

Guidelines for Smallpox Response and Management in the Post-Eradication Era

[Version 2]

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This document revises the *Interim Guidelines for Smallpox Management and Response in the Post-Eradication Era* - published December 2nd 2002.

Executive Summary

1. This smallpox plan outlines the pre and post-event activities that need to be, or would be undertaken, in response to a smallpox emergency.
2. Many biological agents could be used to attack civilians, however, only a few, such as smallpox virus, have the ability to cause illness or panic to the extent that existing medical and public health systems would be overwhelmed.
3. Although smallpox was declared eradicated in 1980, there remains concern that smallpox virus may exist in laboratories other than the two WHO designated repositories; the Center for Disease Control and Prevention (CDC) Atlanta, USA, and the State Research Center of Virology & Biotechnology, (the Vektor Institute) Novosibirsk, Russia.
4. If an outbreak of smallpox were to occur, several factors could contribute to a more rapid spread of smallpox than was routinely seen before this disease was eradicated. These factors include:
 - low population immunity to smallpox in the absence of naturally occurring disease and the discontinuation of routine vaccination
 - delayed recognition of smallpox by health professionals who are unfamiliar with the disease, and
 - increased mobility and crowding of the population.
5. Because of these factors, a single case of smallpox would require an immediate and co-ordinated public health and medical response to contain the outbreak and prevent further infection of susceptible individuals.
6. The plan incorporates, and extends, many of the concepts and approaches that were successfully used 30 to 40 years ago to control smallpox. It is based on the *Memorandum on the Control of Outbreaks of Smallpox* published in 1975 by the Department of Health Social Security and the Welsh Office.
7. Since National, regional and local healthcare workers, emergency planners/advisers, and a wide variety of other government departments (OGDs) are at the heart of an effective response to any smallpox emergency, their advice and guidance is continually being sought.
8. The plan will continue to be updated as experience and discussions proceed, but is however, operational and would be implemented should a smallpox emergency occur.
9. Smallpox is caused by the variola virus. The only known host is the human.

10. The most frequent mode of **transmission** is person-to-person spread via direct deposit of infective droplets onto the nasal, oral, or pharyngeal mucosal membranes, or the alveoli of the lungs from close, face-to-face contact with an infectious individual.
11. Indirect spread (not requiring face-to-face contact) via fine-particle aerosols or fomites containing the virus has been reported, but is less common.
12. In the majority of cases, **symptoms** of disease usually begin within 7-17 days (median 12) following exposure to the virus and consist of a 2-3 day prodrome of high fever, malaise, and prostration with severe headache and backache. This pre-eruptive stage of the disease is then followed by the appearance of a maculopapular rash (eruptive stage) that progresses to papules (1-2 days after appearance of rash), vesicles (4-5th day), firm pustules (by 7th day), and finally scab lesions (14th day). The rash generally appears first on the oral mucosa, face, and forearms, then spreads to the trunk and legs.
13. Lesions are also seen on the palms of the hands and soles of the feet. The skin lesions of smallpox are deeply embedded in the dermis and feel like firm round objects embedded in the skin. As the skin lesions heal and the scabs separate, pitted scarring gradually develops.
14. Smallpox patients are infectious with the onset of fever and are at their most infectious during the first week of the rash. At this time the oral mucosa lesions ulcerate and release the large amounts of virus into the saliva. Patients are less infectious once the lesions have scabbed over. A patient is no longer infectious once all the scabs have separated (usually 3-4 weeks after the onset of the rash).
15. Atypical forms of smallpox, such as haemorrhagic or flat type, occurs in around 10% of patients and these have a rapid progression with a higher mortality rate of over 95%.
16. Smallpox vaccine is a highly effective, live-virus vaccine composed of vaccinia virus, an orthopoxvirus which induces antibodies that also protect against smallpox.
17. Although smallpox vaccine is considered a relatively safe vaccine, post-vaccination adverse events can occur. Death also occurs in about one per million primary vaccinations and is usually a result of progressive vaccinia, post-vaccinial encephalitis, or severe eczema vaccinatum.
18. Several groups have a higher risk of developing post-vaccination complications. These include:
 - persons with eczema (including a history of eczema) or other forms of atopic dermatitis,
 - persons with altered immune states (e.g. HIV, AIDS, leukaemia, lymphoma, immunosuppressive drugs, etc.)
 - children aged < 1 year.

In addition, because of the small risk for fetal vaccinia, vaccination is not recommended during pregnancy.

19. Although one risk is relatively low, there is a need to consider protection of close contacts of people who have been vaccinated in view of shedding of vaccinia virus.
20. Early recognition and appropriate management of initial cases is key to rapid implementation of outbreak containment measures.
21. The first and foremost public health priority during a smallpox outbreak is control of the epidemic. The plan aims to control an outbreak by isolation of confirmed and suspected smallpox cases with contact tracing, quarantine and ring vaccination and close surveillance of contacts to these cases, as well as vaccination of the household contacts of the contacts.
22. Vaccinating and monitoring a 'ring' of people around each case and contact, will help to protect those at the greatest risk for contracting the disease, as well as form a buffer of immune individuals to prevent the spread of disease.
23. However, mass vaccination would be considered if
 - there were multiple attacks,
 - new cases arose with no epidemiological link to previous cases or
 - there was overwhelming public demand, in the face on increased threat – for example driven by cases already occurring outside the UK.
24. If the initial release was overt, with a specific event, the Home Office and Police would co-ordinate the initial response with the formation of bronze, silver and gold commands. If the initial release was covert, the Department of Health would lead.
25. Whether overt or covert, once smallpox was confirmed, central Government emergency co-ordination would immediately be activated and COBRA called.
26. As part of the plan a number of specialist healthcare and laboratory staff have been asked, as volunteers, to be part of Regional Smallpox Diagnosis and Response Groups (RSDRG). These groups have a co-ordination and organisational role. The Group will be responsible for ensuring that the planning is in place, including the provision of a Smallpox Diagnostic Expert (SDE) and the composition of Smallpox Management and Response Teams (SMART). Member of these teams will have been vaccinated in advance and would be able to deal quickly and safely with any potential smallpox outbreak
27. There is a Regional Smallpox Diagnosis and Response Group (RSDRG) in each of the nine English government regions. Each group is headed by the Regional Epidemiologist (RE) on behalf of the Regional Director of Public Health (RDPH).
28. Initial and continuation training of the Regional Response Teams, crucial for the success of any response and is underway.

29. A series of alert levels have been identified to assist planning according to the action required. Any change in the alert level would be announced by the Chief Medical Officer (CMO).
30. Suitable buildings to be used as Smallpox Care Centres, in the event of smallpox, are being identified in each region.
31. This document is organised into multiple sections and provides guidelines for many of the specific actions and procedures that should be followed in preparation for, and in response to, a smallpox emergency.
32. These sections outline criteria for smallpox response plan implementation, notification procedures for suspected cases, responsibilities and activities including some that should take place prior to a smallpox emergency. It also provides a range of appendices, figures and tables for national, regional and local health professionals, agencies and OGDs, to assist in implementation.
33. The plan is being intermeshed with emergency plans of OGDs, their agencies and the services that they oversee
34. In summary, the plan sets out the strategies and actions that would guide us through a smallpox incident. It is designed to ensure that we are fully prepared for any possible smallpox emergency should it occur inside or outside the UK.

1 Natural history and clinical features

Introduction

- 1.1 Following global eradication of smallpox in 1980, the smallpox virus has been retained legally under strict security in two World Health Organisation (WHO) collaborating centres: the Centers for Disease Control and Prevention (CDC), Atlanta, USA and the Laboratory for Applied Microbiology at Koltsovo in Novosibirsk Region, Russian Federation.
- 1.2 Although it is highly unlikely, concern remains that illicitly obtained smallpox virus could be deliberately released as a biological weapon. Without containment measures, this would almost certainly lead to rapid spread because:
 - the majority of the population of the United Kingdom, as elsewhere, is susceptible, vaccination having ceased in the 1970s
 - population mobility is far greater than thirty years ago
 - there may be delays in diagnosing the disease due to clinicians' unfamiliarity with the presenting features.
- 1.3 Since smallpox no longer exists as a naturally acquired infection, the two most likely causes for its re-emergence would be:
 - a deliberate release of the organism. This may occur without warning and it is possible that many people would be exposed, either via infected person(s) or environmental release of smallpox virus. A criminal investigation would need to proceed in parallel with the public health response.
 - an accidental release in one of the two approved collaborating centres for smallpox. This is unlikely because both laboratories undergo frequent WHO inspections and have stringent safety and security procedures in place.
- 1.4 Since the public health consequences would be severe, it is essential that contingency plans are available nationally and locally should smallpox re-emerge in the UK or elsewhere in the world.
- 1.5 This interim plan outlines the strategies and approaches that would guide national and local responses to a smallpox emergency. It is based on the *Memorandum on the Control of Outbreaks of Smallpox* published in 1975 by the Department of Health and Social Security and the Welsh Office.
- 1.6 Smallpox (variola) was one of the most severe infectious diseases affecting humans. It was present throughout the world during most of recorded history. It is specifically a human disease with no reservoir in any animal species. The infection no longer exists in nature, having been declared eradicated in 1980 following a global campaign led by the WHO.
- 1.7 Smallpox virus is a DNA virus. It is a member of the genus orthopox virus, which includes vaccinia and monkeypox. Only smallpox is readily transmissible from person to person.

1. Natural history and clinical features

- 1.8 The last community-acquired case was in Somalia in 1977. Following eradication in 1980 the WHO recommended that all countries cease vaccination. Routine vaccination in the UK and other European countries had ceased prior to this in the 1970s. Knowledge of the natural history of smallpox is from historical records and the personal experience of a relatively small number of senior physicians, virologists and epidemiologists who dealt with the disease in the past.
- 1.9 Patients are infectious with the onset of fever, however the typical vesicular rash does not appear until 4 to 7 days later. The rash is preceded by a prodromal period of 1 to 3 days of fever, malaise, headache and backache followed by 2 to 4 days of a macular rash. Clinical pictures to illustrate the rash can be found on the HPA website: www.hpa.org.uk/infections/topics_az/deliberate_release/menu.htm
- 1.10 Control and ultimately eradication of smallpox was achieved by vaccination. The vaccine is based on vaccinia virus, a live virus of low pathogenicity. Although effective in the eradication of smallpox, the vaccine can cause serious adverse effects, and for this reason vaccination in the UK was discontinued in the 1970s because the risks from vaccination outweighed the risks from disease.
- 1.11 In the absence of any clear evidence that smallpox may re-emerge, this remains the case. In the event of an outbreak, the containment strategy will centre on isolation of cases and vaccination of contacts. However, it is planned that sufficient supplies are available to vaccinate the entire population of the UK should this be deemed necessary.
- 1.12 The duration of complete immunity provided by vaccination is uncertain, but is unlikely to be more than 10 years. **Individuals vaccinated in the past are therefore unlikely to be protected** from infection although the disease may be less severe. They will develop immunity more quickly on revaccination.

Incubation period

- 1.13 For smallpox, this is usually defined as the time between exposure and onset of fever. The range given by most authorities is 7 to 17 days, **usually 10 to 16 days**, with a median of 12 days. The typical vesicular rash appears 4 to 7 days later.

Transmission

- 1.14 There is no known animal reservoir or vector for the smallpox virus. The most frequent mode of transmission is person-to-person spread via direct inoculation of infective droplets on to the oral, nasopharyngeal or respiratory mucosa during close contact with an infectious individual. From the mucosa the virus is transferred to local lymphoid tissue where replication occurs.
- 1.15 **Patients are not infectious during the asymptomatic incubation period.** They become infectious with the onset of fever. Infectiousness then increases until the onset of vesicular rash and remains high for the next 7 days.

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As a precaution, for the purpose of contact tracing, patients should be regarded as infectious from 24 hours prior to the time when fever was first recognised.

- 1.16 Patients remain infectious until the last scabs fall off. As a precaution, WHO isolation policy during the eradication campaign required that patients remain in isolation, in hospital or at home, until the last scab had separated. However, the virus shed from the skin is not highly infectious and exposure to patients in the late stages of the disease is unlikely to produce infection in susceptible contacts.
- 1.17 The most efficient transmission of smallpox occurred during **close contact with infected persons**. Household contact produces the highest attack rate, and contact in an open ward was a major cause of spread. In outbreaks in Asia and Africa, the attack rate in households varied from 37% to 96%, with some of the variation probably related to different living conditions and crowding, as well as to strain variation among variola viruses.
- 1.18 Casual contact, such as working in the same building, is much less likely to result in infection, although airborne spread of virus in draughts or air conditioning systems is known to cause transmission. Contaminated clothing or bed linen can also spread the virus.
- 1.19 Members of the SMART and those working in the Smallpox Care Centres who will be in close contact with patients, must be strict about personal protective clothing to ensure no onward transmission.

Organism survival

- 1.20 In normal environmental conditions (ambient temperature, ordinary levels of humidity and exposure to sunlight) the virus is very unlikely to survive for more than 48 hours.
- 1.21 Depending on the conditions, variola viruses can survive for long periods in dry scabs (13 years has been documented), however this is not considered to represent an infectious threat.

Clinical features

- 1.22 Smallpox has two distinct clinical forms: variola major, which produces severe smallpox, and variola minor, which is a much milder disease. Approximately 90% of cases of variola major in non-immune individuals would be expected to have the characteristic clinical presentation described below.
- 1.23 Following infection, asymptomatic viraemia develops on the 3rd or 4th day, followed by dissemination and replication in the spleen, bone marrow and lymphoid tissues. A secondary viraemia begins around the 8th day and is associated with onset of a characteristic illness around 12 days following exposure.

1. Natural history and clinical features

- 1.24 Variola major has a characteristic clinical presentation. The illness progresses as outlined below
- Sudden onset of high fever with malaise, prostration, headache and backache.
 - A macular rash develops 1 to 3 days later, firstly on the oral and pharyngeal mucosa, spreading to the face and forearms, trunk and legs.
 - The macular rash becomes papular after 1 to 2 days and then vesicular after a further 1 to 2 days. The vesicular rash is typically more prominent on the face and extremities than on the trunk (centrifugal distribution).
 - The vesicular rash becomes pustular after a further 2 to 3 days. Pustules are round, tense and deep in the dermis. They may affect the palms of the hands and soles of the feet.
 - Vesicles and pustules are typically at the same stage of development in any area of skin.
 - The pustules form scabs after 5 to 8 days.
 - The scabs gradually separate leaving characteristic pitted scarring. The scars are most evident on the face.
- 1.25 Full blood count shows a lymphocytosis or a predominance of lymphocytes, with many atypical and activated mononuclear cells. Haemorrhagic disease is preceded by a fall in the platelet count.

Differential diagnosis

- 1.26 Experience from the global eradication campaign was that atypical cases of chickenpox (varicella-zoster virus (VZV) and disseminated herpes simplex virus (HSV) infection presented the greatest difficulties in the differential diagnosis.
- 1.27 Chickenpox can be distinguished from smallpox by its much more superficial lesions, their presence on the trunk rather than on the face and extremities (centripetal distribution), and by the development of successive crops of lesions in the same area (i.e. lesions at different stages of development). The WHO has produced training materials to help health staff recognise smallpox, distinguish it from chickenpox, and avoid diagnostic errors. These materials are available electronically: <http://www.who.int/emc/diseases/smallpox/smallpox-english.ppt>
- 1.28 Disseminated HSV infection may also present a problem for differential diagnosis. However, VZV and HSV are both herpes viruses, and should be readily distinguished from orthopox virus particles by electron microscopy (EM) of vesicular fluid preparations.
- 1.29 Other causes of rash such as measles virus, enterovirus, parvovirus B19 or rubella virus may also cause uncertainty but should be distinguishable clinically, as well as in the laboratory. Molluscum contagiosum is a pox virus that may resemble variola on EM, but is usually distinguishable from smallpox on clinical grounds (lesions are umbilicated from an early stage and the patient is well).

1. Natural history and clinical features

- 1.30 The final diagnosis in consultations for suspected smallpox with a single UK smallpox panellist are listed in Table 1. These were made over a 20-year period in an immunised population, during which there was one outbreak of variola major and one of variola minor.

Table 1: Final diagnosis in consultations for smallpox

Diagnosis	Number of cases
Smallpox	4
No diagnosis, but proved not smallpox (3 cases required isolation)	15
Chickenpox	113
Papular vesicular urticaria	34
Generalised vaccinia and other reactions to vaccination	23
Staphylococcal folliculitis	9
Erythema multiforme	9
Scabies	6
Bacterial septicaemias	4
Herpes simplex	3
Secondary syphilis	2
Others included measles, Coxsackie, acute leukaemia, Anaphylactoid purpura, fungal infections, septic spots, insect bites, Pityriasis rosea, sweat rash	18

Mortality

- 1.31 Estimates of mortality are complicated by the fact that documented epidemics were modified by the presence of some immune individuals in the population or by interventional vaccination. Importation into smallpox naïve and unvaccinated populations caused the highest mortality.
- 1.32 Some clinical forms of smallpox were highly virulent (variola major) and others much less so (variola minor). The highest mortality was seen in children aged less than 1 year, in the elderly, in pregnant women who were more susceptible to haemorrhagic disease, and in people immunocompromised due to medical disorders or treatments. There are now many more vulnerable individuals in the elderly and immunocompromised groups than in the past.
- 1.33 Those who are unimmunised will suffer disease of varying severity, with an overall case-fatality rate of around 30%. Approximately 40% of cases will be severe or ‘fulminant’ with a fatality rate of over 90%.
- 1.34 Vaccinated individuals who become ill despite vaccination suffer mild or moderate disease in 95% of cases, with a case-fatality rate of less than 1%.

Atypical presentations

- 1.35 Along with the typical presentation of smallpox, two other rare forms are described: haemorrhagic and malignant smallpox.

1. Natural history and clinical features

- 1.36 Cases of haemorrhagic smallpox were uniformly fatal. They occurred among all ages and in both sexes, with pregnant women particularly susceptible. Haemorrhage into the mucous membranes and the skin accompanied the rash. Haemorrhagic smallpox was most commonly misdiagnosed as haemorrhagic chickenpox, meningococcal septicaemia or acute leukaemia.
- 1.37 Cases of malignant smallpox were characterised by lesions that did not develop to the pustular stage but remained soft and flat.
- 1.38 Vaccinated individuals may develop modified smallpox, which is a mild disease, with similar prodromal features, but only a few atypical lesions, and a mortality of well under 1%. Note however that they are still infectious.

2 Planning for smallpox

Alert levels

2.1 **Alert Levels** have been identified to assist planning according to the actions required. Alert Levels generally proceed in a stepwise fashion, but may proceed directly to level 2 or higher.

Alert levels status will be announced by CMO.

Alert Level 0:	Smallpox remains eradicated: No credible threat of a release.
Alert Level 1:	Heightened threat: Case confirmed outside UK. Confirmation of virus found outside the WHO designated repositories and intelligence suggests a credible and imminent threat of a release.
Alert Level 2:	Case confirmed in the UK.
Alert Level 3:	Outbreak occurring in the UK.
Alert Level 4:	Large or multiple outbreak not controlled by ring vaccination.
Alert Level 5:	Outbreak controlled: No further cases occurring.

Regional Smallpox Diagnosis and Response Groups

2.2 **Regional Smallpox Diagnosis and Response Groups (RSDRG)** has been established in each Standard Government Region at Alert Level 0. Each group is headed by the Regional Epidemiologist (RE) on behalf of the Regional Director of Public Health (RDPH).

2.3 RSDRG is responsible for all aspects of planning for possible outbreaks of smallpox in their Region including:

- ensuring a 24 hour emergency response to suspected and probable cases of smallpox is in place
- identifying membership for the NSOCC
- identifying, vaccinating, training and co-ordinating a team of Smallpox Diagnostic Experts (SDE) and Smallpox Management and Response Teams (SMART) and establishing the most appropriate way of working for the region depending on the geographic and demographic needs
- co-ordinating and organising vaccinations to be provided at Alert Levels 0 and monitoring vaccine side effects

- identifying healthcare, emergency, laboratory and other essential personnel who will be vaccinated at Alert Levels beyond 0
- identifying and training groups of vaccinators
- identifying Regional **Smallpox Care Centres**
- identifying Regional **Smallpox Vaccination Centres**
- training clinicians in the recognition and reporting of patients with suspicious illnesses
- distributing a Diagnostic Algorithm to clinicians through Primary Care Trusts (PCTs) and Hospital Trusts to aid the assessment of patients with suspicious illnesses
- developing and ensuring plans are in place for transfer of specimens to the designated Regional Containment 3 laboratories
- developing multi-agency partnerships with local emergency services across the Region to ensure that a co-ordinated response can be mounted to the first suspected or probable case.

Smallpox Diagnostic Experts

- 2.4 **Smallpox Diagnostic Experts (SDE)** may be Infectious Disease (ID) Physicians, or physicians from other specialties who have appropriate background and experience, who are keen to take on the role. At Alert Level 0, the SDE will be vaccinated against smallpox and given advanced training in differential diagnosis so that they are able to assess patients with suspicious illnesses safely and accurately. A network of SDE will be established and trained and co-ordinated by the RSDRG. At Alert Levels 1 or 2, more SDE will be vaccinated and trained.

Smallpox Management and Response Teams

Alert level 0

- 2.5 At Alert Level 0, each RSDRG will have at least five **Smallpox Management and Response Teams (SMART)**. These may function as predefined teams or as a panel of individuals who can be called upon to form a team as necessary to respond to smallpox and a probable case of smallpox. The roles and structure of the teams will be assessed by the RSDRG depending on Regional requirements.
- 2.6 One of these Teams will be on duty at all times to respond to suspected and probable cases of smallpox. They will be contactable through a single emergency telephone number maintained by the RSDRG. To ensure cover at all times, Regions may adopt a fixed regular on-call rota or use a panel system as necessary.
- 2.7 Allowing for regional flexibility, each SMART will consist of the following: a **Public Health Physician** (who is team leader), a **Medical Consultant** (usually an ID Physician), a **Communicable Disease Control Nurse**, a **Clinical Nurse** with experience in acute emergency medicine, and a **Paediatrician**. It is a requirement that all members of the SMART will be vaccinated against smallpox. They will be given training in smallpox diagnosis and management by national specialists and

additional general emergency medical training, such as Advanced Life Support. The SDE is a member of the RSDRG but may or may not be part of the SMART, depending on regional arrangements.

- 2.8 At Alert Level 1, the number of SMART per RSDRG will be increased to allow a response to multiple cases arising simultaneously. The numbers would depend on geographical distribution and size of the outbreak.

Smallpox Care Centres

- 2.9 Buildings suitable for use as Smallpox Care Centres will be identified in each Region, at Alert Level 0, by the RSDRG and arrangements made so that they can be activated within 24 hours if needed. The minimum specifications for these facilities and procedures for transport of patients are summarised in the appendices.
- 2.10 RSDRGs will identify, at Alert Level 0, doctors, nurses and support staff who would be willing to work in Smallpox Care Centres. This list of potential vaccines will be maintained regionally. Ideally they should have been vaccinated at some time in the past so that they could be re-vaccinated with a faster immune response and a lower incidence of side effects.
- 2.11 Observation and treatment wards will be maintained separately to ensure that possible cases are not exposed to infection.
- 2.12 All possible and probable cases will be vaccinated on admission to protect them from infection by confirmed cases if the diagnosis of smallpox is subsequently excluded.

Smallpox vaccination strategy

- 2.13 Vaccine against smallpox contains a live vaccinia virus which produces cross immunity against variola major and minor.
- 2.14 Targeted vaccination and monitoring of contacts, together with isolation of cases, is the mainstay of containment. The containment of transmission depends on early detection of cases and tracing and vaccination of contacts.
- 2.15 This strategy of **ring vaccination** will be used initially to control an outbreak (i.e. Alert level 2/3), and is compatible with WHO recommendations.

Smallpox Vaccination Centres

- 2.16 Vaccination will be carried out at Smallpox Vaccination Centres. Suitable sites will be identified by RSDRG at Alert Level 0, so that they can be activated immediately, if required.

- 2.17 Arrangements for the distribution and administration of vaccine will be made at Alert Level 0.
- 2.18 Vaccination of different groups (healthcare, emergency and essential workers, and contacts) will be required, and a strict triage system will be necessary to ensure prioritisation of vaccine supplies.

Laboratory networks

- 2.19 Laboratory networks will be an essential component to the early diagnosis and response to initial cases.
- 2.20 The collection and transport of clinical specimens from suspected smallpox cases, including the equipment and procedures for taking specimens is described in the Appendices.
- 2.21 Laboratory testing of clinical specimens from initial suspected cases will involve EM at one of the designated Containment 3 Regional laboratories, followed by confirmation by PCR at a Reference Laboratory.
- 2.22 Rapid real-time PCR tests for orthopox, varicella zoster and herpes simplex viruses are currently being evaluated, and it is planned that these could be made available to selected Containment 3 regional laboratories in the future.
- 2.23 Pre-exposure vaccination is required for staff who might be involved in handling clinical specimens from the initial suspected cases. At Alert Level 0, a small number of staff at designated Containment 3 regional laboratories and the reference laboratories will be vaccinated. In the event of an Alert Level 1, a larger number of laboratory staff will be vaccinated in case they are required to handle specimens. They should be identified at Alert Level 0 and should be available to provide 24/7 cover.
- 2.24 It is possible that viral particles resembling smallpox may be identified on routine EM of vesicular fluid. In this event, the specimen should be sent immediately to a reference laboratory according to the procedures described in Appendix 2. The virologist must also immediately inform the referring clinician who should arrange for a Smallpox Diagnostic Expert to assess the patient.

Training

- 2.25 An essential part of preparedness is training. Each SMART should include training in the recognition of smallpox and its differential diagnosis for all members of the teams.
- 2.26 Local, regional and national testing of the plan and its components, will be an essential part of the training.

2.27 Clinicians will be offered training and a Diagnostic Algorithm will be distributed to all clinicians to assist them with the assessment of patients with suspicious illnesses.

2.28 Diagnostic Algorithms will be distributed from the RSDRG via local PCTs and Hospital Trusts who will add the contact details of local SDE.

Definition of outbreak

2.29 In general, the term outbreak is used for a situation when diseases or health events occur at a greater than normal rate than expected, in a specific period and place. An outbreak can be when:

- the occurrence of a greater number of cases or events than would normally occur in the same place compared to the same duration in the past years
- a cluster of cases of the same disease occurs which can be linked to the same exposure.

3 Assessment and management of initial cases

Case definitions and laboratory investigation

- 3.1 The preliminary definitions given below may require revision by clinicians and public health personnel depending upon the scale of the outbreak.
- 3.2 **Clinical case definition.** An illness with acute onset of fever $>38^{\circ}\text{C}$, which is persistent, followed by a rash without other apparent cause characterised by vesicles or firm pustules at the same stage of development and with a predominantly centrifugal distribution. The case definition above describes the typical presentation of smallpox. The predictive value of this clinical case definition is likely to be low in the absence of circulating smallpox. Atypical presentations (haemorrhagic and malignant), and modified smallpox must also be considered.
- 3.3 Laboratory criteria for confirmation. Smallpox viruses are classified as hazard group 4 organisms and must be handled accordingly. Clinical samples from suspected cases must be handled with due regard to the likelihood that smallpox is present, and the appropriate procedures observed. Should it be necessary to conduct work other than in a Containment 4 laboratory, a full risk assessment must be conducted.
- 3.4 The importance, and methods, of laboratory confirmation depend on the epidemiological situation:
- **Electron microscopy (EM).** In the initial cases or unrelated cases in a new geographical area, EM identification of orthopox virus in a patient with symptoms compatible with the clinical case definition indicates a probable case of smallpox. During an outbreak, in the presence of an epidemiological link to other confirmed cases, EM identification of orthopox virus may be regarded as confirmatory.
 - **Polymerase chain reaction (PCR)** and viral isolation from culture (Containment 4 laboratories only). Confirmation using these techniques is required for initial cases or unrelated cases in a new geographical area. They may also be of critical importance in distinguishing cases of variola and generalised vaccinia. Definitive diagnosis of smallpox will be based on the DNA sequence of PCR amplicons and the characteristics of viral isolates.
- EM takes 2 hours and PCR takes 6 hours from receipt of specimens until results can be provided.
- 3.5 In a case with strongly suspicious clinical features and no other diagnosis, failure to detect any organism with EM or PCR does not exclude smallpox, and such cases may be regarded as probable.
- 3.6 If a large outbreak occurs, laboratory capacity will soon be overwhelmed. In this instance, priority for laboratory resources will include:

3. Assessment and management of initial cases

- Testing of clinical specimens from cases with unclear clinical presentations following expert assessment.
- Testing of clinical or environmental specimens that will provide information about a potential source of exposure to facilitate case detection and law enforcement activities. This will depend on circumstances.

In these circumstances, specimens will be triaged by local infectious disease physicians, virologists and public health physicians, according to guidelines issued by the National and Regional Smallpox Outbreak Control Centres.

- 3.7 **Suspected:** a case of fever and rash consistent with the clinical case definition, without laboratory confirmation or an epidemiological link to other cases. Initial cases of smallpox, or unrelated cases in a new geographical area are likely to present as suspected cases.
- 3.8 **Probable:** a case of fever and rash consistent with the clinical case definition, plus:
- For initial cases of smallpox or unrelated cases in a new geographical area - EM identification of orthopox virus or a case with strongly suspicious clinical features and no other diagnosis.
 - During an outbreak - an epidemiological link to a confirmed case.
- 3.9 **Confirmed:** a case of fever and rash consistent with the clinical case definition, plus:
- For initial cases of smallpox or unrelated cases in a new geographical area - laboratory confirmation by PCR or viral isolation.
 - During an outbreak - an epidemiological link to a confirmed case and EM identification of orthopox virus or a case with strongly suspicious clinical features and no other diagnosis.
- 3.10 **Possible:** acute onset of fever but without a rash consistent with the case definition in a person with an epidemiological link to a confirmed case. The fever may be accompanied by prodromal symptoms such as prostration, severe headache or backache, rigors and generalised maculopapular rash. Control of an outbreak will depend on early identification and management of new possible cases, prompt isolation of cases and vaccination of contacts.

3. Assessment and management of initial cases

Table 2: Summary of case classification

Classification	Fever *	Rash *	EM Identification of orthopox	PCR Positive For smallpox	Epidemiological link to another confirmed case of smallpox
Suspected (Initial cases or during outbreak)	+	+	-	-	-
Probable: Initial cases	+	+	+/-#	-	-
	+	+	-	-	+
Confirmed: Initial cases	+	+	+	+	-
	+	+	+/-#	-	+
Possible (During outbreak)	+	-	-	-	+

* Fever and rash consistent with the case definition.

EM not required if the case has strongly suspicious clinical features with no other diagnosis.

The diagnosis of suspected or probable cases according to the clinical case definition requires assessment by a Smallpox Diagnostic Expert.

Diagnosis and response to initial cases

3.11 Early recognition and appropriate management of initial cases is key to rapid implementation of outbreak containment measures. At Alert Levels 0 and 1, the aim will be to alert clinicians to the possibility of a case of smallpox, raise awareness of the presenting symptoms and signs, and encourage appropriate and rapid reporting of patients with suspicious illnesses for further assessment.

Management of initial cases

3.12 Patients with suspicious illnesses may present at a variety of different sites as listed below (in addition, smallpox virus may be seen on routine EM of vesicular fluid). For example:

- At a patient's home
- At a GP Surgery
- At a hospital
- At a Port Health Control Unit.

3.13 General and specific management in the event for each of these scenarios is described in flowchart format at the end of this document.

3.14 Clinicians should assess these patients according to the Diagnostic Algorithm. If they are unable to exclude the diagnosis of smallpox, they should contact their local SDE to request a further assessment. Whilst waiting for the SDE, the referring clinician should remain at the scene, isolate the patient as best as

3. Assessment and management of initial cases

possible, and try and ensure that close contacts of the patient remain close by or record details of those who have left or have to leave.

3.15 SDE will visit the patient, at the site, to make a further assessment. They should use appropriate infection control measures including non-sterile gloves, disposable gowns, head, face and eye protection and shoe covers, in order to minimise the personal contamination and spread on clothing. There are four potential outcomes:

- Smallpox can be excluded on the basis of clinical assessment. The patient can be handed back to the referring clinician for further management.
- Smallpox is highly unlikely but laboratory confirmation of other diagnosis (e.g. atypical chickenpox) is required. The SDE may arrange to send diagnostic specimens to the designated Containment 3 Regional laboratory to confirm the diagnosis and exclude smallpox if necessary, without alerting SMART.
- Differential diagnosis includes smallpox. The patient is now a suspected case of smallpox. Responsibility for management transfers to the SDE. The SDE should contact the SMART and request that they visit the patient on site. On arrival the SMART will take on the responsibility for the management and investigation of the patient. Appropriate treatment for other possible diagnosis should be initiated. The local Consultant in Communicable Disease Control (CCDC) should also be informed.
- The clinical features are strongly suggestive of smallpox and there is no other likely diagnosis. The patient is now a probable case of smallpox. Responsibility for management transfers to the SDE. The SDE should contact the SMART to arrange immediate transfer to isolation facilities, where the physician in charge will take responsibility for the patient including laboratory investigation and further management. Note that patients should not be transferred out of an ICU.

3.16 Local arrangements for the SDE contacting the SMART will apply. However, they must immediately notify:

- the designated Containment 3 Regional Laboratory that they may expect specimens for EM. The Regional laboratory will in turn immediately notify a Reference laboratory.
- the **RE** or **RDPH**, who will in turn notify:
 - Chief Executive of the **Strategic Health Authority** and lead **PCT**
 - Local **police forces** - that there is a suspected case, and that escort to and security at the scene may be required.
 - Local **ambulance services** - that a Containment 3 infectious removal may be required.
 - **Hospital isolation facilities** - that a bed may be required.
 - The local **CCDC**.

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- The local **Health Emergency Planning Advisor**.
- The DH and the **Communicable Diseases Surveillance Centre (CDSC)** would be responsible for national liaison.

3.17 While awaiting the arrival of the SMART, and later while awaiting laboratory results, management of suspected or probable cases requires three key principals, irrespective of the site:

- **Patient care.** The patient should be kept comfortable, and supportive treatment should be provided. This may necessitate transfer to isolation facilities at any stage.
- **Infection control.** Entry and exit of persons and fomites from the potentially contaminated area must be strictly controlled. This may require the assistance of the police to maintain a protective cordon. Potentially contaminated fomites should be placed in yellow clinical waste bags at the earliest opportunity.
- **Preliminary identification of contacts.** The interval should be used for:
 - Establishing the date from which the patient should be regarded as potentially infectious – this is 24 hours prior to the time when the fever was first recognised.
 - Obtaining a detailed account of the patient's movements while potentially infectious and during the incubation period (7-17days, usually 10 –16 days). This is both in order to identify primary contacts, and to investigate potential sources of infection. (It is more difficult to get this information from the patient after admission to hospital.). Use this information to begin drawing up a list of primary contacts.

3.18 Contacts who are present at the site should be encouraged to stay there until smallpox can be excluded or confirmed. This is to facilitate infection control, and because they may then be given immediate vaccination by the SMART if smallpox is confirmed. If this is not possible, full contact details should be obtained.

3.19 Immediate transfer may be requested by the SDE for probable cases of smallpox (unless already in ICU), or for suspected cases that are outside hospital but whose condition is causing concern or deteriorating. In this event the SDE should accompany the patient but must ensure that the referring clinician is able to maintain infection control measures at the site. The SMART will split:

- The Medical Consultant and clinical nurse (and Paediatrician if appropriate) will join the patient at hospital isolation facilities.
- The Public Health Consultant and Communicable Disease Control Nurse will go to the site to ensure that infection control measures are maintained and begin contact identification and tracing.

3.20 Otherwise the SMART will attend the patient with their allocated equipment and supplies. The SMART paediatrician could replace the physician if the patient is under 16 years old.

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- 3.21 When they reach the patient and/or site, responsibility for management transfers to the SMART, and at least one member of the Team should stay with the patient and at the site until smallpox can be confirmed or excluded.
- 3.22 After a clinical assessment, the SDE or SMART will send **diagnostic clinical specimens** for EM. A minimum of four specimens of vesicle fluid should be sent to the nearest designated Containment 3 Regional laboratory, or directly to a Reference laboratory if this is closer.
- 3.23 Ideally one member of the SMART will personally transport specimens and hand over to laboratory staff to ensure correct delivery. On receipt of the specimens the Regional laboratory will immediately dispatch at least two of them to a Reference laboratory for confirmatory tests. Transport of specimens from the field to Regional laboratories and from Regional to Reference laboratories may require a blue light escort for speed. Regional variations of transport arrangements may be necessary. Safe handling, control of infection procedures during transport of specimens etc will be covered during training of the SMART.
- 3.24 If this is not practical on a regional basis, local arrangements should be in place to ensure that the sample is delivered to an identified person in the laboratory.
- 3.25 If diagnoses other than smallpox are also considered possible, the SDE or SMART will send additional relevant specimens and initiate or continue appropriate treatments according to normal procedures.
- 3.26 Further specific management depends on the location of the patient. The on duty SMART will attend and commence clinical and public health management of suspected or probable cases. If they are required to spend long periods at the site whilst awaiting results, if their workload becomes excessive, or if additional suspected or probable cases arise, they may call for support from other SMART in the same or adjacent regions.
- 3.27 EM results should be available within 6 hours of dispatch of specimens from anywhere in the UK. There are three potential EM results:
- Organism other than smallpox detected (e.g. a herpes virus) – this may be regarded as a **negative result**. The SDE and SMART should refer the patient to appropriate local services.
 - No organism detected – this should be regarded as an **equivocal result**, and the diagnosis of smallpox should not be excluded until there has been confirmation by a Reference laboratory.
 - Orthopox particles detected – this should be regarded as a provisionally positive result, indicating a **probable case**, pending a confirmation by the Reference laboratory.

Action for initial probable cases

- 3.28 The patient will be transferred to isolation facilities if this has not already happened. Ideally, one of the High Security Infectious Disease Units (HSIDU)

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(Coppett's Wood Hospital, North London or Newcastle General Hospital, Newcastle upon Tyne) should be used. However, it may be necessary to use an alternative ID unit if:

- the patient's life will be put at risk by a prolonged ambulance transfer.
- there are large numbers of initial probable or confirmed cases and the high security units are full.

- 3.29 RSDRGs should therefore examine local hospital isolation facilities to determine which ones might be used for the care of initial probable cases of smallpox.
- 3.30 The patient will be transferred in an ambulance, using standard procedures for a Containment 3 infectious removal, accompanied by the SMART Medical Consultant, Clinical Nurse, and Paediatrician if appropriate. The ambulance crew should have minimal contact with the patient who will be handled by members of the team. A police escort is likely to be required. One relative or friend (a parent if the case is a child) may also accompany the patient.
- 3.31 After the ambulance crew has delivered the patient to the isolation facilities, they will park in a secure area, thoroughly clean the vehicle with disinfectant (0.1% hypochlorite) and then lock it. They will then remove and dispose of protective clothing, and shower and change where these facilities are available. They will then leave their contact details with SMART before going off shift pending PCR results. If PCR is positive they will be vaccinated immediately (unless already vaccinated within the previous 6 months).
- 3.32 The SMART Public Health Physician and/or Communicable Disease Control Nurse will remain at the site to ensure that infection control measures are maintained, continue contact identification and tracing, and begin vaccinating contacts if the case is confirmed.
- 3.33 Diagnosis of a probable case will lead to mobilisation of a public health response including preparation of Smallpox Care Centres and Smallpox Vaccination Centres, contact tracing and deployment and distribution of vaccine supplies. However, vaccination should be deferred until confirmation by PCR.
- 3.34 PCR results should be available within 12 hours of dispatch of specimens from anywhere in the UK. A positive PCR is required for confirmation of initial cases. However, in a case with strongly suggestive clinical features and no other diagnosis, smallpox should not automatically be excluded on the basis of a negative PCR result. The case should be reviewed and laboratory tests repeated if necessary.

Action for initial confirmed cases

- 3.35 Until further staff can be immunised, care of the initial confirmed cases, first at hospital isolation facilities and then at Smallpox Care Centres will have to be carried out by SMART members supported by SDE, HSIDU and other staff who have been vaccinated.

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- 3.36 The site at which the patient presented (home, GP surgery, hospital ward) etc. may need to be evacuated until it can be decontaminated. Other areas which the patient may also have contaminated should be identified.
- 3.37 National and Regional Smallpox Outbreak Co-ordination Centres (NSOCC and RSOCCs) will be convened to co-ordinate the public health response and monitor the epidemiological picture.
- 3.38 Major control plans will be initiated with a response at local, regional and national level as described in *Deliberate Release of Biological and Chemical Agents* (DH, March 2000).
- 3.39 Rapid health alerts by CMO's Public Health Cascade and HPA rapid alert system will be sent out for enhanced surveillance for other cases. This will include activation of NHS Direct pathways.
- 3.40 Designated Smallpox Care Centres will be activated as soon as the Alert Level is declared by the CMO, as these will be required to receive new patients once the high security beds are occupied. They will need to be opened within 24 hours of confirmation of the first case.
- 3.41 Designated Smallpox Vaccination Centres will also be activated as soon as possible. These will be required for vaccination of contacts of cases.
- 3.42 Vaccination of contacts will proceed. Further healthcare, laboratory, emergency and other essential personnel, including a large number of additional SMARTs and SDE, as identified at alert level 0, will be vaccinated to allow a response to multiple cases arising simultaneously.

Cases arising in hospital

- 3.43 Cases may be detected in A & Es, general hospital wards, ICUs or ID units. Contacts in the hospital may be particularly susceptible to infection due to immunosuppressive disorders or treatments, or general ill health. Attack rates in hospital outbreaks of smallpox have been high and strict infection control measures are needed.
- 3.44 If a patient with a suspicious illness is recognised, the Hospital Infection Control Team and Trust Management should be informed as early as possible. If possible, hospital air conditioning systems should be turned off immediately and remain off until smallpox has been excluded or decontamination completed. The hospital should have arrangements appropriate to their hospital layout and ventilation systems. This may necessitate deployment of alternative cooling facilities.
- 3.45 The Hospital Infection Control Team should assist the SMART in identifying all areas that the patient has passed through in order to guide implementation of infection control measures. The SMART will provide expert advice on strict

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infection control measures, which may include the closure of the A&E ward or the whole hospital.

- 3.46 Identification of contacts will require consideration of airflows within the hospital. Tracing of contacts will include other inpatients, discharged patients who were in contact with the case during their hospital stay, visitors to the hospital, and staff. Vaccination should be prioritised to those who have had the closest and most prolonged contact with cases.
- 3.47 Depending on the structure of the hospital, and airflow within it, consideration may be given to vaccinating all patients, visitors, staff and others who have been present in the building with an infectious case. At Alert Level 0, Hospital Infection Control Teams should examine their hospitals' plans to determine airflows so that they are prepared for contagious pathogens. In the event of a case of smallpox, this will enable risk areas to be determined rapidly, allowing vaccination to be prioritised and disruption to be kept to a minimum.
- 3.48 Vaccination status of staff who may have close contact with a case:
- if vaccinated within the previous 6 months – no action required
 - if vaccinated more than 6 months previously, but within 3 years – re-vaccinate
 - if not vaccinated within the last 3 years, or never vaccinated – vaccinate immediately. They will require formal monitoring and will not be able to work during the restriction period. This will severely disrupt normal hospital activity and should be incorporated into emergency preparedness/business continuity plans.
- 3.49 Inpatient contacts will require cohort observation, with strict infection control procedures observed to avoid spreading infection from any secondary cases that develop. Special consideration for the management of sick inpatient contacts will be required, bearing in mind contraindications to vaccination. Note also that early symptoms of smallpox may be masked by other underlying medical disorders.
- 3.50 It may be necessary to close large areas of the hospital to admissions, and restrict access to essential staff only, until all inpatient contacts are free of disease for 16 days after their last exposure to infection, since secondary cases may arise elsewhere in the building during the incubation period. Subsequent decontamination may necessitate prolonged closure of large areas of the hospital. Alternative facilities for healthcare provisions will be required and these would be identified by the Strategic Health Authorities. It has to be recognised that routine and elective procedures would be suspended until the outbreak was under control.
- 3.51 It is also possible that in the event of a confirmed case in a hospital (i.e. has had multiple transfers and contacts) the hospital may become a Smallpox Care Centre.

Cases arising at Port Health Control Unit

- 3.52 Cases may present at an airport or seaport. In the event of a case presenting at a port it may be possible to hold both the case and contacts against their will, as the

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Port Medical Officer (PMO) can advise the immigration authorities that passengers should not be allowed to enter the country.

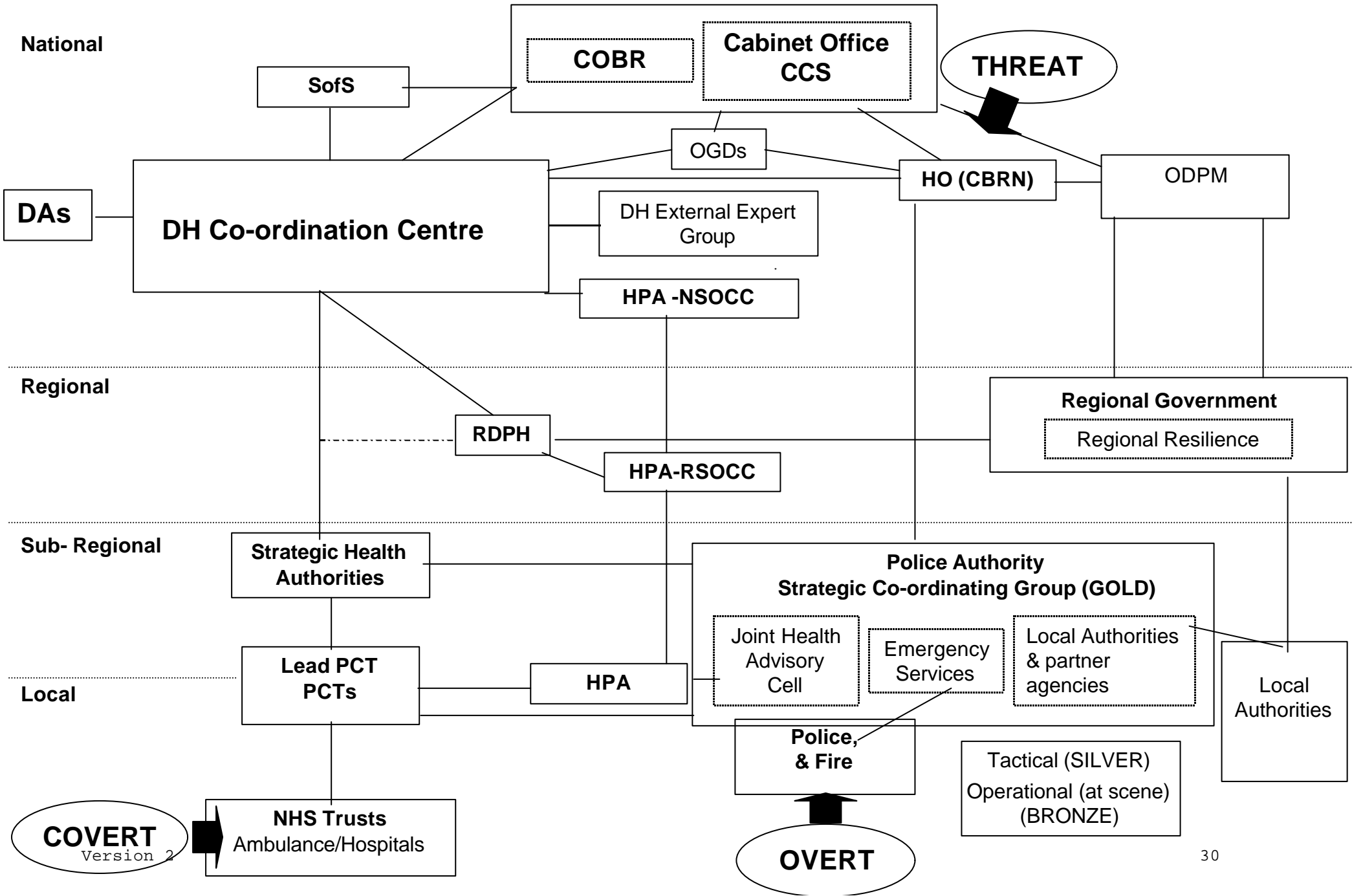
- 3.53 Figure 7 assumes that the Infectious Disease (Aircraft) Regulations or the Infectious Disease (Ships) Regulations have not resulted in prior notification of the case to the Port Health Authorities and the case has presented at the Port Health Control Unit (PHCU).
- 3.54 If there is prior notification to Port Health Authorities, then the PMO should board the aircraft or ship, the case should not be allowed to leave until an assessment has been made and the diagnosis confirmed or excluded. Contacts should be held in a separate area.
- 3.55 If the diagnosis is confirmed then all those on the same plane should be treated as Category A contacts. Contacts on a ship may be Category A or B depending on proximity and duration of exposure. The patient may have had other contacts during their journey through the port, and these will have to be contacted through passenger lists or an official announcement made asking them to identify themselves.
- 3.56 Health services that provide care for asylum seekers in detention, induction and accommodation centres should be aware of the possibility that a case may present in a new entrant to the country.
- 3.57 Isolation of cases and effective identification, tracing, vaccination and monitoring of contacts is essential to prevent the spread of infection. Any delay in intervention is likely to make a large impact on the size of the outbreak. The local HPA team led by the CCDC will be responsible for contact identification, tracing and monitoring contacts.
- 3.58 In order that these activities are properly organised, **National and Regional Smallpox Outbreak Co-ordination Centre (NSOCC and RSOCCs)** will be established following the first confirmed case of smallpox. RSOCCs will be required in all Regions since cases in one Region may have contacts anywhere in the country.
- 3.59 NSOCC will be located in the emergency room of the Health Protection Agency (HPA). It will be accountable to the DH. The DH will also set up its own emergency team. Firm links between both teams and the NHS would need to be established.
- 3.60 The role of NSOCC is the collation and analysis of epidemiological and laboratory information to assist identification of contacts and the source of infection, and the overall co-ordination of the public health response.
- 3.61 The RSDRG should form the foundation of the RSOCC and will be headed by the RE on behalf of the RDPH. The RSOCCs will liaise with the Joint Health Advisory Cell (JHAC). RSOCCs will be accountable to NSOCC.

3. Assessment and management of initial cases

- 3.62 RSOCCs should include members of the RSDRGs and in addition representatives from the agencies and groups listed below.
- Regional HPAs
 - Strategic Health Authorities
 - Regional Government Offices, including Regional Resilience Teams and Home Office
 - PCTs and Acute Trusts - including CsCDC and nurses, ID physicians, frontline clinicians, virologists, hospital infection control specialists and others as appropriate.
 - Data handling, administrative and support staff will be drawn from Regional HPAs and Standard Government Offices.
- 3.63 The role of RSOCCs is to:
- Co-ordinate assessment and management of cases – through the Regional network of SDE
 - Identify and trace contacts, and arrange vaccination and monitoring of contacts
 - Monitor side effects of vaccination
 - Establish essential communication lines
 - Arrange vaccination of essential personnel
 - Ensure infection control including decontamination of affected areas
 - Collect information about the movement of smallpox cases during the incubation period to help identify the source of infection.
- 3.64 Lines of communication and accountability between NSOCC, RSOCCs, DAs and local clinical, laboratory and public health services are summarised in the following table.

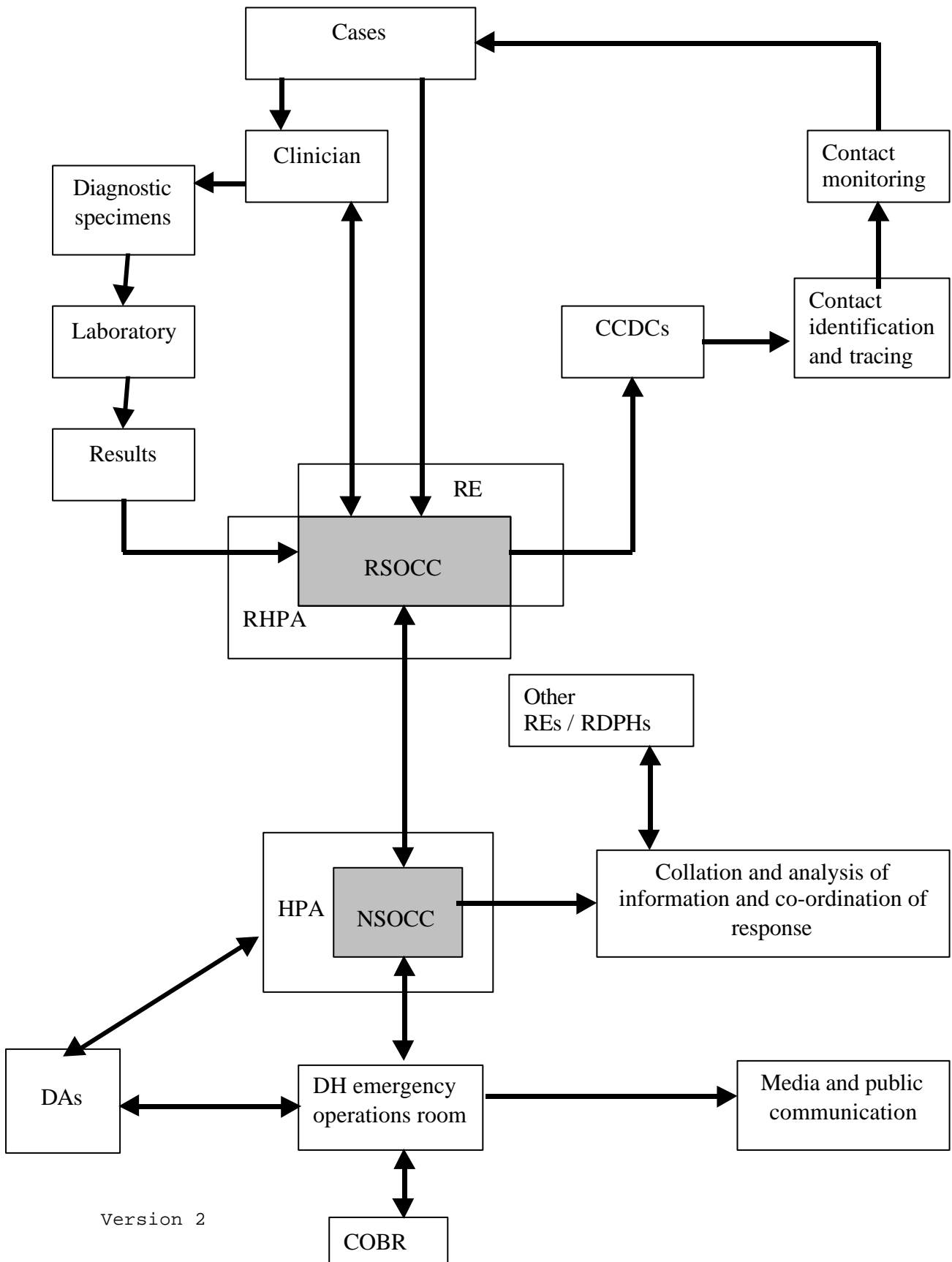
Command, Control and Communication

3. Assessment and management of initial cases



3. Assessment and management of initial cases

Lines of communication and accountability during an outbreak



4 Management of cases and contacts

Isolation of cases

- 4.1 Cases may arise in individuals who are being monitored as contacts, or in individuals who have no known epidemiological link to other cases. **Probable and confirmed cases** will be transferred directly to a treatment ward at a Smallpox Care Centre as soon as this is available. **Possible cases** will be transferred to an observation ward at a Smallpox Care Centre until the diagnosis of smallpox can be confirmed or excluded. Some of these may be due to side effects of smallpox vaccine.
- 4.2 A large number of **suspicious illnesses** are likely to be reported to RSOCC due to heightened awareness and anxiety among clinicians. These should be assessed and managed as during Alert Levels 0 and 1 with assessment by an SDE and further management by an SMART if necessary.
- 4.3 **Suspected cases** in the community whose clinical condition gives cause for concern prior to the availability of laboratory results should be transferred to the Smallpox Care Centre observation ward.

Care of cases

- 4.4 Smallpox is a severe viral infection, the care of which has **three** main components:
 - Clinical care and support for the sick patients
 - Maintenance of infection control during the infectious period
 - Providing adequate healthcare input to ensure continued care until the patient is convalescent.
- 4.5 No antiviral drug is currently known to be effective against smallpox virus. It must therefore be assumed that patients suffering from smallpox will require support through the natural course of infection. Cidofovir has been used to successfully treat the pox infections *molluscum contagiosum* and *orf* in humans. The effectiveness of the drug against established smallpox disease is unknown. Depending on supplies, it may be available as a therapeutic option in some cases.
- 4.6 Transfer to ICU should be avoided in order to contain the infection. The equivalent of high dependency care should be provided in the Smallpox Care Centres. The levels of care that could be provided would depend on the number of cases.
- 4.7 Those with severe disease will require pain relief, hydration, nutrition, maintenance of personal hygiene and airways support, with skin care and treatment for secondary bacterial infections if necessary during the rash phase. Patients with milder disease may remain self-caring in many respects, but should be isolated while infectious, to reduce the risk of generating further cases.

4. Management of cases and contacts

- 4.8 The early rash is accompanied by red and blistering lesions in the throat and upper airway. In severe cases these can be extremely painful and opiate analgesics may be required. If throat swelling threatens the airway, boluses of hydrocortisone may be given to relieve oedema, as for croup or bronchiolitis. The intravenous dose for an adult is 200 mg, and for a child, 5 mg/kg. Although corticosteroids may reduce fever, they have little effect on the evolution of the illness, and do not worsen the outcome of established viral diseases.
- 4.9 Oral hydration, and nutrition with soft food, is preferable as long as it can be adequately maintained. Intravenous hydration is possible in many cases, but a severe skin rash makes the care and maintenance of a peripheral intravenous cannula difficult. It may then be necessary to install a central venous cannula, which will require appropriately trained and vaccinated staff and radiological confirmation of correct positioning of the line.
- 4.10 An extensive rash will result in widespread exudation and crusting, including the scalp area. It may be beneficial to cut the hair short before this happens, to facilitate the shedding of crust and scabs, and to facilitate the maintenance of skin hygiene. Skin swelling can be a major problem, due to the extensive, deep-seated lesions. It is strongly advisable to remove rings and other body jewellery at the onset of the rash, to avoid constriction and ischaemia of digits or of other body areas. The more severe and extensive rashes are painful, and analgesia should be provided.
- 4.11 Skin hygiene contributes importantly to the avoidance of secondary infection, but infection of broken vesicles and pustules, and of denuded skin areas with *Staphylococcus aureus* or *Streptococcus pyogenes* cannot be avoided in all cases.
- 4.12 Treatment with oral or parenteral flucloxacillin or co-amoxiclav is appropriate (oral clindamycin is an alternative, with a higher risk of diarrhoeal adverse effects; co-trimoxazole is a second choice, with a risk of skin, bone-marrow or liver toxicity, particularly in older adults).
- 4.13 Hospital-acquired resistant organisms such as MRSA may require treatment based on the result of culture and sensitivity data. Secondary bacterial infection of the respiratory tract is much less common, but may be caused by staphylococci or streptococci or rarely *Haemophilus influenzae*. Advice should be sought from the medical microbiologist and local antibiotic policies should be followed.
- 4.14 There is often mild conjunctivitis, which requires no specific treatment. Pocks may affect the conjunctiva, but usually heal without affecting sight. The eyes may be closed by oedema as the rash reaches its height. Eye toilet using sterile saline is then helpful. Chloramphenicol eye ointment may be given for short periods of time if secondary bacterial conjunctivitis occurs.
- 4.15 As the fever subsides and the rash begins to heal, the patient will gradually become more mobile. Emotional support may be required at this stage, especially if there is significant facial scarring.

- 4.16 The need for continued isolation, until scabs have all been shed, may also be very trying for patients who are mobilising well. The last deep scabs (or ‘seeds’) tend to remain in the thick skin of the soles of the feet. In some circumstances it may be beneficial to remove these, using a needle to release them from hardened pockets of skin. The patient who is free of scabs can be released from isolation.

Contacts: Classification

- 4.17 Rapid identification and tracing of contacts is essential since vaccination should be carried out as soon as possible and at most within 4 days of exposure to infection, because the degree of protection diminishes as the interval between exposure and vaccination increases. Contacts should be checked for symptoms before vaccination, to ensure that they are not co-primary cases.
- 4.18 If the diagnosis of smallpox in possible or probable cases is subsequently excluded, contacts who have been identified but not yet traced need not be vaccinated or followed up further.
- 4.19 Primary contacts are persons who have had contact with confirmed cases of smallpox during the infectious period or with contaminated fomites. As a precaution, the infectious period should be regarded as from 24 hours prior to the first recognised symptoms until the last scab has been shed.
- 4.20 **Primary contacts** may be divided into two categories, A and B according to their risk of infection. These categories should be regarded as a guide. Individuals’ risk of infection should always be considered in the context of the **proximity and duration of exposure**.
- 4.21 Contacts may be asymptomatic or symptomatic. Symptomatic contacts are people who fit the contact definitions, and in addition have prodromal symptoms that may indicate early smallpox infection. These are prolonged high fever (above 38 °C) and/or constitutional symptoms such as prostration, severe headache or backache, rigors and generalised maculopapular rash.
- 4.22 Secondary contacts are people in close contact with Category A primary contacts.

Category A contacts

- 4.23 **Category A** contacts are people who are likely to have been exposed to infection through face-to-face close contact with a case or contaminated fomites. They include:
- Household contacts:** all persons usually resident at the same address as infectious cases of smallpox, and other visitors who have spent substantial periods of time at this address during the infectious period. Note that in documented outbreaks the secondary attack rate among household contacts was around 50%.

4. Management of cases and contacts

Face-to-face contacts: all persons who have had prolonged interactions with infectious cases of smallpox within a distance of 2 metres (6.5 feet). These may include contacts at work, in social settings, and unvaccinated healthcare and emergency workers.

Fomite contacts: all persons who have had direct contact with clothing or articles that have recently been used by infectious cases of smallpox. Again these may include contacts at work, in social settings, and unvaccinated healthcare and emergency workers.

- 4.24 As a prompt, Category A contacts may be identified by asking about family members, relatives, close friends and close work colleagues who may have had **contact** with infectious **cases** of smallpox.
- 4.25 Other persons thought to have shared a common exposure with cases of smallpox, including the initial release of the virus.

Management and monitoring

- 4.26 Category A contacts should be vaccinated as a matter of urgency.
- 4.27 There are **no contraindications** for vaccination of Category A contacts. Vaccinators at Smallpox Vaccination Centres will have access to expert advice. If a Category A contact has severe skin disease or immunosuppression, they may be given VIG to prevent vaccine complications. If vaccination is indicated, depending on supplies, they may be given VIG to prevent vaccine complications. Adverse effects may be treated with cidofovir, although renal toxicity may limit its use. Category A contacts will be asked to return to a separate part of the Smallpox Vaccination Centre for assessment of their papule by a trained clinician (to avoid possible risk of transmission to others).
- 4.28 Category A contacts must be formally monitored for the development of symptoms for a period of 16 days from the last exposure to an infectious case. Formal monitoring involves daily recording of body temperature, measured orally, and daily reporting of this, and the presence of other constitutional symptoms to a designated Smallpox Contacts Telephone Number, which will be dedicated solely for this purpose.
- 4.29 An oral thermometer preferably single-use and disposable, a temperature chart, instructions on the measurement and recording of body temperature, general advice, and the Smallpox Contacts Telephone Number will be provided. In addition, a mobile telephone may need to be provided to those who do not have access to a mobile or land telephone at home.
- 4.30 Category A contacts who fail to make their daily health report or return for follow-up will be actively traced by the local HPA, by telephone or in person.

Restrictions on activity (Quarantine)

- 4.31 Legal/Emergency powers may be invoked to restrict activities if smallpox cases do occur.
- 4.32 Category A contacts who develop a fever or other constitutional symptoms must stay at home and immediately telephone the Smallpox Contacts Telephone Number.
- 4.33 The restriction period is the time during which Category A contacts are at greatest risk of developing symptoms and becoming infectious. The incubation period for smallpox is usually 10 to 16 days, and as a precaution patients should be regarded as infectious from 24 hours prior to the first recognition of symptoms.
- 4.34 The restriction period therefore extends from 9 days after the first exposure until 16 days after the last exposure to an infectious case. During this time, restrictions on activity of Category A contacts apply. **Contacts should stay at home**. They **must**:
- stay away from work or school
 - avoid contact with unvaccinated individuals
 - stay away from crowded areas/gatherings
 - remain within their local area
- 4.35 If they develop **any** symptoms however minor, they must remain at home and report to Smallpox Contact Telephone Number. Arrangements for the delivery of food and other essential items will be arranged with local authorities.
- 4.36 Outside the restriction period, and as long as they are well, Category A contacts may continue normal activities, although they must not travel abroad and should be advised to stay within their local area until the end of the formal monitoring period and until their vaccination site has completely healed.
- 4.37 There is no legislation to enforce compliance with restrictions on activity. However, in what will be a mainly susceptible population, the onset of symptoms in smallpox cases will be rapid and debilitating, and the patient is unlikely to continue their normal activities.

Action to be taken in the event of symptoms

- 4.38 Category A contacts who develop prodromal symptoms should be regarded as possible cases and transferred immediately to the observation ward of a Smallpox Care Centre. Those who also develop a vesicular rash should be regarded as probable cases and transferred to the treatment ward.

Category B Contacts

- 4.39 **Category B** contacts are people who have a lower chance of having been exposed to infection via aerosol. They include all persons who have shared rooms or other

4. Management of cases and contacts

enclosed spaces with infectious cases of smallpox, and who do not fall into the groups of face to face or fomite contacts described above.

- 4.40 It is accepted that it is difficult to be specific about the definition of Category B primary contacts. However, these may include work colleagues, and people who have visited the same premises or travelled on the same public transport (buses, trains, tubes and planes) as smallpox cases. People who have shared air-conditioned buildings with infectious cases should be managed as Category B contacts. However transient or distant contacts should not be managed as Category B contacts. NSOCC may need further advice as required to assist identification of Category B contacts.
- 4.41 It is accepted that the majority of individuals who fall into this category will be at minimal risk.

Management and monitoring

- 4.42 Category B contacts should be vaccinated unless they have contraindications in which case the risk from vaccination should be weighed against the risk from disease.
- 4.43 Category B contacts do not require formal monitoring. However, their details should be recorded, and they should be given an advice sheet including the Smallpox Contacts Telephone Number that they must call immediately if they develop a fever or other constitutional symptoms during the 16 days following their last exposure to infection.
- 4.44 Category B contacts will be given written instructions describing what the papule should look like. They need only return to the Smallpox Vaccination Centre for professional assessment if they are concerned that their papule has not formed.

Restrictions on activity

- 4.45 If asymptomatic no restrictions on activity are necessary for Category B contacts, however, they must not travel abroad until they have been free of symptoms for 16 days following their last exposure to infection, and until their vaccination site has completely healed.

Action to be taken in the event of symptoms

- 4.46 Category B contacts who have a fever or other constitutional symptoms or who develop prodromal symptoms will be assessed and referred to the observation ward of a Smallpox Care Centre if it is likely they are a possible case. Those who also develop a vesicular rash should be regarded as probable cases and transferred to the treatment ward.

Secondary Contacts

4. Management of cases and contacts

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

Management

- 4.49 All secondary contacts of Category A contacts should be vaccinated.
- 4.50 If they have any contraindications to vaccination then they should avoid contact with the primary contact until the primary contact's vaccination site is completely healed because of the risk of transfer of vaccinia infection. This may mean leaving the house.
- 4.51 No monitoring or restrictions on activity are necessary unless the primary contact becomes symptomatic, and therefore becomes a possible or probable case.
- 4.52 If smallpox is confirmed in the primary contact, then the secondary contacts become Category A contacts themselves and must be managed accordingly.
- 4.53 Secondary contacts will be given written instructions on what the post-vaccination papule should look like. They only need to return to the vaccination centre for professional assessment if the papule has not occurred by day 3.

Transient and distant contacts

- 4.54 There may be large numbers of people who are concerned about having been exposed through brief or remote contact with smallpox cases but who do not fall into the groups of Category A or Category B contacts, and are therefore not at risk of infection. These may include passing contacts for example in the street or shops, and people who have spent short periods of time in large well-ventilated areas with smallpox cases.
- 4.55 These individuals do not need to be traced and do not require vaccination. However, they may identify themselves once details of the case become public. Their details should then be recorded, and they should be given an advice sheet for reassurance. This will require a clear communication message and rationale for them not receiving vaccination.
- 4.56 These individuals should not be offered vaccination because this would divert resources away from the essential measures of tracing and vaccinating all Category A and B contacts. It is accepted that this may be difficult to enforce because of public pressure. Contingency plans for wider vaccination may be necessary.

Identification and tracing of contacts

- 4.57 SDE, SMART and clinicians at Smallpox Care Centres will establish the time from which cases of smallpox have been infectious. They will then:
- compile a list of household contacts.
 - obtain a detailed account of the patient's movements during the infectious and incubation periods. This is both in order to identify other primary contacts, and to investigate potential sources of infection.
- 4.58 Information about household contacts and the patient's movements during the infectious period will be passed to RSOCC for further investigation and action.
- 4.59 Vaccination and monitoring of household contacts can be arranged immediately. Other Category A and B contacts will need to be traced urgently so that vaccination and monitoring can be arranged. This will be done through CCDC and their health protection teams.
- 4.60 It may be possible to trace contacts through official lists and social networks. However, if this is not possible, consideration should be given to making a public announcement asking contacts to identify themselves. This should be done with consideration to maintaining the confidentiality of smallpox patients.
- 4.61 A Smallpox Contact Tracing Number will be required so that contacts can identify themselves to RSOCC. They may also identify themselves to their GP or through NHS Direct, which will help to categorise contacts by using telephone triage to grade individuals' risk of exposure to infection.
- 4.62 At the same time as making arrangements for formal monitoring of Category A contacts, their secondary contacts should be identified and offered vaccination.
- 4.63 Full details of all contacts identified will be recorded on a database along with the management and outcome of each.

Unimmunised primary contacts

- 4.64 These include primary contacts who refuse vaccine, fail to respond to vaccination, or who are vaccinated late (more than 3 days after their first exposure to infection).
- 4.65 Primary contacts who fail to show a response to a first dose of vaccine after 3 days should be re-vaccinated.
- 4.66 Non-responders and those vaccinated late may be given additional prophylaxis against smallpox concurrently with (re) vaccination in an effort to attenuate disease. Supplies of additional prophylactic treatments should be prioritised to those most at risk of disease:
- Contacts vaccinated between 3 and 8 days after first exposure to infection may be given VIG.

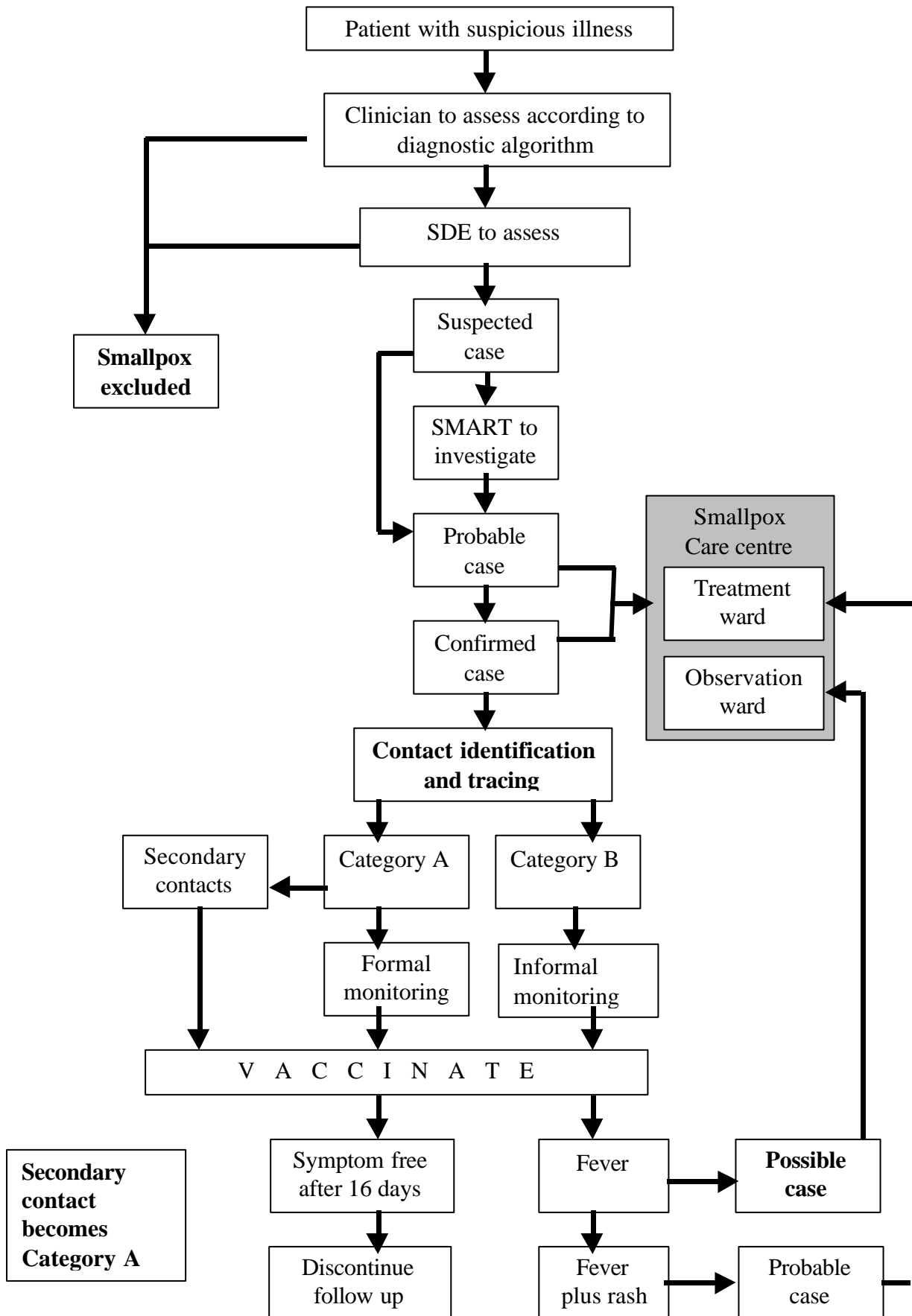
4. Management of cases and contacts

- Contacts vaccinated more than 8 days after first exposure may be given cidofovir.
- 4.67 Unimmunised primary contacts will also require additional monitoring and/or restrictions on movement:
- those in Category A will be asked to stay in isolation accommodation until the end of the incubation period
 - those in Category B should be followed up as Category A contacts with a period of formal monitoring and identification and vaccination of secondary contacts.
- 4.68 **Isolation accommodation** will be required for unimmunised Category A contacts. Appropriate facilities, with individual rooms will need to be identified, which may include local hotels, university halls of residence etc. Staff, who have been vaccinated, will also be required to provide pastoral care and ensure contacts stay in their rooms and mixing does not occur.

Special issues

- 4.69 Individuals in certain groups such as illegal immigrants and overstayers, and homeless persons and drug users may pose problems. If they are cases, they may be reluctant to trust and engage with healthcare services when they become ill, thereby delaying access to healthcare and exposing more contacts. Even if they are close contacts, their details may not be volunteered by smallpox cases, which may mean that vaccination is delayed or overlooked. There could be difficulties explaining the need for admission to a centre, restricting their movements and logistical issues of monitoring for the development of symptoms.
- 4.70 Clear advice is needed to emphasise the severity of the problem, and guarantees may be required to protect the confidentiality of contacts and to protect illegal immigrants and over-stayers from prosecution. Engagement through voluntary and community groups may be effective. Interpreters should be available locally, and information sheets for those for whom English is a second language have been drawn up.

Summary of management of cases and contacts



5 Vaccination

General principles

- 5.1 Vaccine against smallpox contains a live virus, vaccinia, which produces cross immunity against variola major and minor.
- 5.2 Targeted vaccination and monitoring of contacts, together with isolation of cases, is the mainstay of containment. The containment of transmission depends on early detection of cases and tracing and vaccination of contacts. This strategy of **ring vaccination** will be used initially to control an outbreak, and is compatible with WHO recommendations.
- 5.3 Smallpox vaccination carries a risk of complications, which occurred at a higher frequency than that now acceptable for a modern vaccine. These complications occurred more frequently in people who were immunosuppressed, people with eczema and pregnant women. Because of this, mass vaccination of the population is not a first line option either prior to or in the event of an outbreak.
- 5.4 There is a need to consider protection of close contacts of people who have been vaccinated in view of shedding of vaccinia virus (e.g. children with eczema should not share a house with someone who has been vaccinated until their vaccination site has completely healed).
- 5.5 Vaccinated individuals shed vaccinia virus until the pock has completely healed. Individuals who have been vaccinated should avoid contact with others who may be at risk from vaccinia. These are: people who are immunosuppressed, people with eczema and pregnant women. Individuals in these categories who normally live in the same household as vaccinees should move to alternative accommodation.

Efficacy and 'take' rate

- 5.6 Successful vaccination produces a **characteristic papule after 3 days**. This evolves into a vesicle at 4 to 5 days and a pustule at 6 to 7 days. The pustule is a reliable indication that protective antibody levels have developed. i.e. there has been a successful take. A more rapid response is seen in persons who have had previous vaccination.
- 5.7 Take rates depend, amongst other things, on potency of vaccine, age of vaccinee, past vaccination history and vaccination technique. For primary vaccination, take rates have historically varied from 85% to 99.9%. The primary take-rate of an appropriately potent (10^8 pock-forming unit/ml) and properly administered vaccine is likely to be greater than 99%. For re-vaccination, take rates have been lower, from 54% to 93% with a mean of about 70%. With the cessation of routine vaccination so long ago now, residual immunity is likely to be negligible, and any vaccination now may resemble the primary vaccinations of the past.

- 5.8 For pre-exposure vaccination, a successful take provides full protection against smallpox. Post-exposure vaccination given up to 3 days after exposure also provides protection, although it may not completely prevent infection, and patients may develop mild modified disease.

Contraindications and complications

- 5.9 Contraindications to vaccination include eczema, immunosuppression and pregnancy, among others. Full details can be found in the appendices.
- 5.10 Serious adverse effects associated with vaccination include inadvertent inoculation at other sites, generalised vaccinia, eczema vaccinatum, progressive vaccinia and post-vaccination encephalitis.
- 5.11 Surveys from the US have found that the overall risk of serious adverse events was between 50 and 1000 per million vaccinees, with inadvertent inoculation and generalised vaccinia the most common complications
<http://www.bt.cdc.gov/agent/smallpox/vaccine-safety/adverse-events-chart.asp>
- 5.12 However, these data may not be directly applicable to the current UK situation for the following reasons:
- A different strain of vaccine virus will be used (Lister instead of New York Board of Health)
 - There are more people at risk of adverse effects because the prevalence of eczema and immunosuppression is higher than in the survey populations.
 - The incidence of complications is up to ten times higher in primary vaccinees than re-vaccinees.
- 5.13 In the same surveys, the risk of fatal complications was approximately 1 per million in primary vaccinees. In a study in England and Wales in the 1950s it was estimated at 3 per million. Death is most often the result of post-vaccinal encephalitis or progressive vaccinia. Fatal complications occur in approximately 1 per 4 million in re-vaccinees.
- 5.14 Contra-indications are relative. Those in close contact (i.e. Category A) of a case, will be offered vaccine and there is no contra-indication.
- 5.15 In mass population vaccination, the offer of vaccination to individuals with no contact with the disease would depend on circumstances-in particular the potential vaccinee's proximity to the Region affected and the number of cases.
- 5.16 See 'Contra-indication to vaccination at different alert levels' table at the end of this chapter.

Vaccination strategies at progressive Alert levels

Vaccination strategy at Alert Level 0 (No credible threat of release)

- 5.17 A central register will be kept of all persons vaccinated. This will be held at HPA/CDSC in accordance with the Data Protection Act and Caldicott requirements. People on the register will be contacted annually to ensure that their details are correct. This provides a list of staff who can be accessed should the need arise.
- 5.18 The risk of adverse effects of vaccination must be balanced against the risk of leaving vulnerable those specialist healthcare and laboratory workers who would be first to be exposed in the event of a case and who would not have adequate time for vaccination to become fully effective. Some specialist healthcare and laboratory workers will therefore need to be vaccinated at Alert Level 0 to act as a first line of defence, even without an identifiable, specific threat. In the event of a case occurring, they will then be able to make the diagnosis, care for the patient, analyse clinical specimens, and initiate public health action to contain the outbreak. To maintain immunity, **revaccination will be required every three years.**

Those vaccinated at Alert Level 0 will be:

- Staff at each of the designated Category 3 Regional laboratories where diagnostic clinical specimens may be sent for EM diagnosis. (Staff at the two Reference laboratories are already routinely vaccinated to protect them against other orthopox infections.)
- The SDEs
- The SMARTs
- Selected ambulance staff who would support the SMART
- High security ID staff
- A small number of vaccinators, including Occupational Health staff and other healthcare staff who would be ready to vaccinate and train others in the event of cases.

Essential service personnel who would be vaccinated at alert level 1 should also be identified. It is recognised that the alert level may not progress in a sequential manner. Other groups for vaccination may be identified or the identified groups may receive a different priority depending on the nature of the incident.

Vaccination strategy at Alert Level 1 (Case confirmed outside the UK)

5.19 At alert level 1 the following staff will be vaccinated:

- Additional SDEs and SMARTs
- Medical, nursing and support staff (porters, cooks, cleaners, laundry staff, etc.) who might be required to work at Smallpox Care Centres
- All Front-line clinical staff, dermatologists and port health staff

- Additional vaccinators
 - Front-line Ambulance crews
 - All laboratory staff who might handle diagnostic clinical specimens (for EM and/or PCR)
 - Epidemiological staff who might be involved in contact tracing
 - Pathologists and mortuary staff who might handle infected bodies
 - Environmental health officers who might decontaminate premises
 - Individuals who might be required to join NSOCC or RSOCCs
 - Front line staff of 'blue light' services
 - Other workers from key industries necessary to maintain essential services, such as gas, water, electricity, fuel, telecommunications, food, transport etc. depending on the nature of threat.
- 5.20 RSDRGs should have identified these personnel within their Region at Alert Level 0. To maintain immunity, **re-vaccination will be required every three years**.
- 5.21 Vaccination will also be offered to the following:
- All healthcare workers and ancillary staff
 - Other 'blue-light' service staff
- 5.22 Should there be any cases outside the UK the DH will work closely with the WHO. Legal/emergency powers may be necessary to enforce travel restrictions.
- 5.23 Vaccination may be considered for travellers from the UK to infected countries, or from the UK in the event of an outbreak to countries that remain smallpox free.
- 5.24 All staff identified above where possible will be vaccinated in their workplace.
- 5.25 Essential personnel will be **screened** to ensure that neither they nor their household contacts has any contraindications to smallpox vaccine. An immune response will be verified before essential personnel are allowed to become involved in smallpox diagnosis, patient care, analysis of specimens or public health action.
- 5.26 Essential personnel will be **re-vaccinated every 3 years** in order to guarantee immunity.
- 5.27 The household contacts of immunised essential personnel will vaccinated if there is a possibility that the worker has come into contact with smallpox. This is as a precaution in case infection is brought into the household either via contaminated fomites or if staff members develop modified disease.

Vaccination strategy at Alert Level 2 (Case confirmed in UK)

- 5.28 In the event of confirmed smallpox in the UK vaccination of key workers responsible for maintenance of essential services and utilities will commence.

Vaccination of personnel supporting the essential services may also need to be considered e.g. contractors and suppliers.

- 5.29 Eligible healthcare, laboratory and other essential personnel who were not vaccinated at Alert Level 1, will be vaccinated.
- 5.30 The contraindications to vaccination would change at this level because now many of these workers would be at risk of disease. Vaccinated staff would have to take precaution to avoid spread of vaccination virus to susceptible household contacts. If necessary, priority will be given to workers in the Regions where there are cases.
- 5.31 Smallpox Vaccination Centres will be activated on confirmation of the first confirmed case for vaccination of **contacts of cases**. Vaccination will be provided by staff trained as vaccinators. Details of the contacts vaccinated will be maintained on databases that will be maintained Regionally and Nationally by the HPA.

Vaccination strategy at Alert Level 3 (Outbreak occurring in the UK)

- 5.32 As multiple cases occur vaccination of the above key groups would continue.

Vaccination strategy at Alert Level 4 (Large outbreak not controlled by “ring”)

- 5.33 Circumstances may arise when mass vaccination may be required to raise the level of immunity to smallpox:
- A large number of cases occurring simultaneously all over the country
 - Uncontrolled spread resulting from large or multiple deliberate release
 - Many secondary cases occurring without identifiable contact with a primary case, implying that contact tracing and enhanced surveillance for cases has been ineffective.
- 5.34 Public demand may also influence the decision to implement mass vaccination. General public demand for vaccination is not necessarily inevitable if public relations are good from the outset.
- 5.35 Decisions about whether to implement mass vaccination must be taken with due consideration of:
- the risk of adverse effects from vaccination, which may exceed the risk from disease
 - vaccination complications, especially generalised vaccinia, may create difficulties in the diagnosis of smallpox
 - vaccination resources, including vaccine supplies; there is a danger that mass vaccination could divert resources from essential outbreak control measures.

Vaccination strategy at Alert Level 5 (Outbreak controlled)

5.36 Following an outbreak at Alert Level 5, in order to maintain an immunised workforce/response team identified healthcare, emergency, laboratory and other essential personnel should be re-vaccinated every 3 years, and in addition if they are re-exposed if this is more than 6 months since their last vaccination.

Mass Vaccination

5.37 Isolation of cases, contact tracing, quarantine and ring vaccination remain the first line strategy for containment of an outbreak of smallpox. This is consistent with WHO advice. However, mass vaccination would be considered if there were

- multiple simultaneous outbreaks of smallpox
- new cases of smallpox arising which were not epidemiologically linked with previous cases
- overwhelming public demand.

The decision to extend beyond ring vaccination will be announced by the DH.

5.38 Vaccination centres would be set up in each Region. To minimise disruption to normal primary care services, these centres would **not be** within existing primary care facilities.

5.39 The planning logistics and operational details of such a campaign, including staffing of the centres, vaccine delivery and equipment necessary, are being developed by the DH in collaboration with OGDs.

5.40 Those with contra-indications for vaccination who had not been in contact with a case would be excluded. These contra-indications would vary depending on the Alert Level and are described in the table at the end of this chapter.

5.41 An extensive nation-wide communication exercise including national and local TV, radio and press would be mounted to inform the public about the mass vaccination programme.

Contra-indications to vaccination at different Alert Levels
For individuals in the absence of exposure to disease (i.e. no known contact)

Contra-indication	Alert Level 0 Smallpox Remains eradicated	Alert Level 1 Case confirmed <u>outside</u> the UK	Alert Level 2 Case confirmed in the UK	Alert Level 3 Outbreak occurring in the UK
				Depends Vaccinee's proximity to outbreak and severity of contra-indication
History of eczema (past or present) or current skin exanthema*	X	X	X	X
Pregnancy or planning pregnancy	X	X	X	X
Immuno-suppression	X	X	X	X
Cardiac risk factors	X	#	#	#
Under 1 year old	No	#	#	#
Household or sexual contact of an individual with skin eruptions-recent or current eczema	X	X	#	#
Household or sexual contact of a pregnant woman	X	#	#	#
Household or sexual contact of an individual of severely immuno-suppressed persons	X	X	#	#

Contra-indication (continued)	Alert Level 0 Smallpox Remains eradicated	Alert Level 1 Case confirmed <u>outside</u> the UK	Alert Level 2 Case confirmed in the UK	Alert Level 3 Outbreak occurring in the UK
				Depends Vaccinee's proximity to outbreak and severity of contra-indication
Household member under 1 year	X	#	#	#
Inflammatory eye conditions that may lead to rubbing of the eyes	X	#	#	#
Previous allergic reaction to vaccinia vaccine	X	X	#	#
Allergy to any vaccine ingredients	X	X	#	#
Currently ill with an infection with a high temperature(>38°C)	X	X	#	#
Recent immunisation with a live vaccine	X	#	#	#
Screening questionnaire for risk of HIV or pregnancy	Tested for both	Yes	Yes	Public announcement

X contra-indication # Vaccination

* Examples of skin exanthema - acne, burns, recent incisions, impetigo, contact dermatitis

6 Enhanced surveillance following an outbreak

Identification of the source of infection

- 6.1 There may have been an overt release of virus. All those deemed to have been exposed, according to an evaluation at the site and time of release, will then be managed as Category A contacts.
- 6.2 It is more likely that the virus will be released covertly. Detection of the location of the event will depend on analysis of information given by patients about their movements during the incubation period. This information will be collated and analysed by NSOCC in order to identify potential sources of infection, which may be other cases or the initial release.
- 6.3 If a potential source of infection is identified from common exposure histories, then others who have shared the same exposure should be regarded as Category A contacts and traced as a matter of urgency.

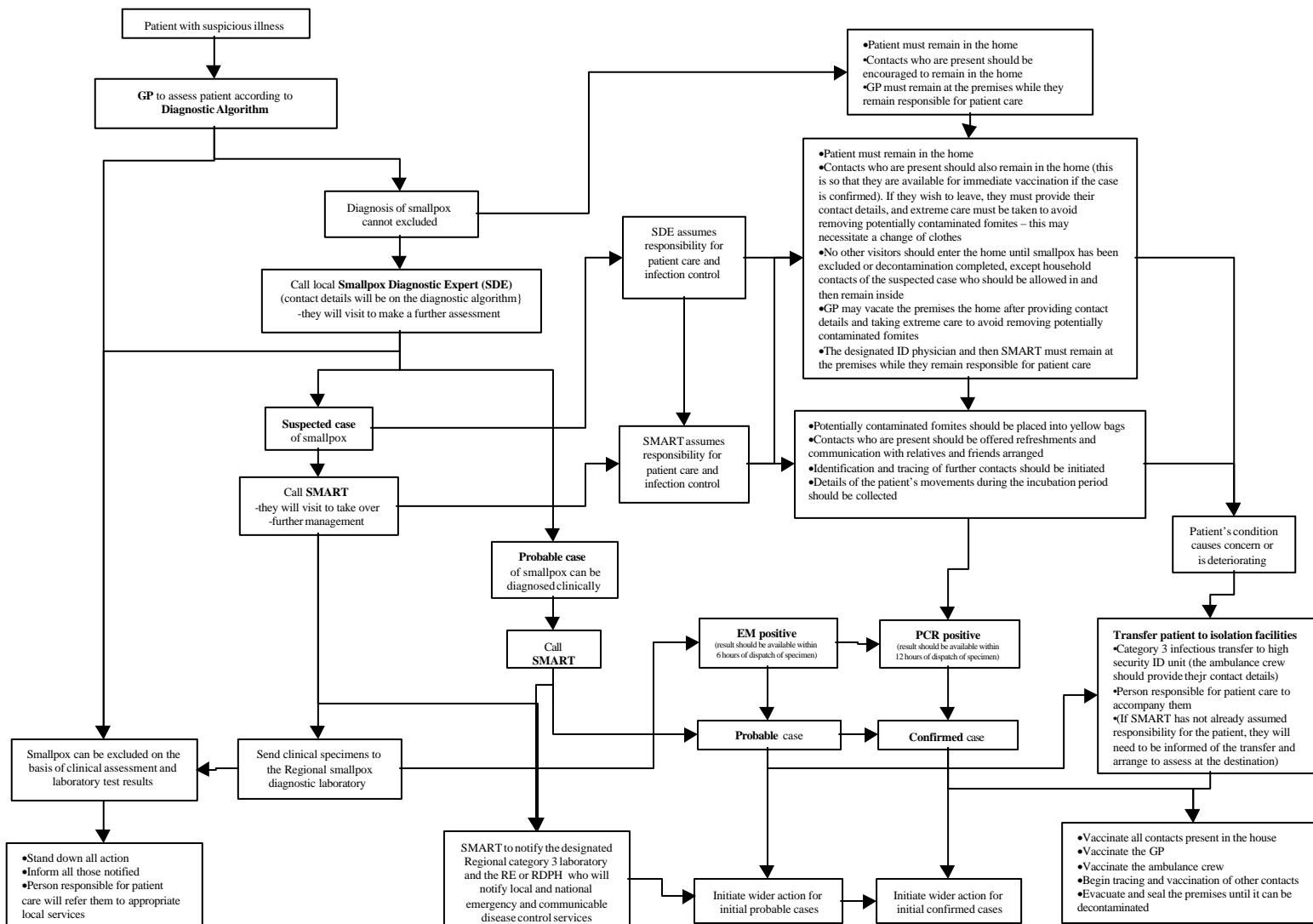
Case finding following a release

- 6.4 **At Alert Level 1**, clinicians (via CMO Public Health cascade) will be informed of the nature of the heightened threat, reminded of the presenting clinical features and case definitions, and the procedure for reporting and assessment of patients with suspicious illnesses as well as other sources of relevant information.
- 6.5 **At Alert Levels 2 and 3**, cases may arise in individuals who are being monitored as contacts, or in individuals who have no known epidemiological link to other cases. The latter will be assessed by one of the expanded number of SDE.
- 6.6 More intensive surveillance will be necessary to ensure that all cases are recognised and control measures implemented as early as possible. Clinicians will again be reminded of the presenting clinical features and case definitions, and the procedure for reporting and assessment of patients with suspicious illnesses.
- 6.7 SDE will be issued with **Smallpox Reporting Forms** including a **Smallpox Reporting Telephone Number** for reporting of suspected cases to RSOCC.
- 6.8 Active surveillance of hospitals may be required in order to reliably exclude additional cases. All hospital inpatients with suspicious illness, and recent unexplained deaths, should be reviewed retrospectively to exclude the diagnosis of smallpox.
- 6.9 NHS Direct will activate algorithms combining details about symptoms and exposures in order to assess the significance of symptoms in concerned individuals and provide reassurance or referral to local experts as necessary.

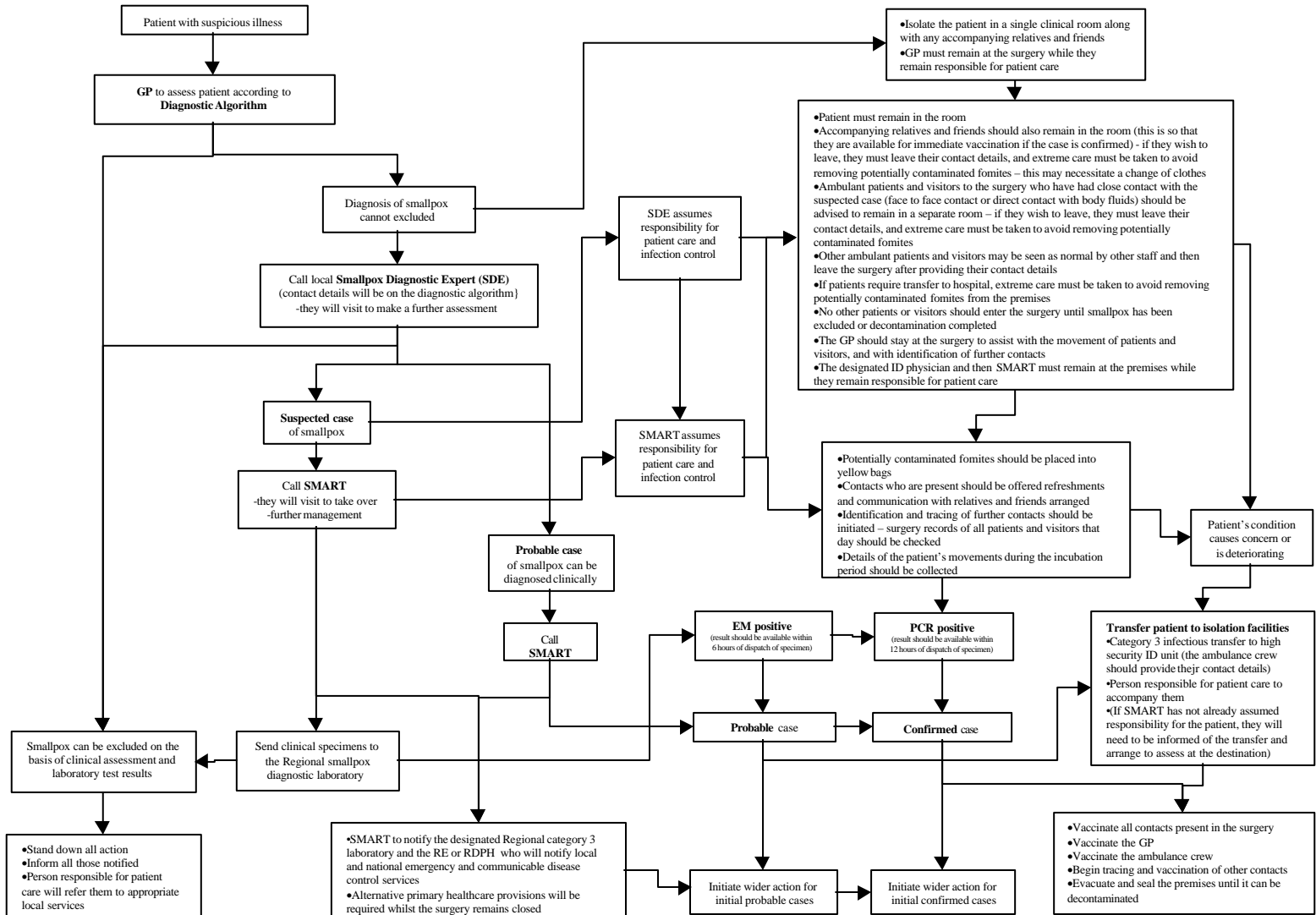
Handling data

- 6.10 Even a small outbreak may generate considerable quantities of epidemiological data. Forms and tools to assist with the collection, collation and analysis of information about cases and contacts can be found in the plan appendices. These include:
- Smallpox case reporting form.
 - Contact identification and monitoring form.
- 6.11 Epidemiological data will be collected at regional level by the HPA and passed to NSOCC for collation and analysis.
- 6.12 Epidemiological data will be used to inform real-time modelling of the spread of the outbreak and the effectiveness of interventions in order to inform further outbreak control measures

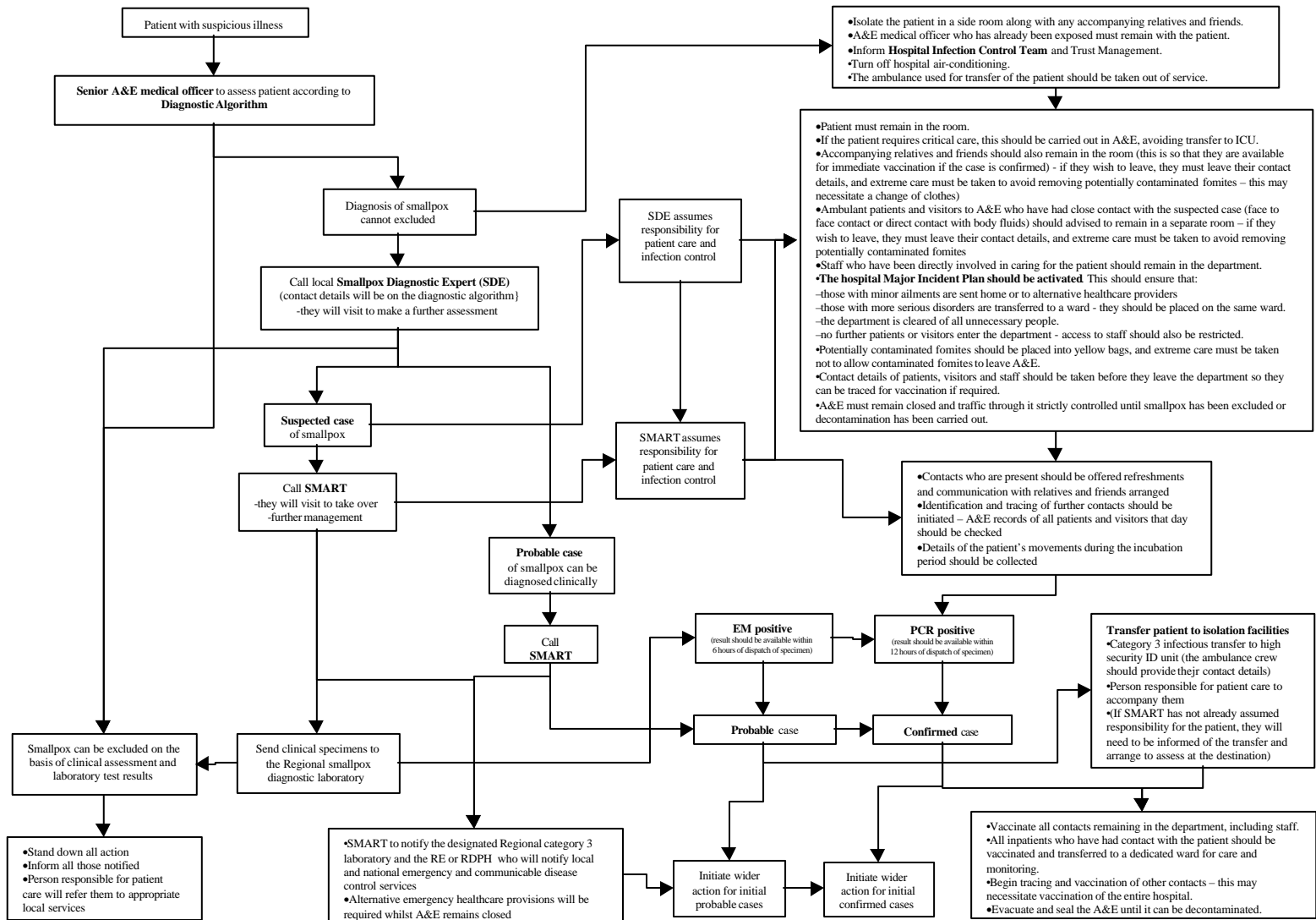
Management of initial suspected cases - patient at home



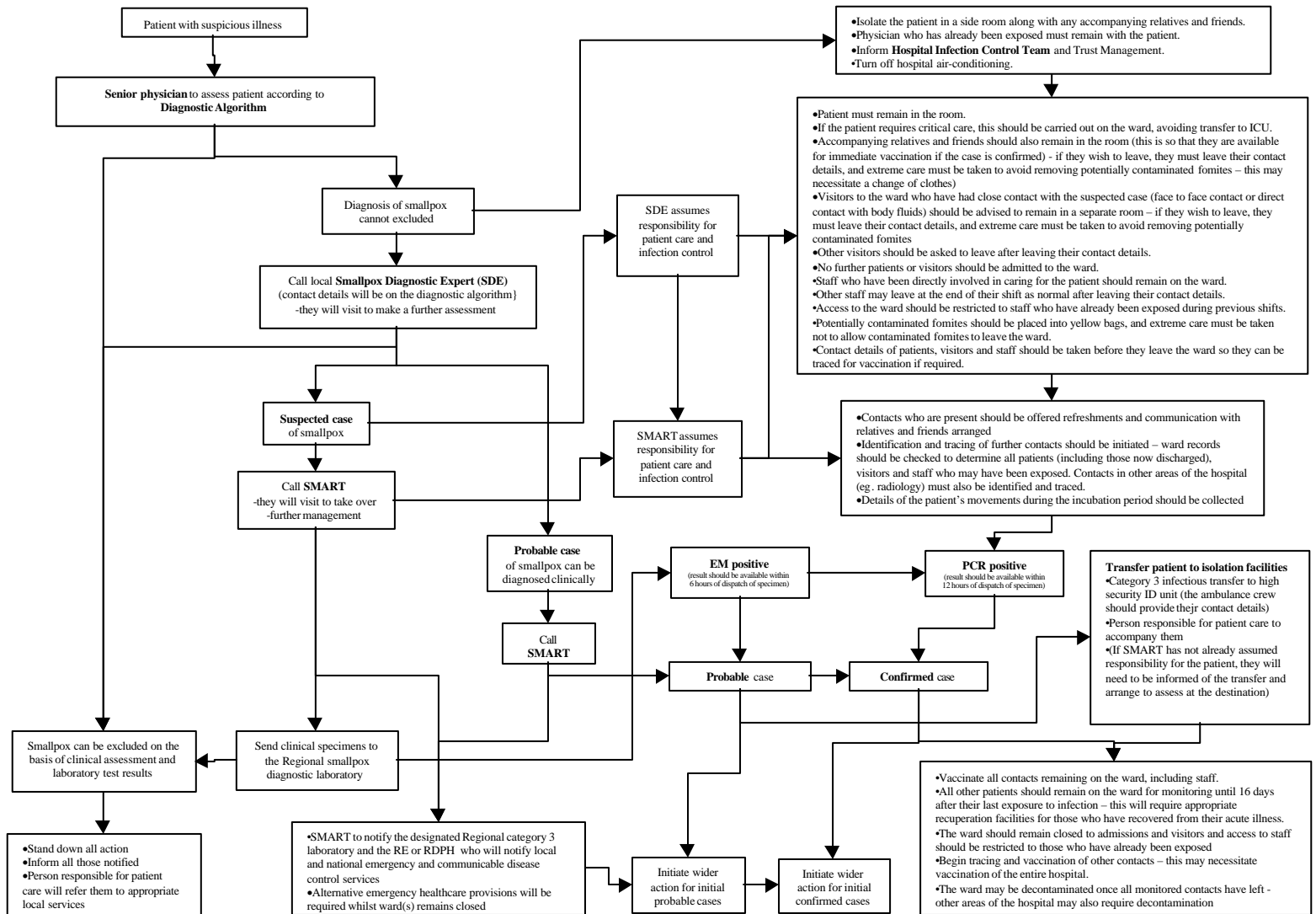
Management of initial cases - patient at GP surgery



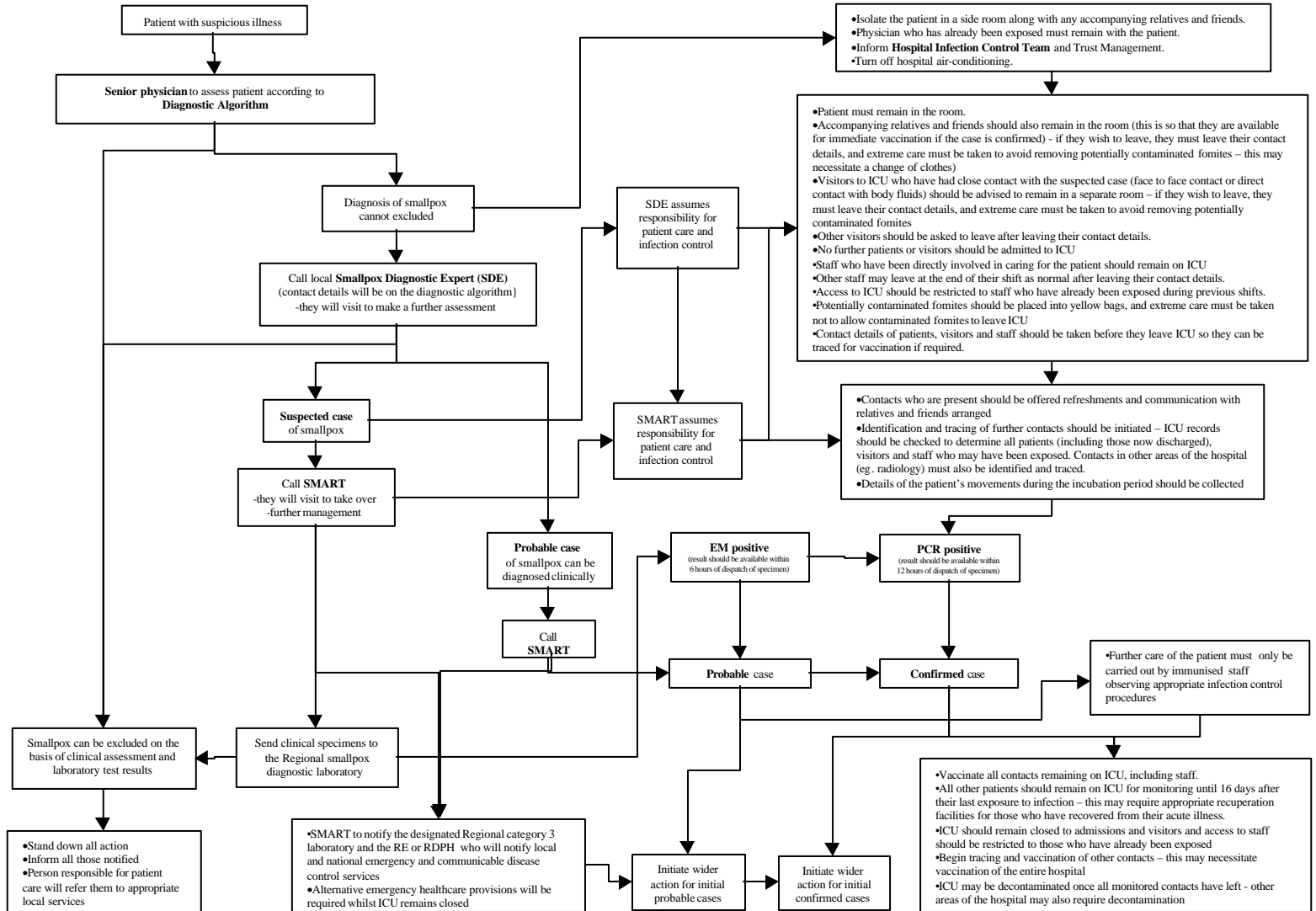
Management of initial cases - patient in Accident and Emergency



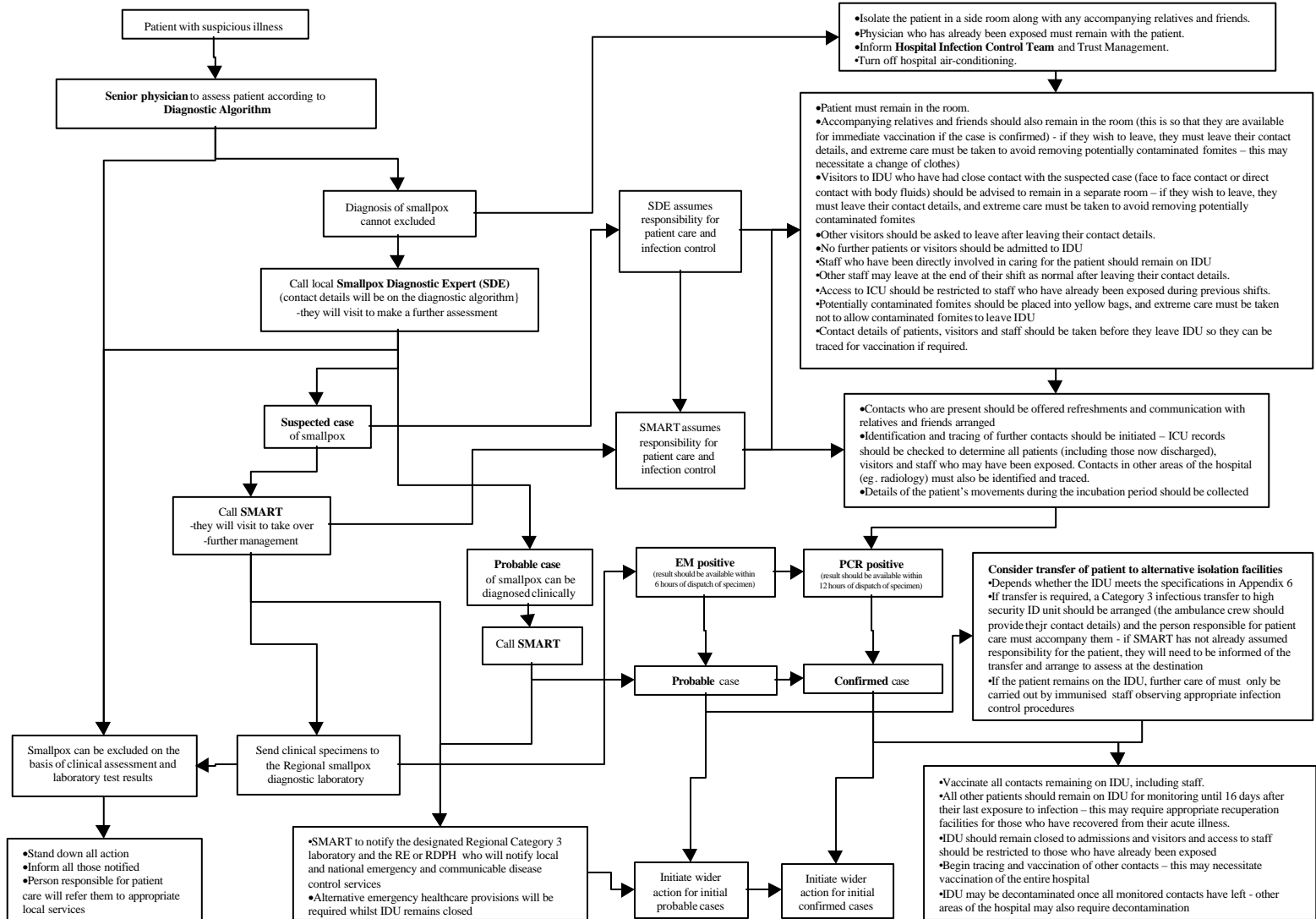
Management of initial cases - patient on General Ward



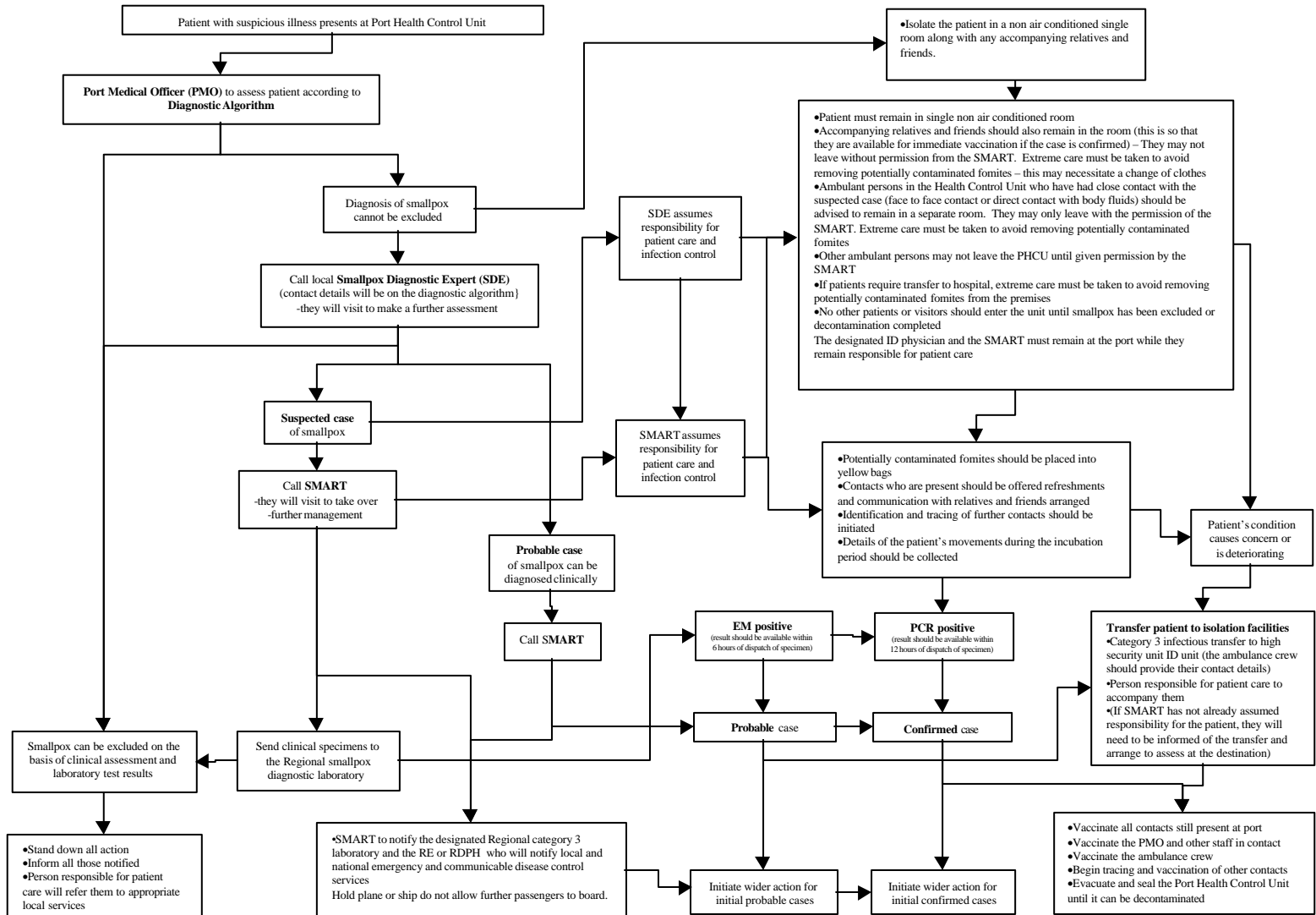
Management of initial cases - patient in Intensive Care Unit



Management of initial cases - patient in Infectious Disease Unit



Management of initial cases - patient at Port Health Control Unit



Glossary

CAMR	Centre for Applied Microbiology and Research
CCDC	Consultant in Communicable Disease Control
CCS	Civil Contingency Secretariat
CDC	Centre for Disease Control and Prevention
CDCN	Communicable Disease Control Nurse
CDSC	Communicable Disease Surveillance Centre
COBR	Cabinet Office Briefing Rooms
CPHL	Central Public Health Laboratory
CMO	Chief Medical Officer
DH	Department of Health
DA	Devolved Administrations
EM	Electron Microscopy
EPCU	Emergency Planning Co-ordination Unit
GP	General Practitioner
HPA	Health Protection Agency
HEPA	Health Emergency Planning Advisor
HIV	Human Immunodeficiency Virus
HO	Home Office
HSV	Herpes Simplex Virus
HSIDU	High Security Infectious Disease Unit
ICU	Intensive Care Unit
IDU	Infectious Disease Unit
IM	Intra Muscular
IV	Intra-Venous
JHAC	Joint Health Advisory Cell
LA	Local Authority
MRSA	Methicillin Resistant Staphylococcus Aueus
NHS	National Health Service
NSOCC	National Smallpox Outbreak Co-ordination Centre
ODPM	Office of the Deputy Prime Minister
OGDs	Other Government Departments
PCR	Polymerase Chain Reaction
PCT	Primary Care Trust
PHCU	Port Health Control Unit
PHLS	Public Health Laboratory Service
PIL	Patient Information Leaflet
PMO	Port Medical Officer
PO	Proper Officer
QA	Quality Assurance
RDPH	Regional Director of Pubic Health
RE	Regional Epidemiologist
RSDRG	Regional Smallpox Diagnosis and Response Groups
RSOCC	Regional Smallpox Outbreak Co-ordination Centres
SCC	Smallpox Care Centre
SDE	Smallpox Diagnostic Expert
SMART	Smallpox Management and Response Team
SVC	Smallpox Vaccination Centre
UN	United Nations
VIG	Vaccinia Immunoglobulin
VZV	Varicella-Zoster Virus
WHO	World Health Organisation