



Australian Government  
Department of Health and Ageing

# Guidelines for Smallpox Outbreak, Preparedness, Response and Management





Guidelines for  
Smallpox Outbreak,  
Preparedness, Response and  
Management

**Australian Government Department of Health and Ageing**

**January 2004**



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ISBN: 0 642 82298 0

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PA 3928 (JN 7814)

Publications Production Unit  
Australian Government Department of Health and Ageing

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# How to use this document

This document provides technical information about the management of a threat, or an outbreak, of smallpox. It supplements the Australian Government Department of Health and Ageing (DoHA) Standard Operating Procedures in case of an outbreak of smallpox. The document will be provided to States and Territories as guidelines to assist in their smallpox response plans and to outline the role of the Australian Government Department of Health and Ageing in a smallpox emergency.

Australia has a system of response codes that change with the risk of a smallpox outbreak. The main body of this document provides operational guidelines for each of the levels. The appendixes provide detailed information on specific topics and are referenced in the relevant areas of the text.

While this document provides guidance for health care workers, the most important action if a case, or a suspected case, were to occur in Australia would be to seek expert advice.

# Acknowledgments

The Australian Government Department of Health and Ageing would like to acknowledge the Infectious Disease Emergency Response (IDER) Working Group and the IDER subgroups for their expert advice in compiling these guidelines.

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The working group values the contributions of numerous practitioners in health care around Australia.

# Abbreviations and acronyms

AIDS	acquired immune deficiency syndrome
AQIS	Australian Quarantine and Inspection Service
CDC	Centers for Disease Control and Prevention
CDNA	Communicable Diseases Network Australia
COMDISPLAN	Commonwealth Government Disease Response Plan
DNA	deoxyribonucleic acid
DoHA	Australian Government Department of Health and Ageing
EM	electron microscopy
HEPA	high-efficiency particulate air (filter)
HIV	human immunodeficiency virus
HSV	herpes simplex virus
IATA	International Air Transport Association
IGA	intergovernmental agreement
IDER	Infectious Disease Emergency Response
IM	intramuscular
IV	intravenous
NHSQL	National High Security Quarantine Laboratory
NIR	National Incident Room
PC	physical containment (laboratory facility classification)
PCR	polymerase chain reaction
PHLN	Public Health Laboratory Network
SLE	systemic lupus erythematosus
TGA	Therapeutic Goods Administration
VAER	Vaccine Adverse Event Report
VIDRL	Victorian Infectious Diseases Reference Laboratory
VIG	vaccinia immune globulin
VZV	varicella–zoster virus
WHO	World Health Organization

# Glossary

- Category A contacts** – People who are likely to have been exposed to infection through large droplets or contaminated fomites.
- Category B contacts** – People who have less chance of having been exposed to infection than Category A contacts, usually through aerosol contact; includes all those who have shared rooms or other enclosed spaces with infectious cases of smallpox, and who do not fall into face-to-face or fomite contact groups.
- Cidofovir** – A nucleoside analogue active against many deoxyribonucleic acid (DNA) viruses, including herpes group viruses, adenoviruses and poxviruses.
- Eczema** – Generic term for inflammatory conditions of the skin, particularly with vesiculation in the acute stage, typically erythematous, edematous, papular, and crusting; followed often by lichenification and scaling and, infrequently, hyperpigmentation; often accompanied by sensations of itching and burning; the vesicles form by intraepidermal spongiosis; often hereditary.
- Fomite** – Physical objects that serves to transmit an agent from person to person for example infected clothing or dust particle containing infectious virus from droplets infected saliva.
- Polymerase chain reaction (PCR)** – A technique used to amplify the number of copies of a specific region of DNA, to produce enough DNA to be adequately tested.
- Index case** – An initial case of a disease or unrelated cases in a new geographical area.
- Incubation period** – The time between exposure and the onset of noticeable symptoms; for smallpox this is usually 10–16 days (range 7–17 days, median 12 days).
- Physical containment level 3 (PC3)** – Clinical, diagnostic and other facilities where work may be carried out with microorganisms that pose a serious risk of infection to humans, animals or plants.
- Physical containment level 4 (PC4)** – Facilities where work may be carried out with dangerous microorganisms that pose a high individual risk of life-threatening disease and may be readily spread to the community.
- Prodrome** – A symptom indicating the onset of a disease; smallpox has a prodromal period of 1–3 days, characterised by fever, malaise, headache and backache.
- Smallpox** – A severe illness with acute onset of fever  $> 38^{\circ}\text{C}$ , which is persistent, followed by a rash without other apparent cause, characterised by vesicles or firm pustules at the same stage of development and with a greater concentration of lesions on the face and limbs with predominantly centrifugal distribution.
- Vaccinia immune globulin (VIG)** – Antibody purified from the blood of people who are immune to smallpox; used to treat adverse effects following vaccination against smallpox with vaccinia virus.

**Vaccinia virus** – The virus used in the smallpox vaccine; like the variola virus, it is a member of the orthopox family of viruses.

**Variola virus** – The causative agent of smallpox; a member of the orthopox family of viruses.

**Viraemia** – A condition occurring in some viral infections, in which the infecting virus is found in the blood.

# Contacts

## State and Territory health department communicable disease contacts

Australian Capital Territory	(02) 6205 2155
Northern Territory	(08) 8922 8044
(ah) Royal Darwin Hospital:	(08) 8922 8888
Queensland	(07) 3234 1155
South Australia	(08) 8226 7177
Tasmania	1800 671 738
Victoria	1300 651 160
Western Australia	(08) 9388 4999 (bh) (08) 9480 4960 (ah)
New South Wales	See list below

## New South Wales

The public health units listed below facilitate the reporting of communicable disease cases in New South Wales:

Public health unit	Phone	Fax
Central Coast Public Health Unit	(02) 4349 4845	(02) 4349 4850
Central Sydney Public Health Unit	(02) 9515 3180	(02) 9515 3182
Corrections Health Service Public Health Unit – Long Bay	(02) 9289 2977	(02) 9311 3005
Far West Public Health Unit	(08) 8080 1219	(08) 8080 1683
Greater Murray Centre for Public Health	(02) 6021 4799	(02) 6021 4899
Hunter Public Health Unit	(02) 4924 6477	(02) 4924 6490
Illawarra Public Health Unit	(02) 4255 2200	(02) 4255 2222
Macquarie Centre for Population Health	(02) 6841 2216	(02) 6884 7223
Mid North Coast Population Health Unit	(02) 6588 2750	(02) 6588 2837
Mid-Western Public Health Unit	(02) 6339 5500	(02) 6339 5555
New England Public Health Unit	(02) 6766 2288	(02) 6766 3003
Northern Rivers Institute of Health and Research	(02) 6620 7500	(02) 6622 2151
Northern Sydney Public Health Unit	(02) 9477 9400	(02) 9482 1650
South Eastern Sydney Public Health Unit	(02) 9382 8333	(02) 9382 8334
Southern NSW Public Health Unit	(02) 6124 9941	(02) 6299 6363
South Western Sydney Public Health Unit	(02) 9828 5944	(02) 9828 5955
Wentworth Public Health Unit	(02) 4734 2022	(02) 4734 3300
Western Sector Public Health Unit (Sydney)	(02) 9840 3603	(02) 9840 3608

# Part 1

## Background



# Section 1

## Introduction

In 2002, the Australian Government, State and Territory governments signed an intergovernmental agreement (IGA) designed to enhance Australia's counter-terrorism capability through cooperative partnership. The IGA recognises joint responsibility for the national counter-terrorism capability. The agreement gives the Australian Government responsibility for determining policy and broad strategies in a declared national terrorist situation, in close consultation with affected States and Territories. The National Counter-Terrorism Plan sets out high-level strategy and is complemented by the National Counter-Terrorism Handbook. The Handbook details the nationally agreed arrangements for managing a Counter-Terrorist incident. The State and Territory governments have a primary operational role in dealing with terrorist situations in their jurisdictions.

The Commonwealth Government's Disaster Response Plan (COMDISPLAN), which sets out the Australian Government's primary operational response to terrorist events, is administered by Emergency Management Australia and is available online.<sup>1</sup>

The Australian Government Department of Health and Ageing (DoHA) is developing an overall bioterrorism response strategy in line with the principles of the IGA and the department's lead role. *Guidelines for Smallpox Outbreak Preparedness, Response and Management* — a working document subject to revision — is part of this strategy. All State and Territory health authorities are expected to maintain emergency management plans and capabilities to respond to bioterrorist incidents.

Although the last recorded case of smallpox occurred in the late 1970s, concern exists that, however unlikely, illicitly obtained smallpox (variola) virus could be deliberately released as a biological weapon.

Without containment measures, the virus could spread rapidly because:

- most people in Australia, and elsewhere, have low immunity and are therefore susceptible to smallpox
- population density and mobility is far greater than it was 30 years ago
- there may be delays in diagnosing the disease due to clinicians' unfamiliarity with its presenting features.

<sup>1</sup> <http://nationalecurity.ag.gov.au/ema/emaInternet.nsf>

Because the public health consequences would be severe, it is essential that contingency plans are available nationally and locally should smallpox re-emerge in Australia or elsewhere.

These guidelines outline overall policy in relation to national response codes for a smallpox threat or outbreak, and the mobilisation of vaccine. They present nationally agreed case definitions and epidemiological response plans, which will allow national comparison and international reporting. The guidelines also provide details, which in practice might vary between jurisdictions, of the composition of smallpox response teams, suggested levels of authority within jurisdictions, and the functions, staffing and deployment of smallpox care centres and smallpox vaccination centres.

# Section 2

## Characteristics of smallpox

### Case definitions

Box 1 summarises the case definitions of smallpox.

#### Box 1 Case definitions of smallpox

Clinical signs are an important element of suspected, probable and confirmed case definitions.

##### The clinical definition is:

A severe illness with acute onset of fever  $> 38^{\circ}\text{C}$ , which is persistent, followed by a rash without other apparent cause, characterised by vesicles or firm pustules at the same stage of development, and with a greater concentration of lesions on the face and limbs in a predominantly centrifugal distribution.

#### A. First cases of smallpox in a nonaffected geographical region

##### Index case

A first case of smallpox or unrelated cases in a new geographical area.

##### Confirmed case

A case of fever and rash consistent with the clinical definition, plus laboratory confirmation by polymerase chain reaction (PCR) or viral isolation.

##### Probable case

A case of fever and rash consistent with the clinical definition plus electron microscopy identification of orthopoxvirus.

##### Suspected case

A case of fever and rash consistent with the clinical definition, without laboratory confirmation or an epidemiological link to other cases, in the absence of other laboratory diagnosis and reviewed by an infectious diseases physician.

#### B. Outbreak situation (subsequent cases in a cluster)

##### Confirmed case within an outbreak

A case of fever and rash consistent with the clinical definition, plus either:  
(a) electron microscopy identification of orthopoxvirus; or  
(b) a case with strongly suspicious clinical features and no other diagnosis.

##### Probable case within an outbreak

A case of fever and rash consistent with the clinical definition, plus an epidemiological link to a confirmed case during an outbreak.

##### Possible case

Acute onset of fever but no rash in a person with an epidemiological link to a confirmed case, and reviewed by an infectious diseases physician.

In the event of an outbreak, control will depend on early identification and management of possible cases of smallpox. Surveillance should be sensitive enough to detect such cases. Any initial cases, or unrelated cases in a new geographical area, are likely to present as suspected cases and should be reviewed by an infectious diseases physician as soon as possible. However, highly specific case definitions for confirmed and probable cases are used early in an event because of the impact on public health responses. Later, within an outbreak, the definitions for confirmed and probable cases are less rigorous.

Clinical signs are an important element of suspected, probable and confirmed case definitions.

## Infectious agent

Smallpox is caused by infection with the variola virus. Variola is a deoxyribonucleic acid (DNA) virus and is a member of the genus *Orthopox*, which also includes vaccinia (used to produce the smallpox vaccine) and monkeypox. Smallpox is a human disease with no reservoir in any other animal species.

## History

Smallpox is one of the most severe infectious diseases affecting humans. Before the World Health Organization (WHO) eradication campaign, smallpox was a common disease worldwide and it is estimated to have killed more than 300 million people in the 20th century. The last community-acquired case of smallpox was in Somalia in October 1977 — almost 40 years after the last case seen in Australia. Since global eradication, the smallpox virus has been retained legally under strict security in two WHO collaborating centres: the Centers for Disease Control and Prevention (CDC) in Atlanta in the United States, and the Laboratory for Applied Microbiology at Koltsovo in Novosibirsk Region, Russian Federation.

The earliest known cases of smallpox in Australia were amongst Aborigines near Sydney in late 1789; the last recorded Australian case was in 1938. Vaccination against smallpox was introduced in Australia in the 1850s and was used widely during a 1917 epidemic in New South Wales. Routine vaccination of the Australian public ceased in the early 1970s, but vaccination of some travellers and defence force staff continued until 1979. A handful of laboratory workers who work with smallpox-related viruses have continued to be immunised using vaccine obtained through the Special Access Scheme of the Therapeutic Goods Administration (TGA).

First-hand knowledge of smallpox transmission and infection is found only in historical records and from the personal experience of a relatively small number of senior physicians, microbiologists and epidemiologists who have dealt with the disease in the past.

## Clinical features

The incubation period for a disease is usually defined as the time between exposure and onset of noticeable symptoms (in the case of smallpox, the onset of fever). The range given by most authorities for smallpox is 7–17 days, usually 10–16 days, with a median of 12 days.

Following infection, asymptomatic viraemia develops on day 3 or 4, followed by dissemination and replication in the spleen, bone marrow and lymphoid tissues. A secondary viraemia begins around day 8 and is associated with the onset of the disease's characteristic fever and rash. Patients are most infectious with the development of the rash, although they are likely to be infectious from the onset of fever.

The typical vesicular rash does not appear until 4–7 days after the onset of fever. The rash is preceded by a prodromal period of 1–3 days of fever, malaise, headache and backache, followed by 2–4 days of a macular rash that progresses through vesicular, pustular and crusted stages over the following two weeks. Clinical pictures are available on the CDC's website.<sup>2</sup>

Approximately 90% of cases of smallpox in nonimmune individuals can be expected to have the characteristic clinical presentation.

A modified form of smallpox can occur, and is more commonly found in previously vaccinated individuals. Modified smallpox is characterised by a generally similar prodromal period and transmission of virus, although when the skin lesions appear they are fewer and evolve more quickly.

Less frequent but severe presentations of smallpox include flat and haemorrhagic types.<sup>3</sup> Flat type or malignant smallpox is rare and usually fatal. It occurs more frequently in children and is characterised by an intense toxæmia. The skin lesions develop slowly and remain flat and soft.

In haemorrhagic smallpox, the incubation period is shortened, and is followed by an intense prodromal period with severe abdominal pains. Erythema (flushing of the skin) develops, followed by petechiae (small round flat dark-red spots caused by bleeding into the skin) and skin and mucosa haemorrhages. Death usually occurs by day 5 or 6 of the rash. Although rare, haemorrhagic smallpox occurs more often in adults; pregnant women, in particular, seem to be more susceptible.

## Differential diagnoses

Experience in the global smallpox eradication campaign showed that chickenpox (varicella–zoster virus or VZV) and disseminated herpes simplex virus (HSV) infection presented the greatest difficulties for differential diagnosis of smallpox.

## Chickenpox

In chickenpox the lesions are more superficial, tend to occur more on the trunk rather than on the face and extremities (centripetal distribution), and are less likely to appear on the palms and soles. Lesions at different stages of development may be present in one area and their evolution from macules, papules, vesicles and crusts is quicker (this can be within 24 hours). The prodrome may be absent or mild, and patients are rarely toxic or moribund. Many people (50–80%) will recall an exposure to chickenpox or shingles 10–21 days before the onset of the rash. WHO has produced training materials to help health staff recognise smallpox, distinguish it from chickenpox, and avoid diagnostic errors. These materials are available on the internet.<sup>4</sup>

### Box 2 Symptoms characteristic of chickenpox<sup>5</sup>

Chickenpox (varicella), the condition most likely to be confused with smallpox, is characterised by the following symptoms:

- prodrome is absent or mild
- lesions are superficial vesicles: ‘dewdrop on a rose petal’
- lesions appear in crops; on any part of the body there are lesions in different stages (papules, vesicles, crusts)
- distribution is centripetal: greatest concentration of lesions on the trunk, fewest lesions on distal extremities; may involve the face and scalp; occasionally entire body equally affected
- first lesions appear on the face or trunk
- patients are rarely toxic or moribund
- rapid evolution: lesions evolve quickly from macules to papules to vesicles to crusts (< 24 hours)
- palms and soles rarely involved
- patients lacks reliable history of varicella or varicella vaccination
- 50–80% recall an exposure to chickenpox or shingles 10–21 days before onset of rash.

## Herpes simplex virus infection

Disseminated HSV infection can also present a problem in differential diagnosis. However, both VZV and HSV are herpes viruses, and can be readily distinguished from smallpox by laboratory testing.

2 <http://www.bt.cdc.gov/agent/smallpox/smallpox-images/index.asp>

3 <http://www.bt.cdc.gov/agent/smallpox/index.asp>

4 <http://www.who.int/emc/diseases/smallpox/smallpox-english.ppt>

## Vaccination adverse events

The differential diagnosis includes adverse events from smallpox vaccination, such as generalised vaccinia, eczema vaccinatum, inadvertent inoculation and progressive vaccinia. Adverse vaccination events can occur in the recently vaccinated person or in someone who has been in recent contact with a recently vaccinated person, in Australia or overseas.

## Others

Other causes of rash such as enteroviruses (eg hand, foot and mouth disease), measles, parvovirus B19, rubella, secondary syphilis, bacterial folliculitis or septicaemia may also cause uncertainty, but should be distinguishable both clinically and in the laboratory. Molluscum contagiosum caused by poxvirus (genus *Molluscipoxvirus*) is distinguishable from smallpox on clinical grounds (lesions are umbilicated from an early stage and the patient is well) and by laboratory tests. Drug reactions, Stevens–Johnson syndrome, urticaria, erythema multiforme and scabies or insect bites may also need to be excluded (see Table 1).

**Table 1 Common conditions that might be confused with smallpox<sup>6</sup>**

Condition	Clinical clues
Chickenpox do not have a prodrome	Most common in children < 10 years; children usually
Disseminated herpes simplex immunocompromised host	Lesions indistinguishable from varicella;
Disseminated herpes zoster	Immunocompromised or elderly persons; rash looks like varicella (chickenpox), usually begins in dermatomal distribution
Enteroviral infection, especially hand, foot and mouth disease	Summer and autumn; fever and mild pharyngitis 1–2 days before rash onset; lesions initially maculopapular but evolve into whitish-grey, tender, flat (often oval) verticals; peripheral distribution (hand, foot and mouth or disseminated)
Drug eruptions	Exposure to medications; rash often generalised
Erythema multiforme minor	Target, ‘bull’s eye’, or iris lesion; often follows recurrent herpes simplex virus infections; may involve hands and feet (including palms and soles)
Erythema multiforme (including Stevens–Johnson syndrome)	Major forms involve mucous membranes and conjunctivae; may be target lesions or vesicles
Contact dermatitis	Itching; contact with possible allergens; rash often localised in pattern suggesting external contact
Scabies; insect bites (including fleas)	Itching is a major symptom; patient is not febrile and is otherwise well
Molluscum contagiosum	May disseminate in immunosuppressed persons
Impetigo ( <i>Streptococcus pyogenes</i> , <i>Staphylococcus aureus</i> )	Honey-coloured crusted plaques with bullae are classic but may begin as vesicles; regional not disseminated rash; patients generally not ill

5 *Evaluating Patients for Smallpox*, available online at <http://www.bt.cdc.gov/agent/smallpox/diagnosis/evalposter.asp>

6 *Evaluating Patients for Smallpox*, available online at <http://www.bt.cdc.gov/agent/smallpox/diagnosis/evalposter.asp>

## Mortality

Estimates of mortality from smallpox are complicated by the fact that documented epidemics were modified by the presence of some immune individuals in the population or by interventional vaccination. Importation into smallpox-naïve and unvaccinated populations caused the highest mortality.

Overall, mortality is accepted to be 30% in ordinary smallpox. Mortality in modified smallpox is less than 1%, but with flat and haemorrhagic forms it is greater than 95%. The highest mortality was seen in children aged less than one year and in people who were immunocompromised due to medical disorders or treatments. There are now many more vulnerable individuals in the elderly and immunocompromised groups than in the past.

## Vaccination

Australia has stocks of 30-year-old vaccine that is approved for use only in emergencies. DoHA is in the process of purchasing newer style vaccine, grown in cell cultures.

Vaccination with vaccinia virus is highly effective at preventing smallpox infection. The vaccine uses a live vaccinia virus, an orthopoxvirus, which induces antibodies that cross-protect against smallpox. Although effective in the eradication of smallpox, the vaccine can cause serious adverse effects.

In the absence of any clear evidence that smallpox may re-emerge, the risk of adverse events from the vaccine outweighs the risk from the disease. In the event of an outbreak, the containment strategy will centre on the isolation of cases and vaccination of contacts.

The duration of complete immunity provided by vaccination is uncertain, but 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. Such individuals will develop immunity more quickly on revaccination, and are less likely to have adverse reactions following revaccination.

See Appendix 1 for a more detailed discussion of vaccination.

# Section 3

## Epidemiology of smallpox

### Transmission

Natural smallpox infection is predominantly spread to people in close contact with a case, such as those living in the same household.

During the smallpox era, the disease had secondary household or close contact attack rates of up to 80%. Droplets from a symptomatic person's respiratory tract can infect another individual by contact with their mucous membranes and respiratory tract. Although the virus is present in pustules or scabs, its infectivity from these sources is less than when it is released in respiratory secretions. Objects around a symptomatic person, such as cutlery they sneeze on or linen on their bed, can harbour the virus and allow the infection to spread to others. Casual contact is much less likely to result in infection, although airborne spread of virus in draughts or air conditioning systems is known to cause infection.

In normal environmental conditions (ambient temperature, ordinary levels of humidity and exposure to sunlight) the virus is unlikely to survive longer than 48 hours.

### Incubation

The incubation period for smallpox (the time between exposure and onset of fever) is usually 10–16 days (range 7–17 days, median 12 days). The typical vesicular rash appears 4–7 days after the onset of fever.

Patients are not infectious during the asymptomatic incubation period; they become infectious with the onset of fever.

### Period of infectivity

After the onset of fever, infectiousness increases until the onset of rash (which often commences in the oropharynx) and remains high for the next 7 days. As a precaution, for the purpose of contact tracing, patients should be regarded as infectious from 24 hours before the first recognition of fever.

Patients remain infectious until the last scabs fall off. As a precaution, WHO isolation policy during the eradication campaign required that patients remain in isolation, in

hospital or at home, until the last scab had separated. However, scabs are not highly infectious and exposure to patients in the late stages of the disease is unlikely to produce infection in susceptible contacts.

## **Part 2**

### Response codes of alert



## Section 4

# Overview of response codes of alert

Australia's approach to a possible outbreak of smallpox is to maintain vigilance, with early detection of cases, vaccination of close contacts and surveillance of distant contacts.

Historically, this approach of case detection and outbreak containment was more effective in control of smallpox than mass vaccination (Fenner et al 1988). Vaccination of 12.5 million people in Iran in 1970 and a further 19.8 million in 1971, without good surveillance, did not halt the spread of the disease. Even when vaccination coverage was as high as 94%, transmission of smallpox continued (Jakarta 1969). In contrast, good case detection and containment controlled smallpox transmission in areas of Indonesia and other developing countries.

Developed countries achieved control by surveillance and outbreak management. Of 34 cases of smallpox imported into Europe between 1959 and 1978, 14 did not spread to others and 12 led to only one or two generations of transmission.

The search and contain strategy is effective when natural transmission of smallpox occurs from case to case. If smallpox were to be intentionally released at multiple sites, mass vaccination of people in affected areas would be required, combined with quarantine and isolation measures, and search and contain responses.

The resources needed for detection and containment of smallpox are great. To detect a first case, surveillance needs to be sensitive and therefore resource intensive. If a case were to occur, management of cases and contacts would need to be methodical. In 1970, some 400 people in Denmark were contacted and followed up for a single index case; in 1961, 100 contacts were followed up for one case in the United Kingdom.

Vaccination would need to be delivered rapidly: in a laboratory outbreak in the United Kingdom, 250,000 people were vaccinated within five days, even though only 1400 people were close contacts.

An investigation into the source of infection would require skilled epidemiologists. Public concern would make effective communication strategies essential.

The plan incorporates actions to be taken at five levels of alert (Response codes 0 to 4, with stepwise increases in alert), shown in Box 3. It is possible to progress directly from Response code 0 to Response code 2 or Response code 3.

### Box 3 Australian response codes for smallpox

- Response code 0: Smallpox remains eradicated — no credible threat of a release
- Response code 1: Imminent threat or a case overseas
- Response code 2: One case or a cluster of related cases in Australia
- Response code 3: Unrelated cases or unrelated clusters occurring in Australia
- Response code 4: Outbreak controlled — no further cases occurring

## Roles and responsibilities

Clear roles, 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 the Australian Government Department of Health and Ageing (DoHA) will include overseeing the national response and supplying vaccine as described below.

### States and Territories

While each State and Territory needs to determine governance structures, the guidelines advise the following model, in which the smallpox response teams report to an overarching smallpox response coordinating committee. States and Territories should decide on levels of authority and clarify roles and responsibilities.

The coordinating committee should be responsible for decisions about travel restrictions, opening of smallpox care centres and smallpox vaccination centres, national media liaison and liaison with DoHA.

State and Territory plans for response to a smallpox outbreak should give consideration to:

- smallpox vaccination centres (see Appendix 3)
- smallpox care centres (see Appendix 5)
- operational plans for hospitals
- implementation of infection control measures in health care facilities and the community
- designation of dedicated smallpox health facilities and closure of hospitals
- establishment of smallpox response teams
- laboratory management and surge capacity
- processes for requesting vaccine and vaccinia immune globulin (VIG)
- the State or Territory's own stock of antivirals
- maintenance of a register of vaccinated health care workers
- data collection and data transfer to national collation
- media liaison
- security at facilities and of vaccines and medical supplies
- notification to law enforcement agencies.

## Smallpox response teams

Smallpox response teams, the members of which are volunteers, form the main operating units in a smallpox emergency. The roles of these teams differ according to the response code level (see below).

The smallpox response teams will perform the following functions:

- ensure pre-event vaccination procedures for other smallpox response teams
- determine and implement the vaccine administration protocol
- establish the status of a case as a possible, probable or confirmed case of smallpox
- arrange confirmation of the diagnosis through DoHA and the National High Security Quarantine Laboratory (NHSQL), at the Victorian Infectious Diseases Reference Laboratory (VIDRL)
- arrange immediate clinical care and management of any suspected, probable or confirmed smallpox case
- identify individuals who have been exposed to the case and arrange appropriate management
- advise on, or implement, isolation measures
- establish surveillance
- arrange or confirm the vaccination of additional health care workers, as appropriate
- arrange for an epidemiological investigation into the source of infection
- communicate as required with governments and the media according to established protocols
- responsibility for on site security.

Each State or Territory should consider a minimum of two teams, each of approximately 15 members. Smaller States and Territories may choose to share teams to ensure overall cover.

Each team should include:

- one public health physician (the team leader) for coordination, surveillance and liaison
- one infectious diseases physician for diagnosis and case management
- one doctor/epidemiologist for surveillance and contact tracing
- two clinical care nurses for care and management of cases
- three vaccinating nurses to vaccinate contacts and workers
- three communicable disease nurses for surveillance, contact tracing, information and education
- three administrative workers for paperwork and database entry
- a dedicated media liaison officer, provided by the State or Territory health department.

Possible additional team members could be other medical specialists (such as a paediatrician/dermatologist), designated coordinator, occupational health and safety officer (OHS), a media officer or drivers. It is essential that the team has the correct skills to enable it to respond rapidly.

Members of the first smallpox response teams require vaccination as soon as possible: they should be prescreened for any contraindication to vaccination and be willing to be vaccinated ahead of time. People who have previously been vaccinated are likely to have lower rates of side effects. Details of the vaccine, contraindications and method of vaccination are given in Appendix 1.

Any contraindication to vaccination should be rigorously adhered to. An exception can only be made if a member's contraindication arises from their residence with someone else: the member could be vaccinated if they agree to reside elsewhere until their inoculation site has healed.

## Australian Government

DoHA will provide overall national coordination, give logistic support to States and Territories and activate the National Incident Room (NIR).

Specific smallpox response and management at the Australian Government level will include:

- consultation to refine these guidelines with State or Territory representatives
- assistance to States or Territories in coordinating the response
- delivery of vaccine and VIG to each State or Territory, according to the criteria outlined at each response code level
- assistance to States and Territories to provide training and education
- maintenance of a database of vaccination 'take' and adverse reactions
- establishment of methods for national surveillance of smallpox cases and contacts of cases
- communication of the national status of an outbreak to the media and the general public, and to the international community through the World Health Organization
- ensuring Australia's capacity to diagnose smallpox through the NHSQL.

## Action by response code level

Table 2 summarises responses to smallpox at each response code level.

**Table 2 Summary of actions for smallpox response at each code level**

	<b>Response code 0</b> Smallpox remains eradicated — no credible threat of a release	<b>Response code 1</b> Imminent threat or a case overseas	<b>Response code 2</b> One case in Australia and carry out following tasks in affected area	<b>Response code 3</b> Unrelated cases or clusters in Australia Manage outbreak and carry out following tasks in designated regions <sup>a</sup>	<b>Response code 4</b> Outbreak controlled — no further cases occurring
Smallpox response team	Establish, train and vaccinate	Vaccinate additional smallpox response teams	Establish more teams Sensitive surveillance	Expand Consider wider vaccination and quarantine	Maintain vaccination of smallpox response teams every 3 years
Extended health personnel	Vaccinate network of ID physicians Prescreen List 1 personnel <sup>b</sup> for suitability for vaccination	Vaccinate List 1 personnel Screen List 2 personnel <sup>c</sup>	Vaccinate List 2 personnel	Expand	Nil
Emergency personnel — fire, police, others	Nil	Nil	Prescreen personnel	Vaccinate	Nil
Smallpox care centres	Identify	Available for immediate use	Activate	Establish additional centres as required	Close and debrief
Smallpox vaccination centres	Identify	Available for immediate use	Activate	Establish additional centres as required	Debrief
Airport isolation facilities	DoHA to begin discussion with DFAT	Initiate	Consider landing and travel restrictions	As for Response code 2	Debrief
DoHA	Coordinate State / Territory plans	Plan	Initiate communication centre	Daily national teleconference	Debrief

(Continued overleaf)

**Table 2 Summary of actions for smallpox response at each response code level (Continued)**

	<b>Response code 0</b> Smallpox remains eradicated — no credible threat of a release	<b>Response code 1</b> Imminent threat or a case overseas	<b>Response code 2</b> One case in Australia Manage outbreak and carry out following tasks in affected area	<b>Response code 3</b> Unrelated cases or clusters in Australia Manage outbreak and carry out following tasks in designated regions <sup>a</sup>	<b>Response code 4</b> Outbreak controlled — no further cases occurring
Laboratories	Vaccinate 2 personnel at each designated regional laboratory and the reference laboratory	Plan for surge; vaccinate more personnel Consider private laboratories	As for Response code 1	Review capacity Implement surge capacity plans	Debrief
Communicate with doctors	Clinical diagnostic algorithm	Smallpox response team contact numbers; clinical algorithm; list of planned smallpox care centres; methods for collection and transport of clinical specimens	As for Response code 1 and ensure readiness	As for Response code 2 Daily teleconferences with DoHA, CDNA and members of the State and Territory smallpox coordinating committees Contact numbers for advice	Debrief
Communicate with community	Develop relationship with key media members Provide general information to public	Establish communication command centre at DoHA	Activate dedicated smallpox website, national enquiry line, regular news bulletin	As for Response code 2	Continue dedicated website and provide debriefing information
Days postvaccination measure of 'take'	At 7 days	At 7 days	At 3 days	At 3 days	At 7 days

CDNA = Communicable Diseases Network Australia; DEAT = Australian Government Department of Foreign Affairs and Trade; DoHA = Australian Government Department of Health and Ageing; ID = infectious diseases.

<sup>a</sup> Designated region or regions as defined by the Australian Government Chief Medical Officer (CMO) in consultation with advisory and jurisdictional groups.

<sup>b</sup> List 1 personnel: front-line personnel at designated hospitals; ambulance workers; additional laboratory staff and pathology workers; mortuary and funeral workers and doctors; nurses and support personnel who would be willing to work in smallpox care centres; border control personnel at airports; Australian Quarantine and Inspection Service staff at airports; customs officers.

<sup>c</sup> List 2 personnel: supplementary smallpox response teams and individuals for national or regional response teams; designated infectious diseases physicians; medical, nursing and support staff who might be required to work at smallpox care centres; epidemiological personnel who might be involved in contact tracing; environmental health officers who might be required to decontaminate premises; additional vaccinators.

## Laboratory testing by response code level

At Response code 0, the designated Public Health Laboratory Network (PHLN) laboratories will perform investigations for differential diagnoses of smallpox, such as varicella–zoster and herpes simplex (see Table 1), using physical containment level 3 (PC3) processing and staff who have been vaccinated against smallpox. If no alternative

**Table 3 Summary of laboratory testing for smallpox at response code levels**

National alert level	Testing characterised by:	Laboratory action
<b>Response code 0</b> <ul style="list-style-type: none"> <li>Smallpox remains eradicated</li> </ul>	<b>Decentralised exclusion of smallpox:</b> <ul style="list-style-type: none"> <li>low pretest probability of smallpox</li> <li>moderate containment requirement</li> <li>modest throughput demand</li> </ul>	<ul style="list-style-type: none"> <li>designated PHLN labs are lead agencies</li> <li>PC3 processing + immune staff</li> <li>differential diagnoses tested (VZV, HSV)</li> <li>negatives smallpox tested by EM plus referral to NHSQL for PCR<sup>a</sup></li> </ul>
<b>Response code 1</b> <ul style="list-style-type: none"> <li>Specific threat or release/case(s) overseas</li> </ul>	<b>Centralised screening for the first smallpox case:</b> <ul style="list-style-type: none"> <li>elevated pretest probability of smallpox</li> <li>high containment requirement</li> <li>increased throughput demand</li> </ul>	<ul style="list-style-type: none"> <li>NHSQL lead agency</li> <li>PC4 processing + immune staff</li> <li>smallpox tested (PCR)</li> <li>NHSQL tests differential diagnoses</li> </ul>
<b>Response code 2</b> <ul style="list-style-type: none"> <li>Release or case in Australia</li> </ul>	<b>Centralised screening for the first smallpox case:</b> <ul style="list-style-type: none"> <li>increasing pretest probability of smallpox</li> <li>high containment requirement</li> <li>high throughput demand</li> </ul>	<ul style="list-style-type: none"> <li>NHSQL lead agency</li> <li>PC4 processing + immune staff</li> <li>smallpox tested (PCR)</li> <li>NHSQL tests differential diagnoses</li> </ul>
<b>Response code 3</b> <ul style="list-style-type: none"> <li>Outbreak in Australia</li> </ul>	<b>Decentralised confirmation of widespread smallpox:</b> <ul style="list-style-type: none"> <li>high pretest probability of smallpox</li> <li>diminished containment requirement</li> <li>high throughput demand</li> </ul>	<ul style="list-style-type: none"> <li>a) <i>Case epidemiologically linked to laboratory-proven smallpox</i> <ul style="list-style-type: none"> <li>laboratory confirmation not necessary</li> </ul> </li> <li>b) <i>No epidemiological link</i> <ul style="list-style-type: none"> <li>designated PHLN labs are lead</li> <li>PC3 processing + immune staff</li> <li>smallpox tested (EM, or referral to NHSQL)</li> <li>PHLN lab tests differential diagnoses</li> <li>undiagnosed cases referred to NHSQL</li> </ul> </li> </ul>

EM = electron microscopy; HSV = herpes simplex virus; NHSQL = National High Security Quarantine Laboratory; PC3, PC4 = physical containment level 3, 4; PCR = polymerase chain reaction; PHLN = Public Health Laboratory Network; VZV = varicella–zoster virus.

<sup>a</sup> At Response code 0, confirmatory PCR assays could be batched.

- Notes:
- PC4 facilities to guarantee containment, and central diagnostic responsibility, are important during screening for initial cases in the elevated-risk Response code 1 and 2 phases.
  - PC3 facilities and immune staff provide acceptable staff safety, maximal laboratory capacity and simplified logistics, both in the low-risk Response code 0 phase, and later in Response code 3 when widespread community circulation of smallpox makes high-security laboratory containment irrelevant.

diagnosis is made, electron microscopy should be pursued with appropriate laboratory precautions. Samples should also be forwarded to the NHSQL for PCR.

At Response code 2, NHSQL will be the lead agency and perform differential diagnostic testing. Specimens will be processed by immune staff with PC4 security.

At Response code 3, some cases will have epidemiological links to confirmed cases and therefore will not need confirmatory laboratory testing. If there is no epidemiological link, the samples should be treated as at Code 0; that is, the designated PHLN laboratories will perform investigations for differential diagnoses of smallpox, such as varicella–zoster and herpes simplex, using PC3 processing and staff who have been vaccinated against smallpox. If no alternative diagnosis is made, electron microscopy should be pursued with appropriate laboratory precautions. Samples should also be forwarded to NHSQL for PCR.

At Response code 4, confirmation by electron microscopy and PCR will be required to ensure that there are no further smallpox cases.

# Section 5 – Response code 0

## Smallpox remains eradicated, no credible threat of a release

**A**t Response code 0, the requirements at State and Territory level are to:

- establish the capacity and infrastructure to deal with a smallpox emergency
- establish smallpox response teams.

### Prescreening and vaccination

The Infectious Diseases Emergency Response (IDER) working group will forward recommendation to the Australian Chief Medical Officer in regard to vaccinate smallpox response teams at Response code 0. This will be based on vaccine registration, details of vaccine trials and the current global threat and risk assessments.

#### Establish and vaccinate smallpox response teams

All members of the team require vaccination as soon as vaccine and suitable clinical treatment for side effects are available.

The risk of adverse effects of vaccination must be balanced against the risk of leaving vulnerable those specialist health care and laboratory workers who would be the first to be exposed in the event of a case, and who would not then have adequate time for vaccination to become fully effective. Some specialist health care and laboratory workers will therefore need to be vaccinated at Response code 0 to act as a first line of defence, even without an identifiable, specific threat. In the event that a case occurs, these workers will then be able to make the diagnosis, care for the patient, analyse clinical specimens, carry out additional vaccinations and initiate public health action to contain the outbreak.

Enough vaccine, suitable for pre-event vaccination, will be provided to vaccinate 40 people for each million population (ie sufficient for approximately 800–1000 members of smallpox response teams). Vaccination process will be discussed with the States and Territories; a logistical factor to be taken into consideration is that the vaccine is only supplied in 100-dose vials.

Vaccination of smallpox response teams will take place only after careful screening of volunteers. The vaccine used will be one that has been approved by the Therapeutic Goods Authority for use before an emergency. A supply of VIG will be available to treat any adverse events following vaccination.

At the IDER meeting on the 26 September 2003 it was agreed that vaccination of smallpox response teams at Response code 0 would be reviewed when a registered vaccine is available.

## Personnel to be prescreened

An extended list of staff (*List 1 — Personnel to be prescreened at Response code 0*, below) should be educated about the vaccine and screened to allow rapid vaccination at the time of a smallpox emergency.

Hospitals designated by State and Territory plans as facilities to deal with smallpox should, if possible, prescreen and pre-educate front-line personnel (emergency department workers, designated infectious diseases workers, caterers, cleaners and laundry workers). Consideration should be given to prescreening emergency department staff of designated facilities and other major hospitals.

### List 1 — Personnel to be prescreened at Response code 0

The following personnel should be prescreened at Response code 0:

- front-line personnel at designated hospitals
- ambulance workers
- additional laboratory staff and pathology workers who might be required to receive diagnostic clinical specimens (for electron microscopy or polymerase chain reaction)
- mortuary and funeral workers
- doctors, nurses and support staff who would be willing to work in smallpox care centres
- border control staff at airports and international seaports
- Australian Quarantine and Inspection Service (AQIS) staff at airports who have face-to-face contact with travellers or contact with items in baggage
- customs officers who have face-to-face contact with travellers or contact with items in baggage.

## Management activities

### Identify sites for smallpox care centres and smallpox vaccination centres

See appendixes 3 and 5.

### Ensure laboratory capacity and contingency plans

Vaccinate at least two staff at each designated laboratory and the investigation team at the National High Security Quarantine Laboratory.

### **Communicate with other health authorities**

At Response code 0, the protocols for State/Territory and national surveillance data are to be confirmed. The data, to be reported daily after a confirmed smallpox case, include morbidity and mortality figures, geographic location of cases, number of contacts under surveillance etc.

### **Communicate with doctors and the community**

Ideally, communication and education will help ‘demystify’ smallpox. The aim will be to improve understanding of smallpox disease and immunisation, and of the general approaches and concepts that would be used after a confirmed case or outbreak. Specifically, the role of isolation and the aims of vaccination strategies should be explained.

At Response code 0, it is important to start to build relationships with key media personnel who can be used to convey information to the public should an event occur. The task is to increase the range and type of smallpox information material available to the public, health care providers, policy makers and the media.

Communications should outline how the public health system will respond, the roles and responsibilities of the different sectors involved, and reasonable expectations regarding the scope and effects of public health actions. Preprepared media responses directed to these groups may be useful. The Australian Government Department of Health and Ageing Media Unit has undertaken such work, in conjunction with national security agencies and the media advisers of State and Territory health departments.



# Section 6 – Response code 1

## Imminent threat or a case overseas

**A**t Response code 1, sufficient vaccine will be distributed to all States and Territories to vaccinate additional smallpox response teams, plus the front-line health care workers and staff required to manage the smallpox vaccination centres and smallpox care centres (if activated). Each State or Territory will be required to submit a request to the Australian Government Department of Health and Ageing (DoHA) for vaccine, which may be made available, depending on the reason for the Response code 1.

If a smallpox case occurs overseas, one or two major airports may be designated to receive incoming flights from the region/country with the case. The decision to allow craft to land or disembark passengers will be made by Australian Government authorities and will depend on circumstances at the time.

Passengers from affected regions/countries allowed to disembark will be taken to a designated area for screening. If they have not been vaccinated in the country of origin, they will be offered vaccination. If vaccination is contraindicated, or is refused, they will be required to be isolated for 17 days. All passengers will be followed up by public health personnel to monitor vaccination take and for surveillance purposes.

### List 1 — personnel to be vaccinated

If the event of a heightened threat, more health care, emergency, laboratory and other personnel will be vaccinated, including all those who are likely to be directly involved in the assessment, management and investigation of smallpox cases. All staff prescreened at Response code 0 should now be vaccinated. Screening of List 2 personnel should begin.

### List 2 — personnel to be screened

The following personnel should be screened at Response code 1:

- supplementary smallpox response teams and individuals who might be required to join national or regional response teams
- designated infectious diseases physicians
- medical, nursing and support staff (porters, cooks, cleaners, laundry workers etc) who might be required to work at smallpox care centres
- epidemiological staff who might be involved in contact tracing
- environmental health officers who may be required to decontaminate premises.

## Communication

Inform doctors of the nature of the heightened threat. Remind them of presenting clinical features and case definitions, and the procedures for transporting samples, reporting, and assessment of patients with suspicious illnesses. Provide a list of planned smallpox care centres.

Begin teleconferences with peak communicable disease groups, such as Communicable Diseases Network Australia and the Public Health Laboratory Network.

## Media

The DoHA Media Unit, in conjunction with the Australian Chief Medical Officer and relevant national security agencies, will take the lead role in explaining to the media the nature of the heightened threat and the response required. This communication will include strong messages about specific measures that may need to be taken by the general public.

Continue and update Response code 0 communication activities.

## Smallpox care centres

At Response code 1, preparations need to begin for the possible use of smallpox care centres, which must be able to be activated within 24 hours of the first confirmed case. A Response code 1 alert or diagnosis of the first *probable* case requires preparation to activate the centres.

# Section 7 – Response code 2

## One case in Australia

All activities undertaken at previous response codes continue.

Management of an Australian case is outlined in Part 3 of this document, *Outbreak management*.

The amount of vaccine released at Response code 2 will be determined by the affected State or Territory in conjunction with the Australian Chief Medical Officer. The amount of vaccine released will depend on:

- known or estimated number of cases
- known or estimated number of contacts
- known or estimated number of areas affected
- number of personnel requiring vaccination
- vaccine availability.

### Smallpox response team activities in affected area

#### Confirm the case

The first task of the smallpox response team will be to assess the report of a possible index case. Laboratory confirmation can be obtained within 48 hours through the Australian Government Department of Health and Ageing (DoHA) or the National High Security Quarantine Laboratory. A confirmed index case of smallpox is a case of fever and rash consistent with the clinical definition, plus laboratory confirmation by polymerase chain reaction or viral isolation.

The smallpox response team will advise the State or Territory smallpox coordinating committee.

Smallpox care centres might need to be used before the first case is confirmed, because a care centre will admit a possible or probable case. Smallpox vaccination centres will be activated if the case is probable, and vaccination will begin if the case is confirmed. Details of requirements for smallpox vaccination centres, smallpox care centres and handling of specimens can be found in Section 11 (*Establishing logistic services and priorities*) and in appendixes 3, 4 and 5.

## Manage the case and contacts

Case and contact management in the affected area after confirmation of the index case is detailed in Section 12 (*Management of cases and contacts*).

## Smallpox response team activities in nonaffected areas

### Convene national teleconference

When a case occurs in another jurisdiction, smallpox response teams will be convened, and will review information about the case and its management. Daily teleconferences should be held between smallpox response teams in nonaffected jurisdictions, DoHA and the liaison person appointed by the activated smallpox response team.

### Establish early detection surveillance

Surveillance systems within each jurisdiction should be reviewed to ensure the earliest possible detection of a case in the jurisdiction. Systems should include strategies such as careful triage and health education to increase detection at primary care and emergency department level.

Contact numbers for advice should be redistributed to doctors.

### Communication

Doctors will be sent clinical algorithms and smallpox response team contact details. State and Territories need to ensure that health care workers have knowledge of planned smallpox care centres, and of methods for collection and transport of clinical specimens (see Appendix 4).

DoHA will activate a dedicated smallpox website and a national telephone enquiry line. DoHA's Media Unit will collaborate closely with Communicable Diseases Network Australia and media advisers in State and Territory health departments, particularly with the health department of the State or Territory where the case has occurred. The Media Unit will also work closely with national security agencies and will activate the National Emergency Media Response Network to coordinate a national public response, including media conferences and public statements.

# Section 8 – Response code 3

## Unrelated cases or clusters, occurring in Australia

All activities for Response code 1 and Response code 2 should be implemented during Response code 3, in addition to the specific outbreak guidelines below.

### Mass vaccination or regional vaccination and quarantine

Vaccine will be distributed according to the requirements of the situation. Mass vaccination, or regional vaccination and quarantine, may be required to raise the level of immunity to smallpox if ‘contain’ (‘ring fencing’) immunisation has been ineffective, or if there are deliberate multiple releases of smallpox. Deliberate releases at multiple sites would result in nearly simultaneous cases across the country.

Decisions about whether to implement mass regional vaccination must be taken after due consideration of:

- whether the risk of contracting the disease is greater than the risk of the vaccination
- difficulties in diagnosis (vaccination complications, especially generalised vaccinia, can mimic smallpox)
- vaccination resources, including vaccine supplies (there is a danger that mass vaccination could divert resources from essential outbreak control measures).

Mass vaccination will only be implemented after Australian Government Department of Health and Ageing (DoHA) consultation with State and Territory authorities and expert groups.

### Communication with media

The full resources of the DoHA Media Unit will be deployed to handle media management, and the National Emergency Media Response Network activated at its highest level of response. The national media plan for a response to a chemical, biological or radiological incident in Australia will be invoked, involving national security agencies and State and Territory governments.

DoHA will establish a national communication centre. The centre will be staffed by media advisers from DoHA and seconded media officers, and will probably operate

24 hours a day and 7 days a week. An advisory team will be appointed, consisting of medical officers familiar with smallpox response plans and epidemiologists from the DoHA Surveillance and Epidemiology Section. The national communication centre will respond to inquiries from media, the public and health care providers.

## Section 9 – Response code 4

### Outbreak controlled, no further cases occurring

**A**t Response code 4, all workers in the smallpox response will need to be debriefed.

The smallpox response teams will need to be maintained and be vaccinated every three years. It might be necessary to recruit new members to the teams during this time.

Equipment and plans will need to be reviewed and updated regularly.



# **Part 3**

## Outbreak Management



# Section 10

## Categories of contacts

### Category A primary contacts (higher risk of infection)

Category A contacts are people who are likely to have been exposed to infection through large droplets or contaminated fomites, and include the following:

- *Household contacts*: all persons usually resident at the same address as infectious cases of smallpox, and visitors who have spent more than 1 hour at that address during the infectious period.
- *Face-to-face contacts*: all persons who have face-to-face contact with infectious cases of smallpox, within a distance of 2 metres (6.5 feet). These may include contacts at work and in social settings, and unvaccinated health care and emergency workers.
- *Fomite contacts*: all persons who have had direct contact with clothing or articles that have recently been used by infectious cases of smallpox.<sup>7</sup> These contacts may include health care and emergency workers.

To identify Category A contacts, prompt by asking about family members, relatives, close friends and close work colleagues.

### Category B primary contacts (lower risk of infection)

Category B contacts have less chance of having been exposed to infection. They include all persons who have shared rooms or other enclosed spaces with infectious cases of smallpox, and who do not fall into the face-to-face or fomite contact groups described above.

These may include work colleagues, and people who have visited the same premises or travelled on the same public transport (buses, trains and planes) as smallpox cases. People who have shared floors of buildings or air-conditioning with infectious cases should be managed as Category B contacts.

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<sup>7</sup> There is good evidence of transfer of infection from fomites, such as bed linen, when the fomes have been contaminated by a severely unwell and symptomatic case. However, fomite contact was not important in school settings in Brazil, where shifts using the same classroom as child cases did not acquire infection (Klauber and Angulo 1974ab, 1976).

## Secondary contacts

Secondary contacts are people who will have ongoing household contact with a Category A contact during the formal monitoring period. They may therefore be exposed to infection if the primary contact becomes symptomatic. Secondary contacts include all persons usually resident at the same address as a Category A primary contact, and other visitors who will be required to spend substantial periods of time at the Category A contact's address during the formal monitoring period.

## Unimmunised primary contacts

Unimmunised primary contacts include primary contacts who refuse vaccine, who fail to respond to vaccination, or who are vaccinated late (more than 3 days after their first exposure to infection). Primary contacts who fail to show a response to a first dose of vaccine after 3 days should be revaccinated. Primary contacts who refuse vaccination should be quarantined.

## Special issues relating to contacts

Management of individuals in certain groups (such as illegal immigrants and overstayers, and homeless persons) may pose problems. Some may be reluctant to trust and engage with health care services when they become ill, thereby delaying access to health care and exposing more contacts. Their details might not be passed on by smallpox cases, even if they are close contacts, and vaccination might therefore be delayed or overlooked. There could be difficulties in explaining the need for their admission to a centre or for restrictions on their movements, and the logistical issues involved in monitoring for the development of fever.

Advice should clearly emphasise the severity of the problem, and guarantees could be required to protect the confidentiality of contacts and possibly to protect illegal immigrants and overstayers from prosecution. Engagement through voluntary and community groups may be effective. Interpreters should be available locally, and information sheets for those for whom English is a second language should have been drawn up.

# Section 11

## Establishing logistic services and priorities

In a smallpox outbreak, isolation of cases and effective identification, tracing, vaccination and monitoring of contacts are essential to prevent the spread of infection. Any delay in intervention is likely to increase the size of the outbreak. Procedures for management of cases and contacts are summarised in Figure 1.

Box 4 summarises the logistic services required.

### Box 4 Summary of logistic services required

- Smallpox care centre
- Smallpox vaccination centre
- Telephone advice line for community
- Smallpox case report telephone line for doctors
- Smallpox contacts advice line
- Prescreening sites for essential service workers.

### Smallpox care centres

Smallpox care centres may need to be operational following the first suspected case (ie before the first case is confirmed).

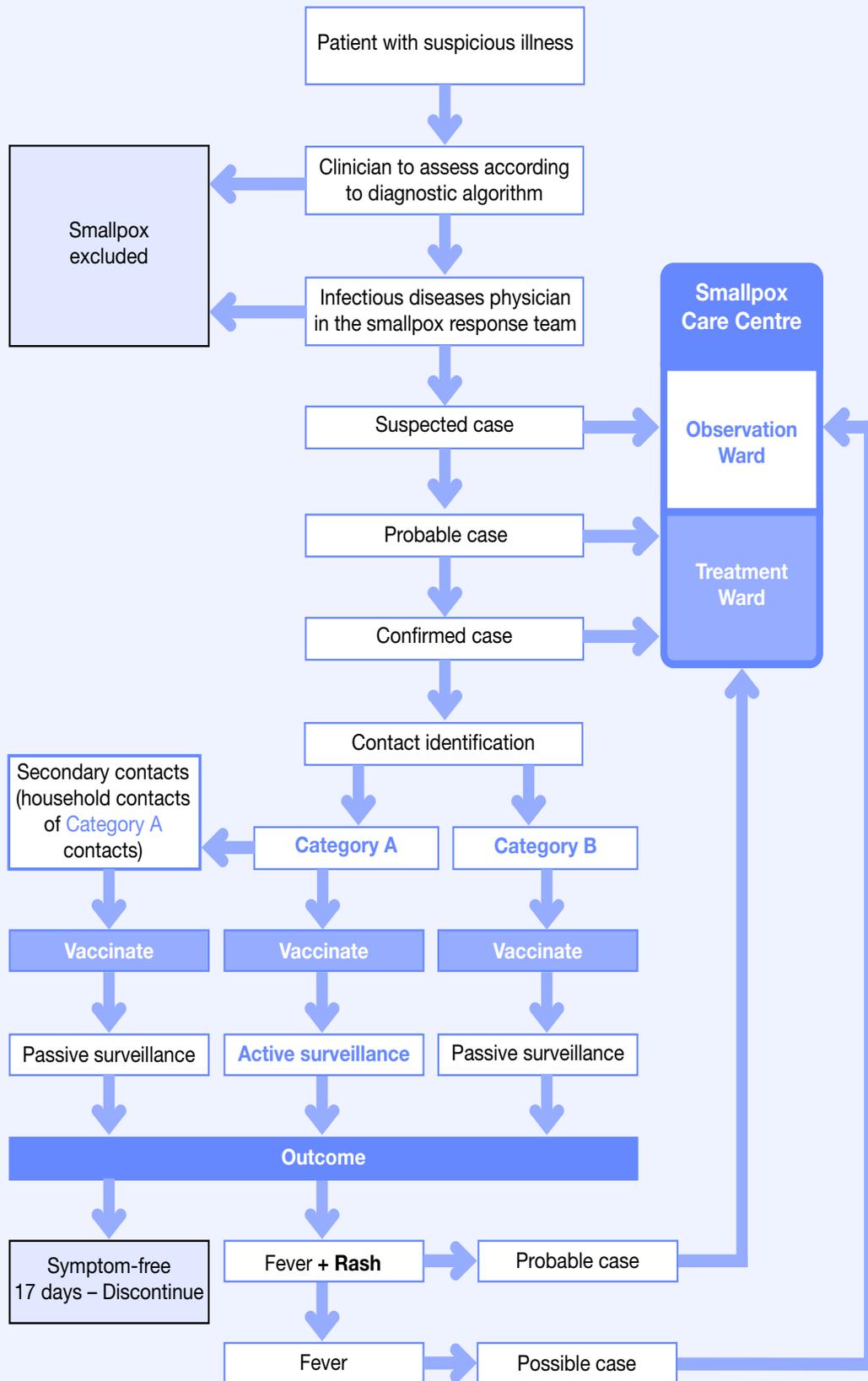
Observation and treatment wards, which will be maintained separately to ensure that possible cases are not exposed to infection, should be designated.

All possible and probable cases should be vaccinated on admission to protect them from infection by confirmed cases, in the event that their diagnosis of smallpox is subsequently excluded (see Appendix 5).

### Fever clinics or early assessment sites

The tasks of an early assessment site are to screen patients for possible smallpox, to provide information, and to protect febrile patients who do not have smallpox from exposure to the disease during assessment. Possible cases should be assessed in an area where they are not likely to come into contact with probable or confirmed cases. An appropriate initial assessment site would be near to, but separate from, a smallpox care centre. The clinic should preferably be in its own freestanding building separate

**Figure 1 Summary of management of cases and contacts**



from a health care institution. If part of a larger institution, the clinic must be physically isolated and should have negative pressure relative to that institution. The recommendations of the Canadian health authorities for severe acute respiratory syndrome screening provide a model (Health Canada 2003).<sup>8</sup>

### Smallpox vaccination centres

Appendix 3 gives operational guidelines for smallpox vaccination centres. Nurses and doctors trained in smallpox vaccination will conduct vaccinations at the centres.

Vaccination should not be offered to individuals who demand vaccination without an epidemiological indication (ie those who do not fall into primary contact categories A or B, as defined in Section 10 (*Categories of contacts*)).

Smallpox vaccination centres will provide:

- assessment of contraindications (screening)
- vaccination
- assessment of adverse reactions
- assessment of immune response ('take')
- referral
- advice and information.

Household contacts of vaccinated List 1 and List 2 staff should be vaccinated if the first case is confirmed.

### Smallpox advice line for the community

Many people who do not fall into the groups at risk of infection might be concerned about having been exposed through brief or remote contact with smallpox cases (eg passing contacts in the street or shops, or for short periods in large, well-ventilated areas).

These people do not need to be traced and do not require vaccination, but they may identify themselves once details of the case become public. Their details should then be recorded, and they should be given an information sheet for reassurance (see Appendix 12). They should not be offered vaccination, because this would divert resources away from the essential measures of tracing and vaccinating all Category A and Category B contacts.

These people will be more worried than most, and could require individual intervention: particular media attention should be directed at their concerns. If they develop fever or other constitutional symptoms they will be able to call a smallpox advice line that will be set up for the general public.

<sup>8</sup> <http://www.hc-sc.gc.ca/pphb-dgsp/ars-sras/pdf/sars-ic-outpatient-05-27.pdf>

### Smallpox report line for doctors

Intensive surveillance will be necessary to ensure that all cases are recognised and control measures implemented as early as possible. Clinicians will again be reminded of the presenting clinical features and case definitions, and the procedure for reporting and assessment of patients with suspicious illnesses. Designated infectious diseases physicians will be issued with smallpox reporting forms (see Appendix 11), and a telephone number for reporting of suspected cases.

Active surveillance of hospitals may be required to search for additional cases. Recent unexplained deaths and all suspicious illness among hospital inpatients should be reviewed to exclude the diagnosis of smallpox.

### Smallpox contacts line for contacts

The dedicated smallpox contacts line telephone number is for contacts of a case of smallpox who have developed symptoms.

### Prescreening of other essential service personnel

As at list 2, fire, police and other essential services should consider pre-screening at Response code 2. Prescreened essential workers should be vaccinated at Response code 3 in designated areas (town, region or State and Territory, depending on epidemiology).

# Section 12

## Management of cases and contacts

### Management strategy

#### Isolate and arrange care of cases at smallpox care centres

Cases may arise in individuals who are being monitored as contacts, or in individuals who have no known epidemiological link to other cases. See Box 1 in Section 1 of this document for case definitions.

*Probable and confirmed cases* will be transferred directly to a treatment ward at a smallpox care centre as soon as this is available (care centres will be listed as they are designated).

*Possible cases* will be transferred to an observation ward at a smallpox care centre until the diagnosis of smallpox can be confirmed or excluded. Some of these admissions may be due to the side effects of smallpox vaccine.

If the diagnosis of smallpox in possible or probable cases is subsequently excluded, contacts who have been identified but not yet traced need not be vaccinated or further followed up.

#### Complete case reports

Smallpox response teams and clinicians at smallpox care centres will establish the time from which cases of smallpox have been infectious. They will then compile a list of household contacts and obtain a detailed account of the patients' movements during the infectious and incubation periods. This is necessary both in order to identify other primary contacts, and to investigate potential sources of infection.

Full details of all contacts identified will be recorded in a database, along with details of the management and outcome of each. Once arrangements for vaccination and active surveillance for Category A contacts have been made, secondary contacts (those that live with Category A contacts) can be identified. See Appendix 11 for the required forms.

#### Identify and categorise contacts

Rapid identification and tracing of contacts is essential. Vaccination should be carried out as soon as possible (preferably within 3 days and at most within 7 days of

exposure to infection), because the degree of protection diminishes as the interval between exposure and vaccination increases. Contacts should be checked for symptoms before vaccination, to ensure that they are not co-primary cases.

Contacts are categorised by their risk of exposure. Categories should be regarded as a guide: individuals' risk of infection should always be considered in the context of their proximity to and duration of exposure.

Contacts may be asymptomatic or symptomatic. Those who have mild symptoms, such as fever or other constitutional symptoms, require restriction of travel (see below): such symptoms might be prodromal for early smallpox infection.

## Action for Category A contacts

### Vaccinate urgently

Category A contacts should be vaccinated as a matter of urgency. Postexposure vaccination given up to 3 days after exposure also provides protection (with possibly some protection from vaccination up to 7 days postexposure), although it may not completely prevent infection, and patients may develop mild modified disease. These actions are summarised in Box 5.

#### **Box 5 Summary of actions for Category A contacts**

- Vaccinate urgently
- Start active surveillance
- If symptomatic, admit to smallpox care centre
- Restrict movements, days 7–17

### Start active surveillance

Category A contacts must be formally monitored for the development of symptoms for 17 days from the last exposure to an infectious case.

Formal monitoring involves daily recording of body temperature, measured orally, and daily reporting of this, and the presence of other constitutional symptoms, by phone to the designated smallpox contacts line that will be dedicated solely for this purpose. An oral thermometer (preferably a plastic model that can be disposed of after the formal monitoring period), a temperature chart, instructions on the measurement and recording of body temperature, general and special contacts advice (see Appendix 12), and the smallpox contacts line telephone number should be provided to each contact.

Category A contacts who fail to make their daily health report will be actively traced, by telephone or in person.

## Admit to smallpox care centre if prodromal symptoms develop

Category A contacts who develop a fever or other constitutional symptoms must stay at home and immediately telephone the smallpox contacts line.

Category A cases developing fever should be regarded as *possible* cases and transferred immediately to the observation ward of a smallpox care centre.

Category A contacts who also develop a vesicular rash should be regarded as *probable* cases and transferred to the treatment ward.

## Restrict activities

Asymptomatic Category A contacts are restricted during the period of their greatest risk of developing symptoms and becoming infectious. The restriction period therefore extends from *7 days after the first exposure* until *17 days after the last exposure* to an infectious case. During this time, category A contacts must:

- stay away from work or school
- avoid contact with unvaccinated individuals
- remain within their local area as defined by the local/State health authority.

Outside the restriction period, and as long as they are well, Category A contacts may continue normal activities, although they must not travel abroad and should be advised to stay within their local area until the end of the formal monitoring period and until their vaccination site has completely healed.

## Action for Category B contacts

### Vaccinate unless contraindicated

Category B contacts should be vaccinated unless they have contraindications, in which case the risk from vaccination should be weighed against the risk from disease. These actions are summarised in Box 6.

#### Box 6 Summary of actions for Category B contacts

- Vaccinate unless contraindicated
- Start passive surveillance
- If symptomatic, admit to smallpox care centre and restrict

### Establish passive surveillance

Category B contacts do not require formal monitoring but are requested to check for pustules daily. However, their details should be recorded, and they should be given a contacts information sheet (see Appendix 12). The advice should include the

smallpox contacts line telephone number, which contacts must call immediately if they develop a fever or other constitutional symptoms during the 17 days following their last exposure to infection. No other restrictions on their activity are necessary, except that they must not travel abroad until they have been free of symptoms for 17 days following their last exposure to infection, and until their vaccination site has completely healed.

### Admit to smallpox care centre if prodromal symptoms develop

Category B contacts who develop fever should be regarded as *possible* cases and transferred immediately to the observation ward of a smallpox care centre.

Category B contacts who also develop a vesicular rash should be regarded as *probable* cases and transferred to the treatment ward.

### Restrict activity if symptomatic

Category B contacts who have a fever or other constitutional symptoms must stay at home and remain in contact with their physician.

## Action for secondary contacts

### Vaccinate unless contraindicated

All secondary contacts of Category A contacts should be vaccinated unless they have contraindications to vaccination (see Appendix 1). If vaccination is contraindicated, secondary contacts should avoid contact with the primary contact until the primary contact's vaccination site is completely healed, because of the risk of transfer of vaccinia infection. These actions are summarised in Box 7.

#### Box 7 Summary of actions for secondary contacts

- Vaccinate unless contraindicated
- Passive surveillance
- If not vaccinated, avoid contact with

### Passive surveillance and restrictions

No monitoring or restrictions on activity are necessary for secondary contacts unless the primary contact becomes symptomatic and therefore becomes a possible or probable case. Provide contact information sheets (Appendix 12) to secondary contacts.

## Reassess status

If smallpox is confirmed in the primary contact, secondary contacts themselves become Category A contacts and must be managed accordingly.

## Action for unimmunised primary (Category A or B) contacts

People vaccinated late and those who do not respond to the vaccine may be given additional prophylaxis against smallpox concurrently with vaccination or revaccination, in an effort to attenuate disease.

Contacts who were vaccinated between 3 and 8 days after first exposure to infection may be given vaccinia immune globulin (VIG) depending on the clinical situation, VIG supply and the advice of the smallpox response team's infectious diseases specialist.

Contacts who were vaccinated more than 8 days after first exposure may be given cidofovir depending on the clinical situation, cidofovir supply and the advice of the smallpox response team's infectious diseases specialist.

Unimmunised contacts will also require additional monitoring and/or restrictions on movement:

- those in Category A will be asked to stay in isolation accommodation until the end of the incubation period
- those in Category B should be followed up actively (as if they were standard Category A contacts), with a period of formal monitoring and identification and vaccination of secondary contacts.

Isolation accommodation will be required for unimmunised Category A contacts. Appropriate facilities will need to be identified, and might include local hotels, university halls of residence etc.

## Investigating source of infection

The smallpox response team should arrange for an epidemiology team to investigate the source of infection, because conducting such an investigation while managing the outbreak would call for more resources than the team will have. The investigation team will need to work with local and national police.

Investigation will begin with hypothesis-generating interviews with smallpox cases to discover their movements over the previous 16 days. If a hypothesis is formed for the source of infection, an analytical epidemiological study may be undertaken in parallel with police investigations.

If there has been an overt release of virus, all those deemed to have been exposed, according to an evaluation of the site and time of release, will be managed as Category A contacts.

If a potential source of infection is identified from common exposure histories, others who have shared the same exposure should be regarded as Category A contacts and traced as a matter of urgency.

## Communication

Smallpox response teams should include a dedicated media liaison officer who will report relevant operational details to the State or Territory health department. Media officers from the Australian Government Department of Health and Ageing Media Unit will liaise with their counterparts in State and Territory health departments to ensure that accurate and relevant detail of the work of the teams is communicated to media and the general public.

## **Part 4** Appendices



# Appendix 1

## Vaccination

Australia has stocks of Aventis vaccine (Lister strain) that, because of the paucity of clinical data, can be used only in an emergency outbreak. The Australian Government is in the process of purchasing vaccine that will be reviewed by the Therapeutic Goods Administration (TGA) for approval for pre-event vaccinations.

The vaccine (after TGA approval) and vaccinia immune globulin (VIG) will be provided to States and Territories by the Australian Government Department of Health and Ageing (DoHA).

Vaccine against smallpox contains a live virus, vaccinia, which produces cross-immunity against variola. It should be kept frozen at  $-30^{\circ}\text{C}$ . the shelf life of the vaccine is 24 hours once it is thawed. Once thawed, the vaccine should be kept below  $5-8^{\circ}\text{C}$ .

Targeted vaccination and monitoring of contacts, together with isolation of cases, is the mainstay of containment. The efficacy of vaccination in preventing the spread of smallpox depends on early detection of cases, and identification and tracing of contacts. This 'ring vaccination' strategy is compatible with World Health Organization (WHO) recommendations.

Historically, smallpox vaccination has carried a risk of complications, which occurred at a higher frequency than that now acceptable for a modern vaccine. Complications occurred more often in people who were immunosuppressed, people with a history of eczema or other chronic skin diseases, and pregnant women. Because of this, mass vaccination of the population would have serious implications, whether carried out before or in the event of an outbreak.

There is a need to consider protection of close contacts of people who have been vaccinated, because vaccinees could shed vaccinia virus. For example, children with eczema should not share a house with someone who has been vaccinated until the vaccination site has completely healed.

### Screening for contraindications

For any vaccination, the risk from disease must be weighed against the risk from adverse events arising from vaccination. Screening for suitability for vaccination applies to all individuals intended to receive the vaccine.

- Where vaccination is contraindicated in *health care workers*, they should not be vaccinated and should not be involved in any aspects of the smallpox response. In an emergency, they should consult an infectious diseases physician.
- Where vaccination is contraindicated in *Category A contacts*, their cases should be reviewed by a doctor to balance the risks of smallpox against the risks of vaccination. If these individuals require vaccination following exposure to smallpox infection, and depending on supplies, they may be given VIG to treat vaccine complications. Adverse effects may also be treated with cidofovir.

### List of contraindications

- *Immunodeficiency*: persons with diseases that cause immune deficiency such as human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), leukaemia, lymphoma, generalised malignancy, agammaglobulinaemia; or people undergoing therapy with alkylating agents, antimetabolites, radiation or large doses of steroids.
- *Eczema*: persons who have ever been diagnosed with eczema, even if the condition is mild or not presently active.
- Persons with acute or chronic skin conditions such as atopic dermatitis, impetigo and varicella–zoster (chickenpox and shingles) should not vaccinated until the condition resolves.
- People with a history of neurological disorder.
- Women who are pregnant or planning to become pregnant. Women should be advised to avoid pregnancy for three months after vaccination.
- Women who are breastfeeding.
- Children under the age of one year.
- Anyone living in a household with a member who has any of the conditions listed above.
- People with serious, life-threatening allergies to the antibiotics polymyxin B, streptomycin, tetracycline or neomycin (this may depend on brand of vaccine used).
- Persons vaccinated in the past 30 days with a live vaccine.
- Known coronary disease, including:
  - previous myocardial infarction (heart attack)
  - angina (chest pain caused by lack of blood flow to the heart)
  - congestive heart failure
  - cardiomyopathy (heart muscle becomes inflamed and does not work as well as it should)
  - stroke or transient ischaemic attack (a ‘mini-stroke’ that produces stroke-like symptoms but no lasting damage)
  - chest pain or shortness of breath with activity (such as walking up stairs)
  - other heart conditions under the care of a doctor.

Anyone who receives smallpox vaccine should avoid further vaccination with a live vaccine for one month after receiving the smallpox vaccine.

Contacts with contraindications to vaccination should consider housing themselves separately from vaccinated household members until vaccination sites have healed, to decrease the risk of contact transmission of virus.

## Vaccination techniques

The vaccine is ideally delivered by a special bifurcated needle of the same design that was used towards the end of the WHO smallpox eradication campaign. If a bifurcated needle is not available, an alternative is the back surface of the bevel of a green needle.

It takes approximately two hours to train someone to vaccinate using either of these techniques. A webcast and other training resources are available on the website of the United States Centers for Disease Control and Prevention (CDC).<sup>9</sup>

Smallpox vaccine is a live virus vaccine. Although much less pathogenic than smallpox itself, the vaccinia virus almost always causes local papulovesicular lesions (pocks). It can also produce metastatic pocks in the skin and mucosae and, in debilitated and immunocompromised patients, spreading skin lesions or viraemic disease.

It is therefore important to:

- obtain informed consent from the vaccinee (a consent form is in Appendix 11)
- use personal protective equipment when performing vaccinations
- dispose of unused vaccine and used equipment safely.

## Equipment list for vaccination

- Vials of vaccine, which should not be thawed until needed
- Bifurcated needles
- Thick gloves for opening the diluent vials
- Sharps disposal bin
- Clinical waste disposal bag
- Handwashing facilities or alcohol hand rub
- Wound dressings.

## Personal protective equipment

- Disposable apron or gown
- Dust–mist mask
- Eye protection
- Disposable gloves
- Shoe covers.

<sup>9</sup> <http://www.bt.cdc.gov/agent/smallpox/training/webcast/dec2002/index.asp>

## Administration procedures

It is suggested that two vaccinators work together: one primes the needles and the other vaccinates. This avoids the risk of contaminating vaccine by mistakenly placing a used needle back into the multidose vial.

All vaccinators should wear disposable gloves, change gloves between vaccinees and wash their hands regularly. At the end of the session, all sharps, including the vaccine vials and needles, should be discarded into a sharps bin, which should then be securely closed. Aprons and gowns, masks, eye protectors, gloves and shoe covers should be discarded into a clinical waste disposal bag, which should then be secured.

Vaccinators should then wash their hands thoroughly with soap and running water.

### Administration using a bifurcated needle

- Vaccination is best performed on the upper left arm, just below the insertion of the deltoid muscle, which is just behind the midline at the junction of the upper and middle thirds of the humerus.
- *Do not clean or prepare the skin* (alcohols or disinfectant will inactivate the vaccine).
- If the skin is dirty, rinse with soap and water and dry thoroughly before vaccination.
- Dip the 'forked' end of the bifurcated needle into the vaccine suspension.
- Transfer the drop of vaccine held in the notch of the needle to the skin of the inoculation site.
- Spread the vaccine suspension over an area about 5 mm ( $\frac{1}{4}$  inch) in diameter.
- Hold the bifurcated needle at an angle of 90 degrees to the surface of the skin, with the vaccinator's wrist resting on the skin.
- With the double point of the bifurcated needle, inoculate the vaccine into the skin, using 15–20 light 'jabbing' movements. The aim is to penetrate the epidermis without causing bleeding, but a few small blood spots are acceptable, as they indicate that the epidermis has truly been penetrated.
- *Do not put the needle back in the vaccine vial at any point. If this occurs, the vial must be discarded.* Discard the used needle into a sharps box for disposal.
- Cover the vaccinated area of skin with a transparent dressing.
- If another person is to be vaccinated, remove your gloves and clean your hands by washing, or by using alcohol rub, then put on clean gloves and use a clean bifurcated needle for the next procedure.
- Use the remaining vaccine to vaccinate more recipients until it is all used up.
- Ensure that a fresh needle is used for each person, and do not accidentally contaminate the vaccine with a used needle.

## Dressing the vaccination site

To avoid secondary infection with environmental organisms, vaccinators and vaccinees should avoid touching the vaccination site with either gloved or ungloved hands.

The dressing on the skin site should consist of a ring of gauze that encircles the vaccination site, with transparent dressing stretching across the vaccination site and gauze ring. The dressing should be kept dry.

Vaccinees will need a supply of dressings in case dressings fall off. Used dressings should be placed and sealed in a small yellow waste disposal bag, a supply of which will also be required, and returned to the vaccination centre for disposal.

## After vaccination

The vaccinee should take home:

- an information sheet that includes advice to avoid people with contraindications to the vaccine (see Appendix 12).
- instructions for covering the vaccine site and handwashing (see Appendix 12)
- the smallpox contact line telephone number
- an appointment for assessment of ‘take’
- gauze and additional clear-type covering to reduce shedding of virus
- yellow waste disposal bags.

## Examination for vaccine ‘take’

Most people experience normal, typically mild reactions to the vaccine, which indicate that it is beginning to work.

Successful vaccination produces a *characteristic papule after 3 days*. This evolves into a vesicle at 4–5 days and a pustule at 6–7 days. The pustule is a reliable indication that protective antibody levels have developed (ie that there has been a successful ‘take’). A more rapid response is seen in persons who have had previous vaccination. The immune response to vaccination in nonemergency situations will be determined 7 days after vaccination. In emergencies, the site should be examined earlier.

### **During Response codes 0, 1 and 4: examine at day 7**

The site should be examined at 7 days, at which time a major reaction should be clearly visible as a pustule. It may be reduced in size and severity in people who have been previously vaccinated.

### **During Response codes 2 and 3: examine at day 3**

The site should be examined 3 days after vaccination for the initial sign of a take, which will be a papule. Individuals who do not show any signs of a reaction should

be revaccinated. A major reaction should be clearly visible as a pustule at 6–7 days. It may be reduced in size and severity in people who have been previously vaccinated.

### Expected take rates

Take rates depend, amongst other things, on potency of vaccine, age of vaccinee, past vaccination history and vaccination technique. For primary vaccination, take rates have historically varied from 85% to 99.9%. The primary take rate of an appropriately potent ( $10^7$  pock-forming units/mL) and properly administered vaccine is likely to be greater than 99%. For revaccination, take rates have been lower: from 54% to 93%, with a mean of about 70%.

With routine vaccination having ceased so long ago, residual immunity is likely to be negligible, and any vaccination now is likely to resemble the primary vaccinations of the past.

### Recognition of expected vaccine reactions/take

Successful vaccination is normally associated with tenderness, redness, swelling and a lesion at the vaccination site. Primary vaccination may also be associated with fever for a few days and enlarged, tender lymph nodes in the axilla of the vaccinated arm. These symptoms are more common in persons receiving their first dose of vaccine (15–20%) than in persons being revaccinated (0–10%).

The clinical manifestations of vaccination with vaccinia virus depend on the immune status of the vaccine recipient. Local reactions to vaccination may be classified as a major (primary) reaction or an equivocal reaction.

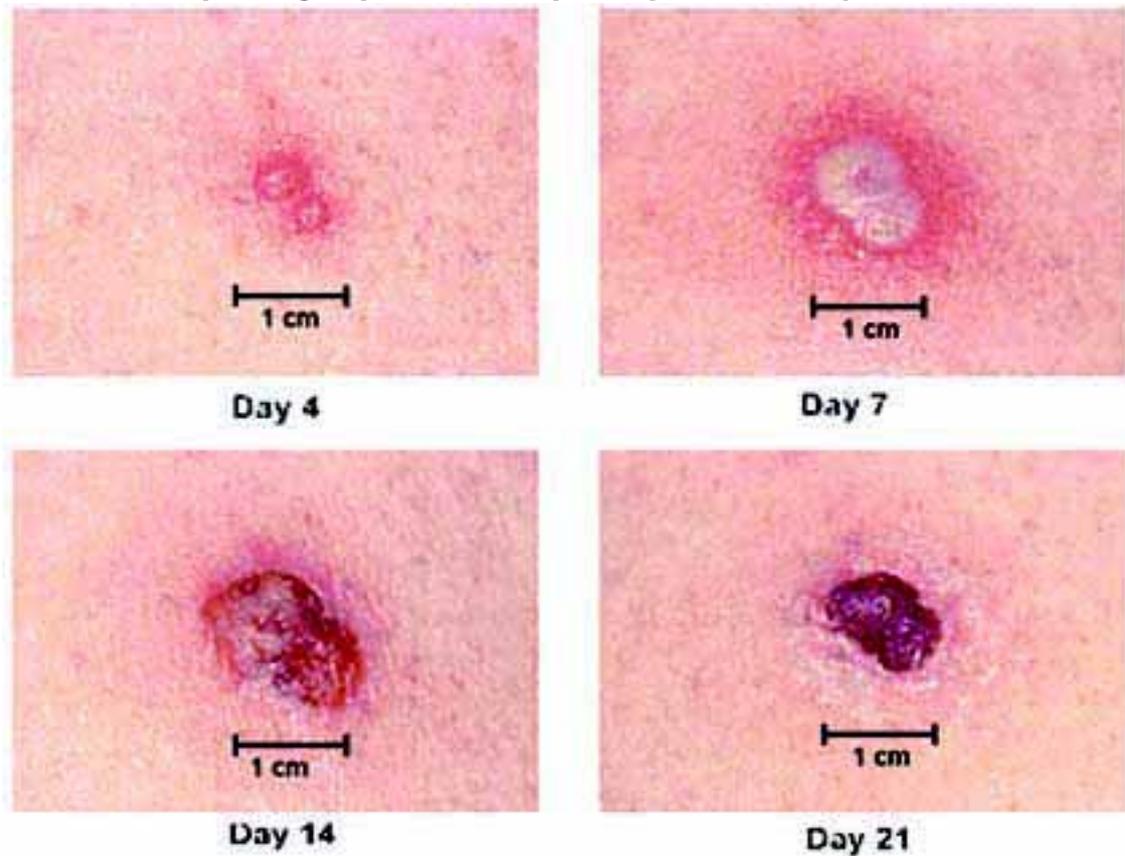
#### Primary (major) reaction

This reaction would be expected in persons receiving their first or primary smallpox vaccination or in those who had received a primary vaccination many years previously. Most people today would fall within one of these two groups. The inoculation site becomes reddened and pruritic 3–4 days after vaccination (see Figure 2). A vesicle surrounded by a red areola then forms and becomes umbilicated and then pustular by day 7 to day 11 after vaccination. The red areola enlarges substantially by this time. The pustule begins to dry, the redness subsides, and the lesion becomes crusted between the second and third week. By the end of the third week, the scab falls off, leaving a permanent scar that is initially pink in colour but eventually becomes flesh coloured. At the end of the first week between the vesicular and pustular phases, there may be a variable amount of fever, malaise, and regional lymphadenitis. These symptoms usually subside within 1–2 days and are more likely to occur in older children and adults than in infants.

#### Equivocal reaction

All responses other than a major (primary) reaction are defined as equivocal reactions. These blunted reactions could be a result of a high level of immunity (eg in a person who has received multiple previous smallpox vaccinations) or vaccination failure caused by improper vaccine administration technique or less potent vaccine.

**Figure 2** Major (primary) reaction — Expected local reaction after *primary* smallpox vaccination (or revaccination after a prolonged period since primary vaccination)



If an equivocal reaction is observed, the vaccination procedures should be checked and vaccination repeated with vaccine from another vial or vaccine lot, as it would be difficult to determine if the blunted reaction was caused by immunity or vaccine-take failure.

### Adverse reactions

The overall risk of serious complications following vaccination with vaccinia vaccine is low. Complications occur more frequently in persons receiving their first dose of vaccine, and among young children (< 5 years of age). VIG or cidofovir may be used to treat vaccine complications. Surveys in the United States found that the overall risk of serious adverse events was between 50 and 1000 per million vaccinees, with inadvertent inoculation and generalised vaccinia the most common complications. For adverse event rates, see the website of the CDC.<sup>10</sup>

The incidence of complications is up to 10 times higher in primary vaccinees than in revaccinees. In the same surveys, the risk of fatal complications was approximately one per million in primary vaccinees, but in a study in England and Wales in the 1950s, it was estimated at three per million. Fatal complications occur in approximately one per four million revaccinees. Death is most often the result of postvaccinal encephalitis or progressive vaccinia (see below).

<sup>10</sup> <http://www.bt.cdc.gov/agent/smallpox/vaccine-safety/adverse-events-chart.asp>

The most frequent complications of vaccination and their descriptions are listed below. For details of treatment of adverse reactions, see Appendix 9 (*Medical management and treatments for smallpox and vaccinia*).

### Inadvertent inoculation at other sites

Inadvertent inoculation at other sites was the most frequent complication of vaccinia vaccination and accounted for about 50% of all complications following primary vaccination and revaccination.

**Figure 3** Inadvertent inoculation of lower eyelid



Photo from Fenner et al 1988, reprinted with permission

This complication occurred at a rate of about 1 in 2000 primary vaccinations and usually resulted from autoinoculation, in which the virus is transferred by hand from the site of vaccination to other areas. The most common sites involved were the face, eyelid (Figure 3), nose, mouth, genitalia and rectum. Inadvertent inoculation should be much less common when the vaccination site is covered with a dressing. Most lesions healed without specific therapy, but VIG may be useful for some cases of inadvertent ocular inoculation (see Appendix 9). VIG is contraindicated, however, if vaccinia keratitis is present. Inadvertent inoculation can be prevented by handwashing after touching the vaccination site.

### Generalised vaccinia

Generalised vaccinia (Figure 4) is characterised by a vesicular rash of varying extent resulting from bloodborne dissemination of vaccinia virus. It is most frequently seen following primary vaccination and occurs at a rate of about 1 in 5000 vaccinations. Lesions occur 6–9 days following vaccination and can be few or generalised. The rash is generally self-limited in persons with no underlying illnesses (immune deficiencies) and usually requires no treatment with VIG except in patients who appear toxic or who have serious underlying conditions.

### Eczema vaccinatum

This complication is seen in vaccine recipients who have active or healed eczema or other chronic skin conditions. It can also occur in persons with these conditions who come into contact with a recently vaccinated individual. Vaccinia skin lesions can progress to cover all or most of the area(s) that are or were affected by the eczema or

**Figure 4** Generalised vaccinia in an apparently normal child, who recovered without sequelae



Photo courtesy of John M Leedom, MD

chronic skin condition (Figure 5). Fever and generalised lymphadenopathy may also occur. The illness is usually mild and self-limited, but can be severe and occasionally fatal. The most serious cases appear to occur in primary vaccinees and close contacts with eczema, and are independent of the activity of the underlying eczema. Previous studies have indicated that this complication occurs at a rate of about 1 in 26,000 primary vaccinations. VIG is effective in treating serious cases of eczema vaccinatum.

**Figure 5** Eczema vaccinatum



Photo courtesy of John M Leedom, MD

## Progressive vaccinia (vaccinia necrosum or gangrenosa)

**Figure 6** Progressive vaccinia (that was fatal) in a child with an immunodeficiency



Photo from Fenner et al 1988, reprinted with permission

This severe and potentially fatal complication (Figure 6) occurs in persons with underlying immune deficiencies and can occur following primary vaccination or revaccination. It is characterised by failure of the vaccine site lesion to heal, with progressive necrosis of the vaccination site and surrounding areas.

Secondary lesions may appear at other sites of the body and also exhibit progressive necrosis. VIG has been used to treat this complication with varying success.

### Postvaccination encephalitis

Encephalitis, characterised by fever, headache, vomiting, drowsiness, and occasionally by

spastic paralysis, meningeal signs, convulsions, or coma, occurred between 8 and 15 days postvaccination at a rate of 1 case per 300,000 vaccinations. Most cases occurred in primary vaccinees under one year of age. The incidence of postvaccination encephalitis in primary vaccinees also increased with increasing age. There are no other known predisposing factors for this complication. Approximately 15–25% of cases with postvaccination encephalitis died and an additional 25% had permanent neurological sequelae. There is currently no known treatment for postvaccination encephalitis and VIG is *not* effective or indicated for this complication.

### National biosecurity response team vaccination register

The States and Territories will establish a register of health care workers who will be vaccinated against smallpox and other potential disease agents.

The aims of the register are to:

- provide a contact register of expert individuals immune to smallpox for each State and Territory
- identify adverse reactions to smallpox and other vaccines in order to:
  - compare the frequency with reported rates of reactions
  - monitor the effectiveness of prevaccination screening
  - identify cases for investigation to exclude new contraindications for vaccination

- identify secondary cases of vaccinia infection, or infection from other live virus vaccines, and establish the rate of secondary transmission.

The register will include health care staff members who agree to be part of smallpox response teams in the event of an outbreak of smallpox and who agree to be vaccinated with the vaccinia vaccine. Recipients of the vaccine will be required to sign an agreement that their personal identification and contact details will be stored confidentially.

The initial database will hold approximately 800 records of smallpox vaccination and adverse events. Subsequently, the database may need to store information about other vaccines, such as anthrax vaccine, and/or expand to include more health care workers.

De-identified data will be forwarded to a central database held by the Australian Government Department of Health and Ageing (DoHA).

Database hardware, software and reporting protocols are to be developed with States and Territories and with the Surveillance and Epidemiology Section of DoHA. The frequency of reporting is yet to be determined with States and Territories.

The criteria listed in Table 4, below, will be used to categorise reported adverse events for their level of association with vaccination.

### **Equipment and supplies**

The smallpox response team will be allocated a set of equipment and supplies that should be stored at a safe and easily accessible location, so that it is available at any time the team is called to manage a suspected case.

**Table 4** Criteria for reporting adverse events following vaccination

Criteria	Definition
Certain	<ul style="list-style-type: none"> <li>● confirmed by case definitions; and/or</li> <li>● confirmed by laboratory data; and/or</li> <li>● reaction onset is immediately following vaccine administration (within 60 minutes if injection was the method of administration); and/or</li> <li>● precise spatial correlation with administration (for example, at the exact site of injection).</li> </ul>
Probable	<ul style="list-style-type: none"> <li>● temporal or spatial (for example, skin) correlation with administration; and/or</li> <li>● an uncommon clinical phenomenon associated with the administration of the vaccine in the absence of other factors.</li> </ul>
Possible	<ul style="list-style-type: none"> <li>● a possible alternative explanation exists; and/or</li> <li>● more than one vaccine is suspected; and/or</li> <li>● data are incomplete; and/or</li> <li>● recovery follows withdrawal of more than one drug/vaccine; and/or</li> <li>● time relationship is not clear; and/or</li> <li>● outcome of the reaction is not recorded.</li> </ul>
Unknown	Association not known
Unrelated	Adverse event unrelated to vaccination (ie not certain, probable, possible, unknown or unclear)
Unclear	This classification applies where a clinical event may well be explained as arising from factors related to underlying disease, or other nonvaccine aetiology. Reports given this classification are not used in further evaluation or statistical studies. However, they are held in case future developments alter their significance.

# Appendix 2

## Resources for smallpox response teams

### Personal protective equipment

- Nonsterile gloves
- Disposable gowns
- Face and eye protection
- Shoe covers.

### Diagnostic equipment

- Thermometer, torch, spatula, stethoscope, sphygmomanometer, watch and other routine diagnostic equipment
- Equipment for taking diagnostic clinical specimens as described in Appendix 4.

### Treatment supplies

- *Antipyretics*: paracetamol tablets and liquid for symptomatic treatment of fever in adults and children (with dosage chart for child doses — for example, BMA child dose charts or paediatric vade mecum)
- *Analgesics*: strong analgesic such as injectable codeine phosphate (controlled drug may be more difficult) or rectal diclofenac, for the relief of severe pain (with dosage chart for child doses); analgesic mouth spray
- *Antibiotics*: a small 24-hour supply of oral and injectable broad-spectrum antibiotic, such as amoxicillin/clavulanic acid and cefotaxime, at doses appropriate for meningococcal disease
- *Intravenous fluids*: intravenous (IV) cannulae (range of sizes), two bags of normal saline for infusion (with infusion volume chart for children) and an IV giving set
- (Possibly) an infusion machine, to reduce the need for nursing input to watch the infusion
- Antiseptic lotions and dressings
- Blankets and Tyvek coveralls
- Charts — for recording temperature, pulse and blood pressure.

### Resuscitation equipment

- Smallpox response teams will also be given training in advanced life support.

**Disinfection, decontamination and waste disposal equipment**

- *Disinfection*: hypochlorite that is not diluted until day of use, for local disinfection and spillage control (see Appendix 7)
- *Waste disposal*: 6 large, yellow clinical waste bags, and tape for sealing them; ready-written luggage labels including the instruction ‘incinerate without delay’, or some similar agreed instruction; large rigid yellow plastic bins for safe storage of clinical waste during transport.

**Other support equipment and supplies**

- *Communication and information technology*: phone/email/fax, with preprogrammed protocol files and contact numbers/addresses
- A *small generator* with electrical power board and extension cable, in case there is no power available at the site
- *Refreshments*: cartons of juice with attached straws to provide safe hydration for the team (but locally provided cups of hot tea and coffee would also be safe in most settings)
- *Clean clothing*: for example, theatre greens that can be provided to people who need to remove their clothes due to heavy contamination
- *Case report forms*
- *Information sheets* about vaccination and contacts (see Appendix 12).

# Appendix 3

## Smallpox vaccination centres

State and Territory plans at Response code 0 will identify sites suitable for use as smallpox vaccination centres.

At Response code 1, smallpox vaccination centres should be readied for immediate activation. It must be possible to activate centres within 24 hours of the first confirmed case.

At Response code 2, the smallpox vaccination centre in the locality of the outbreak should be open for as many days and as many hours per day as required. The smallpox response team will determine these hours. The centre's times of opening should be clearly posted at the site and through the media.

Vaccination of Category A and B contacts at Response codes 2 and 3, and mass vaccination if required at Response code 3, will be carried out at the smallpox vaccination centres.

### Location and facilities

The smallpox vaccination centre should ideally be accessible by public transport, have sufficient parking space, and be close to the area it will be serving. It may be advisable to check the suitability of buildings used as polling stations during elections, as these will be well known to the local community.

As well as space for vaccinators to operate, space will be required for large numbers of support staff, who will be involved in screening, obtaining consent, and organising the flow of vaccinees.

Large school or community halls, colleges, travel clinics, child health clinics and dentists' clinics may be appropriate for conversion into smallpox vaccination centres. Each centre must be capable of vaccinating around 1000 people per day.

As well as the main hall used for vaccinations, the centre will require an office for communications, kitchen facilities for staff, an isolation room, a 'resting' room for those suffering from adverse reactions to the vaccine, and additional rooms for counselling and consultation.

A separate area is required for assessing responses to vaccination ('take') at day 3 in emergencies or at day 7 in nonemergency situations.

Seating areas will be required at both ends of the hall for people waiting on arrival and before departure. The main hall should preferably be accessible from front and rear to reduce crowding on entry.

Security of the smallpox vaccination centre is vital to ensure safe supply and storage of vaccine and protection for personnel. Concerned individuals, other than those in need of vaccination, might approach the centre, so a strict triage system will be necessary to prioritise vaccination. Police might be needed to control people who are not offered vaccine and to prevent theft of materials.

### Special resources

Suitable smallpox vaccination centre sites must have:

- appropriate vaccine storage capabilities (vaccine is stored for use at normal refrigerator temp (5–8°C), or at –30°C when frozen)
- communication capabilities, including at least telephone and fax.

### Staff

At maximum throughput, around 26 medical staff (doctors and nurses) will be required to run the centre. At least four of the medical staff should be doctors.

Administrative staff may be required for taking patient details on entry and exit. They could possibly even take over some of the roles seen as medical, such as initial patient consultation, if medical staff are in short supply. Someone will also be needed to oversee the centre, answering telephone enquiries and dealing with the public.

Consideration should also be given to recruiting people such as counsellors, security staff and drivers. Local services will be well placed to assess, in the light of their own population mix, the need for interpreters or religious representatives of various faiths.

All staff working at the centre should be vaccinated, whether working in a medical capacity or not.

### System of vaccination

The vaccination procedure outlined in Appendix 1 must be rigorously adhered to. All details must be recorded on vaccination consent and register forms (see Appendix 11).

To maximise speed, vaccinees will be interviewed briefly for screening and obtaining consent, and then assigned for immediate vaccination or further review. In order to speed up the vaccination process, it may be necessary to test for pregnancy or make arrangements for fast-track HIV testing. Vaccinators must also ensure that vaccinees have read relevant information sheets, have no apparent contraindications, and read, understand and sign the consent form.

It is envisaged that, on arrival, a patient would go through the following process:

- receive the general information sheet on the vaccine (*What you need to know about smallpox vaccine*)
- fill out a form relating to possible contraindications
- discuss the form with a nurse and give consent if possible

- if consent cannot be given at this stage due to contraindications, go on for further consultation to a doctor who will assess and discuss the risk with the person to be vaccinated
- if informed consent cannot be given due to age or the inability to consent, the person may need to be isolated until a guardian is found or legal advice is obtained
- if vaccination is recommended by the doctor, the patient will be vaccinated; if not, the patient will give their details to an administrative assistant for monitoring purposes
- if vaccinated, the patient will wait for 15 minutes before leaving, and fill out a form on departure giving details of their address for further monitoring; the patient will be given a smallpox contact telephone number for advice and general information.

### Layout of vaccination hall

In order to streamline the process of vaccination, at least two points will be needed for patients to go through their medical history with a nurse before giving consent.

Separate vaccination points will be required for males and females. The female vaccination points should be screened off. Again, to keep the process moving, two vaccination points will be needed for males and two for females.

Two doctors will be required at all times to offer consultation or assistance to those suffering adverse reactions to the vaccine.

Two administration points will be needed at the end of the vaccination stream to take address data from those vaccinated. A further point will be required for those not vaccinated, as this will entail a different process.

An estimated time interval of approximately 10–30 minutes will be required for each individual.

### Consumables required

- Forms (see Appendix 11)
- Pens
- Video player and television
- Antibacterial handwashing solutions
- Paper towels
- Temperature charts to take away
- Permeable transparent dressings
- Take-home dressings
- Take-home yellow infectious waste disposal bags
- Sharps bins at the point of vaccination.



# Appendix 4

## Clinical specimens, transport and laboratory testing procedures

When a patient with suspected smallpox is identified during a Response code 1 or Response code 2 alert, the National High Security Quarantine Laboratory (NHSQL) at the Victorian Infectious Diseases Reference Laboratory (VIDRL) will carry out testing of specimens.

NHSQL should be notified through the relevant State or Territory chief quarantine officer. 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 physical containment level 3 (PC3) or level 4 (PC4) laboratories can receive specimens in the relevant jurisdiction.

The VIDRL on-call microbiologist can be contacted on **(03) 9280 2656**, or on mobile **0417 340 553**.

For the diagnosis of initial cases, the smallpox response team should take a minimum of four specimens of vesicle fluid plus additional specimens (smears, crusts and blood) as available.

### Equipment for collection of specimens

Appropriate equipment for obtaining specimens includes:

- personal protective equipment
- a ‘tuberculin’ syringe and needle for aspirating fluid from vesicles
- 20 mL syringe and hypodermic needle for taking blood specimens
- ethylenediaminetetraacetic acid- (EDTA-) and heparin-containing tubes, and a tube without anticoagulant for serum collection
- a small scalpel blade for removing the roofs and upper tissue from lesions, and for lifting scabs
- clean plastic microscope slides
- Eppendorf tube or bijou container for transporting crusts
- a sterile universal container for transporting scabs
- tourniquet
- cotton wool buds

- a permanent marker pen for writing the patient's identity and the date on the slides
- a slide container for the safe transfer of slides
- a waterproof sharps container for needles, syringes, scalpels and unused slides
- waterproof plasters
- a sealable plastic specimen bag, absorbent packaging material, and a strong metal outer container, plus biohazard tape to seal the bag
- fresh 0.1% hypochlorite solution to clean the outside of the container before transport to the laboratory
- 'high-risk' labels
- a clinical waste bag for the disposal of discarded dressings and personal protective equipment.

### Procedure for collection of specimens

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

- put on personal protective equipment
- puncture a vesicle with the tuberculin syringe, draw up fluid and express it onto a clean plastic microscope slide
- cover the punctured vesicle with a waterproof plaster
- allow the slide to air dry — do not wave it in the air
- mark the slide clearly to indicate the surface used and the position of the sample
- use a plastic slide carrier to transfer the slide to the laboratory
- 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.

Smears can be made by using a scalpel blade to scrape material from the base of the lesion, and to spread it onto a clean plastic microscope slide.

*Vesicle crusts* may be removed and sent for examination in a small sealed container (Eppendorf tube or bijou).

*Venous blood samples* must be collected with extreme care to avoid self-inoculation. Ten millilitres of clotted blood should be placed in a sealed plastic container. Glass containers should not be used.

Blood-taking equipment should be placed into a rigid plastic container filled with disinfectant solution and autoclaved or incinerated. Needles should not be recapped, bent, broken, removed from disposable syringes or otherwise handled. Disposable sharp objects, such as scalpel blades, should not be handled unnecessarily after use and should be autoclaved or incinerated.

## 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, the 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 plastic containers are resistant to temperatures as low as  $-80^{\circ}\text{C}$ .
- Wrap the primary container in sufficient absorbent material (eg 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. This secondary container should be sealed with tape.
- Several primary containers may be placed in one secondary container to a maximum of 50 mL of specimen material.
- On the outside of the secondary container, attach the specimen labels and other relevant information.
- Place the second container in a secure box or mailing tube addressed to:

National High Security Quarantine Laboratory  
Victorian Infectious Diseases Reference Laboratory  
10 Wrecker Street  
Parkville, Victoria 3052

Use a competent door-to-door courier. Because individual commercial and noncommercial 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. Should it be necessary to conduct work other than in a physical containment level 4 (PC4) laboratory, a full risk assessment must be conducted.

Specimens from suspected cases will be sent to one of the designated PC 3 regional laboratories for diagnosis. Investigation will require:

- Handling of samples in a Class I or III cabinet based within a PC3 laboratory, preferably by vaccinated staff.
- Inactivation of the sample by 5% formalin for electron microscopy (EM) or inactivation of the sample by guanadinium for polymerase chain reaction (PCR), to be undertaken within a Class I or III cabinet in a Level 3 laboratory (see next section).

One poxvirus infection, molluscum contagiosum, is endemic in Australia. If viruses are visualised by EM, the result should be discussed urgently with the referring clinician. It will be important to conduct differential tests for varicella–zoster virus (VZV) and herpes simplex virus (HSV) at the same time, to enable a rapid risk assessment.

### Occupational health and safety issues

Staff at the designated EM regional laboratories will be vaccinated at smallpox Response code 0.

Wider vaccination of laboratory staff is not justified at Response code 0, since the risks of adverse effects from vaccination outweigh those from smallpox. However, staff liable to be involved in diagnostic work at Response codes 2 and 3 should be identified and screened in advance for suitability for vaccination.

### Guidance notes on EM of suspected smallpox specimens

Suspected smallpox specimens must be inactivated before processing. All work must be carried out in a cabinet (Class I or III).

#### Formalin

Solutions of formalin at 5% and 10% (v/v) should be freshly prepared from 40% (v/v) stock solution just before use.

#### Vesicle fluid specimens

- Rehydrate the specimen in 10 µl to 50 µl solution of 5% formalin in distilled water.
- Continue with staining and grid preparation according to local protocol.

- Reconstitution of the specimen in formalin does not disrupt the virus particles but does destroy infectivity.
- Some detail of surface structure may be lost, but herpes group and pox group viruses should be clearly recognisable.
- It may not be possible to distinguish between orthopoxvirus and molluscum contagiosum (although infection with these viruses should be clinically distinct).

### **Vesicle crust specimens**

- Place crust in a plastic Griffith's tube with a few drops of 5% formalin in distilled water and grind to disrupt.
- Alternatively, disrupt crusts on a clean microscope slide with a few drops of 5% formalin solution using forceps.
- The resulting homogenate may be used for grid preparation.

### **Other liquid material (eg TCF)**

Mix equal volumes of sample and 10% formalin solution to inactivate virus. Process as usual.

### **Requirements for virus identification by EM**

#### **Examination of grids**

Grids should be examined for 20 minutes before being considered negative. At least two virus particles must be seen and photographed before reporting as positive.

#### **Microscope**

Viruses measure roughly 20–300 nm, so an electron microscope with good resolution is required. An electron microscopist will normally scan a grid (on the large fluorescent screen) at a screen magnification of  $\times 40,000$  and check any possible virus using the binoculars and small screen. Viruses would normally be photographed at between  $\times 40,000$  and  $\times 60,000$ . The microscope must be able to resolve well beyond  $\times 40,000$ . The tested resolution of the EM should be better than 1 nm.

#### **Calibration**

The microscope should be properly calibrated, using a cross grating and if possible something like catalase crystals. Do not trust the magnification given by the instrument: old microscopes, in particular, can give incorrect readings unless calibrated. Size is important in virus identification. Smallpox measures about 250 nm  $\times$  200 nm.

#### **Photography**

All possible viruses and virus-like particles should be photographed.

#### **Stains and grids**

Usually a negative stain such as phosphotungstic acid is used. Good results are achieved with pH 7. Homemade Formvar carbon-coated copper 400-mesh grids are best.

## Literature

There are a number of good atlases of virus morphology. Recommended texts are *Virus Morphology* (Madeley and Field 1988) and *Electron Microscopy in Diagnostic Virology* (Doane and Anderson 1987).

## Laboratory test procedures for smallpox by response code

National alert level	Testing characterised by:	Laboratory action
<b>Response code 0</b> <ul style="list-style-type: none"> <li>Smallpox remains eradicated</li> </ul>	<b>Decentralised exclusion of smallpox:</b> Low pretest probability of SPX Moderate containment requirement Modest throughput demand	<ul style="list-style-type: none"> <li>Designated PHLN labs are lead agencies</li> <li>PC3 processing + immune staff</li> <li>Differential diagnoses tested (VZV, HSV)</li> <li>Negative samples tested for smallpox by EM plus referral to NHSQL for PCR<sup>a</sup></li> </ul>
<b>Response code 1</b> <ul style="list-style-type: none"> <li>Specific threat or</li> <li>Release/case(s) overseas</li> </ul>	<b>Centralised screening for the first smallpox case:</b> Elevated pretest probability of smallpox High containment requirement Increased throughput demand	<ul style="list-style-type: none"> <li>NHSQL lead agency</li> <li>PC4 processing + immune staff</li> <li>smallpox tested (PCR)</li> <li>NHSQL tests differential diagnoses</li> </ul>
<b>Response code 2</b> <ul style="list-style-type: none"> <li>Release or case in Australia</li> </ul>	<b>Centralised screening for the first smallpox case:</b> Increasing pretest probability of smallpox High containment requirement High throughput demand	<ul style="list-style-type: none"> <li>NHSQL lead agency</li> <li>PC4 processing + immune staff</li> <li>smallpox tested (PCR)</li> <li>NHSQL tests differential diagnoses</li> </ul>
<b>Response code 3</b> <ul style="list-style-type: none"> <li>Outbreak in Australia</li> </ul>	<b>Decentralised confirmation of widespread smallpox:</b> High pretest probability of smallpox Diminished containment requirement High throughput demand	<b>c) Case epidemiologically linked to laboratory proven smallpox</b> <ul style="list-style-type: none"> <li>laboratory confirmation not necessary</li> </ul> <b>d) No epidemiologic link</b> <ul style="list-style-type: none"> <li>designated PHLN labs are lead agencies</li> <li>PC3 processing + immune staff</li> <li>smallpox tested (EM, or referral to NHSQL)</li> <li>PHLN lab tests differential diagnoses</li> <li>Undiagnosed cases referred to NHSQL</li> </ul>

EM = electron microscopy; HSV = herpes simplex virus; NHSQL = National High Security Quarantine Laboratory; PC3, PC4 = physical containment level 3, 4; PCR = polymerase chain reaction; PHLN = Public Health Laboratory Network; VZV = varicella-zoster virus.

<sup>a</sup> at Response code 0, confirmatory PCR assays could be batched.

- Notes:
- PC4 facilities to guarantee containment, and central diagnostic responsibility, are important during screening for initial cases in the elevated-risk Response code 1 and 2 phases.
  - PC3 facilities and immune staff provide acceptable staff safety, maximal laboratory capacity and simplified logistics, both in the low-risk Response code 0 phase and later in Response code 3 when widespread community circulation of smallpox makes high-security laboratory containment irrelevant.

# Appendix 5

## Smallpox care centre and hospital isolation specifications

An initial probable case should be transferred to the smallpox care centre. However, if the patient requires clinical care before the centre is operational, they should be sent to an isolation unit identified by the State or Territory response plan.

The isolation unit must be an established infectious diseases unit with substantial experience in contagious pathogens, equipped with negative pressure rooms. Ideally, facilities should have staff who have been previously vaccinated and who could be revaccinated with a faster immune response and lower incidence of side effects.

When feasible, further possible, probable and confirmed cases of smallpox will be transferred to specialist smallpox care centres as identified in State and Territory plans.

Smallpox care centres need to begin to be prepared for possible use at Response code 1. It must be possible to activate centres within 24 hours of the first confirmed case. A Response code 1 alert or diagnosis of the first *probable* case should lead to preparations to activate the centres.

### Building

#### Location

It is strongly suggested that any smallpox care centre be accessible, with sufficient parking. Ideally the care centre should not be placed in a high population area.

#### Access and security

The smallpox care centre should have its own private entrance surrounded by a perimeter wall or fence that prevents unauthorised entry to or exit from the facility. Additional capacity and flexibility could be achieved by choosing a site with sealed surfaces around the centre (eg a car park), which could be used to extend the care centre if needed.

#### Wards

Two wards need to be established, with separate air supplies:

- an observation ward
- a treatment ward.

Due to the risk of spread of infection amongst patients, the observation ward would ideally incorporate separate rooms with their own ventilation and negative pressure. If possible, a separate but adjacent building would house the treatment ward, which needs to have a combination of bays of four beds and individual rooms for seriously ill patients.

Air should be filtered through a high-efficiency particulate air (HEPA) filter before being vented to the atmosphere.

Note that vapours from decontamination procedures will be required to be exhausted to the outside and not recirculated to the rest of the ward or medical areas. This may be difficult in many existing facilities. Allocation of treatment should take into account practicalities of decontamination by vapour.

### **Clinical rooms**

Clinical rooms at the smallpox care centre should include the following:

- an X-ray room with a dedicated X-ray machine, development equipment and viewer
- a pharmacy store
- a large store of medical and nonmedical items (many of which may be disposable)
- a laboratory area — if at all possible, a care centre should have an on-site laboratory containing clinical chemistry, haematology analyser, blood coagulation, blood transfusion, bacteriology, a fridge and a freezer (equipment could be moved from an acute care hospital site to the care centre at the beginning of an outbreak)
- a safe area for the secure storage of clinical waste before it is either treated or transported.

### **Additional facilities**

Additional facilities could include:

- staff common room
- facility for accommodation of parents of children
- dedicated clinical rooms for preparation of laboratory specimens
- dedicated room for preparation of medications
- general office space for the clinical team to use
- telephones and dedicated line to State/Territory coordinating centre
- personal computers with internet access
- a garage for care centre ambulances and delivery vehicles
- on-site parking for staff

- space for decontamination of up to 120 L of waste per person per day
- dedicated food delivery area for prepacked meals
- dedicated food preparation and dishwashing area
- a communal area with recreational facilities for mild cases and cases who are convalescing
- a mortuary with appropriate facilities for undertaking a postmortem examination and appropriate infection control containment in place
- staff accommodation
- changing facilities, including a cleansing room with a shower must be available; these should be accessible through external and internal doors so that they can be used by smallpox ambulance personnel (see *Transport*, below) as well as smallpox care centre staff.

## Staff

Smallpox care centres should have their own dedicated health care and domestic staff who have been appropriately trained in the care of patients with infectious disease, including smallpox.

All staff present at the centre should be vaccinated. All members of the immediate families of staff should also be vaccinated.

The estimated staffing level for a smallpox care centre is approximately 120, comprising three shifts of nurses, doctors, cleaners, laundry operators, orderlies, drivers and cooks. Including staff members' families, approximately 360 people would therefore need to be vaccinated to staff each care centre. This figure does not include intensive care staff.

Infectious diseases staff around Australia form a pool of personnel who could be vaccinated and staff smallpox care centres if necessary. The posts left vacant in infectious diseases wards could then be filled by other doctors and nurses. This would pose far less risk than putting staff unused to infectious diseases into a smallpox care centre.

## Smallpox care centre protocols

Protocols will be required for:

- visitors (see below)
- infection control – including respirators (see Appendix 6)
- disposal of the deceased (see Appendix 7)
- movement in and out of the centre (see Appendix 7)
- clinical care of cases (see Appendix 9)
- procedures for requesting, delivering and receiving consumables.

## Protocol for visitors

Only immediate family and other household members will be allowed to visit smallpox patients. Facilities should be available to allow visitors to change into personal protective equipment before entering clinical areas, and to shower and change back into their normal clothes after leaving clinical areas.

## Transport of patients

Standard Category 3 infectious removal procedures should be used, with ambulance crews wearing masks and Tyvek suits. In addition, the patient should be given a surgical mask and a Tyvek wrap, to help further limit the spread of infection. Ambulances used for transfer of these patients should have separate air supplies for cabins and bays.

During an outbreak, *smallpox ambulances* should be used. These ambulances will be dedicated solely to this purpose for the duration of the outbreak, and will not be used for the transport of other patients during this period.

Ambulance personnel should be vaccinated, and in addition should observe the appropriate infection control procedures for the care of smallpox patients, as described in Appendix 6.

Following each transfer, the ambulance should be decontaminated, following the procedures described in Appendix 7.

# Appendix 6

## Infection control procedures for the care of smallpox patients

These infection control procedures must be observed by all health care and emergency staff and others who are involved in the care of suspected, possible, probable and confirmed cases of smallpox, including visitors to patients, members of smallpox response teams, ambulance personnel and health care staff working at smallpox care centres. All staff caring for a smallpox patient must be vaccinated against smallpox. Anyone having close contact with a smallpox patient must wear protective clothing.

From the onset of fever in a case of smallpox, respiratory secretions are infectious and airborne transmission is possible. Body fluids are also highly infectious. Infectiousness increases for the next 4–7 days until the onset of vesicular rash, and remains high for the next 7 days. Thereafter infectiousness wanes, but the pustules of the rash, and the dried scabs, which remain embedded in the skin during early healing, both contain infectious virus.

Patients with the most severe forms of the disease remain infectious for the 3–10 days of their survival. Others may be diminishingly infectious for up to three weeks or more, until their acute disease is over, convalescence is established and all scabs are finally shed.

During acute disease, the main hazards are:

- exposure to infectious droplets and body fluids
- exposure to discarded dressings and other clinical waste
- exposure to clothing, sheets and towels that have been contaminated by infectious body fluids or scabs shed in the later stages of disease.

### Handwashing

Strict handwashing with a disinfectant soap should be carried out immediately after all episodes of care, even if sterile gloves have been worn.

### Protective clothing

Health care workers and visitors may become contaminated by body fluids, droplets or scabs, which could be deposited on clothing or hair. They should therefore change into appropriate clothing before entering and leaving the infected area.

Appropriate clothing includes:

- surgical or examination gloves
- theatre cottons with head covers
- disposable aprons
- eye protection
- footwear that is only worn within the facility (this is preferable to overshoes)
- a high-efficiency face mask such as the P2 face mask (this is a filtering face mask made for an 8-hour working day; with a protection factor of around 100; it protects against 0.2–10 micron particles, if fitted and worn correctly).

### Leaving the infected area

Staff and visitors should change when leaving the infected area. They should remove smallpox care centre clothing, shower and wash their hair before donning their street clothing and shoes.

# Appendix 7

## Disinfection and decontamination

### General principles

People engaged in disinfection must themselves be fully protected by vaccination and must wear suitable protective clothing. Heat is the most effective antimicrobial agent and viable counts of the smallpox virus are reduced within an hour or less to about  $10^{-7}$  of their initial value by exposure at atmospheric pressure to 60°C.

Whenever possible, contaminated articles should be destroyed by burning. If this cannot be done, articles should be autoclaved where practicable (see Australian Standards for steam disinfection). If neither burning nor autoclaving is practical, chemical disinfection should be considered using 0.1% hypochlorite (after organic matter has been removed by washing), formaldehyde vapour or ethylene oxide in a special chamber.

### Incinerate clinical waste

Disposable and clinical waste should be placed in clinical waste bags. As the action of loading and unloading can expel air and fluid, bags should preferably be closed by heat-sealing and disposed of by incineration without delay.

### Decontaminate linen and clothing

Health care establishments and commercial linen services should have documented policies and procedures for the collection, transport and storage of all linen. Appropriate personal protective equipment should be worn when handling any linen suspected of being in contact with smallpox. Linen heavily soiled with body substances or other fluids should be contained within suitable, securely closed, impermeable bags and marked 'smallpox'.

Decontamination of nondisposable linens and clothing should be possible by hot-cycle washing. Used items should be packed, without shaking, into laundry bags containing an inner soluble plastic bag, and marked 'smallpox', for laundering at the appropriate centre. This bag can be gently released from the outer bag and should be gently placed into a hot wash at a temperature of at least 71°C. The outer bag should also be gently placed into the hot wash (see Appendix 8).

Because a number of outbreaks have occurred among laundry workers who handled linen and blankets used by patients, in any outbreak all such staff, and their household contacts, should be vaccinated. If laundry has to be processed by unvaccinated staff, it must first be autoclaved.

## Decontaminate 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.

### Patient did not have pustules

If the patient has been removed from the premises in the early stages of disease, before the rash has become pustular, formaldehyde fumigation alone may be relied on.

The most practical method for formaldehyde fumigation is the vaporisation of formaldehyde solution BP by boiling. This ensures the necessary high relative humidity. There are two methods of achieving this: chemical and electrical.

### Electrical method

A stainless steel vessel of about 7 L capacity should be used, equipped with an electric heating element and a thermostatic cutout to ensure automatic interruption of the current if the vessel boils dry. An additional precaution would be a time switch set to open just before evaporation is completed. This apparatus is suitable for a room of about 85 m<sup>3</sup>. For larger rooms, a number of these units can be dispersed.

Mix 1.14 L of water to 0.57 L of formaldehyde solution BP (ie 33% formaldehyde in water) for each 28 m<sup>3</sup> of space. The use of larger quantities than these is undesirable. Seal the room by blocking of vents and shut off any mechanical ventilation to the room, post appropriate worded warning signs on entrances, and if possible maintain the temperature above 18°C. The exposure time should be not less than six hours, and fumigation is therefore best done overnight.

After fumigation, the operator should enter the room wearing a full face respirator, with formaldehyde canister or other approved respirator to AS 1715 (1994), and open all the windows. Alternatively, switch on mechanical ventilation to maximum flow rate so that air is exhausted, with no recirculation. If insufficient ventilation is available to disperse the vapour quickly or the premises are required urgently, a cloth impregnated with 0.14 L of strong ammonia solution BP for each 28 m<sup>3</sup> of space may be suspended in the centre of the room for two hours. The room should not be re-occupied until air tests have shown that formaldehyde vapour is below the occupational exposure standard.

### Chemical method

A chemical method can be used when the electrical method cannot be applied. For each 28 m<sup>3</sup> of space, a 2.27 L jar containing 0.57 L of formaldehyde solution BP is required. The jar should stand in a bucket or on a large tray. The room should be sealed and 170 g of permanganate of potash dropped into each vessel. The operator should quickly withdraw and seal the door: within 10 seconds, violent boiling begins. Extra water is not required because this is liberated during the chemical reaction. The exposure time is the same as for the electrical method.

## **Patient had pustules**

If the patient had pustules, assume that smallpox crusts will be contaminating the environment.

### **1. Fumigate as above**

### **2. Vacuum**

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 autoclaved after use, but the liner and its contents must be burned. The vacuum cleaner should be one designated for hospital use (that is, one equipped with a HEPA filter at the air exit point). The vacuum cleaner should be thoroughly wiped with a cloth soaked in a clear phenolic disinfectant (1 in 40) after making sure that it is detached from the electricity mains supply.

### **3. Scrub**

After vacuuming, all horizontal surfaces should be washed and scrubbed with clear phenolic disinfectant (1 in 40). Any particulate matter collected should be burnt.

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

Smallpox ambulances and their contents should normally be disinfected by the ambulances' own crews. The crew must not discard their protective clothing until disinfection of the vehicle has been completed.

## **Incinerate or autoclave waste and equipment**

Disposable and clinical waste should be placed in clinical waste bags. As the action of loading and unloading can expel air and fluid, bags should preferably be closed by heat-sealing and disposed of by incineration without delay. Articles that can be discarded should be sealed in stout paper bags and taken for immediate incineration; articles that can be autoclaved should be sealed in paper or cloth bags.

## **Bag laundry**

Blankets and stretcher canvases used in the removal of the patient should be placed, without shaking, into laundry bags containing an inner soluble plastic bag, and marked 'smallpox', for laundering at the appropriate centre (see Appendix 8).

## **Spray with disinfectant**

All removable fittings inside the vehicle, including any loose floor coverings, should be removed, sprayed with a disinfectant 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 sprayed systematically: 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 sprayed. A suitable disinfectant solution is a clear phenolic (1 in 40).

It is preferable to use a power sprayer, so that the work can be done thoroughly without entering the ambulance, but with weaker sprayers or other cleansing methods it will be necessary to enter the vehicle. In the absence of spraying apparatus, the same basic procedure may be carried out by wiping with a sponge soaked in disinfectant. After either procedure, the doors and windows of the vehicle should be left open to the air for at least five minutes. If necessary, the treated ambulance can then be dried out, using chamois leather or disposable wipes (whichever are used, they should then be placed in a plastic bag and incinerated).

### **Wash and change at smallpox care centre**

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 with an alginate-stitched lining and marked 'smallpox', for laundering at the appropriate centre (see Appendix 8)
- enter the cleansing room at the smallpox care centre and wash thoroughly, paying particular attention to hands, face and hair
- put on clean clothing.

### **Disposal of bodies**

Disposal of bodies is the responsibility of States and Territories. Bodies of smallpox cases should be safely and promptly disposed of by appropriately vaccinated, equipped and trained personnel.

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

Before removal from the deathbed, the body should be enshrouded by double bagging in impervious plastic bags. Sepulchre should only be carried out by vaccinated personnel wearing appropriate personal protective equipment — gloves, gown, apron, mask, headgear, eye protection and rubber overshoes.

The coffin should be sealed with the lid secured, and the outside of the coffin washed down with phenolic disinfectant.

# Appendix 8

## Washing of linen used on a suspected smallpox patient

**Note:** *these instructions are for employees involved in the operation of linen services*

The hospital in which a smallpox patient is located will notify the laundry facility operations manager or production supervisor when contaminated linen is due to arrive.

Hospitals will use marked or tagged linen bags, lined with soluble plastic bags, to contain linen used on a patient with smallpox, and will separate it from other linen.

Only the personnel listed below (who must also have been recently and successfully vaccinated) should handle the marked bags. They should wear protective clothing (including gowns, properly fitted high-efficiency facemasks such as P2, heavy-duty disposable gloves, protective eyewear and surgical booties).

On receipt of the bags at the laundry facility, the staff will alert the following people:

- occupational health and safety (OHS) representative
- production supervisor
- operations manager.

**Note:** the bags must be isolated until collected by one of the above staff, who are the only staff authorised to handle them.

The OHS representative or production supervisor will then:

- secure a washing machine in the batch wash
- don appropriate personal protection equipment (including gown, properly fitted high-efficiency facemask such as P2, heavy-duty disposable gloves, protective eyewear and surgical booties)
- take the bags directly to the washroom as soon as the machine becomes available, keeping tagged bags separate from all other bags to prevent contamination
- place the bags containing the linen into the machine and open the linen bags, leaving the soluble plastic bags sealed, and leaving all items in the machine
- select appropriate wash cycle
- wash all bags, including inner plastic bags
- dispose of all personal protection equipment into a yellow biohazard plastic bag for incineration
- when the wash cycle is complete, distribute the linen as required.

Part 1

Part 2

Part 3

Part 4

**8**

Part 5

# Appendix 9

## Medical management and treatments for smallpox and vaccinia infection

### Use of human vaccinia immune globulin

Human vaccinia immune globulin (VIG) is made from the blood of people who have been given the smallpox vaccine more than once. The part of the blood (antibodies) that gives protection from vaccinia infection is extracted, purified and bottled, and is known as immune globulin. There are two types of VIG, for intramuscular (IM) and intravenous (IV) injection.

VIG is in short supply and should be reserved for individuals with definite indications and prioritised to those who will derive the most benefit. That is, it should be used:

- to treat vaccine complications
- to prevent vaccine complications by concurrent administration to those who have known contraindications to vaccination
- to attenuate smallpox disease in contacts who have not been adequately protected by vaccination.

### VIG use to treat vaccine complications

Treatment of vaccine complications should be initiated at the first sign of adverse effects. Complications may be treated by VIG or cidofovir (a nucleoside analogue active against many DNA viruses, including herpes group viruses, adenoviruses and poxviruses) depending on supplies.

The vaccine complications that may be treated by VIG are:

- inadvertent inoculation of the eye or eyelid without vaccinal keratitis
- severe generalised vaccinia if patient is toxic
- eczema vaccinatum
- progressive vaccinia.

VIG is not recommended for treatment of postvaccinal encephalitis or vaccinal keratitis.

The suggested dose of VIG for treatment of vaccine complications is given below. It may be given IV or IM in divided doses over a 24 to 36-hour period.

- under 1 year — 2000 units/Kg
- 1–6 years — 4000 units/Kg
- 7–14 years — 6000 units/Kg
- 15 years or over — 8000 units/Kg

**(It is recommended to follow the manufacturer's guidelines for use).**

## VIG use to prevent complications in those with contraindications

VIG should be given at the same time as vaccination to prevent vaccine complications in individuals who;

- have active eczema or a history of eczema, or other acute or chronic skin conditions
- are pregnant
- are immunosuppressed due to medical disorders (leukaemia, lymphoma, generalised malignancy, hypogamma globulinaemia, chronic neutropenia, granulocytopenia) or treatments (cyclophosphamide, methotrexate and oral steroids).

Individuals who are human immunodeficiency virus (HIV)-positive can be vaccinated without VIG if their CD4 count is above 200, but should be given VIG if their CD4 count is below 50. Those with a CD4 count within this range should be assessed according to their HIV disease state.

The use of VIG does not affect the vaccine 'take'.

The dose of VIG for prevention of vaccine complications is less than for their treatment (contact the infectious diseases specialist in the smallpox response team for dose rates).

If given IM at the same time as vaccination, VIG should be given in a different limb from the vaccine.

## VIG use for contacts who have not been protected by vaccination

Supplies permitting, VIG may be given to attenuate smallpox disease in primary contacts who are vaccinated more than 3 days but less than 8 days after their first exposure to infection. This includes primary contacts in whom the first vaccination shows no sign of a take on the third day. VIG should be given concurrently with revaccination.

## Use of cidofovir

There are no data on the effectiveness of cidofovir against vaccinia or variola in humans. However, it is active against variola in vitro, and can prevent or attenuate

vaccinia in mice and monkeypox in nonhuman primates. Cidofovir has been used successfully to treat other orthopox infections in humans.

Cidofovir is administered as an IV infusion at a dose of 5 mg/kg bodyweight. It should be infused in at least 100 mL normal saline over at least one hour. Further doses should be repeated if necessary after an interval of not less than 7 days.

Cidofovir has significant renal toxicity. To minimise nephrotoxicity, the patient should be well hydrated, and probencid should be administered orally: 2 g prior to the infusion, 1 g one hour after the infusion has finished, and 1 g eight hours after the infusion has finished. Other adverse effects of cidofovir include asthenia, nausea, headache, alopecia and reversible neutropenia.

Cidofovir is in short supply and should be reserved for those with definite indications and prioritised to those who will derive the most benefit. That is, it should be used:

- to treat vaccine complications
- to attenuate smallpox disease in contacts who have not been adequately protected by vaccination.

#### **Cidofovir use to treat vaccine complications**

Treatment of vaccine complications should be initiated at the first sign of adverse effects. Complications may be treated by cidofovir or VIG, depending on supplies.

Cidofovir may be used to treat all complications of vaccination.

#### **Cidofovir use for contacts who have not been protected by vaccination**

Cidofovir may be given, supplies permitting, to attenuate smallpox disease in primary contacts who are vaccinated more than 8 days after their first exposure to infection. This includes primary contacts in whom the first vaccination shows no sign of a take on the third day.

#### **Cidofovir use treat established smallpox disease**

Supplies permitting, cidofovir may also be considered for the treatment of established smallpox disease.

### **Smallpox case management and treatment**

Currently, there is *no* proven treatment for clinical smallpox (variola). Clinical trials conducted during the smallpox era evaluated several antiviral compounds, including N-methylisatin B-thiosemicarbazone (Methisazone), adenide arabinoside, cytosine arabinoside, and idoxuridine, but failed to demonstrate clinical efficacy for these compounds.

Evaluation of modern antiviral compounds is ongoing. Cidofovir (see above) has shown some in vitro and in vivo (animal studies) activity against orthopoxviruses. However, its effectiveness for treating clinical smallpox or vaccine adverse events has

not been studied. This medication is labelled for the treatment of cytomegalovirus retinitis and has been associated with renal failure.

### **Patient management**

Medical management of a patient with smallpox is mainly supportive and consists of:

- isolation of the patient to prevent transmission of the variola virus to nonimmune persons
- monitoring and maintaining fluid and electrolyte balance
- skin care
- monitoring for and treatment of complications.

In addition, unless the diagnosis of smallpox has been confirmed in the laboratory, the patient should also receive smallpox vaccination if they will be isolated with other confirmed or suspected smallpox cases. Vaccination of suspected cases of smallpox is done to prevent the accidental transmission of smallpox virus to any uninfected patients who have been misdiagnosed as smallpox cases.

### **Isolation**

In a smallpox outbreak, isolation of confirmed or suspected 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 the time the rash appears until all of the scabs have separated, about 3–4 weeks) to nonimmune individuals, while maintaining an appropriate care and comfort level for the patient. All potential methods of patient isolation must be considered with these goals in mind. Several are outlined below, but medical personnel should consult with public health officials to determine the most appropriate.

### **Hospital isolation**

If a confirmed or suspected smallpox patient requires hospital care, the following steps must be taken while they are hospitalised:

1. The patient should be placed under strict respiratory and contact isolation in a room with negative air pressure (and individual high-efficiency particulate air (HEPA) filtered ventilation exhaust, if available). This room should have private shower/bathroom 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 for dedicated smallpox areas, should be detailed in State and Territory plans.

2. Protective clothing (including gowns, properly fitted high-efficiency facemasks such as P2 masks, gloves, protective eyewear and surgical booties) should be

worn by anyone entering and leaving the isolation room. Recently and successfully vaccinated personnel should also exercise contact precautions (gowns, gloves etc) and should wear a surgical mask and eye protection as indicated for procedures where contact with body fluids could occur.

3. All protective clothing should be removed and discarded into biohazard waste disposal containers before personnel leave the isolation room and re-enter other areas of the hospital.
4. All infectious waste and contaminated protective clothing should be disposed of or sterilised appropriately (incineration for disposable materials; autoclaving, ethylene oxide decontamination, or laundering in hot water and bleach for reusable equipment or clothing). Public health officials should be consulted for specific waste disposal and decontamination guidelines.
5. Personnel entering the isolation room or handling infectious waste or clinical specimens from the patient should be vaccinated or have documented successful recent smallpox vaccinations (within the past three years). Public health officials should be contacted to request vaccination.
6. Steps should be taken to confirm or rule out the diagnosis of smallpox, as detailed in Appendix 4.

### **Nonhospital isolation**

Public health officials should be consulted before nonhospital isolation is initiated. Confirmed or suspected smallpox patients who do not require hospital care may be isolated in nonhospital facilities that do *not* have shared ventilation systems with other facilities.

Nonhospital isolation facilities should have appropriate climate-control capabilities (heating, air conditioning), running water and bathroom facilities. If suspected and confirmed smallpox patients are isolated together, all patients should receive smallpox vaccination to prevent accidental transmission because of misdiagnosis. All persons entering these facilities must have documented, successful, recent smallpox vaccinations (within the past three years).

### **Fluid and electrolyte balance**

During the vesicular and pustular stages of smallpox, patients may experience significant fluid losses and become hypovolaemic or develop shock.

Fluid loss can result from:

- fever
- nausea and vomiting
- decreased fluid intake due to swallowing discomfort from pharyngeal lesions
- body fluid shifts from the vascular bed into the subcutaneous tissue
- massive skin desquamation in patients with extensive confluent lesions.

Electrolyte and protein loss can also occur in these patients. Fluid and electrolyte balance should be monitored in hospitalised patients, with appropriate oral or intravenous correction of imbalances.

Patients with less severe disease who do not require hospitalisation should be encouraged to maintain good oral intake of fluids. They should also be educated on the signs and symptoms of hypovolaemia and dehydration, and counselled on when to seek medical attention if it should occur.

### **Skin care**

The skin should be kept clean and efforts should be made to avoid rupturing vesicles or pustules. No salves or ointments should be applied.

In general, scab lesions should be allowed to heal and separate on their own. All scabs should separate by 3–4 weeks, but lesions on the palms and soles may persist longer unless artificially removed.

Bacterial superinfection of lesions may occur and should be treated with appropriate antibiotics.

### **Monitoring and treatment of complications**

Several complications can occur during the course of smallpox infection. These include:

- haemorrhagic
- secondary bacterial infections
- corneal ulceration and/or keratitis
- arthritis or ‘osteomyelitis variolosa’
- respiratory
- encephalitis
- gastrointestinal
- genitourinary.

These complications and their treatment are described below.

### **Haemorrhagic**

Minor haemorrhagic manifestations, such as subconjunctival haemorrhages, occur commonly in smallpox patients. If subconjunctival haemorrhages are isolated and are not accompanied by evidence of a consumption coagulopathy or active bleeding (decreasing haemoglobin, haematocrit or platelets), no specific therapy is needed. However, if signs of more extensive haemorrhage are present (mucosal bleeding, bleeding into smallpox lesions, ecchymoses, haematemesis, haematuria etc) the patient should be evaluated for disseminated intravascular coagulation and treated appropriately.

Haemorrhagic complications may indicate a more severe form of the disease called 'haemorrhagic smallpox', which has a poor prognosis. Also, because of a high, sustained viraemia coupled with mucosal haemorrhaging during their course of illness, haemorrhagic smallpox patients are highly infectious.

### **Secondary bacterial infections**

Bacterial superinfections can include abscesses of skin lesions, pneumonia, osteomyelitis, joint infections, and septicaemia. Laboratory diagnostics (gram stain, culture, antibiotic susceptibility testing etc) should be performed to help guide antibiotic therapy.

### **Corneal ulceration and/or keratitis**

These complications occurred more frequently in haemorrhagic smallpox but were occasionally seen in the more typical ordinary smallpox. In one case series (Rao 1972), corneal ulcers occurred in 1% of nonhaemorrhagic smallpox cases and keratitis occurred in about 0.25%. Corneal ulcerations can appear around the second week of illness and begin at the corneal margins. Ulcers can heal rapidly, leaving a minor opacity, or on occasion may cause severe corneal scarring. Keratitis and corneal ulceration was far more common in malnourished individuals. Topical idoxuridine has been used but its efficacy is undocumented.

### **Arthritis or 'osteomyelitis variolosa'**

This complication occurred in approximately 1.7% of the cases in case series reviewed by Rao (1972). It usually occurred after the 15th day and was accompanied by a brief recurrence of fever during the scabbing stage. The elbow was the most commonly affected joint and symmetrical, bilateral involvement was frequently seen. The complication was most often caused by viral infection of the metaphyses of growing bones. Most cases resolved without permanent deformity.

### **Respiratory**

Viral bronchitis and pneumonitis can be common complications of severe smallpox and are considered part of the normal disease syndrome. Treatment is symptomatic, with measures to treat hypoxaemia with supplemental oxygen and/or intubation and ventilation as indicated.

Secondary bacterial pneumonia can occur and should be treated with appropriate antibiotics as guided by laboratory diagnostics (gram stain, culture, antibiotic susceptibility testing etc).

Pulmonary oedema is common in the more severe haemorrhagic and flat types of smallpox, and should be treated with careful monitoring of oxygenation, fluid status and blood pressure, with supplemental oxygen and diuretics administered as needed.

Patients with a cough during the first week of disease may transmit disease more readily than patients without a cough, as this is the period when oral secretions contain the largest amount of virus. Patients who develop a cough later in the course of disease (after day 10), when viral counts in secretions are lower, are not as infectious as those who develop coughs earlier.

**Encephalitis**

Encephalitis occurred in about 1 out of every 500 cases of smallpox, and usually appeared between day 6 and day 10 of illness when the rash was still in the papular or vesicular stage. During the smallpox era, this complication was a minor contributor to the case–fatality rate of classical smallpox (*variola major*), the most common form of smallpox. Although sometimes slow, recovery was usually complete.

**Gastrointestinal**

Nausea and vomiting can occur in the earlier stages of smallpox, especially in the prodromal period before rash development, and should be treated symptomatically. Diarrhoea may occasionally occur in the prodromal period or in the second week of illness and should also be treated symptomatically. Acute dilation of the stomach occurred rarely and was more common in infants. In some severe cases of smallpox (especially flat type), extensive viral infection of the intestinal mucosa occurred, with sloughing of the mucosal membrane. Most of these cases were fatal.

**Genitourinary**

Orchitis occurred in 0.1% of the Rao (1972) case series and was usually unilateral. Haematuria can be present in haemorrhagic smallpox if bleeding into the pelvis of the kidney occurs.

# Appendix 10

## Communication strategies

A smallpox outbreak in Australia would generate global media interest. Good communication during such an event is crucial to reduce public anxiety and improve the effectiveness of emergency service responders and health care workers. The public should understand that a plan is being followed, and they need to be given explanations for various actions being undertaken. One of the primary communication objectives is to instill and maintain public confidence by providing the public with information that addresses their questions, fears and concerns.

The Media Unit of the Australian Government Department of Health and Ageing (DoHA) would play the leading role in national coordination of media response to a smallpox outbreak. The unit has devised communication strategies and procedures for handling multiagency media management during an outbreak or other major chemical, biological or radiological incident. Plans call for the activation of the National Emergency Media Response Network and include close liaison with State and Territory governments, health departments and allied organisations that will have a role during such an event.

The DoHA Media Unit is also a key member of national security media arrangements undertaken by the National Security Media Liaison Network, which is administered by the Australian Government Attorney-General's Department, Public Affairs Unit.

### Objectives

In a smallpox outbreak, the DoHA communications strategy will seek to:

- provide national leadership and guidance to State and Territory health and other relevant media teams/officers during the incident
- ensure the smooth and rapid distribution of accurate information to the Australian and overseas media, relevant agencies and organisations, and the Australian public
- ensure that public confidence is maintained in the Australian Government's system to respond to the incident.



# Appendix 11

## Forms to assist field work

- **11a: Pre-event release of vaccine**
- **11b: Screening for contraindications**
- **11c: Consent for vaccination**
- **11d: State and Territory smallpox response team vaccination register**
- **11e: Interim vaccination certificate**
- **11f: Case report**
- **11g: Contact surveillance form**

## Form 11a: Release of Australian Government-controlled smallpox vaccine into State/Territory control as a result of a suspected or confirmed outbreak of smallpox

I \_\_\_\_\_ being the Chief Health Officer or Delegate, of the State / Territory of \_\_\_\_\_ accept receipt of \_\_\_\_\_ smallpox vaccine vials from the Australian Government Department of Health and Ageing.

The vaccine supplied is to be used in the control or prevention of a suspected smallpox outbreak within the State or Territory.

I hereby agree to store the vaccine vials as a single item in dedicated and locked freezers. The storage temperature is to be between minus 20 and minus 40 degrees Celsius. Adequate temperature monitoring systems and freezer failure alarms are to be used.

I agree to keep proper vaccination records, in a manner as prescribed by the Australian Chief Medical Officer or his Delegate (Attachment A – Smallpox Vaccine Administrators Form 3).

I also agree to send all original forms to the Biosecurity Section, Department of Health and Ageing, MDP 27, GPO Box 9848, Canberra 2601, within seven days under registered mail or via secure courier.

### Chief Health Officer or Delegate:

Printed name: \_\_\_\_\_

Printed title: \_\_\_\_\_

Sign: \_\_\_\_\_

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

### Australian Government Witness:

Printed name: \_\_\_\_\_

Printed title: \_\_\_\_\_

Sign: \_\_\_\_\_

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

## Form 11b: Screening for contraindications

Date: \_\_\_\_\_ Patient identifying number: \_\_\_\_\_

Please check only one:

- Passport #
- Birth certificate # and State/Territory issued \_\_\_\_\_
- Driver's licence # and issuing State/Territory \_\_\_\_\_
- Other \_\_\_\_\_
- List \_\_\_\_\_
- None available

### Participant Information:

Print name \_\_\_\_\_

Date of birth \_\_\_\_/\_\_\_\_/\_\_\_\_ (dd/mm/yy) Sex:  M  F

Current address \_\_\_\_\_

City \_\_\_\_\_ State/Territory \_\_\_\_\_ Postcode \_\_\_\_\_

Contact number, including area code ( \_\_\_\_\_ ) \_\_\_\_\_

### Screening:

Do the following apply to you or to your child?

**Yes No Maybe**

- Immune system problems such as HIV/AIDS, cancer, leukaemia, lymphoma, organ transplant, agammaglobulinaemia
- Do you have/had a history of a heart disease/condition.
- Autoimmune system problems like lupus that weakens your immune system
- Currently taking medicines like oral steroids (such as prednisone), chemotherapy agents/radiation, or organ transplant medications.
- Eczema, atopic dermatitis, or a history of eczema or atopic dermatitis
- Other skin condition such as burns, impetigo, contact dermatitis, or zoster
- Currently pregnant
- Allergy to antibiotics polymixin B, streptomycin, chlortetracycline, neomycin
- Age less than 1 year old
- Have additional questions about any health condition you might have and whether you should be vaccinated
- Are you less than 18 years of age and your parent or guardian is not with you?
- Do you have any questions you would like to have answered before you decide on vaccination?
- This adult is incapacitated and this screening consent signature form is being completed by the parent or guardian (checked box for this question alone does not require additional screening counselling)

## Form 11c: Consent for vaccination

[Note: this is a *SAMPLE* consent form and may need to be altered to meet manufacturers' requirements]

[Form must be completed prior to smallpox vaccination and be accompanied with the **Information Statement for ACAM2000 Smallpox Vaccine** on page 102]

### Person to be vaccinated:

Surname: \_\_\_\_\_ Name: \_\_\_\_\_ Middle initial: \_\_\_\_\_

Birth date: \_\_\_\_\_ Gender: \_\_\_\_\_

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

Phone number: Home (\_\_\_\_) \_\_\_\_\_ Work (\_\_\_\_) \_\_\_\_\_

Mobile: \_\_\_\_\_ Other: \_\_\_\_\_

### If the person named to be vaccinated cannot give consent, the parent or guardian must complete the section below:

Surname: \_\_\_\_\_ Name: \_\_\_\_\_ Middle initial: \_\_\_\_\_

Relationship to the person named to be vaccinated: \_\_\_\_\_

### Do you, your child, or any person with whom you have close physical contact have:

- now, or a past history of, eczema (atopic dermatitis), active or quiescent eczema?  Yes  No  Unsure
- received products derived from human blood plasma (eg, immune globulins) in the last 6 months?  Yes  No  Unsure
- been vaccinated with a live vaccine in the last 60 days?  Yes  No  Unsure
- other active skin lesions, including exfoliative dermatitis, varicella zoster, impetigo, wounds, burns?  Yes  No  Unsure
- diseases or conditions which cause immunodeficiency or immune suppression, such as leukaemia, lupus, HIV, AIDS, lymphoma, generalised malignancy, agammaglobulinemia, chemotherapy, radiation therapy, organ transplant medication, or large doses of corticosteroids (>20 mg prednisone/day or equivalent)?  Yes  No  Unsure
- a history of severe allergic reactions to the smallpox vaccine components, including polymyxin B and neomycin?  Yes  No  Unsure
- a serious heart disease or vessel conditions (such as angina, heart attack, artery disease, congestive heart failure, stroke, or other cardiac problems)?  Yes  No  Unsure
- have a history of neurological disorder including encephalitis?  Yes  No  Unsure

**Are you or any person with whom you have close physical contact:**

- less than 12 months of age? Yes No Unsure
- pregnant or planning pregnancy within 1 month? Yes No Unsure
- live with people with any of the conditions listed above? Yes No Unsure

If you answered **Yes** to any of the questions above, you should not get vaccinated because smallpox vaccination may lead to serious illness or health problems, including postvaccinal encephalopathy or encephalitis, and even death.

If you are unsure about any of the questions above, ask a medical screener for assistance.

However, if you have had close physical contact with a person who currently has smallpox [or with a person who has had close physical contact with that person], inform a medical screener, who will review the above information with you to determine if you are eligible to be vaccinated and that your consent is given voluntarily.

**SMALLPOX VACCINE CONSENT FORM DECLARATION**

1. I have read and understand the information provided on smallpox vaccine.
2. I understand that smallpox vaccination may cause serious adverse reactions.
3. I have considered my own health status as well as the health status of my close physical contacts.
4. I have responded to the questions above to the best of my ability.
5. I have been given an opportunity to have my questions answered.
6. I understand that the decision to be vaccinated is voluntary and agree to proceed with smallpox vaccination.
7. By signing this form, I expressly waive any rights of legal action I might otherwise have in connection with the smallpox vaccination.

\_\_\_\_\_  
Signature of the Person Named to be  
Vaccinated or Parent/Guardian

\_\_\_\_\_  
Signature of Medical Screener

Date \_\_\_\_\_

Date \_\_\_\_\_

Patient identifying number: \_\_\_\_\_

Vaccine administered (brand and batch number): \_\_\_\_\_

Name of vaccinator: \_\_\_\_\_

Date of vaccination: \_\_\_\_\_

Clinic name: \_\_\_\_\_

Clinic address: \_\_\_\_\_

## INFORMATION STATEMENT FOR ACAM2000 SMALLPOX VACCINE

### Introduction

Before agreeing to be vaccinated with ACAM2000 smallpox vaccine, it is important that you read and understand the following information.

If you are not completely truthful regarding your current medical conditions and your medical history, you may harm yourself and others by receiving the vaccine.

**Please read the information provided below carefully and do not hesitate to ask medical staff any questions you may have.**

ACAM2000 has not yet been approved by the United States Food and Drug Administration (FDA) or by the Australian Therapeutic Goods Administration (TGA).

The effectiveness of the vaccination will be measured by observing whether or not a "pock", which resembles a blister, forms at the site of the vaccination, and if there are specific antibodies in your blood. The pock is a typical response to smallpox vaccination and leaves a small scar or depression of the skin at the site of vaccination. Antibodies are chemicals your body produces to inactivate smallpox virus.

### Procedures

To be eligible to be vaccinated with ACAM2000 smallpox vaccine you must:

- Have signed an informed consent document.
- Be in general good health.
- Female recipients must not be pregnant or breastfeeding and must not become pregnant for 30 days post vaccination.
- Not have children one (1) year old or younger in the household or have close contact with children one(1) year old or younger.
- Not have known or suspected immunodeficiency (e.g., HIV infection, primary immunodeficiency disorder, leukemia, lymphoma), or be currently undergoing radiation treatment of using immunosuppressive or anti-neoplastic drugs (except for small doses of some steroids used for reasons other than immunosuppression).
- Not have known cardiac disease including: previous myocardial infarction (heart attack); angina (chest tightness/pain); congestive heart failure; cardiomyopathy; stroke or transient ischaemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage); chest pain or shortness of breath with activity (such as walking up stairs); or other heart conditions under the care of a doctor
- Not have been diagnosed with any of the following:
  - high blood pressure;
  - elevated blood cholesterol;
  - Diabetes mellitus or high blood sugar.

- Not have a first degree relative (for example mother, father, brother, or sister) who had a heart condition before the age of 50, or smoke cigarettes.
  - Not have a past history or current diagnosis of renal disease, adverse reactions to drugs characterised by renal impairment, a serum creatinine > 1.5 mg/dL, or presence of 2+ protein in urinalysis at screening.
  - Not have a current diagnosis or past history of eczema of any kind (including atopic dermatitis, neurodermatitis, lichen simplex, or other eczematous condition of known or unknown cause).
  - Not have a presence of acute, chronic, or exfoliative ("skin shedding") skin conditions, open wounds, or burns.
  - Not have household members or intimate contact with any person with any of the conditions listed directly above.
  - Not have a known allergy or past allergic reactions to latex gloves or to antibiotics present in trace amounts in ACAM2000 vaccines (antibiotics include neomycin, streptomycin, chlortetracycline, and polymyxin B)
  - Not have a known allergy or past allergic reactions to blood products, including immunoglobulin preparations.
  - Not have a known allergy or past allergic reactions to sulfa-containing drugs, including probenecid, trimethoprim, and sulfonamide antibiotics.
  - Not have a history of allergic phenomena following smallpox vaccination in the past, including urticaria, erythema multiforme, or Stevens-Johnson syndrome.
  - Not have had a transfusion of blood or treatment with any blood product, including intramuscular or intravenous serum globulin, within the previous six months.
  - Not have a positive serum test for HIV, hepatitis B surface antigen, or hepatitis C.
  - Not have a household member or direct contact who is pregnant or breastfeeding.
  - Not have a body temperature greater than 40°C or an acute illness within 3 days prior to vaccination.
  - Not have active inflammatory eye disease.
  - Not have been inoculated with any other live vaccine within the previous 60 days.

There is a risk that fluid in the blister from your vaccination site can be transferred to people with whom you have close contact. If this occurs, the person to whom the fluid is transferred would be exposed to the same risks as someone who has been vaccinated. The risk of transfer (or accidental vaccination) is small, but can result in serious adverse effects to certain groups of people.

Because of this, you **MUST NOT** be vaccinated with ACAM2000 if you have close contact with someone who is pregnant/breastfeeding, has a weak immune system, has eczema or other skin disorders, or is less than one-year old. Alternatively, you may be vaccinated if you agree not to live with the person until the vaccination site has fully healed.

## Vaccination

You will be vaccinated by a process called scarification. Scarification is done by dipping a small 2-pronged needle into the vaccine and then pressing the needle with the vaccine against the skin. Next, the needle is pressed through the liquid and into the skin, puncturing the surface of the skin. This puncture is repeated about 15 times. Correct vaccination technique requires that a drop of blood form at the puncture site (more than 15 punctures may be required if this does not occur).

In addition, it is expected that after vaccination, you will develop a sore that turns into a blister and then scabs over. This blistering and healing will take about 2-3 weeks to complete. The scab probably will leave a small flat scar about a centimetre in diameter. Initially this scar may be somewhat reddish in colour, but it should fade over time and become flesh coloured. The vaccination scar usually is permanent.

From the time when the blister forms to when it heals, the fluid in the blister is infectious, and there is a potential that you can infect other parts of your body and people you have contact with. If the fluid from your blister comes in contact with another person, they could also develop a blister and scar, just as described above. Also, that person will be subject to the same risks that are described in the next section. If a person you are in close contact with develops a blister or a "pock-like" wound on the skin, you should notify the medical staff immediately.

Following vaccination, medical staff will put a bandage over the injection site to protect it and to prevent the spread of the vaccine and the fluid in the blister (should it develop) to other people. You will be informed on ways to avoid spreading the fluid to other parts of your body and to others. You will also be given written instructions for care of the vaccination site, and you will be given latex gloves and extra bandages. It is very important that you follow all instructions to prevent the spread of virus to pregnant women, children less than one year old, people with the skin disease eczema, and people with disorders of the immune system.

The vaccination site will be inspected after several days to ensure that the vaccine has worked. You will be informed of when you are required to return to the clinic for this inspection. After examining the vaccination site, medical staff will change the dressing site. After a hard scab forms, the dressing will no longer be necessary.

## Risks

All therapies have potential to cause some side effects or other reactions.

ACAM2000 vaccine is made from the vaccinia virus that is grown in cell culture and was derived from an earlier type of smallpox vaccine called Dryvax®. Dryvax® was grown in the skin on the sides of cows. The virus for ACAM2000 vaccine was not grown in animals. Rather ACAM2000 was grown in a manufacturing facility using a variety of animal and human-derived materials. Normal vaccine manufacturing procedures include testing the study vaccine for possible contaminating agents, including viruses, to assure the purity of the final product. While ACAM2000 vaccine has been tested for many infectious agents that are known to infect humans

and animals, and that could possibility contaminate the ACAM2000 vaccine, some of the viral testing is incomplete. It is unknown whether or not viruses for which testing is incomplete are contaminating the ACAM2000 vaccine.

There will be pain, soreness, redness, and swelling at the vaccination site. Also, you may have fever, chills, swollen glands, rash, aches and pains, nausea, headache, and fatigue as a result of your vaccination. These side effects usually don't last long and no special treatment is needed. As with all vaccines, there is a chance you may have an allergic reaction, which produces rash, hives, or difficulty breathing. Allergic reactions can be dangerous if untreated, and clinic staff will watch you for about an hour after vaccination for any unusual reactions.

When smallpox vaccines are administered by scarification, typical reaction includes formation of a blister, which eventually forms a scab and leaves a scar at the vaccination site. It usually takes 14 to 28 days for the blister to heal; the scar usually is permanent.

Other, less common reactions have been associated with the administration of smallpox vaccines and should therefore also be assumed to exist with respect to ACAM2000. Many of these reactions, and by far the most common, are relatively minor and usually resolve without complication. These minor reactions include:

#### **Lymphadenitis**

Swelling and tenderness of the draining lymph nodes generally beginning on day 5 may persist for several weeks after the skin lesion has healed.

#### **Fever and systemic symptoms**

During the height of the cutaneous (skin) reaction, approximately 10% of subjects may experience one or more days of fever (oral temperature  $>37.7^{\circ}\text{C}$ ). Systemic symptoms (malaise, fatigue, headache, and myalgia (muscle soreness)) occur in a higher proportion of subjects.

#### **Large vaccination reactions (Robust Takes)**

Large vaccination reactions ( $>10$  cm in diameter) are expected in approximately 10% of vaccinees who have not previously received a smallpox vaccine.

#### **Bacterial superinfection**

Rare cases with bacterial superinfection (a new infection caused by an organism different from that which caused the initial infection) of the skin have been described.

#### **Nonspecific rashes and weals (urticaria)**

A variety of rashes have been associated with vaccination, usually in first time vaccinees during the first and second weeks after inoculation. The rashes may be intensely itchy, but are self-limited.

**There are other, more serious reactions which have been associated with smallpox vaccines. While these reactions are quite rare, they have occurred in the past, and you should assume that they may also occur in connection with the administration of ACAM2000. These more serious possible reactions include the following:**

### **Postvaccinal encephalitis (PVE)**

This is one of the most serious adverse events associated with smallpox vaccine, but fortunately occurs very infrequently. It is most common in infants <2 years and occurs principally after primary vaccination. The disease is characterised by brain inflammation. The case-fatality rate is approximately 15-25%, and permanent damage to the brain may occur in 25% of survivors. The maximum risk of encephalitis in adults appears to be in the range of 3.5-4.5 per million.

### **Progressive vaccinia (vaccinia necrosum)**

This is a serious, often fatal adverse event seen only in persons who are immunosuppressed as a result of an immune deficiency disorder, including HIV, leukemia and lymphoma, or treatment with high doses of cortisone medications or with cancer chemotherapy drugs. Progressive vaccinia is characterised by failure of the primary cutaneous lesion to heal, with progressive enlargement, spreading, and ulcer formation.

### **Eczema vaccinatum**

This is a serious adverse event that occurs in individuals with active or quiescent eczema. Non-emergency vaccination is contraindicated in individuals with these risk factors and in individuals who have household contacts with eczema or a past history of eczema.

The term "eczema" is used today by non-dermatological practitioners to describe scaly, red skin conditions. The specific condition that appears to be associated with eczema vaccinatum is "atopic dermatitis (AD)". AD is associated with T cell dysregulation in the skin, and thus may be considered a cutaneous immune deficiency. A case definition of AD in children is shown below:

Must have: Itchy skin condition in the past 12 months. Plus 3 more of the following:

- Age at onset younger than 2 years
- History of flexural involvement
- History of a generally dry skin
- History of other atopic diseases, e.g. asthma in self or first-degree relative
- Visible flexural dermatitis

Adults often 'out-grow' AD. However, a history of AD in childhood in the subject or a household contact constitutes a contraindication to vaccination of adult subjects.

The incidence of *eczema vaccinatum* in surveys conducted during the era of routine vaccination was 10.4 per million in the United States and 38.5 per million in a survey undertaken in ten American states in persons undergoing primary vaccination and 0.9 and 3.0 per million, respectively in persons undergoing revaccination.

### **Generalised vaccinia**

Generalised vaccinia occurs in persons with normal systemic and cutaneous immune systems, who develop a generalised rash illness characterised by multiple skin lesions resembling the local reaction at the vaccination site accompanied by fever and chills. This complication occurs at highest incidence in infants < 1 year of age. The rash is self-limited, with complete healing and no fatalities.

**Ocular complications**

Accidental infection of the eye may result in infection of the eyelid or cornea. This can be painful and occasionally may result in damage to the cornea and even blindness. You will be instructed on the importance of avoiding touching the vaccination site, hand washing and keeping the site covered in order to avoid transfer of the virus to the eye or other areas of the skin.

**Cardiac complications**

Heart attacks and angina (chest pain/tightness), including several deaths, have been temporally associated with vaccination during recent vaccination campaigns in the United States. Although a relationship to vaccination is unproven, the Centres for Disease Control has recommended temporary suspension of vaccination of persons with underlying heart disease. In addition, at least 13 cases of myocarditis (inflammation of the heart muscle), pericarditis (inflammation of the sac covering the heart), or both conditions (myopericarditis) have been described, principally following primary vaccination of United States military personnel. The incidence of this complication may be as high as 1 person in 12,821. Patients with these conditions may have chest pain, shortness of breath and feeling fatigued 1-2 weeks after vaccination. These events have been self-limited, with full recovery. However, historical reports describe rare fatalities from myocarditis.

**Inadvertent vaccination in pregnancy**

Congenital infection, principally occurring during the first trimester, may be associated with generalised vaccinia of the foetus, resulting in stillbirth. This complication was exceedingly rare during the era of routine vaccination, and there are less than 50 cases reported in the literature. Congenital birth defects have not been described. If you are a woman able to bear children, you will be advised of the importance of using birth control methods for the month before and after vaccination.

**Vaccinia Immune Globulin**

If any serious side effects occur, the drug VIG (Vaccinia Immune Globulin) may be administered. VIG is an investigation drug that is made from plasma obtained from the blood of people who have been immunised with smallpox vaccine. This drug is effective for eczema-like reactions and accidental infections of the eye. It usually is not given to people with severe reactions at either the vaccination site or other parts of the body unless they are very ill, and has not been shown to be effective in the treatment of postvaccinal encephalitis. VIG may not be adequately effective as a treatment if a complication does occur.

**Cidofovir**

If a serious side effect occurs and the treatment with VIG does not appear to be strong enough, additional treatment is available with a medicine called Cidofovir. Cidofovir is approved by the TGA for the treatment of an infection caused by the herpes virus called cytomegalovirus, which is different from the infection that may be caused by vaccination. While Cidofovir has not been approved by the TGA for treatment of side effects associated with vaccination, there is some evidence from studies with animals that Cidofovir may be effective for infections caused by smallpox virus and similar viruses.

Cidofovir can cause serious kidney damage, sometimes after just one or two doses. If medical staff consider it is necessary to administer Cidofovir, you will be hospitalised.

If used, Cidofovir will be administered intravenously. In addition to kidney damage, the use of Cidofovir has been associated with abnormal urine test results (protein in urine), nausea, fever, a decrease in the white cells in the blood, and decreased pressure in the eye. Adverse events that also may occur include headache, rash, diarrhoea, pain, and abnormal blood tests.

## Form 11d: State and Territory Smallpox Response Team Vaccination Register

### Demography

Unique identifier ( DoHA) \_\_\_\_\_ Office use \_\_\_\_\_  
 Name \_\_\_\_\_  
 \_\_\_\_\_

Has this vaccinee completed the consent to be placed on the register? Yes / No  
 If No: Do not forward to the Australian Government Department of Health and Ageing

Is this vaccinee prepared to be contacted for investigations about effects of vaccination? Yes / No

Sex Male / Female

Date of birth \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Medicare/ Veterans Affairs Gold Card number \_\_\_\_\_

Usual employment address \_\_\_\_\_  
 \_\_\_\_\_

Phone contact Work \_\_\_\_\_  
 Home \_\_\_\_\_  
 Mobile \_\_\_\_\_

Email address \_\_\_\_\_

Home address \_\_\_\_\_  
 \_\_\_\_\_

Secondary contact name address and phone \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Number of people living in household at time of vaccination \_\_\_\_\_

Role in smallpox event team (*please circle*) Team leader, infectious diseases physician, epidemiologist, nurse vaccinator, clinical care nurse, communicable disease nurse, doctor, clerical  
 Other please specify \_\_\_\_\_

**Medical history**

Have all contraindications to vaccination been excluded (see Appendix 10) Yes / No

Is the vaccinee taking any regular medications? Yes / No

If yes, please specify \_\_\_\_\_

\_\_\_\_\_

Does the vaccinee suffer from any chronic illness? Yes / No

If yes, please specify \_\_\_\_\_

\_\_\_\_\_

Any other significant past medical history? Yes / No

If yes, please specify \_\_\_\_\_

\_\_\_\_\_

**Vaccination details**

Number of times previously vaccinated for smallpox (0 if never previously vaccinated) \_\_\_\_\_

Is paper evidence of previous vaccination produced Yes / No

Year of last vaccination \_\_\_\_\_

Name of vaccine given \_\_\_\_\_

Vaccine lot number \_\_\_\_\_

Date this vaccine given \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Vaccination centre's name or place name \_\_\_\_\_

Site of vaccination on body \_\_\_\_\_

Evaluation of take — number of days after vaccination \_\_\_\_\_ days

Description of vaccination site at take (circle description) macule, papule, vesicle, ulcer, crust, none

Other (specify) \_\_\_\_\_

Diameter of vaccination response in mm \_\_\_\_\_ mm

**Description of minor adverse reaction**

Fever Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

If fever was present what was the maximum temperature recorded? \_\_\_\_\_ degrees celsius

Myalgia

Nausea Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

Fatigue Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

Other (please specify) Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Did vaccinee seek medical care? Yes / No

Did vaccinee miss days from work? Yes / No

If yes, how many days? \_\_\_\_\_ days

**Description of major adverse events**

Inadvertent inoculation at other site? Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

If yes, what body site was affected? Eye, mouth, face, nose, genitalia, rectum

Other (please specify)

\_\_\_\_\_

Was a cover used on inoculation site? Yes / No

Was the adverse event

Eczema vaccinatum? Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

Generalised vaccinia? Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

Progressive vaccinia? Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

Post vaccination encephalitis? Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

Other major event (please specify) Yes / No If yes, date of onset \_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Was any treatment given for the adverse event? (circle treatment) No treatment / VIG / cidofovir

Was the vaccinee hospitalised? Yes / No  
 If yes, date of hospitalisation \_\_\_\_/\_\_\_\_/\_\_\_\_

Outcome? Survived / Died

How long was the vaccinee ill? \_\_\_\_\_

Name and phone number of treating doctor who may be contacted for further information \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_

### Secondary transmission

Was there any spread of the vaccinia virus to any one else from this vaccinee? Yes / No

If no: Thank you, this is the end of the report form. If yes: Please continue.

What was the secondary case's relationship to vaccinee? Spouse / child / sibling / parent / housemate  
 Other (please specify)

\_\_\_\_\_

What was the date of onset of illness in the secondary case? \_\_\_\_/\_\_\_\_/\_\_\_\_

Date of birth of secondary case \_\_\_\_/\_\_\_\_/\_\_\_\_

Gender of secondary case Male / Female

Description of illness \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_

Duration of illness \_\_\_\_\_ days

Days missed work/school \_\_\_\_\_ days

Treatment given \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_

Outcome Survived / died

## Form 11e: Interim vaccination certificate

**IMPORTANT:**  
**Do not throw this form away. Keep it and bring it with you  
to your vaccination site exam**

You have just been vaccinated with smallpox vaccine. This sheet will serve as your proof of vaccination until you come back to the clinic for your vaccination site exam. On that date, you will get your permanent immunisation card.

### INTERIM PROOF OF VACCINATION:

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

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

Clinic: \_\_\_\_\_

Clinic telephone no: \_\_\_\_\_

### APPOINTMENT FOR REQUIRED VACCINATION SITE EXAM:

Date of appointment: \_\_\_\_/\_\_\_\_/\_\_\_\_

Clinic: \_\_\_\_\_

Clinic telephone no: \_\_\_\_\_

### WHAT TO DO IF YOU THINK YOU ARE HAVING A BAD REACTION TO THE VACCINE:

Call: \_\_\_\_\_, call your health care provider, or  
visit an emergency room.

**IMPORTANT:**  
**Do not throw this form away. Keep it and bring it with you  
to your vaccination site exam**

## Form 11f: Case report

*\* Indicates data needed at national level*

Case reference number:\* \_\_\_\_\_

### Patient's details

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

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

Telephone: \_\_\_\_\_ DOB:\* \_\_\_\_\_

Gender: \* M / F      Ethnicity:\* \_\_\_\_\_      ATSI    Yes / No

Occupation:\* \_\_\_\_\_

Work address: \_\_\_\_\_

Where is the case now? Provide description and address: \_\_\_\_\_

If information about the case was not provided by the patient, give details of person providing information:

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

Address and telephone: \_\_\_\_\_

### Category of illness (see clinical algorithm form)\*

At initial interview      Possible case / Probable case / Confirmed case

At 24 hours                  Possible case / Probable case / Confirmed case

At 48 hours                  Possible case / Probable case / Confirmed case

At 72 hours                  Possible case / Probable case / Confirmed case

Date of report:\* \_\_\_\_/\_\_\_\_/\_\_\_\_

Reported by (name, position, organisation): \_\_\_\_\_

Was this case under surveillance as a contact of another case?\*    Yes/No

If yes, provide contact identification number: \_\_\_\_\_

**Clinical data**

Infectious diseases physician name and contact: \_\_\_\_\_

\_\_\_\_\_

Date of onset of symptoms (t):\* \_\_\_\_/\_\_\_\_/\_\_\_\_

Initial symptoms/signs: \_\_\_\_\_

\_\_\_\_\_

Laboratory tests (dates of specimens and results): \_\_\_\_\_

\_\_\_\_\_

**Management**

Outcome:\* Survived / Died

**Medical and vaccination history**

Smallpox vaccine given prior to this outbreak? Yes / No Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Smallpox vaccine given during this outbreak?\* Yes / No Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Pre-existing medical conditions Yes / No

Details: \_\_\_\_\_

Immunosuppressive disorders or treatment Yes / No

Details: \_\_\_\_\_

Description of current symptoms: \_\_\_\_\_

Infectious period

Onset date (= t): \_\_\_\_\_

Earliest date for start of infective period (= t - 1 day): \_\_\_\_\_

Earliest date for start of incubation period (= t - 14 days): \_\_\_\_\_

Epidemiological links to other cases (reference numbers):\* \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



## Form 11g: Contact surveillance

### *\* Indicates data are needed at national level*

Category A contacts receive active surveillance.  
Category B contacts are under passive surveillance.  
Category S contacts are secondary contacts.

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

Type of contact:\*      Category A / Category B / 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:\* \_\_\_\_\_      Gender:\* M / F

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:\* \_\_\_\_/\_\_\_\_/\_\_\_\_

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

Vaccination site assessed:\*      Take / No take      Date:\*

Surveillance arranged:\*      Formal / Informal / None

**Contact surveillance**

<b>Day</b>	<b>Date</b>	<b>Contact phoned (Y/N)</b>	<b>Contact visited (Y/N)</b>	<b>Tempera ture (degrees Celsius)</b>	<b>Other symptoms</b>	<b>Status: S: symptomatic A: asymptomatic</b>	<b>Signed (print name)</b>
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							

# Appendix 12

## Information sheets

- **What you need to know about smallpox vaccine**
- **Reactions after smallpox vaccination**
- **Reactions after smallpox vaccination (supplement)**
- **Smallpox vaccination site appearance and care, for health care workers**
- **What you need to know about smallpox if your child is less than one year old**
- **What you need to know about smallpox if you are pregnant**
- **Skin conditions that mean you should not get smallpox vaccine**
- **A weakened immune system means you should not get smallpox vaccine**
- **What you should know if someone in your household is being vaccinated against smallpox**
- **Advice for Category A smallpox contacts**
- **Advice for Category B smallpox contacts**
- **Advice for secondary smallpox contacts**
- **Advice about smallpox for concerned individuals**

## Information sheet:

# What you need to know about smallpox vaccine

## What is smallpox?

Smallpox is a serious disease caused by a virus called variola, which is spread from person to person through close contact.

Smallpox kills up to 30% of people infected with it. It can also cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness.

The world's last case of naturally acquired smallpox occurred in 1977. It is believed that hostile terrorists or governments might possess the smallpox virus and could use it as a biological weapon.

The Australian Government, State and Territory governments have planned a response to any potential smallpox emergency. The plans call for vaccination to protect the health care workers and others who would form first-response teams. Depending on the situation, vaccination may also be necessary for some members of the public.

## Why get vaccinated?

Smallpox vaccine currently protects people who work with smallpox or related viruses in laboratories.

Getting the smallpox vaccine *before* exposure to the variola virus will protect most people from smallpox. Getting the vaccine *within 3 days after exposure* can prevent the disease or at least make it less severe. Getting the vaccine *within a week after exposure* can still make the disease less severe.

Protection from infection lasts three to five years, and protection from severe illness and death can last 10 years or more.

## The smallpox vaccine

Smallpox vaccine is made from a virus called vaccinia. Vaccinia virus is similar to smallpox virus, but less harmful, and vaccinia vaccine can protect people from smallpox. The smallpox vaccine does *not* contain smallpox virus.

## Who should get the vaccine and when?

If a case of smallpox occurs, first-responder teams will need protection from the disease. These teams will identify other people who need to be vaccinated to control the outbreak, and establish smallpox vaccination centres.

### Routine nonemergency use (no outbreak)

- Laboratory workers who handle cultures or animals contaminated or infected with vaccinia or other related viruses (eg monkeypox, cowpox, variola) should be vaccinated.
- Public health, hospital and other personnel, generally 18–65 years of age, who may have to respond to a smallpox case or outbreak, should be vaccinated.

### Emergency use (smallpox outbreak)

- Anyone *directly exposed* to smallpox virus should get one dose of vaccine as soon as possible after exposure.
- Anyone *at risk of exposure* to smallpox virus may need to get one dose of vaccine when the risk occurs or becomes known.

Vaccinated persons may need to be revaccinated after 3–10 years, depending on continuing risk.

## After the vaccination

A blister should form at the vaccination site. Later it will form a scab. Finally, the scab will fall off, leaving a scar.

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

## Care of the 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, keep the vaccination site loosely covered with a gauze bandage. Health care workers will need additional measures, such as a semipermeable dressing covering the gauze, while at work.

Change the bandage as needed: every 1–3 days if using only gauze bandages, and at least every 3–5 days for semipermeable dressings. Cover with a waterproof bandage while bathing.

Don't touch the vaccination site and then another part of your body without washing your hands first. Don't scratch or put ointment on the vaccination site. Don't touch your eyes or any part of your body after changing the bandage or touching the vaccination site.

Wear a shirt that covers the vaccination site as an extra precaution, particularly in situations of close physical contact, such as parenting young children.

Put used bandages in a plastic 'ziplock' bag before throwing them away. Do the same with the scab when it falls off. Don't share towels. Wash any items that have touched the vaccination site. Wash your hands after touching the vaccination site or bandages, clothing, sheets or towels that have touched the site.

## People who should not get smallpox vaccine or who should wait

### Routine nonemergency use (no outbreak)

- Anyone who has a history of heart disease or a heart condition should not get the vaccine.
- Anyone who has history of neurological disorder should not get the vaccine.
- Anyone who has eczema or atopic dermatitis, or has a past history of either condition, should not get smallpox vaccine.
- Anyone with a skin condition that causes breaks in the skin (such as an allergic rash, severe burn, impetigo, chickenpox, shingles or severe acne) should wait until the condition clears up before getting smallpox vaccine.
- Anyone whose immune system is weakened should not get smallpox vaccine, including anyone who:
  - has human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) or another disease that affects the immune system
  - has significant immune system suppression from a severe autoimmune disease, such as systemic lupus erythematosus
  - is being treated, or has recently been treated, with drugs that affect the immune system, such as steroids, some drugs for autoimmune disease, or drugs taken in association with an organ or bone marrow transplant
  - has leukaemia, lymphoma, or most other cancers
  - is taking cancer treatment with X-rays or drugs, or has taken such treatment in the past three months.
- Pregnant women should not get smallpox vaccine.
- Women who are breastfeeding should not get smallpox vaccine.
- Women should avoid getting pregnant for four weeks after getting smallpox vaccine.

**Note: if you live with or have close physical contact with someone who falls into any of the above categories, you should not receive smallpox vaccine because of the risk it poses to that close contact. Close contacts include anyone living in your household and anyone you have close physical contact with, such as a sex partner; they do not include friends or people you work with.**

- Smallpox vaccine is not recommended for infants under one year of age.
- People who have ever had a life-threatening allergic reaction to polymyxin B, streptomycin, chlortetracycline, neomycin, or a previous dose of smallpox vaccine, should not get smallpox vaccine.
- People using steroid drops in their eyes should not get smallpox vaccine.
- People who are moderately or severely ill at the time the vaccination is scheduled should usually wait until they recover before getting smallpox vaccine.

### **Emergency use (smallpox outbreak)**

In a smallpox outbreak, medical staff will explain the risks of vaccination and the risks of infection to individuals in the above groups or to their carers. The choice to be vaccinated will rest with the individual, but those choosing not to be vaccinated may be subject to isolation (quarantine) if it is possible that they are infected.

**Information sheet:****Reactions after smallpox vaccination****What are the risks from smallpox vaccine?**

The following information is about *known* reactions to smallpox vaccine. A vaccine, like any medicine, can cause serious problems, perhaps including some we do not yet know about, as well as severe allergic reactions.

The risk of smallpox vaccine causing serious harm, or death, is small. Statistics on adverse reactions are from populations who may not have had careful screening for contraindications. For every million people vaccinated in the past, between 14 and 52 had a life-threatening reaction to smallpox vaccine and between 1 and 2 died.

People who come into direct contact with the vaccination site of a vaccinated person, or with materials that have touched the site, can also have a reaction if they become infected with the vaccine virus.

**Mild to moderate problems**

- Mild rash, lasting 2–4 days.
- Fever of over 39°C (about 10% of adults).
- Blisters elsewhere on the body (about 1 in 1900 people).

About one-third of people getting the vaccine may feel sick enough to be absent from work or school or to curtail recreational activities, or may temporarily have trouble sleeping.

**Moderate to severe problems (that need immediate medical attention)**

- Eye infection due to spread of vaccinia virus (the vaccine agent) to the eye, which can lead to loss of vision.
- Rash on entire body (as many as 1 in 4000 people), which usually resolves without problems.

**Potentially life-threatening problems**

- Severe rash on people with eczema or atopic dermatitis (as many as 1 per 26,000), which can lead to scarring or death.
- Encephalitis, a severe brain reaction that can lead to permanent brain damage or death (as many as 1 per 83,000).

- Severe progressive infection, beginning at the vaccination site, which can lead to scarring or death (as many as 1 per 667,000; mostly people with weakened immune systems).
- Perimyocarditis and exacerbation of coronary disease including: previous myocardial infarction, angina, congestive heart failure, cardiomyopathy, stroke or transient ischaemic attack, and chest pain or shortness of breath with activity.

### What to look out for

Look out for:

- a vaccination site that looks like it is not healing normally
- a rash or sore on other parts of your body
- an eye infection
- persistent headache or fever
- confusion, seizures, difficulty staying awake or another unexpected problem.

Signs of a *serious allergic reaction* can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heartbeat or dizziness occurring within a few minutes to a few hours after the vaccination.

### What to do if there is a moderate or severe reaction

If the vaccinated person, or a close physical contact, experiences any of the above conditions, or if they are concerned about *any* condition experienced after vaccination:

- Call a health care provider, or get the person medical care right away. If the person has been vaccinated, tell the health care provider that they were vaccinated with smallpox vaccine and when.
- Ask the doctor or nurse to file a Vaccine Adverse Event Report (VAER form) and to contact their State or Territory health department.

### Treating serious reactions

Vaccinia immune globulin (VIG) can help people who have certain serious reactions to smallpox vaccine. A second drug, cidofovir, may be used in some situations. Neither drug is currently licensed for this purpose, and they may have side effects of their own.

### Cost of treating vaccine reactions

- Treatment of severe reactions can be very expensive.
- Workers compensation or health insurance may not cover these expenses.
- There is no Australian Government program for reimbursement for time lost from work, either because of illness due to vaccination or because of concern about spreading the virus to others. Reimbursement may be available through the workplace.

## Information sheet supplement:

### Reactions after smallpox vaccination

The smallpox vaccine is made from a live virus related to smallpox and called vaccinia (it is not made from smallpox virus). 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. For most people, live virus vaccines are safe and effective.

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. Consult the information sheet *What you need to know about smallpox vaccine* for information on people who should not be vaccinated at this time.

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 run a low fever
- 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.

A recent study found that:

- the average size of the pustule (pus-filled blister) at the vaccination site was 1.25 cm
- the average size of the redness and/or swelling at the vaccination site was 2 cm
- up to 15% of people vaccinated had redness and/or swelling larger than 7 cm, sometimes involving the whole arm; this is usually seen around 7–10 days after vaccination
- up to 47% of people vaccinated reported pain at the vaccination site, but most said it did not keep them from normal activities

- about 10% of people vaccinated had a fever of 39°C or more; this can be treated with ibuprofen or acetaminophen
- an allergic rash sometimes occurred where the adhesive tape holding the gauze bandage in place touched the vaccine recipient's skin.

### **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, call the phone number provided on the *Postvaccination and follow-up information sheet* given to you at the time of your vaccination, or call your health care provider.

### **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.

Be watchful for the following symptoms:

- your vaccine site doesn't look as though it is healing normally
- you develop a rash or sore on another part or parts of your body
- you develop a persistent headache (lasting more than 24 hours) or high fever, confusion or seizures
- you have difficulty staying awake
- you have difficulty breathing, hoarseness or wheezing
- you develop hives, paleness, weakness, a fast heartbeat or dizziness
- you develop an eye infection
- you develop some other unusual, unexpected problem.

If any of the above occurs, call the phone number provided on the *Postvaccination and follow-up information sheet* given to you at the time of your vaccination, or call your health care provider.

### **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 (erythema multiforme)*. 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.

### **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.

These 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.
- Perimyocarditis.

### **What to do if you believe you are having a serious reaction**

Call the phone number provided on the *Postvaccination and follow-up information sheet* given to you at the time of your vaccination, call your health care provider, or visit an emergency room.

### **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. Neither drug is currently licensed for this purpose, and each may have side effects of its own. More information these drugs will be available at the smallpox vaccination centre, or can be found at the website listed below.

### **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.

For more information, visit the Australian Government Department of Health and Ageing website: <http://www.health.gov.au>.

**Information sheet:****Smallpox vaccination site appearance and care, for health care workers**

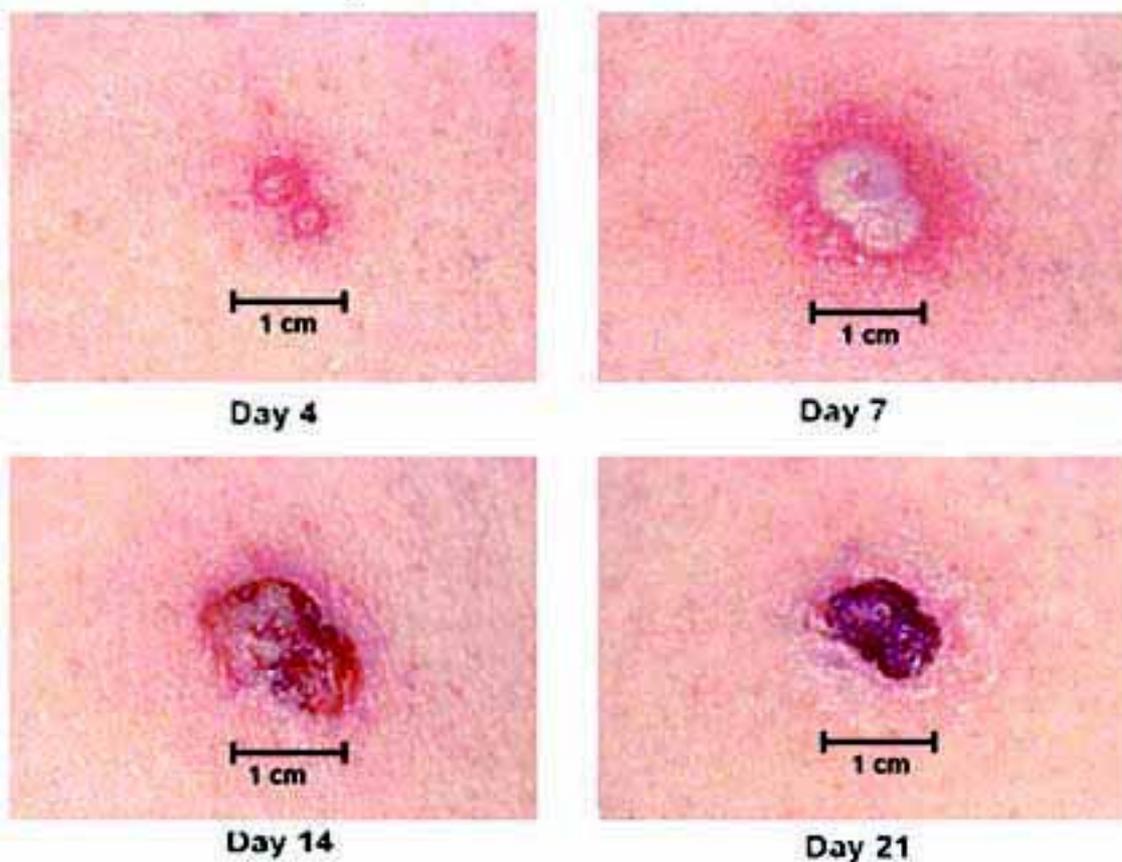
There will be vaccinia virus (the active agent of the smallpox vaccine) at the site of your vaccination until the scab that forms after vaccination falls off on its own 2–3 weeks after vaccination.

During this time, vaccinia can be spread to other parts of your body or to other people through direct contact (touching the vaccination site, or a bandage or clothing contaminated with virus, and then touching another part of your body or someone else before hand washing). You should avoid the spread of virus and keep the vaccination site clean and dry. Follow the instructions below carefully.

**Appearance**

If the vaccination is successful, a red and itchy bump develops at the site of vaccination in three or four days. In the first week, the bump becomes a 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, leaving a small scar. People vaccinated for the first time may have a stronger reaction than those who are being revaccinated.

The following pictures show the usual progression of the vaccination site:

**Primary Vaccination Site Reaction**

## Vaccination site evaluation

About seven days after vaccination, you will need to keep an appointment for a vaccination site exam, so that someone can evaluate your vaccination site to determine whether the vaccination was successful. The details of this appointment are on the *Postvaccination and follow-up information sheet* given to you at vaccination.

### What to look out for

If your vaccination site doesn't look like it is healing normally, or if you develop a rash or sore on other parts of your body, an eye infection, a persistent headache (lasting more than 24 hours) or high fever, confusion, seizures, difficulty staying awake, difficulty breathing, wheezing, hoarseness, hives, paleness, weakness, a fast heartbeat, dizziness or some other unexpected problem, call the phone number on the *Postvaccination and follow-up information sheet*, or call your health care provider.

## Vaccination site care instructions

Follow these instructions until the scab that forms at the vaccination site has fallen off on its own.

### What you should do

- *When working in a health care 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 semiocclusive) 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.
- *When not at work in a health care 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, such as gels or foams, 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 contact spread.
- *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.
- *Put contaminated bandages in a sealed plastic bag* and throw them away in the trash.
- *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 your hands afterwards.
- *When the scab falls off*, throw it away in a sealed plastic bag. Remember to wash your hands afterwards.

### **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 health care 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.

### **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.

For more information, visit the Australian Government Department of Health and Ageing website: <http://www.health.gov.au>.

## Information sheet:

# What you need to know about smallpox if your child is less than one year old

Please refer to your smallpox vaccine general information sheet (*What you need to know about smallpox vaccine*) for additional information about smallpox, smallpox vaccine, vaccine reactions, and vaccine site care instructions.

## What is smallpox?

Smallpox is a serious disease. It is caused by a virus called *variola*, which is spread from person to person through close contact. The last naturally occurring case of smallpox was in 1977.

Smallpox can cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness
- death (in up to 30% of those infected).

## Why is my child being offered smallpox vaccine?

Your child is being offered smallpox vaccine because one of the following has happened:

- your child has been exposed to smallpox virus
- your child has been in close contact with someone who has smallpox
- your child has not been exposed to the virus but lives with someone who was exposed and who could develop smallpox
- your child has not been exposed to the virus yet, but there has been a smallpox outbreak and the child may be exposed in the future.

## What do I need to know about smallpox disease in young children?

Smallpox in very young children can be very severe. Children under 4 years old have a greater risk of dying from smallpox than older children. Children older than 4 years usually handle smallpox better than younger children and have less risk of dying from the disease.

## What additional risks does my child have from the vaccine if the child is younger than one year old?

All people who receive smallpox vaccine can have some risks from the vaccine. These risks are discussed in your smallpox vaccine general information sheet (*What you need to know about smallpox vaccine*).

Infants less than 1 year old who are vaccinated may have a greater risk of developing complications from the vaccine, such as brain swelling or a total body rash. Brain swelling is a rare complication, but can occur in about 42 out of every 1 million infants who are vaccinated. Brain swelling can lead to permanent brain damage or even death.

The total body rash that can develop after vaccination is usually mild and goes away without treatment. On rare occasions, it can be severe and require medical treatment.

Young children may also be more likely to touch the vaccination site with their hands and transfer vaccine virus to another part of the body (such as the eyelid, face, mouth or genital area), causing a similar sore to develop there. This may be avoided by covering the vaccination site and making sure the child doesn't touch it. If the child does touch the site, their hands should be washed immediately and thoroughly.

## Should my child get the smallpox vaccine?

In an outbreak emergency, everyone who has been in contact with a person with smallpox or who was exposed to the virus is recommended to receive the one-dose vaccine, regardless of age, allergies, pregnancy or medical conditions.

If your child was exposed to smallpox virus in an outbreak emergency, the vaccine would be recommended to you in order to prevent the disease or lessen its severity.

## If my child is less than 1 year old, should they be vaccinated?

If your child has *not* been in contact with smallpox virus or a person with smallpox, you should consider waiting until they are older than 1 year to have them vaccinated.

If the child *has* been in contact with smallpox, the public health officer will discuss the risks with you.

## What should I do if my child is vaccinated and I think that they are having a bad reaction to the vaccine?

Call a doctor right away. Tell the doctor what is happening, the date and time that it started, and when the vaccination was given. The doctor will advise you on what to do next.

## What are the treatments for reactions to smallpox vaccine?

There are two treatments that may help if your child has a serious reaction to the smallpox vaccine. They are called vaccinia immune globulin (VIG) and cidofovir. Both of these medications are given by a needle into the vein (intravenous, or 'IV') and require the patient to be in a hospital. These treatments are still under investigation, and may cause a number of serious side effects themselves. They would not be effective for brain swelling from vaccination, but other medical treatments would then be used.

## What if I decide not to get the smallpox vaccine for my child?

- It is your choice whether or not to get the vaccine for your child.
- If your child *has* been in contact with a person who has smallpox and you decide *not* to get the vaccine for your child, the child may be placed in isolation for 18 days. This means that your child will not be able to be in contact with other people who have not been vaccinated, and may not be able to stay at home. Your child will be watched to be sure that they do not develop smallpox and to be sure that they do not give smallpox to others if they do develop the disease.
- If your child *has not* been in contact with anyone with smallpox and you decide *not* to get the vaccine for your child, your child should stay away from anyone you suspect may have smallpox.
- If your child is *not* vaccinated and lives in the same house with a person who *has* been vaccinated because they were exposed to smallpox virus, you should consider having your child live elsewhere for a while, and avoid contact with that person until they are no longer at risk of developing smallpox. Public health officials will tell you when your household member is no longer at risk for developing smallpox. Usually, this period is for 18 days after their contact with smallpox virus or 14 days after their vaccination.

For more information, visit the Australian Government Department of Health and Ageing website: <http://www.health.gov.au>.

## Information sheet:

# What you need to know about smallpox if you are pregnant

## What is smallpox?

Smallpox is a serious disease. It is caused by a virus called *variola*, which is spread from person to person through close contact. The last naturally occurring case of smallpox was in 1977.

Smallpox can cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness
- death (in up to 30% of those infected).

## Why am I being offered smallpox vaccine?

You are being offered smallpox vaccine because one of the following has happened:

- you have been exposed to the smallpox virus
- you have been in close contact with someone who has smallpox
- you have not been exposed to the virus but live with someone who was exposed and who could develop smallpox
- you have not been exposed to the virus yet, but there has been a smallpox outbreak and you may be exposed in the future.

## What do I need to know about smallpox disease during pregnancy?

If you are pregnant and are exposed to smallpox virus, and if you develop the disease, you may have a more serious illness and a higher risk of dying than a woman who is not pregnant. While the baby could be born with no problems or infection, the following could also occur:

- miscarriage
- stillbirth
- premature birth.

Before smallpox was officially declared eradicated in 1980, smallpox infections caused pregnancies to end early in 75% of pregnant women who developed the disease early in their pregnancy and in 60% of the women who developed the disease later in their pregnancy.

## What additional risks do I have from smallpox vaccine if I am pregnant?

All people who receive smallpox vaccine can have some risks from the vaccine. These risks are discussed in your smallpox vaccine general information sheet (*What you need to know about smallpox vaccine*).

Smallpox vaccine is a 'live virus' vaccine made from a virus called vaccinia. In general, vaccination with vaccines that have live viruses is not recommended during pregnancy. On rare occasions, smallpox vaccine can cause an infection in the unborn child of a pregnant woman who was vaccinated during her pregnancy, possibly leading to premature delivery, stillbirth, or the death of the child soon after delivery. Even though millions of people have been vaccinated against smallpox, fewer than 50 cases of this have been reported.

## Should I get the smallpox vaccine?

In an outbreak emergency, everyone who has been in contact with a person with smallpox or who was exposed to the virus is recommended to receive the one-dose vaccine, regardless of age, allergies, pregnancy or medical conditions.

If you are pregnant and were exposed to smallpox virus in an outbreak emergency, the vaccine would be recommended to you in order to prevent the disease or lessen its severity.

## If I am pregnant, when should I *not* be vaccinated, or *wait* to be vaccinated?

If you have *not* been in contact with smallpox virus or a person with smallpox, you should consider waiting to be vaccinated until after you have delivered your baby.

## What should I do if I am vaccinated and think that I am having a bad reaction to the vaccine?

Call a doctor right away. Tell the doctor what is happening, the date and time that it started, and when the vaccination was given. The doctor will advise you on what to do next.

## What are the treatments for reactions to smallpox vaccine?

There are two treatments that may help if you have a serious reaction to the smallpox vaccine: vaccinia immune globulin (VIG) and cidofovir. Both of these medications are given by a needle into the vein (intravenous, or 'IV') and require you to be in a hospital. They are still under investigation and may cause a number of serious side effects themselves.

The Commonwealth Department of Health and Ageing will pay for the costs of these medicines. The other costs of hospital and medical care will *not* be covered by the department and will need to be paid by you, your insurer, or Medicare.

## What if I decide not to get the smallpox vaccine?

- It is your choice whether or not to get the vaccine.
- If you *have* been in contact with a person who has smallpox and you decide *not* to get the vaccine, you may be placed in isolation for 18 days. This means that you will not be able to be in contact with other people who have not been vaccinated. You will not be able to stay at home or go to work. You will be watched to be sure that you do not develop smallpox and to be sure that you do not give smallpox to others.
- If you have *not* been in contact with anyone with smallpox and you decide *not* to get the vaccine, you should stay away from anyone you suspect may have smallpox.
- If you choose *not* to be vaccinated and you live in the same house as a person who *has* been vaccinated because they were exposed to smallpox virus, you should consider living apart from and avoiding contact with that person until they are no longer at risk of developing smallpox. Public health officials will tell you when your household member is no longer at risk for developing smallpox. Usually this period is for 18 days after their contact with smallpox virus or 14 days after their vaccination.

## Information sheet:

### Skin conditions that mean you should not get smallpox vaccine

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not from smallpox virus). See your general information sheet (*What you need to know about smallpox vaccine*) for basic information about the vaccine.

Smallpox vaccine stimulates the immune system to react against the vaccinia virus, and develop immunity to it. Immunity to vaccinia also provides immunity to smallpox.

For most people, live virus vaccines are safe and effective. However, people with certain skin conditions are more likely to have rare and serious reactions to the smallpox vaccine, including bad skin rashes (eczema vaccinatum). This results when virus from the vaccine site gets into broken skin and causes a rash in that area. While most people recover from this rash with treatment, it can be quite severe, sometimes leading to scarring or even death.

For these reasons, some people with particular conditions should not be vaccinated against smallpox in the absence of a smallpox outbreak emergency. In an emergency, risks and priorities will change (see *What if there is an outbreak of smallpox?*, below).

#### Skin conditions that mean you should not be vaccinated

- Individuals who have ever been diagnosed with *eczema* or *atopic dermatitis* (conditions involving repeated episodes of red, itchy or inflamed skin), even if the condition is mild, not presently active, or if they had it only as a child, should not get the vaccine.
- Individuals with *Darier's disease* should not get the vaccine.
- Individuals in *close contact* with someone who has ever been diagnosed with eczema or atopic dermatitis, even if the condition is mild, not presently active, or if they had it only as a child, should not get the vaccine because of the risk it poses to that close contact.

Close contacts include anyone living in your household and anyone you have close physical contact with, such as a sexual partner.

#### Skin conditions that mean you should wait before being vaccinated

Individuals with *breaks in their skin* should not be vaccinated until the skin is fully healed.

Individuals in *close physical contact* with someone who has breaks in their skin should not be vaccinated until the skin is fully healed.

Examples of conditions that can result in breaks in the skin include:

- impetigo (a skin infection)
- varicella (chickenpox or shingles)

- pityriasis rosea
- acute contact dermatitis
- recent significant burns where skin has not completely healed
- other conditions that cause significant rash or breaks in the skin, including moderate or extensive psoriasis, epidermolysis bullosa, severe acne (face or body) and pemphigus vulgaris.

### What are eczema and atopic dermatitis?

The word *eczema* describes certain kinds of inflamed skin. Early eczema can be red, blistering or oozing areas of skin. Later on, eczema can be scaly, brownish or thickened. Almost always, eczema itches. There are several different types of eczema: a special type called atopic dermatitis or atopic eczema has the greatest risk for severe rashes after smallpox vaccination.

*Atopic dermatitis* is a chronic disease that affects the skin. ‘Dermatitis’ means inflammation of the skin. ‘Atopic’ refers to a group of diseases that run in families and often occur together (including, for example, hay fever and asthma). In atopic dermatitis, the skin becomes extremely itchy and inflamed, causing redness, swelling, cracking, weeping, crusting and scaling. This often occurs at creases in the elbows or knees. Atopic dermatitis most often affects infants and young children, but it can continue into adulthood or appear later in life. In most cases, there are times when the disease is worse, called exacerbations or flares, followed by periods when the skin improves or clears up entirely, called remissions. Many children with atopic dermatitis will completely recover from this skin disease when they get older, although their skin often remains dry and easily irritated. Environmental factors can bring on symptoms of atopic dermatitis at any time in someone who has inherited the atopic disease trait.

Although it is difficult to know exactly how many people are affected by atopic dermatitis, an estimated 10% of infants and young children experience symptoms of the disease. Roughly 60% of these children continue to have one or more symptoms of atopic dermatitis into adulthood. None of these people should be vaccinated against smallpox or be in close contact with someone who has been vaccinated, because of the potential risk posed by exposure to the live virus in the smallpox vaccine.

### What if there is an outbreak of smallpox?

If there is a smallpox outbreak emergency, recommendations on who should get vaccinated will change. Anyone who is directly exposed to smallpox should get vaccinated because the disease poses a greater risk than the vaccine. Public health authorities will recommend who should be vaccinated at that time.

### How can I learn more?

Talk to your health care provider if you have any questions or concerns about skin conditions.

For more information on eczema and atopic dermatitis, visit the Australian Government Department of Health and Ageing website: <http://www.health.gov.au>.

**Information sheet:****A weakened immune system means you should not get smallpox vaccine**

The smallpox vaccine is made from a live virus related to smallpox called vaccinia (not from smallpox virus). 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.

For most people, live virus vaccines are safe and effective. However, people with immune system problems are usually advised to avoid live virus vaccines because their immune systems may not be able to stop the growth of the virus in their bodies. With smallpox vaccine, while the risk for severe complications for someone with a weakened immune system is unknown, there have been cases of serious reactions to the vaccine. Someone with a weakened immune system might develop a widespread, severe, vaccinia rash (generalised vaccinia), or ongoing severe skin destruction at the vaccination site (progressive vaccinia or vaccinia necrosum).

For these reasons, some people with particular conditions should not be vaccinated against smallpox in the absence of a smallpox outbreak emergency. In an emergency, risks and priorities will change.

Conditions that mean you should not be vaccinated

- People with *suppressed immune systems* should not get the smallpox vaccine.
- People who are undergoing, or have recently undergone, *medical treatment that can weaken their immune system* should not get the smallpox vaccine.
- People in *close physical contact* with someone who falls into these categories should not get smallpox vaccine because of the risk it poses to that close contact. Close contacts include anyone living in your household or anyone you have close physical contact with, such as a sexual partner.

**What are some illnesses that can weaken the immune system?**

- Human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS)
- Cancer
- Leukaemia
- Lymphoma
- Multiple myeloma
- Primary immune deficiency disorders (such as ‘common variable immune deficiency’)
- Humoral (antibody) immunity problems (such as agammaglobulinaemia or lack of normal antibodies).

Some people with severe autoimmune diseases, such as systemic lupus erythematosus (SLE), may have significant immune system suppression.

### What else could cause a weakened immune system?

Immunosuppressive medications or other treatments, such as:

- high-dose oral or intravenous steroid therapy for two weeks or longer within the past month (eg prednisone at 2 mg/kg per day)
- cancer chemotherapy agents within the past three months
- radiation therapy within the past three months
- organ or bone marrow transplant
- medications that suppress the immune system, including steroids, some drugs for autoimmune disease, or drugs taken in association with an organ or bone marrow transplant.

If you have questions about any of the above conditions, consult your health care provider *before* being vaccinated.

### More on HIV/AIDS

Over 18,000 people in Australia may be infected with HIV and not know it. You can have HIV infection but seem completely well. If you have HIV, you are at risk of a bad reaction to smallpox vaccine, including a severe rash or a blood infection.

Factors that may place you at higher risk for having HIV infection include:

- use of needles to inject anything not prescribed by your doctor
- an accidental needlestick injury
- sexual contact with someone who has HIV/AIDS or who has had a positive test for HIV/AIDS
- sexual contact with a prostitute or someone else who accepts money, drugs or other payment for sex
- sexual contact with someone who ever has used needles to inject anything not prescribed by a doctor
- *for women:* sexual contact with a man who has ever had sexual contact with another man
- *for men:* sexual contact with another man.

If any of these situations apply to you, talk to your health care provider about getting tested for HIV before being vaccinated for smallpox.

Because some people with HIV do not have these risk factors, you should get tested if you have any concerns about HIV.

## What if there is an outbreak of smallpox?

If there is a smallpox outbreak emergency, recommendations on who should get vaccinated will change. Anyone who is directly exposed to smallpox should get vaccinated because the disease poses a greater risk than the vaccine. Public health authorities will recommend who should be vaccinated at that time.

## How can I learn more?

If have any questions about whether your immune system may be weakened, consult your health care provider.

For more information, visit the Australian Government Department of Health and Ageing website: <http://www.health.gov.au>.

## Information sheet:

# Advice for household members of people being vaccinated against smallpox

If someone you have close, physical contact with (your spouse, partner or other member of your household) is considering getting the smallpox vaccine, there are some things you should know.

## Before vaccination

The smallpox vaccine contains a live virus called vaccinia, which is related to smallpox, though milder. The vaccine does *not* contain smallpox virus.

While smallpox vaccine is safe and effective for most who receive it, people with certain health conditions are more likely to have serious reactions to the vaccine. These people should not be vaccinated and they should not be in close contact (household or similar intimate physical contact) with someone who has been vaccinated.

Careful screening measures are in place to help ensure that people who are more susceptible to serious reactions, or who live with others who are more susceptible, are not vaccinated. Because your close contact is considering vaccination, it is important that you actively participate in this screening process. Inform your close contact if you have any of the conditions listed below, or even if you have any concerns about any of them.

Health conditions that would mean you should not be in close contact with someone who has been vaccinated are:

- a diagnosis of eczema or atopic dermatitis, past or present
- a weakened immune system, for whatever reason (human immunodeficiency virus (HIV), cancer and cancer treatment, some autoimmune diseases and some treatments for autoimmune conditions can weaken the immune system)
- a skin condition with breaks in the skin (chickenpox, shingles, burns, severe acne etc)
- pregnancy.

If any of these conditions apply to you, you should not be in close contact with someone who has had smallpox vaccine because of the risk it poses to you (or your baby if you are pregnant).

## After vaccination

If neither you nor your close contact has any condition that might place you at increased risk from a serious reaction, and your close contact decides to get vaccinated, there are still some things you should keep in mind.

The main concern for people who have close, physical contact with someone who has had the vaccine is that the vaccinia virus can be spread from the vaccination site, causing rash (mild to severe), fever, and headaches and body aches. Vaccinia is spread by touching a vaccination site before it has healed or by touching bandages, clothing or other material contaminated with live virus from the vaccination site, and then touching another part of the body or touching someone else. The vaccination site often becomes itchy, which may lead to scratching, rubbing or touching the site.

Vaccinated persons can spread vaccinia to other people. In the past, when vaccination against smallpox was common, this was reported to occur between 20 and 60 times among each 1 million people vaccinated for the first time, and often involved children. Vaccinia transmission mostly happened through close contact, such as in households or similar situations, and where careful hand hygiene and care of the vaccination site had not been carried out.

People getting the vaccine will receive instructions for special care to minimise the risk of spreading vaccinia by touch, but you can also take precautions to protect yourself. These measures should be followed until the scab that forms at the vaccination site after vaccination falls off on its own (in two to three weeks).

- Do not touch the vaccination site or any materials that might be contaminated with live virus from the site (such as bandages, towels, clothing or washcloths used by the person who received the vaccine).
- If you accidentally come into contact with the vaccination site, or something that may be contaminated with live virus, immediately wash with soap and warm water.
- If you share a bed with the vaccinated person, be sure that they are wearing a gauze bandage held in place with first-aid adhesive tape over the vaccination site. As an extra precaution, the person who received the vaccine can wear a shirt or pyjamas that cover the bandaged vaccination site. If they do not, you may choose to sleep in a separate bed. (When involved in direct patient care, vaccinated health care workers cover the gauze bandage with an additional, semipermeable dressing as an extra barrier.)
- Keep a separate laundry hamper for items like clothing, towels or bedding that have come into direct contact with the vaccination site or drainage from the site. Launder these items, using hot water with detergent and/or bleach, and wash your hands carefully afterwards.
- Remind the person who received the vaccine to follow site care and handwashing instructions. If their hands are contaminated and they touch you, you could contract vaccinia.

For more information, visit the Australian Government Department of Health and Ageing website: <http://www.health.gov.au>.

## Information sheet:

# Advice for Category A smallpox contacts

## Why do I need to take action?

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

## Should I be vaccinated against smallpox?

You will be offered vaccination at a designated vaccination centre. You will be assessed at the centre three days after vaccination to see whether the vaccination has been successful. Vaccination is most effective if given within three days of exposure, and 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 a greater risk of side effects from vaccination. These will be discussed with you. It is always necessary to weigh up the risk from side effects against the risk from disease.

## What else do I need to do?

You should monitor yourself carefully for the next 16 days for symptoms of smallpox, so that infection can be detected early and you can be admitted to a specialist centre for observation or treatment. You will be given a thermometer, temperature chart and instructions on how to use them.

## How do I monitor myself for symptoms?

You should take your temperature daily, at the same time each day, with the thermometer. You should record your daily temperature measurement on the chart, and then report it to the smallpox contacts line (the phone number is given below). If your temperature rises above 38°C at any time (the red line on the chart), or if you feel unwell, you should immediately call the smallpox contacts line.

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

If you have a temperature above 38°C or feel unwell, you should stay at home.

*During the restriction period* indicated below:

- you should *not* go to work
- you should avoid contact with unvaccinated people
- you should remain within your local area.

*Outside the restriction period*, you may continue your normal activities, but you should not travel outside Australia and you should avoid travelling long distances within Australia for the next 17 days.

**Smallpox contacts line:**

**This number is staffed 24 hours a day.**

**Dates of restriction period:**

(Nine days after first exposure until 17 days after last exposure to an infectious case)

## Information sheet:

# Advice for Category B smallpox contacts

## Why do I need to take action?

You have been in contact with a patient who appears to have infectious smallpox.

However, you have not been in close contact with the patient and your risk of infection is low. As a precaution, there are a number of actions that need to be taken to protect you from infection. If the patient turns out not to have smallpox, you will be advised.

## Should I get vaccinated against smallpox?

You will be offered vaccination at a designated vaccination centre. You will given instructions on how to check that your vaccination has been effective; if you are concerned, you may return to the vaccination centre to have the vaccination site checked by a professional.

Vaccination is most effective if given within three days of exposure, and 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 a greater risk of side effects from vaccination. These will be discussed with you. It is always necessary to weigh up the risk from side effects against the risk from disease.

## What else do I need to do?

Over the next *17 days*, if you develop a high temperature (above 38°C) or if you feel unwell, you should immediately call the smallpox contacts line (the phone number is given below). This is so that any smallpox infection can be detected early and you can then be admitted to a specialist centre for observation or treatment.

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

If you have a high temperature or feel unwell, you should stay at home.

Otherwise, you may continue your normal activities, but you should not travel outside Australia for the next 17 days.

**Smallpox contacts line:**

**This number is staffed 24 hours a day.**

**Information sheet:****Advice for secondary smallpox contacts****Why do I need to take action?**

You may be spending time with a person who has had close contact with a patient who appears to have infectious smallpox.

The person you have been in contact with will be monitored for the development of symptoms of smallpox over the next 17 days. There are a number of actions that you need to take in case that person develops symptoms.

If the patient with suspected smallpox turns out not to have the disease, you will be advised.

**Should I be vaccinated against smallpox?**

You will be offered vaccination at a designated vaccination centre. You will be given instructions on how to check that your vaccination has been effective; if you are concerned, you may return to the vaccination centre to have the vaccination site checked by a professional.

Vaccination is most effective if given within three days of exposure, and 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 a greater risk of side effects from vaccination. These will be discussed with you. If you have any of these conditions, it would be preferable to avoid vaccination, and avoid spending time with the contact of the suspected smallpox patient for the next 17 days.

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

You do not need to take any special precautions, and need take no further action unless the contact of the smallpox patient develops symptoms, in which case you will be advised further. Over the next 17 days, if you have any concerns you may call the smallpox contacts line for help (the telephone number is given below).

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

No, you may carry on your normal activities. However, if you are vaccinated, you should not travel outside Australia for the next 17 days.

**Smallpox contacts line:**

**This number is staffed 24 hours a day.**

**Information sheet:****Advice about smallpox for concerned individuals****What action do I need to take?**

You have not had close contact with a smallpox patient, and therefore you do not have a significant risk of infection.

**Should I be vaccinated against smallpox?**

You do not require vaccination. Smallpox vaccine can have unpleasant and sometimes fatal side effects and is therefore not normally recommended for people who are not at significant risk of infection.

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

You do not need to take any special precautions. Over the next *17 days*, if you feel unwell or have any concerns, you may call the smallpox advice line for help (the telephone number is given below).

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

No, you may carry on your normal activities.

Smallpox advice line:

**Smallpox contacts line:**

**This number is staffed 24 hours a day.**

Part 1

Part 2

Part 3

Part 4

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Part 5

## **Part 5** References

## References

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