

Anthrax: Public health response plan for Australia

**Guidelines for preparedness, response and
management following the deliberate release
of *Bacillus anthracis***

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1. INTRODUCTION

In 2002, the Australian Government and 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 IGA established the National Counter-Terrorism Committee and national strategy supported through the National Counter-Terrorism Plan and the National Counter-Terrorism Handbook. State and territory governments have a primary operational role in dealing with terrorist situations in their jurisdictions.

The Australian Government's Disaster Response Plan (COMDISPLAN) and associated plans, which set out the Government's primary operational response to disasters, is administered by Emergency Management Australia (EMA) on behalf of the Attorney-General and is available online

(<http://www.em.gov.au/Emergencymanagement/Preparingforemergencies/Plansandarrangements/Pages/AustralianGovernmentEmergencyManagementPlans.aspx>).

In February 2003, the Australian Health Disaster Management Policy Committee (now known as the Australian Health Protection Principal Committee (AHPPC)) was established by the Australian Health Ministers' Council to better coordinate national health emergency responses, particularly mass casualty events. This group is chaired by the Australian Government Department of Health and Ageing (DoHA). It is supported by the Attorney-General's Department's, Emergency Management Australia and the Australian Government Department of Defence, and includes the Chief Health Officers of all states and territories.

In the event of an attack using anthrax in Australia, the AHPPC would quickly be convened, and become the primary, high-level, National-State health decision-making body. It would provide advice about the capacity of states and territories to deal with the health consequences of an incident and coordinate assistance between the Australian Government and the states and territories. This may include, for example, the use of the National Medical Stockpile or the transfer of patients between states.

DoHA is developing an overall CBRN Incidents of National Consequence Plan in line with the principles of the IGA and the department's lead role. This document '*Guidelines for preparedness, response and management following the deliberate release of Bacillus anthracis*', 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.

The deliberate release of *B. anthracis* spores into the environment in Australia would constitute a major public-health emergency. The public health consequences and the public's reaction would be significant and it is essential that contingency plans are available nationally and locally should such a release occur.

Purpose of this document

These guidelines outline overall policy in relation to national codes of alert for an anthrax threat or release, and the implementation of specific measures such as public education campaigns and deployment of antibiotics. They present nationally agreed case definitions and response plans, which will allow national comparison and international reporting. The guidelines also provide details, which in practice may vary between jurisdictions, of the operational aspects of a response, and suggested levels of authority within jurisdictions.

These guidelines are based on the best information available at the date of compilation. As it is likely that the guidelines will require revision in the future, it is recommended that readers check for updates on the Australian Government DoHA web site at www.health.gov.au.

2. BACKGROUND

Infectious agent

Bacillus anthracis is a Gram positive, aerobic spore-forming bacterium, approximately 1µm wide and 2–10µm long. It is easily cultured in the laboratory on simple media, and vegetative forms grow in chains. It sporulates readily, and the spores are heat resistant and persist for long periods in the environment. Virulent strains produce a toxic complex of three factors: oedema factor, protective antigen factor and lethal factor. Virulence genes can be readily detected by reference laboratories using PCR methods.

Epidemiology

The organism is generally regarded as an obligatory pathogen, whose persistence in the environment is dependent on replication in a susceptible host, in addition to the relative resistance of the spores to desiccation, heat and ultraviolet light. The disease is a zoonosis which can be contracted naturally from a number of species including cattle, sheep, goats, pigs, dogs, cats and horses, and their products such as hides and meat. Natural anthrax infection is rarely contracted through drinking milk from an infected animal.

The vegetative form of *B. anthracis* is relatively fragile and will not survive in this form in the environment. However, on release from an infected animal and exposure to air, vegetative cells sporulate and may remain viable and infectious in this form for many years in some soils. Spores are highly resistant to desiccation and much more heat resistant than the vegetative form. Animals may contract anthrax through exposure to grass and other feeds contaminated with spores of *B. anthracis*.

Human-to-human transmission of anthrax is exceedingly rare. One report of possible community transmission of cutaneous anthrax has been published. This article, published in 1975, suggests a possible link for spread of subclinical disease via communal loofahs [1]. Standard infection control precautions are adequate to prevent transmission.

Australian situation

Anthrax occurs sporadically in herbivorous animals such as cattle, sheep and goats in Australia. Only cutaneous anthrax has ever been recorded in humans in Australia. For this reason alone, a single case of either inhalational or gastrointestinal anthrax should be viewed with a high index of suspicion of deliberate release of *B. anthracis*.

In the 1920s, cutaneous cases were associated with infected shaving brush bristles. In the early 1960s a farm worker died, after he refused early medical treatment, from the complications of cutaneous anthrax contracted after conducting post mortems on sheep. Only eleven human cases were reported from 1977 to 2010. Anthrax has been nationally notifiable since 1 January 2001.

Potential for anthrax as a biological weapon

B. anthracis has major potential as a biological weapons agent because:

- it can be isolated and cultured in large quantities with relatively simple equipment and culture media;
- it produces large quantities of spores which can remain viable in the environment for many years; and
- inhalational and possibly gastrointestinal forms have a high case fatality rate.

Successful delivery of spores to produce the inhalational form of the disease requires that the agent be dispersed in an aerosolised form. Producing a powdered form with the appropriate particle size and physical properties, and which will remain suspended for sufficient periods of time to be effective, **is technologically difficult**. Lower grade material may be effective in causing large numbers of infections if dispersed in sufficient quantities. Foods adulterated with anthrax spores may be an effective vehicle for causing an outbreak of intestinal anthrax. Foods that are eaten cold are most likely to be amenable to deliberate contamination.

An anthrax release is likely to be first suspected based on the following:

- any case of inhalational or gastrointestinal anthrax
- one or more human cases of anthrax where there is no identified occupational or other epidemiological link to *B. anthracis*;
- claim of release of anthrax into the environment by an individual or group; or
- analysis of 'suspicious unidentified substances'.

Strains of *B. anthracis* isolated from the environment are generally sensitive to a number of antibiotics, including penicillins, tetracyclines, macrolides, chloramphenicol and quinolones. *B. anthracis* strains may have constitutive and inducible beta-lactamases. *B. anthracis* is resistant to cephalosporins. Because of potential for laboratory genetic manipulation of *B. anthracis*, all clinical isolates should be tested for antibiotic susceptibility by validated test methods.

Surveillance for deliberate releases of anthrax

Anthrax is an exceedingly rare disease in Australia. Only eleven cases of cutaneous anthrax have been reported since 1977, and inhalational and intestinal anthrax have never been reported in this country. A high index of suspicion of a deliberate release of anthrax should be entertained if even one case of inhalational or intestinal anthrax is diagnosed.

A deliberate release of anthrax should be considered in the event of one or more cases of human anthrax where there is no plausible occupational or other relevant contact history, or advice from State or Australian Government animal health authorities of an outbreak of anthrax in animals.

The occurrence of multiple cases of cutaneous anthrax should be interpreted in the light of the patients' histories (e.g. exposure to livestock or livestock products). If such a history exists, agricultural authorities should be consulted as part of the assessment of the likelihood of a deliberate exposure.

All cases of suspected and confirmed human anthrax should be reported immediately to the local public health unit, together with all available clinical and epidemiological information. The State/Territory health authority will advise the Communicable Diseases Network of Australia (CDNA) Secretariat of confirmed cases who will advise other State/Territory jurisdictions and the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF). State/Territory health authorities should also advise their respective departments of agriculture. Each agency should also advise their respective media response teams. A coordinated media response plan will be activated by the respective jurisdictions.

If a deliberate release of *B. anthracis* is suspected, national security agencies, including the Attorney-General's Department Crisis Coordination Centre, Australian Federal Police (AFP) and State/Territory police will also be notified.

3. CLINICAL ASPECTS OF ANTHRAX

Anthrax is an acute infection caused by *B. anthracis*. The incidence of disease, in order of decreasing frequency in **naturally** acquired cases, is: cutaneous (>95%), gastrointestinal and inhalational, although this order varies in different parts of the world. Meningitis has been reported as a secondary complication in cutaneous, inhalational and intestinal infection. Photographic images of these presentations are available at:

- <http://phil.cdc.gov/phil/default.asp>
- <http://www.bt.cdc.gov/agent/anthrax/anthrax-images/index.asp>

Initial presentation

Patients are likely to present in one of two ways, either:

- with clinical signs and symptoms where anthrax should be considered in the differential diagnosis (see below); or
- Asymptomatic and seeking post exposure prophylaxis as the result of potential exposure due to a 'suspicious substance incident'.

If the patient has symptoms of anthrax, travel, occupational and recreational histories should be taken to establish a possible epidemiological link with the disease. People who work with susceptible animals (herbivores such as cattle, sheep and goats) or their products (such as wool and hides) are at risk of the disease, particularly cutaneous anthrax.

Cutaneous anthrax

In cutaneous anthrax, infection is believed to occur by penetration of spores through a skin lesion, although in some cases the patient will not be aware of the lesion. Following the 2001 deliberate release of anthrax spores in the United States of America (USA), seven confirmed and four suspected cases of cutaneous anthrax were diagnosed. None of the patients reported skin trauma prior to the infection.

Symptoms of cutaneous anthrax begin with the appearance of a small papule at the infection site. After 1 to 2 days, the papule develops into a vesicle which ruptures to form the painless ulcer with the central necrotic dry black scab— the typical anthrax eschar. Its size ranges from about 1 cm to several centimetres across, and there is usually little or no pain, despite its ugly appearance. The eschar becomes painful only if a secondary infection (generally staphylococcal or streptococcal) occurs. The eschar is surrounded by oedema and numbers of haemorrhagic vesicles. Oedema affecting the head and neck, which is usually more extensive than on other parts of the body, may become life-threatening. Malignant oedema is a rare complication which may progress to toxæmic shock.

Findings that are strongly suggestive of cutaneous anthrax include:

- absence of pain associated with the eschar;
- extensive oedema which is out of proportion to the size of the eschar; and
- the rarity of polymorphonuclear leukocytes on Gram stain.

In uncomplicated cases, the eschar begins to resolve about 10 days after appearance of the initial infection. Surgical intervention is not indicated. Irrespective of treatment, the eschar will continue to develop, and will take 2 to 6 weeks to resolve completely. Scarring is rare. Swabs of lesions should be taken for culture and sensitivity testing (see Appendix 2).

Infectious dose

There are no data on the infectious dose for cutaneous anthrax.

Incubation period

The incubation period for cutaneous anthrax is usually 2 to 5 days [2], with a range of 12 hours to 14 days. Of 11 cases of cutaneous anthrax associated with the deliberate release of anthrax spores in the USA in 2001, the incubation periods ranged up to 10 days [3]. There are a few reports of up to 12 days [4, 5] and one report of 14 days [6]. The shortest incubation periods recorded have been one day [2, 3, 7-9] and one report of a pustule developing 12 hours after an abrasion caused by an infected horse brush [10].

Case fatality rate

The case fatality rate of untreated cutaneous anthrax is variable but low, unless complications arise. Untreated, approximately 20% of cases are fatal due to either secondary septicaemia or respiratory distress caused by cervical or upper thoracic oedema. In one case series (N=101), the case fatality rate was 3% [6]. In another series (N=27), the case fatality rate was 11% [7].

Inhalational anthrax

Symptoms of inhalational anthrax begin insidiously, and mortality rates are high, even with vigorous antibiotic therapy. It is therefore imperative that treatment is initiated as soon as the diagnosis is suspected.

Initial symptoms usually resemble those of a viral upper respiratory tract infection, and include fever, chills, malaise, myalgia and non-productive cough. Some patients may experience a brief period, of perhaps a few days, when the symptoms appear to be resolving. This is a dangerous phase as toxin accumulates. It is followed by fulminant illness, characterised by dyspnoea, stridor, cyanosis, chest pain, nausea, vomiting, prostration and shock, followed by death [11]. The duration of the fulminant phase is less than 24 hours. A recent study indicated that non-headache neurological symptoms (such as confusion, dizziness or loss of consciousness), dyspnoea, nausea or vomiting, and any finding on lung auscultation were suggestive of anthrax rather than an upper respiratory tract infection in the context of a suspected deliberate release of anthrax [12]. Chest X-rays show a widened mediastinum early in the course of the disease. All 11 cases of inhalational anthrax seen following the 2001 bioterrorist attacks in the USA had abnormal chest X-rays on initial presentation. Seven had mediastinal widening, seven had infiltrates

and eight had pleural effusion. Mediastinal widening is considered highly suggestive of inhalational anthrax (but see also 'Gastrointestinal anthrax' below).

Specimens should be taken for diagnostic testing as outlined in Appendix 2, but therapy should begin immediately, and not be delayed until after results are available. Every effort should be made to get specimens before treatment is started, which should not cause significant delay.

Infectious dose

Estimates of the infectious dose for inhalational anthrax in humans are imprecise. Based on studies in monkeys, one author made a conservative estimate of LD50 in humans of 4000 spores [4]. This figure should not be regarded as precise for various reasons, including the fact that humans are generally regarded as being more resistant to anthrax than monkeys, and the proportion of an inoculum which reaches the lungs is dependent on particle size. Other authors give an estimate of the LD50 in humans of 2500 to 55 000 spores, based on non-human primate data (quoted in [3]). Recent estimates of the human lethal dose, based on published studies in non-human primates is LD10 = 50-98 spores, and LD1 = 1-3 spores [13]. Modelling, based on the anthrax release in Sverdlovsk in the former Soviet Union in 1979, suggests that the infectious dose in humans was possibly as low as 2 spores [14]. Clearly, given the range of these estimates, any person who has been exposed to aerosolised *B. anthracis* spores should be regarded as at risk.

Incubation period

The incubation period of inhalational anthrax is usually 1 to 5 days [2], with a range up to 43 days [3, 5]. Following the deliberate release of anthrax spores in the USA in 2001, 11 people were diagnosed with inhalational anthrax. The incubation period ranged from 4 to 6 days in this series [13]. In a series of cases following an atmospheric release of anthrax in the former Soviet Union in 1979, one patient fell ill with the disease 43 days after the incident [5]. Because of the limited data available, the upper limit is not known precisely.

Case fatality rate

Untreated, the case fatality rate of inhalational anthrax approaches 100% and, even with aggressive therapy, is about 80%. In a series of cases following an atmospheric release of anthrax (N=77), the case fatality rate was 86% [5]. Following the deliberate release of anthrax spores in the USA in 2001, five of 11 patients with confirmed inhalational anthrax died, a case fatality rate of 45% [15]. Regardless of the intervention, cases which had progressed to the fulminant stage prior to commencement of treatment died [16].

Gastrointestinal anthrax

This form has two presentations: intestinal and oropharyngeal. Both are very rare diseases in developed countries, and the data on variables such as incubation periods and case fatality rates are limited.

Naturally occurring intestinal anthrax is associated with the consumption of contaminated meat. The symptoms begin insidiously with mild fever, malaise and gastrointestinal disturbance, including diffuse abdominal pain with rebound tenderness, and constipation or diarrhoea. These symptoms last for up to a few days, and are followed by the sudden onset of fever, chills, prostration and shock. Nausea and vomiting are common and, due to

ulceration of the gastrointestinal tract, vomitus is often blood-tinged or has a 'coffee grounds' appearance. Stools may be either melaenic or blood-tinged. Ascitic fluid, which ranges in appearance from clear to purulent, develops 2 to 4 days after onset of symptoms, accompanied by a reduction in the severity of abdominal pain. Mediastinal widening on chest x-ray has rarely been reported in intestinal anthrax.

Oropharyngeal anthrax is also associated with consumption of contaminated meat, but is less common than intestinal anthrax. Initial symptoms include dysphagia and dyspnoea due to cervical oedema and lymphadenopathy, secondary to necrotic ulcerations in the oropharynx. Some lesions may appear pseudomembranous [17].

Infectious dose

There are no data available on the infectious dose for gastrointestinal anthrax.

Incubation period

The incubation period of intestinal anthrax is usually 2 to 5 days [2], with a range of 15 hours to 10 days. In one outbreak of 143 cases, the incubation period was 15 to 72 hours [18]. There is one report of an incubation period of 10 days [19]. There are few data on the incubation period of oropharyngeal anthrax. In one series of cases, the range was reported as 2 to 144 hours [8].

Case fatality rate

The case fatality rate of intestinal anthrax is variable. One reviewer quoted a case fatality rate of greater than 50% [20]. However, some authors report a much lower mortality rate. In three case series from Uganda [14] (N=143), Thailand [21] (N=72) and Lebanon [19] (N=6), the case fatality rates were 6%, 4% and 17% respectively, with a weighted mean of 6%. If intestinal anthrax progresses to septicaemia, the mortality rate approaches 100%. Although data are limited, it appears that the case fatality rate of intestinal anthrax is higher in children. In two case series, all the deaths recorded were in children [18, 22].

The case fatality rate from oropharyngeal anthrax is generally reported as being lower than for intestinal anthrax, although in one series reported from Thailand, there were three deaths from 24 cases of oropharyngeal anthrax, a case fatality rate of 13% [8].

Subcutaneous anthrax

In early 2010 there was an anthrax outbreak in heroin injecting drug users in the United Kingdom and Europe with 47 confirmed cases and 13 deaths. Some cases had findings of necrotising fasciitis. In other cases toxæmia, septicaemia and neurological symptoms occurred [23]. One article has since been published reviewing 3 of the cases and suggesting that subcutaneous anthrax may be a new diagnosis of the cutaneous anthrax group. All of the cases lacked the typical cutaneous anthrax manifestations, leading to the suggestion that significant swelling, serous fluid and oedema may be characteristic of *B. anthracis* acquired by subcutaneous or intravenous inoculation [24].

Anthrax meningitis

Anthrax meningitis may be a complication of cutaneous, intestinal, inhalational, or subcutaneous anthrax, and is almost invariably fatal [20]. In a series of 42 fatal cases of anthrax which occurred as the result of an atmospheric release of *B. anthracis* spores, 50% showed histopathological evidence of meningitis [25].

Laboratory confirmation of anthrax cases

The Public Health Laboratory Network in collaboration with the Australian (Counter) Bioterrorism Laboratory Network has produced a Guideline on the Handling of Suspicious Substances¹. This guideline may be of use to medical laboratory staff where responsibilities in the Chemical, Biological and Radiological setting may include the acceptance of and/or processing of suspicious substance specimens for biological analysis, and should be read in conjunction with this document.

Collection of clinical specimens

The microbiological laboratory should be contacted for advice on the collection and preparation of specimens for transport, and advice given as to when they are likely to arrive. The clinical context should be provided with the specimen when it is sent to the laboratory—e.g. whether the patient has symptoms (and their nature) or is well with possible environmental exposure. Staff taking and handling specimens should also ensure that chain of custody of specimens is maintained to ensure they are admissible as evidence in court proceedings.

Clinical samples from a patient with suspected anthrax should not be sent to the usual diagnostic laboratory for routine culture. They should be sent directly to a specified reference laboratory able to do culture on selective media, if necessary, and properly validated PCR on suspicious specimens. Based on the clinical signs and symptoms, specimens to be taken from cases may include:

- blood for culture
- sputum
- swabs from cutaneous lesions
- faeces
- swabs from oropharyngeal lesions
- cerebrospinal (CSF) fluid².

Specimen collection and storage methods are outlined in Appendix 2.

¹ Document is available on request. Contact CBRN@health.gov.au.

² This can be extremely helpful if anthrax meningitis is present as there are a lot of large Gram positive bacilli in cerebrospinal fluid which can lead to rapid presumptive diagnosis with consistent clinical information.

Post-mortem specimens

Unless necessary for coronial or other reasons, full post-mortem examination **should not be performed, due to the risk of dissemination of spores into the environment**. If a full post mortem is undertaken, infection control practitioners should be consulted and specimens of mediastinal lymph nodes, pleural fluid, pleura, lung and spleen taken for diagnostic purposes.

When a full post mortem is not performed, the following post-mortem specimens could be taken to assist in diagnosis:

- venous blood
- nasal swabs
- swabs of haemorrhagic exudate from orifices
- aspirated pleural fluid
- samples from the centre and the periphery of the eschar
- CSF

If a limited dissection is permitted additional tissue samples may be obtained, including:

- wedge biopsy of both lungs
- biopsy of obviously involved lymph nodes
- tru-cut biopsy of solid organs

Specimen handling and transport

Clinical and environmental specimen handling and transport is subject to Commonwealth, state and territory legislation governing the transport of Biological agents (such as the Australian Dangerous Goods Code for Road and Rail and the Civil Aviation Safety Regulations for Air Transport).

Anthrax is a Tier 1 SSBA, a biological agent of the highest security concern to Australia. Handling of Tier 1 SSBA agents is subject to the National Health Security (NHS) Act 2007, NHS Regulations 2008 and the Security Sensitive Biological Agents (SSBA) Standards [26], including requirements for reporting to the Department of Health and Ageing (See <http://www.health.gov.au/SSBA>).

If you are handling or sending suspected SSBAs for confirmatory testing you must:

- comply with Commonwealth, state and territory legislation governing the transport of Biological agents (such as the Australian Dangerous Goods Code for Road and Rail and the Civil Aviation Safety Regulations for Air Transport)
- ensure that the receiving entity will accept the suspected SSBA prior to dispatch of the agent (a record must be maintained of the acceptance)
- notify the receiving entity of the shipment details
- report the transfer within two business days of the transfer occurring [27]

B. anthracis is a Risk Group 3 pathogen in accordance with the Standards Australia AS/NZS 2243.3:2010, Safety in microbiology laboratories Part 3: Microbiology. This standard prescribes the appropriate biosafety and physical containment requirements when handling this agent.

Specific protocols should be developed by each jurisdiction for the packaging and transport of specimens, including labelling as a possible/confirmed Risk Group 3 pathogen. Clinical specimens should be transported to the on-site laboratory according to routine protocols with the addition of chain-of-custody requirements. Specimens should be taken directly to the laboratory. The laboratory must be notified that specimens are being taken and when they will arrive to minimise handling and simplify chain-of-custody procedures.

Specimens or culture isolates transported to the reference laboratory by air must be packed in biohazard containers according to Civil Aviation Safety Regulations for Air Transport. The reference laboratory must be notified that samples are en route and chain-of-custody requirements must be followed. Samples must be taken directly to the laboratory. Blood culture and swab specimens can be transported at room temperature. Other body fluids, sputum and faeces should be refrigerated during transport.

Identification and characterisation of *B. anthracis*

B. anthracis is a non-motile, non-haemolytic, Gram positive bacillus. Whenever *B. anthracis* is suspected on the basis of these characteristics, the laboratory should institute appropriate containment and disinfection methods. If anthrax was not suspected and the initial characterisation performed by a clinical laboratory, specimens and cultures should be forwarded immediately to the appropriate public health reference laboratory for diagnosis and detailed characterisation. Further identification and characterisation should not be undertaken by the clinical laboratory. When the identity of the organism is confirmed by standard laboratory methods, antibiotic sensitivity studies should be undertaken by the reference laboratory as a matter of urgency. The reference laboratory should undertake testing for the presence of virulence genes by PCR methods, and independent assessment of antibiotic sensitivities.

Antibiotic sensitivity

Isolates should be tested for sensitivity to antibiotics, including benzyl penicillin, amoxycillin, ciprofloxacin, doxycycline, rifampicin and vancomycin. Results of sensitivity testing should be conveyed immediately to the treating doctor by telephone, followed by written confirmation.

Laboratory waste disposal and spills clean-up

Environmental surfaces that may have been exposed to *B. anthracis* spores should be cleaned with 0.5% hypochlorite solution, by staff using standard infection control precautions, including appropriate personal protective equipment (PPE). Buckets, mops and other equipment should be rinsed thoroughly in tap water, and waste water disposed of in accordance with State/Territory regulations. Spills of laboratory cultures of *B. anthracis* should be absorbed on to paper towels and disposed of as clinical waste. The contaminated surfaces should be treated with 2.0-2.5% sodium hypochlorite, left for one hour, and cleaned again with paper towels that are disposed of as clinical waste.

Occupational health and safety for laboratory staff

B. anthracis is a Risk Group 3 pathogen, and laboratory studies should only be undertaken in a Physical Containment Level 3 facility using a Class 1 or 2 safety cabinet, and should comply with the appropriate standards. There is no indication for antibiotic prophylaxis for laboratory staff unless there is a laboratory accident in which staff are likely to have been exposed to aerosolised spores, swallowed viable *B. anthracis*, or suffered a parenteral inoculation with the organism. Most clinical samples contain the vegetative form of anthrax which is not easily transmissible to laboratory workers [17].

Subject to the availability of a vaccine, staff who work with cultures of *B. anthracis* may be considered for vaccination. However, as there is currently no anthrax vaccine on the Australian Register of Therapeutic Goods, this could only be undertaken on a case-by-case basis, with the informed consent of the person to be vaccinated, and with the approval of the Therapeutic Goods Administration (TGA). Laboratory managers who wish to consider offering vaccination to their staff should contact the relevant public health unit for further advice (see Appendix 10: Contacts). Approval for vaccination of staff is unlikely to be given unless a Response Code 1 or higher alert is in place.

Incident response to possible deliberate release of anthrax

The *Anthrax: Public Health Response Plan for Australia* is a sub-plan of the *Domestic Response Plan for Chemical Biological and Radiological Incidents of National Consequence (Health CBRN-INC Plan)*. The Health CBRN-INC Plan sets out arrangements for Standby, Response and Standown phases. The Anthrax plan specifies five response codes for the deliberate release of anthrax. States and Territories are encouraged to consider modelling any Standard Operating Procedures (SOPs) on the five response codes to maintain consistency with other States and Territories and the Australian Government, and to facilitate a coordinated response to an event.

Australia's health approach to a possible deliberate release of anthrax spores is to maintain vigilance, with early detection of cases and exposed persons, and vigorous post exposure prophylaxis and treatment where indicated. Vaccination of high risk groups may also be considered, subject to availability of vaccine.

Rapid and effective deployment of response teams and prophylactic agents and the establishment of dedicated pre-exposure prophylaxis and treatment centres, and possibly vaccination centres, may be necessary. Where one or more human cases of anthrax are identified with no obvious occupational or other epidemiological link, skilled epidemiologists may be required to investigate the source of infection. Public concern would make effective communication strategies essential.

If a deliberate release is suspected, relevant jurisdictional police should be notified immediately and procedures instituted, to the extent possible and consistent with public health imperatives, to ensure that forensic evidence is identified and preserved. The plan incorporates actions to be taken at five response levels (Codes 0 to 4), shown in the following box.

Table 1: Australian response codes for anthrax

Response Code 0: No credible threat of release
Response Code 1: Credible threat of release
Response Code 2: Release imminent
Response Code 3: Overt release or suspected covert release
Response Code 4: Multiple releases

4. RESPONSE ACTIONS

Immediate response

If a credible threat or confirmed anthrax release, the appropriate response code will be declared by the Australian Government Chief Medical Officer (CMO), through the Australian Health Protection Principal Committee (AHPPC) and the DoHA National Incident Room will be activated. Times of operation, contact phone and fax numbers, 1800 public information numbers, email addresses and details of operational procedures will be promulgated to CDNA Jurisdictional Executive Group (CDNA-JEG) and PHLN by the Secretariat. Teleconferences will be called at the discretion of the CMO, as chair of AHPPC, or CDNA/PHLN chairs. Media liaison on the incident will be established through the National Emergency Media Response Network (NEMRN), coordinated through DoHA.

Aerosol release or suspicious substance incidents

In the event of a suspected aerosol release of anthrax spores, or the threat of a release, the police should be advised immediately by telephone. The release zone should be regarded as a crime scene, and advice sought from police. Environmental samples should be taken by emergency services personnel at the direction of public health authorities and/or police, as outlined in Appendix 5. Detailed instructions are contained within the *National Counter-Terrorism Committee Suspicious Substances/Packages Assessment Guidelines, September 2011*. Environmental samples and clinical specimens taken from those exposed should be regarded as potential forensic material, and appropriate chain-of-custody procedures put in place.

First responders and any members of the public who have possibly been exposed should be offered post-exposure prophylaxis (PEP) where indicated, as outlined in Section 5. PEP should be discontinued only if the incident is confirmed as a hoax.

A decision as to whether PEP will be offered, and to which groups, will be taken by the State/Territory health authority, in consultation with emergency services authorities. Consideration will be given to the nature of the release, credibility of threat, accessibility of the exposed zone to the community and other groups (e.g. shopping centres, office buildings or open air sporting venues). An extensive contact tracing exercise may be necessary to identify all exposed persons. Names and contact details of all exposed persons should be taken by the local health authority for follow-up purposes.

Environmental clean-up and disinfection will be undertaken as outlined in Appendix 9.

Food-borne release

If food-borne release of anthrax is suspected, or cases of gastrointestinal anthrax are diagnosed, the State/Territory health authority and police should be advised immediately. Details of the incident or outbreak should be forwarded to the chairs of AHPPC and CDNA, who may request an urgent meeting of the AHPPC/CDNA-JEG by teleconference, and the chair of Food Standards Australia New Zealand (FSANZ), who may activate the National Food Incident Response Protocol. Where indicated, States/Territories should make urgent inquiries as to the incidence and aetiology of recent cases of gastrointestinal disturbance presenting to emergency departments of hospitals in their jurisdictions.

Where a foodstuff is implicated in the outbreak, urgent consideration should be given to implementing a nationwide recall of the food, using the usual FSANZ procedures. The recall should be given the widest possible publicity by FSANZ, and through media releases and interviews/media conferences coordinated by the NEMRN. The World Health Organization (WHO) will also be advised promptly by the Australian Government.

If the implicated food has been exported to foreign countries, the operational response to the recall will be coordinated through the Australian Quarantine and Inspection Service (AQIS). The countries involved should be advised of the recall as a matter of urgency, through the Australian Government Department of Foreign Affairs and Trade (DFAT), on advice from FSANZ. If the implicated food has been otherwise exported (e.g. in meals provided to passengers on international airlines or cargo or cruise ships) the Australian Government will urgently advise WHO and the countries served by those airlines and vessels of the food recall, together with relevant epidemiological information, such as the dates on which the food may have been consumed.

PEP, where indicated (see section 5), should be offered to persons who have eaten implicated foods, and discontinued only if the foodstuff is confirmed as not contaminated with *B.anthraxis*.

Covert release

If a covert release of anthrax is suspected—e.g. one or more cases of anthrax without an obvious occupational or other epidemiological link are identified—all State/Territory health authorities should be contacted through the CDNA Secretariat, and an urgent teleconference convened to determine whether other cases may have occurred, with data collated and coordinated by the Australian Government through the AHPPC/CDNA Secretariat or the National Incident Room, as appropriate.

Where appropriate, information will be provided to the public on the status of the incident and protective measures which should be taken, through media releases, media conferences and interviews with the CMO, CHOs and their delegates. Appropriate technical information will also be provided to professional groups such as the Royal Australian College of General Practitioners, police and emergency services agencies. Extensive use will be made of the Australian Government and State health authorities' web sites, and all communications activities will be coordinated at the Australian Government level through the NEMRN.

DoHA's Health Issues Media Unit will work closely with the Public Affairs Unit of the Australian Government Attorney-General's Department which, under current National Security Public Information Guidelines, must approve all communications activities.

If a patient with anthrax has an overseas travel history which coincides with the incubation period for the disease, both the country from which the patient came and WHO will immediately be advised of the case by the Australian Government, to enable appropriate epidemiological studies and contact tracing to be undertaken. Border protection agencies (AQIS, DFAT, DIAC) and the Australian Government Department of Transport and Regional Services (DoTARS) will also be notified to enable additional controls to be implemented.

Response codes and associated actions

Response Code 0: No credible threat

Intelligence organisations advise there is no credible threat of a deliberate release of anthrax spores in Australia.

Jurisdictional actions

- Review laboratory capability, including test availability and validation, staff training, and surge capacity.
- Consider a list of high-risk laboratory personnel who may be appropriate for vaccination if available.
- Develop and implement bioterrorism (BT) training programs for health-care workers and emergency workers who would be called upon to respond to an incident.
- Develop and maintain plans for receipt of activated components of the National Medical Stockpile (NMS).
- Develop and maintain plans and logistical support for rapid distribution of antibiotics, vaccine and PPE as required.

Australian Government actions

- Regularly assess the inventory of key antibiotics in Australia e.g. doxycycline, ciprofloxacin, amoxicillin.
- If a vaccine is available, regularly assess the inventory, expiry dates and location of stocks of anthrax vaccine in Australia.
- Develop and maintain plans and logistical support for rapid deployment of antibiotics and vaccine as required.
- Develop databases for registration of exposed or symptomatic patients, clinical presentation of patients, PEP or therapy administered and adverse reactions to these, and mortality/recovery.
- Prepare content for educational materials with the Communicable Diseases Network Australia (CDNA).
- Review and update frequently asked question (FAQ) sheets for the public on the signs, symptoms, treatment, and preventive measures including personal hygiene measures, for anthrax.
- Develop the logistics for distribution of FAQ sheets (e.g. hard copy by mail, email, web sites, and newspaper advertisements). Do not distribute at this stage.
- Prepare content for posters with CDNA for hospitals and doctors' surgeries concerning procedures for decontamination of clothing if a patient presents without prior decontamination. Do not distribute at this stage.
- Prepare summary information on case detection, diagnostic testing, clinical management, and infection control for hospitals and doctors' surgeries. Don't distribute at this stage.
- Build relationships with key media personnel (see Section 4).

Response Code 1: Credible threat of release

Intelligence authorities advise that there is a credible threat of release of anthrax spores in Australia e.g. release of anthrax overseas and intelligence of threat in Australia, or overt threat from a credible terrorist group or individual. No cases of human anthrax in Australia. Actions as per Response Code 0, plus the following:

Jurisdictional actions

- If a vaccine is available, consider vaccination of the 'code 1' list of high-risk laboratory personnel. On the basis of intelligence reports, decisions are to be taken as to whether to offer vaccination to the entire code 1 list, or only those in a particular geographical location, or to defer all vaccination.
- Participate in teleconferences of the AHPPC, CDNA Jurisdictional Executive Group (CDNA-JEG) and Public Health Laboratories Network (PHLN).
- Activate logistical support for receipt of components of the NMS.
- Activate logistical support for rapid distribution of antibiotics and vaccines.
- Activate logistical support for surveillance and contact tracing.

Australian Government actions

- The Department of Health and Ageing (DoHA) will establish an Australian Government Interdepartmental Committee to deal with national policy and implementation issues.
- DoHA will convene teleconferences of the AHPPC, CDNA-JEG and PHLN.
- DoHA will assess the adequacy of antibiotic stocks, and obtain additional supplies if necessary. Deploy supplies of the stockpile as required to strategic locations as identified by State/Territory health authorities.
- If a vaccine is available, DoHA will assess the adequacy of vaccine stocks, and obtain additional supplies if necessary.
- Review and update posters for hospitals and doctors' surgeries on procedures for decontamination of clothing if a patient presents without prior decontamination.
- Review and update the summary information on case detection, diagnostic testing, clinical management, and infection control for hospitals and doctors' surgeries.
- DoHA's Health Issues Media Unit (HIMU), in conjunction with the Australian Government Chief Medical Officer and the media units of relevant national security agencies, to take a lead role in explaining to the media the nature of the heightened threat and the response required. Such communications will be approved by the Public Affairs Unit of the Australian Government Attorney-General's Department according to the current arrangements for clearance under the National Security Public Information Guidelines. These communications will include strong messages about any specific measures that may need to be taken by the general public. The HIMU will also convey relevant information to state and territory health authority media units via regular teleconferences or other means as appropriate.
- DoHA will notify the Attorney-General's Department Crisis Coordination Centre (CCC) of actions taken and provide any other information relevant to the elevated threat.

Response Code 2: Release imminent

Intelligence agencies advise that the release of anthrax spores in Australia is imminent. Actions as per **Response Code 1**, plus the following:

Jurisdictional actions

- PHLN member laboratories notify clinical laboratories.
- Clinical and reference laboratories review their ability to respond if a release occurs.

Australian Government actions

- Public health laboratories and reference laboratories to be notified by DoHA through ABLN and PHLN member laboratories. Private laboratories are covered through PHLN private laboratory representatives.
- CDNA and PHLN report to AHPPC.
- DoHA to convene an Australian Government Interdepartmental Committee.
- Distribute posters and infection control guidelines for health-care facilities to hospitals, doctors in private practice (including dermatologists, gastroenterologists and infectious diseases physicians) and postal facilities.
- It is likely in this scenario that the Australian Government's Special Incident Task Force (SITF) will be convened. DoHA is a member of that task force and will ensure open dialogue with the SITF about actions being taken by health authorities.

Response Code 3: Overt release or suspected covert release

Overt release of *B. anthracis* in Australia is identified by State/Territory health authorities, or covert release is suspected because, either:

- one or more cases of human anthrax without plausible exposure history are identified, and AHPPC considers there is adequate suspicion of possible covert release or
- intelligence agencies advise that such an event has occurred.

Actions **as per Response Codes 1 and 2**, plus the following:

Jurisdictional actions

- Reference laboratories implement staff rosters to deal with *B. anthracis* identification and additional workload.
- States and Territories to initiate logging of data on exposed or symptomatic patients, clinical presentation of patients, nature of PEP or therapy administered and adverse reactions to these, mortality/recovery. Particular attention to be paid to adverse reactions in pregnant women and children in respect of off-label indications.
- DoHA in coordination with States/Territories will distribute FAQ sheets for the public concerning signs, symptoms, treatment, preventive measures for anthrax, as required. Distribution by mail, email, web sites, newspaper advertisements.
- State health authorities notify the local police and DoHA of new cases of anthrax where criminal activity is suspected.
- Liaison with police and security agencies on new suspected or confirmed anthrax cases, by telephone in the first instance, followed up with details in hard copy.

Australian Government actions

- DoHA activates the National Incident Room (NIR) within the department.
- National data to be collated by the Australian Government.
- Liaise and share relevant data with the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF).
- DoHA's Health Issues Media Unit to activate the National Emergency Media Response Network (NEMRN), establish a national communications centre and invoke the national media response plan
- Participate in SITF.
- A suspected covert release of anthrax may constitute an act of terrorism against Australia. In this case, the National Counter-Terrorist Plan (NCTP) may be activated. The NCTP outlines responsibilities, authorities and the mechanisms to prevent or, if they occur, manage acts of terrorism and their consequences within Australia. The ramifications of any terrorist attack will necessitate high-level decision making in the Australian Government and the States and Territories.
- The response will need to take into account public anxiety and any international dimensions. The scale of the situation may also dictate special cooperative responses. Throughout the response, the primary goals are minimising loss of life, preventing further attacks, and recovery.
- Report to the World Health Organisation (WHO).

Response Code 4: Multiple releases of anthrax spores

This situation is to apply when two or more releases of anthrax spores in Australia have been confirmed, or a single release has been confirmed and intelligence agencies advise that a second release is imminent. The decision to go to Code 4 will rest with DoHA's Secretary, Deputy Secretary or Chief Medical Officer on advice from relevant intelligence agencies. Actions **as per Response Code 3**, plus the following:

Jurisdictional actions

- Manage surge capacity in health-care system.
- Report on the response and any requirements in CDNA and PHLN teleconferences.
- CDNA nominated representative informs Australian Health Protection Principal Committee (AHPPC) of status.

Australian Government actions

- Assist jurisdictions with coordination of medical response from other jurisdictions through AHPPC and EMA.
- Arrange international assistance if required.
- Extend more widely education of the public through distribution of FAQs and media advertisements.

Key stakeholders

Clear roles, responsibilities and lines of communication, both within the States and Territories concerned, and between the States and Territories and the Australian Government, are required to implement an effective response to an anthrax release.

In essence, the state and territory health authorities are responsible for disease control. The role of DoHA will include overseeing the national health response, including maintenance of the National Medical Stockpile and (in conjunction with the Attorney-General's Public Affairs Unit) coordination of the national news media response.

The response to an anthrax threat may differ between jurisdictions according to lead authority arrangements and the requirements of the State concerned. The roles and responsibilities of the Australian and State/Territory governments are set out below. Response plans should be complementary to the following Australian Government plans, coordinated from the National Incident Room, the health aspects of which are:

- a. National Health Emergency Response Arrangements
- b. Domestic Response Plan for Chemical Biological and Radiological Incidents of National Consequence (Health CBRN-INC Plan)
- c. Australian Government Disaster Response Plan (COMDISPLAN)
- d. Australian Government Overseas Disaster Assistance Plan (AUSASSISTPLAN)
- e. Australian Veterinary Emergency Plan (AUSVETPLAN)
- f. National Counter-Terrorism Plan (NCTP)
- g. National Counter-Terrorism Handbook and
- h. National Security Public Information Guidelines.
- i. Guidance on the national coordination arrangements for responding to the deliberate use of chemical biological and radiological materials

DAFF coordinates AUSVETPLAN, the national plan for dealing with exotic animal disease emergencies. DoHA has no operational responsibilities under this plan, but may provide assistance to the States and Territories under COMDISPLAN in support of AUSVETPLAN operations.

When the incident involves livestock or other animals, the State or Territory department of agriculture, primary industries or other relevant animal health authority will respond operationally according to the national AUSVETPLAN Disease Strategy for Anthrax. The Australian Chief Veterinary Officer (CVO) will also be notified of the event and national arrangements made to ensure effective management of the disease both nationally and internationally. This may involve convening the Consultative Committee on Emergency Animal Diseases (CCEAD), which will coordinate a national veterinary response to the incident.

The Australian Government Attorney-General's Department and the Crisis Coordination Centre coordinates the plans mentioned at points f, g, and h above. DoHA has operational, national coordination and media management roles in all these plans.

Roles and Responsibilities

State and territory roles and responsibilities

While each state and territory needs to determine governance structures, the guidelines advise the following model, and the States and Territories should decide on levels of authority and clarify roles and responsibilities in an anthrax event.

State and territory plans for response to an anthrax event should give consideration to:

- hoax assessment and identification of suspicious unidentified substances
- developing protocols for reporting to, and requesting assistance from, DoHA
- incident-site management planning, including defining the area of contamination, determining who has been exposed, evacuation of people at risk, containing the agent, collecting evidence and samples, sealing and/or decontamination of the affected area, and confirmation that the area is safe after decontamination
- data collection and data transfer for national collation
- operational plans for hospitals including surge capacity
- decontamination plans
- promulgation of infection-control requirements in health-care facilities and the community
- laboratory management and surge capacity
- processes for requesting vaccine and antibiotics from the Australian Government
- the State or Territory's own stock of antibiotics
- logistical arrangements for the receipt and rapid distribution of vaccine and antibiotics
- media liaison
- developing databases including:
 - PEP or therapy administered and adverse reactions to these,
 - clinical presentation of patients.
 - mortality/recovery register(s) of exposed or symptomatic patients

State and territory departments of agriculture are responsible for the response to animal health aspects of an incident.

Australian Government roles and responsibilities

The Australian Government Department of Health and Ageing will provide overall national coordination of the health response, liaise with the international community, give logistic support to States and Territories, activate the National Incident Room, and provide leadership in the coordination of national emergency media management arrangements.

Australia is signatory to the International Health Regulations (IHR) which requires notification to WHO of the release of chemical, biological or radiological agents with the potential to cause widespread injury, illness or death. DoHA is the nationally competent authority responsible for notification of WHO under the IHR.

In a large-scale emergency involving anthrax cases, it is likely that the Australian Government will form an IDC or taskforce to coordinate the work of Australian Government departments and agencies. The lead agency of the IDC or taskforce will be determined at the time of the emergency.

DoHA maintains a stockpile of antidotes, antibiotics, vaccines and treatments to be mobilised to aid in the management of a chemical or biological incident. The department, in close collaboration with state and territory Chief Health Officers or their delegates, will direct the distribution of elements of the stockpile.

The Australian Defence Force maintains the Special Operations Engineering Regiment, which may be deployed to assess and respond to CBRN incidents. The circumstances of a terrorist event will determine whether or not security agencies will declare it a national terrorist situation.

If a national terrorist situation is declared, overall responsibility for policy and broad strategy transfers to the Australian Government, in close consultation with relevant States or Territories. This may involve determining overall policy objectives, setting priorities between policy objectives where resources are inadequate, pre-positioning resources, international liaison and determining public communication messages. The Australian Government's role does not include operational management and deployment of emergency services. The Commissioners of Police, including the Commissioner of the Australian Federal Police (AFP), will determine the command and resourcing of the national police response. In other respects the management arrangements in a national terrorist situation will replicate those in other terrorist situations.

Specific response and management of an anthrax event at the Australian Government level will include:

- consultation to refine these guidelines with state and territory representatives
- assistance to States and Territories in coordinating the response, maintenance of pharmaceutical stock levels, and delivery to each state and territory according to the criteria outlined at each code level
- assistance to states and territories in provision of training materials
- communication of the national status of an event to the media and general public and to the international community through the World Health Organization
- development of databases including:
 - stock levels and deployment of vaccine and antibiotics
 - adverse reactions to vaccine
 - exposed cases and PEP.

Media response to an outbreak of anthrax infection in Australia

Background

An anthrax outbreak in Australia, either naturally occurring or from a deliberate release, would generate significant 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 be given explanations for the various actions being undertaken. One of the primary communication objectives is to instil and maintain public confidence by providing the public with information that addresses their questions, fears and concerns.

In a deliberate anthrax release, media arrangements and public statements would be coordinated as specified in the National Counter-Terrorism Committee *National Counter-Terrorism Plan 2008*.

DoHA's Health Issues Media Unit (HIMU) would play a leading role in the national coordination of health-related media responses to an anthrax outbreak. Coordination arrangements are specified within the *National Health Security Agreement*. Plans include the activation of the National Emergency Media Response Network (NEMRN) and close liaison with state and territory governments, health departments and allied organisations that would have a role during such an event.

The HIMU also provides media services to the Australian Government's Chief Medical Officer who would be a key national spokesperson during an anthrax outbreak.

The HIMU is also a key member of national security media arrangements undertaken by the Australian Government Attorney-General's Department Public Affairs Unit. The HIMU will work closely with this unit, which will approve all communications activities according to current arrangements for clearance under the National Security Public Information Guidelines.

Objectives

In an anthrax 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.

Communications activities according to response codes

Response Code 0

At 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 anthrax 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. Pre-prepared media responses directed to those groups might be useful. DoHA's Health Issues Media Unit has undertaken such work, in conjunction with national security agencies and the media advisers of state and territory health departments.

Response Code 1

HIMU, in conjunction with the 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 Code 0 communication activities.

Response Code 2

DoHA will activate a dedicated anthrax web site and a national telephone inquiry line. HIMU will collaborate closely with CDNA and media advisers in state and territory health departments, particularly in the State or Territory where the threat is imminent. HIMU 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.

Response Codes 3 and 4

The full resources of HIMU will be deployed to handle media management, and the NEMRN 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/Territory governments.

DoHA will establish a national communication centre, 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 anthrax response plans and epidemiologists from the DoHA Surveillance and Epidemiology Section. The national communication centre will respond to inquiries from the media, public and health-care providers.

5. DISEASE CONTAINMENT

Epidemiological investigation

A single case of anthrax should be considered an outbreak and should be managed with great urgency. If one or more patients seem to have been infected in an unusual way, such as no evidence of exposure to infected animals or their products, a deliberate release of anthrax organisms must be considered. Active case finding would be required.

Containment strategies

- **Control of case:** The treatment advice in the following sections is advisory only. Always consult the most recent edition of Therapeutic Guidelines: antibiotic (Therapeutic Guidelines Limited) and seek the advice of an infectious diseases physician.
- **Control of contacts:** Whilst there is no person-to-person transmission of anthrax, State/Territory health authorities will trace and follow up anyone who may have been exposed to the same source. Contacts include workers involved in environmental control.
- **Control of the environment:** Samples will be collected from the affected area and tested. The affected area will be quarantined until decontaminated. State/Territory health authorities will notify State Departments of Agriculture if an animal anthrax case is suspected.

Infection control measures

Initial patient presentation

Patients presenting with symptomatic anthrax are unlikely to be harbouring infectious spores unless these are still present in the clothing following, for example, a deliberate release of anthrax spores. Following a suspected deliberate release, the patient's skin and clothing should be regarded as infectious. The clothing should be removed and double bagged in sealed, tagged plastic bags until either decontaminated or shown to be non-infectious for a BT agent.

Other items such as watches and jewellery should be stored similarly, in separate sealed, tagged bags. All of the patient's personal effects should be handled as little as possible before bagging, and by staff wearing PPE, including contact and respiratory protection. The patient should be bathed or showered thoroughly with soap and water as soon as practicable after initiation of antibiotic therapy.

If the patient's clothing and other personal effects are negative for infectious, radiological and chemical BT agents, the items may be returned. If the patient has been exposed to an agent, their personal effects must be retained as evidence. If an item cannot safely be decontaminated and retain function, the patient should be informed and the item disposed of.

Routine patient management

Standard infection-control precautions are adequate, and should be observed with all patient contact, and when the patient is moved. Standard precautions are standard operating procedures that apply to the care and treatment of all patients, regardless of their perceived infectious risk. These precautions include aseptic technique, hand washing, use of personal protective equipment, appropriate reprocessing of instruments and equipment, and implementing environmental controls. Standard precautions should incorporate safe systems for handling blood (including dried blood), other body fluids, secretions and excretions (excluding sweat), non-intact skin and mucous membranes.

Airborne transmission from person to person does not occur with any form of anthrax. Neither a single room nor a negative pressure room is necessary. Human-to-human transmission of anthrax is extremely rare. There is one published report where community transmission of cutaneous anthrax was associated with sharing a communal loofah [1]. Skin lesions in cutaneous anthrax and faeces in intestinal anthrax may be infectious, but standard precautions will prevent transmission.

Hospital cleaning, disinfection and waste disposal

Contaminated environmental surfaces in health care facilities should be cleaned with 0.5% hypochlorite solution, by staff using standard infection control precautions, including appropriate PPE. Buckets, mops and other equipment should be rinsed thoroughly in tap water, and waste water disposed of according to State regulations.

Clinical management of patients

Most strains of *B. anthracis* are susceptible to a range of antibiotics, including penicillin, ciprofloxacin and doxycycline. Cephalosporins are ineffective for the treatment of anthrax.

Specimens should be taken for culture and sensitivities before therapy is started (see Appendix 2). For patients with clinical anthrax, these specimens should be regarded as potential forensic evidence, and the chain of custody maintained. If *B. anthracis* is suspected on the basis of a threat assessment, specimens should be sent immediately to a reference laboratory for detailed characterisation. Empirical antibiotic therapy should commence as soon as possible, and before the results of culture and sensitivity testing are known. A delay in the initiation of treatment may result in a fatal outcome.

Inhalational, gastrointestinal, subcutaneous and meningeal anthrax

Where the diagnosis is suspected but not confirmed, it will be necessary to start empirical treatment to cover the possibility of anthrax. It will also be necessary, however, to treat concurrently for other possible causes of the patient's symptoms. Recommended antibiotic treatments for inhalational, gastrointestinal, subcutaneous and meningeal anthrax are set out in Table 2.

Repeated drainage of pleural effusions is recommended in inhalational anthrax. Surgical intervention with resection of affected bowel and primary re-anastomosis, as well as antibiotic therapy and resuscitation, has also been advocated in severe cases of intestinal anthrax [19].

Table 2: Recommended treatment for inhalational, gastrointestinal, subcutaneous and meningeal anthrax. Adapted from reference [28]

	Initial therapy	Duration
Adults	Ciprofloxacin 400 mg IV 12 hourly PLUS Clindamycin 600 mg IV 8 hourly PLUS one or two of amoxy/ampicillin, benzyl penicillin, meropenem, rifampicin, vancomycin	When clinically appropriate switch to oral therapy as for cutaneous anthrax for a total of 60 days
Children	Ciprofloxacin 10 mg/kg (up to 400 mg) IV 12 hourly PLUS Clindamycin 15 mg/kg (up to 600 mg) IV 8 hourly PLUS one or two of amoxy/ampicillin, benzyl penicillin, meropenem, rifampicin, vancomycin	When clinically appropriate switch to oral therapy as for cutaneous anthrax for a total of 60 days
Pregnant women	Same as for non-pregnant adults	Same as for non-pregnant adults
Immunocompromised persons	Same as for non- immunocompromised adults and children	Same as for non- immunocompromised adults and children

Doxycycline may be less effective in anthrax meningitis due to poor CNS penetration. At the time of writing, doxycycline is not registered by the TGA for treatment or prophylaxis of anthrax

Cutaneous anthrax

Recommended treatments for cutaneous anthrax are set out in Table 3. A 60- day treatment period is recommended because of the likelihood of exposure to aerosolised *B. anthracis* in the context of a deliberate release of spores.

Table 3: Recommended treatment for cutaneous anthrax. Adapted from reference [28]

	Initial therapy	Duration
Adults	Ciprofloxacin 500 mg oral 12 hourly OR Doxycycline 100 mg oral 12 hourly. After improvement, if sensitive, Amoxicillin 500 mg oral 8 hourly	60 days
Children	Ciprofloxacin 15 mg/kg (up to 500 mg) oral 12 hourly OR Doxycycline, if > 8 yrs, 2.5 mg/kg (up to 100mg) oral 12 hourly. After improvement, if sensitive, Amoxicillin 25 mg/kg (up to 500 mg) oral 8 hourly	60 days
Pregnant women	Same as for non-pregnant adults	60 days
Immunocompromised persons	Same as for non-immunocompromised adults and children	60 days

Potential contacts, and Post Exposure Prophylaxis

Initial patient presentation

Post Exposure Prophylaxis (PEP) may be indicated after the suspected deliberate release of *B. anthracis*. Whether PEP should be offered will be determined by the level of threat, as assessed by the State or Territory health authority, in consultation with the Australian Government Department of Health and Ageing, and police and national security agencies.

Asymptomatic patients presenting after a credible suspected aerosol release of anthrax should be asked to shower with soap and water, and put on clean clothes. A release of an unidentified suspicious substance will be subject to a rapid risk assessment and on-scene screening analysis by police and emergency services scientific officers. Such screening usually eliminates the requirement for unnecessary decontamination through preliminary identification of hoax or other substances.

Following an aerosol release, the patient's clothing and other personal effects should be regarded as contaminated unless the patient has already disposed of clothing worn at the time of the incident. The clothing and other personal effects should be double bagged in sealed, labelled, plastic bags. Staff responsible for these items should also maintain the

chain of custody to ensure that they are admissible as evidence in court should criminal proceedings be undertaken. Any vehicle (e.g. car or ambulance) in which the patient has travelled since the suspected exposure should also be regarded as potentially contaminated, and either disinfected or isolated until tests have shown that *B. anthracis* is not present.

If the patient presents after a suspected food-borne release, clothing and other personal effects would not be infectious.

The treating doctor should contact the relevant public health unit for advice on the level of perceived threat, and whether PEP is indicated. Jurisdictional public health experts should provide advice regarding the exposure zone. PEP, where indicated, should commence as soon as possible, and before the results of culture and sensitivity testing are known. A delay in the initiation of treatment may result in a fatal outcome. The patient should be counselled as to the need for compliance with the recommended regimen.

Informed consent should be obtained where unregistered drugs are used and the patient advised to seek medical advice immediately if symptoms develop. The treating doctor should also consult the relevant public health unit before any diagnostic specimens, whether patient or environmental samples (e.g. suspicious substances or clothing swabs) are sent for laboratory testing. This will minimise the frequency of unnecessary requests for testing in the event of hoax incidents, and ensure that specimens are sent to the appropriate laboratory for diagnosis and characterisation where there is a genuine threat.

Diagnostic specimens

There is little predictive value in assessing whether a patient has been exposed to *B. anthracis* by taking nasal or skin swabs from persons who are well, but have had possible exposure to aerosolised anthrax. Nasal swabs would need to be collected within 30 minutes of exposure ending and prior to decontamination or blowing the nose. Particles are spontaneously cleared from the nose within this timeframe. However, if obtainable, this information may be useful for epidemiological purposes.

It may be impractical to obtain faecal specimens from an asymptomatic person possibly exposed to food-borne *B. anthracis*, however a rectal swab and an oropharyngeal swab should be considered.

Test results should be conveyed to the treating doctor, and then to the patient immediately they are available, together with advice as to the need for continued PEP and any changes to antibiotics that may be required. Changing antibiotic as a result of confirmed sensitivity should be managed carefully. Perceptions may develop that authorities are providing a 'lesser' antibiotic when changing from ciprofloxacin to amoxicillin. Good communication strategies are required around this issue. Should the specimens be negative for *B. anthracis*, advice should be sought from the relevant public health unit on the need for continued PEP.

Specific post exposure prophylaxis

When a decision has been taken to offer PEP, antibiotic therapy should commence as soon as possible, as outlined in Table 4 below. Prophylaxis should be continued until exposure to *B. anthracis* has been excluded. If *B. anthracis* exposure is confirmed, or remains uncertain, antibiotic therapy should continue for 60 days. The patient should be counselled as to the need for rigorous adherence to the regimen, and given written information about the disease, its epidemiology, symptoms and treatment. The patient should also be advised to seek medical attention immediately if symptoms develop.

Table 4: Recommended post exposure prophylaxis after exposure to *B. Anthracis*. Adapted from reference [28]

	Initial therapy	Duration
Adults	Ciprofloxacin 500 mg oral 12 hourly OR Doxycycline 100 mg oral 12 hourly	60 days
Children	Ciprofloxacin 15 mg/kg (up to 500 mg) oral 12 hourly OR Doxycycline, if > 8 yrs, 2.5 mg/kg (up to 100mg) oral 12 hourly. After culture, if sensitive, Amoxicillin 25 mg/kg (up to 500 mg) oral 8 hourly	60 days
Pregnant women	Ciprofloxacin, 500 mg bd	60 days
Immunocompromised persons	Same as for non-immunocompromised adults and children.	60 days

Amoxicillin may be suitable as an alternative therapy in children if the specific *B. anthracis* strain has been shown definitively to be sensitive to penicillin/amoxicillin.

Pharmacokinetic studies have shown that ciprofloxacin achieves far higher concentrations in lung macrophages than penicillins, and therefore may be a more effective prophylactic antibiotic. Ciprofloxacin and Doxycycline have the added advantage that they are also effective prophylactic treatments for other potential agents that may be used in deliberate release scenarios such as plague and tularemia.

Contacts of cases

Generally, there is no need to provide antibiotic prophylaxis to contacts of patients. Exceptions to this would be where the contact:

- may have also been exposed to the initial release
- is a member of the same household, and may have come into contact with the patient's contaminated clothing or other personal effects immediately after the release.

Immunisation

There is no human vaccine currently registered for general marketing in Australia. There are, however, vaccines made and approved for use in the United States of America and the United Kingdom, which may be available for use in Australia under exceptional circumstances.

Other vaccines are also under development including oral vaccines currently being assessed in clinical studies.

At present, anthrax vaccine is not available for civilian use in Australia. Subject to the availability of a vaccine in the future, it will only be provided under the Special Access Scheme administered by the TGA for those groups at highest risk of infection with *B. anthracis*, that is, laboratory staff working with cultures of the organism. Vaccination will be offered to these staff only when the threat assessment is sufficiently high. Should this policy change, advice on the place of anthrax vaccination in the prevention of this disease will be available through the relevant State/Territory public health authority (see Appendix 10: Contacts).

Adverse reactions to Anthrax Vaccine Adsorbed (AVA), the US vaccine manufactured by BioPort Corporation, are generally mild and self-limiting. Serious adverse reactions were reported at a rate of 76 per 1.8 million doses in one US study [29], and not all were causally associated with the vaccine. Two deaths were reported in that study but were not proven to be related to vaccine use. In a review of data obtained by the US Vaccine Adverse Event Reporting System (VAERS), six of 602 events judged to be clinically important were considered possibly or probably due to the vaccine [30]. These included aggravation of spondyloarthropathy (2), anaphylactoid reaction (1), arthritis (2) and bronchiolitis obliterans organising pneumonia (1).

Reports of adverse reactions to the UK vaccine, manufactured by the Health Protection Agency, are limited. In one series [31], 18% of military personnel receiving anthrax vaccination suffered incapacitation for up to 120 hours. In 74% of these (13% overall), pain at the injection site prevented lifting or driving for 48 hours. Other adverse reactions reported by the authors were mild. In another series [32], 72 reports of adverse reactions were received from 956 doses of anthrax vaccine (prevalence of 7.5%) and in 11% of recipients. Only mild adverse reactions were observed including flu-like illness, fever, malaise, arthralgia, myalgia, gastrointestinal symptoms, sinusitis, headache, paraesthesia or a general feeling of being unwell. No vaccinated person reported having been incapacitated. It is not known why incapacity was reported in one study, but not the other. Although it is possible that this was due to batch variations, there are no data to support this hypothesis.

Further information on vaccines that may be used is contained in Appendix 3. A model consent form for the administration of anthrax vaccine is contained at Appendix 4.

Environmental surveillance

Environmental sampling

Requests for environmental sampling may be made by police or public-health authorities for forensic and/or public health purposes. Initial samples will be collected, packaged and labelled for transport to the testing laboratory by emergency services personnel. Subsequent sampling may be conducted by other personnel, including contractors. Although the agency which collects the material may vary between jurisdictions, the methods used should take into account the need for personal protection and chain-of-custody requirements to be met. A model sampling protocol is outlined in Appendix 5.

Samples will only be accepted by public health reference laboratories for anthrax testing if the correct sampling, labelling and packaging procedures have been observed, approval in writing for the testing has been obtained from the appropriate public health or emergency management unit in the jurisdiction concerned, and an Analysis Request Sheet has been completed for each sample. A model Analysis Request Sheet is at Appendix 6.

Testing of suspicious substances

The extent of testing of suspicious substances will depend on the intelligence report on the possible nature of the threat. The National Counter-Terrorism Committee *Suspicious Substances/Packages Assessment Guidelines (September 2011)* provides policy and procedural guidelines relating to the testing of suspicious substances. In the absence of specific advice from intelligence agencies, the material should be assessed in the following order for (1) explosives, (2) radioisotopes and (3) toxic chemicals such as cyanide salts or neurotoxins such as cholinesterase inhibitors (nerve gases). In most jurisdictions police will assess the explosive threat. Testing for radioisotopes and chemicals will be undertaken by police, fire or ambulance services depending on jurisdictional policy and prevailing circumstances. If these agents are excluded, or intelligence suggests they are unlikely, the material should then be tested for biological agents such as pathogenic microorganisms and toxins (e.g. ricin), if warranted by the risk assessment.

Laboratories undertaking the microbiological testing should be advised of the results of environmental screening. Analysis of the sample should be undertaken in accordance with an algorithm approved by the laboratory manager.

Chain of custody of forensic evidence

In the event that a criminal prosecution is launched as a result of the incident, it will be necessary to show that the chain of custody has been maintained for all physical evidence tendered to the court. This may include, for example, tissue specimens and clothing taken from a patient. This is to ensure, among other things, that the specimen or personal effects can be identified as coming from a particular person, and that there has been no tampering with the material.

Each state and territory and the Australian Government has legislation that may vary slightly, but, in general, the collection, custody and presentation in court of evidence must be accompanied by details of the person/persons who collected it, had custody of it and analysed it. States and Territories are encouraged to develop guidelines which will ensure that their respective statutory requirements are met in relation to evidence tendered in court. These guidelines should be consistent with the National Counter Terrorism Committee *Protocols for evidentiary recovery by health professionals*.

Occupational health and safety issues

First responders to a deliberate release of anthrax spores include all emergency staff at the scene of the incident, those responsible for environmental decontamination, and health-care workers who treat persons exposed to the organism. At the time of the incident, the identity of the agent may not be known, and full protective equipment should be worn. Following an overt aerosolised release of anthrax spores, the area affected by the primary release will depend on factors such as the time and place of release, wind patterns and whether air-conditioning systems were in use. Advice will be provided by jurisdictional public-health experts as to what constitutes the exposed zone.

This zone presents a high risk of infection, and anyone entering it should wear full protective equipment. Health-care workers may be asked to enter this zone to treat casualties e.g. if an explosive device has accompanied the release of a biological agent. In this case full protective clothing should be worn. If there are no injuries, exposed persons will normally be moved from the exposed zone, through decontamination, and into a place of safety for medical assessment and commencement of prophylactic treatment. Those involved in decontamination, and others who have any contact with contaminated clothing

and fomites, should observe standard infection-control precautions including appropriate PPE against aerosol contamination.

Emergency staff who attend exposed persons after decontamination has been completed do not need to take any special precautions. For health-care workers involved in the management of hospitalised patients with all forms of anthrax, standard precautions provide sufficient protection, and mortuary staff should use similar barrier protection. More sophisticated countermeasures for airborne protection such as HEPA filter respirators are **not** required.

Specific pre and post exposure prophylaxis

There is no human vaccine for anthrax currently registered for general marketing in Australia. Emergency services personnel and others who have been inadvertently exposed to environmental sources of *B. anthracis*, where indicated, should be offered antibiotic PEP as soon as practicable after the incident, in accordance with the schedule in Table 4 Section 5. The initial therapeutic regimen may be modified after the particular strain of *B. anthracis* has been cultured and characterised.

Environmental decontamination

There are several options for environmental decontamination, including HAZMAT plans and those outlined in AUSVETPLAN, which is available at <http://www.animalhealthaustralia.com.au/programs/emergency-animal-disease-preparedness/ausvetplan/ausvetplan-manuals-and-supporting-documents/>. Model environmental decontamination protocols are outlined in Appendix 9. state and territory authorities should develop detailed plans based on one or more of these options, consistent with local occupational health and safety and environmental statutory requirements.

APPENDIX 1: Anthrax Case Definitions

Reporting

Only confirmed cases should be notified.

Confirmed case

A confirmed case requires either:

- laboratory definitive evidence; OR
- laboratory suggestive evidence AND clinical evidence.

Laboratory definitive evidence

Isolation of *Bacillus anthracis* organisms, confirmed by a reference laboratory.

Laboratory suggestive evidence

- Demonstration of *Bacillus anthracis* –like organisms by microscopic examination of stained smears; OR
- Positive nucleic acid test for *Bacillus anthracis*.

Clinical evidence

Cutaneous:

painless skin lesion evolving over 1–6 days from a papular through a vesicular stage, to a depressed black eschar invariably accompanied by oedema that may be mild to extensive;
OR

Gastrointestinal:

abdominal distress characterised by nausea, vomiting, haematemesis, bloody diarrhoea, anorexia, abdominal pain, ascites and septicaemia, and followed by fever; OR

Oro-pharyngeal:

painless, necrotic oral or oro-pharyngeal ulceration which may be pseudo-membranous, accompanied by dysphagia, dyspnoea, cervical adenopathy and cervical oedema and fever;
OR

Inhalational:

prodromal illness resembling viral infection followed by rapid onset of hypoxia, dyspnoea, cyanosis and high temperature, with radiological evidence of mediastinal widening and perhaps, pleural effusions; OR

Subcutaneous:

severe soft tissue infection, including necrotising fasciitis or severe cellulitis and abscess formation or severe sepsis in association with intravenous drug use; OR

Meningeal:

acute onset of high fever, convulsions, loss of consciousness and meningeal signs and symptoms in association with one of the other clinical syndromes.

APPENDIX 2: Patient specimen collection

Suspected cutaneous anthrax:

- For vesicular lesions, two swabs of vesicular fluid from an unopened vesicle, one for culture and the second for Polymerase Chain Reaction (PCR). Aseptically collect vesicular fluid on sterile dry swabs from previously unopened vesicles.
- For eschars, the edge should be lifted carefully and two swab samples rotated underneath and submitted, one for culture and the second for PCR.
- For ulcers, the base of the lesion should be sampled with two saline moistened swabs and submitted, one for culture and the second for PCR.
- Blood cultures obtained prior to antimicrobial therapy, if the patient has evidence of systemic symptoms.
- A full thickness punch biopsy of a papule or vesicle including adjacent skin should be obtained from all patients with a lesion being evaluated for cutaneous anthrax, to be submitted in 10 percent formalin for histopathology, special stains and immunohistochemistry (IHC). Biopsies should be taken from both vesicle and eschar, if present.
- In patients not on antibiotic therapy or on therapy for <24 hours, a second biopsy specimen should be submitted for culture and PCR
- Acute and convalescent serum samples for serologic testing.

Suspected inhalation anthrax:

- Blood cultures obtained prior to antimicrobial therapy.
- Pleural fluid, if present, for culture and PCR. Collect >1 ml of a pleural fluid into a sterile container
- CSF, in patients with meningeal signs, for microscopy, culture and PCR.
- Pleural and/or bronchial biopsies for IHC.
- Acute and convalescent serum samples for serologic testing.
- Autopsy tissues from fatal cases; See Post Mortem Specimens section (Page 11) and only proceed when sporulation has not occurred in the patient. For microbiology investigation and PCR analysis and histopathology, special stains, and IHC. The preferred specimens would be a minimum of 8 blocks and fixed tissue representing different pulmonary sites listed below:
 - Hilar lung with regional lymph nodes, bronchi, and trachea
 - Peripheral pulmonary parenchyma from both lungs
 - Specimens should be included from the major organs, particularly any organs showing significant gross or microscopic pathology.

Suspected gastrointestinal anthrax:

- Blood cultures obtained prior to antimicrobial therapy.
- Ascites fluid for culture and PCR.
- Stool or rectal swab for culture and PCR. An aseptically collected stool sample may be obtained in addition to or instead of a rectal swab. Stool: collect 5-10g in a clean, sterile, leak-proof container. Rectal swab: insert swab 2.5cm beyond the anal sphincter. Rotate swab to sample anal crypts.

- Oropharyngeal lesion, if present, for culture and PCR. Using a sterile moist swab (pre-moistened with sterile saline), aseptically swab surface and edges of suspected lesions in the oropharynx or buccal cavity, or on the tongue, tonsils or posterior pharyngeal wall, for culture and PCR.
- Acute and convalescent serum samples for serologic testing.
- CSF, in patients with meningeal signs, for microscopy, culture and PCR.
- Autopsy tissues from fatal cases; See Post Mortem Specimens section (Page 11) and only proceed when sporulation has not occurred in the patient. For microbiology investigation and PCR analysis and histopathology, special stains, and IHC

All specimens should be transported to the laboratory within an hour of collection, at room temperature. If a delay in processing is expected, specimens should be held at 2-8°C, or on wet ice, and processed within 24 hours. In addition, specimens that are not heavily contaminated should also be cultured in an enrichment broth and plated after 24 hours.

APPENDIX 3: Anthrax vaccine information for laboratory staff

There is no anthrax vaccine approved by the Therapeutic Goods Administration for human use in Australia. There are, however, vaccines made and approved for use in the United States of America and the United Kingdom, which may be available for use in Australia under exceptional circumstances. The US vaccine is known as Anthrax Vaccine Adsorbed (AVA) and is made by Bioport (Lansing, Michigan). The UK vaccine is produced by CAMR (Centre for Applied Microbiology and Research, Porton Down, UK). Neither is currently available in Australia for civilian use, but may, should circumstances change, be provided for the vaccination of laboratory staff at particular risk of exposure to *B. anthracis* in the course of their work.

Vaccination schedule

The US vaccine is given intramuscularly as a 0.5mL dose at 0, 2, and 4 weeks, with booster doses at 6, 12 and 18 months, followed by yearly 0.5ml boosters. The UK vaccine is given intramuscularly at 0, 3 and 6 weeks, with a fourth dose administered 6 months after the third, followed by yearly 0.5ml boosters.

Efficacy of the vaccine

Because of the rarity of the naturally occurring disease, few clinical trials have been undertaken with anthrax vaccine. One study in the early 1960s showed a protective efficacy of 92.5% against anthrax, predominantly the cutaneous form.

Adverse reactions to the vaccine

Adverse reactions to the vaccine are generally mild and self-limiting, and include a painful injection site, and less often, fever. In one study of the UK [22] vaccine, 18% of military personnel suffered incapacitation for up to 120 hours. In 74% of these (13% of the study group), pain at the injection site prevented lifting or driving for 48 hours. Serious adverse reactions are very rare (76 per 1.8 million doses in a US study), and not all causally associated with the vaccine. Two deaths were recorded but were not proven to be related to vaccine use.

Significance of the fact that anthrax vaccine is not registered for use in Australia

There has been no application under the Therapeutic Goods Act 1989 to register an anthrax vaccine for general use in Australia. Accordingly, the Therapeutic Goods Administration has not conducted a detailed evaluation of the safety and efficacy of the vaccine. For this reason, although vaccination of certain risk groups (e.g. some laboratory workers) may be desirable, it is necessary to obtain written informed consent from each person before vaccination commences.

If you have any concerns about the vaccine or the vaccination procedure, you should ask about these before agreeing to be vaccinated.

APPENDIX 4: Anthrax vaccine consent form

Surname: _____

Given names: _____

Address: _____

Date of birth: _____ Sex: _____

I, _____ (Full name) hereby consent / do not consent * to the administration of anthrax vaccine for myself. (* strike out whichever is not applicable)

In addition, I confirm that I understand that this product is not included on the Australian Register of Therapeutic Goods, and that it is not approved for sale in Australia, but that it has been approved for importation.

I have read the information titled 'Anthrax vaccine information sheet for laboratory staff' and dated _____ relating to the use of anthrax vaccine and understand the information presented.

I understand that I am being offered the AVA/CAMR* vaccine (* strike out whichever is not applicable).

I have discussed the use of this vaccine and the reasons that it is being offered to me with a medical officer, and have been offered the opportunity to ask questions.

I understand that I may refuse to accept anthrax vaccine without prejudicing my medical care, but that I may not be permitted to undertake certain work related activities for occupational health and safety reasons.

I understand that in accepting anthrax vaccine I do so without prejudicing my right to workers' compensation entitlements *and* I have signed this form in the presence of a health-care professional.

Signed: _____ Date: _____

I confirm that I have discussed this vaccine and its use with the above-named person.

Signed: _____ Date: _____

Printed name: _____

Position/Designation: _____

APPENDIX 5: Environmental sampling after 'suspicious unidentified substances' incidents

Introduction

Following the suspected release of *B. anthracis* spores, it may be necessary to collect environmental samples for forensic and/or public health purposes.

Detailed instructions are contained within the National Counter-Terrorism Committee *Suspicious Substances/Packages Assessment Guidelines*, September 2011, as well as the Public Health Laboratories Network *Guidelines on the handling of suspicious substances ("White powders")*, September 2006.

Outlined below is a model process for collecting, packaging and delivery of samples for microbiological testing, although it is recognised that some procedures may vary between jurisdictions.

Emergency services responsibilities at the site

- A risk assessment of the nature of the sample and its priority will be made by the emergency services, in consultation with police and intelligence agencies before collection.
- It is the responsibility of the emergency services to sample the substance, and package and transport the sample to the laboratory in a safe manner (i.e. approved packaging).
- All samples must be screened for explosives, radiation and chemicals prior to arrival at the microbiology laboratory.
- If the sample is urgent, an emergency services officer should accompany the sample to the laboratory and the laboratory informed to expect the sample.
- All requests for microbiological identification are to be approved in writing by an appropriate public health unit in the jurisdiction.
- Emergency services are responsible for safe decontamination of the area after sampling.

Collection method

- Any sampling should be conducted by persons who are competent in sample collection for the suspect agent wearing the appropriate personal protective clothing
- Most PHLN laboratories prefer a small sample (no more than 2 g) of the suspicious substance. In order to reduce the risk of aerosolisation, suspicious powders should generally be prepared in the field using distilled water to provide added protection to medical laboratory scientists. Sampling requirements should be confirmed with the relevant PHLN laboratory.
- The sample should be collected into a sterile yellow-top transparent container (MSU container, or 10mL centrifuge tube) for shipment to the laboratory. Small quantities may be collected using a sterile sampling brush or sterile (wooden) spatula.
- When collecting material, every effort will be made to avoid surface contamination of the sampling container.

Sample packaging and labelling

- Primary containers should be clearly labelled and placed in a rigid outer container that complies with packing instruction no. 602 of the *IATA Dangerous Goods Regulations*. The *National Guideline* mentions "Ziploc®" bags. These are not safe as sole containers for transport. The sample must always be placed into a clean plastic container in accordance with IATA Dangerous Goods Regulations.
- The transport container must be labelled clearly with all relevant identifier information.
- The transport container should then be immersed in a 0.5% hypochlorite solution for a period of 10 minutes to decontaminate its outer surface.
- The transport container should then be wiped down to remove residual hypochlorite and placed in an outer transport container.
- For all submissions the outer transport container should be placed into a fresh leak proof non-contaminated outer plastic (clip seal or equivalent) bag suitable for handling without personal protective attire.
- When necessary (e.g. when the sample is to be stored en route) continuity of evidence requires tamper evident sealing of the package
- The accompanying documents should be placed with the transport container and the ensemble prepared for dispatch to the receiving laboratory.
- A properly completed laboratory request form (or similar) must accompany each separate sample ensemble.
- The request form should contain a description of the incident and confirm that a risk assessment has been performed by a competent person, and the substance has been screened for chemical, explosive and radioactive hazards
- The request form should indicate to whom the report is sent and to whom copies are sent. Full contact details of the receiving person/entity must be supplied.
- Any materials used in the sampling process other than the materials going to the laboratory for analysis should be placed in an appropriate (biohazard) container for incineration.

Sample transport

The receiving laboratory must be notified prior to sample transport.

- The sample will be collected from the incident site, risk assessed and if necessary screened for potential hazards prior to transport by a designated police officer to preserve the chain of evidence.
- The sample will be registered with a unique forensic number and transported by Police.
- Upon arrival at the microbiology laboratory the sample will receive a unique laboratory number.
- The sample will be given directly to a responsible staff member who will accept the specimen for processing.
- The sample will be taken directly to the microbiology laboratory, bypassing Specimen Reception. The sample should be handed directly to the investigating microbiologist. The sample will be booked into a specific register for suspicious substance samples and the emergency services officer should make note of this information and the laboratory number assigned to the sample. Details of the incident and samples should be placed on an appropriate emergency services' register so that laboratory results may be forwarded to a known location and person e.g. forensic register, police register. It is recognised that procedures will differ slightly between States.

Chain of custody

Each sample must be accompanied by a "chain of custody form". In general the chain of custody form must contain:

- Date and time of the incident.
- Officer in charge of the incident.
- Brief description of the incident.
- Description of the sample contained within e.g., powder, granules.
- Details of all parties having responsibility for collection, packaging and transport of the specimen.
- Name of receiving laboratory person.
- Time of receipt (as there may be a delay in transit).
- Contact numbers for result communication.

Note: If it is only a sample of the suspect substance and not the whole item itself that is being tested at the PHLN laboratory, the sample can be destroyed during analysis. When there are only trace amounts of the substance in total, this must be documented on the request form so that the sample may be retained by police as evidence.

APPENDIX 6: Environmental sample analysis request sheet

Name of person requesting analysis: _____

Your reference number: _____

Name of organisation: _____

Address of organisation: _____

Contact telephone number: _____ Fax number: _____

Contact email: _____

Analysis required (sampler's comments, known hazards): _____

The following must be answered before a sample can be accepted.

Result of screening assessment and how determined:

Who made this assessment? Name _____

Does this sample contain explosive material?

Does the sample contain electronic circuitry?

Has a radiation test been carried out on the sample?

Has on-site chemical testing occurred?

Has the bioterrorism potential of this incident been assessed by a public health medical officer?

Name of medical officer: _____

Has a reference laboratory scientist been contacted?

Name of scientist: _____

Are there fatalities or people in hospital, on medication, isolated or quarantined?

Date submitted: _____ Signature: _____

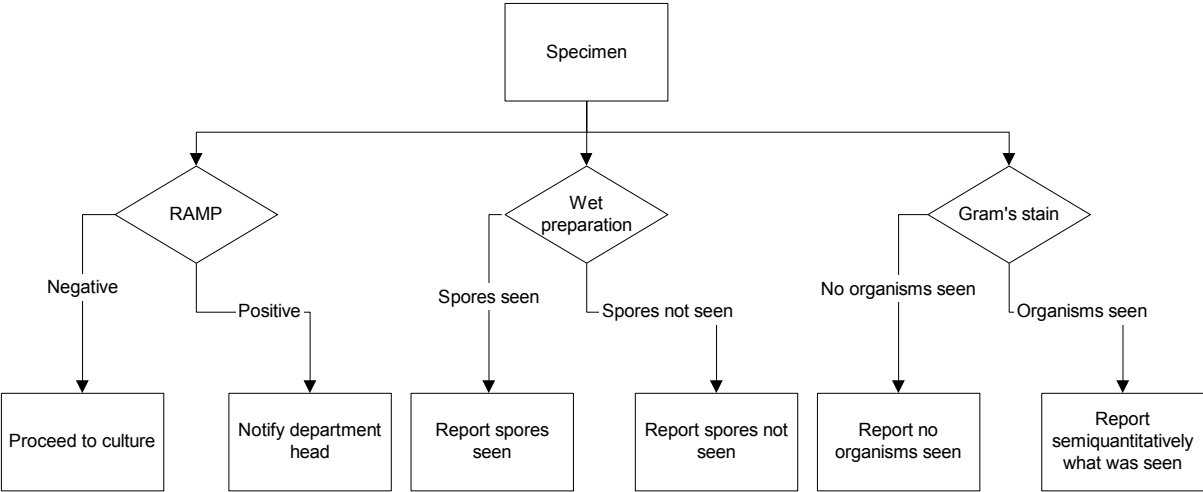
REQUEST APPROVED BY AUTHORISED PUBLIC HEALTH OFFICER

Name in full: _____

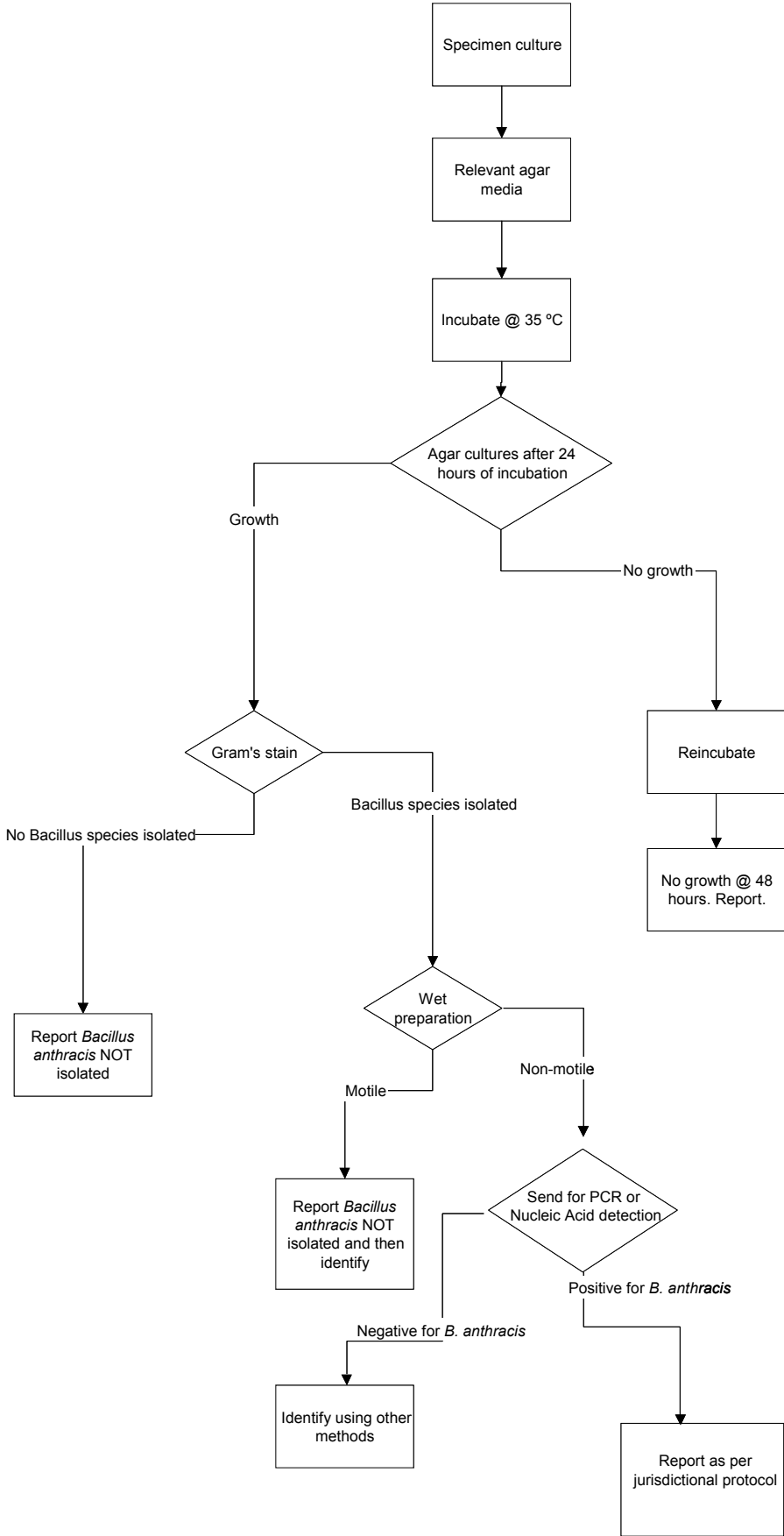
Signature: _____

Position: _____

APPENDIX 7: Initial specimen processing



APPENDIX 8: Culture of *B. anthracis*



APPENDIX 9: Environmental decontamination

Planning the disinfection process

Following the deliberate release of *B. anthracis* spores, environmental clean-up and decontamination will be undertaken by emergency services personnel. The operational procedures and methods employed, including the disinfection technology, will be dependent on a number of factors. These include the size of the contaminated zone, the nature of the material contaminated, the cost-effectiveness of decontamination versus removal and destruction of contaminated items, and the sensitivity of contaminated items to the physical and chemical agents employed. For these reasons, disinfection strategies should be developed on a case-by-case basis, with the relevant State/Territory emergency services agency taking the lead role.

All stakeholders should be consulted throughout the disinfection planning phase. These should include, as appropriate, owners and lessees of contaminated premises; police and security agencies; State and local government health and environmental protection authorities; staff representatives (e.g. unions); technical experts such as architects, engineers, microbiologists and air-conditioning experts; owners of personal property on the premises; and other affected members of the public.

A site safety plan should be developed to protect workers inside and outside the contaminated area, as well as the surrounding population. The manager overseeing the remedial work should notify employees, employee representatives and members of the public who may be affected, of the nature and scope of the work and its likely duration.

Due to the relative physical and chemical resistance of *B. anthracis* spores, disinfection is likely to be a multi-stage process, which may involve the use of several different processes and technologies. Primary considerations in selecting appropriate technologies are: the safety and effectiveness of the processes, and maintaining the functional integrity of the materials being disinfected. The various methods differ in their effectiveness on different materials—e.g. chemically reactive vs. chemically non-reactive, or porous vs. non-porous—and under different environmental conditions. Some processes may damage particular items. The best approach will have to be considered during the planning phase taking into account efficacy, product integrity and OH&S issues in respect of the operators and others who may come into contact with the contaminated materials. For example, some fumigants will adversely affect electronic devices; gamma radiation will be unsuitable for undeveloped photographic or X-ray film; and aqueous disinfectants will damage paper-based materials. In such situations, other methods should be considered, or a decision taken to destroy the item.

Although disinfection may be undertaken off-site, consideration should be given in the planning phase to the potential for spreading contamination, and to the costs of packaging and transporting contaminated materials. Should off-site disinfection be considered, the responsible authority will have to meet all State and local statutory requirements in respect of the packaging, labelling, transport and storage of biological hazards. The extent of contamination and the means whereby the organism was spread are critical in isolating affected areas and selecting appropriate decontamination methods. For example, if spores have been widely dispersed through an air-conditioning system, disinfection may involve extensive isolation and fumigation. In contrast, if the contamination is limited to a small area and spores are not likely to become airborne, then minimal isolation and disinfection methods may suffice.

The need to disinfect building systems such as air-conditioning systems and lift wells, personal effects, sensitive items such as computers and irreplaceable items such as historical archival material should also be considered in developing a disinfection plan.

Techniques used on building surfaces or items may not be effective for disinfecting ventilation systems, and if spores have been dispersed into the air, disinfection of the ventilation system may be vital to the effectiveness of the program. Disinfection plans for personal items should be developed in consultation with their owners.

Consideration should also be given to the presence of potentially hazardous materials in personal effects or other workplace materials. In areas where there is a high potential for spread of contamination—e.g. ventilation systems, lift wells and high-traffic hallways—it may be appropriate to decontaminate those areas even though sampling may show no evidence of contamination.

Finally, the disinfection plan should include a carefully developed strategy for confirming that viable *B. anthracis* has been eliminated from the site, and that chemical residues from the disinfecting agents are removed or reduced to levels that meet statutory requirements.

Preparation for disinfection

In most situations, it will be necessary to isolate the contaminated area to prevent the spread of contamination by movement of workers or equipment. The nature of the isolation methods used will depend on factors such as the size of the affected area, the types of surfaces, and the extent of contamination. The decision to establish an isolation area should be taken in consultation with relevant experts such as architects, engineers and public health officers. If the area of contamination is small, discrete and confined to limited surfaces, it may suffice to cordon off the area. Larger areas can be closed off using polypropylene sheeting, tape or other products. If needed, a higher level of isolation can be achieved by creating negative air pressure to prevent the outward flow of air. A negative pressure environment can be produced by using portable HEPA-filtered air units in the affected areas.

It may also be necessary to seal the air-conditioning ducts serving the affected area. Plastic sheeting, tape or other products may be used to minimise the movement of air in to or out of these ducts. The ducts may be sealed within the affected room or at external locations as long as the selected disinfection process (e.g. fumigation) will effectively disinfect the duct work between the room and the external seal. An air-conditioning specialist should be consulted before beginning this work.

The disinfection process should address:

- Hidden sources of contamination. Desktop computers and other objects with internal fans that draw air into the case have filters or electrostatic devices to control dust intake. These filters, the equipment chassis or some of the electronic components may be reservoirs of contamination. If the processes selected may damage the item or may not penetrate all locations, these items should be disinfected by a different process. Alternatively, excessive amounts of dirt or other organic material on the surface to be disinfected may decrease the effectiveness of the selected disinfection method. Using certain techniques, such as HEPA vacuuming, to remove some of the dirt and debris may reduce the need to perform more aggressive chemical decontamination. For example, accumulated dust inside the central processing unit due to the operation of internal fans in a desktop computer may adversely affect the efficacy of disinfection, and it may be advisable to open the case and clean the overtly dirty components before disinfecting the machine.
- Removal of items. To reduce the potential spread of contamination, items should be decontaminated in place if possible. If the selected process will destroy an item that must be retained, then the item may be removed and disinfected elsewhere. In this situation, the item must be packaged, transported and stored in a manner which complies with jurisdictional statutory requirements.

Disinfection methods

Disinfection methods can be divided into three categories:

- Surface disinfection methods are used to treat spores on hard, non-porous surfaces such as desks, walls and hard flooring.
- Fumigation involves the use of an antimicrobial gas to destroy aerosolised spores and those adhering to surfaces.
- Other decontamination products are primarily used in disinfection chambers or other specialised equipment. There are also physical methods such as peelable coatings, surface removal, dismantling and removal of selected components may be appropriate for materials unable to be decontaminated by other means.

Selection of the appropriate method will require an evaluation of the specific site conditions and nature of contamination. Other considerations include the conditions required for effective application (e.g. humidity for fumigations or pH for certain surface treatments), how the method will affect the area or item being treated, and the risks associated with use (e.g. physical, chemical and toxicological properties of the product).

Methods used on surfaces

Methods used to treat surfaces include vacuuming, which can be used on both porous and non-porous surfaces for the physical removal of spores, and liquid antimicrobial products (e.g. aqueous chlorine dioxide, sodium hypochlorite, and a combination of hydrogen peroxide and peroxyacetic acid), which are primarily used for non-porous surfaces to eliminate and/or reduce the number of spores.

High efficiency particulate (HEPA) vacuuming

Cleaning surfaces with a vacuum cleaner equipped with a HEPA filter fulfils two purposes: removal of dirt that may reduce the effectiveness of subsequent disinfection, and reduction of the number of spores to be killed by subsequent disinfection. A variety of vacuum assemblies are needed for the many surfaces and shapes to be treated.

Where possible the HEPA vacuum cleaner should be systematically applied to collect spores from the area of lowest contamination to the area of highest contamination, and from the highest to lowest elevation. The collected dust and material may be sampled to determine the presence of spores. After vacuuming, the area should be disinfected using another method and then sampled to determine whether any contamination remains.

A limitation of this method is that it only removes surface contamination (e.g. spores in the interior of a computer may not be removed effectively). The operator must also avoid allowing the exhaust to stir the air in the affected room.

Liquid antimicrobial products for impermeable surfaces

Liquid antimicrobial products may be used to inactivate spores on impermeable surfaces only. These products can be applied by pouring, mopping or spraying and include oxidising agents such as aqueous chlorine dioxide, sodium hypochlorite, hydrogen peroxide and peroxyacetic acid.

Several factors should be considered when deciding which liquid antimicrobial products to use and how to apply them. Each product affects surfaces differently in terms of corrosiveness, staining and residue. These products will be effective only if the directions for use of the product are followed precisely (e.g. mixing directions, application method and dosage rate, pre-cleaning of surfaces, and contact time).

Fumigation

Fumigation is defined as the application of a gas to reduce or eliminate spores in an indoor area (e.g. a room or building). In addition to disinfecting a variety of surfaces, fumigants are able to disinfect airborne spores that surface disinfectant would miss. Examples of fumigants are chlorine dioxide and paraformaldehyde.

Selecting a specific fumigant requires an assessment of the chemical and physical properties of the various chemicals, their toxicological properties, and their compatibility with other materials. They also vary in the rate at which they dissipate and their ability to penetrate various materials.

Determining whether to use fumigation and which fumigant to use also requires an understanding of the preparation and application requirements.

The success of fumigation will depend on:

- containing the fumigant by thoroughly sealing the area to be decontaminated
- understanding how liquid spills or organic material may absorb or chemically inactivate the fumigant
- developing means to distribute the fumigant evenly
- achieving the required temperature, humidity, and other conditions prior to commencement of fumigation
- monitoring the fumigant concentration to ensure that the required concentration is maintained for the required amount of time (taking into account potential loss of fumigant to organic items such as carpeting)
- monitoring outside the area for leaks during the fumigation process and during subsequent aeration
- following all directions and precautions specified by the manufacturer and statute for the product and in the site-specific disinfection plan
- allowing sufficient time following fumigation for aeration (i.e. off-gassing) of fumigant and by-products formed during the treatment process, and
- using qualified operators.

Other disinfection products

Methods that can be used to disinfect specific items outside the affected area or environment include chemical sterilisation and irradiation. Factors that have been used to evaluate these options include the cost and risk of transporting contaminated materials, the potential for spread of contamination, the availability of mobile equipment to bring the technology to the site, and the availability of facilities capable of performing the task.

Chemical sterilisation

In chemical sterilisation, chemicals such as ethylene oxide, chlorine dioxide or paraformaldehyde are used to kill spores on discrete items placed in a chamber. Sufficient aeration of the items following treatment is necessary to remove residual amounts of the sterilant and any toxic by-products that may have formed. For effective disinfection, specific conditions of temperature, relative humidity, concentration and duration of application must be observed for the particular sterilant used.

Irradiation

Numerous irradiation methods, including cobalt-60 and electron beam technologies, can be used to inactivate *B. anthracis*. These methods are likely to be available only off-site. They

may destroy magnetic media or chemical (e.g. silver bromide) based photographic film, and are usually expensive.

Validation of the disinfection process

Expert advice should be sought as to suitable method(s) for validating the various disinfection or sterilisation processes used. Validation methods involving culture of material for *B. anthracis* should only be undertaken by public health reference laboratories.

For items disinfected in an off-site sterilisation or disinfection chamber, it may be appropriate to place surrogate spore test strips in the chamber along with the items. Expert microbiological advice should be sought as to the nature of the test strips, the number that should be used, and their placement in the chamber (or inside the items). Each situation should be assessed on a case-by-case basis. While, for example *Bacillus stearothermophilus* spore test strips may be appropriate for validation of a steam sterilisation process, they may not be appropriate for some other methods. *B. stearothermophilus* spores may be more sensitive to certain chemicals than are *B. anthracis* spores. Post-sterilisation validation tests may be necessary, based on microbiological advice.

To determine whether disinfection of a site has been effective, a thorough round of environmental sampling should be performed following the disinfection process. Post-decontamination sampling strategies should be developed in consultation with an industrial hygienist. Samples should be cultured for *B. anthracis* by a public health reference laboratory.

Environmental sampling should be done in all disinfected sites, regardless of the disinfection method used. In areas that are disinfected by fumigation, it may be appropriate to place spore indicator strips in strategic locations prior to fumigation, to assess effectiveness of the process. Results of the culture of both environmental samples and biological indicators, if used, should be evaluated to determine the effectiveness of the process. If the first round of disinfection does not eliminate all viable *B. anthracis* spores, it may be advisable to use a different method for the second round of disinfection.

Reoccupation of the premises

On completion of the disinfection process, controls on access to the premises may be removed. Those using the premises should, however, be advised that while rigorous disinfection methods have been used to remove viable anthrax spores, and that follow-up validation of the process has been undertaken, there can be no absolute guarantee that all viable spores of *B. anthracis* have been eliminated. They should be advised that, while the risk of acquiring anthrax within the building is low, they should obtain medical advice promptly if they experience symptoms consistent with anthrax. Frequent communication with building occupants and users throughout the disinfection process provides transparency and builds trust, facilitating confidence in the efficacy of the work.

In consultation with microbiologists, public health officers and industrial hygienists, a periodic monitoring plan should be developed and implemented; including a 'sunset clause' for cessation of the program should no positive findings be made. This should include regular environmental sampling and culture for *B. anthracis*. Strategic sampling sites should be identified in the planning phase. These might include, for example, air-conditioning filters and the heat sinks or other internal components of computers where large amounts of dust accumulate.

APPENDIX 10: Key Contacts

Jurisdiction	Contact details
Australian Government	Chief Medical Officer Department of Health and Ageing (02) 6289 8408 National Incident Room (02) 6289 3030
ACT	Chief Health Officer ACT Health (02) 6205 2108
Northern Territory	Chief Health Officer Northern Territory Department of Health and Families (08) 8999 2768
NSW	Chief Health Officer NSW Health Department (02) 9391 9181
Queensland	Chief Health Officer Queensland Health (07) 3234 1137
South Australia	Chief Health Officer South Australia Health (08) 8226 6006
Tasmania	Chief Health Officer South Australia Health (03) 6222 7729
Victoria	Chief Health Officer Department of Health (03) 9096 5174
WA	Chief Health Officer Department of Health (08) 9222 2207

APPENDIX 11: Acronyms

ADF	Australian Defence Force
AFP	Australian Federal Police
AHMAC	Australian Health Ministers Advisory Committee
AHPPC	Australian Health Protection Principal Committee
AQIS	Australian Quarantine and Inspection Service
ARTG	Australian Register of Therapeutic Goods
ASIO	Australian Security Intelligence Organisation
AUSASSISTPLAN	Australian Government Overseas Disaster Assistance Plan
AUSVETPLAN	Australian Veterinary Emergency Plan
AVA	Anthrax vaccine adsorbed
BT	Bioterrorism
CAMR	Centre for Applied Microbiology and Research
CBRN	Chemical, Biological, Radiological and Nuclear
CBRN-INC	CBRN incident of national consequence
CCC	Crisis Coordination Centre
CCEAD	Consultative Committee on Emergency Animal Diseases
CDC	Centers for Disease Control and Prevention
CDNA	Communicable Diseases Network Australia
CDNA-JEG	Communicable Diseases Network Australia – Jurisdictional Executive Group
CHO(s)	Chief Health Officer(s)
CMO	Chief Medical Officer
CNS	Central nervous system
COMDISPLAN	Australian Government Disaster Response Plan
CPU	Central processing unit
CSF	Cerebrospinal fluid
CVO	Chief Veterinary Officer
CXR	Chest X-ray
DAFF	Department of Agriculture, Fisheries and Forestry
DFAT	Department of Foreign Affairs and Trade
DIAC	Department of Immigration and Citizenship
DoHA	Department of Health and Ageing
DoTARS	Department of Transport and Regional Services
EMA	Emergency Management Australia
FAQ	Frequently asked questions
FSANZ	Food Standards Australia New Zealand
HCW(s)	Health-care worker(s)
Health CBRN-INC Plan	Domestic Response Plan for Chemical, Biological and Radiological Incidents of National Consequence
HEPA	High efficiency particulate air
HIMU	Health Issues Media Unit
IATA	International Air Transport Association
IDC	Interdepartmental committee
IDER	Infectious Disease Emergency Response Working Group
IDETF	Inter-Departmental Emergency Task Force
IGA	Intergovernmental agreement
IHC	Immunohistochemistry
IM	Intramuscular
IV	Intravenous
LD1	Lethal dose for 1% of exposed individuals
LD10	Lethal dose for 10% of exposed individuals
LD50	Lethal dose for 50% of exposed individuals
MSU	Mid-stream urine
N	Number
NATA	National Association of Testing Laboratories, Australia
NCTP	National Counter-Terrorism Plan

NHEMRN	National Health Emergency Media Response Network
NHEMS	National Health Emergency Management Sub-committee
NHS	National Health Security
NHSQL	National High Security Quarantine Laboratory
NIR	National Incident Room
NMS	National Medical Stockpile
o	Oral (by mouth)
OHS	Occupational Health and Safety
PC	Physical containment (laboratory facility classification)
PCR	Polymerase chain reaction
PEP	Post Exposure Prophylaxis
PHLN	Public Health Laboratory Network
PPE	Personal protective equipment
SITF	Special Incident Task Force
SOPs	Standard Operating Procedures
SSBA	Security Sensitive Biological Agent
TGA	Therapeutic Goods Administration
VAERS	Vaccine Adverse Event Reporting System
WHO	World Health Organization

APPENDIX 12: References

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