

Ontario Public Health Standards:
Requirements for Programs, Services and Accountability

Infectious Disease Protocol

Appendix 1: Case Definitions and Disease- Specific Information

Disease: Smallpox and other Orthopoxviruses including Monkeypox

Effective: June 2022

Smallpox and other Orthopoxviruses including Monkeypox

Communicable

Virulent

[Health Protection and Promotion Act \(HPPA\)](#)

[Ontario Regulation \(O. Reg.\) 135/18 \(Designation of Diseases\)](#)

Provincial Reporting Requirements

Confirmed case

Probable case

Suspect case

Person under investigation

As per Requirement #3 of the "Reporting of Infectious Diseases" section of the *Infectious Diseases Protocol, 2022* (or as current), the minimum data elements to be reported for each case are specified in the following:

- [O. Reg. 569](#) (Reports) under the HPPA;
- The [iPHIS User Guides](#) published by Public Health Ontario (PHO);
- For certain vaccines, information to be entered into the applicable provincial inventory system (i.e. Panorama); and
- Bulletins and directives issued by PHO.

Smallpox

Canada is certified as being smallpox-free. In any country that has previously interrupted transmission of smallpox, a single case is considered a public health emergency.

Please note that smallpox requires immediate notification to the ministry. The reporting of this event will be notified to the Public Health Agency of Canada (PHAC) and the World Health Organization under the International Health Regulations.

Reporting of smallpox is by phone and through the ministry during business hours by calling 416-327-7392. After-hours and on weekends and holidays please call the ministry's Health Care Provider Hotline at 1-866-212-2272. The Public Health Ontario Laboratory (PHOL) duty officer must also be contacted at 416-605-3113 to discuss the case with a microbiologist.

Monkeypox

Suspect, probable or confirmed cases of monkeypox do not need to be reported immediately to the ministry. Reports shall comply with the timely entry of case requirements as set out in *iPHIS Bulletin* "[Timely entry of cases and outbreaks for diseases of public health significance](#)" (2020, or as current).

Type of Surveillance

Case-by-case

Case Definition

Smallpox

Confirmed Case

Laboratory confirmation of infection:

- Isolation of variola virus from an appropriate clinical specimen (e.g., whole blood, lesion (vesicular or pustular) fluid, crust material)

OR

- Detection of variola virus nucleic acid

Note: Any testing related to suspected smallpox should be carried out under level 4 containment facilities at the National Microbiology Laboratory (NML).

Probable Case

- Clinical evidence of illness (see Clinical Evidence section) in a person who is

epidemiologically linked to a laboratory-confirmed case or to a probable case

Suspect Case

- Clinical evidence of illness in a person who is not epidemiologically linked to a laboratory-confirmed case or to a probable case of smallpox

OR

- Atypical lesion known to be associated with the variola virus on a person who is epidemiologically linked to a laboratory-confirmed or probable case.

Monkeypox

Confirmed Case

A person who is laboratory confirmed for monkeypox virus by detection of unique sequences of viral DNA either by nucleic acid amplification test (NAAT) (e.g. real-time polymerase chain reaction [PCR]) and/or sequencing.

Probable Case

A person who meets the criteria in 1, 2, OR 3:

1. a. Presents with an unexplained^[1] acute rash or lesion(s)^[2]

AND

^[1] Common causes of an acute illness associated with rash are enteroviruses including coxsackieviruses (e.g. hand-foot-and-mouth disease), varicella zoster, herpes zoster, measles, herpes simplex, syphilis, chancroid, lymphogranuloma venereum.

^[2] Monkeypox illness presentation includes a progressively developing rash that usually starts on the face and then spreads elsewhere on the body. The rash can also affect the mucous membranes in the mouth, tongue, and genitalia. The rash may affect the palms of hands and soles of the feet. The rash can last for 2–4 weeks and progresses through the following stages: macules, papules, vesicles, pustules, and scabs. There are case reports from North America of an atypical monkeypox illness presentation starting with genital, perianal, or oral rash/lesion(s) which may precede other typical signs and symptoms of monkeypox virus.

b. Meets at least one of the following within the 21 days before their symptom onset:

- Has an epidemiological link to a probable or confirmed monkeypox case, such as a high-risk exposure^[3]
- Has an epidemiological link to a location/event where transmission of monkeypox is suspected or known to have occurred
- Has a relevant zoonotic exposure^[4]

AND

c. Monkeypox virus has not been ruled out by an *Orthopoxvirus* or monkeypox virus NAAT

2. a. Presents with an unexplained^[1] acute rash or lesion(s)^[2]

AND

b. Has an indeterminate *Orthopoxvirus* or monkeypox virus NAAT result

3. a. Has a positive *Orthopoxvirus* NAAT result

AND

b. Is pending monkeypox virus NAAT.

^[3] High risk exposure is defined by Public Health Ontario's [Monkeypox Virus: Interim Case and Contact Management Guidance for Local Public Health Units](#)

^[4] A relevant zoonotic exposure may include contact with a dead or live wild animal or exotic pet that is an African endemic species, or use of a product derived from such animals (e.g., game meat, creams, lotions, powders, etc.)

Suspect Case

A person in whom Monkeypox virus has not been ruled out by a negative *Orthopoxvirus* or monkeypox virus NAAT result and meets the criteria in 1 OR 2:

1. a. An unexplained^[1] acute rash^[2]

AND

b. Has at least one of the following signs or symptoms:

- Fever
- Chills and/or sweats
- Lymphadenopathy (swollen lymph nodes)
- Headache
- Myalgia (muscle/ body aches, back pain)
- Sore throat
- Cough
- Coryza
- Prostration or asthenia (profound weakness)

2. An unexplained^[1] acute genital, perianal or oral lesion(s)

Person Under Investigation (PUI)

A person with a pending *Orthopoxvirus* or monkeypox virus NAAT result

AND

Does not meet criteria for a suspect, probable, or confirmed case of monkeypox.

Outbreak Case Definition

Smallpox

A single case of smallpox is a public health emergency.

Monkeypox

Not applicable at this time.

Clinical Information

Clinical Evidence

Smallpox

Smallpox is characterized by a febrile prodrome consisting of fever $> 38.3^{\circ}\text{C}$ and systemic symptoms (prostration, headache, back pain, abdominal pain, and/ or vomiting), which generally lasts two to four days and is followed by the development of a characteristic rash.

The rash consists of deep, firm, well-circumscribed pustules that are mostly all in the same stage of development. The lesions are characteristically umbilicated. The lesions initially appear as macules, evolving into papules, vesicles and then pustules in a matter of days. Finally, crusted scabs form; they then fall off several weeks after the initial appearance of the rash.

Lesions initially appear in the oral mucosa/palate and then progress in a centrifugal pattern to involve the face, arms, legs, palms and soles. Atypical presentations include flat velvety lesions that do not evolve into vesicles and more severe forms with confluent or hemorrhagic lesions.

Monkeypox

Monkeypox closely resembles smallpox clinically, but lymphadenopathy is a more prominent feature in the prodrome and early stages of monkeypox illness. The prodrome period usually lasts one to three days before the rash develops. Like smallpox, lesions appear and evolve through stages of macules, papules, vesicles, pustules, to crusts/scabs before falling off.¹ Atypical presentations include initial signs of a genital or peri-anal rash prior to prodrome symptoms which may not spread to other parts of the body, and having lesions at different stages of development.²

Clinical Presentation

Smallpox

Smallpox is a systemic viral disease.³ Clinical presentation in the prodromal period

has been described as sudden onset of high fever, malaise, severe headache and backache, prostration, occasional abdominal pain and vomiting.³ After 2-4 days the fever begins to fall, followed by a characteristic eruption of a rash of skin lesions.³ The rash on any one part of the body is in the same phase of development and progresses through successive stages of macules, papules, vesicles, pustules described as “pearls of pus”, then crusted scabs that fall off 3 - 4 weeks later.³

Monkeypox

Monkeypox is usually self-limiting and closely resembles the clinical presentation of smallpox. The prodrome symptoms include fever, chills, myalgia, fatigue, headache, backache, and sometimes sore throat and cough. The rash develops after one to three days and usually lasts two to four weeks, progressing through successive stages of macules, papules, vesicles, and pustules before the lesions crust and fall off with new skin formed.¹

Laboratory Evidence

Smallpox

Laboratory Confirmation

Any of the following will constitute a confirmed case of Smallpox:

- Positive variola virus culture in an appropriate clinical specimen (e.g., whole blood, lesion (vesicular or pustular) fluid, crust material)
- Positive for variola virus nucleic acid detection by nucleic acid amplification test (NAAT)

Approved/Validated Tests

- Standard culture for variola virus
- NAAT for variola virus

Indications and Limitations

- Polymerase Chain Reaction (PCR) can definitively diagnose infection with

variola virus; all other tests screen for orthopoxviruses

- Diagnostic investigation should include ruling out varicella-zoster virus and other common conditions that cause a vesicular/pustular rash illness (e.g. enterovirus)
- Any testing related to suspected smallpox should be carried out under level 4 containment facilities at NML
- In the event of a suspected case, immediately contact the PHOL Customer Service Centre at 416-235-6556/1-877-604-4567 or the after-hours Duty Officer at 416-605-3113. PHOL medical and clinical microbiologists will provide advice prior to sampling. PHOL can assist with arranging safe transportation of clinical specimens to NML in compliance with the [*Transportation of Dangerous Goods Act, 1992*](#).
- For further information about human diagnostic testing, contact the [Public Health Ontario Laboratories](#)

Monkeypox

Refer to PHOL's Laboratory testing information at: [Monkeypox Virus | Public Health Ontario](#)

Case Management

Smallpox

The WHO regards even a single case of smallpox anywhere in the world as a global health emergency;³ the identification of a single case constitutes a public health emergency.

At time of a case, the Ministry Emergency Operations Centre (MEOC) will be activated to coordinate and direct the health system's response to a case of smallpox. This will include providing supports and guidance to assist medical officers of health, other board of health staff, health care providers and other health workers in managing a case of smallpox.

Monkeypox

Confirmed or probable cases in whom hospitalization is not clinically indicated should **self-isolate at home** until the end of the period of communicability for a monkeypox case (**i.e., until lesion scabs have fallen off and new intact skin has formed below**, a process which varies by individual but typically takes **2-4 weeks**).

- Ending of the self-isolation period should be assessed on an individual case basis and in consultation with the local public health unit.

Public health units should follow up with cases during their isolation period and identify potential barriers/resources to support effective isolation

- Note: all individuals for whom monkeypox testing is being performed should be advised to self-isolate at home (or in the community) pending test results.

Advice for cases:

- Stay in a separate room/area away from other household members if possible and use a separate bathroom if available/feasible
- Avoid contact with those at higher risk of severe monkeypox illness including immunosuppressed people, pregnant women, and children under age 12 years
- Avoid leaving the home unless necessary (e.g., to seek essential medical care)
- Avoid non-essential household visitors
- Wear a mask for source control (medical mask preferred), especially if respiratory symptoms are present
- Cover skin lesions as much as possible (e.g., long sleeves, long pants)
- Avoid contact with animals, including household pets:
 - **Keep your pets in the home.** If possible, ask someone else in the home who is not sick and who has not been exposed to care for the pet. This is especially important for rodents, rabbits and non-human primates.

- **Avoid close or prolonged contact with pets**, for example, avoid direct contact, including touching, snuggling, and kissing animals, especially if the case has unhealed sores on the face, hands, or arms.
- **Take precautions when providing care for pets**, for example, wear a mask when in the same room as any pet, especially if the case has sores in the mouth or is coughing/sneezing. Wash hands with soap and water or use an alcohol-based hand rub immediately before and after touching pets, their food, or supplies; if the case has rash/sores on the hands and must touch an animal should be advised to wear disposable gloves to avoid potential disease transmission.
- Any person who may have been exposed to monkeypox should not work with wildlife, livestock, or poultry until they are advised by their physician or public health unit that they don't pose any risk for further transmission of the virus.
- Public health units with knowledge of a confirmed case with ongoing exposure to mammals (excluding dogs and cats) should report the animal details (no personal health information) to the Ontario Ministry of Agriculture, Food and Rural Affairs at 1-877-424-1300 for an animal health risk assessment.

For more information on case management of monkeypox refer to [Monkeypox Virus: Interim Case and Contact Management Guidance for Local Public \(publichealthontario.ca\) \(2022, or as current\).](#)

Contact Management

Smallpox

The MEOC will be activated to coordinate and direct the health system's response to a case of smallpox. This will include providing supports and guidance to assist medical officers of health, other board of health staff, health care providers and other health workers in managing all contacts.

Monkeypox

Contacts of a probable or a confirmed case of monkeypox should monitor for signs and symptoms for 21 days from last exposure: e.g, new skin rash/lesions, fever, chills, headache, lymphadenopathy.

If contacts develop any **symptoms** of monkeypox including prodromal symptoms, they should self-isolate immediately.

Asymptomatic contacts are not required to self-isolate and can attend routine daily activities (e.g., attend school, work) and

- consider wearing a mask for source control in enclosed indoor settings.

The definitions for close contacts are described in PHO's [Monkeypox Virus: Interim Case and Contact Management Guidance for Local Public \(publichealthontario.ca\)](#) (2022, or as current), and should be used to categorize close contacts based on the extent of exposure to the case, inform contact management recommendations, and identify groups eligible for post-exposure prophylaxis (PEP). Priority for administration of PEP should be in accordance with the [Monkeypox Interim Vaccine Guidance for Post-Exposure Prophylaxis \(PEP\) and How to Access Tecovirimat](#) (June 2022, or as current). For guidance on the eligibility and priority for administration of pre-exposure prophylaxis (PrEP), visit [Monkeypox Virus \(gov.on.ca\)](#).

Outbreak Management

Smallpox

The MEOC will be activated to coordinate and direct the health system's response to a case of smallpox. This will include providing supports and guidance to assist medical officers of health, other board of health staff, health care providers and other health workers managing a case of smallpox.

For additional information on bioterrorism preparedness, please refer to information posted on the WHO and the Centres for Disease Control and Prevention's (CDC)

web sites.^{6,7}

Monkeypox

For cases of monkeypox, please see the *Infectious Diseases Protocol, 2022* (or as current) for the public health management of outbreaks or clusters in order to identify the source of illness, manage the outbreak and limit secondary spread.

Prevention and Control Measures

Personal Prevention Measures

There is no cure or specific treatment for smallpox and monkeypox. Prevention is by vaccination and isolation. Administering smallpox vaccine (vaccinia vaccine) within four days after exposure can ameliorate illness in nearly all cases of smallpox exposure and may prevent monkeypox infection or lessen disease severity in those who go on to develop monkeypox infection. The disease is stopped because the immune response to the vaccine is fast enough to stop the virus. Once a person shows symptoms, however, treatment is limited to supportive therapy and antibiotics to treat secondary bacterial infections. As well, several antiviral drugs are currently being tested.⁸

For more information on eligibility and access to vaccinia vaccine and antiviral drugs, refer to the ministry's website: [Monkeypox Virus \(gov.on.ca\)](https://www.gov.on.ca)

The National Advisory Committee on Immunization has also provided the [following interim guidance](#) on the use of Imvamune.

The Government of Canada has adopted a "search and contain" strategy recommended by public health experts in Canada and around the world, including Canada's National Advisory Committee on Immunization, Canada's Council of Chief Medical Officers of Health, and the World Health Organization. This is the same approach that was used to eliminate smallpox globally in the late 1970s.⁸

"Search and contain" starts immediately upon the confirmation of a case of smallpox. Anyone that may have come into contact with the virus is rapidly identified and vaccinated within the four-day window. Vaccinated individuals are isolated to help

ensure containment.⁸

Infection Prevention and Control Strategies

Smallpox

Airborne and contact precautions are required in addition to routine practices. A single room for suspected cases with negative air flow and a closed door are required in healthcare settings. The disease can also be transmitted by contaminated clothes and bedding, though the risk of infection from this source is much lower.⁷

Monkeypox

For individuals with suspected, probable, or confirmed monkeypox, refer to the [Infection Prevention and Control \(IPAC\) Recommendations for Monkeypox in Health Care Settings \(publichealthontario.ca\)](https://www.health.gov.on.ca/en/publications/ipac-recommendations-for-monkeypox-in-health-care-settings) (2022, or as current).

Refer to [PHO's website](#) to search for the most up-to-date information on Infection Prevention and Control (IPAC).

Disease Characteristics

Aetiologic Agent

Smallpox - Infectious agent is the variola virus, a species of *Orthopoxvirus*.³

The virus used in the live smallpox vaccine is known as the vaccinia virus, also a member of the genus *Orthopoxvirus*.³

In 1979, the World Health Organization (WHO) declared that smallpox (variola) had been eradicated successfully worldwide however, it remains a potential weapon for bioterrorism.^{3,4}

Monkeypox - Infectious agent is the monkeypox virus, a species of *Orthopoxvirus*.³

There are two genetically distinct clades of monkeypox virus: the West African clade and the Congo Basin clade.³ The West African clade of monkeypox virus is generally associated with less severe disease compared to the Congo Basin clade.¹

Modes of Transmission

Smallpox - Infection from smallpox usually occurred by respiratory tract via respiratory secretions or by skin inoculation.³

Monkeypox - Human infection historically occurred from exposure to an infected animal.³ In outbreaks which began in 2022, person-to-person transmission usually occurs via direct contact with skin lesions/scabs, bodily fluids, respiratory secretions, mucus membranes, and materials contaminated with monkeypox virus (e.g. contaminated bedding, linens, towels, lesion dressings).¹

Incubation Period

Smallpox - From 7-19 days; commonly 10-14 days from infection to onset of illness, then 2-4 more days to onset of rash.³

Monkeypox - From 6-13 days; commonly 5-21 days from infection to onset of illness, then 1-3 more days to onset of rash.¹

Period of Communicability

Smallpox - Communicable from the time of development of the earliest lesions and until the disappearance of all scabs about 3 weeks after the onset of rash.³ Risk of transmission appears to be highest at the appearance of the earliest lesions through droplet spread from the oropharyngeal enanthem.³

Monkeypox - Transmission may take place during the prodromal period, but generally starts with the onset of rash until all lesions have crusted, fallen off, and new skin has formed, about 2 to 4 weeks.¹

Reservoir

Smallpox - Exclusively human disease with no other known reservoirs.³

Currently the virus exists only in two WHO reference laboratories in the United States and Russia.³

Monkeypox - A viral zoonosis with some non-human primates, rodents, hedgehogs, opossums, and rabbits known to harbour the virus. There are no known endemic animal reservoirs in Canada.^{1,3}

Host Susceptibility and Resistance - All unvaccinated individuals are susceptible.³

Formerly, smallpox was a widespread worldwide disease, however the last occurrence of endemic smallpox was in Somalia in 1977 and the last case in the world was a laboratory acquired infection in 1978 in England.³ Global eradication of smallpox was certified by the World Health Organization (WHO) in 1979.^{3,4}

Comments

Boards of health must contact the Ministry of Health, immediately using the 24-hour Healthcare Provider Hotline: 1-866-212-2272 in the event of a suspected case of smallpox.

Clinicians must contact their local medical officer of health prior to collecting specimens on any suspect or probable case of smallpox for laboratory diagnosis.

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Document History

Revision Date	Document Section	Description of Revisions
April 2022	Entire Document	New template. Appendix A and B merged. No material content changes.
April 2022	Epidemiology: Occurrence section	Removed.
April 2022	ICD Codes	Removed.
June 2022	Entire Document	<p>Addition of content on orthopoxviruses (including monkeypox) as it was designated a DOPHS on June 16, 2022.</p> <p>Updated laboratory information for smallpox testing.</p>