COVID-19 Vaccination Clinical Guidance

last update: 08 February 2022

This document provides supplemental guidance to the BCCDC Immunization Manual regarding clinical aspects of COVID-19 vaccination. The BCCDC Immunization Manual is the 'source of truth' and this document is intended to provide clarification on clinical guidance and to describe processes specific to Island Health.

This document is reviewed by the Clinical Advisory Group with accountability resting with the Physician Lead, COVID-19 Vaccination (currently Dr. Mike Benusic).

Raise any concerns/discrepancies/suggestions to *Jennifer.Murray2@islandhealth.ca* or *Michael.Benusic@islandhealth.ca* (if urgent).

Consult with Public Health Immunization Support Team and/or Medical Health Officer as required (refer to *Immunization Consultation Pathway*).

This document is frequently updated and posted on the Island Health Intranet COVID-19 page and Public Health Immunization Support SharePoint COVID 19 page.

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1. ELIGIBILITY, SPACING AND VACCINE PRODUCTS

Note: for urgent guidance related to medical eligibility and previous dose reactions, refer to *Immunization Consultation Pathway*.

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 (not pediatric doses)** for:
  - Primary series doses (e.g. first, second, or third dose if eligible) at the *minimum* interval as per *Question 1.6*
  - Booster doses at the *routine/preferred* interval as per *Question 1.6* (discretion can be used to provide as early as the *minimum* interval as per BCCDC guidance: "for a minority of individuals for practical reasons, including pregnant persons, with consideration of the individual risk-benefit")
  - **Note:** facilitate the above walk-ins at 5-11 clinics if supply and capacity permits and to prioritize vaccination over wastage
- Walk-ins are, in general, not permitted for:
  - Pediatric doses
- At pediatric (5-11) specific clinics:
  - No walk-ins for pediatric doses
  - Facilitate first dose walk-ins for adults/adolescents (at least 12 years old) if supply/capacity permits
  - Second and third doses do not need to be offered, but can be provided by site discretion
- 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 vaccine for Dose #1?

- Refer to *Vaccine Products & Intended Age Group*
- Age: **30 years and older** at time of presentation**:**
  - Pfizer Comirnaty Adult-Adolescent or Moderna Spikevax can be medically used, what is available in clinic to be used is based on supply and determined by logistics
  - For efficiency and because of current supplies, offer Moderna Spikevax as default first dose if available
    - If clients ask for Pfizer Comirnaty and it is available and not reserved for another population, provide Pfizer Comirnaty
    - If client has questions, inform them both mRNA products are nearly equivalent and essentially equivalent in safety and effectiveness for their age group
- Age: **12-29 years old** at time of presentation:
  - Pfizer Comirnaty Adult-Adolescent is the preferred product for this age group due to relatively higher rates of myocarditis/pericarditis with Moderna Spikevax. The absolute risk of myocarditis/pericarditis is still very low with either product.
  - Moderna Spikevax can be provided to this age group in the following situations, but they should be informed of the relatively higher risk of myocarditis/pericarditis as described in the COVID-19 mRNA Vaccines HealthFile:
    - At client's request
    - Pfizer Comirnaty Adult-Adolescent is not available or is reserved for another population, which includes in outreach situations where Moderna Spikevax is being used. There is not a requirement to always have both products in outreach clinics.
    - **Note:** as this is only a preferential use recommendation, it is **not** an error if a 12-29 year old is provided Moderna Spikevax
  - Pfizer Comirnaty (**Pediatric presentation**) should **not** be used in this age group – there are no exceptions
- Age: **5-11 years old** at time of presentation
  - Only **Pfizer Comirnaty Pediatric can be provided**
  - The only exception to this is if a client is 11 years old and turning 12 in the calendar year and the pediatric formulation is unavailable, the Pfizer Comirnaty Adult-Adolescent formulation may be given

1.3 Is there a preferred vaccine for Dose #2?

- Refer to *Vaccine Products & Intended Age Group*
- Age: **30 years and older** at time of presentation**:**
    - 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 brand matching. It is extremely likely clients will be offered a matched brand for second dose booked appointments.
    - In the following situations, offer the alternate brand:
        - If brand used for first dose is not readily available or reserved for another population (e.g. Pfizer Comirnaty Adult-Adolescent reserved for 12-29 year olds)
            - NACI defines this as "easily available at the time of vaccination without delay or vaccine wastage"
            - Prioritize brand matching for booked appointments and follow *Question 1.1* for second dose walk-ins if unable to accommodate
    - When 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 brand matching. They can choose to defer the vaccine today, but there is no process to guarantee they will get their specific brand in the future.
            - They can rebook through the provincial system at any time
    - If client requests an alternate brand than provided for first dose and the alternate brand is available and not reserved for another population:
        - Explain the default is to receive the same brand for the second dose
        - Client can be provided an alternate brand as requested for the second dose. It should be clearly documented this was at the request of the client.
- Age: **12-29 years old** at time of presentation:
    - Pfizer Comirnaty Adult-Adolescent is the preferred product for this age group due to relatively higher rates of myocarditis/pericarditis with Moderna Spikevax. The absolute risk of myocarditis/pericarditis is still very low with either product.
    - Moderna Spikevax can be provided to this age group in the following situations, but they should be informed of the relatively higher risk of myocarditis/pericarditis as described in the COVID-19 mRNA Vaccines HealthFile
        - At client's request (e.g. if seeking second dose brand match)
        - Pfizer Comirnaty Adult-Adolescent is not available or is reserved for another population, which includes in outreach situations where Moderna Spikevax is being used. There is not a requirement to always have both products in outreach clinics.
        - **Note:** as this is only a preferential use recommendation, it is **not** an error if a 12-29 year old is provided Moderna Spikevax
- **Clients who received Pfizer Comirnaty Pediatric for dose 1:**
    - Less than 12 years of age at time of presentation for dose 2 can only receive Pfizer Comirnaty Pediatric
    - 12 years and older at time of presentation for dose 2 should receive Pfizer Comirnaty Adult-Adolescent
- **Clients who received Vaxzevria (AstraZeneca)/COVISHIELD for dose 1:**
    - Clients are eligible to receive either Vaxzevria (AstraZeneca)/COVISHIELD or mRNA vaccine
    - There is no preferred mRNA brand. The default is to provide what is being used for first doses at the site as described in *Question 1.2*
        - Those seeking mRNA vaccine should book through the provincial system and present to an immunization clinic
        - See question 1.8 for those seeking another viral vector vaccine

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

- **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 to clients we expect **did** mount a sufficient immune response after the primary series, but that immunity has since waned
- Individuals who are deemed moderately-severely immunocompromised* are eligible for a **third dose**.
    - Information for people who are moderately to severely immunocompromised
    - Approximately 115,000 people in BC and 23,000 people in Island Health qualify for a third dose
    - ***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 primary series of vaccine.
    - Clients identified in the provincial system will have an alert and risk factor for a 3-dose primary series entered in their record. These alerts and risk factors are provincially applied based on provincial data indicating these clients are moderately-severely immunocompromised and eligible for a 3-dose primary series. Immunizers do not need to confirm if someone meets the criteria.
    - **Note:** if a client states they are mislabelled as CEV-I and they are presenting for what they thought was a booster dose, they can be provided a booster dose as per *Question 1.5* and *Question 1.6* below and be instructed to call the provincial call centre to request that their CEV-I status be removed.

1.5 Is there a preferred vaccine for Third Dose and Booster Dose?

- **Third dose** (see definition in *Question 1.4*)
    - Preferentially offer Moderna Spikevax vaccine, regardless of dose matching because:
        - Moderna Spikevax has three times the amount of mRNA than Pfizer Comirnaty Adult-Adolescent and has been shown to produce a higher immune response in those who are immunocompromised
        - Travel requirements are currently based on the 2-dose primary series so the brand of a third vaccine should have no impact on this
        - **Dose:** Moderna Spikevax full-dose (100mcg, 0.5ml) preferred, Pfizer Comirnaty Adult-Adolescent (30mcg, 0.3ml) is an alternative valid dose
- **Booster dose** (see definition in *Question 1.4*)
    - Age: **12-29 years old** at time of presentation:
        - Pfizer Comirnaty Adult-Adolescent is the preferred product for this age group due to relatively higher rates of myocarditis/pericarditis with Moderna Spikevax. The absolute risk of myocarditis/pericarditis is still very low with either product.
        - Moderna Spikevax can be provided to this age group in the following situations, but they should be informed of the relatively higher risk of myocarditis/pericarditis as described in the COVID-19 mRNA Vaccines HealthFile:
            - At client's request
            - Pfizer Comirnaty Adult-Adolescent is not available or is reserved for another population, which includes in outreach situations where Moderna Spikevax is being used. There is not a requirement to always have both products in outreach clinics.
            - **Note:** as this is only a preferential use recommendation, it is **not** an error if a 12-29 year old is provided Moderna Spikevax
    - Age: **30 years and older** at time of presentation:
        - Booster doses are brand-agnostic
        - In rare situations, an AEFI recommendation may include a specification of a brand of vaccine moving forward.
        - 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
            - as of 2 Feb 2022:
                - Inform clients who request Pfizer Comirnaty that this product is in shortage and needs to be reserved for those under 30 as there is a lower risk of myocarditis

with Pfizer Comirnaty in those under 30, but the same very low rate with either brand in those over 30
        - If client still refuses Moderna Spikevax, provide Pfizer Comirnaty if it is available and not reserved for another population that day (e.g. <30 year olds with booked appointments). If unavailable/reserved, provide choice to receive Moderna Spikevax now or rebook at a later date when Pfizer Comirnaty may be available.
    - **Dose:** Pfizer Comirnaty Adult-Adolescent: full dose (30mcg, 0.3ml)
    - **Dose:** 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
            - If a client in this group requests a half-dose (50mcg, 0.25ml) Moderna Spikevax, this can be provided, but this option does not need to be offered
            - **Note:** if a client is provided a half-dose (50mcg, 0.25ml), this dose is valid and is **not** an error. If a client is concerned they are 'underdosed', they can have the half-dose (50mcg, 0.25ml) invalidated and provided with a full booster dose (100mcg, 0.5ml).
    - **Dose:** Moderna Spikevax: half dose (50mcg, 0.25ml): all others 12+

1.6 What are the spacing requirements between doses?

Scenario	Minimum Spacing	Routine OR Preferred Spacing
Pfizer Comirnaty Adult-Adolescent → any 2nd dose	3 weeks / 21 days	8 weeks (*preferred*)
Pfizer Comirnaty Pediatric → any 2nd dose	3 weeks / 21 days	
Moderna Spikevax → any 2nd dose	4 weeks / 28 days	
Vaxzevria (AstraZeneca) → any 2nd dose	4 weeks / 28 days	
2nd dose → 3rd dose (for CEV-I)	4 weeks / 28 days	4 weeks / 28 days *(routine)*
Booster dose (based on time since completion of primary series: for most that is a 2-dose primary series but for CEV-I that is a 3-dose primary series and for Janssen recipients that is a 1-dose primary series)	8 weeks / 56 days	6 months / 180 days (*routine*)

Note: Any client presenting with a booked appointment (or walk-in when applicable – see *Question 1.1*) that meets the minimum spacing above should be offered vaccine and do not need to be informed/counselled if they are before the routine OR preferred spacing. If questions are raised, they can choose to defer vaccination to a later date.

- When doing outreach, choose clinic date based on when most clients in that setting would meet the routine/preferred spacing. For operational efficiency, offer vaccine to anyone who meets the minimum spacing requirement.
- For homebound booster outreach, can provide vaccine as early as 4 months if there are operational efficiencies (e.g. providing concurrent influenza vaccine)
- There is no maximum interval.

1.7 What are the timing considerations for 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.
- Refer to Immunosuppressive Therapies and Timing with COVID-19 Vaccination

1.8 What about the viral vector (Janssen and AstraZeneca) vaccines?

- Two viral vector vaccines are intermittently available in Island Health clinics: Janssen and Vaxzevria (AstraZeneca). These products will be organized in select Island Health vaccination sites depending on demand.

- Clients can choose to receive a viral vector vaccine as a primary series and/or as a booster dose by calling the provincial system at 1-833-838-2323
- Only one dose of Janssen vaccine is required for a primary series, otherwise the products are interchangeable
- Minimum age for either vaccine is turning 18 in the calendar year

1.9 How soon after COVID-19 infection can/should someone receive a COVID-19 vaccine?

- The decision on when to be vaccinated after an infection is solely on the client if they are otherwise eligible for vaccination. The below can be explained to a client if they ask, and immunizers can provide further guidance based on their scope of practice:
    - The BCCDC COVID-19 product pages state that "A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed SARS-CoV-2 infection" and does not otherwise provide guidance on timing of COVID-19 vaccine after COVID-19 infection.
    - NACI provides suggested intervals between infection and vaccination – see Table 1

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 to those 12 years and older.

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 as clients can refuse what is being offered.
- 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 re-obtained 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 practice applies to booster doses
- 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 previous dose reactions, refer to *Immunization Consultation Pathway*.

3.1 Are there known serious adverse reactions to the vaccines?

- For information on the AEFI process, see MHO Newsletter (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 clients 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 a 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
- 30-minute wait is necessary when 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
  Note: site capacities now permit a return to post-vaccination supervision as per 3.2, and as of 14 Jan 2022 all settings are to return to this routine standard.

3.3 What if a client has an allergy to a component of the vaccine?

- 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)

3.4 What to do when a client has an adverse event following a previous 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 Comirnaty vaccine. Reviewed MHO recommendation with client in accordance with COVID-19 Urgent Vaccination Consult Guidance. Dose 2 provided.”

- If an AEFI needs to be submitted, follow one of these options:

  1. Complete 2-page *Report of Adverse Event Following Immunization with COVID-19 Vaccine* (Electronic preferred)
     - Save electronic or scanned paper copy of completed **AEFI Report**
       - Document name: **AEFI Report, client initials**
     - Attach completed **AEFI Report** and e-mail to *publichealthimmunizationsupport@islandhealth.ca*
       - 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 Panorama, 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.")
     - Immunization Team will forward to BCCDC Rapid Response Team for end-to-end complete processing

  2. Complete Panorama Adverse Event following guidelines in Adverse Event Following Immunization Documentation Workflow

Adverse Events Following COVID-19 Vaccine and Required Action

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.

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 in the 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 to do when a vaccine administration or handling error happens (e.g. wrong injection site, incorrect vial dilution or dose volume, dose given too early etc.)?

- Notify client of vaccine administration error immediately if noted at time of client appointment
- Advise clinic lead of the error or potential error
- Review this document and BCCDC Guidance Document on the Management of Inadvertent Vaccine Errors 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 by following *Intake Process for Immunization Questions and Consultations*.
- 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.
- 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 so Provincial Product Concern Process form can be completed
- If clean needle stick injury occurs:
    - If staff member who experienced clean needle stick injury is eligible for a 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 clean needle stick injury is **not** eligible for a 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

4.5 What to do with remaining vaccine in 14-dose Moderna Spikevax vials after 20 punctures?

- Moderna Spikevax vials cannot be punctured more than 20 times
- Any remaining vaccine in the vial after 20 punctures needs to be wasted, as per provincial direction

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 or recap a pre-drawn syringe?

- 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 onto 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?

- Aspiration is **not** recommended during injection because it increases pain during immunization with more needle contact time and more lateral movement of the needle
- However, aspiration is very unlikely to cause harm
- If a client requests aspiration during vaccination and refuses to receive vaccine if immunizer does not, review best practice and if immunizer is comfortable doing so, 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 COVID-19 Vaccine 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**. It is preferable to store a punctured vial in the fridge overnight for use in clinic the next day.

6.2 Once a vial of Pfizer Comirnaty Adult-Adolescent 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 prior to dilution **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 COVID-19 Vaccine Cold Chain Incidents*.
- When **unopened** vials need to be returned to fridge after being exposed to room temperature (> +8°C) for a **cumulative duration <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 >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.

6.4 What is the consultation process for a cold chain incidents or vaccine usability question?

- **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 Extension 18777, locally 250-370-8777 toll free 1-877-563-3152 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)

7. DOCUMENTATION

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

- Written documentation is required and 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 record at https://www.immunizationrecord.gov.bc.ca/
- To determine eligibility for further vaccination, refer to BCCDC WHO Emergency Use Authorization Qualified COVID-19 Vaccines
    - 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 client can be immediately vaccinated.
    - If client received a previous dose that **is** WHO EUA qualified:
        - Dose is valid. Considered fully vaccinated if client received a complete series.
    - Eligible for mRNA vaccine if:
        - Does not have a complete series of WHO EUA qualified vaccine

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?

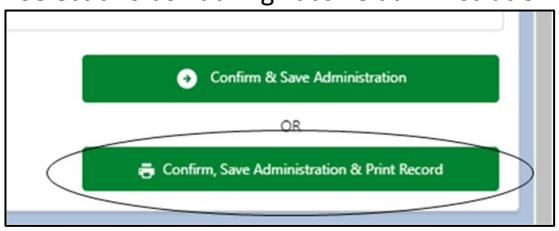
- As per BCCDC Immunization Manual, written documentation of immunization is preferred and verbal reports should not be accepted as evidence of immunization
- With defaults set in ImmsBC, it is possible for the wrong product to be recorded
- If a paper record (e.g. client's immunization card, sticker 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.

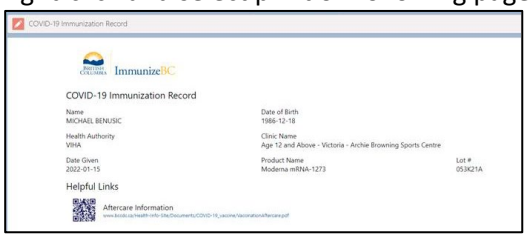
7.3 How do clients access their immunization records?

- BC Vaccine Card is required to access some events, services and businesses
- Clients can access their immunization record through https://www.healthgateway.gov.bc.ca/

- Access to this 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 as Health Gateway must be used for official documentation to travel and uploaded into ArriveCan app
- ***Options to Access Your COVID-19 Records*** can be found on *Panorama SharePoint → COVID Vaccine → C19 Records*

- Clients can 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
- For booster doses clients should be informed that their electronic record will be automatically updated. If they request a paper proof of vaccination provide one of the following:
  - Manually complete a new paper vaccine card
  - Print record during vaccination:
    - Select this box during vaccine administration and Right-click and select print on following page





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
- It is the responsibility of the client to be aware of vaccine requirements to locations they are travelling to
- More information at http://www.bccdc.ca/health-info/diseases-conditions/covid-19/prevention-risks/travel

8.4 How do I manage requests for expedited vaccination?

- See *Question 1.1* for criteria for a walk-in dose
- If client does not qualify for a walk-in dose they must register and book an appointment
  - Register and book through https://www.getvaccinated.gov.bc.ca/s/. Client will be sent an invite when they are eligible to book an appointment.
- Expedited appointments are **not** available, including for 2nd doses for 5-11 clients (the only availability before the routine interval of 8 weeks is through leftover doses)
- **Note:** Evidence shows that protection from acquiring COVID-19 does wane over time, but protection against harm from COVID-19 (e.g. 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 primary series with standard spacing). This is not a third dose or booster dose, this is a replacement primary 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 17 Jan 2022 medical exemptions are available for the BC Vaccine Card. Requests go through the Office of the Provincial Health Officer, **not** through Island Health: 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

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"

8.9 Are there timing requirements for COVID-19 vaccine administration in relation to other vaccines?

- As per BCCDC guidance, COVID-19 vaccines can be provided at anytime in relation to other vaccines, including concurrently. This applies to all age groups.

8.10 What is the process for homebound clients less than 19 years old who are not connected to Nursing Support Services (NSS) to get their vaccine?

- Phone 1-888-533-2273 – Option 1 to initiate request
- Jenny Nijhoff, NSS Manager will be notified and connect with health unit Clinical Coordinator to make arrangements for either NSS or PHN to do a HV to administer vaccine

8.11 What if the client is pregnant, breastfeeding, immunocompromised or has an autoimmune disorder?

- 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

8.12 What if the client has history of multisystem inflammatory syndrome in children (MIS-C)/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

8.13. What if the client is taking medications, including biological products or a blood product?

- 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.

9. DECISION SUPPORT TOOLS

- Internal resources for Public Health staff are accessible on *Immunization Support SharePoint* → *COVID 19*
- Internal resources for Non-Public Health staff are accessible on *Island Health Intranet* → *COVID-19*
- Refer to these internal resources for access to a variety of guidelines, resources and forms related to the COVID-19 Immunization Campaign
- BCCDC Healthcare Provider Q&A
- BCCDC HCP Vaccination Toolkit

10. IMMUNIZATION CONSULTATION PATHWAY

- Refer to this document (COVID-19 Vaccination Clinical Guidance). If the question is not addressed in this document, refer to BCCDC Healthcare Provider Q+A and BCCDC HCP Vaccination Toolkit
- In cases where the information differs, this document overrides

Non-Urgent: *Refer to Intake Process for Immunization Questions & Consultations* and submit consult to *PublicHealthImmunizationSupport@islandhealth.ca*

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

- Monday – Friday until 4:30pm:

Geography	Phone Number
Geo 1: North Island (Mt. Waddington, Campbell River, Comox Valley)	250-331-8591
Geo 2: Central Island (Parksville/Oceanside, Nanaimo, Port Alberni, West Coast)	250-519-3411
Geo 3: Cowichan (Ladysmith, Duncan, Lake Cowichan)	250-737-2020
Geo 4: South Island (Juan De Fuca, West Shore, Victoria, Saanich, Salt Spring Island)	250-519-3411

- Weekdays after 4:30pm and weekends: contact MHO on-call at 1-800-204-6166
  (***state that you need to speak to Medical Health Officer on-call for an urgent public health issue***)