

COVID-19 Vaccination Clinical Guidance

last update: 08 October 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 <u>Melissa.Mclean@islandhealth.ca</u>, or <u>Michael.Benusic@islandhealth.ca</u> 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: <u>https://intranet.islandhealth.ca/covid-19/Documents/covid-19-vaccination-clinical-guidance.pdf</u>
- Immunization Support SharePoint: <u>https://connect.islandhealth.ca/depts/phs/immunization-support/_layouts/15/start.aspx#/</u>

Table of Contents

ELIGIBILITY, SPACING AND VACCINE PRODUCTS
1. What if a client presents without an appointment?3
2. What are the spacing requirements for dose #2?
3. Is there a preferred mRNA-based vaccine for Dose #1?3
4. Is there a preferred vaccine for Dose #2?4
5. Who is eligible for doses after the primary series is completed (Dose 3 and Boosters)?
6. What if a client received a vaccine outside of BC?5
7. What are the timing considerations for COVID-19 vaccination and clients on immunosuppressive therapy?6
INFORMED CONSENT
8. Can minors provide their own consent?6
9. What information about vaccine products should be communicated to clients?
10. Do clients have to be provided with a copy of the mRNA Health File and After Care Sheet?
11. Does consent need to be reobtained for dose #2 when both doses are with an mRNA vaccine?
ADVERSE EVENTS FOLLOWING IMMUNIZATION & POST-IMMUNIZATION WAIT7
12. Are there known serious adverse reactions to the vaccines?7
13. Which clients should wait for 15 minutes vs 30 minutes after their vaccine?7
VACCINE USABILITY7
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?
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?8

IMMUNIZATION SUPPLIES AND PRACTICE STANDARDS
18. Can syringes be pre-assembled in advance?8
19. Can saline be pre-drawn into a syringe in advance?8
20. What is the safest way to engage the safety device on a needle and recap needle?
21. Does the vial rubber stopper need to be swabbed with an alcohol swab before each puncture?
22. When pre-drawing vaccine, there is vaccine leak around the needle insertion site. How do I prevent this?9
23. What is the recommended way to prepare a syringe when a 1.5 inch needle is required?
24. Do issues with supplies (syringes, needles) need to be reported?9
COLD CHAIN AND VACCINE MANAGEMENT9
25. Once a vial of Moderna is exposed to room temperature (>+8°C to +25°C), can it be returned to the fridge?9
26. Once a vial of Pfizer is exposed to room temperature (>8°C +25°C), can it be returned to the fridge?10
27. What steps should be taken to manage vaccine and supplies when ambient temperatures inside Mass Immunization Clinic are rising due to warmer weather?10
OTHER
28. How should I proceed if I receive a client complaint?10
28. How should I proceed if I receive a client complaint?10
28. How should I proceed if I receive a client complaint?10 29. Are there considerations for Tuberculin skin testing (TST) or interferon gamma release assay (IGRA)?10
 28. How should I proceed if I receive a client complaint?
 28. How should I proceed if I receive a client complaint?
 28. How should I proceed if I receive a client complaint?
28. How should I proceed if I receive a client complaint?
28. How should I proceed if I receive a client complaint?
28. How should I proceed if I receive a client complaint?
28. How should I proceed if I receive a client complaint?

ELIGIBILITY, SPACING AND VACCINE PRODUCTS

Note: for urgent guidance related to medical eligibility and first-dose reactions, refer to <mark>Urgent Vaccination</mark> Consult Guidance for COVID-19<u>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 **routine** schedule/interval recommended in the BCCDC Immunization Manual, as there may not be enough time for the body to respond effectively. Routine schedules/intervals are:
 - Pfizer \rightarrow 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 2nd dose is not known. As studies continue, there probably will be an 'optimal' timing suggested, but anyone who has received their 2nd 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 2nd 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 ask for Pfizer, and it is available and not reserved for another population, provide Pfizer.
 - If there are questions, inform them that they are nearly equivalent and nearly as safe and effective (there is some evidence for a small increased risk of myocarditis & pericarditis with Moderna but also a small increase in protection with Moderna – see <u>this report from Public</u> <u>Health Ontario</u> for more information).
 - Clients can seek out AstraZeneca if they prefer as per <u>https://www.bcpharmacy.ca/resource-</u> <u>centre/covid-19/vaccination-locations/astrazeneca</u>
- 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.
 - In the following situations, offer the alternate brand:
 - If brand is not readily available
 - <u>As per NACI</u> 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 2nd dose appointments. Sites are to prioritize booked appointments for brand matching and follow process below for walk-in dose 2s if unable to accommodate
 - 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." (<u>https://www2.gov.bc.ca/gov/content/covid-19/vaccine/dose-2</u>)
 - 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 2nd 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> <u>SharePoint</u> -> <u>COVID 19</u> -> Client Handouts -> Vaccine Availability Q&A
 - 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 request to receive a different brand than previous, they can be provided this 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. For those seeking AstraZeneca, refer them to <u>https://www.bcpharmacy.ca/resource-centre/covid-19/vaccination-locations/astrazeneca</u>
 - There is no preferred mRNA brand. The default is to provide what is being used for 1st doses at the site (see question 3).

5. Who is eligible for doses after the primary series is completed (Dose 3 and Boosters)?

- There are two categories of vaccines provided after the primary series (which for most vaccines is 2 doses):
 - Third dose: provided to clients where we expect that they did **not** mount a sufficient immune response after the primary series
 - Booster dose: provided when we expect they **did** mount a sufficient immune response after the primary series, but that immunity has since waned
- As of 13 Sept 2021, a select group of people who are moderately-severely immunocompromised are eligible for a third dose. This was expanded on 6 Oct 2021:
 - o Details are at https://www2.gov.bc.ca/gov/content/covid-19/vaccine/register#immunocompromised
 - The initial group is very small (15,000 in all of BC, ~3,000 in Island Health), and second group is larger (115,000 in all of BC, ~23,000 in Island Health)
 - Interval is at least 28 days since second dose

- Preferentially offer Moderna vaccine, regardless of dose matching
 - Rationale:
 - Moderna has three times the amount of mRNA than Pfizer, and has been shown to produce a higher immune response in those who are immunocompromised
 - At this point of time, travel requirements are based on the primary series, so the brand of a third vaccine should have no impact on this.
 - If a client refuses Moderna, offer Pfizer
- The process is:
 - They will be notified directly through ImmsBC either by text or email (*note:* on 17 Sept 2021 it was reported that some fake text messages are being sent)
 - For these clients, it will show in ImmsBC that they are eligible for Dose 3 proceed to vaccination **after** this is confirmed
 - If a client reports they have been notified they are eligible for Dose 3 but this is **not** what is shown in ImmsBC, escalate to Public Health Clinician for review
 - If they believe they meet criteria and are not notified, they are to discuss with their healthcare provider who can provide an attestation letter if they qualify: <u>https://www.doctorsofbc.ca/sites/default/files/cevi_attest_final.pdf</u>. This form is to be brought to clinic (does not need to be collected or copied).
 - If a client presents without the above being met, they can be offered a third dose if they clearly
 meet the current criteria (example, claiming they are on Rituximab or are a transplant recipient),
 do not require 'proof' of criteria just verbal confirmation of a criteria on the list. If in doubt, ask
 them to see their healthcare provider to discuss and request an attestation letter. If concerns,
 consult Physician Lead.
- Booster doses for LTC and Assisted Living residents has been announced, and will roll-out over October and November. These will be done within the LTC and AL sites themselves.
 - o Preferentially offer Moderna vaccine, regardless of dose matching
 - Rationale:
 - Moderna has three times the amount of mRNA than Pfizer, and has been shown to produce a higher immune response, which is important for elderly and immunocompromised residents in congregate care settings who are at the highest risk of harm from COVID-19.
 - At this point of time, travel requirements are based on the primary series, so the brand of a third vaccine should have no impact on this.
 - If a client refuses Moderna, offer Pfizer
 - The preferred timing for this booster is 6 months after 2nd dose, however, as per the province anyone within this setting who has received their 2nd dose at least 28 days prior is eligible.
 - The rationale for this is that many in this setting also have moderate-severe immunocompromising conditions and are eligible for dose 3 at 28 days since dose 2, and also for operational efficiency.
 - Select Independent Living residents are eligible:
 - IL residents are co-located in the same unit, building or campus with shared common areas (where masks are not required) with LTC or AL residents, AND the majority of the residents in your campus of care are LTC and/or AL (this is being determined by operations).
 - Those deemed moderately-severely immunocompromised and eligible for a 3rd dose

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 <u>https://www.immunizationrecord.gov.bc.ca/</u>
- To determine eligibility for further vaccination, refer to http://www.bccdc.ca/Health-Info-Site/Documents/COVID-19_vaccine/WHO-EUA-qualified-covid-vaccines.pdf

- If client received a previous dose that is **not** WHO EUA qualified (ie. listed as 'pending', not listed, or cannot determine based on information provided):
 - Dose is invalid
 - eligible for mRNA vaccine, there is no waiting period to receive a mRNA vaccine and can be immediately vaccinated
- 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': <u>https://www.canada.ca/en/public-health/services/diseases/2019-novelcoronavirus-infection/guidance-documents/recommendations-thosevaccinated-with-vaccines-not-authorized-health-canada-staying-canada-livework-study.html. 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.
 </u>

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: <u>Immunosuppressive Therapies and Timing with COVID-19 Vaccination</u>

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 <u>Mature Minor Consent Process</u>.

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 <u>scope of practice</u>) 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
 - 3. Reoffer <u>BCCDC COVID-19 Vaccination Aftercare Sheet</u>

ADVERSE EVENTS FOLLOWING IMMUNIZATION & POST-IMMUNIZATION WAIT

Note: for urgent guidance related to medical eligibility and first-dose reactions, refer to Urgent Vaccination Consult Guidance for COVID-19 at the end of this document.

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

- For information on the AEFI process, see https://www.islandhealth.ca/sites/default/files/mho/newsletter/pnl-326-covid19-vaccination-update.pdf (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 https://health-infobase.canada.ca/covid-19/vaccine-safety/

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.
 - 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"
 - The amount of volume that may be trapped in the 'dead-space' of a 1" needle versus 1½" 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 1½" 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 <u>Moderna</u> 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:
 - o 24 cumulative hours at room temperature AND
 - o 24 hours of first vial puncture AND
 - 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:
 - o 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 <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 **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
 - o Consult with <u>PublicHealthImmunizationSupport@islandhealth.ca</u> 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 <u>Storing, Monitoring and Transporting mRNA Vaccine</u>.
- Recommended epinephrine storage temperature is +15°C to +30°C. Do not store in fridge. Consult with
 <u>PublicHealthImmunizationSupport@islandhealth.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 <u>PatientCareQualityOffice@islandhealth.ca</u>.

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: <u>https://travel.gc.ca/travelling/health-safety/travel-health-notices/221</u>
- 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 https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html. 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 WHO for more information about WHO-authorized 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 WHO for more information about WHO-authorized COVID-19 vaccines.
- 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 show that they will indeed be denied access to a country/work due to receiving a 'mixed' vaccine series:
 - A third dose can be provided, at least 28 days after second dose
 - Client should be informed that the risks and benefits of this third dose are not known
 - \circ $\;$ Physician Lead can be consulted, but this is no longer required

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 <u>do not</u> 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 https://www.healthgateway.gov.bc.ca/. Access to the website requires the BC Services Card mobile app and a modern browser such as Google Chrome. Clients can email https://www.healthgateway.gov.bc.ca/. Access to the website requires the BC Services Card mobile app and a modern browser such as Google Chrome. Clients can email https://www.healthgateway.gov.bc.ca/. Access to the website requires the BC Services Card mobile app and a modern browser such as Google Chrome. Clients can email https://www.healthgateway@gov.bc.ca/. 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 ArriveCan App. Handout Options to Access Your COVID-19 Records 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 <u>https://www2.gov.bc.ca/gov/content/covid-19/vaccine/plan#proof</u>

 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?

- See question 5 for eligibility criteria
- Any requests for dose 3 that does not meet question 5 and any requests for boosters should be informed that:
 - The province is evaluating the benefits and risk of additional COVID-19 vaccines for certain populations.
 - \circ $\;$ If further doses become recommend, this will be announced provincially.
 - \circ ~ If request is related to travel requirements, 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.

35. Are there exemptions available for Covid 19 Vaccine?

- As of 14 Sept 2021:
 - Exemptions are available for the LTC/AL staff mandatory vaccination see pg 15 for process (handled provincially): <u>https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/covid-19/covid-19-pho-order-vaccination-status-information.pdf</u>
 - \circ $\;$ Expect a similar process as above for upcoming Healthcare worker mandatory vaccination order $\;$
 - No exemption process for the BC Vaccine Card, Dr. Henry has mentioned that there is one in development for very limited circumstances. When/if announced, will be outlined at <u>https://www2.gov.bc.ca/vaccinecard.html</u>

36. What if clients ask me to sign a liability form?

- Do not sign.
- Our role at the clinics is to provide vaccines and the information available to us from the healthfile. There is no obligation to try to answer questions outside of the healthfile. If other questions come up, the client is free to seek further information and return at a later date.
- Our clinics do not force vaccines, and will only provide under the request of a client.
- If clients have concerns for being 'required' to be vaccinated they should direct that to whoever is making that requirement (ie. employer, Ministry of Health, Office of the Provincial Health Officer).

DECISION SUPPORT TOOLS:

- Internal (accessible at <u>Immunization Support SharePoint</u> → <u>COVID 19</u>)
 - \circ Guidelines
 - Storing, Monitoring and Transporting mRNA Vaccine
 - Mature Minor Consent Process
 - 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:
 - 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 (<u>http://www.bccdc.ca/healthprofessionals/clinical-resources/covid-19-care/covid-19-vaccinations/healthcare-provider-q-a</u>). In cases where the information differs, this document overrides.
 - Cold chain incidents, vaccine usability:
 - Mon to Fri 0830 1630: Contact Biological Products Consultant (BPC) using <u>Intake Process for</u> <u>Reporting COVID-19 Vaccine Cold Chain Incident</u> Or <u>Intake Process for Immunization Questions</u> <u>and Consultations</u>
 - Afterhours/Weekends:
 - Non-Urgent Cold Chain Incidents and Vaccine Usability questions that occur afterhours (e.g. vaccine has been quarantined and is not required until after next business day):
 - E-mail or phone Immunization Support Team at local 32628 or 250-519-5300 local 32628. An Immunization Clinician will respond during regular business hours.
 - Urgent Cold Chain Incidents and Urgent Vaccine Usability questions only (e.g. vaccine dose(s) will be wasted or additional vaccine will need to be ordered from pharmacy if vaccine quarantined until next business day):
 - Contact Public Health Manager on-call to review cold chain incident/vaccine usability question. Manager may contact BPC for direction PRN.
 - Non Public Health staff contact COVID Immunization Central Support Line at 1-888-519-1880 to access Public Health Manager on-call
 - Assess vaccine supply on-site. If additional vaccine urgently required for clinic, contact Operations Manager on-call.
 - Contact MHO on-call for all other urgent consults (e.g. eligibility, vaccine consults)
 - Client medical eligibility, in clinic (e.g., allergy, reaction to 1st dose):
 - Refer to Urgent Vaccination Consult Guidance for COVID-19 below
 - 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): <u>PublicHealthImmunizationSupport@islandhealth.ca</u>
 - Related to vaccine safety (administration, AEFIs, cold chain): <u>PublicHealthImmunizationSupport@islandhealth.ca</u>
 - Client non-medical eligibility (e.g. exception requests): see question #1

DEPARTMENT: Physician Lead, COVID-19 Vaccination

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)
 - $\circ \quad \text{do not vaccinate} \\$
 - 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:
 - o 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 1ST DOSE (OR 2ND DOSE IF PRESENTING FOR 3RD 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 follow one of these steps:

- Complete 2-page *Report of Adverse Event Following Immunization with COVID-19 Vaccine* (Electronic preferred) Found at BCCDC.ca →<u>Immunization Clinical Resources</u>→<u>Adverse Events Following</u> <u>Immunization</u> →<u>Report ...COVID-19 Vaccine</u>
 - Save electronic or scanned paper copy of completed *Report*
 - Document name: **AEFI Report, client initials**
 - Attach completed *Report* and e-mail to *publichealthimmunizationsupport@islandhealth.ca*; include in:
 - Body of e-mail: client identifiers, e.g., initials, BD, Panorama ID or Personal Health Number,
 - Subject of e-mail: Panorama Adverse Event [COVID, Client ID # & Initials].
 - In client's Panorama e-record, author client level NOTE (e.g., "Report of Adverse Event Following Immunization with COVID-19 Vaccine completed, submitted to Immunization Support Team to forward to BCCDC Rapid Response Team.")
 - o Imms Team will forward to BCCDC Rapid Response Team for end-to-end, complete processing.
- II. Complete Panorama Adverse Event following guidelines in <u>Adverse Event Following Immunization</u> <u>Documentation Workflow</u> (2021-Jun-09)

AEFI	Action
Local:	Offer vaccination, use alternate site if applicable:
Abscess	 AEFI does not need to be reported
Cellulitis	Document decision in note in ImmsBC
Nodule	
Pain/redness/swelling	
Systemic:	Offer vaccination, use alternate site if applicable:
 Adenopathy/lymphadenopathy 	 AEFI does not need to be reported
• Fever	Document decision in note in ImmsBC
Rash (except hives appearing	
within 48h of vaccination)	
• Nausea, vomiting, diarrhea	
Arthritis	
 Herpes Zoster (Shingles)* 	
Rash concerning for hives: (raised, red,	Consult MHO, who will provide recommendation
round, itchy) appearing within 48h of	depending on clinical picture:
vaccination	 Vaccination with normal monitoring
	 Vaccination with extending monitoring
	 Submission of AEFI for formal review and
	recommendation for subsequent vaccination
Anaphylaxis: 1 st 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 :
Anaesthesia/Paraesthesia	Vaccinate in alternate site
	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 possible relationship to vaccine, such as:	Vaccinate only in accordance with written recommendations in Panorama
Bell's Palsy	
Convulsion/seizure	Do not vaccinate if no recommendations provided:
Guillain-Barré syndrome (GBS)	Initiate AEFI process if not started
Thrombocytopenia and	
Thrombosis syndrome (TTS)	
Leaky Capillary Syndrome	
Myocarditis/pericarditis	
 Encephalopathy, encephalitis, myelitis, transverse myelitis, or ADEM 	
Emergency Hospitalization for unusual event	

**note re: shingles:* if client has concerns, can provide following information: Shingles (herpes zoster) is caused by a reactivation of the varicella-zoster virus (VZV), the virus that also causes chickenpox. After being infected with VZV, the virus remains within humans and can reactivate and cause shingles. The reasons why VZV reactivates are not fully understood, but risk factors include increasing age and immunosuppression. Shingles following vaccination may be coincidental, or may be reflective of vaccines causing a transient change in the immune state which theoretically could increase the risk of VZV reactivation. There are no contraindications to receiving COVID-19 vaccines during or after an episode of shingles, and my professional recommendation would be to receive subsequent COVID-19 vaccinations as per standard provincial recommendations as the benefits to receiving vaccination likely far outweigh any theoretical risk of inducing shingles

OTHER

- Check the <u>BCCDC Q&A</u> before consulting MHO
 - 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 <u>PublicHealthImmunizationSupport@islandhealth.ca</u>