COVID-19 Vaccination Clinical Guidance

last update: 26 November 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, COVID-19 Vaccination (currently Mike Benusic). Please raise any concerns/discrepancies/suggestions to *Jennifer.Murray2@islandhealth.ca* or if urgent to *Michael.Benusic@islandhealth.ca.*

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

This document is frequently updated and posted:

- Island Health Intranet
- Public Health Immunization Support SharePoint

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1. ELIGIBILITY, SPACING AND VACCINE PRODUCTS

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.*

1.1 What if a client presents without an appointment?

- All clients are strongly encouraged to book an appointment, but walk-ins are permitted for **adult/adolescent doses (ie. not pediatric doses)** below:
    - first doses for anyone meeting age-eligibility (at least 12 years old)
    - second doses for anyone at least 28 days/4 weeks after their first dose
    - third doses for those eligible (moderately-severely immunocompromised), at least 28 days/4 weeks after second dose
- Walk-ins are, in general, not permitted for:
    - booster doses
        - If a client arrives without an appointment and is eligible to receive a booster dose, refer/assist them to the provincial booking system. If they are very unlikely to book an appointment and return (e.g. unable to navigate system or difficult to return to site), provide booster dose as walk-in if supply/capacity permits
    - Pediatric doses
- At pediatric (ie. 5-11) specific clinics:
    - No walk-ins for pediatric doses
    - If supply/capacity permits, facilitate first-dose walk-ins for those age 12 and up (ie. adolescent/adult dosage).
    - Second and third doses do not need to be offered, but can be provided by site discretion
- The brand of mRNA vaccine provided for walk-in second dose should follow Question 1.3 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 Comirnaty for 12-17 year olds, booked appointments for dose 2).
- Sites need to ensure they reserve daily vaccine supply for booked appointments, including matching brands for dose 2 appointments.
- If unable to accommodate walk-in doses, ask client to return at a later date and/or refer/assist them to the provincial booking system.

1.2 Is there a preferred mRNA vaccine for Dose #1?

- For those **18 years old and older** at age of presentation**:**
    - Either Pfizer Comirnaty or Moderna Spikevax 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 Spikevax as default first dose if available.
        - If there are clients that ask for Pfizer Comirnaty, and it is available and not reserved for another population, provide Pfizer Comirnaty.
        - If there are questions, inform client both mRNA products are nearly equivalent and nearly as safe and effective (there is some evidence for a small increased risk of myocarditis & pericarditis with Moderna Spikevax but also a small increase in protection with Moderna Spikevax – see report from Public Health Ontario for more information).
    - Clients can seek out AstraZeneca Vaxzevria if they prefer: https://www.bcpharmacy.ca/resource-centre/covid-19/vaccination-locations/AstraZeneca
- For those **between 12-17 years old** at age of presentation:
    - Either Pfizer Comirnaty or Moderna Spikevax 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 Comirnaty as default first dose 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 Spikevax if available.
    - Pfizer Comirnaty (**Pediatric presentation**) should **not** be used in this age group – there are no exceptions
- For those **5 years old and older AND younger than 12 years old** at age of presentation

- Only **Pfizer Comirnaty (Pediatric presentation) can be provided**
- The only exception to this is if a client is 11 years old and turning 12 in the calendar year but the pediatric formulation is unavailable, the adult/adolescent formulation may be given

1.3 Is there a preferred vaccine for Dose #2?

- **For those provided an adult/adolescent dose for Dose 1:**
  - By default, first dose and second dose brands are matched and the Coordination Committee will continue to try to provide supplies to all sites to facilitate matching.
  - 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 Comirnaty for 12-17 year olds or daily demands of second dose appointments. Sites should prioritize booked appointments for brand matching and follow process below for second dose walk-ins if unable to accommodate
  - If an alternate brand is being offered:
    - Inform client which brand they will be receiving before administering vaccine
    - 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 they would get their specific brand in the future. *[currently, 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
  - If client **requests** an alternate brand than provided as first dose and the alternate brand is available and not reserved for another population:
    - Explain the default is to receive the same brand
    - They can be provided an alternate brand as requested for second dose if brand is available. It should be clearly documented this was at the request of the client.
- **For those provided a pediatric dose for Dose 1:**
  - If still under 12 years of age when presenting for Dose 2, can only receive Pfizer Comirnaty (Pediatric presentation)
  - If 12 years old or older when presenting for Dose 2, should receive Pfizer Comirnaty (adult/adolescent presentation)
- **After Dose 1 of AstraZeneca Vaxzevria/COVISHIELD:**
  - People are eligible to receive either AstraZeneca Vaxzevria/COVISHIELD or mRNA vaccine. Only those seeking mRNA vaccine are to book through the provincial system and present to an immunization site. For those seeking AstraZeneca Vaxzevria, refer them to https://www.bcpharmacy.ca/resource-centre/covid-19/vaccination-locations/AstraZeneca Vaxzevria
  - There is no preferred mRNA brand. The default is to provide what is being used for first doses at the site (see question 1.2).

1.4 What is the difference between a third dose and a booster dose?

- There are two categories of vaccines provided after the primary series (which for most COVID-19 vaccines is 2 doses):
  - **Third dose:** provided to clients we expect did **not** mount a sufficient immune response after a 2-dose primary series, and require an additional dose to complete their 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:
  - 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)
- *Note: this is a subset of clients who met the previous 'Clinically Extremely Vulnerable (CEV)' criteria, and is referred to as CEV-I. The reason all CEVs are not eligible for this third dose is that those who are not moderately-severely immunocompromised may have greater potential of harm from COVID-19, but are expected to have excellent protection from a 2-dose series of vaccine. See question 1.8 on what to do if a CEV client presents for a third dose, but does not meet the eligibility criteria of CEV-I.
- **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 they are eligible for third dose – proceed to vaccination **after** this is confirmed
    - If a client reports they have been notified they are eligible for third dose 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 should discuss with their healthcare provider who can provide a third dose attestation letter if they qualify. This form should be brought to clinic (does not need to be collected or copied).
    - If a previous attestation letter is used (ie - those used to identify the original Clinically Extremely Vulnerable group), follow direction below
  - If a client presents without the above being met, they can be offered a third dose if they **clearly** meet the current criteria (See BCCDC COVID-19 Vaccine Eligibility Primary Series A: Eligibility criteria moderately to severely immunosuppressed – 12 years of age and older). Clients **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 MHO.

- If there is ambiguity if a client is presenting for a third dose or a booster dose (which only really matters if client is below 70 years old and being offered Moderna Spikevax as the dosage would be different depending of if third dose or Booster dose):
  - Treat as third dose if one/more of below:
    - Client is presenting with a completed third dose attestation letter OR a letter from a physician or nurse practitioner specifically requesting a third dose
    - Client is presenting for a booked appointment earlier than 4 months since 2nd dose
    - Client expresses that they are moderately-severely immunocompromised (not required to ask):
      - Show attestation letter – if the client can indicate a specific category they fit into, treat as third dose and document reason in ImmsBC. If they can't indicate a specific category, they can either be provided a booster dosage today, or they can have healthcare provider complete the attestation letter and re-book at a later date.
  - Treat as booster dose if:
    - Not meeting criteria above
- Booster dose eligibility, prioritization, and timing is available at https://www2.gov.bc.ca/gov/content/covid-19/vaccine/booster
  - ***Note: this is only for reference of general prioritization, see question 1.5 on medical eligibility for being offered a booster in-clinic***

1.5 What are the spacing requirements?

Scenario	Minimum Spacing	Routine OR Preferred Spacing
Pfizer Comirnaty (*adult/adolescent*) → any 2nd dose	3 weeks / 21 days	6-8 weeks (*preferred*)
Pfizer Comirnaty (*pediatric*) → any 2nd dose	3 weeks / 21 days	8 weeks (*preferred*)
Moderna Spikevax → any 2nd dose	4 weeks / 28 days	6-8 weeks (*preferred*)

AstraZeneca Vaxzevria → any 2nd dose	4 weeks / 28 days	6-8 weeks (*preferred*)
3rd dose (for CEV-I)	4 weeks / 28 days	4 weeks / 28 days *(routine)*
Booster dose	8 weeks / 56 days	6 months / 180 days* (*routine*)

While there is evidence to support a preferred interval for 2nd doses based on duration of protection, there is a lack of evidence on the preferred interval for booster doses. As per 12 Nov 2021 update to the BCCDC Imms Manual, "**During November and December 2021 invitations may be issued by the BC Get Vaccinated system at a 5 month interval to manage clinic capacity and such invitations for booster doses should be honoured at clinics." During this period, the direction is to treat **5 months as the routine interval.

- **Any client presenting with a booked appointment (or walk-in when applicable – see question 1.1) that meets the minimum spacing above is to be offered vaccine, but if they are earlier than the routine or preferred spacing should be informed of this and can *choose* to defer vaccination to a later date.**
    - To be explicit, **do not** 'screen' clients with a booked appointment for a booster for what 'prioritized' group they are a part of. If they have an appointment, the reason they have been provided the appointment is irrelevant at the clinic level.
- If doing outreach, orient timing based on when most clients in a specific setting would meet the preferred timing. For operational efficiency, can offer at that time to anyone who meets minimum timing.
- For homebound booster outreach, can provide as early as 4 months if there are operational efficiencies (eg. providing influenza vaccine).
- 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 second dose is recommended between 4-6 years but if they receive it after, it is still valid and will provide just as good protection.
- Note: the PHO Order for healthcare workers may require them to be vaccinated before the preferred interval. Island Health does not have authority to provide exemptions/deferral to the PHO Order – if clients express concern, direct them to PHOExemptions@gov.bc.ca with the subject line "Requests for Reconsideration Question".

1.6 What brand of mRNA vaccine should be provided for third dose and boosters?

- For **Third dose** (see definition in question 1.4)
    - Preferentially offer Moderna Spikevax vaccine, regardless of dose matching
        - Rationale:
            - Moderna Spikevax has three times the amount of mRNA than Pfizer Comirnaty, 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
        - Moderna Spikevax is to be provided at full-dose (100mcg, 0.5ml), Pfizer Comirnaty is to be provided at full-dose (30mcg, 0.3ml)
- For **Boosters** (see definition in question 1.4)
    - Offer whatever mRNA vaccine is available and not reserved for another population, guided by operations [as of 11 Nov 2021, offer Moderna Spikevax by default due to supply imbalance]
        - Rationale:
            - Boosters are brand-agnostic
            - The only reason to brand match for the primary series was due to travel concerns, **not** clinical. If someone received a mixed primary series of viral vector vaccine and mRNA vaccine, can dose match mRNA vaccine for booster to remedy travel concerns, upon request.
        - If client refuses mRNA brand offered, provide alternate brand if it is available and not reserved for another population
    - Dosages:
        - Pfizer Comirnaty: standard full dose (30mcg, 0.3ml)
        - Moderna Spikevax:

- standard full dose (100mcg, 0.5ml): Residents of LTC, assisted living, independent living facilities, alternate level of care clients awaiting LTC, individuals 70 years of age and older
- half-dose (50mcg, 0.25ml): all others

1.7 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.
- Immunosuppressive Therapies and Timing with COVID-19 Vaccination

1.8 What to do if a CEV client presents for third dose, but does not meet the current eligibility criteria (ie – moderately to severely immunosuppressed – 12 years of age and older)?

- Confirm they do not meet the criteria as per current **BCCDC COVID-19 Vaccine Eligibility** document
- Provide information that at this time clients who are CEV, but are not moderately to severely immunosuppressed, are considered to mount a good immune response to a 2 dose vaccine series and are not currently eligible for a third dose
- If the evidence changes over time that will be considered in B.C.'s provincial vaccine strategy moving forward
- Will qualify for a booster dose at least 6 months after completion of the primary series – See question 1.5 RE: spacing requirements.

1.9 What about the Janssen COVID-19 vaccine?

- A limited amount of Janssen COVID-19 vaccine will be available in Island Health in Nov 2021
- This product will be offered to those who are born in 2003 or earlier who are unvaccinated or partially vaccinated as follows:
    - Island Health healthcare workers: have received an offer directly through Island Health HR
    - General public: call Provincial registration system at 1-833-838-2323 to express interest
- Clinics will be organized in select locations, depending on demand
- Product information is at: http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%202%20-%20Imms/Part4/COVID-19_Vaccine_Ad26.COV.2_Janssen.pdf
    - In addition to the information provided in the link above, the use of this product as a 2nd dose for those who are partially vaccinated is an off-label use. As part of informed consent, clients should be informed that there is no direct evidence on safety and effectiveness of this product as a 2nd dose and it is not approved by Health Canada for use in this manner, but clients can receive if they choose.
- Note: the Island Health COVID-19 vaccination screening questions have been updated 26 Nov 2021 to cover both mRNA and viral vector vaccines – if using viral vector vaccines ensure you are using this document.

2. INFORMED CONSENT

2.1 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. While there is no minimum age, in general consider offering mature minor consent only those age 12 and above.

2.2 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.
- Vaccine brand (e.g. 'Pfizer Comirnaty' or 'Moderna Spikevax') should be included on the client immunization record card.

2.3 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.

2.4 Does consent need to be reobtained for subsequent doses?

- Standard practice for vaccination is that informed consent is obtained for a series and does not need to be reobtained for subsequent doses in the series
- Provincially, there is ambiguity if this standard applies to boosters
- Within Island Health, as directed by the Physician Lead, COVID-19 Vaccination, as long as informed consent is documented from a previous dose of COVID-19 vaccine:
    - Informed consent does not need to be reobtained
    - Client must have access to the Healthlink file, must review the Island Health screening questions, must have opportunity to ask questions, and must be offered the BCCDC COVID-19 Vaccination Aftercare Sheet

2.5 Who can provide consent on behalf of a minor?

- As per the BCCDC Immunization Manual, informed consent can be provided for a minor by:
    - Parents
    - Foster parents
    - Other custodial caregivers (defined as when a child is in the day to day care of an individual other than a parent and that individual makes health care decisions for the child; It is not necessary to ask the custodial caregiver for proof of authority)
    - Other adults, but written documentation must be provided by a parent/guardian to permit this individual to provide informed consent on behalf of their child

3. 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.*

3.1 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/

3.2 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

4. VACCINE USABILITY

4.1 A small amount of liquid sprayed out of the Pfizer Comirnaty 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.

4.2 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 **Guidance Document on the Management of Inadvertent Vaccine Errors** 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***.
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 prn.
5. Complete **Patient Safety Learning System Report**

4.3 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.

4.4 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.

5. IMMUNIZATION SUPPLIES AND PRACTICE STANDARDS

5.1 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.

5.2 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).

5.3 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.

5.4 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.

5.5 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.

5.6 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.

5.7 Do issues with supplies (syringes, needles) need to be reported?

- Yes, complete the PHSA Supply Chain - Provincial Product Concern Process form. Lot number and expiry date of equipment should be documented and included when reporting

5.8 Is aspiration recommended during injection of Covid-19 Vaccine?

- Aspiration is **not** recommended during injection because it increases pain during immunization with more needle contact time and more lateral movement of the needle.
- Aspiration cannot cause harm either. With proper land marking, no large blood vessels exist at recommended intramuscular vaccination sites and blood draw back will not occur.
- If a client requests aspiration during vaccination and refuses to get vaccine if immunizer does not, review best practice and provide vaccination with aspiration.

6. COLD CHAIN AND VACCINE MANAGEMENT

6.1 Once a vial of Moderna Spikevax 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 Spikevax vaccine must be used within:
    - 24 cumulative hours at room temperature **AND**
    - 24 hours of first vial puncture **AND**
    - 24 hours of being loaded into a syringe
- If Moderna Spikevax 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 **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 vial is returned to the fridge after being exposed to room temperature:
    - Attach ***Moderna Spikevax 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 Spikevax 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. It is preferable to store a punctured vial in the fridge overnight for use in the clinic the next day.

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

- Yes, time at room temperature is cumulative.
- Pfizer Comirnaty vaccine must be used within:
    - 2 cumulative hours at room temperature **AND**
    - 6 hours after dilution
- If Pfizer Comirnaty 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 Comirnaty 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@islandhealth.ca* for instruction on vaccine use

6.3 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 *PublicHealthImmunizationSupport@islandhealth.ca* 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.

7. DOCUMENTATION

7.1 What if a client received a vaccine that is not documented in their electronic health record?

- 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, instruct client to upload on https://www.immunizationrecord.gov.bc.ca/
- 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 (e.g. listed as 'pending', not listed, or cannot determine based on information provided):
    - Dose is invalid and 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 (e.g. as of 8 Sept 2021: 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': 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. Although the PHAC guidance is for those 'staying in Canada to live, work or study' immunizers should **not** 'screen' clients to determine this in order to have an efficient and fair approach.

7.2 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 **no** paper record (e.g. client's immunization card, sticker sheet), the product in Panorama cannot be changed. If client is confident they received a different product for first dose than recorded in Panorama, they can choose either mRNA vaccine product for second dose. Advise client their immunization record will reflect the product(s) recorded in Panorama. If they choose a product for second dose that is different from the product documented in Panorama for first dose, there **may** be travel restrictions if a country does not recognize that as fully immunized.

7.3 How do clients access their immunization records?

- BC Vaccine Card is required to access some events, services and businesses – refer to website
- If 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 *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 https://www2.gov.bc.ca/gov/content/covid-19/vaccine/plan#proof
- Note: for booster doses, clients should be *offered* proof of vaccination (by writing on a new empty vaccine card), but this is opt-in and is not required

8. OTHER

8.1. 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@islandhealth.ca*.

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

- No, there are no longer any space considerations

8.3 Are there any concerns regarding travel requirements?

- In general, Island Health does not provide travel advice related to COVID-19 vaccinations or otherwise
- 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. As of 25 October 2021, the US considers those who are fully vaccinated as having completed a vaccine series with a WHO EUA authorized vaccine, and includes 'mix-and-match' combinations
- More information at http://www.bccdc.ca/health-info/diseases-conditions/covid-19/prevention-risks/travel
- If a client requests an additional dose for travel related reasons after receiving a mixed series:
    - Must provide some written documentation showing that they would be denied access to travel/work due to their current vaccination status – the onus is solely on the client for obtaining this
    - If they provide written documentation as above:
        - 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
- Physician Lead can be consulted, but this is no longer required

8.4 How do I manage requests for expedited vaccination?

- See question 1.1 for who can be provided doses as walk-in
- For all others who must register and book appointment:
    - Expedited appointments are **not** available
    - Register and book through https://www.getvaccinated.gov.bc.ca/s/, will be sent invite when they are eligible
    - For boosters:
        - Evidence shows that protection from acquiring COVID-19 does wane over time, but protection against harm from COVID-19 (ie. hospitalization, ICU admission, death) remains extremely high.

While we encourage boosters when invited, **there is not a rush to be vaccinated to remain highly protected against harm**

8.5 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 third dose 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.

8.6 Are there exemptions available for COVID-19 Vaccine?

- As of 28 Oct 2021
    - Medical exemptions are available for the LTC/AL staff and HCW mandatory vaccination order, process is through the Office of the Provincial Health Officer, **not** through Island Health - see https://www2.gov.bc.ca/gov/content/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/current-health-topics/covid-19-novel-coronavirus
    - No exemption process for BC Vaccine Card. Dr. Henry mentioned there is one in development for very limited circumstances. When/if announced, will be outlined on BC Vaccine Card website.

8.7 What if clients ask me to sign a liability form?

- **Do not sign**
- Our role at the clinics is to provide vaccines and information available to us from the Healthfile. There is no obligation to answer questions outside 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 vaccines under the request of each client, and informed consent based on the information available in the Healthfile.
- If clients have concerns they are being 'required' or 'forced' to be vaccinated, they should direct that to whoever is making that requirement (e.g. employer, Ministry of Health, Office of the Provincial Health Officer).

8.8 What are infection prevention and control requirements and guidance for immunization clinics?

- See BCCDC Infection Prevention and Control Guidelines for Community Immunization Clinics
- As of 13 October 2021, "Physical distancing or maintaining a distance of two metres between two or more people is no longer required."

9. DECISION SUPPORT TOOLS

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

    BCCDC Healthcare Provider Q&A
    BCCDC HCP Vaccination Toolkit

10. 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. 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 ***Intake Process for Reporting COVID-19 Vaccine Cold Chain Incident*** Or ***Intake Process for Immunization Questions and Consultations***
        - **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): *PublicHealthImmunizationSupport@islandhealth.ca*
    - Related to vaccine safety (administration, AEFIs, cold chain): *PublicHealthImmunizationSupport@islandhealth.ca*
    - Client non-medical eligibility (e.g. exception requests): see Question #1

UPDATED: November 26, 2021

DEPARTMENT: Physician Lead, COVID-19 Vaccination

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

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 Comirnaty and Moderna Spikevax 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
    - **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
    - If client has questions/concerns:
        - No known harm in these situations but trials did not focus on these groups
        - Higher risk of harms from COVID-19 infection to pregnant and immunocompromised, therefore strongly recommend vaccination

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 until after speaking with care provider.

CONCERNS WITH ADVERSE EVENT FOLLOWING 1ST DOSE (OR 2ND DOSE IF PRESENTING FOR 3RD DOSE / BOOSTER)

- 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 Comirnaty 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:

I. Complete 2-page ***Report of Adverse Event Following Immunization with COVID-19 Vaccine*** (Electronic preferred) Found at BCCDC.ca →Immunization Clinical Resources→Adverse Events Following Immunization → *Report …COVID-19 Vaccine*
   - 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.")
   - Imms Team will forward to BCCDC Rapid Response Team for end-to-end, complete processing.

II. Complete Panorama Adverse Event following guidelines in Adverse Event Following Immunization Documentation Workflow (2021-Jun-09)

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

Chest pain without diagnosis (within 1 month after vaccination)	If short-lived (3 days or less) and/or mild severity • Offer vaccine • AEFI does not need to be reported If symptoms lasted more than 3 days and/or severe symptoms and/or associated with other symptoms (palpitations, shortness of breath, decreased exercise tolerance): • Do not vaccinate • Initiate AEFI process • If client is insistent on vaccination today, consult MHO If symptoms are persistent: • Do not vaccinate • Initiate AEFI process • Recommend client seek urgent medical attention • If client is insistent on vaccination today, consult MHO
Other significant events where there is a possible relationship to vaccine, such as: • Bell's Palsy • Convulsion/seizure • Guillain-Barré syndrome (GBS) • Thrombocytopenia and Thrombosis syndrome (TTS) • Capillary Leak Syndrome • Myocarditis/pericarditis (within 3 months following vaccination) • Encephalopathy, encephalitis, myelitis, transverse myelitis, or ADEM • Emergency hospitalization for unusual event	**Vaccinate only in accordance with written recommendations in Panorama** **Do not vaccinate if no recommendations provided:** • Initiate AEFI process if not started

***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 BCCDC Q&A 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:
  - *Before December 6*, call 250-519-3411 (administrative assistant)
  - *Starting December 6*, call respective geographic Medical Health Officer office:

Location	Office #
Geo 1 - North Island (Tri-port, Campbell River, Courtenay)	250-331-8591

Geo 2 – Central Island (Oceanside, Nanaimo, Port Alberni, Westcoast)	250-519-3411
Geo 3 – Cowichan (Ladysmith, Duncan, Lake Cowichan)	250-737-2020
Geo 4 – South Island (Juan De Fuca, Westshore, Victoria, Saanich, Salt Spring Island)	250-519-3411

- 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@islandhealth.ca*