

# **COVID-19 Vaccination Clinical Guidance**

last update: 8 September 2021

This document provides guidance regarding frequently asked questions related to clinical aspects of COVID-19 vaccination. It is considered the Island Health 'source of truth' and is reviewed by the Clinical Advisory Group with accountability resting with the Physician Lead, Mass Vaccination Planning. Please raise any concerns/discrepancies/suggestions to <a href="Mariah.Siminoff@viha.ca">Mariah.Siminoff@viha.ca</a>, or <a href="Michael.Benusic@viha.ca">Michael.Benusic@viha.ca</a> if it requires immediate attention.

Consult with the Public Health Immunization Support Team and/or Medical Health Officer as required (see bottom of document for pathway).

This document is frequently updated at:

- Island Health Intranet: <a href="https://intranet.islandhealth.ca/covid-19/Documents/covid-19-vaccination-clinical-guidance.pdf">https://intranet.islandhealth.ca/covid-19/Documents/covid-19-vaccination-clinical-guidance.pdf</a>
- Immunization Support SharePoint: <a href="https://connect.islandhealth.ca/depts/phs/immunization-support/layouts/15/start.aspx#/">https://connect.islandhealth.ca/depts/phs/immunization-support/layouts/15/start.aspx#/</a>

#### **Table of Contents**

ELIGIBILITY, SPACING AND VACCINE PRODUCTS
1. What if a client presents without an appointment?
2. What are the spacing requirements for dose #2?
3. Is there a preferred mRNA-based vaccine for Dose #1?
4. Is there a preferred vaccine for Dose #2?
6. What if a client received a vaccine outside of BC?4
7. What are the timing considerations for COVID-19 vaccination and clients on immunosuppressive therapy?5
INFORMED CONSENT5
8. Can minors provide their own consent?5
9. What information about vaccine products should be communicated to clients?5
10. Do clients have to be provided with a copy of the mRNA Health File and After Care Sheet?5
11. Does consent need to be reobtained for dose #2 when both doses are with an mRNA vaccine?5
ADVERSE EVENTS FOLLOWING IMMUNIZATION & POST-IMMUNIZATION WAIT6
12. Are there known serious adverse reactions to the vaccines?6
13. Which clients should wait for 15 minutes vs 30 minutes after their vaccine?6
VACCINE USABILITY6
14. A small amount of liquid sprayed out of the Pfizer vial when the needle was removed after dilution or withdrawing a dose, can the vaccine from that vial still be used?6
15. What should I do if I think I have made a vaccine administration or handling error (e.g. wrong injection site, incorrect vial dilution or dose volume, dose #2 given too early etc)?
16. Can vaccine be used after a vial or pre-filled syringe containing mRNA is accidentally shaken or dropped on the floor from waist height (1 m or lower)?
17. Can vaccine be used if the needle punctures through cap when recapping the needle after drawing up a dose?7
IMMUNIZATION SUPPLIES AND PRACTICE STANDARDS

18. Can syringes be pre-assembled in advance?	7
19. Can saline be pre-drawn into a syringe in advance?	7
20. What is the safest way to engage the safety device on a needle and recap needle?	7
21. Does the vial rubber stopper need to be swabbed with an alcohol swab before each puncture?	8
22. When pre-drawing vaccine, there is vaccine leak around the needle insertion site. How do I prevent this?	8
23. What is the recommended way to prepare a syringe when a 1.5 inch needle is required?	8
24. Do issues with supplies (syringes, needles) need to be reported?	8
COLD CHAIN AND VACCINE MANAGEMENT	8
25. Once a vial of Moderna is exposed to room temperature (>+8 $^\circ$ C to +25 $^\circ$ C), can it be returned to the fridge?	8
26. Once a vial of Pfizer is exposed to room temperature (>8°C +25°C), can it be returned to the fridge?	8
27. What steps should be taken to manage vaccine and supplies when ambient temperatures inside Mass  Immunization Clinic are rising due to warmer weather?	9
OTHER	9
28. How should I proceed if I receive a client complaint?	9
29. Are there considerations for Tuberculin skin testing (TST) or interferon gamma release assay (IGRA)?	9
30. Are there any concerns regarding travel requirements?	9
31. What to do when there is a discrepancy between the vaccine product documented in Panorama and the product the client reports they received?	
32. How do clients access their immunization records?	10
33. How do I manage dose 3 / booster requests?	10
34. What is the process for revaccination following Hematopoietic Stem Cell Transplant?	11
DECISION SUPPORT TOOLS:	11
CONSULTATION PATHWAY:	11

# **ELIGIBILITY, SPACING AND VACCINE PRODUCTS**

Note: for urgent guidance related to medical eligibility and first-dose reactions, refer to <u>Immunization</u>

<u>Support SharePoint</u> → <u>COVID 19</u> → Guidelines → <u>Urgent Vaccination Consult Guidance for COVID-19 [also at the end of this document]</u>

#### 1. What if a client presents without an appointment?

- Walk-ins are permitted and encouraged for **first doses** for anyone meeting age-eligibility (born in 2009 or earlier, and second doses for anyone at least 28 days / 4 weeks past their first dose.
- The brand of mRNA vaccine provided for walk-in second dose should follow Question 4 below (default is same brand provided for first dose unless that brand is not readily available, use of it would result in wastage, or it is reserved for another population e.g. Pfizer for 12-17 year olds, booked appointments for dose 2).
- Sites need to ensure that they reserve daily vaccine supply for booked appointments, including matching brands for dose 2 appointments. If unable to accommodate walk-in doses, ask them to return at a later date and/or refer them to the provincial booking system.

## 2. What are the spacing requirements for dose #2?

- Vaccine should not be provided before the **minimal** interval recommended by the manufacturer, as there may not be enough time for the body to respond effectively. Minimum clinical intervals are:
  - Pfizer -> Pfizer/Moderna: 3 weeks / 21 days
  - Moderna -> Moderna/Pfizer: 4 weeks / 28 days
  - AstraZeneca/COVISHIELD -> Moderna/Pfizer: 4 weeks / 28 days
  - AstraZeneca/COVISHIELD -> AstraZeneca/COVISHIELD: 4 weeks / 28 days (note: preferred interval is 8-12 weeks)
- The 'optimum' timing of 2<sup>nd</sup> dose is not known. As studies continue, there probably will be an 'optimal' timing suggested, but anyone who has received their 2<sup>nd</sup> dose after the minimum interval should be very reassured that they are highly protected against COVID-19. People can choose to receive vaccine at a later interval.
- There is no maximum interval. Most vaccines do not have a maximum interval. For instance, if someone received a measles vaccine at 1 year of age, the 2<sup>nd</sup> dose is recommended between 4-6 years but if they receive it after, it's still very valid and will provide just as good of protection.

#### 3. Is there a preferred mRNA-based vaccine for Dose #1?

- For those born in 2003 or earlier:
  - Either Pfizer or Moderna can be medically used, and what is available in clinic to be used is based on supply and determined by logistics
  - For efficiency, offer Moderna as default dose 1 if available. If there are clients that refuse Moderna, inform them that they are nearly equivalent and are just as safe and effective. If they decline, offer Pfizer.

#### For those born between 2004-2009:

- Either Pfizer or Moderna can be medically used, and what is available in clinic to be used is based on supply and determined by logistics
- Continue to offer Pfizer as default dose 1 when available due to the higher level of comfort and acceptance of this product with this demographic and parents. Clients can request and receive Moderna if available.
- The youngest eligibility age is 'born in 2009', therefore some 11 year olds are eligible as per PHO and BCCDC.

### 4. Is there a preferred vaccine for Dose #2?

- mRNA-based vaccine brands are interchangeable:
  - By default, dose 1 and dose 2 brands are matched and the Coordination Committee will continue to try
    to provide supplies to all sites to facilitate matching. This now includes clients born between 2004-2009
    who were provided Moderna either intentionally or unintentionally: brand match by default.

- o In the following situations, offer the alternate brand:
  - If brand is not readily available
    - As per NACI this is defined as "easily available at the time of vaccination without delay or vaccine wastage"
    - This also includes if the other brand is reserved for another population such as Pfizer for 12-17 year olds or daily demands of 2<sup>nd</sup> dose appointments. Sites are to prioritize booked appointments for brand matching and follow process below for walk-in dose 2s if unable to accommodate
- o If an alternate brand is being offered:
  - Inform the client before administering which brand they will be receiving
  - Explain that provincial guidance is that "both the Pfizer and Moderna mRNA vaccines are effectively interchangeable and are safe to mix." (<a href="https://www2.gov.bc.ca/gov/content/covid-19/vaccine/dose-2">https://www2.gov.bc.ca/gov/content/covid-19/vaccine/dose-2</a>)
  - If client objects:
    - Explain that due to supply issues and logistical constraints, we cannot facilitate providing them their brand. They of course can choose to not receive the vaccine today, but there is no process to guarantee that they would get their specific brand in the future. [as of 28 July 2021, it is extremely likely that clients will be offered a matched brand for 2<sup>nd</sup> dose booked appointments]
    - They can rebook through the provincial system at any time
    - Provide client with Vaccine Availability Q&A handout at <u>Immunization Support</u> SharePoint -> COVID 19 -> Client Handouts -> Vaccine Availability Q&A
- o If client *requests* an alternate brand then they were provided as first dose and the alternate brand is available and not reserved for another population:
  - Explain that the default is to receive the same brand
  - If there are clients that refuse to receive the same brand as previous, they can be provided the alternate brand if available and it should be clearly documented that this was at the request of the client.

#### • After Dose 1 of AstraZeneca/COVISHIELD:

- People are eligible to receive either AstraZeneca/COVISHIELD or a mRNA vaccine. Only those seeking mRNA vaccine are to book through the provincial system and present to an immunization site.
- There is no preferred mRNA brand. The default is to provide what is being used for 1<sup>st</sup> doses at the site (see question 3).

#### 6. What if a client received a vaccine outside of BC?

- Written documentation is required, client is responsible for obtaining
  - If they cannot provide proof of vaccination, those dose(s) should not be documented and they should be considered as not having received them.
  - If they have proof of vaccination, either document directly into Panorama or instruct client to upload on https://www.immunizationrecord.gov.bc.ca/
- To determine eligibility for further vaccination, refer to <a href="http://www.bccdc.ca/Health-Info-site/Documents/COVID-19">http://www.bccdc.ca/Health-Info-site/Documents/COVID-19</a> vaccine/WHO-EUA-qualified-covid-vaccines.pdf
  - o If client received a previous dose that is **not** WHO EUA qualified (ie. listed as 'pending' or not listed):
    - Dose is invalid
    - eligible for mRNA vaccine, there is no waiting period to receive a mRNA vaccine and can be immediately vaccinated
  - o If client received a previous dose that is WHO EUA qualified:
    - Dose is valid
    - Considered fully vaccinated in BC if received a complete series
    - Eligible for mRNA vaccine if:
      - Do not have a complete series of WHO EUA qualified vaccine

- Does have a complete series of a WHO EUA qualified vaccine that is not approved by Health Canada (ie. as of 8 Sept 2021 is SinoPharm Covilo/BBIBP-CorV and Sinovac CoronaVac)
  - Can be provided one dose of mRNA vaccine at request. This is based on Public Health Agency of Canada guidance for 'those staying in Canada to live, work or study': <a href="https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/recommendations-those-vaccinated-with-vaccines-not-authorized-health-canada-staying-canada-live-work-study.html">https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/recommendations-those-vaccinated-with-vaccines-not-authorized-health-canada-staying-canada-live-work-study.html</a>. Although the PHAC guidance is for those 'staying in Canada, immunizers should **not** 'screen' clients to determine this in order to have an efficient and fair approach.

## 7. What are the timing considerations for COVID-19 vaccination and clients on immunosuppressive therapy?

- It is the responsibility of the client, in consultation with their care providers, to determine the optimal timing for vaccination if they are on immunosuppressive therapy.
- This guidance document can be referred to in order to aid in determining timing considerations: Immunosuppressive Therapies and Timing with COVID-19 Vaccination

#### **INFORMED CONSENT**

#### 8. Can minors provide their own consent?

• Yes, they can provide Mature Minor Consent. If a minor presents without a parent/guardian or signed consent form, followed Mature Minor Consent Process.

#### 9. What information about vaccine products should be communicated to clients?

- Informed consent is obtained for the antigen (COVID-19 mRNA). However, prior to immunizing the client, they should be informed of the vaccine brand they will be receiving and clients can refuse (see question 4)
- Vaccine brand (e.g. 'Pfizer' or 'Moderna') should be included on the client immunization record card.

#### 10. Do clients have to be provided with a copy of the mRNA Health File and After Care Sheet?

• It is acceptable to use laminated copies of both the mRNA Health File and After Care Sheet as long as the sheets are wipes between each client and there are printed copies of each available for clients who would like to take a copy home.

#### 11. Does consent need to be reobtained for dose #2 when both doses are with an mRNA vaccine?

- Informed consent is obtained for a series and **does not** need to be reobtained as long as consent is documented electronically
- BCCDC Immunization Manual states an immunizer can assume consent for vaccine series is in place and proceed
  with immunization if consent was obtained by a Public Health Nurse or Community Health Nurse working in a
  First Nations Community in B.C. This is because Public Health and First Nations Community Nurses follow the
  same informed consent practice guideline outlined in the Immunization Manual. All COVID-19 Pandemic
  Immunizers who are able to obtain informed consent (based on scope of practice) have been educated and
  orientated to obtain consent following BCCDC practice standards.
- To meet all informed consent requirements, client should be offered a copy of the <u>COVID-19 Vaccines BC</u>
   <u>HealthFile</u> and <u>BCCDC COVID-19 Vaccination Aftercare Sheet</u> when obtaining consent. Immunizers obtaining informed consent should review the common side effects with the client and direct them to review rare side effects listed on page 2 of the *Aftercare* sheet.
- When client presents for dose #2:
  - 1. Assess for any reactions after dose #1 (if patient assessment is not within the scope of practice for the Immunizer (e.g. firefighter etc), another Immunizer must complete this step))
  - 2. Remind client about common side effects

#### ADVERSE EVENTS FOLLOWING IMMUNIZATION & POST-IMMUNIZATION WAIT

Note: for urgent guidance related to medical eligibility and first-dose reactions, refer to <u>Immunization</u>

<u>Support SharePoint</u> → <u>COVID 19</u> → Guidelines → <u>Urgent Vaccination Consult Guidance for COVID-19 [also at the end of this document]</u>

#### 12. Are there known serious adverse reactions to the vaccines?

- For information on the AEFI process, see <a href="https://www.islandhealth.ca/sites/default/files/mho/newsletter/pnl-326-covid19-vaccination-update.pdf">https://www.islandhealth.ca/sites/default/files/mho/newsletter/pnl-326-covid19-vaccination-update.pdf</a> (is public, can be shared with inquiring clients)
- Vaccines are approved based on clinical studies and are always monitored after they are approved to see if there are rare side effects that were not detected during the clinical studies.
- In a population, there will always be unexpected illnesses that develop after vaccination. Most of these will be just by coincidence (because if you are vaccinating everyone, people are going to have illness after 2 weeks just by coincidence).
- The monitoring system determines if the unexpected illnesses are occurring more frequently than expected in that population.
- Safety signals identified in Canada are reported at <a href="https://health-infobase.canada.ca/covid-19/vaccine-safety/">https://health-infobase.canada.ca/covid-19/vaccine-safety/</a>

#### 13. Which clients should wait for 15 minutes vs 30 minutes after their vaccine?

- Advise all clients to remain under supervision for at least 15 minutes after immunization; regardless of whether
  or not they have had the particular product previously.
- The risk of fainting is the more common reason to keep client under observation.
- If client has an allergy (even if severe) but is **not** known to be caused by a component in the vaccine, standard 15 minute monitoring is appropriate.
- If mild or questionable allergy to a component in the vaccine (e.g. abdominal discomfort after PEG), standard 15 minute monitoring is appropriate.
- When the client has had a prior allergic reaction to the biological product or a component of the biological product a 30 minute wait is a safer duration.
- A 30 minute wait is recommended under MHO/PHN consultation either through pre-vaccination or AEFI process.
- Concerns of a severe allergy to a component of the vaccine (e.g. PEG anaphylaxis) require MHO consult

#### **VACCINE USABILITY**

# 14. A small amount of liquid sprayed out of the Pfizer vial when the needle was removed after dilution or withdrawing a dose, can the vaccine from that vial still be used?

Yes, provided aseptic technique was followed and vaccine was diluted and prepared as outlined in BCCDC
Immunization Manual. Use all available doses from vial even when less than the expected number of doses can
be withdrawn from a single vial.

# 15. What should I do if I think I have made a vaccine administration or handling error (e.g. wrong injection site, incorrect vial dilution or dose volume, dose #2 given too early etc)?

- 1. Notify client of vaccine administration error if noted at time of client appointment
- 2. Advise the clinic lead of the error or potential error
- 3. Review this document and the BCCDC <u>Guidance Document on the Management of Inadvertent Vaccine Errors</u> document to see if there is guidance for your issue/error
  - If these guidance documents do not provide direction for your issue, the clinic lead should consult with the Immunization Support Team. Refer to *Intake Process for Immunization Questions and Consultations* on <u>Immunization Support SharePoint</u> (link near top of Home page)

- 4. Advise client of recommendation/information as needed. Responsibility to disclose typically rests with the immunizer in consultation with the clinic lead, public health lead, Immunization Support team, and MHO as necessary.
- 5. Complete Patient Safety Learning System Report

# 16. Can vaccine be used after a vial or pre-filled syringe containing mRNA is accidentally shaken or dropped on the floor from waist height (1 m or lower)?

Assess vial/syringe for any cracks or changes to appearance of the vaccine. If there are no cracks and the vaccine
does not appear different (colour, consistency, bubbles etc), vaccine can be used.

# 17. Can vaccine be used if the needle punctures through cap when recapping the needle after drawing up a dose?

- Needles should be recapped carefully to minimize cap puncture. Notify Clinic Lead as Provincial Product Concern Process form must be completed.
  - If needle stick injury occurred:
    - If staff member who experienced needle stick injury is eligible for first or second dose (using minimal intervals): change needle (**do not** pull back on plunger), draw up residual vaccine to create a full dose and administer dose to staff who experienced needle stick injury.
    - If staff member who experienced needle stick injury is **not** eligible for first or second dose → discard dose.
  - o If needle stick injury **DID NOT** occur: change needle (**do not** pull back on plunger), draw up residual vaccine to create a full dose, use vaccine as usual.

### **IMMUNIZATION SUPPLIES AND PRACTICE STANDARDS**

#### 18. Can syringes be pre-assembled in advance?

- Pre-assembling syringes hours or the day before is not recommended and does not align with the principles of aseptic technique.
- Best practice is to pre-assemble the syringe immediately before use. It is acceptable practice to pre-assemble the syringe shortly (~15 mins) before use.

#### 19. Can saline be pre-drawn into a syringe in advance?

- No, pre-drawing saline has the same safety considerations as pre-assembling syringes.
- Best practice is to draw up saline immediately before use (or for use within ~15 mins).

#### 20. What is the safest way to engage the safety device on a needle and recap needle?

- The system is intended to be a one handed technique
- The safety should be activated with the thumb on the guard base. The index finger could also be used as long as activation occurs at the guard base.
- Activating the safety guard with the alternate hand should not occur as it increases the risk of a needle stick
  injury, the guard not engaging or damage to the guard mechanism. Activation of the safety guard on a thigh is
  also very poor practice and may result in a needle stick injury.
- Activating the safety guard on a solid surface, such as tabletop, is also not an approved or promoted practice for
  activating the safety device. Using this method can result in splashes/droplets being discharged from the needle
  end onto adjacent surfaces or potentially on to the user. These droplets may contain blood or body fluids and
  could contaminate surfaces.
- To safely re-cap a pre-drawn syringe, use the one handed "scoop" technique. Place the cap on a flat surface, with one hand use the needle to scoop up the cap, once cap covers needle push cap against hard surface to engage.

### 21. Does the vial rubber stopper need to be swabbed with an alcohol swab before each puncture?

• Yes. 70% alcohol wipes must be used in between draws and allowed to air dry before accessing with a sterile needle. A new alcohol swab should be used each time.

### 22. When pre-drawing vaccine, there is vaccine leak around the needle insertion site. How do I prevent this?

• The vaccine vial has to be punctured several times. To minimize vaccine leaking out around the needle insertion site, puncture the rubber stopped in the middle of the vial to inject the diluent and then rotate in the peripheral of the vial stopper to draw the doses.

## 23. What is the recommended way to prepare a syringe when a 1.5 inch needle is required?

- Option #1: draw up and administering with a 1½" needle
- Option #2: draw up with a 1" needle, pull back on plunger and change to a 1½"
  - O The amount of volume that may be trapped in the 'dead-space' of a 1" needle versus 1%" needle (~0.01 0.02 mL) is negligible. Consider the context of a vaccine contained within a pre-filled syringe format; when using a 1" or 1%" needle, the actual volume of the vaccine would remain the same, and what is most important is to use a needle of sufficient length to reach the largest part of the muscle.

#### 24. Do issues with supplies (syringes, needles) need to be reported?

• Yes, complete the PHSA Supply Chain - Provincial Product Concern Process form. The link is posted on Immunization Support SharePoint → COVID 19 → COVID 19 Resource Links (on right hand side). Lot number and expiry date of equipment should be documented and included when reporting.

#### COLD CHAIN AND VACCINE MANAGEMENT

# 25. Once a vial of Moderna is exposed to room temperature (>+8°C to +25°C), can it be returned to the fridge?

- Yes, time at room temperature is cumulative.
- Moderna vaccine must be used within:
  - 24 cumulative hours at room temperature AND
  - o 24 hours of first vial puncture AND
  - o 24 hours of being loaded into a syringe
- If Moderna vaccine is exposed to temperatures between >+8°C to +25°C while being stored or during transport and the cumulative exposure is less than 24 hours the vaccine does <u>not</u> need to be reported as a cold chain incident. Label vials as per instructions below. If duration of exposure is unknown or clinician has any questions consult with Immunization Support Team following *Intake Process for Reporting Cold Chain Incidents*.
- When vial is returned to the fridge after being exposed to room temperature:
  - Attach *Moderna Vial Label* to vial and record time vaccine exposed to room temperature and date and time of first puncture (if applicable) before returning to the fridge.
  - Use vial(s) previously exposed to room temperature first at next clinic.
- Although the newest guidelines for Moderna allow for storage of the vaccine in a syringe for 24 hours, **best practice is to draw up and use the vaccine as soon as possible** in clinic (see question 18). It is preferable to store a punctured vial in the fridge overnight for use in the clinic the next day.

#### 26. Once a vial of Pfizer is exposed to room temperature (>8°C +25°C), can it be returned to the fridge?

- Yes, time at room temperature is cumulative.
- Pfizer vaccine must be used within:
  - 2 cumulative hours at room temperature AND
  - o 6 hours after dilution
- If Pfizer vaccine is exposed to temperatures between >+8°C to +25°C while being stored or during transport and the cumulative exposure is less than 2 hours the vaccine does not need to be reported as a cold chain incident.

Label vials as per instructions below. If duration of exposure is unknown or clinician has any questions consult with Immunization Support Team following *Intake Process for Reporting Cold Chain Incidents*.

- When **unopened** vials need to be returned to fridge after being exposed to room temperature (> +8°C) for a **cumulative duration of <2h**:
  - Attach *Pfizer Vial Label* to vial and record time vaccine exposed to room temperature before returning to the fridge.
  - Use vial(s) previously exposed to room temperature first at next clinic.
- When unopened vials need to be returned to fridge after being exposed to room temperature (> +8°C) for a cumulative duration of >2h:
  - Quarantine vials, label 'DO NOT USE,' mark with date/time and place in a monitored vaccine fridge
  - Consult with PublicHealthImmunizationSupport@viha.ca for instruction on vaccine use

# 27. What steps should be taken to manage vaccine and supplies when ambient temperatures inside Mass Immunization Clinic are rising due to warmer weather?

- Follow recommendations outlined in Storing, Monitoring and Transporting mRNA Vaccine.
- Recommended epinephrine storage temperature is +15°C to +30°C. Do not store in fridge. Consult with
   <u>PublicHealthImmunizationSupport@viha.ca</u> if supply is exposed to temperature outside of the recommended range.
- Recommended normal saline diluent storage temperature is +2°C to +25°C. Exposure to temperatures >+25°C +30°C is not recommended, but is considered acceptable. Vials with a current temperature of > +30°C should not be used to dilute vaccine until they have returned to temperatures < +30°C. Vials stored at temperatures > +30°C to < +40°C for > 24 hours must be discarded. Vials must be discarded if exposed to temperatures > 40°C for any duration. Do not freeze diluent.

## **OTHER**

#### 28. How should I proceed if I receive a client complaint?

• Direct clients with complaints to the operational manager. If the manager is not on site, advise the client to contact the Island Health Patient Care Quality Office PatientCareQualityOffice@viha.ca.

#### 29. Are there considerations for Tuberculin skin testing (TST) or interferon gamma release assay (IGRA)?

- There is a theoretical risk that mRNA or viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results.
- If tuberculin skin testing or an IGRA test is required:
  - It should be administered and read before immunization OR delayed for at least 4 weeks after vaccination.
- In cases where an opportunity to perform the TST or IGRA test might be missed, testing should not be delayed due to recent receipt of COVID vaccine since considerations are theoretical.
  - 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 in order to avoid missing cases due to potentially falsenegative results.

#### 30. Are there any concerns regarding travel requirements?

- In general, Island Health does not provide travel advice related to COVID-19 vaccinations or otherwise
- As of 24 August 2021, the Public Health Agency of Canada continues to "advise travellers to avoid non-essential travel outside of Canada" source: <a href="https://travel.gc.ca/travelling/health-safety/travel-health-notices/221">https://travel.gc.ca/travelling/health-safety/travel-health-notices/221</a>
- It is the responsibility of the client to be aware of vaccine requirements to locations they are travelling to
- What countries and individual businesses are requiring for entry and/or quarantine related to COVID-19 (testing, vaccination) is very much in flux, and there is a lot of misconceptions and confusion around this.

- For travel to the US, review US CDC guidance at <a href="https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html">https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html</a>. As of July 15, the US considers those who are fully vaccinated as having completed a vaccine series currently authorized for emergency use by the Food and Drug Administration: Pfizer-BioNTech, Moderna, and Johnson and Johnson (J&J)/Janssen COVID-19 vaccines. This guidance can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (e.g. AstraZeneca/Oxford). See <a href="https://www.cdc.gov/coronavirus/2019-ncov/co
- More information at http://www.bccdc.ca/health-info/diseases-conditions/covid-19/prevention-risks/travel
- If a particular situation comes up where someone is able to prove they will be denied access to a country/work due to receiving a 'mixed' vaccine series, escalate to the Physician Lead.

# 31. What to do when there is a discrepancy between the vaccine product documented in Panorama and the product the client reports they received?

- As per BCCDC Immunization Manual, written documentation of immunization is preferred and verbal reports should not be accepted as evidence of immunization
- With defaults set in ImmsBC, it is possible for the wrong product to be recorded
- If a paper record (e.g. client's immunization card, sticker sheet) lists a product different than Panorama, update Panorama with the product details listed on the paper record. The client's immunization card is considered a 'source of truth' and Panorama should be updated to match what is recorded on the paper record. If the client reports receiving a product different than what's in Panorama and they do not have an immunizations record card, consult with Clinic Lead to review documentation on sticker sheet. Sticker sheet is also considered a 'source of truth' and Panorama should be updated to match what is recorded on the paper record.
- If there is <u>no</u> paper record (e.g. client's immunization card, sticker sheet), the product in Panorama <u>cannot</u> be changed. If client is confident they received a different product for dose #1 than recorded in Panorama, they can choose either mRNA vaccine product for dose #2. Advise client their immunization record will reflect the product(s) recorded in Panorama. If they choose a product for dose #2 that is different from the product documented in Panorama for dose #1, there <u>may</u> be travel restrictions if a country does not recognize that as fully immunized.

#### 32. How do clients access their immunization records?

- The paper vaccination card is proof of vaccination
- If clients no longer have their vaccination card or they require further proof, they can access their records through <a href="https://www.healthgateway.gov.bc.ca/">https://www.healthgateway.gov.bc.ca/</a>. Access to the website requires the BC Services Card mobile app and a modern browser such as Google Chrome. Clients can email <a href="healthgateway@gov.bc.ca">healthgateway@gov.bc.ca</a>, call 1-888-268-4319, or text 1-604-630-0300 for difficulties using the App. All clients should be referred to this as the first step. Health Gateway must be used for official documentation to travel and uploaded into <a href="healthgateway">ArriveCan</a> App. Handout <a href="healthgateway">Options to Access Your COVID-19 Records</a> can be found on Panorama SharePoint → COVID Vaccine → C19 Records.
- New as of 19 August 2021:
  - Clients can now request mailed copy of immunization record by phone or receive a printed copy at all Service BC offices, for more information see <a href="https://www2.gov.bc.ca/gov/content/covid-19/vaccine/plan#proof">https://www2.gov.bc.ca/gov/content/covid-19/vaccine/plan#proof</a>
- If clients are unable to access the above resource, they can call their local public health unit to print off a Panorama record. This is not recognized as an official document for travel. Other records, including letters from MHOs, are not available.

#### 33. How do I manage dose 3 / booster requests?

- As of 19 August 2021, there are no groups eligible for dose 3 / boosters.
- Any requests for dose 3 / boosters should be informed that:
  - The province is evaluating the benefits and risk of additional COVID-19 vaccines for certain populations.
  - o If further doses become recommend, this will be announced provincially.
  - If request is related to travel, refer to question 30

#### 34. What is the process for revaccination following Hematopoietic Stem Cell Transplant?

- Hematopoietic Stem Cell Transplant (HSCT) patients who received COVID-19 vaccination before transplant are
  eligible for revaccination (2 doses as a standard series with standard timing). This is not a dose 3 or booster –
  this is a replacement series which is standard for many vaccinations following HSCT.
- Eligible clients will be provided a form requesting they walk-in to COVID-19 vaccine clinic. There is a section of the form that requires completion on-site.
- The replacement series should be entered in ImmsBC as per usual.

#### **DECISION SUPPORT TOOLS:**

- Internal (accessible at Immunization Support SharePoint → COVID 19)
  - o Guidelines
    - Urgent Vaccination Consult Guidance for COVID-19
    - Storing, Monitoring and Transporting mRNA Vaccine
    - Mature Minor Consent Process
  - o Remaining Vaccine Doses
    - Decision Tool for Remaining Vaccine Doses (all settings)
- External

BCCDC Healthcare Provider Q&A BCCDC HCP Vaccination Toolkit

#### CONSULTATION PATHWAY:

- Immediate issues:
  - o First refer to this document (COVID-19 Vaccination Program: Clinical Guidance). If the question is not addressed in this document, refer to the BCCDC Healthcare Provider Q+A (<a href="http://www.bccdc.ca/health-professionals/clinical-resources/covid-19-care/covid-19-vaccinations/healthcare-provider-q-a">http://www.bccdc.ca/health-professionals/clinical-resources/covid-19-care/covid-19-vaccinations/healthcare-provider-q-a</a>). In cases where the information differs, this document overrides.
  - Cold chain incidents, vaccine usability:
    - Contact the Biological Products Consults (BPC) on weekdays (830-1630) using the Intake process for reporting COVID 19 Vaccine Cold Chain Incident Or Intake Process for Immunization Questions and Consultations on Immunization Support SharePoint -> COVID 19 -> Cold Chain Management Or Immunization Support Home
    - During on-call hours 0700-0830 & 1630-1900, Sat/Sun 0700-1900 refer to Biological Products
       Consultant On Call for Cold Chain and Vaccine Usability Consults on Immunization Support
       SharePoint -> COVID 19 -> Cold Chain Management
    - Contact for cold chain incidents, and vaccine usability questions only (e.g. dropped vials, unable to retrieve expected number of doses from vial etc.)
    - Please contact the MHO on-call for all other urgent consults (e.g. eligibility, vaccine consults)
    - **Do not email,** call the BPC directly. Email is not monitored on weekends.
  - Client medical eligibility, in clinic (e.g., allergy, reaction to 1<sup>st</sup> dose):
    - Refer to <u>Immunization Support SharePoint</u> -> <u>COVID 19</u> → Guidelines → Urgent Vaccination Consult Guidance for COVID-19
  - Requiring immediate review by CAG (or subset of members) related to vaccine safety (administration, AEFIs, cold chain):

 Issue to be managed through email, unless higher complexity issue requiring an in-person meeting.

# • Non-urgent issues:

- Client medical eligibility with 7-10 day turnaround in response (e.g. concurrent medications, AEFI):
   PublicHealthImmunizationSupport@viha.ca
- o Related to vaccine safety (administration, AEFIs, cold chain): <a href="mailto:PublicHealthImmunizationSupport@viha.ca">PublicHealthImmunizationSupport@viha.ca</a>
- o Client non-medical eligibility (e.g. exception requests): see question #1



UPDATED: July 20, 2021

DEPARTMENT: Physician Lead, Mass Vaccination Planning

# COVID-19 Urgent Vaccination Consult Guidance mRNA Vaccines (Pfizer, Moderna)

#### ALLERGY:

- The only absolute contraindication to COVID-19 vaccination is allergy to an ingredient in the vaccine.
   Polyethylene glycol (PEG) is the main ingredient of concern in Pfizer and Moderna vaccines.
- If a client indicates known or suspected previous allergy to polyethylene glycol (PEG), such as through use of PEG laxative like Restoralax/Go-lytely (note: sensitivities to cosmetics is not considered a suspected PEG allergy)
  - do not vaccinate
  - o consult MHO for further direction, which may include:
    - vaccination under normal monitoring
    - vaccination with extending monitoring
    - referral back to primary care provider for referral to immunology
    - facilitated referral to immunology (usually if client does not have primary care provider)

#### SPECIAL CONSIDERATION GROUPS

- If client is pregnant, breastfeeding, immunocompromised, and/or has an autoimmune disorder:
  - Discussion/approval by a physician is not required
  - o If client has questions/concerns:
    - No known harm in these situations, but trials did not focus on these groups
    - Can either receive now or defer until after discussion with primary care provider and/or specialist

#### HISTORY OF MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (MIS-C) AND ADULTS (MIS-A)

- It is unclear if there is a risk of recurrence of the same dysregulated response following reinfection with SARS-CoV-2 or in response to a COVID-19 vaccine.
- These individuals should delay vaccination until they have recovered from illness and for 90 days after the date
  of diagnosis of MIS-C or MIS-A, recognizing that the risk of reinfection and, therefore, the benefit from
  vaccination might increase with time following initial infection.

#### OTHER MEDICATIONS, INCLUDING BIOLOGICS AND BLOOD PRODUCTS

- The only time when vaccine needs to be delayed in respect to other medications is for persons who received
  monoclonal antibodies or convalescent plasma for treatment of COVID-19, which is not a common treatment in
  BC. In these scenarios, at least 90 days should elapse prior to vaccination with a COVID-19 vaccine.
- For all other medications, biologics, blood products: offer vaccination. If client has concerns about timing, can
  defer vaccination after speaking with care provider.



#### CONCERNS WITH ADVERSE EVENT FOLLOWING 15T DOSE

- Check Panorama to see if AEFI was reported and recommendation already provided
- If no AEFI in Panorama, follow guidance below
- If a client is vaccinated based on guidance below, document within ImmsBC action taken and guidance followed
  - E.g. "Client reported local reaction including pain, redness and swelling that extended beyond shoulder joint following dose 1 of Pfizer vaccine. Reviewed MHO recommendation with client in accordance with COVID-19 Urgent Vaccination Consult Guidance. Dose 2 provided."
- If an AEFI is to be submitted as per 'Action' below:
  - 1. If Public Health Nurse available on site submit AEFI through Panorama (preferred)
    - Notify PublicHealthImmunizationSupport@viha.ca of AEFI submission
  - If no Public Health Nurse available on site submit <u>Report of Adverse Event Following Immunization with</u> <u>COVID-19 Vaccine</u> to initiate AEFI creation
    - \*\*Note: AEFI reporting must be initiated at time client reports AEFI. Do not redirect client to call 811 or Health Unit to report AEFI.
- If questions/concerns, consult MHO

AEFI	Action
Local:	Offer vaccination, use alternate site if applicable:
<ul> <li>Abscess</li> </ul>	<ul> <li>AEFI does not need to be reported</li> </ul>
<ul> <li>Cellulitis</li> </ul>	<ul> <li>Document decision in note in ImmsBC</li> </ul>
<ul> <li>Nodule</li> </ul>	
<ul> <li>Pain/redness/swelling</li> </ul>	
Systemic:	Offer vaccination, use alternate site if applicable:
<ul> <li>Adenopathy/lymphadenopathy</li> </ul>	<ul> <li>AEFI does not need to be reported</li> </ul>
<ul> <li>Fever</li> </ul>	<ul> <li>Document decision in note in ImmsBC</li> </ul>
<ul> <li>Rash (except hives appearing</li> </ul>	
within 48h of vaccination)	
<ul> <li>Nausea, vomiting, diarrhea</li> </ul>	
<ul> <li>Arthritis</li> </ul>	
<ul> <li>Herpes Zoster (Shingles)</li> </ul>	
Rash concerning for hives: (raised, red,	Consult MHO, who will provide recommendation
round, itchy) appearing within 48h of	depending on clinical picture:
vaccination	<ul> <li>Vaccination with normal monitoring</li> </ul>
	<ul> <li>Vaccination with extending monitoring</li> </ul>
	<ul> <li>Submission of AEFI for formal review and</li> </ul>
	recommendation for subsequent vaccination
Anaphylaxis: 1st dose managed with	Vaccinate only in accordance with written
epinephrine	recommendations in Panorama
	Do not vaccinate if no recommendations provided:  • Initiate AEFI process if not started



Neurological:	If in region of injection or distal on limb:
<ul> <li>Anaesthesia/Paraesthesia</li> </ul>	<ul> <li>Vaccinate in alternate site</li> </ul>
	If systemic or other location offer client option to:  Receive vaccine today OR  Submit AEFI for formal review and recommendation for subsequent vaccination
Other significant events where there is a	Vaccinate only in accordance with written
possible relationship to vaccine, such as:	recommendations in Panorama
Bell's Palsy     Convertion (seizure)	Donat control to the control of the
Convulsion/seizure	Do not vaccinate if no recommendations provided:
Guillain-Barré syndrome (GBS)	<ul> <li>Initiate AEFI process if not started</li> </ul>
Thrombocytopenia and	
Thrombosis syndrome (TTS)	
Leaky Capillary Syndrome	
Myocarditis/pericarditis	
Encephalopathy, encephalitis,	
myelitis, transverse myelitis, or ADEM	
<ul> <li>Emergency Hospitalization for unusual event</li> </ul>	

#### OTHER

- Check the <u>BCCDC Q&A</u> before consulting MHO
  - o www.bccdc.ca → Health Professionals → Immunization Clinical Resources → Recent Updates and Q&As

For urgent consults (e.g. client at clinic, awaiting vaccination), contact Medical Health Officer:

- Monday Friday until 4:30pm: 250-519-3411 (administrative assistant)
- Weekdays after 4:30pm, and weekends: 1-800-204-6166 (please state that you need to speak to Medical Health Officer on-call for an urgent public health issue)

For non-urgent consults (response within 7-10 business days), email Immunization Practice Support Team at PublicHealthImmunizationSupport@VIHA.CA

