

	Standard Operating Procedure Monkeypox: Clinical Assessment, Testing and Public Health Follow Up	Doc. No.	SOP.XXXX
		Rev.:	00
		Rev. Date:	N/A

SITE APPLICABILITY:
<p>Vancouver Coastal Health Communicable Disease (VCH CD) Program, Regional Public Health Units, Youth Clinics, Primary Care, Urgent Primary Care Centres (UPCCs) and STI Testing and Treatment Clinics Note: With manager approval</p>
PURPOSE:
<p>To outline the standard operating procedure (SOP) of clinical assessment and follow up processes at Vancouver Coastal Health community health care sites for individuals experiencing symptoms associated with <i>Orthopoxvirus genus</i> monkeypox infection.</p>
SCOPE:
<p>This document outlines the clinician responsibilities for Physicians, Nurse Practitioners (NP) Licensed Practice Nurses (LPN) and Registered Nurses (RN) in assessing & testing of suspect monkeypox infections as well as reporting requirements.</p> <p>This SOP serves as both an external assessment and testing guidance document for VCH health care providers, and an internal document for the public health follow up conducted at VCH CD Program.</p> <p><i>Note: Interim guidance for the public health management of Monkeypox case and contacts is currently under development by the BC CDC, PHAC and NACI. This SOP may be subject to change based on their upcoming recommendations.</i></p>
RESPONSIBILITIES:
<p>Leadership/Managers:</p> <ul style="list-style-type: none"> Implement the guidance in this standard operating procedure, appropriate personal protective equipment and testing materials to prepare for a suspect Monkeypox client presentation. Ensure staff are trained and aware of assessment and testing pathways as per this procedure. <p>Physicians & Nurse Practitioners:</p> <ul style="list-style-type: none"> Follow the guidance outlined by BCCDC in the assessment and testing recommendations for suspect Monkeypox cases. <p>Registered Nurses, Psychiatric Registered Nurses, and Licensed Practical Nurses:</p> <ul style="list-style-type: none"> Review relevant history taking as outlined in this SOP and consult with clinical medical director/lead where appropriate.
PROCEDURE:
<p>Monkeypox is a self-limited viral infection caused by <i>Orthopoxvirus Genus</i>. It is related to smallpox, but with much less severe sequelae depending on the particular circulating strain.</p> <ul style="list-style-type: none"> Exposure Risk <p>Transmission</p> <ul style="list-style-type: none"> Skin-to-skin contact especially when lesions present. More likely to transmit in close physical contact such as household contact and sexual contact (skin to skin). Prolonged face-to-face contact (over several hours) via exposure to respiratory droplets. Fomite contact with contaminated linens, clothing, shared sex toys and towels. Related Travel History, please see World Health Organization map for up-to-date monkeypox endemic countries and non-endemic countries experiencing clusters. Within Canada, as of June 6th, 2022 there are currently 78 confirmed cases of Monkeypox, the majority within Quebec (71), Ontario (5), Alberta (1) and British Columbia (1).

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- **Clinical Presentation**
- [Monkeypox](#) typically has an incubation period of 5-7 days but can be as long as 21 days post exposure.
- Clinical presentation may occur in 2 stages with the first stage of symptoms can last 2-4 weeks and the rash may appear 1-5 days after initial symptom onset.
- **First stage symptoms (can last 2-4 weeks):** Fever, chills, intense headache, swollen lymph nodes, back pain, muscle pain, fatigue or exhaustion.
- **Second stage symptoms (1-5 days post first stage):** rash can evolve from lesions (macules, papules, vesicles then pustules) often starting on the face or legs and arms, and can affect other parts of the body such as hands feet, mouth and genitals ([Reference BCCDC, 2022](#)).



Note: Differential diagnoses should be considered and may include vesicular rashes which can be caused by a number of viruses, such as [Herpes Simplex Virus \(HSV\)](#), [Varicella](#), [Syphilis](#), [Chancroid](#), [Molluscum Contagiosum](#), and [Lymphogranuloma Venereum \(LGV\)](#). Please assess and test accordingly for these infections.

- **Case Definitions and Reporting**

The following case definitions are provided by [BCCDC \(June 2022\)](#)

- **Confirmed case (AKA Lab confirmed):** A person who is laboratory confirmed for monkeypox virus by detection of unique sequences of viral DNA either by polymerase chain reaction (PCR) and/or sequencing.
- **Probable case:** A person of any age who presents with an unexplained acute rash or lesion(s), **AND** has one or more of the following:
 - Has an epidemiological link to a probable or confirmed monkeypox case in the 21 days before symptom onset
 - Or reported travel history in the previous 21 days to an area where transmission of monkeypox has been officially reported
- **Suspect case:** A person of any age who presents with one or more of the following:
 - An unexplained acute vesicular or pustular rash in the oral, genital or perianal region
 - OR unexplained acute vesicular or pustular rash in any other region **AND** has at least one of the following **new-onset** signs or symptoms:
 - Headache
 - Acute onset fever (>38.5 C)
 - Lymphadenopathy (swollen lymph nodes)
 - Myalgia
 - Back pain
 - Asthenia (profound weakness)
 - Unexplained acute genital, perianal or oral lesion(s)

For the purposes of public health monitoring and follow up, immediately report only probable and confirmed of monkeypox to the MHO by emailing VCH CD Program:

- Email MHOandCDNurseOnCall@vch.ca OR
- Call 604-675-3900 (Mon- Fri, 8:30am-5:00pm, excluding stats)

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- Call 604-527-4893 afterhours MHO On-Call
- **Testing Criteria**
- Testing is recommended for individuals who meet the above suspect case definition AND have an appropriate associated exposure scenario.
- For up to date testing recommendations on sample collection please see [BCCDC Monkeypox page](#).
- Suspect cases for which clinical presentation is highly suggestive of monkeypox should be discussed with your site medical leadership, microbiologist or an infectious disease specialist before sampling.
- **The medical microbiologist on-call at BCCDC Public Health Laboratory (PHL) should be contacted at 604-661-7033 for all monkeypox sample testing.**
- Report all tests and suspect cases via email to MHOandCDNurseOnCall@vch.ca.
- Include the following: case initials, DOB, PHN and date of test.
- Public Health will be monitoring individuals with pending results. For public health follow up purposes and to offer education on self-isolation and infection control measures.
- All individuals meeting suspect clinical criteria and testing for Monkeypox should be advised to return home immediately to self-isolate pending results of testing.

- **Specimen Collection**

- For further information on lab requisition and collection sample please refer to [BCCDC Public Health Laboratory \(PHL\) test menu on eLAB](#)
- Monkeypox diagnosis is confirmed by PCR testing (Monkeypox virus NAT)
- BCCDC PHL preliminary results may be available as early as 1-2 days, NML confirmatory results will take 5-7 days
- Specimens are sent to BCCDC PHL which are forwarded NML in Winnipeg. However, BCCDC PHL is currently working on implementing specimen processing
- Indicate on BCCDC PHL [Virology Requisition](#)
- Under **“ORDERING PRACTITIONER. Name and MSC#:”** indicate **clinic physician**
- Order test **“Monkeypox”** under **“PATIENT STATUS/TRAVEL HISTORY*/EXPOSURE (Please provide travel history where indicated)”** and include a note about any known travel or exposures

PATIENT STATUS / TRAVEL HISTORY* / EXPOSURE

(Please provide travel history where indicated*)

Monkeypox

Travel to West Africa 1 week ago.

- Individuals presenting with vesicular lesions should also be tested for HSV/VZV/entero. This can be completed off the same swab. Please indicate accordingly on requisition.
- The lab will automatically then run varicella and enterovirus.

Lesion swab (PREFERRED)

Direct lesion PCR testing is preferred method of testing, with 98% specificity/sensitivity in detection of monkeypox. Use the COPAN blue-top with Universal Transport Media (same as “HSV swab”) to collect the specimen. The following steps describe how to collect a sample:

- Consider use of N95 Mask for lesion swabbing in a private room, if available.
- Unroof the blister with a tuberculin syringe needle or broken edge of a sterile swab shaft.
- Swab the fluid of broken blister. Place the swab in transport media, label the sample appropriately and transport to BCCDC PHL.
- Alternatively the contents of the vesicular lesion may be aspirated with the syringe and transferred to the vile of transport medium
- Collect dry swab if the lesion(s) has crusted over.

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Oropharyngeal swabs, nasopharyngeal swabs, EDTA blood and urine specimens (ALTERNATIVE)

Please discuss with an MHO, Infectious Disease Specialist or Microbiologist on-call at 604-661-7033 before collecting and submitting samples.

For highly suspect individuals who **meet first stage clinical symptoms with an appropriate exposure scenario**, but do not have a lesions. Consider alternative specimens, listed in order of samples preference:

- Oropharyngeal (OP) swabs or [nasopharyngeal \(NP\)](#) swabs are considered an alternative form of testing.
 - Nasopharyngeal (NP) swab: COPAN red-top with Universal Transport Media
 - Collection kit includes flocked swab and tube of transport medium.
 - Oropharyngeal Swab: COPAN red-top with Universal Transport Media
- EDTA blood or urine can also be considered for testing, but not required if NP/OP swab testing is available.
 - Urine specimen (first catch): Sterile container, optimal: 50 mL. Min: 5mL
 - EDTA Blood for PCR testing: EDTA (purple top) 5 ml blood tube

COPAN blue-top with Universal Transport Media: monkeypox, HSV, VZV, enterovirus	COPAN red-top with Universal Transport Media: Nasopharyngeal, Oropharyngeal swabs	EDTA Blood: EDTA (purple top) blood tube *consult with microbiologist first	Urine: Sterile container (optimal: 50 mL, min 5mL)
			

Ordering Sample Containers

- Order sample container using the [PHSA Sample Container Order Form](#) by emailing kitorders@hssbc.ca OR faxing to 604-707-2606.
- For further inquiries on ordering please phone PHSA CDC Receiving at 604-707-2507

Transportation of Specimens

- Collected specimens should be stored and shipped under refrigeration 2-8 degrees (cooler) to BCCDC PHL lab
- As of June 2, 2022, clinical specimens from patients undergoing monkeypox testing have been temporarily reclassified as UN3373 Biological Substance, Category B for land transport.

Infection Prevention & Control Guidelines

- Monkeypox doesn't generally spread easily between people. Human-to-human transmission occurs via:
 - Direct contact with cutaneous or mucosal lesions
 - Fomites, i.e. contaminated material such as linens or clothing;
 - Respiratory droplets from prolonged face-to-face contact
- It is unknown if airborne transmission occurs, although it does not appear to be a primary mode of transmission
- The client should wear a medical mask and perform hand hygiene
- When providing direct care and lesions are uncovered (i.e., specimen collection), implement the following in addition to routine infection prevention and control practices:
 - Use a private room with the door closed whenever possible.
 - Use gown, gloves, eye protection and fit tested N95 respirator.
- Refer to monkeypox guidelines in [VCH IPAC Diseases and Conditions Table: Recommendations for Management of Patients, Residents & Clients](#)

Management of Case- VCH CD Program Follow up

- Probable and confirmed cases will be followed by public health in consultation with the MHO

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- Cases of severe disease may be admitted to hospital under infectious disease for appropriate monitoring and treatment.
- **Self Isolation** is recommended for the period of communicability for *probable and confirmed cases, as well as pending test results for suspect cases*
- **Period of communicability** is defined as the date of symptom onset (including prodromal symptoms) until the resolution of lesions (ex. crusts have shed and new skin grown). This period may last from 2-4 weeks.
- **Antiviral treatment** is available for cases of severe disease status. Please see [US CDC Interim Clinical Guidance for the Treatment of Monkeypox](#).

Management of Contacts

- Exposure period is considered contact that occurred **during the period of prodromal illness or up to 5 days prior to rash appearance**.
- MHOs may exercise discretion based on specific circumstances of exposure scenarios.
- Within the region of VCH, case and contact tracing will be done by the VCH CD Program. Please contact: 604-675-3900 or MHOandCDNurseOnCall@vch.ca

Classification of Contacts

Risk Level	Contact Tracing	Self-Isolation	Recommendations
Contact of a Confirmed or Probable case			
High Risk Exposure: <ul style="list-style-type: none"> - Unprotected, direct skin-to-skin contact, or contact with mucous membrane where lesions present or bodily fluids exchanged. - Unprotected skin contact with objects that have been in contact with contaminated body fluids (bedding, clothing, towels etc) with a confirmed case. 	Generally no, unless contact could be classified as probable case or a large exposure event is identified.	No	<ul style="list-style-type: none"> - PEP recommended - Public health will monitor as appropriate up to 21 days post exposure - Educate contacts on monkeypox symptoms - Request contact reduce any unnecessary social activities; however strict quarantine not required if asymptomatic
Medium Risk Exposure: <ul style="list-style-type: none"> - Close proximity to case for prolonged duration but no direct physical contact to cases body or potentially contaminated objects. 	Not required	No	<ul style="list-style-type: none"> - PEP recommended - Passive surveillance x 21 days, contact advised to call public health if they become symptomatic - Educate contacts on monkeypox symptoms
Low Risk Exposure: <ul style="list-style-type: none"> - Close prolonged contact with case; however precautions in place (ex. mask) and no activity that meeting high risk exposure. 	Not required	No	<ul style="list-style-type: none"> - PEP can be considered at discretion of MHO - Public health to encourage case to inform low risk contacts - Educate contacts on Monkey pox symptoms - Passive surveillance x 21 days contact advised to contact public health if they become symptomatic

If **any** contact becomes symptomatic during self monitoring period, advise:

- Cover any rash at all times that appears and wear a medical mask
- Seek medical care and testing at a primary care clinic or STI testing site.

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- Return home immediately to self-isolate pending results of testing
- Maintain physical distance, keep separate linens/towels and mask around other household contacts. Try not to share a bed, if possible.
- While monkeypox has been shown to affect some animals, mainly rodents, no zoonotic transmission has yet been identified in the current outbreak. At this time, as a precaution, we suggest limiting or reducing close contacts with pets if that is all possible. The risk to pets is considered very low. Any advice will be revised as new evidence arises.

Post Exposure Prophylaxis: [Imvamune Vaccine](#)

Imvamune is released by the BCCDC Physician on-call in consultation with VCH CD MHO.

MHO approval is required for PEP use. Close contacts of a confirmed case will be assessed and offered PEP if not yet symptomatic. Most contacts will be identified via case and contact tracing completed by the VCH CD Program. In the event that a close contact presents to a health care setting requesting vaccine, refer to VCH CD Program 604-675-3900

To refer a close contact for consideration of PEP:

- Contact VCH CD Program with details of client and exposure for consideration.
- If client approved for PEP, VCH MHO/public health designate initiates vaccine request by contacting BCCDC pharmacist Monday-Friday 0830-1630 at 604-707-2580 or afterhours at 604-809-4670 (switchboard 604-875-2161 ask for BCCDC pharmacist on-call).
- BCCDC pharmacy will prepare the release of vaccine upon direction from MHO/public health designate.
- VCH CD Program will contact BCCDC pharmacy at 604-702-2580 or afterhours at 604-809-4670 and arrange to procure vaccine from BCCDC pharmacy located at 655 West 12th Ave.
- VCH CDC staff will arrange for administration of vaccine.

Administration of PEP

At this time, the Health Canada approved product is [IMVAMUNE](#), a live-attenuated, non-replicating vaccine indicated for the prevention of monkeypox and smallpox in adults 18 years of age and older. The vaccine is produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated non-replicating *orthopoxvirus*. The product does not contain any monkeypox or smallpox virus, so cannot cause monkeypox or smallpox disease.

Considerations

- **Pediatrics:** There is currently no safety data in subjects under 18 years of age for INVAMUNE. Off-label use may be considered by an MHO in this population based on risk of exposure. Before the eradication of smallpox disease, smallpox vaccination was administered routinely during childhood since the benefits were considered to outweigh the risks. IMVAMUNE should be administered to children only if they are at risk of infection with variola virus and if the benefit of immunization outweighs the potential risks to the child.
- **Geriatrics:** No overall differences in safety and immunogenicity were observed between subjects in this population
- **Pregnant individuals:** Available human data on IMVAMUNE administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. Animal reproductive studies did not reveal any evidence of impaired fertility or harm to the fetus. IMVAMUNE should be administered to pregnant women only if they are at risk of infection with variola virus and if the benefit of immunization outweighs the potential risks to the mother and fetus.
- **Breast-feeding individuals:** Safety during lactation has not been established. It is unknown if vaccine antigens or antibodies are excreted in human milk. IMVAMUNE should be administered to women who are breastfeeding only if they are at risk of infection with variola virus and if the benefit of immunization outweighs the potential risks.
- **Immunosuppressed individuals:** The use of IMVAMUNE in immunosuppressed patients is supported by clinical trials which include individuals who are human immunodeficiency virus (HIV) infected (CD4 \geq 100 cells/ μ L). An adequate immune response may be diminished in HIV positive individuals as well as in other patients with immunodeficiency or patients receiving immunosuppressive therapy.

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Contraindications

- History of anaphylactic reaction to a previous dose or any component of the vaccine
- Delay in individuals with acute febrile conditions if used for non-emergency (pre-event) prophylaxis

Product Components

Potential Allergens: Chicken protein, gentamicin, ciprofloxacin

Other components: Trometamol, sodium chloride, benzonase

- No preservatives or adjuvants
- Supplied in a borosilicate glass vial with a sterile bromobutyl rubber stopper and an aluminum cap covered with a polypropylene closure

Product Presentation

- 2mL single dose vial containing 0.5mL of product supplied as a liquid frozen suspension

Cold chain

- Long term storage is carried out at -20C (+5C) or -80C (+10C), expiry depends on storage temperature
- Once thawed, vaccine may be stored at 2-8C for up to 2 weeks
- Do not refreeze a vial once it has been thawed
- Store in original package to protect from light

Doses and Schedule

Post-Exposure Prophylaxis: 1 dose given as 0.5 mL **SC**. Consider 2nd dose 4 weeks later if ongoing risk of exposure.

Pre-Exposure Prophylaxis: 2 doses given as 0.5 mL **SC**, 4 weeks apart. Those who have previously been vaccinated against smallpox should receive 1 dose. NOTE: Indications for pre-exposure use in BC have not been identified at this time.

Administration

For post-exposure prophylaxis (PEP), **one dose is indicated within 4 days (up to 14 days)** since first event of close exposure in a non-symptomatic contact. For pre-event prophylaxis, the primary vaccination schedule consists of two doses of 0.5mL four weeks apart. Vaccine will not be offered for pre-event prophylaxis at this time.

- Thaw vaccine at room temperature (approximately 10-15 minutes) until vaccine no longer cold to touch.
- To ensure homogeneity upon thawing, swirl the vial gently (do **not** shake) for at least 30 seconds
- Product should appear as a pale milky coloured homogenous suspension
- Withdraw vaccine from vial using aseptic technique
- Inject entire contents (0.5ml) of the vial subcutaneously (5/8" needle), preferably in the deltoid region of the non-dominant upper arm
- Interactions with other vaccines have not been established. If co-administration with another vaccine is indicated, immunization should be carried out on separate limbs if possible.

Adverse reactions

Most common local adverse reactions at injection site:

- Pain
- Erythema
- Induration and swelling

Most common systemic adverse reactions:

- Fatigue

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- Headache
- Myalgia
- Nausea

Most reported adverse drug reactions were mild to moderate intensity and resolved within the first seven days following vaccination

An [Adverse Event Following Immunization](#) form is to be completed if the vaccine administration resulted in a reportable adverse reaction. For contact information for reporting to the local public health, follow [this link](#), or fax to VCH CDC at 604-731-2756, or email report to vaccine.adverse.events@vch.ca.

Enhanced post-administration monitoring

Post vaccine follow-up will be performed by the Health Authority of vaccine recipients on day 7 post administration. BCCDC is developing a post vaccine questionnaire to be used for follow up.

Documentation:

Testing Site:

- Documentation to be done on site according to VCH and site policies

VCH CD Program:

- Case documentation to be completed in [PARIS CDV2 and related CD Contact Application](#) under disease Monkeypox.
- Completed [PHAC interim Case Report Form \(CRF\)](#) and send to BCCDC via scanning and saving in shared drive.
- Any Contacts under investigation please enter in Paris CD contact Application.

GENERAL REQUIREMENTS:

- As there will be an order required to ensure follow-up by an MD, for NP swabs:
 - LPNs who have prior training, education and experience collecting NP swabs for COVID19 testing, should be good to go for Monkeypox NP swabs (unless individual competency concerns).
 - LPNs with no prior experience, will need training, education and support of CRN/Clin Ed to gain competency in this skill. Resources can include:
 - [Nasopharyngeal Swab, How to Use](#)
 - [How to perform a nasopharyngeal swab](#)
 - [BCCDC Specimen collection and Labelling](#)
 - Check [eLabHandbook](#) for updates
- Follow [BCCDC PHL](#), local laboratory & site specific specimen collection and processing guidelines & policies.
- Follow VCH Infection Control & Prevention, as per the [Home and Community Care Resource Manual](#)
- Follow [VCH Infection Prevention and Control \(IPAC\) Diseases and Conditions Table](#)
- Follow [Phlebotomy for Blood Sample Collection via Venipuncture in Community Settings DST](#)
- Required training BCCDC Immunization Certified Practice and knowledge of [BCCDC Immunization Manual](#)
- [Anaphylaxis Training](#)
- [Phlebotomy Training](#)

Competency

Nurses (RN/RPN/LPN) will demonstrate clinical competency to perform Monkeypox testing by:

- Conducting thorough/accurate clinical history and physical assessment
- Reviewing this SOP
- Demonstrating clinical competence through observation, and demonstration with an experienced health care provider
- Consulting with and/or referring to physician or nurse practitioner as needed

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Physicians and Nurse Practitioners will demonstrate clinical proficiency by:

- Taking thorough/accurate clinical history and physical assessment
- Reviewing this SOP
- Consulting accordingly with MHO, Microbiologist and/or Infectious Disease Specialist as needed

REFERENCES/ASSOCIATED DOCUMENTS:

[BCCDC Viral Requisition \(July 2020\)](#)
[Infection Prevention and Control \(IPAC\) Diseases and Conditions Table: Recommendations in VCH Health Care Settings](#)
[Interim Clinical Guidance for the Treatment of Monkeypox \(US CDC\)](#)
[Imvamune Product Monograph](#)
[Monkeypox Patient Handouts \(multiple languages\)](#)
[PHAC: Interim guidance on infection prevention and control for suspect probable or confirmed Monkeypox within health care settings \(May 27, 2022\)](#)
[Phlebotomy for Blood Sample Collection via Venipuncture in Community Settings DST](#)
[Physicians Update – June 3, 2022](#)
[Paris User Guide for CD and Minimum Data Standards for all CD/Enteric Diseases](#)

APPROVALS			
(Operations Director)	Meaghan Thumath		June 6, 2022
(Manager)	Esther Sigurdson		June 6, 2022
(Medical Director)	Dr. John Harding		June 6, 2022
REVISION HISTORY			
Revision#	Description of Changes	Prepared by	Effective Date
	Initial Release	Laura Zerr	June 9, 2022

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