopenic purpura	Unvaccinated	1-21 days	0	4	N
Immune thrombocytopenia	Unvaccinated	1-21 days	0	21	N
Kawasaki disease	Unvaccinated	1-21 days	0	1	N
MIS-C and MIS-A	Unvaccinated	NA	0	NA	N
Myocarditis / pericarditis	Unvaccinated	1-21 days	0	12	N
Narcolepsy and cataplexy	Unvaccinated	N/A	0	8	N
Stroke, hemorrhagic	Unvaccinated	1-21 days	1	85	N
Stroke, ischemic	Unvaccinated	1-21 days	0	197	N
Transverse myelitis	Unvaccinated	1-21 days	0	0	N
Venous thromboembolism	Unvaccinated	1-21 days	3	408	N
Pulmonary embolism (subset of VTE)	Unvaccinated	1-21 days	0	132	N

- Preliminary results of VSD unvaccinated concurrent comparator analyses for COVID-19 vaccine safety
- No signals as of January 16

VSD RCA next steps – next analyses

- Vaccinated concurrent comparator analysis
  - Start when informative comparator follow-up available (expected within a week)
- Dose 1, Dose 2 analysis for each vaccine
  - Both the 1-21 and 1-42 day risk intervals
- Historical comparator analysis
  - General age comparable background rates
  - Rates following well care visits among those that received influenza vaccine in the past 18 months
  - Planning to start in mid-March

Update on anaphylaxis following COVID-19 vaccine

Anaphylaxis reports to VAERS following COVID-19 vaccines

- Suspected anaphylaxis reports to VAERS through January 18, 2021
  - Detected through early screening to identify suspected anaphylaxis reports prior to formal processing and MedDRA coding
  - Detected through a MedDRA code search strategy after formal processing and coding
- Suspected anaphylaxis reports were assessed by physicians at CDC who conducted medical record review and additional follow-up if necessary
- Cases were classified according to the Brighton Collaboration case definition criteria* (Brighton Levels 1, 2, and 3 are cases, 4 and 5 are not)
- CDC and FDA met to discuss and further adjudicate cases if necessary

* Rüggeberg et al.; Brighton Collaboration Anaphylaxis Working Group. Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2007;25(31):5675-84.

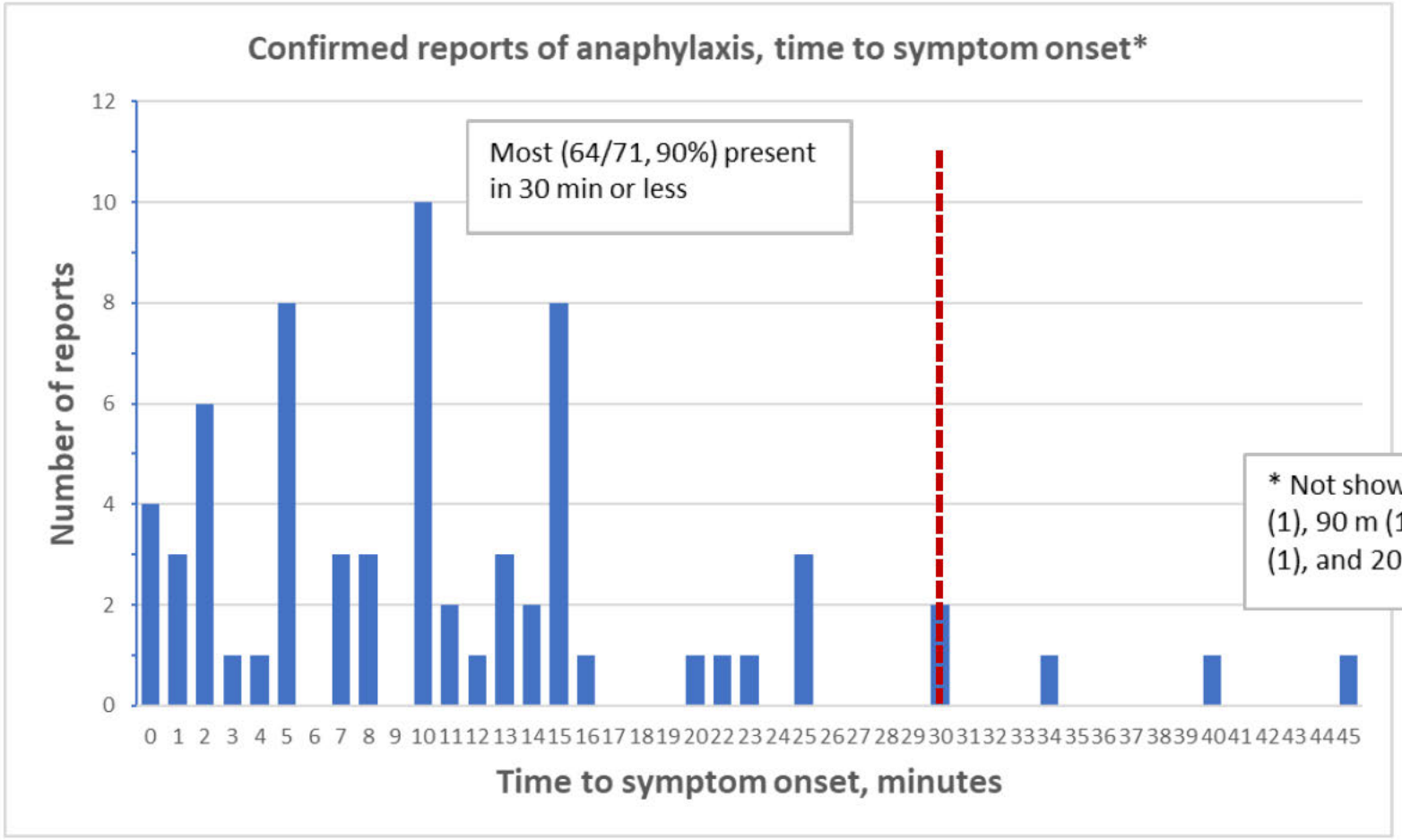
Anaphylaxis reports to VAERS following COVID-19 vaccines*

Characteristics	Pfizer-BioNTech (N = 50)	Moderna (N = 21)
Median age, years (range)	38.5 (26–63)	39 (24–63)
Female (%)	47 (94)	21 (100)
Minutes to symptom onset, median (range)	10 (<1–1200 [20 hr])†	10 (<1-45)
Symptom onset ≤15 minutes (%)	37 (74)	18 (86)
Symptom onset ≤30 minutes (%)	45 (90)	19 (90)
Documented h/o of allergies or allergic rxns (%)	40 (80)	18 (86)
Documented h/o of prior anaphylaxis (%)	12 (24)	5 (24)
Dose number (1st, 2nd, unknown)	42, 3, 5	19, 1, 1

- Common allergies and allergic reactions included to drugs and foods
- Anaphylaxis cases occurred following drugs, foods, contrast media, vaccines, insect stings, unspecified

* Reports received through January 18, 2021; Includes case reports that met Brighton Collaboration case definition criteria for anaphylaxis at Levels 1, 2, or 3

† 20 hour onset was an outlier, the remaining onset for cases with onset >30 minutes were 34, 54, 90, and 150 minutes



Data through January 18, 2021

Estimated anaphylaxis reporting rates following COVID-19 vaccines based on VAERS reports and reported doses administered*

Reported vaccine doses administered	Anaphylaxis cases	Reporting rate (analytic period Dec 14-Jan 18)
Pfizer-BioNTech: **9,943,247**	50	5.0 per million doses admin.
Moderna: **7,581,429**	21	2.8 per million doses admin.

- Total COVID-19 vaccine doses administered thru Jan 18 by sex: Female 61%, Male 36%, Unk 3%
- Previously reported rate for Pfizer-BioNTech vaccine: 11.1 per million doses admin (Dec 14-Dec 23)
  https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm
- Previously reported rate for Moderna vaccine: 2.5 per million doses admin (Dec 21-Jan 10)
  https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm

* Data through January 18, 2021

Reports of deaths and mortality following COVID-19 vaccination

Processing and follow-up on reports of death to VAERS

- Upon receipt or notification of a reported death after COVID-19 vaccine,* the VAERS contractor:
  - Expedites processing of the report (processed the day of report)
  - Contacts the reporter for additional information (medical records, death certificate, autopsy report, etc.)
  - Notifies state Vaccine Safety Coordinator (VSC) of the death and provides copy of the initial report to the VSC via Epi-X
- Physicians in the CDC's Immunization Safety Office and at FDA review all reports of death following COVID-19 vaccination as soon as notified in the daily VAERS priority report and make an assessment if any immediate action is necessary
- Attempts (multiple if necessary) are made to obtain death certificates and autopsy reports, when an autopsy is conducted, to ascertain cause of death

* A similar process occurs for reports of death following influenza vaccine

Reports of deaths (due to any cause) following COVID-19 vaccination to VAERS* (N = 196)

Characteristics	Reports of death (N = 196)
Median age, years (range)	79 (25–104)
Age <65 years (%)	43 (22)
Female (%)	91 (46)
Long-term care facility (LTCF) resident (%)	129 (66)
Pfizer-BioNTech vaccine	113
Moderna vaccine	83

- These reports of death to VAERS involve temporally associated deaths following vaccination due to any cause; adverse event reports to VAERS, including deaths, should not be assumed to be causally related to vaccination

* Data through January 18, 2021

Reports of death following COVID-19 vaccination: Background mortality in long-term care facility (LTCF) residents

Estimated background mortality in LTCF residents

- Estimated 2 million COVID-19 vaccine doses administered in LTCFs through January 18, 2021 (CDC COVID Data Tracker)
  - Assume 65% administered to LTCF residents (1.3 million residents)
  - Assume a 22% annual mortality rate* (n = 286,000)
- Risk period
  - Assume December 21 was when vaccinations commenced in LTCFs
  - Therefore, risk period=29 days (December 21-January 18)
  - Assume each resident contributes 14.5 person-days (~ mid-point of risk period)
  - 14.5 days = 4% of a calendar year

* Thomas et al, J Gerontol A Biol Sci Med Sci, 2019, Vol. 74, 219–225

Estimated background mortality in LTCF residents (cont.)

- Among 1.3 million LTCF residents (2M x 65%) vaccinated over the 29-day risk period (December 21-January 18)
  - Expect **11,440 deaths** among LTCF residents (= 286,000*4%) following vaccination
- By comparison, VAERS received **129 reports of deaths** following COVID-19 vaccination in LTCF residents through January 18, 2021
- Mortality in LTCF residents is high and substantial numbers of deaths in this population will occur following vaccination as temporally-associated coincidental events

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Genesis

NIH National Institute on Aging

Genesis Healthcare analysis

This research was supported, in part, by a grant from the National Institute on Aging [5U54AG063546S5] with supplemental funding from the Centers for Disease Control and Prevention (CDC) under an inter-agency agreement.

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School of Public Health

Vaccine Safety Monitoring among Residents of 284 Genesis Skilled Nursing Facilities

On behalf of: Barbara Bardenheier, PhD, MPH, MA
Assistant Professor of Health Services, Policy, and Practice
Assistant Professor of Epidemiology
Brown University School of Public Health

BROWN
School of Public Health

Background

- Genesis Healthcare is the largest nursing home company in the United States, spanning 24 states
  - Analysis included Skilled Nursing Facilities (284 Facilities with about 25,000 residents)
- COVID-19 vaccination began on December 18, 2021
  - By December 31, first dose of vaccine was administered in 118 facilities among 7,006 residents (61.4% in those facilities)
- Assessed 7-day mortality rates among the vaccinated and unvaccinated residents in 118 facilities as well as 17,076 residents in the 166 facilities that started vaccinating after January 1, 2021

Results

- After excluding residents with a positive SARS-CoV-2 diagnostic test within 20 days prior to their 7-day observation window
  - Mortality was lower among vaccinated versus unvaccinated residents within the same facilities and compared to residents in not-yet-vaccinated facilities, with overlapping 95% confidence intervals

Conclusions

- Findings suggest that short term mortality rates appear unrelated to vaccination for COVID-19 in skilled nursing facility residents
- This study underscores the value of having an analytic infrastructure to support near real-time monitoring of adverse events and safety during rapid vaccine deployment in this vulnerable population

ACKNOWLEDGMENTS

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Elizabeth White
Chris Santostefano
Neil Sarkar
Jeff Hiris

Reports of deaths following COVID-19 vaccination in LTCF residents to VAERS

Reports of deaths in LTCF residents following COVID-19 vaccination to VAERS* (N = 129)

Characteristics	Reports of death (N = 129)
Median age, years (range)	84 (51–104)
Female (%)	65 (50)
Hospice, DNR, or DNI (%)	43 (33)
Autopsy conducted, results pending	2
Death certificate available	18
Death certificate unavailable or autopsy results pending†	112

- Initial assessment indicated that many case reports documented ill health and a history of multiple co-morbidities and common age-related diseases (e.g., heart disease, type 2 diabetes, dementia, etc.)

* Data through January 18, 2021; †Standard follow-up on reports of death includes attempts to collect and review death certificates and autopsy reports

Reports of deaths in LTCF residents following COVID-19 vaccination to VAERS with death certificates available*(N = 18)

Cause of death from death certificate
Hypertension, leading to acute myocardial infarction, leading to anoxic brain injury
Atherosclerotic cardiovascular disease, acute myocardial infarction
Arteriosclerotic Disease
Cardiac arrest, cardiopulmonary arrest
Acute congestive heart failure, non-ischemic cardiomyopathy
Congestive heart failure, non-ischemic cardiomyopathy
Congestive heart failure
Congestive heart failure
Heart failure, hypertension
End stage chronic obstructive pulmonary disease
Acute kidney failure, resulting from acute liver failure, resulting from liver masses
Hypertension, hypothyroidism, bipolar disorder, peripheral vascular disease
Pneumonia, cardiac arrest and shock
Aspiration, frontotemporal dementia
Hypertension, mixed Alzheimer's and vascular dementia
Dementia
Chronic alcohol abuse and severe malnutrition, alcohol withdrawal, electrolyte derangement, ventricular arrhythmia, cardiogenic shock
Failure to thrive

* Data through January 18, 2021

Impression on deaths and mortality in LTCF residents following COVID-19 vaccination

- Mortality in LTCF residents is high due to the underlying health status of the LTCF resident population
- The available evidence from VAERS monitoring and Genesis population-based surveillance does not suggest a safety problem with respect to deaths in older adults residing in LTCFs
- Case reports of deaths in LTCF residents following COVID-19 vaccination to VAERS include many persons:
  - With multiple co-morbidities, including some with cognitive impairment
  - In ill health and declining states health
  - In hospice or DNR or DNI status (in one-third of reported deaths)
- Deaths in LTCF residents following COVID-19 vaccination are consistent with expected all cause mortality in this population

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GACVS COVID-19 Vaccine Safety subcommittee meeting to review reports of deaths of very frail elderly individuals vaccinated with Pfizer BioNTech COVID-19 vaccine, BNT162b2

22 January 2021 | Statement | Reading time:

The GACVS COVID-19 Vaccine Safety subcommittee met virtually on Tuesday, 19 January 2021, to review available information and data on deaths reported in frail, elderly individuals who had received the Pfizer BioNTech COVID-19 mRNA vaccine, BNT162b2 (hereafter, BNT162b2). Experts invited from the European Medicines Agency (EMA) and the Uppsala Monitoring Center (UMC) provided an overview of deaths reported in Europe and in the WHO global database (VigiBase) following vaccination with BNT162b2.

Based on a careful scientific review of the information made available, the subcommittee came to the following conclusions:

The current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of BNT162b2. Reports are in line with the expected, all-cause mortality rates and causes of death in the sub-population of frail, elderly individuals, and the available information does not confirm a contributory role for the vaccine in the reported fatal events. In view of this, the committee considers that the benefit-risk balance of BNT162b2 remains favourable in the elderly, and does not suggest any revision, at present, to the recommendations around the safety of this vaccine.

Related

COVID-19 vaccine safety surveillance manual

https://www.who.int/news/item/22_-01-2021-gacvs-review-deaths-pfizer-biontech-covid-19-vaccine-bnt162b2

Reports of deaths following COVID-19 vaccination in community dwelling adults aged <65 years

Background: Sudden cardiac death in community residents

- Rate of sudden cardiac death = 29.6 per 100,000 person-years*
  - Out-of-hospital cardiac arrest in people 18–90 years of age in San Francisco County
    - Inclusion criteria: sudden unexpected death either within 1 hour of symptom onset (event witnessed), or within 24 hours of having been observed alive and symptom free (unwitnessed)
    - Excludes: (1) subjects with chronic/terminal illness in which imminent death not unexpected; (2) hospice residents; (3) subjects with identifiable noncardiac etiology of death at presentation, including drug abuse/overdose, trauma, homicide, or suicide; (4) subjects with hospital admission within prior 30 days for noncardiac illness or surgical procedure.

* Tseng et al, Circulation. 2018;137:2689–2700

Background: Sudden cardiac death in community residents

- Estimate ~13.7 million community residents vaccinated December 14–January 18, 2021 (CDC COVID Data Tracker)
- Risk period
  - Risk period = 35 days (December 14–January 18)
  - Assume each resident contributes 15 person-days (~ mid-point of risk period, adjusted downward to account for Moderna not used until December 21)
  - Total person-years contributed = 566,650 ([13.7million*15 days]/365.25)
- Expected sudden cardiac death count: 168 deaths (29.6*5.66)
- *Reported* VAERS sudden cardiac death count following COVID vaccination: 18 deaths

Reports of deaths following COVID-19 vaccination to VAERS in community dwelling adults aged <65 years* (N = 28)

Characteristics	Reports of death (N = 28)
Median age, years (range)	54 (25–63)
Female (%)	12 (43)
Median time from vaccination to death (range), days	5 (day of vax–25)
Pfizer-BioNTech	16
Moderna	12
Autopsy (completed, pending)	1, 4
Death certificate/autopsy report available	11

* Data through January 18, 2021

Reports of deaths following COVID-19 vaccination to VAERS in community dwelling adults aged <65 years with death certificate or autopsy report available* (N = 11)

Cause of death from death certificate or autopsy report
Atherosclerotic cardiovascular disease
Atherosclerotic cardiovascular heart disease, hypertension
Cardiac arrest, COVID-19
Cardiac arrest, hypertension, morbid obesity
Cardiopulmonary arrest, hypertensive heart disease, hypertension, DM type II
Hypertensive cardiovascular disease
Myocardial infarction, ventricular fibrillation
Drug overdose
Pulmonary hemorrhage from squamous cell cancer of the lung
Subarachnoid hemorrhage, intraparenchymal hemorrhage, intraventricular hemorrhage
COVID-19 stroke, COVID-19 acute respiratory failure

* Data through January 18, 2021

Closing

Closing thoughts

- 23.5 million COVID-19 vaccine doses have been administered in the United States
- During this time, the U.S. government has implemented the most intense and comprehensive vaccine safety monitoring program in history
- Overall, the safety profiles of COVID-19 vaccines are reassuring and consistent with that observed from the pre-authorization clinical trials
- Anaphylaxis has been observed following mRNA COVID-19 vaccines, though rarely
- The data do not suggest a signal with respect to overall safety or deaths following vaccination in older adult residents of LTCFs
- Additional population-based monitoring systems will continue to gather safety data safety as vaccination increases and the immunization program broadens
  - CDC's Vaccine Safety Datalink, FDA monitoring in CMS data, VA electronic health record

Acknowledgments

We wish to acknowledge the contributions of investigators from the following organizations:

Centers for Disease Control and Prevention

COVID-19 Vaccine Task Force

COVID-19 Vaccine Task Force, Vaccine Safety Team

Immunization Safety Office

Division of Healthcare Quality Promotion

Vaccine Safety Datalink

Clinical Immunization Safety Assessment Project

V-safe Team

U.S. Food and Drug Administration

Office of Biostatistics and Epidemiology

National Institutes of Health

National Institute on Aging

Brown University School of Public Health

Genesis

Questions

From: Melissa Holmes
To: [redacted]@umontreal.ca; [redacted]@toh.ca; [redacted]@sickkids.ca; [redacted]@usherbrooke.ca; [redacted]@ubc.ca; [redacted]@mail.ubc.ca; [redacted]@cheo.on.ca; [redacted]@usask.ca; [redacted]@ssss.gouv.qc.ca; [redacted]@ualberta.ca; [redacted]@gmail.com; [redacted]@albertahealthservices.ca; Derfalvi, Beata; [redacted]@ircm.qc.ca; [redacted]@muhc.mcgill.ca; [redacted]@crchudequebec.ulaval.ca; [redacted]@inspq.qc.ca; [redacted]@gmail.com; [redacted]@albertahealthservices.ca; [redacted]@eastlink.ca; [redacted]@ircm.qc.ca; [redacted]@bcchr.ubc.ca; [redacted]@toh.ca; [redacted]@mail.chuq.qc.ca; [redacted]@cw.bc.ca; [redacted]@albertahealthservices.ca; [redacted]@sickkids.ca; Karina Top; [redacted]@cw.bc.ca; McHenry, Mary; McNeil, Shelly; [redacted]@bcchr.ca; [redacted]@mcmaster.ca; [redacted]@mail.ubc.ca; [redacted]@chudequebec.ca; [redacted]@vch.ca; [redacted]@gmail.com; Scott Halperin; [redacted]@sickkids.ca; shelley.deeks@novascotia.ca; [redacted]@cheo.on.ca; [redacted]@me.com; [redacted]@ualberta.ca; [redacted]@unityhealth.to; [redacted]@albertahealthservices.ca; [redacted]@allergyvic.com; [redacted]@uhn.ca; [redacted]@albertahealthservices.ca; [redacted]@medportal.ca
Subject: ACIP slides on COVID vaccine effectiveness and safety studies
Date: Friday, January 29, 2021 9:00:40 AM
Attachments: 09_COVID_Fleming-Dutra_Jan_2021.pdf
06-COVID-Shimabukuro.pdf

Dear SI05 Investigators,

Please see some attached slides from the CDC presented at the Advisory Committee on Immunization Practices (ACIP) for your interest.

Cheers,

Melissa Holmes
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Canadian Center for Vaccinology (CCfV)
IWK Health Centre
Goldbloom RCC Pavilion, 4th Floor
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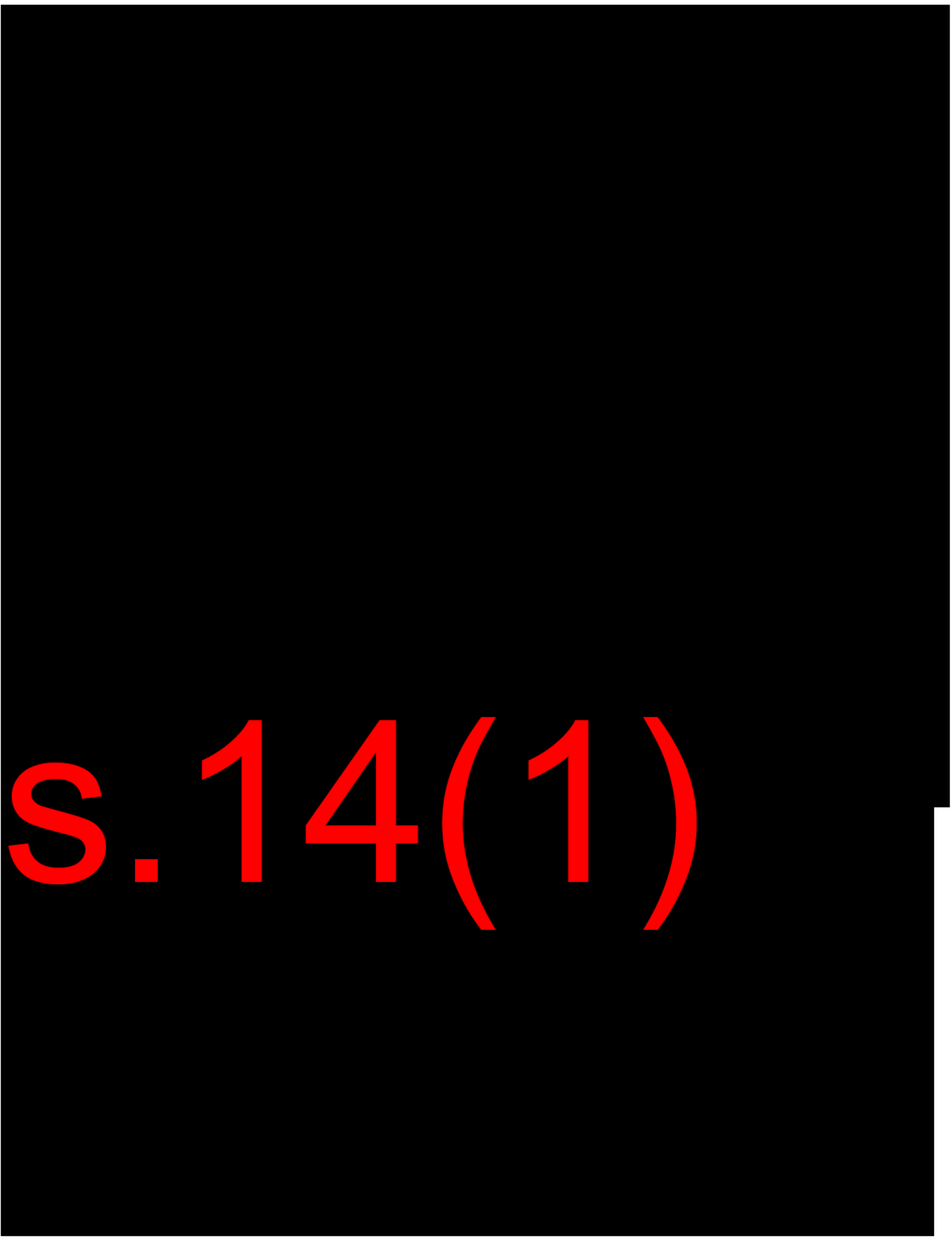
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Dear Healthcare Professional,

On behalf of everyone at AstraZeneca Canada, thank you for your tireless efforts on the frontlines, helping to support the health of Canadians through this devastating pandemic. We want to take this opportunity to provide an update on important recent developments related to *AstraZeneca COVID-19 Vaccine* and highlight resources available to Canadians and healthcare practitioners.

As background, Health Canada (https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75389a-eng.php) recently completed their ongoing safety review of the *AstraZeneca COVID-19 Vaccine*, concluding that very rare reports of blood clots associated with low levels of blood platelets (i.e., combination of thrombosis and thrombocytopenia) may be associated with our vaccine. They indicated that "the safety of the AstraZeneca vaccine meets its strict safety standards and the Department is adjusting the product's labelling to reflect the available scientific evidence. The potential risk of these events is very rare, and the benefits of the vaccine in protecting against COVID-19 outweigh its potential risks."

Patient safety remains our highest priority, and it always will. We have been collaborating and continue to work closely with Health Canada and healthcare practitioners to define the nature of these extremely rare blood clot events. We also continue to work closely with Health Canada to monitor all adverse events from around the world and provide up-to-date information on our vaccine to ensure Canadian healthcare practitioners and patients receive accurate guidance and understand the benefits and risks.

We recognize many Canadians may have questions, even concerns, about the risk of blood clots following immunization with our vaccine. You will find a number of different resources on the *AstraZeneca COVID-19 Vaccine* website (https://www.azcovid-19.com) and Health Canada's COVID-19 resources website (https://covid-vaccine.canada.ca/astrazeneca-covid-19-vaccine/product-details) to help support you in discussions with patients.

Beginning April 28th, AstraZeneca Canada is introducing a series of educational webinars – *Practical Guide to COVID-19 Immunization* – for all Canadian healthcare practitioners, where you will have the opportunity to review and discuss the latest Health Canada information, National Advisory Committee on Immunization (NACI) recommendations, and evidence surrounding all of the Canadian-approved COVID-19 vaccines (https://covid19-immunization-learning-program-2021.ca).

To change the course of the pandemic, COVID-19 vaccines need to be available globally and accessible to all who need them. In Canada, we are working very diligently with the Public Health Agency of Canada (PHAC) to expedite the delivery of vaccines for Canadians. We also remain focused on delivering on a commitment we have made to make the vaccine available broadly and equitably, at no profit during the pandemic, to people around the world.

Healthcare practitioners can reach out to AstraZeneca's Medical Information Department at ASK-Medical@astrazeneca.com with any inquiries. Thank you again – we are incredibly grateful for your unwavering leadership and personal sacrifices throughout this challenging period.

Best regards,

s.20(1)

Neil Maresky
Vice President, Scientific Affairs
AstraZeneca Canada

From: Deeks, Shelley
To: McNeil, Shelly
Subject: FW: National Post: Why NACI went dark: Canada"s expert panel on vaccines stops COVID briefings, interviews
Date: Friday, October 15, 2021 4:13:11 PM

Don't know how I feel about this.

Shelley Deeks, MD, MHSc, FRCPC, FAFPHM
Deputy Chief Medical Officer of Health
Department of Health and Wellness

From: s.20(1) [redacted] @hc-sc.gc.ca> **On Behalf Of** Media Monitoring / Suivi des Medias (HC/SC)
Sent: 2021-10-15 10:17 AM
Subject: National Post: Why NACI went dark: Canada's expert panel on vaccines stops COVID briefings, interviews

s.20(1) [redacted]

October 15, 2021
Why NACI went dark: Canada's expert panel on vaccines stops COVID briefings, interviews
As Canada considers COVID boosters for the general population and a vaccine rollout for millions of children aged five to 11, NACI is suddenly silent
National Post, Sharon Kirkey

When a leader of the expert panel advising the nation on COVID-19 vaccines suggested she would not advise a loved one to get the AstraZeneca shot, it was a low moment for vaccine confidence that left risk communicators cringing.

"If, for instance, my sister was to get the AstraZeneca vaccine and die of a thrombosis (blood clot) when I know that it could have been prevented and that she's not in a high-risk area, I'm not sure I could live with it," Dr. Caroline Quach-Thanh, then co-chair of the National Advisory Committee on Immunization, told CTV's Power Play in May.

Now, months later, as questions swirl around if — or when — third doses of a COVID vaccine for the general population might be needed, as the country prepares for a vaccine rollout to millions of children ages five to 11, NACI has gone virtually dark. The panel has stopped giving press briefings to explain its recommendations. Requests to speak with the current chair, Dr. Shelley Deeks, have been declined and the rest of the membership isn't authorized to talk. "For the time being, Dr. Deeks is not available for interviews," the Public Health Agency of Canada's media relations department this week advised the National Post. "If opportunities arise in the coming months, we will reach out to you and let you know."

The panel of voluntary vaccine advisers, once a relatively obscure group that drew little public attention, "has decided to revert to its process of submitting its recommendations to PHAC and to rely on PHAC to convey this advice to the Canadian public and media" so that the panel may focus

on its deliberations and recommendations, the federal health agency said.

NACI itself floated the idea — first of hosting press briefings, and then pulling back. But NACI is playing a key role in vaccination policy making, and there has been considerable public interest in the rationale and evidence behind its recommendations. In a matter of weeks, and not months, a vaccine could be authorized for the under 12s. Is NACI considering prioritizing vaccine doses for children, the way it did for adults? If so, which children might be first? What ethical questions must be weighed when considering shots for kids, who rarely get severely ill with COVID, and, mercifully, die even less often? Even Canada's top medical journal has been stonewalled trying to seek answers from NACI.

"We've heard from all governments during the pandemic, 'We're following the advice of our experts.' Okay, if you are following the advice of experts, precisely what are they telling you?" said Josh Greenberg, director of Carleton University's school of journalism and communication and an expert in risk communication.

NACI's recommendations in the past have sometimes been "less perfectly aligned" to messaging from Health Canada and elected officials, he said. Framing the mRNA vaccines, Pfizer and Moderna, as the preferential shots because of a one in 100,000 risk of a blood clotting disorder associated with AstraZeneca, just as Canadians were being urged to take the first needle offered, created a lot of confusion and avoidable anxiety for people who got jabbed with AZ because it was the first vaccine available.

While an impressive group of scientists, NACI's expertise doesn't extend to how best to communicate risk to the public, and the voluntary panel faced a backlash over some bungled messaging, even though the group made the right call about some very difficult scientific decisions, Greenberg said. An exhausted public that is beginning to get their lives back has little tolerance for more missteps.

At a time when every message is parsed and potentially "weaponized," and amid a final, precarious push to get vaccines into more bodies, "it makes sense to limit the amount of potential harm done by a wayward statement," said University of Ottawa epidemiologist Raywat Deonandan. "It's unfortunate, but understandable."

NACI doesn't authorize vaccines for use in Canada. Health Canada, the drug regulator, does. They also don't set vaccine policy. Provinces and territories do. However, they do make recommendations for the use of vaccines in human bodies, and their advice can be broader or narrower than the conditions of use approved by Health Canada.

The 14-member panel advises on dosing schedules and priority populations. Their decisions aren't binding. However, they can issue "off label" — meaning formally unauthorized — advice in an emergency, as they did in March when, faced with ongoing disease and death from COVID and initially woefully insufficient supplies of vaccines, the panel issued a strong recommendation that provinces space doses out up to four months, instead of the manufacturer recommended three to four weeks, to maximize the number of people protected with at least one shot as quickly as

possible. The controversial decision (British Columbia had announced two days earlier it was going with a 16-week gap) proved fortuitous: a growing body of evidence suggests shorter intervals between shots one and two results in a lower immune response and more rapid waning of protection. The strategy to stretch shots, which Mona Nemer, the federal government's chief science advisor said at the time amounted to a giant "population-level experiment," likely also saved lives.

NACI normally has three face-to-face meetings a year in Ottawa. Its members are all volunteers, with busy day jobs and significant demands on their time. When COVID vaccines began arriving last winter, they began meeting, virtually, weekly and sometimes twice a week. NACI's meetings are closed to the public. It publishes top-of-the-waves summaries of its discussions, though the last was for Sept. 14; there have been four meetings since. Recommendations are also posted on its website and technical information can be found in the published statements.

By contrast, the U.S. Centers for Disease Control and Prevention's vaccine advisory panel, ACIP, or the Advisory Committee on Immunization Practises, holds public meetings where scientific experts weigh in on the data and key questions. In the coming weeks, ACIP is scheduled to debate J&J and Moderna booster shots, as well as vaccinations for children five to 11. Both meetings will be held virtually, and no registration is required to watch the live webcasts.

NACI had never really been a public-facing group, until earlier this year, when Quach-Thanh, a University of Montreal pediatrician and microbiologist, and then co-chair Deeks, Nova Scotia's deputy chief medical officer of health, began holding technical briefings that were broadcast to a nervy nation. Quach-Thanh, who ended her four-year term as chair in June, said she and Deeks wanted to be transparent. "We thought it was important to be there and explain our recommendations," she said in an interview with the National Post Thursday.

The advice kept changing, the age targets kept moving. With AstraZeneca, NACI initially recommended it only be offered to the under 65's, because there were few older people in the initial vaccine trials, then, later, not to anyone under 55 for fear of vaccine-inducted thrombotic thrombocytopenia, the blood clot problem. Both recommendations contradicted Health Canada's position the vaccine could be injected into anyone 18 and older. Then, in April, NACI deemed AZ safe for those 30 and older, if they could find it, and if they didn't want to wait for Pfizer or Moderna. The panel drafted a risk-assessment to allow people to decide for themselves if it was more prudent to hold out for an mRNA vaccine.

In early May, NACI reiterated its position that mRNA vaccines were preferred over the viral vector shots — AZ and Janssen's. A day later, Prime Minister Justin Trudeau sought to soothe rattled and frustrated AZ recipients, repeating that all authorized vaccines are safe and to "make sure you get your shot when it's your turn," whichever brand offered. By June, most provinces had abandoned AZ.

Quach's "if my sister were to get AstraZeneca" interview kneecapped that take-the-first-shot offered slogan and "torqued the issue" in an unnecessarily emotional and dramatic way, Greenberg said. Quach-Thanh later clarified that people at greater risk of infection should take the first jab they

could, especially if they lived in a community with high rates of circulating virus. “The message I tried to convey was that each person needed to do a self-risk assessment,” she said. “And I would be as concerned about that risk assessment, and concerned about the well being of people, whether it is my sister or somebody I don’t know.”

Still, it was PR blunder. In times of crisis, “people are far more likely to act on their emotions than on the careful consideration of statistical risks and benefits,” Greenberg said. The shifting advice was framed as flip-flopping, but when science changes in real-time, people need to pivot.

It's just too much work to be available for all the media requests

Soon after, it was decided PHAC would convey NACI’s advice to the media and public. “It’s just too much work to be available for all the media requests,” Quach-Thanh told the Post. Deeks’ job at the provincial level “is already in itself overwhelming,” she added. Her time as NACI chair was gratifying, but tough, tiring and at times, demoralizing, Quach-Thanh said. “The hardest thing was to get harsh messages from other scientists who were saying that we didn’t know what we were doing, that I should not be there.” There were a lot more encouraging emails than critical ones, she said. “People appreciated the work I was doing.” And she’s not on social media. It helps her sleep better. “But you know how the human brain works. You tend to be more devastated by the negative emails than by the positive ones.”

NACI was never funded or organized to provide rapid-fire communications, and some of it landed badly, said Dr. David Naylor, co-chair of Canada’s COVID-19 immunity task force. “It can actually be a good thing for crisis communications if there is some consistency of voice.”

In an email, the public health agency said that it’s committed to transparency and that it has forever been responsible for communicating NACI’s advice to the Canadian public. Whether future vaccine briefings are done by NACI’s chair, or, as seems far more likely, Canada’s chief public health officer, the preparations need to be meticulous and the messages “crystal clear and strike a strong note of authenticity,” Naylor said, meaning “a frank acknowledgement of what is and isn’t known, and an explanation of how NACI addressed those uncertainties.”

“Not an easy task with the microphones on and cameras running,” he said, “but crucial for public morale given widespread unease about another COVID-19 winter.”

NACI Timeline

Since 1964, the National Advisory Committee on Immunization (NACI) has offered guidance on the use of vaccines in Canada — including shots for smallpox, tetanus and a variety of other common vaccinations.

For many Canadians, its role has been largely ignored. But there have been exceptions. In the late 2000s, NACI’s recommendations were at the centre of discussions about the Gardasil shot, which prevents HPV infections that can cause cervical cancer, and is now given to both girls and boys in Canada.

But the organization was thrust to prominence during the COVID-19 pandemic. While Health Canada approves vaccines, NACI, which reports to the Public Health Agency of Canada, was tasked with making recommendations for the use of COVID-19 vaccines in Canada.

The National Post's Tyler Dawson compiled a timeline of NACI's COVID-related work.

May to October 2020

NACI offered guidance on receiving non-COVID-19 vaccinations during the pandemic. It said regular vaccination programs should continue throughout, and, if necessary given health-care capacity, young children should be prioritized. It also argued in favour of continued influenza vaccinations, to decrease pressure on the health-care system.

July 15, 2020

Even though a COVID-19 vaccine had not yet been developed, NACI was asked for advice on how best to conduct clinical trials of potential vaccines. NACI recommended clinical trials roll out with priority groups. It also listed a number of unknowns about COVID-19 at that point, such as how the disease spread and whether any already marketed vaccines might have a protective effect against COVID-19.

Nov. 3, 2020

NACI laid out its recommendations for who should be vaccinated first. The elderly and those with high-risk health factors should be prioritized in vaccination campaigns, NACI said. It also said the following groups should be prioritized: health-care workers who risk transmitting the virus to vulnerable populations, those working in essential services, such as firefighters, and people whose living or working conditions put them at higher risk of COVID-19.

Dec. 12, 2020

With the Pfizer vaccine approved, NACI made recommendations on its use, including the interval between doses, which they said should be between 19 and 21 days. It also made a number of other recommendations regarding the immunosuppressed and pregnant women, saying the evidence didn't support giving them vaccines.

Dec. 18, 2020

At this point, more precise recommendations were made. NACI specified residents and staff of long-term care, the elderly, health-care workers and Indigenous communities, should get top priority. Recommendations were made for stage two to include prisoners, the homeless and health-care workers not in phase one.

Dec. 23, 2020

NACI updated its recommendations because of the approval of the Moderna vaccine.

Jan. 12, 2021

NACI made a number of revisions to its recommendations for use of the Pfizer and Moderna vaccines. Among them, it said they could now be given to pregnant women and the immunosuppressed.

Feb. 12, 2021

The rollout recommendations were further expanded to adults in the Canadian population, dependant upon vaccine availability. Eligibility in stages one and two were also expanded in this iteration of NACI's rollout recommendations.

March 3, 2021

The vaccine recommendations were updated because of the approval of the AstraZeneca vaccine. At the time, it was not recommended for those aged 65 an older, or people younger than 18.

NACI also suggested extending the interval between first and second doses to four months, in order to maximize the benefits of one dose across the population, when there was a limited vaccine supply.

March 16, 2021

Based on evidence from other jurisdictions, primarily the United Kingdom, NACI changed its recommendation for AstraZeneca, saying it could now be given to those aged 65 and older.

March 29, 2021

NACI recommended not using the AstraZeneca vaccine on those 55 or younger based on reports of Vaccine-Induced Prothrombotic Immune Thrombocytopenia. Health Canada went on to study these reports, and found three cases out of 700,000 doses administered.

April 7, 2021

NACI released a more lengthy statement on why it had made the recommendation on March 3 that intervals between doses be extended.

April 23, 2021

NACI said at this point it "preferentially recommends" the use of Pfizer or Moderna. But, having reviewed Health Canada's research on Vaccine-Induced Prothrombotic Immune Thrombocytopenia, NACI concluded that those 30 years of age or older could get the AsraZeneca vaccine.

May 3, 2021

With the approval of the Janssen vaccine, NACI recommended it to be used for anyone over the age of 30, citing the efficiency of using a single-dose shot for harder-to-reach populations. NACI also "reaffirmed" its recommendation that pregnant women get a full course of vaccination.

May 18, 2021

Prior to this date, the Pfizer vaccine was the only one available to those aged 16 to 18. Based on Health Canada approval, NACI updated its recommendations, saying those between 12 and 18 were now eligible for the Pfizer shot.

May 28, 2021

NACI further updated its recommendations for those who are immunosuppressed, have an autoimmune condition and are pregnant or breastfeeding. It said those people should follow the same recommendations for vaccination as the general adult population.

NACI also said that as vaccine supply increases, second doses should be given as soon as possible.

June 1, 2021

Mixed-dose vaccine schedules are now acceptable, NACI said. The recommendation says that those who received AstraZeneca for their first dose may receive Pfizer or Moderna for dose two; those who received one of the latter two for their first dose should continue with that brand, NACI said.

June 17, 2021

NACI said the Pfizer or Moderna vaccine are preferred to start, though AstraZeneca and Janssen are acceptable. It also said a second dose of Pfizer or Moderna is "now preferred," though the other two vaccines are also effective.

July 2, 2021

NACI updated its recommendations saying those receiving Pfizer or Moderna should have a discussion about the "very rare risk" of myocarditis (inflammation of the heart) and/or pericarditis (inflammation of muscle around the heart) following immunization.

It also said that those who experienced these effects after their first dose should wait to get their second dose, until there's more information.

July 22, 2021

Those who've already had COVID-19 should still get a full course of immunization, NACI said.

Aug. 27, 2021

Moderna, along with Pfizer, is acceptable to give to those between 12 and 18.

Sept. 10, 2021

NACI released guidance on third "booster" doses. For those who are moderately to severely immunocompromised, their initial vaccine schedule should be three doses of Pfizer or Moderna; for those who previously had one or two doses, they should get a third dose of Moderna or Pfizer, with limited use of AstraZeneca for these doses, since there's a lack of evidence.

Sept. 28, 2021

A booster dose of Pfizer or Moderna should be given to long-term care residents and other seniors in congregate care who have received their first vaccine doses. This should come six months after the first round was completed. A booster of AstraZeneca or Janssen should be used only if the recipient cannot receive Pfizer or Moderna or they aren't available.

Previously, NACI said that COVID-19 vaccines should not be given 28 days before and 14 days after other vaccines. On Sept. 28, they scrapped this advice, saying they can now be given at the same time.

https://nationalpost.com/news/canada/national-advisory-committee-on-immunization

---

From: Deeks, Shelley
To: McNeil, Shelly
Subject: Fwd: Thank you
Date: Thursday, April 22, 2021 9:52:57 PM
Attachments: COVID-19 AZ Vaccine letter.pdf

Did you receive too?

Sent from my iPhone

Begin forwarded message:

From: "Saraza, Noel" <Noel.Saraza@astrazeneca.com>
Date: April 22, 2021 at 8:39:16 PM ADT
Cc: "Saraza, Noel" <Noel.Saraza@astrazeneca.com>
Subject: Thank you

Hello,

Please see attached letter from AstraZeneca Canada's Vice President of Scientific Affairs.

Thank you

Noel Saraza, RN, BScN

AstraZeneca Canada Inc.
Value, Access & Policy
1004 Middlegate Road, Mississauga, Ontario, L4Y 1M4
T: (416)986-8106 I VM: (905)566-7323 ext.47343 I Email: noel.saraza@astrazeneca.com

---

From: SICnurse,
To: McNeil, Shelly
Cc: Ring, Laura
Subject: New Covid SIC referrals,
Date: Friday, July 16, 2021 2:51:54 PM
Attachments: s.20(1) [redacted]

Hi Shelly,

Please see attached SIC referrals s.20(1) [redacted]

[redacted]

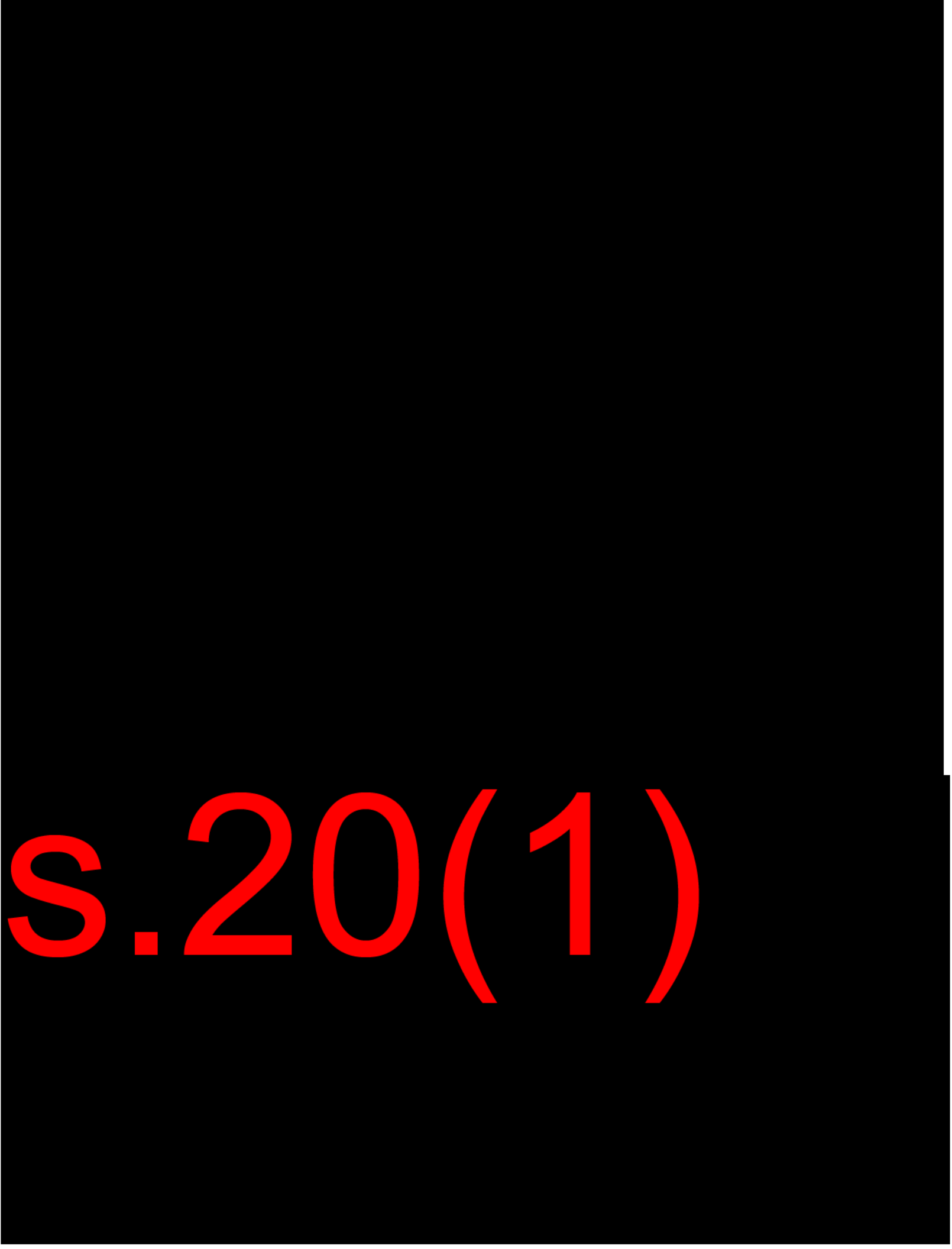
Laura once the patient has been seen by Shelly please send a copy of the letter to SICnuse@iwk.nshealth.ca and also to the CovidAEFI@nshealth.ca as they report back to MOH DR. Whynot.

Thank you,

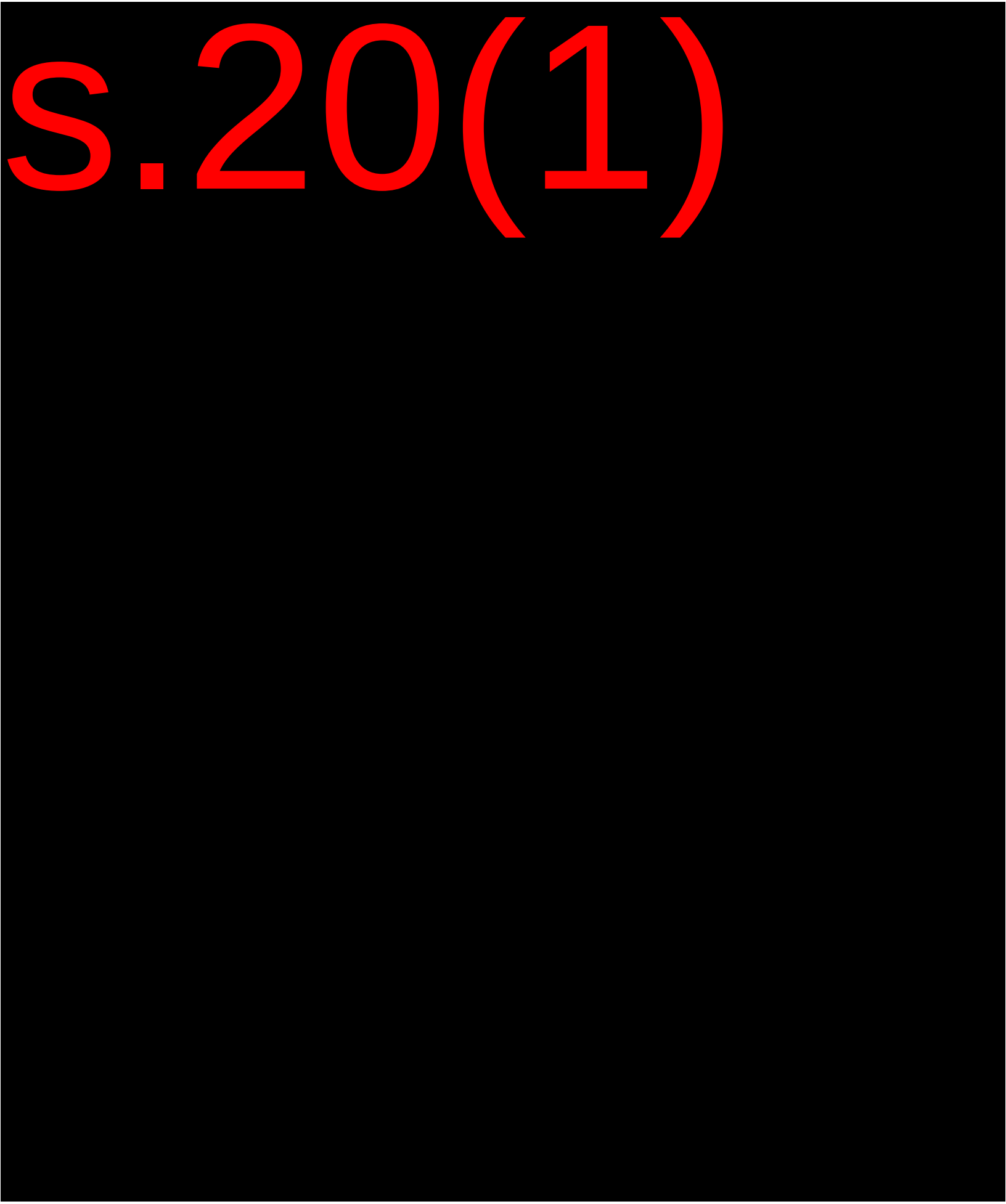
Pam

Pamela MacIntyre RN, CCRP
Research Coordinator / SIC(Special Immunization Clinic)Nurse
Canadian Center for Vaccinology
Goldbloom RCC Pavilion,4th Floor
Halifax, NS B3K 6R8
Tel: (902) 470-8948
Fax: (902) 470-7232
www. vaccineresearch.ca
A collaboration of Dalhousie University, IWK Health & Nova Scotia Health (NSH)

s.20(1)


s.20(1)

s.20(1)


s.20(1)

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s.20(1)

s.20(1)

s.20(1)

From:	McCormick, Bethany
To:	Stevenson, Colin; Adams, Cathy; Bennett, Marsha M; Bond, Paula; Boutilier, Nicole; Carr, Brendan; Carter, Joanne; Ciccarelli, Pam; Davidson, Angie; Grant, Krista L; Hirtle, Jodi; MacDonald, Madonna; McGarry, John; Squires, Stacey; Stevenson, Colin; Tomblin Murphy, Gail; Matthews, Wanda; Pugh, Cheryl; Sullivan, Vickie; Howlett, Todd; MacDougall, Brett; Northcott, Cheryl; Sommers, Ryan; LeBlanc, Angela; Rodier, Pascal; MacDonald, Bruce; Brumwell, Scott; Oxner, Dennis; Ferguson, Delwin; Flinn, Jill
Cc:	McNeil, Shelly; MacQuarrie, Cindy; Hatchette, Todd
Subject:	RE: COVID 19 - Incident Management Call (IMPORTANT) - ELT and Zone Check In
Date:	Monday, March 9, 2020 10:59:00 AM
Attachments:	COVID form 1-3_SAM_IDedits.Mar091_ID6.pdf COVID Patient Info Sheet no risk factor IDedits.pdf COVID Patient Info Sheet with risk factor IDedits.pdf

---

As per the request, Attached are the draft clinical assessment tools. Final versions to be completed tonight.

Bethany

-----Original Appointment-----
From: Stevenson, Colin
Sent: Sunday, March 8, 2020 6:21 PM
To: Stevenson, Colin; ~NSHA ELT; Matthews, Wanda; Pugh, Cheryl; McCormick, Bethany; Sullivan, Vickie; Howlett, Todd; MacDougall, Brett; Northcott, Cheryl; Sommers, Ryan
Subject: COVID 19 - Incident Management Call (IMPORTANT) - ELT and Zone Check In
When: Monday, March 9, 2020 10:00 AM-11:00 AM (UTC-04:00) Atlantic Time (Canada).
Where: Conference Call

We are setting up an ELT/Zone Incident Management Call for 1000 Monday morning. The purpose is get information on activities within operations/zones to prepare for expanded screening requirements.

Conference Number

1-855-453-6962

Passcode – 4772740#

Thank you for your attention.

From: Deeks, Shelley
To: McNeil, Shelly; Top, Karina; Whynot, Lesley
Subject: RE: FYI - VITT Clinical Guidance / List of VITT PT Leads
Date: Friday, May 7, 2021 4:14:15 PM
Attachments: image001.png

---

s.14(1) [redacted]

[redacted]

Shelley Deeks, MD, MHSc, FRCPC, FAFPHM
Deputy Chief Medical Officer of Health
Department of Health and Wellness

From: McNeil, Shelly <Shelly.McNeil@nshealth.ca>
Sent: May 7, 2021 2:50 PM
To: Deeks, Shelley <Shelley.Deeks@novascotia.ca>; Top, Karina <Karina.Top@iwk.nshealth.ca>; Whynot, Lesley <Lesley.Whynot@nshealth.ca>
Subject: RE: FYI - VITT Clinical Guidance / List of VITT PT Leads

Thanks
Yes- Sudeep is the contact for SIC and for NSH therapeutics team
s.14(1) [redacted]

Shelly A. McNeil, MD, FRCPC
Senior Medical Director, COVID Planning and Implementation
Chief, Division of Infectious Diseases
Nova Scotia Health Authority
Rm 5077 Dickson Bldg.
QEII Health Sciences Centre
Halifax, NS B3H 2Y9
Phone: (902) 473-5553
Fax: (902 473-7394
Administrative Assistant: Samantha.milligan@nshealth.ca

From: Deeks, Shelley [mailto:Shelley.Deeks@novascotia.ca]

Sent: Friday, May 7, 2021 2:16 PM
To: McNeil, Shelly <Shelly.McNeil@nshealth.ca>; Top, Karina <Karina.Top@iwk.nshealth.ca>; Whynot, Lesley <Lesley.Whynot@nshealth.ca>
Subject: FW: FYI - VITT Clinical Guidance / List of VITT PT Leads

Sharing this with you. Do you know if Sudeep Shivakumar is the person that we link with through SIC

Shelley Deeks, MD, MHSc, FRCPC, FAFPHM
Deputy Chief Medical Officer of Health
Department of Health and Wellness

From: Shattuck, Kathleen (PHAC/ASPC) <kathleen.shattuck@canada.ca> **On Behalf Of** Cidsc Secretariat (PHAC/ASPC)
Sent: May 7, 2021 2:09 PM
To: s.20(1) @gov.yk.ca s.20(1) @gov.yk.ca>; s.20(1) @health.gov.sk.ca s.20(1) @health.gov.sk.ca>; s.20(1) @gov.nu.ca; s.20(1) @gov.nt.ca; Archibald, Chris (PHAC/ASPC) <chris.archibald@canada.ca>; s.20(1) msss.gouv.qc.ca>; s.20(1) @ontario.ca; s.20(1) @gov.ab.ca; Cidsc Secretariat (PHAC/ASPC) <phac.cidsc.secretariat.aspc@canada.ca>; s.20(1) @health.gov.sk.ca>; s.20(1) @ontario.ca; s.20(1) @bccdc.ca; s.20(1) @gov.nt.ca; s.20(1) @oahpp.ca; Fitzgerald-Husek, Alanna (PHAC/ASPC) <alanna.fitzgerald-husek@canada.ca>; Gaudreau, Marc-Andre (PHAC/ASPC) <marc-andre.gaudreau@canada.ca>; Doyle-Bedwell, George H <George.Doyle-Bedwell@novascotia.ca>; s.20(1) @gnb.ca; s.20(1) @gov.nt.ca; s.20(1) @msss.gouv.qc.ca; 0(1) @oahpp.ca; s.20(1) @gov.ab.ca; s.20(1) GOV.NU.CA; s.20(1) @health.gov.sk.ca; s.20(1) @gov.nt.ca; Dean, Kelly E <Kelly.Dean@novascotia.ca>; s.20(1) @gov.yk.ca; s.20(1) @inspq.qc.ca; s.20(1) @gnb.ca; s.20(1) @ihis.org; s.20(1) @inspq.qc.ca; s.20(1) @bccdc.ca; s.20(1) @gov.pe.ca>; s.20(1) @msss.gouv.qc.ca; Njoo, Howard (PHAC/ASPC) <howard.njoo@canada.ca>; OCMHO@health.gov.sk.ca; s.20(1) @gnb.ca>; s.20(1) @oahpp.ca>; s.20(1) @msss.gouv.qc.ca; s.20(1) @gov.nl.ca; s.20(1) @health.gov.sk.ca; s.20(1) @gov.mb.ca; 1) @gov.nt.ca; Sciberras, Jill (PHAC/ASPC) <jill.sciberras@canada.ca>; s.20(1) @gnb.ca; Deeks, Shelley <Shelley.Deeks@novascotia.ca>; Cole, Teri J <Teri.Cole@novascotia.ca>; s.20(1) @gov.mb.ca; s.20(1) @health.gov.sk.ca; s.20(1) @bccdc.ca
Subject: FYI - VITT Clinical Guidance / List of VITT PT Leads

TAC Members,

As promised at the May 3 TAC meeting, attached is the Clinical Guidance and List of VITT PT leads, as

well as information on a training and education session.

TAC Secretariat

Clinical guidance:

Thrombosis Canada, with agreement from many provincial thrombosis leaders, and in collaboration with PHAC, has developed VITT clinical guidance which has been posted online in English and French.

In order to support provinces with key contacts in their jurisdiction, provincial thrombosis *champions* have been identified. These *champions* have:

1. Concurred on Canadian Guidelines, and will be advised of changes.
2. Agreed to directing care to usual pathway; they can be called by public health or physicians with possible cases and will direct to usual pathways.
3. Agreed to being the point person for directing samples to McMaster Platelet Immunology Laboratory.

The list of VITT Provincial Leads is provided in Appendix B.

Training and Education

Webinar: PHAC, Thrombosis Canada, and the National Collaborating Centre for Infectious Diseases delivered a webinar to inform health care providers on the treatment and reporting of VITT. The webinar was presented in English on April 21, 2021 and in French on April 23, 2021. A recording of the webinar is available in English and in French.

Marina

From: Ramsey, Tasha
To: Boland, Melissa L; McNeil, Shelly
Subject: Re: Myocarditis and pericarditis question
Date: Wednesday, October 27, 2021 3:05:05 PM
Attachments: image001.png

---

s.14(1) [redacted]

[redacted]

Tasha

From: "Boland, Melissa L" <Melissa.Boland@novascotia.ca>
Date: Wednesday, October 27, 2021 at 1:15 PM
To: "Ramsey, Tasha" <Tasha.Ramsey@nshealth.ca>, "McNeil, Shelly" <Shelly.McNeil@nshealth.ca>
Subject: RE: Myocarditis and pericarditis question

Hi Tasha-

s.14(1) [redacted]

[redacted]

[redacted]

Thanks,
Melissa

From: Ramsey, Tasha <Tasha.Ramsey@nshealth.ca>
Sent: October 24, 2021 3:42 PM
To: McNeil, Shelly <Shelly.McNeil@nshealth.ca>; Boland, Melissa L <Melissa.Boland@novascotia.ca>
Subject: Myocarditis and pericarditis question

Hi Shelly and Melissa,

s.14(1) [redacted]

[redacted]

Tasha

Tasha Ramsey (she/her), BSc (Pharm), ACPR, PharmD

Clinical Coordinator– Infectious Diseases and Internal Medicine
Pharmacy Department | Nova Scotia Health
1796 Summer Street, Halifax, NS | Canada | B3H 3A7
Mi'kma'ki—Unceded Mi'kmaq Territory
☎902-473-6829
✉ Tasha.Ramsey@nshealth.ca

Assistant Professor– College of Pharmacy
Dalhousie University
5968 College Street, PO Box 15000| Halifax, NS | Canada | B3H 4R2
✉ Tramsey@dal.ca

From: Boland, Melissa L
To: Ramsey, Tasha; McNeil, Shelly
Subject: RE: Myocarditis and pericarditis question
Date: Wednesday, October 27, 2021 3:48:07 PM
Attachments: image001.png

Hi Tasha-

Thanks for the feedback. CanImms pushes out a new release each time we update, so we can try to work this in with our next s.14(1) revision.

Melissa

From: Ramsey, Tasha <Tasha.Ramsey@nshealth.ca>
Sent: October 27, 2021 3:05 PM
To: Boland, Melissa L <Melissa.Boland@novascotia.ca>; McNeil, Shelly <Shelly.McNeil@nshealth.ca>
Subject: Re: Myocarditis and pericarditis question

s.14(1) [redacted]

[redacted]

Tasha

From: "Boland, Melissa L" <Melissa.Boland@novascotia.ca>
Date: Wednesday, October 27, 2021 at 1:15 PM
To: "Ramsey, Tasha" <Tasha.Ramsey@nshealth.ca>, "McNeil, Shelly" <Shelly.McNeil@nshealth.ca>
Subject: RE: Myocarditis and pericarditis question

Hi Tasha-

s.14(1) [redacted]

[redacted]

[redacted]

Thanks,
Melissa

From: Ramsey, Tasha <Tasha.Ramsey@nshealth.ca>
Sent: October 24, 2021 3:42 PM
To: McNeil, Shelly <Shelly.McNeil@nshealth.ca>; Boland, Melissa L <Melissa.Boland@novascotia.ca>
Subject: Myocarditis and pericarditis question

Hi Shelly and Melissa,

[redacted]5(1)(a)

s.14(1) [redacted]

[redacted]

[redacted]

Tasha

Tasha Ramsey (she/her), BSc (Pharm), ACPR, PharmD

Clinical Coordinator– Infectious Diseases and Internal Medicine
Pharmacy Department | Nova Scotia Health
1796 Summer Street, Halifax, NS | Canada | B3H 3A7
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☎902-473-6829
✉ Tasha.Ramsey@nshealth.ca

Assistant Professor– College of Pharmacy
Dalhousie University
5968 College Street, PO Box 15000| Halifax, NS | Canada | B3H 4R2
✉ Tramsey@dal.ca

From: Miller, Ashley P
To: Quraishi, Ata; Short, Christine; Gruchy, Steven; Magee, Kirk; Sullivan, Vickie
Cc: McNeil, Shelly; Connell, Katherine; Morrison, Michelle; Wiseman, Anthony; Mullaly, Erica; Locke, Sara; Hutchings, Debbie; AbdelWahab, Amir; s.20(1) Anderson, Kim; Bata, Iqbal; Beydoun, Hussein; Bishop, Helen; Cox, Jafna L; Crowell, Richard; Elkhateeb, Osama; Gardner, Martin; Giacomantonio, Nicholas; Gray, Chris J.; Hayami, Doug; Horne, Gabrielle; Jackson, Simon [redacted]; Kells, Catherine; Kidwai, Bakhtiar; Koilpillai, Chris; MacIntyre, Ciorsti J; Mears, Paul; Merrick, Evan P; Moeller, Andrew; Mulvagh, Sharon; Nadeem, Najaf; Parkash, Ratika; Rajda, Miroslaw; Ramer, Sarah; Sapp, John; Sheridan, William; Stewart, Robbie; Styles, Kim; Title, Lawrence; Ahmad Alkharaza; Ahmed Mokhtar; Andrew Caddell; Annaelle Kaczmarek; s.20(1) [redacted]; Belliveau, Daniel J2; Edwin Bamwoya; Joshua Janzen; Kate MacEachen; Murnaghan, Kyle; Adegunna, Olumide; Issa, Nour; Jalal, Dleer; Klimek, Marek; Oun, Afaf; Ramirez, Jose; Stubeda, Iryna
Subject: RE: Telemetry and COVID
Date: Tuesday, March 24, 2020 9:04:33 AM

Thanks so much Ata. s.14(1) [redacted].

s.14(1) [redacted].

Of course feel free to call us at any time to discuss if you are concerned about a patient,
Ashley

From: Quraishi, Ata
Sent: Tuesday, March 24, 2020 8:43 AM
To: Miller, Ashley P; Short, Christine; Gruchy, Steven; Magee, Kirk; Sullivan, Vickie
Cc: McNeil, Shelly; Connell, Katherine; Morrison, Michelle; Wiseman, Anthony; Mullaly, Erica; Locke, Sara; Hutchings, Debbie; AbdelWahab, Amir; s.20(1) Anderson, Kim; Bata, Iqbal; Beydoun, Hussein; Bishop, Helen; Cox, Jafna L; Crowell, Richard; Elkhateeb, Osama; Gardner, Martin; Giacomantonio, Nicholas; Gray, Chris J.; Hayami, Doug; Horne, Gabrielle; Jackson, Simon; [redacted]; Kells, Catherine; Kidwai, Bakhtiar; Koilpillai, Chris; MacIntyre, Ciorsti J; Mears, Paul; Merrick, Evan P; Moeller, Andrew; Mulvagh, Sharon; Nadeem, Najaf; Parkash, Ratika; Quraishi, Ata; Rajda, Miroslaw; Ramer, Sarah; Sapp, John; Sheridan, William; Stewart, Robbie; Styles, Kim; Title, Lawrence; Ahmad Alkharaza; Ahmed Mokhtar; Andrew Caddell; Annaelle Kaczmarek; s.20(1) [redacted] Belliveau, Daniel J2; Edwin Bamwoya; Joshua Janzen; Kate MacEachen; Murnaghan, Kyle; Adegunna, Olumide; Issa, Nour; Jalal, Dleer; Klimek, Marek; Oun, Afaf; Ramirez, Jose; Stubeda, Iryna
Subject: RE: Telemetry and COVID

Hi Ashley

s.14(1) [redacted]

[redacted]

[redacted]

[redacted]

Regards
Ata

Ata ur Rehman Quraishi MBBS, FCPS, FACC
Professor, Faculty of Medicine, Dalhousie University
Head Division of Cardiology
QE II Health Sciences Centre
Room # 2133 Halifax Infirmary
1796 Summer Street
Halifax NS
B3H3A7

Telephone # 902 473 6540
Fax # 902 473 2434
Email: ata.quraishi@nshealth.ca

From: Miller, Ashley P
Sent: Monday, March 23, 2020 4:52 PM
To: Short, Christine <Christine.Short@nshealth.ca>; Quraishi, Ata <Ata.Quraishi@nshealth.ca>; Gruchy, Steven <Steven.Gruchy@nshealth.ca>; Magee, Kirk <Kirk.Magee@nshealth.ca>
Cc: McNeil, Shelly <Shelly.McNeil@nshealth.ca>; Connell, Katherine <Katherine.Connell@nshealth.ca>
Subject: Telemetry and COVID

Hi all,

Something came up today that I wanted to flag…

[redacted]

[redacted]

[redacted]

Thanks,
Ashley

_____
Ashley Miller
General Internist
Director of Outpatient Care, Division of General Internal Medicine
Office 414, Bethune Building, 1276 South Park Street
(902) 473-1923 (office)/(709) 749-0490 (cell)
AshleyP.Miller@nshealth.ca

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From: COVID-19 AEFIs
Sent: Tuesday, July 13, 2021 1:50 PM
To: Whynot, Lesley
Subject: s.20(1) [redacted]

Hi Dr. Whynot,

s.20(1) [redacted]

Thanks,
Kristin

From: Whynot, Lesley <Lesley.Whynot@nshealth.ca>
Sent: Tuesday, July 13, 2021 8:07 AM
To: COVID-19 AEFIs <CovidAEFI@nshealth.ca>
Cc: MacLellan, Kristin <Kristin.MacLellan@nshealth.ca>
Subject: s.20(1) [redacted]

Hi again,

s.20(1) [redacted]

Please keep me posted on the status of this case.

Thanks so much!

Lesley Whynot, MD, CCFP
Physician Lead, AEFI Management, Nova Scotia Health & Wellness
Assistant Professor, Dept. Family Medicine, Dalhousie University
902-719-0520 cell
lesley.whynot@nshealth.ca

From: Whynot, Lesley
Sent: July 12, 2021 2:41:58 PM
To: COVID-19 AEFIs

Cc: MacLellan, Kristin
Subject: Re: s.20(1) [redacted]

Hi there, thanks for the SBAR.

s.20(1) [redacted]

Thanks.

Lesley Whynot, MD, CCFP
Physician Lead, AEFI Management, Nova Scotia Health & Wellness
Assistant Professor, Dept. Family Medicine, Dalhousie University
902-719-0520 cell
lesley.whynot@nshealth.ca

From: COVID-19 AEFIs
Sent: July 12, 2021 12:41:15 PM
To: Whynot, Lesley
Cc: MacLellan, Kristin
Subject: s.20(1) [redacted]

Hi Dr Whynot,

s.20(1) [redacted]
Noella

From: MacLellan, Kristin <Kristin.MacLellan@nshealth.ca>
Sent: Monday, July 12, 2021 12:23 PM
To: COVID-19 AEFIs <CovidAEFI@nshealth.ca>
Subject: s.20(1) [redacted]

Hi Noella – s.20(1) [redacted]

Thanks,
Kristin

s.20(1) [redacted]

s.20(1)

Kristin MacLellan, RN, BScN, MPH
Public Health Nurse
Covid AEFI Response Team
Tel: 902-956-0923
For information on Covid 19, please visit
www.novascotia.ca/coronavirus

July 13, 2021

SIC Team

Dear SIC Team,

Sincerely,

Kristin MacLellan, RN, BScN, MPH
Public Health Nurse
(902)956-0923
CovidAEFI@nshealth.ca
On behalf of MOH: Dr. Lesley Whynot

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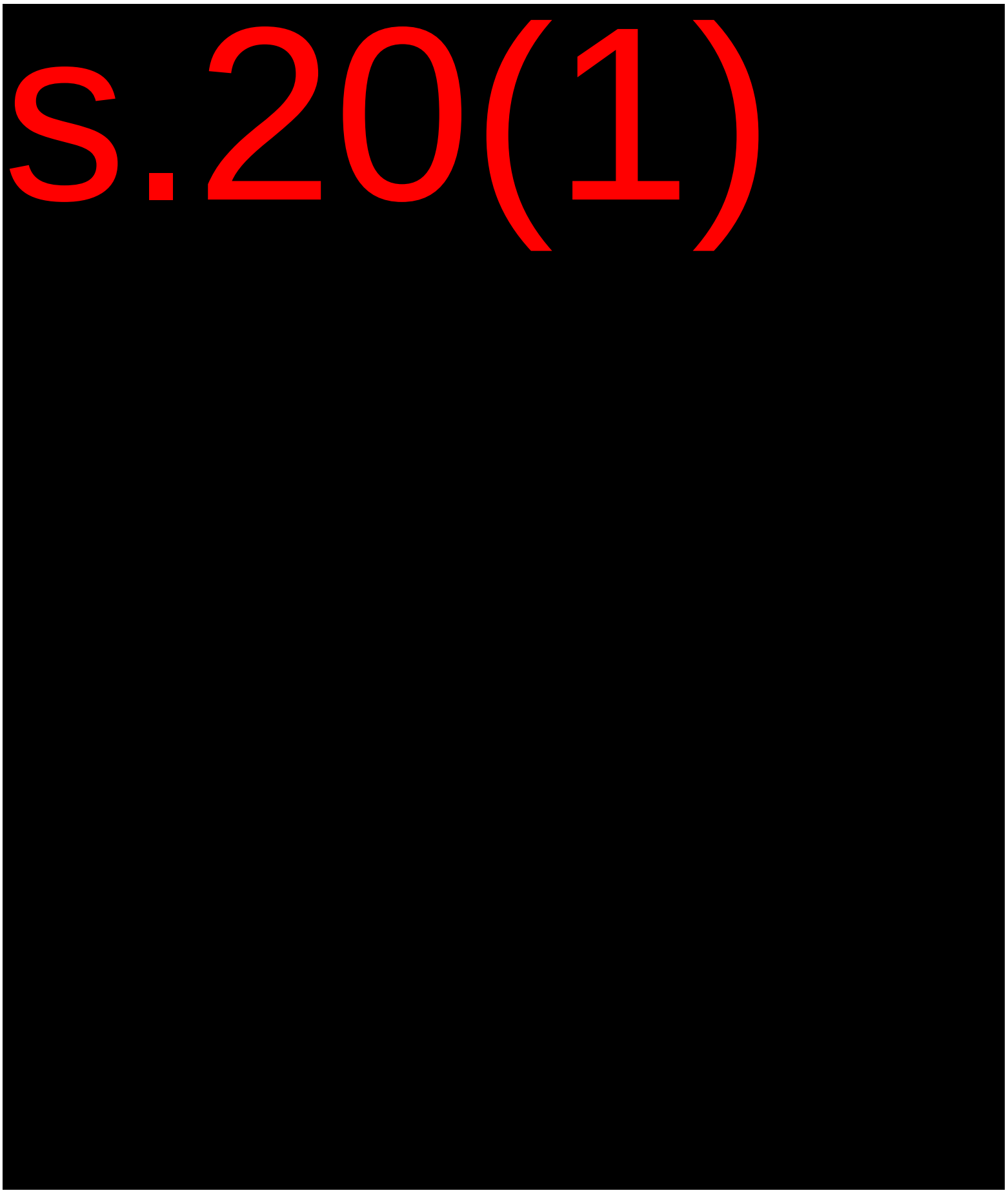
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