Scientific Advisory Group

COVID-19 Scientific Advisory Group Rapid Brief

Medical Exemptions for COVID-19 Vaccine: Jurisdictional Scan

September 7, 2021

Interim Report

Alberta Health Services

Physical distancing works

Table of contents

Lay Summary

- It is very important that all Albertans that are able receive the COVID-19 vaccine to protect themselves, stop the spread, and to end the pandemic.
- Across all of the guidelines reviewed, there were almost no medical reasons that mean someone is not able to get one of the COVID-19 vaccines, although some conditions should be reviewed by a specialist before decisions are made.
  The guidance reviewed can be synthesized and summarized as:
  - Those people who had a documented severe allergic (anaphylactic) reaction to a first dose of vaccine or to a known vaccine ingredient should be seen by an allergist to determine how best to get them the vaccine. It may mean they need to take a different version of the vaccine.
  - Someone that developed a very rare reaction such as myocarditis to the first dose of the vaccine should wait to receive their second dose until advised to do so by their specialist.
  - Some individuals should receive an mRNA vaccine (Pfizer or Moderna) rather than a viral vector vaccine (AstraZeneca/COVIShield). This may include women that are pregnant, those living with some specific chronic diseases, and those that had particular types of reactions to the first dose of that vaccine.
  - Support for physicians and patients who need assessment for any of these possible reasons for delay, exemption, or need for a different vaccine is recommended (that is, creation of a pathway for assessment and referral).
  - Almost all Albertans can receive the COVID-19 vaccine, and should. If individuals have specific questions about their eligibility for the vaccine, then they should speak with their family doctor or call HealthLink.

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Topic: Medical Exemption for COVID-19 Vaccination

1. **What medical conditions should be considered to be valid exemptions from required COVID-19 vaccination using current vaccine products?**

Context

- This review of current guidelines considers medical exemptions and does not address human rights, religious or other possible non-medical reasons for seeking vaccine exemptions.
- This Rapid Review is primarily a Jurisdictional Scan. The purpose of this jurisdictional scan is to identify and review policy/approaches used in other jurisdictions (provinces, nations, organizations), including their evidence base.
- Guidance from major national public health and health organizations with similar populations to Alberta was central in this review. Policies for individual organizations (such as corporations or large employers) was generally not available and is not incorporated in this review.
- This synthesis of policies that consider medical exemptions for vaccination against COVID-19 is provided for consideration of AHS policymakers and clinical groups. Although there was considerable consensus noted, details from specific organizations (especially where there are differences) available in the appendix.

Key Messages from the Evidence Summary

- In existing guidance there are very few absolute medical exemptions for COVID-19 vaccination; this finding was consistent across jurisdictions.
- The most prominent potential exemption is related to severe allergy/anaphylaxis to the COVID-19 vaccine itself, which is noted in all documents; however the guidance on subsequent steps for these individuals varied. Note: severe allergic reaction to the COVID-19 vaccine is rare; even among those deemed as being 'highly allergic' only 0.7% had a severe allergic reaction to the vaccine administered under medical supervision (Shavit et al., 2021). In the United States, the CDC reports 11.1 cases of anaphylaxis for one million doses of vaccine given (CDC, 2021e).
- Most guidance suggests specific assessment of potential significant allergy after the first dose. "Assessment by an allergist is warranted in any individual with a suspected allergy to a COVID-19 vaccine or any of its components" (Canadian Society for Allergy and Clinical Immunologists, 2021).

Table 1. INITIAL dose of COVID-19 vaccine: synthesis of considerations for vaccine exemption, deferral, or modified administration in specific populations

Population	Recommendation
Individuals for whom the first dose should be formally deferred for further exemption assessment, or for a resolution of a potentially complicating condition:	
Severe allergic reaction/anaphylaxis following receiving/ingestion of any component of COVID-19 vaccine (refer for Allergy Assessment Pathway)	• Defer until assessment completed by an allergist/immunologist; assessment may or may not result in exemption • COVID-19 vaccination using a different type of vaccine may be considered for re-immunization • If immunization with a different platform is offered, individuals should be observed for at least 30 minutes after immunization
Current confirmed diagnosis of myocarditis or pericarditis from any cause	• mRNA COVID-19 vaccination should be deferred until myocarditis or pericarditis resolve • Specialist referral should be considered
Persons who received antiviral monoclonal antibody therapy or convalescent plasma for COVID-19 treatment	• These people may not mount a vaccine response • Interim suggestion: deferral of vaccination for 3 months is suggested (based on antibody half-life). • Expert clinical opinion should be sought on a case-by-case basis
Individuals with current COVID-19 infection	• Defer vaccination until person has recovered from the acute illness and more than 10 days have elapsed since symptom onset. (Some guidance suggests vaccination 3 months after acute illness.)
Individuals for whom vaccination i**s recommended** after appropriate counselling and informed consent (based on multijurisdictional risk – benefit assessment)	
Pregnant, breastfeeding, or those of childbearing years	• mRNA COVID19 vaccine **is recommended** for individuals in the authorized age group who are pregnant, breastfeeding, or planning to become pregnant (see appendix for additional information on vaccines and pregnancy, lactation and fertility).
Previous severe allergic reaction to any injectable therapy unrelated to a component of COVID-19 vaccines (e.g., intramuscular, intravenous, or subcutaneous vaccines or therapies)	• People with prior reactions to other therapies or vaccines may be routinely vaccinated and do not need referral • An extended period of observation post-vaccination of 30 minutes should be provided
History of other allergies (allergy not related to a component of authorized COVID-19 vaccines)	• Can receive COVID-19 vaccines without any special precautions
Specific to AstraZeneca/COVISHIELD COVID-19 Vaccine	**Recommendation**
Previous diagnosis of capillary leak syndrome	• Rare reports of patients with CLS developing symptoms after AstraZeneca/COVISHIELD COVID-19 vaccine. • mRNA COVID-19 vaccine should be offered

Table 2. SECOND dose of COVID-19 vaccine: considerations for vaccine exemption, deferral, or modified administration in specific populations

Population	Recommendation
EXEMPTION: Severe allergic reaction/anaphylaxis following COVID-19 vaccination as assessed through Allergy Assessment Pathway	• Defer until assessment completed by an allergist/immunologist; assessment may or may not result in exemption for second dose • COVID-19 vaccination using a different type of vaccine may be considered for re-immunization • If immunization with a different platform is offered, individuals should be observed for at least 30 minutes after immunization
DEFERRAL: History of severe allergic reaction/anaphylaxis following the first dose of mRNA vaccine PENDING Vaccine Allergy Assessment Pathway	• Designation is time limited • Requires referral to Vaccine Allergy Assessment Pathway • Some patients with either immediate or late local reactions to dose one may safely receive a second dose of the same product
DEFERRAL with reassessment: Diagnosed with myocarditis or pericarditis following the first dose of an mRNA COVID-19 vaccine	• Further mRNA COVID-19 vaccination should be deferred until more evidence is available • Designation is time limited • Referral to cardiologist for reassessment in 6-12 months is suggested
Specific to dose 2 of AstraZeneca/COVISHIELD COVID-19 Vaccine	**Recommendation**
Individuals with Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) following AstraZeneca/COVISHIELD COVID-19 vaccine	• Should not receive a second dose of a viral vector COVID-19 vaccine • An mRNA COVID-19 vaccine should be offered (mixed schedule)
Individuals with thrombosis with thrombocytopenia or designated coagulation disorders including DVT, cerebral, or MI or CVA that have a temporal association with vaccination*	• An mRNA COVID-19 vaccine should be considered (mixed schedule) • Referral to thrombosis specialist for management around second vaccination dose

*Relevant definitions can be found at https://open.alberta.ca/dataset/4d885a4c-f9b3-4434-bf5a-5accb63e22a1/resource/c6c6c92d-1015-4c79-ae4a-b9daf9628086/download/health-aip-aefi-covid-19-2021-07-15.pdf

Practical Guidance

1) There are no medical conditions that are universally identified as absolute medical exemption for initial COVID-19 vaccination. There may be a small number of persons with medical exemptions assigned after a formal assessment process, or for whom deferral of a second dose or use of an alternate vaccine (anaphylaxis to COVID-19 vaccine, mRNA associated myo/pericarditis) is currently recommended. Referral for appropriate specialist assessment of some conditions may be required.

2) Deferral of vaccination may be required for individuals experiencing acute COVID-19 illness until the acute infection has resolved and for at least 10 days from the onset of symptoms. Timing of vaccination after that point should be guided by local protocols.
3) A deferral of 3 months is suggested for individuals that have received COVID-19 specific antiviral monoclonal antibodies or convalescent plasma as vaccine doses may not be effective while there are circulating antibodies against COVID-19.
4) Deferral pending designated specialist assessment of potential first dose complications may be warranted. The deferral is time limited and requires documentation of the time frame of the planned assessment/deferral.
5) A referral/assessment process should be developed by AHS to facilitate clinician and patient access to specialist support for assessment of;

a) History of severe allergy/anaphylaxis to the first COVID-19 vaccine dose
b) History of probable myo/pericarditis after the first COVID-19 vaccine dose
c) Documentation of vaccine related thrombosis- thrombocytopenia complications
d) Severe psychiatric or psychologic contraindications such as needle phobia which have been refractory to standard management.
e) Any severe rare adverse event to dose 1 of vaccine (reported to AEFI) where updated review of existing data may be required to guide dose 2 planning (e.g. temporally associated Guillain Barre syndrome or severe dermatologic reactions.)

6) Where necessary any potential vaccine reactions require report through the Adverse Event Following Immunization (AEFI) protocol (the standard recommendation for all health care providers aware of a possible reaction). The standard policy is found at https://open.alberta.ca/dataset/d86b52a9-45f4-4948-8a06-53b2c045135e/resource/c534068f-0382-4434-b1ab-6905ee9495ec/download/aip-adverse-events-following-immunization-policy-2021-07.pdf

The outcome of COVID-19 Vaccination Assessment specialist referral processes may include:

1) Exemption from further COVID-19 vaccination. Exemption status will require annual review given the evolution of medical knowledge and potential availability of new COVID-19 vaccine products.
2) Suggestion of an alternate vaccine product.
3) Provision for monitored vaccination.
4) Continuation of approved deferred status with a stated reassessment date. This will allow for periodic review of current vaccine literature and of different vaccine product availability.

For people with a status of **COVID-19 vaccine exemption or approved deferral**, risk education, and if relevant, discussion of reasonable measures for workplace accommodation is required.

Limitations: This synthesis of guidance reported by jurisdictions including in this scan identifies guidance based on current evidence as assessed by these jurisdictions; this is not a review of the underlying evidence. Further, the included guidance can only reflect

currently knowledge. This review is not a consideration of all possible but as yet unknown medical consequences that potentially may lead to identification of medical exemptions in the future.

Strength of Evidence & Methods

This Jurisdictional Scan identifies guidance but is not a search and synthesis on underlying scientific literature; as such, the evidence and strength of evidence is not assessed. We conducted a search of grey literature, with a focus on websites / documentation from high profile public health and health agencies in North America and Western Europe for guidance on COVID-19 vaccination, specifically medical contraindications or precautions to vaccination. Where available, the supporting scientific evidence for stated exemptions was reviewed, but a primary search and review of the scientific literature for medical exemptions for COVID-19 vaccination was not conducted. Overall, the first pass jurisdictional scan resulted in identification of consistent exemptions among the three national and four provincial jurisdictions included, and search and inclusion of additional guidelines was not conducted as it was deemed unlikely to additive at this time.

Limitations of this review

The Jurisdictional Scan was limited to online resources available reporting medical exemptions for COVID-19 vaccination. Numerous corporations (particularly in the United States) have developed internal policies related to mandatory vaccination and vaccine exemptions that are not readily available. Therefore, this document focuses on available information provided by oversight groups.

Summary of Evidence

What medical conditions should be considered as valid exemptions from required COVID-19 vaccination using current vaccine products?

Evidence from secondary and grey literature

Overall guidelines identify similar potential contraindications, however variability in recommended processes exists.

Below is a summary of specific medical exemption categories and considerations (both contraindications and precautions) described by various organizations, however jurisdiction specific information is available in Appendix A.

Allergy

Note: mild to moderate immediate allergic reactions are defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration. Severe allergic reaction refers to an anaphylactic reaction.

Canadian guidance: NACI indicates that (Government of Canada, 2021b; National Advisory Committee on Immunization, 2021):

- COVID-19 vaccine should not be offered **routinely** to individuals with 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). A COVID-19 vaccine using a different platform may be considered for re-immunization.
- A COVID-19 vaccine should not be routinely offered to individuals who are allergic to any component of the specific COVID-19 vaccine or its components (such as individuals allergic to Polyethylene Glycol (PEG)).
- Individuals with previous severe allergic reaction (e.g., anaphylaxis) to injectable therapy unrelated a component of authorized COVID-19 vaccines may be routinely vaccinated with an extended observation time of 30 minutes.
- Individuals with **suspected but unproven** allergy to a vaccine component (e.g. PEG) may be routinely vaccinated and do not need a specific assessment regarding this suspected allergy with an extended observation time of 30 minutes.
- Individuals with a history of allergy unrelated to a component of COVID-19 vaccines or other injectable therapy (e.g. foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions.

The Canadian Society of Allergy and Clinical Immunology (Canadian Society for Allergy and Clinical Immunologists, 2021) state that:

- Assessment by an allergist is warranted in any individual with a suspected allergy to a COVID-19 vaccine or any of its components.
- Assessment by an allergist is NOT required for individuals with a history of unrelated allergies, including to allergies to foods, drugs, insect venom or environmental allergens.

The National Health Service (NHS), United Kingdom (NHS , 2021b) provides a flowchart to advise on allergic reactions to first dose of vaccine (Appendix B). Additionally, tools that have been developed in the United States and the United Kingdom to assist with determining vaccine safety for specific individuals have been identified in Appendix C as potential resources.

Individuals with a history of myocarditis/pericarditis after first dose of mRNA vaccination

NACI, the CDC and the NHS all have similar recommendations to defer the second dose of mRNA vaccination if the individual experience myocarditis or pericarditis after the first dose, pending further data.

Individuals with underlying medical conditions who should be advised to receive COVID-19 vaccination

A number of individuals may have concerns around vaccination related to medical conditions. Guidance documents from the CDC in the US, Health Canada and the NHS England provide specific reassurance for the following groups:

The CDC states that individuals with underlying medical conditions may be at increased risk of severe outcomes from contracting COVID-19(CDC, 2021c, 2021d). The current

CDC guidance states the following individuals **are advised to be vaccinated**: (this pertains to individuals who have not yet received a first dose of COVID-19 vaccine)

- Individuals with weakened immune systems (such as those living with HIV, taking medications that cause immunosuppression, etc.).
- Individuals with autoimmune conditions.
- Individuals with a history of Guillain Barre Syndrome (GBS). If available, the mRNA vaccine may be preferable.
- Individuals with history of Bell's Palsy.
- Individuals that have received dermal filler. They may experience some swelling near the dermal filler site.
- Individuals with risk factors for venous thromboembolism (VTE), defined as deep vein thrombosis, pulmonary embolism, or both

Health Canada (Government of Canada, 2021b) also states:

- Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications post-vaccination and may be immunized without discontinuation of their anticoagulation therapy.

NHS England (National Health Service, 2021d) addresses immune conditions:

- Individuals taking immunosuppressive medications (such as chemotherapy, those that received organ transplant, long-term immunosuppressive medicines, long-term systemic corticosteroids, etc.) should be prioritized for receiving the COVID-19 vaccine.
- Patients about to begin immunosuppressive therapy should be prioritized to receive the vaccine prior to initiating therapy

Individuals that are pregnant, breastfeeding, or of childbearing years (fertility related concerns)

- Guidance is consistent across jurisdictions that COVID-19 vaccination should be recommended to individuals that are pregnant, breastfeeding or planning to get pregnant. There is evolving data that suggests that pregnancy may be associated with elevated risk of requiring critical care support in COVID-19 infection. A brief summary of information specific to this population is provided in Appendix D.

Viral vector vaccine specific considerations

NACI(National Advisory Committee on Immunization, 2021) states:

- Patients who have experienced venous or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine should not receive a second dose of a viral vector COVID-19 vaccine.
- Individuals who have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia or heparin-induced thrombocytopenia (HIT) should be offered an mRNA vaccine where available. Viral vector vaccine should only be used where the benefit outweighs the potential risk and mRNA is not available.

- Individuals with a history of capillary leak syndrome should not receive the AstraZeneca /COVISHIELD COVID-19 vaccine.

Synthesis of the Information Relating to Question 1

(See Tables 1 & 2) The following summarizes identified potential medical exemptions or deferral of routine administration of the COVID-19 vaccination after formal assessment:

- Anaphylaxis and allergies to a COVID-19 vaccine or any of its components
- Thrombosis and thrombocytopenia following viral vector COVID-19 vaccination (should not receive a subsequent dose of a viral vector vaccine)
- Individuals with a history of capillary leak syndrome should not receive the AstraZeneca /COVISHIELD COVID-19 vaccine.
- COVID-19 vaccines should not be given simultaneously with antiviral monoclonal antibodies or convalescent plasma.

The following summarizes precautions for individuals with the following conditions:

- Individuals with hypersensitivity and allergies may require additional observational periods
- In persons with acute COVID-19 illness, vaccination should be deferred
- In individuals with bleeding disorders, their condition should be managed prior to immunization to minimize the risk of bleeding
- Individuals with a history of both thrombosis and thrombocytopenia should only receive a viral vector COVID-19 vaccine if the potential benefits outweigh the potential risks. An alternate COVID-19 vaccine (mRNA) should be offered
- In those with mRNA associated myocarditis and/or pericarditis, the second dose in the mRNA COVID-19 vaccination series should be deferred

Evolving Evidence

Research on SARS-CoV-2 is continually evolving and as such the evidence will continue to be assessed as new information is provided. It is noted that vaccine safety is constantly monitored and reported.

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Appendix A: Jurisdiction Specific Guidance

NACI

The National Advisory Committee on Immunization (Government of Canada, 2021; National Advisory Committee on Immunization, 2021), which provides independent advice to the Public Health Agency of Canada, recommends the following contraindications to routine administration, some of which are timing related or vaccine dependent:

- Anaphylaxis and allergies to a COVID-19 vaccine
- Thrombosis and thrombocytopenia following vaccination (should not receive a subsequent dose of a viral vector vaccine)
- Individuals with a history of capillary leak syndrome should not receive the AstraZeneca /COVISHIELD COVID-19 vaccine.
- COVID-19 vaccines should not be given simultaneously with antiviral monoclonal antibodies or convalescent plasma.
- The National Advisory Committee on Immunization (Government of Canada, 2021) also recommends precautions for individuals with the following conditions:
    - Hypersensitivity and allergies
    - Acute COVID-19 illness
    - Individuals with bleeding disorders should be managed prior to immunization to minimize the risk of bleeding
    - Individuals that experienced venous or arterial thrombosis with thrombocytopenia should only receive a viral vector COVID-19 vaccine if the potential benefits outweigh the potential risks. An alternate COVID-19 vaccine should be offered
    - Individuals who experience myocarditis or pericarditis following the first dose of the mRNA COVID-19 vaccination should have their second dose deferred until further research is available to provide guidance.
- For individuals that experienced myocarditis or pericarditis post first dose administration of an mRNA COVID-19 vaccine, the second dose of the mRNA COVID-19 vaccination should be deferred.

CDC

The United States Centre for Disease Control (CDC, 2021b, 2021d) suggests:

- Individuals that had a severe allergic reaction or an immediate allergic reaction to any ingredient in an mRNA COVID-19 vaccine should not get the mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna). Consideration may be given to vaccination with Janssen (viral vector) COVID-19 vaccine.
- Individuals that had a severe allergic reaction or an immediate allergic reaction to any ingredient in Johnson & Johnson's Janssen (J&J/Janssen) viral vector COVID-19 vaccine, should not get the J&J/Janssen vaccine.
- Individuals that are unable to receive one type of COVID-19 vaccine due to allergy may be able to receive another vaccine. Those receiving a viral vector after receiving an mRNA vaccine (with a possible reaction) should wait 28 days before receiving the viral vector dose.

- Individuals that are allergic to Polyethylene Glycol (PEG) should not receive the mRNA vaccine. Individuals that are allergic to Polysorbate should not receive the J&J/Janssen viral vector COVID-19 vaccine. Polysorbate allergy is now considered a precaution to vaccination, not a contraindication.
- Individuals that have a history of severe allergic reactions not related to vaccines or injectable medications and those with a history of allergies to oral medications or a family history of severe allergic reactions may receive the vaccine.
- Individuals that have had an immediate allergic reaction to another vaccine or injectable should discuss with their health care provider to most appropriate approach to COVID-19 vaccination.
- Of note, allergy to latex, egg or gelatin are NOT contraindications to receiving the COVID-19 vaccine.
- A delayed-onset local reaction (e.g., erythema, induration, pruritus) at the injection site following first administration of the vaccine is not a contraindication to the second dose. It may be advisable to give the second dose in the opposite arm.
- The CDC suggests the following for individuals with a previous history of myocarditis or pericarditis (CDC, 2021c):
    - Individuals that experienced myocarditis/pericarditis from the first dose of the COVID-19 vaccine should defer the second dose, awaiting further safety data. For those that choose to proceed, the myocarditis/pericarditis and underlying inflammation/symptoms should be completely resolved prior to administration.
    - Individuals that have a personal history of myocarditis/pericarditis (unrelated to first dose administration of COVID-19 vaccination) may receive the COVID-19 vaccine once the current episode of myocarditis/pericarditis and underlying inflammation/symptoms have completely resolved.
- The CDC suggests the following related to viral vector vaccines (note: in the United States they refer specifically to the Janssen/Johnson & Johnson vaccines and do not references the AstraZeneca/COVIShield) (CDC, 2021c):
    - Individuals with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT), should be offered the mRNA vaccine if it has been >90 days since the thrombosis & thrombocytopenia syndrome (TTS) has resolved.
    - Women under the age of 50 years of age may at increased risk for the rare TTS related to viral vector vaccines. While they may receive any vaccine available (assuming no other contraindications), they should be made aware of the rare risk and advised regarding the availability of mRNA vaccine options.

NHS

The National Health Service (NHS) England suggests that there are very few individuals who cannot receive one of the COVID-19 vaccines (National Health Service, 2021a). Where there may be concern of contraindication, referral/advice should be sought from the appropriate specialist rather than withholding the vaccine (National Health Service, 2021a).

The NHS (National Health Service, 2021b) also suggests:

- Individuals with Polyethylene glycol/PEG allergy should defer mRNA vaccine until they are referred to an allergist/immunologist for vaccine consultation.
- If available, a viral vector vaccine (such as AZ) may be used instead, however those with a PEG allergy may also be allergic to polysorbate 80. Polysorbate 80 is used widely in foods and medications, and those who have tolerated it previously (such as in flu shots) can receive the viral vector vaccine under the following conditions:
    - Following a discussion with an allergist/immunologist;
    - in a setting with full resuscitation facilities (e.g. a hospital);
    - with a 30 minute observation period
    - with pre-treatment with antihistamine where necessary (although note that this may mask initial symptoms of a reaction).
    - A history of myocarditis or pericarditis unrelated to COVID-19 vaccination is not a contraindication to receiving a COVID-19 vaccine (National Health Service, 2021c). The mechanism of action and risk of recurrence of mRNA associated myocarditis and pericarditis with a subsequent dose of vaccine are being investigated; current advice is that the second dose should be deferred until further information becomes available, including the results of serological testing (National Health Service, 2021c).
    - Individuals that are currently taking immunosuppressive medications (such as chemotherapy, those that received organ transplant, long-term immunosuppressive medicines, long-term systemic corticosteroids, etc.) should be prioritized for receiving the COVID-19 vaccine. Patients about to begin immunosuppressive therapy should be prioritized to receive the vaccine prior to initiating therapy (National Health Service, 2021d).

Quebec

Quebec guidance states individuals with a previous allergic reaction to a vaccine containing polysorbate can be given the vaccine and observed for 30 minutes afterwards, while those with a PEG allergy should be referred to an allergist (Quebec Ministère de la Santé et des Services Sociaux, 2021).

Ontario

A very recent document that was released in conjunction with a vaccination mandate for healthcare worked was released by The Ontario Ministry of Health (Ontario Ministry of Health, 2021) “Directive #6 for COVID-19 Vaccination Policy in Health Settings”. This states:

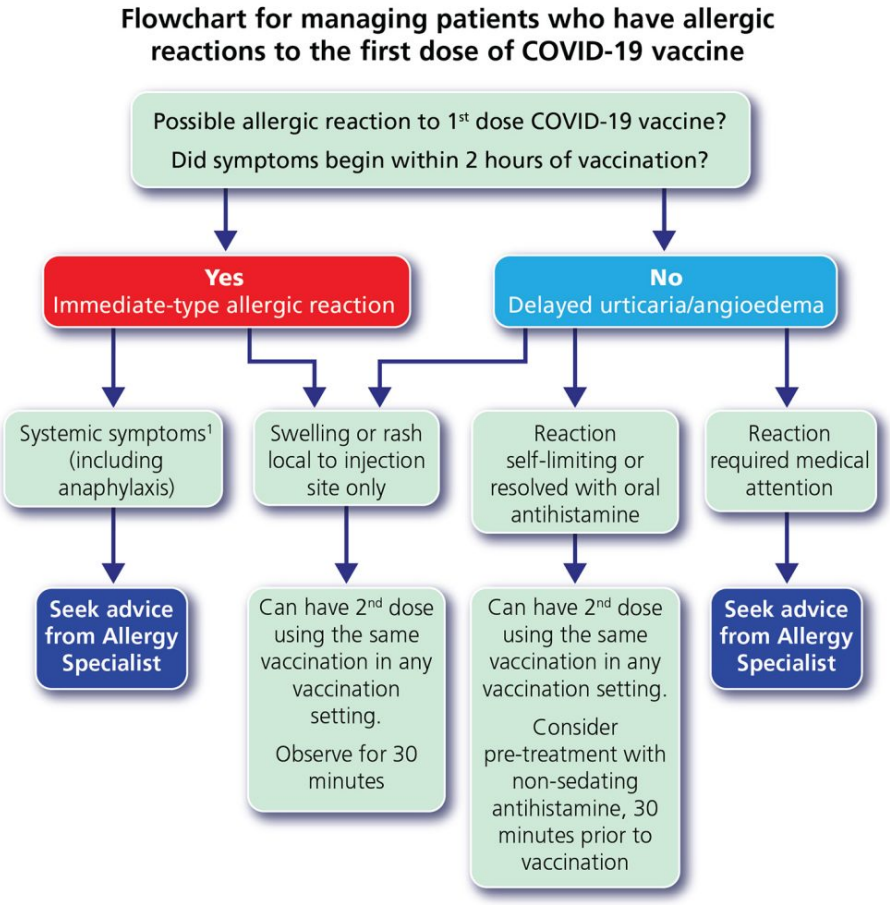
- Individuals that had a severe allergic reaction/anaphylaxis to a first dose of COVID-19 vaccine should receive an urgent referral to an allergist/immunologist to determine suitability for second dose administration. They should not receive subsequent doses in general vaccine clinic.
- Individuals who had an allergic reaction within 4 hours of receiving the first dose of the COVID-19 should not receive the second dose unless they have been evaluated by an allergist/immunologist and advise it is safe to do so.

- Individuals with known or suspected allergies to components of the mRNA vaccines should be referred to an allergist/immunologist for a COVID-19 vaccination assessment. The allergist/immunologist assessment will enable the development of a vaccination care plan which may include recommending an alternative vaccine such as the AstraZeneca/COVISHIELD COVID-19 vaccine.
- Individuals who have had an allergic reaction within 4 hours and/or anaphylaxis from a vaccine or injectable medication that doesn't contain a component or cross-reacting component of the COVID-19 vaccines may still receive the COVID-19 vaccine. The individual should be observed for at least 30 minutes post-administration.
- Individuals with a history of significant allergic reactions and/or anaphylaxis to any food, drug, venom, latex or other allergens not related to the COVID-19 vaccine and those with allergy issues such as allergic rhinitis, asthma and eczema can receive the COVID-19 vaccine. They should be observed for 15 minutes post-administration.

Manitoba

- Individuals that experienced Thrombosis and Thrombocytopenia Syndrome with the first dose of the AZ viral vector vaccine should not receive a second dose, as well as those that have experienced previously experienced episodes of capillary leak syndrome (Manitoba Government, 2021). They indicate the following individuals should speak to their health care provider prior to receiving a viral vector vaccine (and may be better suited for a mRNA vaccine):
    - have had a history of venous sinus thrombosis in the brain or a history of heparin-induced thrombocytopenia (HIT)
    - are pregnant and/or breastfeeding
    - are allergic to an active substance, or any ingredient of the vaccine, or if you have had a severe allergic reaction after the first dose

Appendix B: NHS Flowchart for managing individuals with allergic reactions



Appendix C: Tools that may assist with determining vaccine administration

1) Resource: Determination of what product to use after a reaction to a first dose, from the Specialist Pharmacy Service of the National Health Service in the UK (https://www.sps.nhs.uk/articles/prior-allergy-or-dietary-requirements-and-suitability-for-covid-19-vaccination/)

2) Model: The United States offers the Clinical Immunization Safety Assessment (CISA) Project, COVIDVax can provide clinicians with consultations on individual cases to assess feasibility for vaccine administration (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html)

Appendix D: Pregnancy, Breastfeeding and Fertility and the COVID-19 Vaccine

- In Canada, NACI recommends that pregnant/breastfeeding women receive the mRNA complete vaccine series (Government of Canada, 2021a). “Given pregnant women are at increased risk of severe outcomes from COVID-19 infection, the vaccine is an important component of prenatal care.”
- A new CDC analysis (pre-print) of current data from the v-safe pregnancy registry assessed vaccination early in pregnancy and did not find an increased risk of miscarriage among nearly 2,500 pregnant women who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy (Zauche et al., 2021). Miscarriage rates after receiving a COVID-19 vaccine were 13%, similar to the expected rate of miscarriage in the general population (11-16%) (Zauche et al., 2021).
- According to the CDC, the increased circulation of the highly contagious Delta variant, the low vaccine uptake among pregnant people, and the increased risk of severe illness and pregnancy complications related to COVID-19 infection has created an urgent need for vaccination in pregnant women (CDC, 2021a)
- There is currently no evidence that antibodies made following COVID-19 vaccination or that vaccine ingredients would cause any problems with becoming pregnant now or in the future (CDC, 2021a).
- Additionally, there is no evidence shows that any vaccines, including COVID-19 vaccines, cause male fertility problems (CDC, 2021a).
- Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream one week after the second dose (Government of Canada, 2021b).
- A recent study (pre-print) of the pregnancy outcomes of over 3000 women in the UK during the COVID-19 pandemic found that during Alpha and Delta dominant periods there were more severe infection and worse pregnancy outcomes compared to during the Wildtype infection (Vousden et al., 2021). This demonstrates the increased risk of the Delta variant and the need for vaccination education and optimizing uptake for pregnant women.