

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: October 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, 2018* (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;<sup>5</sup>
- 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 (WHO) 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 within one business day of the PHU receiving initial notification of the case/encounter/episode/incident 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<sup>[1]</sup> acute rash or lesion(s)<sup>[4]</sup>

**AND**

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<sup>[1]</sup> 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.

<sup>[4]</sup> 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 <sup>[4]</sup>
- Has an epidemiological link to a location/event where transmission of monkeypox is suspected or known to have occurred
- Has a relevant zoonotic exposure <sup>[5]</sup>

**AND**

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

**2. a.** Presents with an unexplained<sup>[1]</sup> acute rash or lesion(s)<sup>[2]</sup>

**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.

**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<sup>[1]</sup> acute rash<sup>[2]</sup>

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<sup>[4]</sup> Exposure risk categories are defined in the [Recommendations for the management of cases and contacts of monkeypox in Ontario](#) (2022, or as current).

<sup>[5]</sup> 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.)

## 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<sup>[1]</sup> 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

Declaring an outbreak in a hospital/health care settings

- **Suspect outbreak:** a single probable case of nosocomially acquired monkeypox
- **Confirmed outbreak:** a single confirmed case of nosocomially acquired monkeypox

Declaring an outbreak in a long-term care home or congregate setting

- **Suspect outbreak:** a single probable case of monkeypox acquired in the home/setting
- **Confirmed outbreak:** a single confirmed case of monkeypox acquired in the home/setting

## Declaring an outbreak over

An outbreak may be declared over by the public health unit (PHU) when there are no new cases in residents or staff linked to exposures in the setting after 42 days (two incubation periods) have passed from the last date that others were potentially exposed to an infectious case.

## 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.<sup>1</sup> 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.<sup>2</sup>

## Clinical Presentation

### Smallpox

Smallpox is a systemic viral disease.<sup>3</sup> 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.<sup>3</sup> After 2-4 days the fever begins to fall, followed by a characteristic eruption of a rash of skin lesions.<sup>3</sup> 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.<sup>3</sup>

### 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.<sup>1</sup>



# 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;<sup>3</sup> 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

In addition to the requirements set out in the Requirement #2 of the "Management of Infectious Diseases – Sporadic Cases" and "Investigation and Management of Infectious Diseases Outbreaks" sections of the *Infectious Diseases Protocol, 2018* (or as current), the board of health shall investigate cases to determine the source of infection. Refer to Provincial Reporting Requirements above for relevant data to be collected during case investigation.

Decisions regarding treatment of individual cases, including the use of antiviral medications, are at the discretion of the attending clinicians. In general, treatment is supportive as the infection is self-limiting in nature. Antivirals may be considered for individuals who are severely ill and/or at high risk for severe disease; for more information on antivirals, refer to the Ministry of Health's [Monkeypox Antiviral Guidance for Health Care Providers](#) document.

Cases in whom hospitalization is not clinically indicated should **self-isolate at home** and follow public health recommendations until the end of the period of

communicability (**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 by the local PHU and in consultation with a health care provider, if required.

For more information on case management of monkeypox and criteria for ending self-isolation, refer to [Recommendations for the management of cases and contacts of monkeypox in Ontario](#) (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 quarantine and can attend routine daily activities (e.g., attend school, work) and consider wearing a mask for source control in enclosed indoor settings.

The exposure risk categories for close contacts are described in the [Recommendations for the management of cases and contacts of monkeypox in Ontario](#) (2022, or as current) and should be used to inform contact management recommendations and identify individuals eligible for post-exposure prophylaxis (PEP). For guidance on the eligibility and priority for administration of PEP, see [Monkeypox Vaccine \(Imvamune®\) Guidance for Health Care Providers](#) (2022, or as current).

For additional vaccine information and guidance, visit [Monkeypox Virus \(gov.on.ca\)](https://www.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.<sup>6,7</sup>

### Monkeypox

Refer to the [Recommendations for Monkeypox case and contact management for Ontario](#) (2022, or as current).

## Prevention and Control Measures

There is no cure or specific treatment for smallpox and monkeypox. Prevention is by vaccination and case isolation. Imvamune® is a live attenuated, non-replicating vaccine that is approved in Canada for protection against smallpox, monkeypox, and other orthopoxvirus related illness; it is 3rd generation smallpox vaccine.

Administering Imvamune® 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.<sup>8</sup> Tecovirimat (TPoxx®) is authorized by Health Canada under an extraordinary use indication for the treatment of smallpox disease in adults and pediatric patients weighing at least 13kg. TPoxx® does not have approved indication for the treatment of monkeypox in Canada,

however a licensed healthcare professional may request TPoxx® for eligible patients based on their clinical judgement for treating severe monkeypox infections. For information on TPoxx® refer to [Monkeypox Antiviral Guidance for Health Care Providers](#) and [TPoxx® Information Sheet](#). For additional resources, visit [Monkeypox Virus \(gov.on.ca\)](#).

For more information on indications, eligibility, and access to vaccinia vaccine and antiviral drugs, refer to the National Advisory Committee on Immunization (NACI) [interim guidance](#) on the use of Imvamune® and the ministry's website: [Monkeypox Virus \(gov.on.ca\)](#).

## Smallpox

The Government of Canada has adopted a "search and contain" strategy recommended by public health experts in Canada and around the world, including NACI, Canada's Council of Chief Medical Officers of Health, and the WHO.<sup>8</sup>

"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.<sup>8</sup>

## Monkeypox

A ring vaccination strategy is used to contain the spread of monkeypox. Imvamune® is offered to eligible individuals as pre-exposure prophylaxis (PrEP) or PEP. This approach is continually being evaluated as the epidemiology evolves and vaccine supply expands. For information on the use of Imvamune® for PrEP or PEP, refer to [Monkeypox Vaccine \(Imvamune®\) Guidance for Health Care Providers \(gov.on.ca\)](#) (2022, or as current). For additional vaccine information and guidance, visit [Monkeypox Virus \(gov.on.ca\)](#).

## 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.<sup>7</sup>

## Monkeypox

For individuals with suspected, probable, or confirmed monkeypox, refer to PHO's [Infection Prevention and Control \(IPAC\) Recommendations for Monkeypox in Health Care Settings](#) (2022, or as current).

For more information on general IPAC, refer to PHO's [Infection Prevention and Control](#) website.

# Disease Characteristics

## Aetiologic Agent

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

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

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

**Monkeypox** - Infectious agent is the monkeypox virus, a species of *Orthopoxvirus*.<sup>3</sup> There are two genetically distinct clades of monkeypox virus: Clade one (I) (formerly referred to as the Congo Basin clade) and Clade two (II) (formerly referred to as the West African clade).<sup>11</sup> Additionally, Clade II consists of two subclades: Clade IIa and Clade IIb.<sup>11</sup> The Clade II of monkeypox virus is generally associated with less severe disease compared to Clade I.<sup>1</sup>

## Modes of Transmission

**Smallpox** - Infection from smallpox usually occurred by respiratory tract via respiratory secretions or by skin inoculation.<sup>3</sup>

**Monkeypox** - Human infection historically occurred from exposure to an infected animal.<sup>3</sup> 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).<sup>1</sup>

## **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.<sup>3</sup>

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

## **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.<sup>3</sup> Risk of transmission appears to be highest at the appearance of the earliest lesions through droplet spread from the oropharyngeal enanthem.<sup>3</sup>

**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.<sup>1</sup>

## **Reservoir**

**Smallpox** - Exclusively human disease with no other known reservoirs.<sup>3</sup>

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

**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.<sup>1,3</sup>

**Host Susceptibility and Resistance** - All unvaccinated individuals are susceptible.<sup>3</sup>

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.<sup>3</sup> Global eradication of

smallpox was certified by the World Health Organization (WHO) in 1979.<sup>3,4</sup>

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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:<br>Occurrence section | Removed.  |
| April 2022    | ICD Codes                           | Removed.  |
| June 2022     | Entire Document                     | Addition of content on orthopoxviruses (including monkeypox) as it was designated a DOPHS on June 16, 2022.<br><br>Updated laboratory information for smallpox testing.                     |
| July 2022     | Entire document                     | Information was removed and instead included in the new reference document for monkeypox.<br><br>Monkeypox: outbreak case definitions added and reference to iPHIS Bulletin for data entry. |
| October 2022  | Disease Characteristics             | Monkeypox variant names updated.  |