



## SMALLPOX

### CDNA NATIONAL GUIDELINES FOR PUBLIC HEALTH UNITS

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The Series of National Guidelines ('the Guidelines') have been developed by CDNA and endorsed by the Australian Health Protection Principal Committee (AHPPC). Their purpose is to provide nationally consistent guidance to public health units (PHUs) in responding to a notifiable disease event.

These guidelines capture the knowledge of experienced professionals, and provide guidance on best practice based upon the best available evidence at the time of completion.

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### Contents

<b>1. Summary .....</b>	<b>4</b>
<i>Public health priority.....</i>	4
<i>Actions in the event of a suspected case.....</i>	4
<i>Case management .....</i>	4
<i>Contact management .....</i>	5
<b>2. The disease .....</b>	<b>5</b>
<i>Infectious agents.....</i>	5
<i>Reservoir .....</i>	5
<i>Mode of transmission .....</i>	5
<i>Incubation period.....</i>	5
<i>Infectious period .....</i>	6
<i>Clinical presentation and outcome .....</i>	6
<i>Persons at increased risk of disease.....</i>	7
<i>Disease occurrence and public health significance .....</i>	7
<b>3. Routine prevention activities .....</b>	<b>7</b>
<b>4. Surveillance objectives.....</b>	<b>7</b>
<b>5. Data management .....</b>	<b>8</b>
<b>6. Communications .....</b>	<b>8</b>
<b>7. Case definition .....</b>	<b>8</b>
<i>Confirmed case .....</i>	9
<i>Probable case.....</i>	9
<i>Suspected case .....</i>	9
<b>8. Laboratory testing.....</b>	<b>10</b>
<i>Testing guidelines .....</i>	10
<i>Laboratory test methods used for the diagnosis of smallpox .....</i>	11
<i>Procedure for collection of specimens .....</i>	12
<i>Transport of specimens to the laboratory.....</i>	12
<i>Laboratory procedures.....</i>	13
<b>9. Case management .....</b>	<b>14</b>
<i>Response times .....</i>	14
<i>Response procedure.....</i>	14
<b>10. Contact management.....</b>	<b>15</b>
<i>Contact identification and characterisation .....</i>	15
<i>Management of contacts (primary and secondary) .....</i>	17
<b>11. Smallpox vaccination .....</b>	<b>20</b>
<i>Smallpox vaccine.....</i>	20
<i>Receiving the vaccine.....</i>	21
<i>Post-vaccination care.....</i>	22
<b>12. Infection control .....</b>	<b>22</b>
<i>Overview .....</i>	22
<i>Isolation and restriction .....</i>	23
<i>Environmental decontamination and waste disposal.....</i>	25
<i>Care of deceased smallpox patients.....</i>	27
<b>13. Special situation.....</b>	<b>28</b>
<i>Weaponised bio-agent.....</i>	28
<i>Cases among travellers on aeroplanes .....</i>	29

<b>14. References .....</b>	<b>30</b>
<b>15. Appendices .....</b>	<b>32</b>
<b>Appendix A: Smallpox factsheet .....</b>	<b>33</b>
<b>Appendix B: Smallpox Public Health Unit checklist .....</b>	<b>35</b>
<b>Appendix C: Clinical comparison of smallpox and chickenpox (varicella) infections.....</b>	<b>36</b>
<b>Appendix D: Case investigation form .....</b>	<b>37</b>
<b>Appendix E: Contact surveillance form .....</b>	<b>43</b>
<b>Appendix F: Advice for contacts of a case of smallpox .....</b>	<b>45</b>
<b>Appendix G: Vaccination factsheet .....</b>	<b>47</b>
<b>16. Jurisdiction specific issues.....</b>	<b>51</b>

## 1. Summary

This guideline describes the public health response to a case of smallpox.

This guideline is intended to be used together with the national Plan for Smallpox Outbreak, Preparedness, Response and Management (Smallpox Plan) and jurisdictional smallpox response plans.

A single confirmed or probable case will initiate activation of the smallpox response plans. Other criteria for activation of smallpox response plans include:

- reports of suspected smallpox cases once an outbreak has been confirmed elsewhere
- reports of human exposures to an environmental source containing smallpox virus.

### Public health priority

Urgent. Respond to suspected, probable and confirmed cases immediately.

Smallpox has been eradicated as a naturally occurring infectious illness, with no known animal vector<sup>(1)</sup>. The last naturally acquired case of smallpox occurred in 1977. The re-introduction of smallpox would constitute a Public Health Emergency of International Concern under the International Health Regulations (IHRs)<sup>(2)</sup>. Any delays in reporting or responding to smallpox cases may severely impact disease containment<sup>(3)</sup>.

Smallpox is a nationally notifiable disease, and a listed human disease under the *Biosecurity Act 2015*<sup>(4, 5)</sup>.

### Actions in the event of a suspected case

The aim is to isolate the infectious case and create a barrier of immune persons around the case (ring vaccination). Post exposure vaccination may prevent or modify disease. The following actions should be undertaken as soon as possible:

- identify and isolate smallpox cases to prevent further disease spread
- identify, vaccinate and monitor higher risk and lower risk primary contacts to prevent secondary cases
- identify, vaccinate and educate the household-like contacts of higher risk primary contacts to prevent tertiary cases
- vaccinate first responders (healthcare and emergency workers who may come into contact with a smallpox case or specimens).

This surveillance and containment strategy may be supplemented with large-scale vaccination, based on risk assessments. Targeted mass vaccination in addition to the strategies listed above is important if there were a large number of index cases or delay in commencement of containment. Mass vaccination, of both affected and unaffected communities, may be undertaken.

### Case management

Suspected, probable and confirmed cases should be immediately isolated and notified to the relevant Communicable Disease Branch (CDB) who will report to the National Incident Room (NIR). Immediately commence follow-up investigation. Early in an outbreak, laboratory confirmation should be sought in all cases. Subsequently, laboratory confirmation is not necessary in cases with clinical and epidemiological evidence. Undertake a clinical and exposure risk assessment in consultation with the Chief Human Biosecurity Officer (CHBO) and relevant infectious diseases service.

### Contact management

All contacts of a confirmed or probable case must be traced immediately. The following steps should be taken:

- Categorise primary contacts as either higher risk or lower risk.
- Identify secondary contacts (household-like contacts of higher risk primary contacts) (see Section 10. Contact management).
- Unless there is an absolute contraindication, vaccinate all higher risk primary contacts. Unless there is a relative or absolute contraindication, vaccinate lower risk primary contacts and secondary contacts.
- Quarantine all higher and lower risk primary contracts (until 17 days from last exposure).
- All higher risk and lower risk primary contacts should commence symptom surveillance, including daily public health unit (PHU) check-up.
- Isolate immediately any contact with symptoms compatible with smallpox, and manage as a probable case.

## 2. The disease

### Infectious agents

Smallpox is caused by infection with either of the closely related variola viruses: variola major and variola minor([1](#)). Variola viruses are deoxyribonucleic acid (DNA) viruses of the genus *Orthopoxvirus*, which also includes vaccinia (used to produce the smallpox vaccine), monkeypox and cowpox.

Variola virus is thought to be unlikely to survive on its own for more than 24 hours when exposed to normal environmental conditions (ambient temperature, usual humidity and sunlight)([6](#), [7](#)). The infectious dose is unknown (in aerosol it may be very low, e.g., only 10–100 virions) ([1](#), [7](#), [8](#)). Ten to twenty secondary cases may develop from each primary case([6](#)).

### Reservoir

Smallpox is a human disease with no known animal or environmental reservoir([1](#)). There is no carrier state. Global eradication of smallpox was certified by the World Health Assembly in 1980.

### Mode of transmission

Smallpox had household or close contact attack rates of up to 88%([9](#)). Transmission occurred primarily via the respiratory tract (droplet spread) and to a lesser extent through direct contact such as from pustules. Close contact is usually required (i.e. within 2 metres)([1](#)).

Less commonly, spread occurred from contaminated fomites such as bed linen or clothing([10](#)). The duration of infectivity of fomites is unknown, but likely to be no more than a few days.([11](#)) Spread through fine particle aerosols could occur if cough was present([1](#)). Two hospital-based outbreaks resulting from airborne spread through air corridors have been described([12](#)). The conjunctivae or the placenta were occasional portals of entry of infection([10](#)).

Cases with more severe illness transmit smallpox more effectively than those with mild or moderate illness([12](#)).

### Incubation period

The incubation period for smallpox is 7–17 days; most commonly 12–14 days to onset of prodromal illness and 2–3 days more to onset of rash([7](#), [13](#)).

### **Infectious period**

Cases are not believed to be infectious prior to the onset of symptoms. Cases should be regarded as infectious from the onset of fever. Cases are most infectious from the onset of the rash and for the first 7–10 days of rash(7).

As a precaution and for the purposes of contact tracing, the infectious period is from 24 hours before recognition of fever or other prodromal symptoms until the last scabs from the rash fall off.

Cases have occurred after contact with corpses.(14, 15) The duration of infectivity of corpses is unknown.

### **Clinical presentation and outcome**

Typically smallpox infection has a 2–3 day prodromal stage which is characterised by an acute onset of high fever ( $\geq 38$  °C) and constitutional symptoms such as malaise, prostration, headache, severe back pain and, on occasion, abdominal pain and vomiting(7, 16, 17). A maculopapular rash develops 2–3 days after symptom onset in which individual lesions containing infectious virus appear over a 1–2 day period and then progress over a period of 6 or more days through successive stages of macules, papules, vesicles, and pustules(1, 7). Vesicles are filled with clear fluid and often have a depression in the centre. The vesicles change to pustules which are round, well circumscribed, tense and firm ('bullet like') without an inflammatory flare(1). Crusted scabbing usually begins 8–9 days after rash onset. Scabs fall off leaving depigmented skin and, over time, frequently scars (pockmarks). Classically the rash commences on the mucosa of the mouth and pharynx, then face, hands, forearms and feet (including palms and soles) before occurring on the torso (centrifugal distribution). The rash usually spreads to involve most of the body over a period of 24 hours. Lesions are usually more profuse on the face, forearms and lower legs than the upper arms, thighs or torso. Prominent surfaces and areas exposed to irritation are more heavily involved in the rash while protected surfaces are usually spared. Lesions are usually at the same stage of development in a given area of the body.

Variola major virus causes a severe illness with an overall fatality rate of 30% or more while variola minor virus causes a milder illness with a fatality rate of 1% or less(7).

The World Health Organization (WHO) classified smallpox into five phenotypes as follows(18):

- Ordinary (classic). The majority of variola major cases were of the ordinary type (case fatality approximately 30%) as detailed above(1).
- Flat (malignant). This rare form had a case fatality rate of approximately 96%. It occurred more frequently in children, and was characterised by intense toxemia(1, 19). The skin lesions developed slowly, become confluent, and remained flat and soft ('velvety' to the touch), and never progressed to the pustular stage. Unless fatal, the lesions gradually disappeared without forming scabs. This can be misdiagnosed as haemorrhagic chickenpox(7, 19).
- Haemorrhagic. This rare form of smallpox had a case fatality rate of approximately 96%(1). Severe prodromal symptoms with high fever, severe headache, and abdominal pain began after a shortened incubation period(19). A dusky erythema soon developed followed by petechiae and skin and mucosal haemorrhages. Death usually occurred by the 5th or 6th day of rash, often before more characteristic smallpox lesions developed(7). The two forms of haemorrhagic-type smallpox, early and late, were differentiated by the occurrence of haemorrhages after the appearance of the rash in the late form(19). Haemorrhagic smallpox occurred in all age groups but pregnant women were particularly susceptible. This form can be misdiagnosed as meningococcaemia or acute leukaemia(7, 19).
- Vaccine-modified. The prodromal stage may still consist of severe headache, backache, and fever(19). The skin lesions usually evolved more quickly with crusting completed within 10 days.

The lesions were usually fewer in number and more superficial than in ordinary-type smallpox. Vaccine-modified smallpox was not usually associated with mortality.

- Subclinical infection (called variole sine eruptione (without rash)), was uncommon (20, 21). Subclinical infection occurred in highly immune persons and was not infectious to others(1, 14, 22).

Multiple complications may occur as a result of smallpox including bacterial infection, sepsis, arthritis, corneal ulceration with resulting blindness, osteomyelitis and encephalitis(1). In pregnant women spontaneous abortion and stillbirth may also occur.

In fatal cases, death usually occurred during the second week of illness(7). The exact cause of death in smallpox is unclear but is likely due to toxæmia resulting from circulating immune complexes and variola antigens(10).

See Appendix C for a comparison of smallpox (variola) and chickenpox (varicella) infections.

#### **Persons at increased risk of disease**

The majority of the public will be susceptible to smallpox(1). Susceptibility is universal among those who have not had prior smallpox or been vaccinated. Routine vaccination of the Australian public ceased before 1980(23). The duration of immunity following immunisation is unknown, however it is thought that a single dose of vaccination will offer protection from infection for 5–10 years, and protection from fatal disease may be lifelong(1, 10, 24). Natural infection confers lifelong immunity.(22)

Secondary cases are most likely in the household-like contacts or health-care contacts of cases as most cases self-isolate due to illness prior to the most infectious period(7). Classically, smallpox spreads in expanding rings of close contacts with waves of cases corresponding to the incubation period (normally 12–14 days)(25).

#### **Disease occurrence and public health significance**

The last naturally acquired case occurred in October 1977 in Somalia(26). In 1978 two laboratory-related cases occurred in Birmingham, England(27). Global eradication was certified in 1979 by WHO, and sanctioned by the World Health Assembly in May 1980(10).

A case of smallpox could occur now through:

- natural re-emergence, e.g., mutation of another pox virus(28); or
- laboratory release (deliberate or accidental) of variola virus from one of two known existing repositories, or unknown repository; or
- release of, or self-inoculation with, synthetically manufactured variola virus.

### **3. Routine prevention activities**

A small number of laboratory workers who work with smallpox-related viruses continue to be immunised.

### **4. Surveillance objectives**

- To maintain vigilance and rapidly identify, isolate, and treat human cases and prevent transmission to their contacts.
- To rapidly create a ring of immunity around identified cases by identifying and providing vaccination to primary higher and lower risk contacts and secondary contacts.

## 5. Data management

Probable and confirmed cases should be entered onto the National Notifiable Diseases Surveillance System (NNDSS), ideally within one working day of notification. The date of onset is the date of onset of the illness, not of the rash.

Cases subsequently shown not to have smallpox should be removed from the NNDSS within one working day.

## 6. Communications

A single case of smallpox would result in activation of the Communicable Disease Incident of National Significance protocol. Media and communications should be coordinated in accordance with the Health CBRNINC Plan: Domestic Health Response Plan for Chemical, Biological, Radiological or Nuclear Incidents of National Consequence.

Clear roles and responsibilities and lines of communication are required to implement an effective response to a smallpox emergency. The state and territory health authorities are responsible for disease control. The role of Health will include overseeing the national response and supply of vaccine.

Health will nominate a Media Liaison Officer supported by the NIR who will work in conjunction with the AHPPC and the Attorney-General's Department (AGD) Emergency Management Australia (EMA) to manage public information releases.

Health will provide overall national coordination, provide logistical support to states and territories and activate the NIR. Media releases will aim to reduce the potential for mixed messages and to ensure a common, national message to cases, their families and the general public. The common message will aim to ensure cases and their families receive consistent information about the responsibilities of all agencies involved and the nature of the response.

In the event that a national terrorist situation is declared, the media management arrangements that apply to such situations override the media management arrangements outlined above (refer to the *National Counter-Terrorism Plan* and *National Counter-Terrorism Handbook*).

**Jurisdictional CDBs should notify suspected, probable and confirmed smallpox cases to the NIR by telephone (+61) 2 62893030 or email: [health.ops@health.gov.au](mailto:health.ops@health.gov.au).**

## 7. Case definition

The case definition may have been updated since the publication of this guideline. Please check the [case definitions webpage](#) on the Australian Department of Health's website ([www.health.gov.au/internet/main/publishing.nsf/Content/cdna-casedefinitions.htm](http://www.health.gov.au/internet/main/publishing.nsf/Content/cdna-casedefinitions.htm)) for the latest version.

### Reporting

Both confirmed cases AND probable cases should be notified.



### **Confirmed case**

A confirmed case requires laboratory definitive evidence only.

#### ***Laboratory definitive evidence***

1. Isolation of variola virus, confirmed at the Victorian Infectious Diseases Reference Laboratory (VIDRL);
- OR
2. Detection of variola virus by nucleic acid testing, confirmed at VIDRL.

### **Probable case**

A probable case requires either:

1. Clinical evidence and laboratory suggestive evidence;
- OR
2. Clinical evidence

AND epidemiological evidence.

#### ***Laboratory suggestive evidence***

1. Detection of a poxvirus resembling variola virus by electron microscopy (EM);
2. Isolation of variola virus pending confirmation;
3. Detection of variola virus by nucleic acid testing pending confirmation.

#### ***Clinical evidence***

Credible clinical smallpox as judged by an expert physician<sup>1</sup>.

#### ***Epidemiological evidence***

An epidemiological link to a confirmed case.

### **Suspected case**

1. Clinical syndrome consistent with smallpox as judged by an expert physician<sup>1</sup>; this may include an illness with acute onset of fever  $\geq 38$  °C followed by a rash<sup>2</sup> characterised by firm, deep seated vesicles or pustules in the same stage of development without other apparent cause;
- AND
2. The case does not meet the probable or confirmed case definition.

#### ***Note***

The *Guidelines for Smallpox Outbreak, Preparedness, Response and Management* include separate case definitions for smallpox surveillance both preceding and during an outbreak. The Guidelines define confirmed, probable, suspected and possible cases for the purposes of public health response. The definitions are at some variance with the case definitions for reporting to the National Notifiable Diseases Surveillance System. **Suspected cases** and **possible cases** should also be reported to the State/Territory health department.

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<sup>1</sup> Such as an infectious diseases physician, clinical microbiologist or public health physician. See suspected case for usual clinical presentation.

<sup>2</sup> Note that fever precedes rash. A rash is not required to identify a suspected case in a person with an epidemiological link.

## 8. Laboratory testing

Initial testing for smallpox is undertaken at the National High Security Quarantine Laboratory (NHSQL) in VIDRL or the Institute of Clinical Pathology and Medical Research (ICPMR) (for NSW cases). Confirmatory testing is undertaken at VIDRL.

NHSQL should be notified through the relevant state or territory CHBO.

Polymerase Chain Reaction (PCR) is the primary diagnostic modality employed for detection of smallpox, and collection of appropriate vesicle swabs for this purpose is a priority. Rapid diagnosis is performed using variola-specific and orthopox real-time PCRs. Any positive result in either method must be confirmed using alternative PCR assays targeting different gene segments followed by sequence analysis to verify specificity.

Viral electron microscopy is available as an adjunct to PCR at VIDRL if required.

### ***Security Sensitive Biological Agent***

Smallpox is a Tier 1 Security Sensitive Biological Agent (SSBA) under the *National Health Security Act 2007* (NHS Act) and requires storage in a Physical Containment (PC) Level 4 Laboratory.

The list of SSBA defines which biological agents are of security concern. Tier 1 agents on the list of SSBA are those agents that pose the highest level biosecurity risk to Australia.

### ***Procedure for arranging smallpox testing at the NHSQL in VIDRL***

When a patient with suspected smallpox is identified, the NHSQL at VIDRL will carry out testing of specimens. NHSQL should be notified through the relevant state or territory CHBO. However, direct contact with the medical microbiologist on call at VIDRL is essential to arrange receipt of specimens and obtain advice on specimen collection, safe packaging and transport. In the event of ongoing cases, VIDRL will advise on which PC3 or PC4 laboratories can receive specimens in the relevant jurisdiction.

### VIDRL CONTACTS

- On-call microbiologist **0438 599 437**
- Back up is provided by the following:
- On-call laboratory manager **0438 599 439**
  - Royal Melbourne Hospital switchboard **(03) 9342 7000**

### **Testing guidelines<sup>3</sup>**

The recommended approach to smallpox testing will vary depending upon the current epidemiological context and threat level.

### ***Laboratory test procedures for smallpox by response according to “threat categories”***

The threat categories used are: smallpox remains eradicated; specific threat or release/case(s) overseas; release or case in Australia; outbreak in Australia.

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<sup>3</sup> More details regarding laboratory testing are available in Inger Damon, Hermann Meyer, & Shchelkunov, S. (2010). Laboratory diagnostics for smallpox (variola virus). In A. S. Khan & G. L. Smith (Eds.), *Scientific review of variola virus research, 1999–2010*. Geneva, Switzerland: World Health Organization.

**Table 1 Laboratory test procedures for smallpox by response**

Smallpox status	Laboratory response procedures
<ul style="list-style-type: none"> <li>Smallpox remains eradicated</li> </ul>	<p><b>Decentralised exclusion of smallpox:</b></p> <ul style="list-style-type: none"> <li>Low pre-test probability of smallpox;</li> <li>Moderate containment requirement; and</li> <li>Modest throughput demand</li> </ul>
	<p><i>Laboratory action:</i></p> <ul style="list-style-type: none"> <li>Designated PHLN labs are lead agencies</li> <li>PC3 processing + immune staff</li> <li>Differential diagnoses tested (varicella zoster virus (VZV), herpes simplex virus (HSV))</li> <li>If tests for differential diagnoses are negative, test for variola virus by PCR (if available); and Refer to NHSQL (VIDRL) or Laboratory Response Network (LRN) member laboratory (ICPMR) for PCR</li> </ul>
<ul style="list-style-type: none"> <li>Specific threat or release</li> <li>Case(s) overseas or in Australia</li> </ul>	<p><b>Centralised screening for the first smallpox case:</b></p> <ul style="list-style-type: none"> <li>Elevated pretest probability of smallpox</li> <li>High containment requirements</li> <li>Increased throughput demand</li> </ul>
	<p><i>Laboratory action:</i></p> <ul style="list-style-type: none"> <li>NHSQL lead agency</li> <li>PC4 processing + immune staff</li> <li>Smallpox tested (PCR) by NHSQL (VIDRL)</li> <li>NHSQL (VIDRL) or LRN/PHLN member laboratory tests differential diagnoses</li> </ul>
<ul style="list-style-type: none"> <li>Outbreak in Australia</li> </ul>	<p><b>Decentralised confirmation of widespread smallpox:</b></p> <ul style="list-style-type: none"> <li>High pretest probability of smallpox</li> <li>Diminished containment requirement</li> <li>High throughput demand</li> </ul>
	<p><i>Laboratory action:</i></p> <p><b>Case epidemiologically linked to laboratory-proven smallpox:</b></p> <ul style="list-style-type: none"> <li>Laboratory confirmation not necessary</li> </ul> <p><b>No epidemiological link:</b></p> <ul style="list-style-type: none"> <li>Designated PHLN labs are lead</li> <li>PC3 processing (after deactivation in PC4) + immune staff</li> <li>Smallpox tested by PCR by LRN member laboratories</li> <li>PHLN lab tests differential diagnoses</li> </ul>

**Laboratory test methods used for the diagnosis of smallpox**

***Polymerase chain reaction (PCR)***

PCR will almost always be the diagnostic modality used. Appropriate equipment includes:

- personal protective equipment (PPE)
- a small scalpel blade or tuberculin needle and syringe for removing the roofs and upper tissue from lesions
- Eppendorf tubes, cerebrospinal fluid tube, or similar sterile leak-proof container containing viral transport medium
- dry swabs
- a fine tip permanent marker pen
- a waterproof sharps container for needles, syringes and scalpels

- waterproof dressings
- a sealable plastic specimen bag, absorbent packaging material, a strong metal outer container, biohazard tape to seal it and 0.5% hypochlorite solution to clean the outside before transport to the laboratory
- high risk labels and
- a clinical waste bag for the disposal of discarded dressings and PPE.

***Electron microscopy (only available at NHSQL and only performed when recommended by the Director of VIDRL).***

If for particular reasons electron microscopy is required, the PCR requirements are supplemented by:

- a “tuberculin” syringe and needle for aspirating fluid from vesicles and
- Eppendorf tube or cerebrospinal fluid tube, or similar sterile leak-proof container for vesicle fluid or crusts.

**Procedure for collection of specimens**

**PCR**

The procedure for collecting specimens of vesicle fluid is as follows:

- Put on PPE (See Section 12. Infection control).
- Gently deroof a vesicle using tuberculin needle and syringe. Discard the roof appropriately.
- Firmly rub a dry swab on the base of the lesion using a rotary motion. The objective is to absorb fluid from the vesicle onto the swab, and to dislodge cellular material from the lesion base which will also adhere to the swab.
- Place the swab into a sterile, leak-proof container of viral transport medium, carefully break or snip the swab shaft to allow closure of the tube, and replace the lid.
- Sample, as described above, at least 3 vesicles containing clear (i.e. non-pustular) fluid with the swabs pooled in a single tube.
- Label the tube with patient identifying data, place in the zip-lock plastic specimen bag and seal.
- Repeat to generate a duplicate of 3 swabs in a second tube, labelled and bagged as above.
- Cover the deroofed vesicles with waterproof dressing(s).

***Electron Microscopy (EM)***

The procedure for collecting specimens of vesicle fluid is as follows:

- put on PPE
- puncture a vesicle with the tuberculin needle and syringe, draw up fluid and express it into a sterile leak-proof tube
- cover the punctured vesicle with a waterproof dressing
- vesicle crusts may be removed and sent for examination in a small sealed container (Eppendorf tube or similar sterile leak-proof container) and
- label the tube or container with patient identifying data, place in the zip-lock plastic specimen bag and seal.
- Do not submit vesicle fluids to the laboratory in hypodermic syringes or in capillary tubes, as this could be hazardous to laboratory staff extracting the specimen. Swabs or specimens in viral transport medium are not suitable for EM

**Transport of specimens to the laboratory**

The outside of each specimen container should be swabbed with disinfectant (5000 parts per million available chlorine) and a label should be attached bearing the patient’s name, hospital identification, date of collection and the nature of the suspected infection. The specimens should be double

bagged in secure, airtight and watertight bags, which have been similarly labelled. Bags containing specimens should be sponged with disinfectant before being removed from the patient's room.

Samples should be identified as infectious substances affecting humans (smallpox sample) and packaged and handled as required by International Air Transport Association (IATA) packing instruction 602.

The specimens should be packaged as follows:

- Place the specimens for transport in a tightly sealed, watertight container, such as a screw-cap plastic tube or vial, and seal the cap with tape. Make sure the plastic containers are resistant to temperatures as low as  $-80^{\circ}\text{C}$ .
- Wrap the primary container in sufficient absorbent material (e.g. tissue) to absorb the entire contents in case the container leaks or breaks.
- Place the wrapped, sealed primary container into a durable, watertight, screw-cap mailing tube or metal can and seal this primary container with tape.
- Several primary containers may be placed in one secondary container to a maximum of 50 mL of specimen material.
- Attach the specimen labels and other relevant information on the outside of the secondary container.
- Place the second container in a secure box or mailing tube addressed to:

**National High Security Quarantine Laboratory**  
**Victorian Infectious Diseases Reference Laboratory (VIDRL)**  
**The Doherty Institute**  
**792 Elizabeth Street**  
**Melbourne VIC 3000**

Use a competent door-to-door courier. As individual commercial and non-commercial carriers or shipping services may apply different regulations for transporting biological specimens, contact a representative of the chosen carrier beforehand to ensure that all necessary formalities are fulfilled.

Notify the on-call VIDRL medical microbiologist of the dispatch of the specimen and flight time and number, courier or air waybill number as appropriate. If transport is by air, a dangerous goods declaration must be made (refer to the IATA Dangerous Goods regulations).

## **Laboratory procedures**

### ***Specimen handling***

Clinical samples from suspected cases must be handled with due regard to the likelihood that smallpox is present, and the appropriate procedures observed. Screening for the first case or cases will be centralised in the NHSQL's PC4 facility. While smallpox remains eradicated or should community transmission of smallpox become re-established, smallpox exclusion and diagnosis may be performed by vaccinated staff in a PC4 laboratory. Should it be necessary to conduct work other than in PC4 laboratories, a full risk assessment must be conducted.

When specimens from suspected cases are sent to one of the designated PC3/4 regional laboratories for diagnosis, investigation will require:

- Handling of samples in a Class I or III cabinet based within a PC3/4 laboratory, preferably by vaccinated staff.
- Inactivation of the sample by guanidinium for PCR, to be undertaken within a Class I or III cabinet in a Level 3 laboratory.

### ***Work health and safety issues***

Specimen collection and laboratory testing should only be undertaken by appropriately trained personnel who are wearing appropriate PPE; ideally the personnel should have had a successful smallpox vaccination.

Staff at the designated PHLN jurisdictional laboratories will be vaccinated in the Standby Phase (for more information see the Smallpox Plan).

Wider vaccination of laboratory staff is not justified since the risks of adverse effects from vaccination outweigh the risk of developing smallpox. However, staff liable to be involved in diagnostic work should be identified and screened in advance for suitability for vaccination.

See Section 10. Contact management for information on risk stratification for laboratory personnel handling variola virus.

## **9. Case management**

### **Response times**

Suspected, probable or confirmed cases should be immediately notified to the central state or territory CDB who will need to notify the NIR urgently (via email [health.ops@health.gov.au](mailto:health.ops@health.gov.au) or phone call **02 6289 3030**). The NIR should report to the WHO as soon as possible.

### **Response procedure**

#### ***Case investigation***

A follow-up investigation should begin on the same day as notification for all probable and confirmed cases. The level of response to suspected cases will depend on the level of suspicion after discussion with the NIR and the state Chief Human Biosecurity Officer.

The aim is to identify the source of exposure (e.g. another case or environmental source) and primary contacts. The response to a notification will normally be carried out in collaboration with the clinicians managing the case. The PHU may need to work with local and national police.

PHU staff should ensure that action has been taken to:

- confirm the onset date and symptoms of the illness
- confirm results of relevant pathology tests, or recommend that tests be done
- remind collectors and laboratory staff of appropriate infection control requirements
- determine if the diagnosis has been discussed with the case or relevant care-giver before beginning any interview
- interview case (or care-giver) using Appendix D: Case investigation form
- review public health management of cases and contacts
- ensure case vaccination has been considered if  $\leq 7$  days since exposure (to lessen the severity of the illness)
- ensure appropriate infection control guidelines are followed in caring for the case and
- identify the likely source of infection.

Investigations will begin with a hypothesis-generating interview with every smallpox case (or caregiver) to pinpoint the case's movements over the 17 days prior to the onset of the illness. If a hypothesis is formed for the source of infection, an analytical epidemiological study may be undertaken in parallel with a police investigation.

Note: Interviews with suspected, probable or confirmed cases should be undertaken by telephone where possible, but if undertaken face-to-face, the person conducting the interview must be known to be immune to smallpox or have a thorough understanding of the indicated infection control practices and be competent in using appropriate personal protective equipment (PPE) (see Section 12. Infection control). Treating staff may conduct the interview rather than public health staff to reduce the number of people with contact to the case.

### ***Case treatment***

Treatment of a case is the responsibility of the clinician in consultation with an expert virologist. Use of antivirals may be indicated such as cidofovir, or antivirals which have not been tested against variola but have activity against pox viruses such as brincidofovir (CMX001), tecovirimat (ST-246), ribavirin and rifampicin(1).

### ***Education***

Provide the case with Appendix A: Smallpox factsheet.

### ***Isolation and restriction***

Suspected, probable and confirmed cases, and any person who requires assessment to determine if they are a suspected case, should be immediately isolated and transferred to hospital using appropriate infection control procedures. If hospital facilities are at capacity, suspected smallpox patients who do not require hospital care may be isolated in non-hospital facilities that do not have shared ventilation systems with other facilities. Cases should remain isolated until all scabs have separated or smallpox is excluded.

For further detail, including related to deceased persons, see Section 12. Infection control.

### ***Active case finding***

Alert local doctors and laboratories in the areas where the smallpox case may have acquired infection or was infectious and

- ask them to report cases to the local PHU immediately and
- provide advice on appropriate management including post exposure vaccination for health care workers (HCWs), where relevant.
- Consider the need for communications to assist in case finding (See Section 6. Communications).

## **10. Contact management**

### **Contact identification and characterisation**

#### ***Primary contacts***

Identify primary contacts and categorise by their risk of developing infection.

- Identification of higher risk primary contacts is a higher priority than identification of lower risk primary contacts.
- Prioritise identification of primary contacts exposed during the first 7–10 days of rash in the infectious case.

Note: persons with a confirmed history of smallpox are not at risk.

**Higher risk primary contacts** of a suspected, probable and confirmed smallpox case include:

- **Household-like contacts:** all persons usually resident or who have spent substantial periods of time within the same household during the infectious period. Includes sexual contacts.
- **Face-to-face contacts:** all unvaccinated<sup>4</sup> persons who were not wearing appropriate PPE equipment (or where a PPE breach occurred) who have had prolonged interactions (≥15 minutes) with an infectious case of smallpox within a distance of 2 metres. These may include contacts at work, in social settings, and healthcare and emergency workers.
- **Fomite contacts:** all unvaccinated<sup>4</sup> persons who were not wearing appropriate PPE (or where a PPE breach occurred) who have had direct contact with clothing or articles that have recently been used by an infectious case of smallpox. These may include contacts at work, in social settings, and healthcare and emergency workers.
- **Relative or absolute contraindication to vaccination or vaccination failure:** lower risk primary contacts who are unable to be vaccinated as post exposure prophylaxis (see [Table 4](#)) or who do not have a successful vaccination<sup>5</sup> (See Section 11. Smallpox vaccination).
- **Virus release contacts:** all unvaccinated<sup>4</sup> persons in the vicinity of a release of variola virus.
- **Laboratory contacts:** Hazard level 3 and 4 laboratory contacts. See “Laboratory personnel contact management guidance” below.

**Lower risk primary contacts** of a suspected, probable and confirmed smallpox case include:

- **Aerosol contacts:** all persons who have had any interactions (<15 minutes) with an infectious case of smallpox within a distance of 2 metres, or any interactions (for ≥15 minutes) at a distance of >2 metres within a room or enclosed space. People who have spent ≥15 minutes in an adjacent room or floor with shared air-conditioning (without high-efficiency particulate air (HEPA) filtration). These may include work colleagues, and people who have visited the same premises or travelled on the same public transport (such as buses, trains and planes) as an infectious smallpox case.
- **Non-laboratory HCWs wearing PPE:** persons with contact with an infectious case of smallpox or their fomites whilst wearing appropriate PPE.
- **Previously vaccinated persons:** persons who have been successfully vaccinated within the previous 3 years who have had face-to-face or fomite contact with an infectious case of smallpox.
- **Laboratory contacts:** Hazard level 1 and 2 laboratory contacts (level 1 does not require isolation or monitoring). See “Laboratory personnel contact management guidance” below.

Note: Transient or distant contacts should not be managed as lower risk primary contacts.

### **Laboratory personnel contact management guidance**

Contact management of laboratory personnel depends on a risk assessment of the type of exposure and work context. Vaccination will occur when a trigger event happens and the NHSQL is alerted by the NIR.

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<sup>4</sup> Contacts are classified as unvaccinated if they have not been successfully vaccinated against smallpox within the past 3 years. A successful vaccination requires a confirmed ‘take’ or major reaction indicating immunity.

<sup>5</sup> Contacts who would otherwise be lower risk primary contacts but who are unable to be vaccinated and are now classified as a higher risk primary contact do not need to be managed as a higher primary risk contact regarding vaccination.



Four levels of hazard are identified for medical testing laboratory personnel:

1. personnel in PC4 facilities
2. personnel in dedicated virology laboratories
3. personnel in general pathology laboratories and
4. personnel working in specimen processing who may be exposed inadvertently.

**Table 2 Laboratory personnel hazard levels and contact risk assessment**

Hazard level	Type of exposure	Risk
1	Variola virus exposure in PC4 facilities (space suit or isolator box).	Lower risk primary contact (laboratory personnel with appropriate training to work in PC4, handling Risk Level 4 agents do not require isolation or monitoring). Any breach in procedure should be handled as per the standard operating procedure and will increase the risk rating.
2	Variola virus exposure in dedicated virology laboratory with presence of mitigation procedures to protect against respiratory transmission.	Lower risk primary contact (vaccination and isolation required as soon as specimen has been transported to NHSQL). A breach in procedure would increase the risk to higher risk primary contact.
3	Variola virus exposure in general pathology laboratory (PC2) or in a virology laboratory without respiratory transmission mitigation measures in place, but in both cases done in line with PHLN guidelines for pathology on viral haemorrhagic fever (VHF) specimens.	Higher risk primary contact (vaccination and isolation required as soon as specimen has been transported to NHSQL).
4	Variola virus exposure in specimen reception/laboratory administration environment or routine pathology laboratory in a manner not compliant with PHLN VHF specimen guidelines.	Higher risk primary contact (vaccination and isolation required as soon as specimen has been transported to NHSQL).

### **Secondary contacts**

Identify household-like contacts of higher risk primary contacts.

**Contacts of higher risk primary contacts** of a suspected, probable and confirmed smallpox case include:

- **Household-like contacts:** all persons usually resident or who would be expected to spend substantial periods of time within the same household as the higher risk primary contact during the period the contact is at risk of becoming infectious. Includes sexual contacts.

### **Management of contacts (primary and secondary)**

Contacts require vaccination, monitoring and movement restriction as detailed in the sections below.

- Management of higher risk contacts is a higher priority than management of lower risk contacts.

- If the diagnosis of smallpox in a suspected or probable case is subsequently excluded, contacts that have been identified but not yet traced need not be vaccinated or followed-up.
- Contacts that develop fever or other symptoms of smallpox should be managed as a probable case (including appropriate laboratory testing).

### ***Vaccination of contacts***

Vaccination should be carried out as soon as possible, preferably within 3–4 days and at most within 7 days following exposure to a confirmed case(1, 29). The degree of protection from vaccination diminishes as the interval between exposure and vaccination increases.

Primary contacts should be checked for symptoms before vaccination, to ensure that they are not co-primary cases.

For details on vaccination contraindications see Section 11. Smallpox vaccination.

Higher risk primary contacts:

- Should be vaccinated as a matter of urgency, unless they have an absolute contraindication.
- If a higher risk primary contact has severe skin disease or immunosuppression, they may be given vaccinia immune globulin (VIG) to prevent vaccine complications, depending on supplies. As the dose for VIG is large (0.6 mL/kg) it can be administered intramuscularly over a 24–36 hour period(7). VIG does not impair the response to the vaccine.
- Adverse events following immunisation may be treated with cidofovir, although renal toxicity may limit its use.

Lower risk primary contacts:

- Should be vaccinated unless they have a relative or absolute contraindication, in which case the risk from vaccination should be weighed against the risk from disease.

Secondary contacts (household-like contacts of higher risk primary contacts):

- Should be vaccinated unless they have a relative or absolute contraindication, in which case the risk from vaccination should be weighed against the risk from disease.

The vaccination site should be reviewed by an immunised, trained clinician after 7 days to assess for a successful vaccination. Contacts who fail to show a response to a first dose of vaccine after seven days should be re-vaccinated. Lower risk primary contacts who fail to demonstrate a successful vaccination after the second attempt or who are unable to be vaccinated are re-classified as higher risk primary contacts.

### ***Monitoring of contacts***

All primary contacts should be monitored. Formal monitoring with daily contact for development of smallpox is recommended for higher risk primary contacts and desirable for lower risk primary contacts (use Appendix E: Contact surveillance form).

- Monitor for a period of 17 days from the last exposure to an infectious case.
- Provide the contact with general advice including information on monitoring. Request the contact to immediately telephone the jurisdictional CDB/PHU if they measure a temperature  $\geq 38^{\circ}\text{C}$  or develop any other symptoms of possible smallpox.
- The primary contact should take a daily recording of body temperature, measured orally, preferably in the evening. A disposable oral thermometer, temperature chart, and instructions on the measurement and recording of body temperature should be provided.
- Communicate each day with all higher risk primary contacts, and if possible all lower risk primary contacts, to determine the presence or absence of fever or other symptoms. A mobile

telephone may need to be provided to those who do not have access to a mobile or land telephone at home.

- Higher risk primary contacts who do not respond to the jurisdictional CDB/PHU will need to be visited in person to confirm their health status using appropriate infection control precautions.

### ***Restrictions on activity (quarantine)***

Public health emergency powers may be invoked to restrict activities of primary contacts. The restriction period is the time during which primary contacts are at risk of developing symptoms and becoming infectious. The restriction period extends from the first exposure until 17 days after the last exposure to an infectious case. It is unlikely that the contact will be infectious during the first 7 days after exposure. Material and social support should be provided.

Primary contacts during the restriction period must:

- Remain isolated. In most circumstances this involves isolation at home, however, there are circumstances where other accommodation will need to be found, for example for those who live in shared accommodation such as a boarding house. Appropriate facilities, with individual rooms and ensembles will need to be identified where isolation at the usual place of residence is inappropriate. Any facility staff should have been recently successfully vaccinated (within past 3 years) or have had previous smallpox.
- Avoid contact with non-immune individuals (i.e. persons who have not had smallpox nor been successfully vaccinated against smallpox within the past 3 years). It may be impractical to avoid contact with usual household members whilst awaiting vaccine response.

Secondary contacts (household-like contacts of higher risk primary contacts):

- Non-immune individuals (i.e. those who have vaccine contraindications or if the vaccination was unsuccessful) should be excluded from continuing contact with higher risk primary contacts until they have completed their monitoring period and their vaccination site has completely healed (because of the risk of vaccinia infection). This may mean using alternative accommodation.
- No monitoring or restrictions on activity are necessary unless the higher risk primary contact becomes a suspected, probable or confirmed case.

### ***Prophylaxis***

Vaccine non-responders, primary contacts who receive late vaccination (more than 4 days after their first exposure to infection), and primary contacts who refuse vaccine or are unable to be vaccinated may be given additional prophylaxis against smallpox in an effort to attenuate disease. This may be given concurrently with (re)vaccination.

Supplies of additional prophylaxis should be prioritised to those most at risk of disease:

- contacts vaccinated between 4 and 7 days after first exposure to infection may be given VIG; and
- contacts vaccinated 8 days or more days after first exposure may be given appropriate antivirals such as cidofovir.

### ***Education***

All contacts should be counselled about their risk and the symptoms of smallpox and provided with Appendix A: Smallpox factsheet, Appendix F: Advice for contacts of a case of smallpox and Appendix G: Vaccination factsheet.

**Table 3: Summary of contact risk categories and corresponding management requirements**

Classification	Detail	Quarantine	Vaccination	Monitoring
Higher risk primary contact	<ul style="list-style-type: none"> <li>Household-like contacts</li> <li>Fomite contacts</li> <li>Hazard level 3 &amp; 4 laboratory contacts</li> <li>Vaccination contraindicated/failure</li> </ul>	Quarantine for 17 days from last exposure	Always <sup>6</sup> – unless absolute contraindication (See <a href="#">Table 4</a> )	Yes - daily follow-up by PHU recommended
Lower risk primary contact	<ul style="list-style-type: none"> <li>Aerosol contacts</li> <li>Non-household contacts wearing appropriate PPE</li> <li>Persons successfully vaccinated within the last 3 years</li> <li>Hazard level 1 &amp; 2 laboratory contacts (level 1 laboratory contacts do not require isolation or monitoring)</li> </ul>	Quarantine for 17 days from last exposure	Yes – unless relative or absolute contraindication (See <a href="#">Table 4</a> )	Yes - daily follow-up by PHU desirable
Secondary contacts (Household-like contact of higher risk primary contact)	<ul style="list-style-type: none"> <li>Usual household members and sexual contacts of higher risk primary contact</li> </ul>	Not required	Yes – unless relative or absolute contraindication (See <a href="#">Table 4</a> )	No

## 11. Smallpox vaccination

### Smallpox vaccine

The smallpox vaccine is currently the only way to prevent smallpox, although there has been work on antivirals, such as tecovirimat, to treat the disease. The vaccine is made from a vaccinia virus, another pox-type virus related to smallpox, which cannot cause smallpox. The vaccine helps the body develop immunity to smallpox and was successfully used to eradicate smallpox from the human population.

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<sup>6</sup> Any contact who has been reclassified as higher risk primary contact as he/she could not be vaccinated, still should not be vaccinated.

In the absence of any clear evidence that smallpox may re-emerge or that it is used in an act of biowarfare or bioterrorism, the risk of adverse events from the vaccine outweighs the risk from the disease(30).

Vaccination within 3 days of exposure with replication-competent smallpox vaccine (Aventis Pasteur Smallpox Vaccine(PSV), ACAM2000 or LC16m8 vaccines) will prevent or significantly lessen the severity of smallpox symptoms in the vast majority of people(1, 31). Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of the disease(29).

Traditional smallpox vaccines are based on replicating vaccinia virus strains. Although these vaccines have been effective in eradicating the disease, their use has been associated with a significant risk of adverse events, including severe disability and death. Smallpox vaccines produced and successfully used during the eradication program are called first generation vaccines. Second generation smallpox vaccines use the same smallpox vaccine strains employed for manufacture of first generation vaccines or clonal virus variants plaque purified from traditional vaccine stocks, whereas third generation smallpox vaccines represent more attenuated vaccine strains specifically developed as safer vaccines at the end of the eradication phase by further passage in cell culture or animals.

In the event of an outbreak, the containment strategy will centre on the isolation of cases and vaccination of contacts. In a public health emergency involving smallpox, vaccination with replication-competent smallpox vaccine (i.e. ACAM2000 and PSV) will be the primary response strategy for stopping the chain of transmission and achieving epidemic control. Persons at high risk for complications from replication-competent smallpox vaccines are often at higher risk for severe smallpox. Consequently, persons with a known exposure to smallpox virus (higher risk contacts) should be vaccinated with a replication-competent smallpox vaccine unless absolute contraindications, and lower risk contacts should be vaccinated with a replication-competent smallpox vaccine unless absolute contraindications or relative contraindications(31).

**Table 4: Absolute and relative contraindications to use of replication-competent smallpox vaccine**

Absolute contraindications to use of replication-competent smallpox vaccine	Relative contraindication to use of replication-competent smallpox vaccine
<ul style="list-style-type: none"> <li>• Known anaphylaxis to the vaccine or vaccine component</li> <li>• Severely immunodeficient i.e. bone marrow transplant recipients within 4 months of transplantation, people infected with HIV with CD4 cell counts &lt;50 cells/mm<sup>3</sup>, and people with severe combined immunodeficiency, complete DiGeorge syndrome, and other severely immunocompromised states requiring isolation(32, 33)</li> </ul>	<ul style="list-style-type: none"> <li>• Cardiac disease</li> <li>• Eye disease treated with topical steroids</li> <li>• Congenital or acquired immune deficiency disorders</li> <li>• History or presence of eczema and other skin conditions</li> <li>• Infants &lt; 12 months of age</li> <li>• Pregnancy</li> </ul>

### Receiving the vaccine

Smallpox vaccination will be undertaken by HCWs trained in administration of smallpox vaccine. The smallpox vaccine is given using a bifurcated (two pronged) needle that is dipped into the vaccine solution. When removed, the needle retains a droplet of vaccine solution. The needle is used to prick the skin a number of times in a few seconds. The pricking is not deep, but it will cause a sore spot and one or two droplets of blood to form. The vaccine is usually given in the upper arm.

A successful vaccination requires a confirmed 'take' or major reaction indicating immunity. If the vaccination is successful, a red and itchy bump develops at the vaccine site in three or four days. In the first week, the bump becomes a large blister, fills with pus, and begins to drain. During the second week, the blister begins to dry up and a scab forms. The scab falls off in the third week. People who are being vaccinated for the first time have a stronger reaction than those who are being revaccinated.

As specified in Section 10. Contact management, if a higher risk primary contact has severe skin disease or immunosuppression, they may be given VIG to prevent vaccine complications, depending on supplies<sup>(1)</sup>. Adverse events following immunisation may be treated with cidofovir, although renal toxicity may limit its use.

In addition to cases and contacts, an emergency vaccination program would include HCWs at clinics or hospitals that may receive patients; essential emergency response personnel, such as police, ambulance, fire, and emergency services; laundry staff, public health and emergency management staff; and mortuary staff who may handle bodies. Such staff would need to be vaccinated even if they have been immunised previously. Vaccination would be prioritised for staff likely to have direct contact with the patient, or their clinical specimens or fomites.

#### **Post-vaccination care**

After vaccination, it is important to follow care instructions for the site of the vaccine. Provide all vaccinated persons with Appendix G: Vaccination factsheet. As the vaccine contains live virus, it can potentially spread to other parts of the body, or to other people.

#### **Imvamune<sup>®</sup>**

Imvamune is a new smallpox vaccine based on MVA-BN<sup>®</sup> (a strain of the Modified Vaccinia Ankara virus). It is injected like other modern vaccines rather than pricked into the skin with a bifurcated needle. While the MVA-BN virus is highly attenuated and is thus incapable of replicating in the body, it is still capable of eliciting a potent immune response and does so without producing the post-vaccination complications associated with traditional smallpox vaccines. The strain of vaccinia virus contained in Imvamune was not used during the eradication of smallpox and its efficacy in preventing smallpox in humans in an outbreak is less certain. Furthermore, Imvamune requires 2 doses administered 4 weeks apart to achieve an immune response comparable to that of replication-competent smallpox vaccines. Although persons vaccinated with Imvamune might have a lower risk for serious adverse events, this might be outweighed by the uncertainty in clinical effectiveness to prevent disease and provide rapid protection.

#### **National Medical Stockpile**

The National Medical Stockpile (NMS) is the main source of smallpox vaccine in Australia. The Secretary of the Australian Government Department of Health and the Commonwealth Chief Medical Officer (CMO) have authority to approve an NMS deployment on request from state or territory authorities.

## **12. Infection control**

### **Overview**

These infection control procedures must be observed by all persons who are involved in the care of or in contact with suspected, probable and confirmed cases of smallpox, including visitors to patients, ambulance personal and healthcare staff. All staff caring for a smallpox patient must be (recently or immediately) vaccinated against smallpox. Staff for whom vaccination is contraindicated

should not come into contact with any patient with suspected, probable or confirmed smallpox or their (including recently vaccinated) contacts. Anyone having close contact with a smallpox patient must wear PPE.

A risk assessment approach should be performed to assess the correct level of PPE for providing care to a suspected, probable or confirmed smallpox patient. A risk assessment should take into account the patient's history of exposure to smallpox, their symptoms, the risk of transmission and the type of healthcare activity that will take place.

During acute disease, the main hazards are:

- exposure to infectious droplets and body fluids
- exposure to discarded dressings and other clinical waste and
- exposure to clothing, sheets and towels that have been contaminated by infectious body fluids or sloughed scabs.

### ***Hand hygiene***

Strict hand hygiene with alcohol-based hand rub (ABHR) or disinfectant (liquid) soap should be carried out immediately before and after all episodes of care, including before putting on and after removal of gloves.

### ***Personal protective equipment***

A risk assessment approach should be used before every interaction with a symptomatic patient with suspected, probable or confirmed smallpox, to determine the need for additional infection prevention and control measures, such as enhanced PPE.

PPE must be used by HCWs (including vaccinated personnel) caring for any patients with suspected, probable or confirmed smallpox. At a minimum, PPE should include a fluid-resistant gown and protection of the hands and mucous membranes of the eyes, mouth and nose. All skin and hair should be fully protected if aerosol-generating procedures are being performed or likely to be required urgently.

PPE should be adequate but not excessive. Wearing PPE in excess of that recommended, will potentially restrict movement and vision, increase the risk of heat stress, and make putting on and taking off PPE more complex. The risks, to the HCW or patient, of using items in addition to those recommended may outweigh any theoretical benefits.

Putting on and taking off PPE must be done slowly and methodically, according to an agreed sequence, and supervised by a trained buddy.

### ***Leaving the infected area***

Staff and visitors should change when leaving the infected area. They should remove isolation facility clothing and shower before donning their street clothing and shoes. Hair washing should not be necessary if a hair cover is used.

### ***Isolation and restriction***

Isolation of suspected, probable or confirmed smallpox patients may be accomplished by several different methods, depending upon various factors (number of patients, severity of illness, availability of resources etc.).

The ultimate goal of isolation is to prevent transmission of smallpox from a patient who is infectious (from onset of symptoms until all scabs have separated) to non-immune individuals, whilst

maintaining an appropriate care and comfort level for the patient and their carers. All potential methods of patient isolation must be considered with these goals in mind. Several are outlined below, but healthcare personnel should consult with infection control experts and/or public health officials to determine the most appropriate isolation method.

### ***Hospital isolation***

All suspected, probable and confirmed smallpox patients as well as any person who requires assessment to determine if they are a suspected case, should be isolated in hospital as follows:

1. The patient must be placed under airborne and contact isolation in, or transferred as soon as possible to, a room with negative air pressure (with an individual HEPA filtered ventilation exhaust). This room should have an anteroom and private shower and toilet facilities and not share ventilation with any other part of the hospital. In the event of a large number of smallpox cases, contingency plans, including dedicated smallpox areas, should be outlined in state and territory plans.
2. When caring for an infectious patient with proven smallpox i.e. during the early acute, febrile stage and during the early evolution of the rash, and/or in patients who are very ill (e.g. requiring or likely to require artificial ventilation), high level PPE should be worn to cover all mucous membranes, skin, hair and clothing) by anyone entering and leaving the isolation room. This includes gloves, gown, surgical booties and either
  - a. a fit-tested and checked P2 or N95 respirator plus face shield and balaclava or
  - b. air-purifying respirator (PAPR) - PAPR protects the whole face and hair; provides filtered, cool air; and is more comfortable for longer periods.
3. When the patient is stable and lesions are beginning to crust (so infectivity has lessened), recently (and successfully) vaccinated personnel should continue to observe contact precautions (gowns, gloves, surgical cap and booties) and should wear a surgical mask and eye protection as indicated for procedures where contact with body fluids could occur.
4. All PPE should be removed and discarded into bio-hazard waste disposal containers before personnel leave the isolation room and re-enter other areas of the hospital.
5. Disposable PPE should be used (except components of some PAPRs, which should be decontaminated according to manufacturer's instructions) and should be securely contained in lockable bins and collected by an authorised high risk waste-disposal contractor or sterilised in an autoclave before incineration (see below).
6. Personnel entering the isolation room or handling infectious waste or clinical specimens from the patient should have documented successful recent smallpox vaccinations (within the past three years) or they must be vaccinated immediately. Public health officials should be contacted to request access to vaccine.

### ***Nonhospital isolation***

Public health officials should be consulted before non-hospital isolation is initiated. In special circumstances, such as when hospital capacity is reached, suspected smallpox patients who do not require hospital care may be isolated in non-hospital facilities that do not have shared ventilation systems with other facilities, so long as appropriate compliance can be assured and support provided by recently vaccinated carer(s) (relative, friend, community health worker).

Non-hospital isolation facilities should have appropriate climate control capabilities (heating, air-conditioning), running water and bathroom facilities. All persons entering these facilities must have documented successful, recent smallpox vaccinations.

### ***Release of cases from isolation***

A suspected case may be released from isolation and discharged, if the medical condition allows, after testing negative for smallpox.



Probable and confirmed cases may be released from isolation in consultation with an infectious diseases physician and public health authorities.

## **Environmental decontamination and waste disposal**

### ***General principles***

Staff responsible for environmental cleaning and/or disposal of waste generated during the care of patients with infectious diseases of high consequences, including smallpox, should be informed of potential risks but reassured that risk can be minimised with the careful use of recommended procedures and appropriate PPE. They should be trained (and regularly retrained) in and confident with correct procedures for donning and doffing of appropriate PPE to minimise the risk of accidental contamination and/or industrial action and refusal to undertake these activities. A record should be kept of staff involved in packaging, handling and transport of waste material or linen.

Diligent environmental cleaning, disinfection and safe handling of potentially contaminated materials are required as infected body secretions represent potentially infectious materials. Environmental cleaning should be undertaken using either a two-step cleaning with detergent followed by disinfectant, or a combined 2-in-1 cleaning with detergent and disinfectant. Only disinfectants that are effective and approved by the Therapeutic Goods Administration should be used, and they must be used at the recommended strength following the manufacturer's instructions.

The following section is modified from "Infection prevention and control principles and recommendations for Ebola virus disease"[\(34\)](#):

These recommendations are based on the following assumptions:

- The respiratory secretions and exudate from skin lesions of patients with smallpox are likely to contain variola virus and must be treated as highly infectious.
- Any object (fomite) potentially contaminated with variola virus should be assumed to be a potential vector of infection.
- Clinical waste, including any equipment from a smallpox patient's isolation room, is potentially contaminated. These include:
  - all items of PPE used by HCWs
  - linen (sheets, blankets, pillowcases, other absorbent material)
  - the patient's personal items (such as towels, toothbrush, toothpaste tube, shaving equipment, hair comb and brush)
  - environmental cleaning equipment (mop heads, absorbent material used for cleaning surfaces).

For the purposes of packaging and transport by rail or road, all such clinical waste should be treated as a Category A infectious substance under the Australian Dangerous Goods Code until it can be sterilised or decontaminated (e.g. in an autoclave, by incineration, high temperature laundering or chemical disinfection).

The equipment in the patient room must be limited to what is essential for patient care. All equipment must be dedicated for that patient's sole use and remain within the room for the duration of their hospitalisation. Single-use equipment should be used whenever possible. Large, reusable pieces of equipment, such as mattresses and critical medical equipment are safe for reuse if their surfaces can be properly cleaned and decontaminated. If not they should be discarded.

Clinical waste may also be generated in the home, community or ambulatory healthcare settings, where a person with smallpox has been cared for before admission to a hospital isolation unit. Any items potentially contaminated with smallpox virus should be treated as Category A infectious waste.

#### ***Laundering of non-disposable bed linen, clothing and other fabrics***

Smallpox outbreaks have occurred among laundry staff handling smallpox contaminated clothes or bedding. Only vaccinated personnel should handle laundry (bedding and clothing) or clinical waste potentially contaminated with variola virus. Standard practices to safely contain contaminated laundry and prevent direct contact or generation of aerosols should be followed. Laundry should be placed, with minimal agitation, directly into biohazard bags, without sorting and securely contained in a rigid lockable bin for:

- a) transport by a specialist waste disposal contractor to a central facility, where it will be handled by appropriately trained, vaccinated staff wearing gown, gloves and a P2/N95 respirator and decontaminated at high temperature (90 °C) with hypochlorite added, with appropriate precautions to avoid contact; or
- b) transport by a specialist waste disposal contractor for incineration; or
- c) sterilisation in an autoclave before laundering without the need for special precautions (7).

#### ***Disinfection of contaminated surfaces***

Data on viability of variola virus in the environment is largely based on that of vaccinia and other pox viruses. It is highly resistant to drying, especially when shed in dermal crusts, blood or secretions, over a wide range of temperature, but is killed by moist heat. Nevertheless it can remain viable, if released as an aerosol for several hours, even at relatively high humidity and temperatures. Therefore, contaminated surfaces can be a source of transmission. Due to its low lipid content, it is less sensitive to organic solvents/disinfectants than other enveloped viruses. However, it is sensitive to all common approved disinfection regimens(35).

Surfaces that may be contaminated with variola virus can be decontaminated with disinfectants that are used for standard hospital environmental disinfection, such as freshly reconstituted sodium hypochlorite (500–1000 ppm (0.05–0.1%)), after thorough cleaning (removal of all organic material) with detergent or with a combined detergent/disinfectant agent.

#### ***Emergency decontamination***

Heat is the most effective antimicrobial agent and viable counts of the smallpox virus are reduced within an hour or less by exposure to 60 °C.

Whenever possible, contaminated articles should be destroyed by incineration. If this cannot be done, articles should be sterilised in an autoclave where practicable. If neither incineration nor sterilisation is practical, chemical disinfection should be considered using 0.1% hypochlorite, vapourised hydrogen peroxide or ethylene oxide in a special chamber.

#### ***Incinerate clinical waste***

Disposable and clinical waste should be double-bagged and placed in rigid, lockable bins on wheels for transport by a specialist waste disposal contractor for incineration. As the action of loading and unloading can expel air and fluid, bags should preferably be closed by heat-sealing.

#### ***Decontamination of premises***

The decontamination process for premises differs according to the patient's stage of illness. Virus from respiratory secretions is less protected by organic matter and is easier to disinfect than virus from crusts dried on the skin and bedclothes.

Any reusable equipment should be decontaminated before it is removed from the isolation room or reused. Any visible contamination should first be removed using a hospital-grade disinfectant wipe (e.g. chlorine disinfectant).

The item should be cleaned and disinfected using a two-stage process: a neutral detergent followed by a sodium hypochlorite solution (0.05-0.1%)([34](#)). Vaporised hydrogen peroxide (if available) is also suitable for terminal cleaning of equipment or the patient room after cleaning with neutral detergent. The manufacturers' instructions should be followed.

If the patient has developed a pustular rash while in the premises, the rooms should be cleaned with a vacuum cleaner incorporating a disposable liner inside its cloth bag. The cloth bag should be sterilised after use, but the liner and its contents must be burned. The vacuum cleaner should be sterilised after its use. The vacuum cleaner should be one designated for hospital use (one that is equipped with a HEPA filter at the air exit point). The vacuum cleaner should be thoroughly wiped down after use with freshly prepared sodium hypochlorite 0.05-0.1% (500–1000 ppm).

### ***Decontamination of vehicles, ambulances and crews***

Ambulances that have carried patients with suspected, probable or confirmed smallpox, and their contents should be disinfected by ambulance crews. Clinical waste, laundry and stretcher canvases should be double bagged and disposed of as described above. The crew must not discard their protective clothing until disinfection of the vehicle has been completed.

All removable fittings inside the vehicle, including any loose floor coverings, should be removed, washed in detergent and hot water or wiped with detergent to remove visible dirt and disinfected with freshly prepared sodium hypochlorite solution 0.05-0.1% (500–1000 ppm) and wiped dry. The interior of the vehicle, including the driver's cabin (particularly the steering wheel, brake and gear levers and other controls), should be cleaned with detergent, wiped or sprayed systematically with sodium hypochlorite: first the floor; then the roof; and last the sides, front and rear, including the inside of the door. The handle on the outside of the door should also be disinfected. Alternatively a small portable vaporised hydrogen peroxide system can be used to disinfect the interior of the vehicle.

After disinfecting the ambulance, the crew should:

- disinfect and remove their gumboots
- disrobe with as little disturbance of the infected articles as possible
- place the discarded clothing in a laundry bag as described above
- enter the cleansing room at the designated isolation facility and wash thoroughly, paying particular attention to hands, face and hair
- put on clean clothing.

### **Care of deceased smallpox patients**

Smallpox has occurred from transmission of variola from deceased smallpox cases([14](#)) (See Section Infectious period). The body and immediate environment of the deceased are likely to be contaminated with variola and therefore scrupulous attention to appropriate PPE and cleaning procedures is required.

Bodies of smallpox cases should be safely and promptly disposed of. Only vaccinated personnel trained in handling infected human remains and wearing appropriate PPE should touch or move the body of a person with smallpox.

### ***Disposal of the body***

Cremation is the preferred option, and the advantage of cremation over burial should be explained to relatives as soon as possible(7). Disposable coffins, which are consumed by the cremation process, should be used.

Before removal from the deathbed, the body should be placed in a large, impervious plastic bag, or a disaster pouch, that is sealed airtight with tape and then sealed in a second large, impervious plastic bag prior to being placed in the coffin (preferably in the isolation room, where the patient died).

The coffin should be sealed with the lid secured, and the outside of the coffin washed down with freshly prepared sodium hypochlorite 0.05-0.1% (500–1000 ppm).

### ***Autopsy***

Autopsy should be avoided unless directed by the coroner because infections have been transmitted in this setting. If possible the examination should be limited to the organs/tissue necessary to establish the diagnosis or cause of death (if this is in doubt).

To transport the body to the mortuary, the body should be contained in line with disposal of the body.

Morticians, mortuary workers or medical laboratory scientists, who will handle bodies infected with smallpox, should be recently vaccinated.

Extreme care should be taken to prevent dissemination of variola virus. Contact and airborne precautions should be observed for all contact with the body. Vaccinated personnel should wear disposable clothing, gowns, gloves, caps, booties, masks and face shields or protective eyewear to prevent splashing of the mucus membranes. No personal clothing should be worn. If vaccination prior to participation in the burial preparation is not possible, unvaccinated personnel should wear additional respiratory protection (e.g., PAPR or equivalent).

All clothing articles from the preparation room should be placed in biohazard bags and sterilised in an autoclave or incinerated. Surfaces that may be contaminated with variola virus can be decontaminated with disinfectants that are used for standard infection control, such as hypochlorite or quaternary ammonia. After post-mortem examination the body should be double bagged in another set of impervious plastic bags before being placed in a disposable coffin for cremation.

Autopsy should be performed in a room with HEPA-filtered negative air pressure with respect to surrounding facilities. All doors and windows of the autopsy rooms should be closed during the preparation.

All staff members who have come into contact with the body should be managed as for HCWs caring for living patients with smallpox.

## **13. Special situation**

### **Weaponised bio-agent**

For research purposes, variola virus is retained in two secure facilities in Russia and the United States of America. Unauthorised access to the virus is extremely unlikely. If it were released, variola virus is considered one of the most dangerous viruses in existence. With a population that is largely non-immune, highly mobile and living in densely populated urban areas, a release or intentional infection of one or more persons could conceivably lead to a national epidemic or even a global pandemic.

The most likely smallpox threat to Australia is via air travel from an overseas incident. The expected outcome of this form of release would most likely be large numbers of cases with clustered onsets. Establishing epidemiologic association amongst these cases could be problematic, depending on the site and extent of virus dispersion. If introduced through intentionally infected persons, the origin of the virus (index case) and the extent of the outbreak could likely be tracked using standard epidemiologic and laboratory methods.

### ***Emergency first responders***

Proper selection of PPE for emergency first responders must be based on the hazards anticipated to be present at the scene and the probable impact based on the responder's role. At a minimum PPE should include a fluid resistant gown, protection of the hands and protection of the mucous membranes of the eyes, mouth and nose.

### **Cases among travellers on aeroplanes**

There is negligible public health evidence regarding management of smallpox cases occurring on aeroplanes. Management of any infectious cases occurring on an aeroplane would be assessed on a case by case basis.

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## **15. Appendices**

Appendix A: Smallpox factsheet

Appendix B: Smallpox Public Health Unit checklist

Appendix C: Clinical comparison of smallpox and chickenpox (varicella) infections

Appendix D: Case investigation form

Appendix E: Contact surveillance form

Appendix F: Advice for contacts of a case of smallpox

Appendix G: Vaccination factsheet



## Appendix A: Smallpox factsheet

### What is smallpox?

Smallpox is a very serious disease caused by the variola virus. Unvaccinated people in contact with someone with smallpox will almost certainly become infected.

### Why is smallpox a concern?

Smallpox was eradicated globally in 1979. No known human cases have been reported since then. Any new cases of smallpox would likely be the result of either:

- an accidental release from one of two approved smallpox virus research laboratories the United States of America or Russia; or
- an intentional release (bioterrorist or bio-warfare attack) involving the deliberate infection of a person or a deliberate release of virus into the environment.

A single case of confirmed smallpox would be considered an emergency.

### How is it prevented?

The smallpox vaccine provides protection from smallpox infection for approximately 5–10 years. The vaccine is made from a vaccinia virus, another pox-type virus related to smallpox, which cannot cause smallpox. The vaccine helps the body develop immunity to smallpox and was successfully used to eradicate the disease.

If you are exposed to someone with smallpox, vaccination within 4 days can prevent or lessen the seriousness of smallpox in most people. Vaccination up to 7 days after exposure may offer protection from dying as a result of the infection.

Since eradication, routine vaccination for smallpox has stopped except for a small group of professionals who work with smallpox or related viruses in laboratories.

### Signs and symptoms of smallpox

Smallpox has an incubation period (the time between becoming infected and developing symptoms) of 7–17 days (most commonly 12–14 days).

After this period the first symptoms of smallpox appear and include:

- high fever  $\geq 38^{\circ}\text{C}$
- malaise (general feeling of being unwell)
- severe headache
- backache
- prostration (extreme physical weakness)
- nausea
- occasionally, vomiting and abdominal pain.

After 2–4 days, the fever falls and a distinctive rash appears first as small spots on the tongue and in the mouth. The rash then spreads to the skin, starting on the face and spreading to the arms and legs then to the hands and feet. Usually the rash spreads within 24 hours.

The rash becomes raised bumps called vesicles which become filled with a thick cloudy fluid and often have a depression in the centre like a belly button. The fever will often rise again at this time and remain high until the scabs form over the bumps.

People with smallpox only become infectious around the time fever develops. The most infectious period is during the first week of rash, although a person with smallpox is still infectious until the last scab drops off.

### **Transmission**

Smallpox is highly contagious. It is most commonly spread person to person during close, face to face contact (within 2 metres) through large airborne droplets.

It is possible to spread smallpox through contact with smallpox pustules (pus-filled rash), rash scabs or contaminated objects such as clothing and linen. It is also possible to spread the virus through indirect contact such as through shared air conditioning systems.

### **Treatment**

There is no specific treatment for smallpox. Patients with smallpox may be helped by intravenous fluids, medicine to control fever or pain, and antibiotics for any secondary bacterial infection that may occur. Treating doctors may also use antiviral drugs to help the immune system fight the infection.

### **Outbreak control**

The control of smallpox is based on the identification and isolation of cases and the vaccination and monitoring of close contacts to prevent the disease spreading further.

## Appendix B: Smallpox Public Health Unit checklist

Suspected, probable or confirmed cases should **be immediately notified** to the central state or territory Communicable Disease Branch who will need to notify the NIR urgently (via email [health.ops@health.gov.au](mailto:health.ops@health.gov.au) or phone call **02 6289 3030**). The NIR should report to the WHO as soon as possible.

### Contact the patient or care giver to:

- Identify the likely source of infection
- Confirm onset date and symptoms of the illness
- Complete *Appendix D – Case investigation form*
- Ensure relevant pathology tests have been undertaken at appropriate laboratory facilities
- Ensure isolation and infection control measures are in place
- Identify contacts and obtain their contact details
- Provide *Appendix A - Smallpox factsheet*

### Contact laboratory to:

- Check samples received and obtain outstanding results

### Confirm case:

- Assess information against case definition

### Contact patient's contacts to:

- Assess risk of smallpox (exposure history) and determine category for management
- Determine current symptoms
- Vaccinate and isolate relevant contacts (see Section 10. Contact management)
- Complete *Appendix E - Contact surveillance form*
- Ensure access to thermometer and telephone
- Monitor the case as determined necessary
- Explain symptoms and restrictions to the contact
- Provide *Appendix A - Smallpox factsheet, Appendix F - Advice for contacts of a case of smallpox and Appendix G - Vaccination Fact Sheet*

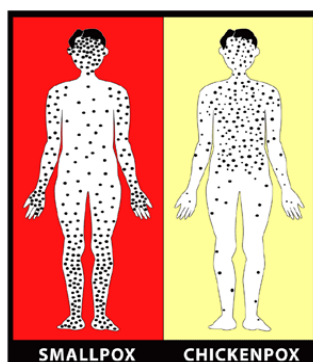
### Other issues:

- Media and communications should be coordinated in accordance with the Health CBRNINC Plan: Domestic Health Response Plan for Chemical, Biological, Radiological or Nuclear Incidents of National Consequence.
- Enter case data into notifiable diseases database

## Appendix C: Clinical comparison of smallpox and chickenpox (varicella) infections

	<b>Smallpox</b> <i>Variola virus (pox virus)</i>	<b>Chickenpox</b> <i>Varicella-zoster virus (herpes virus)</i>
How do initial symptoms differ?	2 to 3 days of severe illness pass before the rash develops.	0 to 2 days of mild illness pass before the rash develops.
	Lesions first appear in the throat or mouth, then on the face, or on the upper arms.	Lesions first appear on the trunk.
How the rash lesions differ	Lesions develop at the same time, and they look alike on any one section of the body, such as the abdomen, arms, or face.	Lesions develop in successive fashion. While some are new others are crusting over (in "crops").
	Lesions change slowly scabbing over after 9 to 15 days.	Lesions change rapidly, crusting over within 24 hours.
	Lesions become firm dome-shaped, and deep in the skin.	Lesions sit on the skin surface and look like small blisters.
	Rash commonly develops on palms of the hands and soles of the feet.	Rash rarely develops on palms and soles.
	Lesions are most concentrated on the face, hands and feet.	Lesions are most concentrated on the torso, with fewest on the hands and feet. Lesions can affect the face and scalp, but rarely affect the entire body equally.

Source: The U.S. Centres for Disease Control and Prevention (CDC)



## Appendix D: Case investigation form

<b>NOTIFICATION</b>	Date notified			
	Notifier name			
	Notifier organisation			
	Telephone			
	Email			
	Treating doctor			
	Telephone			
	Email			
<b>INTERVIEW</b>	Was the case interviewed?	Yes	No	N/A
	If case not interviewed, state who was interviewed and their relationship to the case			
	Date of first interview			
	Name of interviewer			
	Telephone number of interviewer			
<b>CASE DETAILS</b>	Case reference number			
	Name (first name, surname)			
	Date of birth			
	Age (years/months)			
	Sex	Male	Female	
	Occupation			
	Preferred language			
	Address (permanent)			
	Address – temporary (if different from permanent address)			

	Telephone (home)			
	Telephone ( <i>mobile</i> )			
	E-mail			
	Indigenous status	Aboriginal		
		Torres Strait Islander		
		Both Aboriginal and Torres Strait Islander		
		Not Aboriginal or Torres Strait Islander		
		Unknown		
	Country of citizenship			
<b>CLINICAL DETAILS</b>	Date of symptom onset			
	Initial symptoms	Fever	Backache	Malaise
		Headache	Abdominal pain	Prostration
		Vomiting	Vesicular rash	
	If rash is present, specify its location	<input type="checkbox"/> Mouth	<input type="checkbox"/> Legs	
		<input type="checkbox"/> Face	<input type="checkbox"/> Soles	
		<input type="checkbox"/> Arms	<input type="checkbox"/> Torso	
		<input type="checkbox"/> Palms		
	If rash is present, do all lesions on one body section look the same age?	Yes	No	
	Other symptoms ( <i>specify</i> )			
	Maximum temperature			
	<b>Category of illness</b> Interview (insert date) 24 hours (insert date) 48 hours (insert date) 72 hours (insert date)	Suspected	Probable	Confirmed
Date of report				
Was the case a contact of another case?	Yes	No		
If yes, provide contact identification number or name and address				
Infectious diseases physician name and contact				

<b>HOSPITAL AND TREATMENT DETAILS</b>	Hospitalised	Yes	No	Unknown
	Date admitted			
	Date discharged			
	Name of hospital ( <i>specify</i> )			
	Isolated in single room	Yes Date/time:	No	Unknown
	Admitted to ICU or HDU	ICU	HDU	Unknown
	Date admitted to ICU or HDU			
	Date discharged			
<b>OUTCOME</b>	Patient outcome	Alive	Dead	Unknown
	Date outcome information sought			
<b>LABORATORY CRITERIA</b>	Specimens collected Date collected	Blood / Serum / Vesicle fluid / Vesicle crust ---/---/----		
	Laboratory that received specimens			
	Specimens transferred to NHSUK or LRN member laboratory	Yes	No	Unknown
	Isolation of virus	Yes	No	Unknown
	Detection of virus by	Nucleic acid testing/ electron microscopy		
<b>MEDICAL AND VACCINATION HISTORY</b>	Smallpox vaccine given prior to this outbreak?	Yes	No	Date vaccine received
	Smallpox vaccine given during this outbreak?	Yes	No	Date vaccine received
	Pre-existing medical conditions ( <i>specify</i> )			
	Immunosuppressive disorders or treatment ( <i>specify</i> )	Yes	No	
	Infectious period Onset date (=t)	Date		
	Earliest date for start of incubation period (=t-14			

	days)	Date
	Epidemiological links to other cases ( <i>include case reference numbers</i> )	Case reference number
		Case reference number
		Case reference number
		Case reference number



## Contact classification

**Higher risk primary contacts** of a suspected, probable and confirmed smallpox case include:

- **Household-like contacts:** all persons usually resident or who have spent substantial periods of time within the same household during the infectious period. Includes sexual contacts.
- **Face-to-face contacts:** all unvaccinated<sup>7</sup> persons who were not wearing appropriate PPE equipment (or where a PPE breach occurred) who have had prolonged interactions ( $\geq 15$  minutes) with an infectious case of smallpox within a distance of 2 metres. These may include contacts at work, in social settings, and healthcare and emergency workers.
- **Fomite contacts:** all unvaccinated<sup>4</sup> persons who were not wearing appropriate PPE (or where a PPE breach occurred) who have had direct contact with clothing or articles that have recently been used by an infectious case of smallpox. These may include contacts at work, in social settings, and healthcare and emergency workers.
- **Vaccination contraindicated/failure:** lower risk primary contacts who are unable to be vaccinated or who do not have a successful vaccination<sup>8</sup>.
- **Virus release contacts:** all unvaccinated<sup>4</sup> persons in the vicinity of a release of variola virus.
- **Laboratory contacts:** Hazard level 3 and 4 laboratory contacts. See “Laboratory personnel contact management guidance” in “Section 10: Contact Management” of the SoNG.

**Lower risk primary contacts** of a suspected, probable and confirmed smallpox case include:

- **Aerosol contacts:** all persons who have had brief interactions ( $<15$  minutes) with an infectious case of smallpox within a distance of 2 metres, or any interactions (for  $\geq 15$  minutes) at a distance of  $>2$  metres within a room or enclosed space. People who have spent  $\geq 15$  minutes in an adjacent room or floor with shared air-conditioning (without HEPA filtration). These may include work colleagues, and people who have visited the same premises or travelled on the same public transport (such as buses, trains and planes) as an infectious smallpox case.
- **Non-laboratory contacts wearing PPE:** persons with contact with an infectious case of smallpox or their fomites whilst wearing appropriate PPE.
- **Previously vaccinated persons:** persons who have been successfully vaccinated within the previous 3 years who have had face-to-face or fomite contact with an infectious case of smallpox.
- **Laboratory contacts:** Hazard level 1 and 2 laboratory contacts (level 1 does not require isolation or monitoring). See “Laboratory personnel contact management guidance” in “Section 10: Contact Management” of the SoNG.

**Secondary contacts (household-like contacts of higher risk primary contacts)** of a suspected, probable and confirmed smallpox case include:

- all persons usually resident or who would be expected to spend substantial periods of time within the same household as the higher risk primary contact during the potential infectious period (i.e. should the higher risk primary contact become at case). Includes sexual contacts.

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<sup>7</sup> Contacts are classified as unvaccinated if they have not been successfully vaccinated against smallpox within the past 3 years. A successful vaccination requires a confirmed ‘take’ or major reaction indicating immunity.

<sup>8</sup> Contacts who would otherwise be lower risk primary contacts but who are unable to be vaccinated and are now classified as a higher risk primary contact do not need to be managed as a higher primary risk contact regarding vaccination.

**MOVEMENTS DURING INFECTIOUS PERIOD**

*Make at least 6 copies of this page before interview with the case: one for the day before symptoms (t -1), one for the day of onset (t), one for each of the next 4 days (t +1, t +2, t +3, t +4).*

T (day): \_\_\_\_\_

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Places visited	Names of place	Address of place	Phone (if available)	Time
Place 1				
Place 2				
Place 3				
Place 4				
Place 5				
Place 6				

Contact ID number	Contact name	Contact address	Contact phone	Contact email	Place of contact (e.g. Place 1)	Type of contact (e.g. primary household-like)	Date(s) and time(s) of contact

## Appendix E: Contact surveillance form

*Higher risk primary contact* - contacts receive daily active surveillance.

*Lower risk primary contact* - contacts receive daily active surveillance (if possible).

*Secondary contact* – no active surveillance.

Unique ID number for contact:\* \_\_\_\_\_

Type of contact:\* Higher risk primary / Lower risk primary / Secondary

Case reference number/s\* (if more than one): \_\_\_\_\_

or reference number of primary contact if secondary contact: \_\_\_\_\_

### Contact's details

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_ DOB:\* \_\_\_\_\_ Sex:\* M / F

Previous smallpox vaccination (incl. date and type): \_\_\_\_\_

Relevant medical history: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

### Status and management of contact at identification

Status: Symptomatic (S) / Asymptomatic (A)

Date of last contact with case (D): \_\_\_\_\_

Any active rashes / skin conditions or other medical complaints: \_\_\_\_\_

\_\_\_\_\_

Vaccination arranged: Yes / No Date given: \_\_\_ / \_\_\_ / \_\_\_

Batch number: \_\_\_\_\_ Vaccination centre: \_\_\_\_\_

Vaccination site assessed: Successful / Unsuccessful Date assessed: \_\_\_ / \_\_\_ / \_\_\_

Vaccination centre: \_\_\_\_\_

Patient isolation and location: \_\_\_\_\_

Contact surveillance

Day	Date	Contact phoned/ emailed/ SMS (Y/N)	Contact visited (Y/N)	Oral temperature (degrees Celsius)	Other symptoms	Status: S – symptomatic A - asymptomatic	Signed (print name)
D + 1							
D + 2							
D + 3							
D + 4							
D + 5							
D + 6							
D + 7							
D + 8							
D + 9							
D + 10							
D + 11							
D + 12							
D + 13							
D + 14							
D + 15							
D + 16							
D + 17							

## Appendix F: Advice for contacts of a case of smallpox

### Why am I a contact?

You are considered a contact because you have been in contact with someone who has smallpox or the virus itself.

All contacts are assessed and put into the following categories:

- Primary contacts
  - Higher risk primary contacts
  - Lower risk primary contacts
- Secondary contacts

These categories are determined by how close you have been to an infectious person or the virus and how long you have been exposed.

### *Higher risk primary contacts*

Higher risk primary contacts are people who are at most risk of catching smallpox and who have not had a successful smallpox vaccination in the last 3 years. This includes:

- **Household-like contacts:** people who live or have spent a lot of time within the same house as the case while they are contagious. This includes sexual contacts.
- **Face-to-face contacts:** people who have been face to face (less than 2 metres) with a case for more than 15 minutes without any personal protective equipment. This includes people from work, social settings, healthcare and emergency workers.
- **Fomite contacts:** people who have been in contact with anything a smallpox case has also been in contact with (their clothes, bedding etc.). This includes people from work, social settings, healthcare and emergency workers.
- **Vaccination contraindicated/failure:** people who would otherwise be in the 'lower risk primary contact' category, except that they are unable to be vaccinated or the vaccine didn't work.
- **Virus release contacts:** people who are in the area if there is smallpox virus released.
- **Laboratory contacts:** people who work in a laboratory who have been exposed to the virus without proper personal protective equipment.

### *Lower risk primary contacts*

- **Aerosol contacts:**
  - People who have had face to face contact (less than 2 metres) with a case for less than 15 minutes; or
  - have had contact at a distance of more than 2 metres for longer than 15 minutes in a closed space; or
  - have spent more than 15 minutes in a room next door to a case; or
  - have been on the same floor as a case with shared air conditioning.

These may include work colleagues, and people who have visited the same places or travelled on the same public transport (such as buses, trains and planes) as a case.

- **Non-laboratory contacts wearing personal protective equipment:** people who have been in contact with a case or things they have touched while wearing personal protective equipment.
- **Previously vaccinated persons:** people who have been successfully vaccinated within the last 3 years who have had face-to-face contact with a case or things they have touched.
- **Laboratory contacts:** people who work in a laboratory who have had contact with the virus while using the correct personal protective equipment.

### ***Secondary contacts***

Secondary contacts are house-hold like contacts of higher risk primary contacts, including anyone who lives with or usually spends a lot of time in the same house as a primary contact. This includes sexual contacts.

### ***Why do I need to take action?***

You have been in close contact with a person who appears to have infectious smallpox, or the virus itself. This means that a number of actions need to be taken immediately to protect you from infection. If the case you have been in contact with turns out not to have smallpox, you will be advised.

### ***Should I be vaccinated against smallpox?***

Higher risk primary contacts should be vaccinated unless they have a very serious health issue which makes vaccination extremely dangerous as they are at most risk of developing smallpox. Lower risk primary contacts and secondary contacts will be vaccinated unless they have a serious health issue that prevents them from doing so, or they are laboratory workers who have used appropriate personal protective equipment in an accredited laboratory.

Vaccination is most effective if given within 4 days of exposure to smallpox. This is why it is not always possible to wait for the patient's diagnosis to be confirmed before vaccinating contacts.

### ***Are there any special precautions for vaccination?***

There are some medical conditions that put people at greater risk of side effects from smallpox vaccination. These will be discussed and managed with you.

### ***What else do I need to do?***

You should monitor yourself carefully for the 17 days following contact with a case or the virus for symptoms of smallpox. This is very important so that infection can be detected early and you can be admitted to a specialist centre for observation or treatment. It will be ensured that you have access to a thermometer and telephone. Higher and lower risk primary contacts will be contacted daily by public health staff to check on your temperature and any symptoms.

### ***How do I monitor myself for symptoms?***

You should:

- take your temperature daily, at the same time each day, with the thermometer; and
- record your daily temperature measurement.

If your temperature rises above 38 °C at any time, or if you feel unwell and start to show symptoms of smallpox, you should immediately call the public health unit on the number provided to you. You should not present to any doctor or hospital without first calling your local public health unit, except in an emergency.

### ***Do I need to restrict my activities in any way?***

Higher and lower risk primary contacts need to be isolated during the 17 days after contact with a case or the virus. In most circumstances this can be at home, although if you are in shared accommodation alternative accommodation will be provided. During this period you should stay at home or in your accommodation, you should not work and you should avoid contact with people who have not been recently vaccinated against smallpox.

If you are a secondary contact you do not need to restrict your activities, however you should not leave Australia for 17 days following your last contact with a smallpox contact.

## **Appendix G: Vaccination factsheet**

### **The smallpox vaccine**

Smallpox vaccine is made from a live virus called vaccinia. Vaccinia virus is a “pox” virus related to smallpox virus, although it is less harmful and can protect people from smallpox. The smallpox vaccine does not contain smallpox virus and cannot give you smallpox. The vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox. The smallpox vaccine likely protects you from infection for 5–10 years, and protection from severe outcomes following infection could be life-long.

The vaccine is given using a special needle which has two prongs. The needle is dipped into the vaccine solution and when removed, the needle retains a droplet of the vaccine solution. The needle is then used to prick the skin a number of times over a few seconds.

### **Who should get the vaccine and when?**

People exposed to smallpox virus are at a higher risk of developing and spreading smallpox. If a case of smallpox occurs, first responder teams will need protection from the disease and will be vaccinated. These teams will identify other people who need to be vaccinated to control the outbreak.

Anyone who has been in contact with a case of smallpox or the virus itself will be vaccinated as soon as possible after exposure unless they have had the vaccine in the last 3 years, have an absolute contraindication to the vaccine or they have previously recovered from smallpox. There are some special situations where lower-risk contacts will not be vaccinated if they have a serious medical condition that prevents them from receiving the vaccine.

Receiving the vaccine within 4 days after exposure can prevent the disease or at least make it less serious. Receiving the vaccine within 7 days after exposure can still offer some protection against death from smallpox. The duration of complete immunity provided by vaccination is uncertain, but it is unlikely to be more than 10 years. Previously vaccinated people are therefore unlikely to be protected from infection although the disease may be less severe.

### **After the vaccination**

If the vaccination is successful, a red and itchy bump develops at the vaccination site in three or four days. In the first week after vaccination, the bump becomes a large blister, fills with pus and begins to drain. Later it will form a scab. Finally, the scab will fall off and leave a scar.

You may experience swelling and tenderness of the lymph nodes (glands) lasting 2–4 weeks after the blister has healed, itching at the vaccination site, tiredness, mild fever, headache or muscle aches.

### ***Vaccination site evaluation***

About 7 days after vaccination, you will need an appointment for a vaccination site examination, so that a healthcare professional can review your vaccination site to determine whether the vaccination was successful.

### ***Unsuccessful vaccination***

Around 3% of people may have no reaction to the vaccine. This could mean that vaccination was not successful and that you are not protected. In this case, you would need to be vaccinated again.

### ***Care of vaccination site***

Until the scab falls off, you can spread vaccinia virus to other people or to other parts of your own body. To prevent this, follow these instructions until the scab that forms at the vaccination site has fallen off on its own:

#### What you should do

- *If working in a healthcare setting*, cover the vaccination site loosely with gauze, using first-aid adhesive tape to keep it in place. Then cover the gauze with a semipermeable (or semi-occlusive) dressing, which will allow the passage of air but not of fluids. Change the semipermeable dressing at least every 3–5 days in order to prevent build-up of fluids and irritation of the vaccination site. Wear a shirt that covers the vaccination site as an additional barrier to the spread of vaccinia.
- *If not at work in a healthcare setting*, you need only wear the gauze bandage secured by first-aid adhesive tape over the vaccination site. Change it frequently (every 1–3 days). As an added precaution against spread of transmission, wear a shirt that covers the vaccination site. This is particularly important in situations of close physical contact that may occur at home.
- *Wash hands with soap and warm water* or with alcohol-based hand rubs (hand sanitiser), after direct contact with vaccine, the vaccination site, or anything that might be contaminated with live virus, including bandages, clothing, towels or sheets that came into contact with the vaccination site. This is vital in order to remove any virus from your hands and prevent spread. Make sure not to touch the vaccination site and then any other part of your body without washing your hands first.
- *Keep the vaccination site dry*. Cover the site with a waterproof bandage when you bathe. Remember to change back to the loose gauze dressing after bathing. If the gauze covering the vaccination site gets wet, change it.
- *Seal contaminated bandages/dressings* in a plastic ‘zip lock’ bag and dispose of them as general waste. Do the same for scabs as they fall off. Remember to wash your hands afterwards.
- *Keep a separate laundry hamper* for clothing, towels, bedding or other items that may have come into direct contact with the vaccination site or drainage from the site.
- *Wash clothing or any other material that comes into contact with the vaccination site*, using hot water with detergent and /or bleach. Wash hands after handling contaminated clothing etc.

#### What you should **not** do

- *Don’t use a bandage that blocks all air from the vaccination site*. This can cause the skin at the site to soften and wear away. Use loose gauze secured with first-aid adhesive tape to cover the site and then cover this with a semipermeable dressing and shirt when at work in a healthcare setting.
- *Don’t put salves or ointments on the vaccination site*.
- *Don’t scratch or pick at the scab*. The vaccination site can become very itchy, but you should not scratch it.
- *Don’t bathe with others until the lesion is healed*.

#### **Reactions after smallpox vaccination**

After smallpox vaccination, most people experience normal, typically mild reactions to the vaccine, which indicate that the vaccine is beginning to work. Some people may experience more severe reactions that may require medical attention.

Below are details of what you can expect after vaccination, and conditions that you should watch for.

#### ***Normal, typically mild reactions***

These reactions usually go away without treatment.



They can start right away, or they might not start until a week or more after vaccination:

- the arm receiving the vaccination may be sore and red where the vaccine was given;
- the glands in the armpits may become large and sore;
- the vaccinated person may develop a low fever (<38°C);
- the vaccinated person may have other symptoms like fatigue, headache or muscle aches;
- one out of three people may feel bad enough to miss work, school or recreational activity, or have trouble sleeping.

The vaccination site may start itching after a few days; this could last until the scab falls off.

#### What to do if you are concerned about normal reactions

While these reactions usually go away on their own, if you are concerned about reactions of this type, contact your jurisdictional Communicable Disease Branch via the phone numbers provided at the end of this factsheet.

#### ***Symptoms that may mean you require medical attention***

Some people may experience more severe reactions that may require medical attention. You should be aware of symptoms that might indicate you are experiencing such a reaction.

Watch for the following symptoms:

- the vaccine site doesn't look as though it is healing normally;
- a rash or sore on another part or parts of the body;
- a persistent headache (lasting more than 24 hours) or high fever ( $\geq 38^{\circ}\text{C}$ ), confusion or seizures;
- difficulty staying awake;
- difficulty breathing, hoarseness or wheezing;
- development of hives, pallor, weakness, rapid heart rate or dizziness;
- development of an eye infection; and /or
- development of some other unusual, unexpected problem.

If any of the above occurs, contact your jurisdictional Communicable Disease Branch via the phone numbers provided at the end of this factsheet.

#### ***Serious reactions that should be evaluated***

In the past, about 1000 people for every 1 million people vaccinated for the first time had reactions that, while not life threatening, were serious. These reactions may require medical attention:

- *A vaccinia rash or outbreak of sores limited to one area (inadvertent inoculation).* This is an accidental spreading of the vaccinia virus caused by touching the vaccination site and then touching another part of the body or another person before washing the hands. It usually occurs on the genitals or face, and can include the eyes, where it can damage sight or lead to blindness. Washing hands with soap and water after touching the vaccine site will help prevent this. *Note: if the eyes are affected, seek immediate attention.*
- *A widespread vaccinia rash (generalised vaccinia).* The virus spreads from the vaccination site through the blood. Sores break out on parts of the body away from the vaccination site.
- *An allergic rash in response to the vaccine.* This can take various forms, such as red spots, bumps, or hives.
- *Red streaks coming out from the vaccination site.* These are most likely a normal reaction, but could be an infection and should be checked.

If any of the above occurs, contact your jurisdictional Communicable Disease Branch via the phone numbers provided at the end of this factsheet.

#### ***Life-threatening reactions that need immediate attention***

Rarely, people have had very bad reactions to the vaccine. In the past, between 14 and 52 people per 1 million people vaccinated for the first time had potentially life-threatening reactions, and 1 or 2 died. It is important to note that for every million people who contract smallpox, approximately 300,000 will die from it. As such, in an outbreak situation the benefit afforded by the vaccine outweighs the risk.

The following reactions require immediate medical attention:

- *Serious skin rash (eczema vaccinatum)*. This is caused by widespread infection of the skin in people with skin conditions such as eczema or atopic dermatitis, and can lead to scarring or death.
- Ongoing infection of skin at the vaccination site with tissue destruction (progressive vaccinia or vaccinia necrosum) which can lead to scarring or death.
- Inflammation of the brain (postvaccinal encephalitis) which can lead to disability or death.
- New or worsening heart disease (including angina).
- Stroke or mini-stroke.

#### What to do if you believe you are having a serious or life-threatening reaction

Call your jurisdictional Communicable Disease Branch specified below, or visit an emergency department.

#### Treatment for serious or life-threatening reactions

Two treatments may help people who have certain serious reactions to the vaccine; vaccinia immune globulin (VIG) and cidofovir. Use of these depends on availability and the consideration of potential further adverse reactions.

#### Predicted rates of adverse events

Adverse events in Australia today may be more frequent than in the past because there may be more people at risk from immune suppression and eczema or atopic dermatitis. However, the outcome associated with adverse events may be less severe because of advances in medical care.

Rates may be lower for people previously vaccinated.

#### **Jurisdictional Communicable Disease Branch contact details:**

The contact details for [insert state/territory name] are:

## 16. Jurisdiction specific issues

[Links to state and territory public health legislation, the \*Biosecurity Act 2015\* and the \*National Health Security Act 2007\*.](#)