

Protocol Manual For Biological And Chemical Agents

Georgia Department of Human Resources Division of Public Health

June 2004



Protocol Manual For Biological And Chemical Agents

Georgia Department of Human Resources Division of Public Health

June 2004

Approved:

Kathleen E. Toomey, M.D., M.P.H. Kathleen E. Toomey, M.D., M.P.H. Director Division of Public Health Georgia Department of Human Resources <u>5/27/04</u> Date

Protocol Manual For Biological And Chemical Agents 2004

	TABLE OF CONTENTS	
		TAB
INTRODUCTION AND D	SCLAIMER	1
PROTOCOL FOR ANTH	RAX CASES AND EXPOSURE	2
PROTOCOL FOR BLIST AGENTS, LEWISITE, PH	ER AGENT (VESICANT) EXPOSURE (MUSTARD OSGENE OXIME)	3
PROTOCOL FOR BOTU	LISM	4
PROTOCOL FOR BRUC	ELLOSIS CASES AND EXPOSURE	5
PROTOCOL FOR CYAN	IDE EXPOSURE	6
PROTOCOL FOR NERV	E AGENT EXPOSURE	7
PROTOCOL FOR PNEU	MONIC PLAGUE CASES AND EXPOSURE	8
PROTOCOL FOR Q FEV	ER CASES AND EXPOSURE	9
PROTOCOL FOR RICIN	INHALATION, INGESTION OR INJECTION	10
PROTOCOL FOR SMAL	LPOX PRE-EVENT VACCINATION	11
PROTOCOL FOR SMAL	LPOX CASES AND EXPOSURES	12
PROTOCOL FOR TULA	REMIA CASES AND EXPOSURE	13
PROTOCOL FOR VIRAL	HEMORRHAGIC FEVERS (VHF)	14
APPENDICES:		15
APPENDIX A: H	HOME CARE INSTRUCTIONS FOR SELECTED BIOLOGICAL AGENTS	
APPENDIX B:	SUSPICIOUS SUBSTANCES PROTOCOL	
APPENDIX C:	SUMMARY CHART FOR BIOLOGICAL AGENTS	

Acknowledgements for the Revision of this Manual

The revision and updating of this manual began in 2004 with the assistance of the following individuals:

Doris Carnes, Office of Training and Workforce Development Deborah Crippen, Emergency Preparedness Program Camille B. DiClerico, Office of Nursing Olivia Erbele, Office of Nursing Ruth Gilmore, Prevention Services Branch Rachel Gorwitz, Epidemiology Branch Kim Hazelwood, Office of Pharmacy Gary Hlady, Epidemiology Branch Donelle Humphrey-Franklin, Office of Pharmacy Carole Jakeway, Office of Nursing Jerry Kramarczyk (fellow), Office of Training and Workforce Development Susan Lance-Parker, Epidemiology Branch Caminade Moscatiello, Office of Nursing Patrick O'Neal, Emergency Medical Services Mahin Park, State Laboratory Hester Sturrock, Office of Nursing Audrey Ware, Office of Pharmacy

Introduction

- **Purpose:** The purpose of this manual is to provide current guidelines for the assessment, treatment and follow-up of persons who may be exposed to a biological and/or chemical agent. These protocols may be used by healthcare workers, and others, who participate in the response to threats and activities involving one or more of the included biological and/or chemical agents.
- **Contents:** Each protocol begins with a description of the agent, its etiology or mechanism of action, and signs/symptoms of exposure. Those are followed by a plan of care which includes guidelines for diagnostic studies, therapeutics, client education/counseling, follow-up and consultation/referral. A list of references used in developing the protocol is also included.

Attachments to each protocol include Frequently Asked Questions (FAQs) and screening forms. When applicable, reference is made to home care instructions, which can be found in Appendix A.

Protocols are provided for the following agents:

- 1. Anthrax*
- 2. Blister Agents
- 3. Botulism
- 4. Brucellosis*
- 5. Cyanide
- 6. Nerve Agents
- 7. Pneumonic Plague*
- 8. Q Fever*
- 9. Ricin
- 10. Smallpox*
- 11. Tularemia*
- 12. Viral Hemorrhagic Fevers

*Contain guidelines for post-exposure prophylaxis (PEP)

Medications: The federal government has stockpiles of medications [Strategic National Stockpile (SNS)] listed in these protocols, including smallpox vaccine. States may request them for the treatment, post-exposure prophylaxis and follow-up of persons who may be exposed to the above agents.

> Some medications in these protocols have not received approval from the Food and Drug Administration (FDA) to be used for the indications in these protocols. They are considered to be Investigational New Drugs [IND], and are subject to special IND regulations. Federal agencies are currently (as of 6/10/02) collaborating on a process, including standardized forms, to be used when these medications are dispensed or administered. These forms will be provided as soon as they are available. Medications or regimens in these protocols that are subject to IND requirements are denoted by **[IND]**.

Disclaimer

The treatment protocols recommended in this manual are based on a patient that does not exhibit any underlying medical conditions or contraindications. These treatment protocols are not intended to apply to all patients and only serve as general guidance to the health care provider who is responsible for determining a course of treatment that is patient specific. These protocols may have to be modified by the health care provider to treat specific patients based on the patient's medical history and screening form. It is important to note that available resources may impact a health care provider's choice of treatment.

PROTOCOL FOR ANTHRAX CASES AND EXPOSURE

- **DEFINITION** Infectious spores of the anthrax bacterium may be intentionally released through acts of bioterrorism, resulting in human exposure.
- **ETIOLOGY** Bacillus anthracis is a spore-forming, Gram-positive bacillus. Disease occurs most frequently with sheep, goats, and cattle that ingest spores in contaminated soil. Human infection may be acquired through skin contact (cutaneous anthrax), ingestion (gastrointestinal anthrax), or inhalation (inhalational anthrax) of *B. anthracis* spores. Persons with inhalation anthrax are not contagious. Human to human transmission of cutaneous anthrax has been reported but is very rare. Direct exposure to vesicle secretions of cutaneous anthrax lesions may result in secondary cutaneous infection.

SUBJECTIVE & 1. History of exposure to a suspicious substance, or to known anthrax.

- 2. Additional history per the attached Anthrax Screening Form.
- 3. May or may not have signs or symptoms, as follows:
 - a. <u>Inhalational</u> incubation period of 2-60 days
 - Initial signs and symptoms are non-specific and include fever, dyspnea, cough, headache, vomiting, chills, weakness, abdominal pain, and chest pain.
 - The second stage is characterized by fever, dyspnea, diaphoresis, hypotension, cyanosis, and shock accompanied by a widened mediastinum visible on a chest radiograph. Many patients develop hemorrhagic meningitis.
 - 3) Mortality remains extremely high if antibiotic treatment is initiated after the onset of respiratory symptoms.
 - b. <u>Cutaneous</u> incubation period of 1-12 days
 - Direct skin contact with spores or bacilli leads to localized itching and edema, followed by a papular lesion that becomes vesicular and

within 2-6 days develops into a depressed black eschar.

- 2) Death from cutaneous anthrax is rare with antibiotic treatment.
- c. <u>Gastrointestinal</u> incubation period of 1-7 days
 - 1) Abdominal pain, nausea, vomiting, and fever appear following ingestion of contaminated food, usually meat.
 - 2) Symptoms rapidly progress to bloody diarrhea, acute abdomen, and sepsis.
 - 3) Mortality is usually high due to the difficulty of early diagnosis.
- **ASSESSMENT** Exposure to *B. anthracis* (anthrax) Symptomatic, or asymptomatic

NOTE: An individual risk assessment must be made to determine the need for treatment. The Georgia Department of Human Resources' *Advice for First Responders Dealing with Suspicious Substances* (Appendix B) provides some guidance on assessing the credibility of a threat from a suspicious substance. Additional guidance may be obtained by contacting your local or district health department, or the Georgia Division of Public Health.

PLAN If possible, consultation with an infectious disease specialist is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure. Obtain specimens for culture before initiating antimicrobial therapy.

THERAPEUTIC

PHARMACOLOGIC

NOTE: The initial therapies listed in the tables on the following pages should be given until antibiotic susceptibilities are known.

NOTE: Pregnant women should be given the same treatment, including doxycycline, for this life-threatening

illness. Adverse effects on teeth and bones are dose related; therefore, doxycycline might be used for a short time (7-14 days) before 6 months of gestation.

NOTE: Immunocompromised adults and children should receive the same treatment as other adults or children.

Table 1. Inhalational Anthrax Treatment and Post Exposure Prophylaxis (PEP)

NOTE: Ciprofloxacin or doxycycline should be considered an essential part of firstline therapy for inhalational or gastrointestinal anthrax.

Category	Initial Therapy	Continuing Therapy
Adults	 [IND] Ciprofloxacin 400 mg IV every 12 hrs OR Doxycycline 100 mg IV every 12 hrs* 	May alter initial IV therapy based on the patient's clinical course; one or two antimicrobial agents (e.g., ciprofloxacin
	AND One or two additional antimicrobials**	or doxycycline) may be adequate as the patient improves.
	 If organism is susceptible to penicillin, may give; Penicillin V Potassium 7.5 mg/kg po QID OR 	Switch to oral therapy when clinically appropriate: Ciprofloxacin 500 mg po BID
	Penicillin G Procaine 1.2 million units IM every 12 hours.	OR Doxycycline 100 mg po BID
	Penicillin G Potassium/Sodium 8–12 million units IV daily in divided doses every 4 to 6 hours. AND	Continue for 60 days of combined IV and oral therapy.
	One or two additional antimicrobials**	
Adults PEP	1) Ciprofloxacin 500 mg po every 12 hrs OR	
	AND One or two additional antimicrobials**	
Children	 [IND] Ciprofloxacin 10 mg/kg IV*** every 12 hrs, not to exceed maximum 400 mg dose every 12 hrs OR 	May alter initial IV therapy based on the patient's clinical course; one or two antimicrobial agents (e.g., Ciprofloxacin or Doxycycline) may be adequate as the patient improves.
	Doxycycline,* >8 yrs and >45 kg: 100 mg IV every 12 hrs >8 yrs and <u><</u> 45 kg: 2.2 mg/kg IV every 12 hrs <u><</u> 8 yrs: 2.2 mg/kg IV every 12 hrs AND One or two additional antimicrobials**	Switch to oral therapy when clinically appropriate: Ciprofloxacin 15 mg/kg po q12h, not to exceed 500 mg maximum dose every 12 hrs.
	 If organism is susceptible to penicillin, may give Penicillin G Potassium/Sodium: ≤12 yrs 50,000 u/kg IV every 6 hrs >12 yrs 4 million units IV every 4 hrs 	Doxycycline, >8 yrs and >45 kg: 100 mg po BID >8 yrs and <u><</u> 45 kg: 2.2 mg/kg po BID <u><</u> 8 yrs: 2.2 mg/kg po BID
	Children younger than 9 years of age Penicillin V Potassium 50 mg/kg po in 4 divided doses. AND	Continue for 60 days of combined IV and oral therapy.
	One or two additional antimicrobials**	
Children PEP	not to exceed maximum 400 mg IV every 12 hrs OR	
	>8 yrs and >45 kg: 100 mg IV every 12 hrs >8 yrs and <u><</u> 45 kg: 2.2 mg/kg IV every 12 hrs <u><</u> 8 yrs: 2.2 mg/kg IV every 12 hrs	

	AND	
	One or two additional antimicrobials**	
NOTE: The American Academy of Pediatrics recommends the use of tetracyclines for serious infections.	 2) If organism is susceptible to penicillin, may give Penicillin G Procaine 25,000 units/kg IM (maximum 1.2 million units) every 12 hours. AND 3) One or two additional antimicrobials** 	

Table 2. Gastrointestinal Anthrax Treatment

NOTE: Ciprofloxacin or doxycycline should be considered an essential part of firstline therapy for inhalation or gastrointestinal anthrax.

Category	Initial Therapy (intravenous)	Continuing Therapy
Adults	 [IND] Ciprofloxacin 400 mg IV every 12 hrs OR Doxycycline 100 mg IV every 12 hrs* AND One or two additional antimicrobials** 	May alter initial IV therapy based on the patient's clinical course; one or two antimicrobial agents (e.g., Ciprofloxacin or Doxycycline) may be adequate as the patient improves.
	 2) If organism is susceptible to penicillin, may give Penicillin Potassium/Sodium 4 million units IV every 4 hours AND One or two additional antimicrobials** 	Switch to oral therapy when clinically appropriate: Ciprofloxacin 500 mg po BID OR Doxycycline 100 mg po BID Continue for 60 days of combined IV and oral therapy.
Children NOTE: The American Academy of Pediatrics recommends the use of tetracyclines for serious infections.	 [IND] Ciprofloxacin 10 mg/kg IV*** every 12 hrs, not to exceed maximum 400 mg/IV every 12 hrs OR Doxycycline,* >8 yrs and >45 kg: 100 mg IV every 12 hrs >8 yrs and ≤45 kg: 2.2 mg/kg IV every 12 hrs ≤8 yrs: 2.2 mg/kg IV every 12 hrs AND One or two additional antimicrobials** 2) If organism is susceptible to penicillin, may give Penicillin G: ≤12 yrs 50,000 u/kg every 6 hrs >12 yrs 4 million units IV every 4 hrs AND One or two additional antimicrobials** 	May alter initial IV therapy based on the patient's clinical course; one or two antimicrobial agents (e.g., Ciprofloxacin or Doxycycline) may be adequate as the patient improves. Switch to oral therapy when clinically appropriate: Ciprofloxacin 15 mg/kg po q12h, not to exceed 500 mg maximum dose po every 12 hrs. OR Doxycycline, >8 yrs and >45 kg: 100 mg po BID >8 yrs and ≤45 kg: 2.2 mg/kg po BID ≤8 yrs: 2.2 mg/kg po BID Continue for 60 days of combined IV and oral therapy.

* If meningitis is suspected, doxycycline may be less optimal because of poor central nervous system penetration.

**Other agents with *in vitro* activity include: rifampin, vancomycin, penicillin, ampicillin, chloramphenicol, imipenem, clindamycin, and clarithromycin. Because of concerns of constitutive and inducible beta-lactamases in *Bacillus anthracis*, penicillin and ampicillin should not be used alone. Do not use extended-spectrum cephalosporins or

trimethoprim/sulfamethoxazole because anthrax may be resistant to these drugs. Consultation with an infectious disease specialist is advised.

*** If intravenous Ciprofloxacin is not available, oral Ciprofloxacin may be acceptable because it is rapidly and well absorbed from the gastrointestinal tract with no substantial loss by first-pass metabolism. Maximum serum concentrations are attained 1-2 hours after oral dosing but may not be achieved if vomiting or ileus are present.

Table 3. Cutaneous anthrax treatment and Post Exposure Prophylaxis (PEP)

NOTE: Cutaneous anthrax with signs of systemic involvement, extensive edema, or lesions on the head or neck requires intravenous therapy, and a multidrug approach is recommended. See Table 1.

Category	Initial therapy	Continuing Therapy
Adults Treatment	 [IND] Ciprofloxacin 500 mg po BID OR Doxycycline 100 mg po BID Penicillin V Potassium 200-500 mg po QID, when caused by susceptible <i>Bacillus anthracis</i>. OR 4) Penicillin G Procaine 600,000 to 1 million units daily, when caused by susceptible <i>Bacillus anthracis</i>. 	Continue for 60 days, given the likelihood of exposure to aerosolized <i>B. anthracis.</i> [IND] Amoxicillin 500 mg po TID is an option for completion of therapy after infected client improves clinically. Amoxicillin does not have an approved indication for anthrax prophylaxis or treatment, however, the CDC recommends in instances where the
		 specific <i>B.anthracis</i> strain has been shown to be penicillin-sensitive, prophylactic therapy with Amoxicillin (500 mg orally three times a day for 60 days) may be considered. Postexposure prophylaxis may be discontinued sooner if laboratory studies and investigation have ruled out the presence of <i>B. anthracis</i>, or shortened to 30-45 days when vaccine regimen is complete.
Children NOTE: The American Academy of Pediatrics recommends the use of tetracyclines for serious infections.	 [IND] Ciprofloxacin 15 mg/kg po every 12 hrs, not to exceed a maximum dose of 500mg q12h OR Doxycycline,* >8 yrs and >45 kg: 100 mg po every 12 hrs >8 yrs and <u><45 kg</u>: 2.2 mg/kg po every 12 hrs <u><8 yrs</u>: 2.2 mg/kg po every 12 hrs OR Penicillin V Potassium 25-50 mg/kg daily given in 2 or 4 divided doses po QID when caused by susceptible <i>Bacillus anthracis</i>, not to exceed 500 mg po QID. 	Continue for 60 days [IND] Amoxicillin 80 mg/kg/day, divided every 8 hours, is an option for completion of therapy after infected child improves clinically. Postexposure prophylaxis may be discontinued sooner if laboratory studies and investigation have ruled out the presence of <i>B. anthracis</i> , or shortened to 30-45 days when vaccine regimen is complete.

Post-exposure [IND] Anthrax vaccination, if available

For a previously unvaccinated individual, administer vaccine at 0, 2, and 4 weeks of antibiotic prophylaxis. When all three of these vaccine doses have been given, post-exposure antibiotic prophylaxis may be shortened to 30-45 days.

CLIENT EDUCATION/COUNSELING

- 1. Report potential side effects to medication or suspicious symptoms.
- 2. Reaffirm that person-to-person spread of inhalational anthrax does not occur.
- 3. Use standard precautions and contact precautions for cutaneous anthrax and for gastrointestinal anthrax if diarrhea is not controlled.
- 4. See Appendix A for Home Care Instructions and Appendix C for the Summary Chart for Biological Agents.
- 5. See attached FAQs for additional information.

FOLLOW-UP

Each person who begins PEP should be given a postcard to sign and mail back when treatment is completed.

CONSULTATION/REFERRAL

- 1. If client develops suspicious symptoms, or signs of adverse side effects to medication.
- 2. Mental health services, as needed, for victims of bioterrorism.

REFERENCES

- 1. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 2. "Bioterrorism Readiness Plan: A Template for Healthcare Facilities," APIC and CDC, <u>http://www.cdc.gov/ncidod/hip/Bio/13apr99APIC-CDCBioterrorism.pdf</u>.
- 3. Mandell, Bennett, and Dolin (eds.), *Principles and Practice of Infectious Diseases*. 5th ed., Churchill Livingstone, Philadelphia, 2000.
- 4. *Physicians' Desk Reference*, 55th ed., Medical Economics Company, New Jersey, 2001.
- 5. *Medical Management of Biological Casualties Handbook*, 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 6. "Update: Investigation of Bioterrorism-Related Anthrax and Interim Guidelines for Exposure Management and Antimicrobial Therapy, October 2001," *MMWR*, Centers for Disease Control and Prevention, Oct 19, 2001, Vol. 50, No.41.
- 7. "Update: Investigation of Bioterrorism-Related Anthrax and Interim Guidelines for Exposure Management and Antimicrobial Therapy, October 2001," *MMWR*, Centers for Disease Control and Prevention, Oct 26, 2001, Vol. 50, No. 42.
- 8. "Update: Investigation of Bioterrorism-Related Anthrax and Interim Guidelines for Exposure Management and Antimicrobial Therapy, October 2001," *MMWR*, Centers for Disease Control and Prevention, November 2, 2001, Vol. 50, No.43.
- 9. T.V. Inglesby et al. "Anthrax as a Biological Weapon: Medical and Public Health Management," *JAMA*, Vol. 281, No. 18, May 12, 1999, pp.1735-1745.
- 10. "Update: Investigation of Anthrax Associated with Intentional Exposure and Interim Public Health Guidelines, October 2001," *MMWR*, Centers for Disease Control and Prevention, October 26, 2001, Vol. 50, No.41.
- 11. "Conference Summary: Clinical Issues in the Prophylaxis, Diagnosis, and Treatment of Anthrax", Emerging Infectious Diseases, CDC, Feb 2002, Vol 8, No 2.
- 12. <u>http://www.bt.cdc.gov/agent/anthrax/index.asp.</u>
- 13. "Fact Sheet: Anthrax Information for Health Care Providers", CDC, 3/2002, http://www.bt.cdc.gov/agent/anthrax-hcp-factsheet.asp.
- 14. Shepard CW, Soriano-Gabarro M, Zell ER, et al, "Antimicrobial Postexposure Prophylaxis for Anthrax: Adverse Events and Adherence", Emerging Infectious Diseases, Vol 8, No 10, Oct 2002.
- 15. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 4th ed., Center for Disease Control and Prevention, January 2004.
- 16. *American Hospital Formulary Service (AHFS) Drug Information 2004* American Society of Health-System Pharmacists.

ANTHRAX FREQUENTLY ASKED QUESTIONS (FAQs)

What is anthrax?

Anthrax is a bacterium (germ) that may intentionally be released into the air (bioterrorism) and breathed (inhaled) into people's lungs causing severe respiratory distress. The germ can also get into open sores on the skin. Rarely, the germ can be eaten and cause stomachache, vomiting and diarrhea.

Is anthrax spread from person to person?

The inhalational and gastrointestinal forms of the infection are NOT spread from person to person.

How will I know if I was exposed to the germ?

It will depend on how the germ is released, where it was released, and where you were in relation to the release site. The further away you were from the release site the less likely it will be that you were exposed.

How soon will symptoms develop (incubation period)?

Symptoms may start from within a few days to several weeks after exposure to the germ. Since the germ can live for a long time in the environment, symptoms may not start for up to 60 or more days after the germ was released into the air.

What are the symptoms of infection?

If the anthrax germ invades your lungs, you may have a fever, possibly a productive cough, and severe shortness of breath. If the skin is contaminated, an itchy, black spot with swelling may appear. If the germ is swallowed, you may develop a stomachache, vomiting, and diarrhea that may be bloody.

How is the infection treated?

If you have the infection, your health care provider (doctor, nurse, or mid-level provider) will give you an antibiotic.

How is the infection prevented?

If the local health officer determines that you were exposed to the germ, you will be offered an antibiotic. Even if you take the antibiotic, you may develop the infection. If you develop symptoms such as fever or shortness of breath while you are taking the antibiotic, you should go to the nearest emergency service center or hospital immediately.

Adopted in part from the California Dept. of Health Services 2002

ANTHRAX - SCREENING FORM

Current Date://	Medical Record Number: _		
Name: (Last)	(First)		MI:
Street Address#:	City:	State:	Zip:
Home Phone:			
Occupation:	Work Phone:		
Work Address:	City:	State:	_ Zip:
Age:Date of Birth:	Sex: Date Symptoms	Started:	

Questions	No	Yes
Have you been camping in the last 6 weeks?		
Have you had any insect bites in the past 6 weeks?		
Have you had contact with sick animals in the past 6 weeks?		
Are you or could you be pregnant?		

In the past 6 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 6 weeks, have you traveled to any foreign countries? If yes, identify them, and the cities:_____

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)? _____NO ____YES If yes, to what medicine(s)?

Have you had any of the following symptoms in the past 6 weeks?

Symptom	Yes	No	Symptom	Yes	No
Fever			Trouble breathing		
Upset stomach (nausea)			Sweating excessively		
Headache			Pain or tightness in the chest		
Dry cough			Very tired		
Sore muscles			Vomiting blood		
Bloody diarrhea			Black scab on skin		
Pain in the stomach			Sore throat		
Itchy skin			Pain in the neck		
Trouble swallowing					

Adopted in part from the California Dept. of Health Services 2002

PROTOCOL FOR BLISTER AGENT (VESICANT) EXPOSURE (MUSTARD AGENTS, LEWISITE, PHOSGENE OXIME)

- **DEFINITION** Blister agents (vesicants) are chemical compounds which include: mustard agents, lewisite, and phosgene oxime. These agents cause similar injuries, mainly skin blistering and damage to the eyes, respiratory system, and internal organs within a few minutes to 24 hours after exposure.
- **MECHANISM OF ACTION** Blister agents are inhaled in gaseous form, or absorbed through the skin or mucus membranes in either gaseous or liquid form. These agents react with proteins and DNA to cause damage.
- **SUBJECTIVE &** 1. Symptoms due to exposure to lewisite or phosgene oxime appear within minutes; symptoms of mustard agent exposure are delayed for 2-24 hours.
 - 2. Additional history per the attached Blister Agents Screening Form.
 - 3. Blister agents primarily attack the skin, eyes, lungs, and gastrointestinal tract. Injuries range from mild to severe and may include:
 - a. Translucent, yellowish blisters on the skin (blisters are more pronounced in mustard injuries);
 - b. Pain and redness in the eyes accompanied by light sensitivity, heavy flow of tears, and corneal damage;
 - c. Irritation of the mucus membranes with coughing, sneezing, or hoarseness; and
 - d. Nausea, vomiting, abdominal pain and diarrhea.
 - 4. The central nervous system may also be affected, causing symptoms such as apathy and depression.
 - 5. Bone marrow, spleen, and lymphatic tissue are the internal organs most often affected by blister agents.
 - 6. Death may result from damage to the lungs or from infection arising from blisters and/or reduced production of white blood cells.
- **ASSESSMENT** Exposure to blister agent (vesicant); specify agent if known.
- PLAN Consultation with a toxicologist and/or the regional poison control center (1-800-222-1222) is advised. Consultations with an ophthalmologist and plastic surgeon should also be considered.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC

NON-PHARMACOLOGIC

Decontamination

NOTE: Personnel performing decontamination should wear appropriate protective clothing and breathing apparatus.

- 1. Remove client's clothing and rinse skin with large amounts of soap and water or plain water.
- Flush eyes with water or a physiological saline solution for at least five minutes. Do not patch the eyes. Lubricate lids with sterile petroleum jelly to prevent them from sealing.

PHARMACOLOGIC

1. Specific antidote for lewisite or mustard-lewisite

Lewisite or mustard-lewisite mixture exposure may be treated with (dimercaprol) British Anti-Lewisite (BAL) IM for patients who have signs of shock or significant pulmonary injury. Chelation therapy has a high incidence of adverse effects, and should ideally be performed only by trained personnel. Consultation with the regional poison control center is recommended.

NOTE: Do not give BAL intravenously, or to persons with hypersensitivity to peanuts, pre-existing renal disease, or who are undergoing therapy with iron supplements. Use caution in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency as BAL may induce hemolysis.

 a. Non-pregnant adult and child: [IND] Dimercaprol (BAL in oil) 4-5 mg/kg IM q4h for 4 doses, not to exceed 4 ml per injection site. This regimen can be adjusted depending on the severity of the exposure and symptoms.

- b. Pregnant females: Above dose, only in lifethreatening situations. (Drug category C)
- c. In severe exposure, may administer additional doses of 2 mg/kg daily for 3-4 days.
- d. Maintain alkaline urine to prevent nephrotoxicity. If acute renal insufficiency develops, hemodialysis should be considered to remove the Dimercaprol-arsenic complex.

2. Skin

- a. For blisters smaller than 2 cm and erythematous areas, apply topical antibiotics (e.g., Bacitracin ointment), calamine lotion, or other soothing creams several times a day.
- For blisters larger than 1-2 cm, unroof the blisters, irrigate the denuded areas 2 to 4 times a day with sterile saline or another sterile solution, and apply a topical antibiotic such as silver sulfadiazine 1% (not recommended in infants <2 months old, as it may exacerbate bilirubin toxicity), mafenide acetate, or another topical antibiotic to a thickness of 1-2 mm.
 NOTE: Hypersensitivity to silver sulfadiazine has been documented in late pregnancy.
- 3. Ophthalmic (for lesions more severe than conjunctivitis)
 - a. Consultation with an ophthalmologist is advised.
 - Apply topical mydriatics to affected eye (safety in pregnancy is unknown – Category C; topical mydriatics are **contraindicated** in narrow-angle glaucoma):
 - i. Homatropine ophthalmic drops 2-5%, 1-2 gtts q3-4h,
 OR
 - ii. Long-acting atropine ophthalmic drops 1%, 1 gtt bid (or 1% ointment qd/bid)
 - c. Apply topical antibiotics (e.g., erythromycin ophthalmic ointment 1 cm to affected eye, up to 6 times a day).

- d. Apply sterile petroleum jelly to lid edges several times a day.
- e. Ophthalmic steroids (used during the first 24 hours after exposure only) may decrease inflammation.

4. Systemic Antibiotics

Antibiotics may be needed to control infection. For secondary systemic infection, base antibiotic choice on specific organisms recovered and their antibiotic sensitivities.

5. Pulmonary:

Affected lungs can be treated with bronchodilators.

- 6. Pain Management as appropriate.
- 7. Antipruritic agents as needed.
- 8. Tetanus toxoid as needed.

9. Gastrointestinal

Atropine sulfate (0.4-0.8 mg IM or IV), or another anticholinergic drug or antiemetic, should control the early nausea and vomiting.

10. Bone Marrow

Aplastic anemia may occur after mustard exposure. Sterilization of the gut by nonabsorbable antibiotics should be considered to reduce the possibility of sepsis from enteric organisms. Consultation with hematology/oncology specialists is advised.

FOLLOW-UP

Treatment for burns sustained from blister agents is long-term.

CLIENT EDUCATION/COUNSELING

- 1. Those who have potentially been exposed should seek medical treatment if any symptoms appear, especially respiratory symptoms.
- 2. See attached FAQs for additional information.

REFERRAL

Mental health services, as needed, for victims of chemical attacks.

REFERENCES

- 1. *Medical Management of Chemical Casualties Handbook*, 3rd ed., Medical Research Institute of Chemical Defense. Maryland, 2000.
- 2. *Mustard Agents*, Organization for the Prohibition of Chemical Weapons. Available at <u>http://www.opcw.nl/chemhaz//mustard.htm</u>.
- 3. Andre Pennardt, "CBRNE Urticants, Phosgene Oxime, *eMedicine.com*, Jan 13, 2003.
- 4. Daniel J. Dire, "CBRNE Vesicants, Mustard: Hd, HN 1-3, H", *eMedicine.com*, April 16, 2003.
- 5. Geoffrey M. Fitzgerald, "CBRNE Vesicants, Organic Arsenicals: L, ED, MD, PD, HL", *eMedicine.com*, Jan 13, 2003.
- 6. *American Hospital Formulary Service*, 2004, page 2874.

BLISTER AGENTS FREQUENTLY ASKED QUESTIONS (FAQs)

MUSTARD

What is mustard?

Mustard is a blister agent that causes severe skin, lung, or eye damage. The health effects of exposure can be delayed up to 12 hours. Those exposed might notice the odor of mustard, which is similar to onion or garlic.

What are the health effects of mustard exposure?

Hours after exposure, the skin may appear red. Upper respiratory problems such as difficulty breathing, coughing, painful sinuses, or sore throat may occur as well. Over a period of hours, small blisters appear and gradually combine to form large blisters.

How is exposure to mustard diagnosed?

Mustard exposure can be confirmed through a urine test.

What is the treatment for mustard exposure?

There is no antidote for mustard exposure. Using appropriate personal protective equipment, remove the exposed person from the source immediately, and decontaminate by removing, bagging, and sealing the person's clothing. Flush the skin with water and then wash with soap. Because mustard is persistent in the environment, take care to prevent secondary cases from contaminated clothing, ground, vegetation, or equipment.

LEWISITE

What is lewisite?

Lewisite is a blister agent that produces immediate effects. Its vapor causes burning or pain in the eyes, nose, and skin. Fresh air can increase the pain. Lewisite may also produce visible tissue damage within several minutes of contact.

What are the health effects of lewisite exposure?

Severe damage to the skin, eyes, or airways.

How is exposure to lewisite diagnosed?

Lewisite is diagnosed by recognizing its clinical manifestations (immediate pain or irritation of skin and mucous membranes). Other signs and symptoms that may occur later are skin flushing, blisters on the skin, and eye and airway damage.

What is the treatment for lewisite?

Treatment consists of decontamination, the use of the antidote British Anti-Lewsite (BAL), which is available through hospitals, and supportive care. Using appropriate personal protective equipment, remove the exposed person from the source immediately; decontaminate by removing, bagging, and sealing clothing. Flush skin with soap and water. Because lewisite is persistent in the environment, take care to prevent secondary cases from contaminated clothing, ground, vegetation, or equipment.

PHOSGENE

What is phosgene?

Phosgene is a chemical agent that has the odor of newly mowed hay. This highly toxic substance immediately irritates the eyes, nose, and skin. It also produces tissue damage within several minutes of contact.

What are the health effects of phosgene exposure?

It irritates the eyes, nose, and skin. It also produces tissue damage within several minutes of contact.

How is exposure to phosgene diagnosed?

Phosgene exposure is diagnosed by recognizing the signs and symptoms (eye and airway irritation, difficulty breathing, chest tightness, and delayed pulmonary edema).

What is the treatment for phosgene exposure?

There is no specific antidote for phosgene. Decontaminate exposed areas with very large amounts of water.

For more information about blister agents, visit the CDC Web site at <u>www.bt.cdc.gov</u>.

BLISTER AGENTS – SCREENING FORM

Current Date://	Medical Record Number:		
Last Name:	First Name:		MI:
Street Address:	City:	State:	Zip:
Home Phone:	Work Phone:		
Occupation:			
Work Address:	City:	State: _	Zip:
Age: Date of Birth:	Sex: Date Sympto	oms Started	d:

Questions	No	Yes
Are you or could you be pregnant?		
Are you allergic to peanuts?		
Do you have narrow angle glaucoma?		
Do you have kidney disease?		
Do you have G6PD deficiency? (Glucose-6-Phosphate		
Dehydrogenase)		

In the past 3 weeks, have you had contact with any person with a high fever and a rash? _____ NO _____ YES

In the past 3 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 3 weeks, have you traveled to any foreign countries? If yes, identify them, and the cities:

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicines? ____ NO ____ YES If yes, to what medicines?

Have you had any of the following symptoms in the past 3 weeks?

Symptoms	Yes	No
Pain in the eyes		
Pain in the nasal airways		
Cough		
Pain in the sinuses		
Sore throat		
Blisters of any kind		

PROTOCOL FOR BOTULISM

DEFINITION Botulism is a potentially fatal paralytic illness that results when botulinum toxin enters the human body. Botulinum toxin is probably the most toxic substance known.

There are three primary forms of botulism:

- 1. Foodborne botulism, caused by eating foods contaminated with botulinum toxin;
- 2. Infant botulism, caused by ingesting spores which release toxin in the intestine; and,
- 3. Wound botulism, caused by toxin production in an infected wound.
- **ETIOLOGY** *Clostridium botulinum* is an anaerobic gram-positive bacillus that produces botulinum toxin, a potent neurotoxin. *C. botulinum* is found in soil, decaying vegetation, and lake bottoms and thus easily contaminates vegetables and meats. Botulinum toxin may also be inhaled when stirred up in dust or soil. There are seven types of botulinum toxin produced, yet types A, B, E, and F cause most human disease.

SUBJECTIVE &1.Following inhalation, symptoms occur within 24 hours
to several days. Symptoms resulting from ingestion of
botulinum toxin typically manifest in 18-36 hours, but range
from 6 hours to 10 days.

- 2. Additional history per the attached Botulism Screening Form.
- 3. Initial signs and symptoms of all types of botulism include: blurred and double vision, drooping eyelids, nausea and vomiting, slurred speech, difficulty swallowing, and muscle weakness.
- 4. Following signs and symptoms are: descending skeletal muscle paralysis and death due to respiratory failure if not treated.
- 5. Infants suffering from botulism typically have constipation, flaccid paralysis, and generalized weakness.

ASSESSMENT Botulism (foodborne, infant, wound)

PLAN If possible, consultation with an infectious disease specialist is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC

NONPHARMACOLOGIC

- 1. If ingestion occurred within the past few hours, remove contaminated food from the gut by inducing vomiting or using enemas.
- 2. Treat infected wounds.
- 3. Mechanical ventilation may be required for respiratory muscle paralysis.

PHARMACOLOGIC

- 1. Foodborne or wound botulism
 - If diagnosed early, treat with trivalent equine a. antitoxin for serotypes [IND] A, B, and E, obtained from the CDC. Consult manufacturer's labeling prior to administration for details on the uses, usual cautions, precautions, contraindications and warnings associated with this drug. To report suspected cases, obtain clinical consultation, and request antitoxin, call CDC's Emergency Operations Center (770-488-7100) to contact the Foodborne and Diarrheal Diseases Branch medical officer on call.

NOTE: Perform skin test for horse serum sensitivity before administering equine antitoxin. There is a risk of anaphylaxis. It may also cause serum sickness.

For wound botulism, thoroughly debride the b. wound even if it appears to be healing well and inject it with 3% hydrogen peroxide to produce aerobic conditions. The antitoxin may be injected into the wound. Local antibiotics such as penicillin G or metronidazole may be used. Botulism 2 c. A de-speciated equine heptavalent antitoxin against all seven serotypes was developed by the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and is available under **IND** status.

2. Infant botulism

a. Botulism immune globulin IV (Baby BIG) for the treatment of botulism caused by toxin type A or B in infants younger than 1 year of age.
 Consult manufacturer's labeling prior to administration for details on the uses, usual cautions, precautions, contraindications and warnings associated with this drug

50mg/kg (1 ml/kg) administered as a single IV infusion as soon as a clinical diagnosis of botulism is made. Start the infusion at a rate of 25mg/kg (0.5 ml/kg) per hour; if no untoward reactions have occurred after 15 minutes, the rate can be increased to 50mg/kg (1ml/kg) per hour.

- b. Do not use equine antitoxin because of the potential to cause lifelong hypersensitivity.
- c. Consult an infectious disease specialist.
- 3. Post-exposure prophylaxis (PEP)

Post-exposure prophylaxis, using the USAMRIID heptavalent antitoxin, has been demonstrated to be effective in animal studies. However, human data are not available, so it is not recommended for this indication, and should be considered for use in asymptomatic exposed individuals only in extraordinary circumstances.

CLIENT EDUCATION/COUNSELING

- 1. Reassure clients that person-to-person transmission of botulism does not occur.
- 2. Botulism cases sometimes experience psychological dysfunction following recovery, which may require mental health intervention.

- 3. See Appendix A for Home Care Instructions and Appendix C for the Summary Chart for Biological Agents.
- 4. See attached FAQs for additional information.

CONSULTATION/REFERRAL

Mental health services, as needed, for victims of terrorism.

REFERENCES

- 1. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 2. Bioterrorism Readiness Plan: A Template for Healthcare Facilities, APIC and CDC, Available at <u>http://www.cdc.gov/ncidod/hip/Bio/13apr99APIC-CDCBioterrorism.pdf</u>.
- 3. Mandell et al. (eds.), *Principles and Practice of Infectious Diseases*, 5th ed. Churchill Livingstone, Philadelphia, 2000.
- 4. *Medical Management of Biological Casualties Handbook*, 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 5. Edward Bessman, "CBRNE-Botulism", *eMedicine Journal*, October 15, 200I, Vol. 2, No. 10.
- 6. "Immunobiologics Distributed by The Centers for Disease Control and Prevention", Available at
- http://www.cdc.gov/ncidod/dpd/professional/drgsrv_immunobiologics.htm.
- 7. <u>www.bt.cdc.gov/agent/botulism/index.asp</u>.
- 8. Arnon SS, Schechter R, Inglesby TV, et al. "Botulinum Toxin as a Biological Weapon: Medical and Public Health Management", JAMA, Feb 28, 2001, Vol 285, No 8.
- 9. <u>www.cdc.gov/ncidod/dbmd/diseaseinfo/botulism-g.htm</u>
- 10. American Hospital Formulary Service 2004, p. 3134-3135.

BOTULISM - FREQUENTLY ASKED QUESTIONS (FAQs)

What is botulism?

The bacterium (germ) that causes botulism releases a powerful toxin that causes the muscles to become paralyzed. The germ is normally found in the soil and in ocean or lake-water sediment or silt. Most people get botulism from eating (ingesting) improperly cooked or preserved food. However, if the toxin is intentionally released into the air it could be absorbed into the skin and lungs and cause the same symptoms as ingested botulism.

Is botulism spread from person-to-person?

Neither the germ nor the toxin can be spread from person- to-person.

How will I know if I was exposed to the germ that causes botulism?

It will depend on how and where (air, food, water) the toxin was released, and where you were in relation to the release site.

How soon will symptoms of botulism develop (incubation period)?

Usually symptoms develop in 12 - 36 hours, but the incubation period may be from 6 hours up to 10 days depending on how the toxin was released.

What are the symptoms of botulism?

Early symptoms include blurred and double vision and dry mouth. Symptoms later become more intense and include: sore throat, trouble speaking and swallowing, droopy eyelids, muscle weakness, and trouble breathing.

How is botulism treated?

Injectible anti-toxins (some of which are experimental) may be available, but treatment is often symptomatic. It may become necessary to put a tube in your throat that is attached to a breathing machine (ventilator) to help you breathe. You may be paralyzed and require hospitalization for a long time. As time passes, most persons with botulism recover full use of their muscles.

How is botulism prevented?

The local health department will provide you with information about food and water contamination. If the toxin is released into the air, you will need to stay indoors and close all the windows and doors for a short time.

What should I do if I have symptoms of botulism?

If you have any of the symptoms listed above, go to the nearest emergency room immediately. Otherwise, continue with your routine daily activities. DO NOT go to the emergency room unless you are feeling sick.

How can I get more information?

The local health department will make announcements on radio and TV stations.

Adopted in part from the California Dept. of Health Services 2002

BOTULISM - SCREENING FORM

Current Date://	Medical Record Number:		
Last Name:	First Name:		MI:
Street Address:	City:	State:	Zip:
Home Phone :			
Occupation:	Work Phon	e:	
Work Address:	City:	State:	Zip:
Age: Date of Birth:	Sex: Date Sympto	oms Started:	

Questions	No	Yes
Have you been camping in the past two weeks?		
Have you had any insect bites in the past two weeks?		
Have you had contact with sick animals within the past two weeks?		
Have you been diagnosed with IgA deficiency?		
Are you or could you be pregnant?		

In the past 2 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 2 weeks, have you traveled to any foreign countries? If yes, identify them, and the cities:

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)?	NO	YES	If yes, to what medicine(s)?
--------------------------------------	----	-----	------------------------------

Have you had any of the following symptoms in the past 2 weeks?

Symptoms	Yes	No	Symptoms	Yes	No
Fever			Droopy eyelids		
Blurred vision			Double vision		
Dry mouth			Sore throat		
Trouble swallowing			Trouble breathing		
Constipation			Vomiting		
Diarrhea			Nausea		

Adopted in part from the California Dept. of Health Services 2002.

PROTOCOL FOR BRUCELLOSIS CASES AND EXPOSURE

- **DEFINITION** Also known as "undulant fever" brucellosis is a common veterinary disease of the reproductive tract. In the United States, most cases of human brucellosis are associated with the ingestion of unpasteurized dairy products and are primarily limited to slaughterhouse and laboratory workers.
- **ETIOLOGY** Four *Brucellae* species are pathogenic to humans: *B. abortus, B. melitensis, B. suis,* and *B. canis.* The primary reservoirs are cattle, sheep, goats, and swine. Animals such as elk, caribou, bison, deer, and both wild and domestic canines may also be infected. Transmission to humans occurs through (a) direct contact of infected tissue body fluids with broken skin or conjunctivae, (b) ingestion of contaminated meat or dairy products, or (c) inhalation of infected aerosols.
- **SUBJECTIVE &** 1. History of exposure to bacteria of the *Brucella* species.

OBJECTIVE

- 2. Additional history per the attached Brucellosis Screening Form.
- 3. The incubation period ranges from 5 to 60 days.
- 4. <u>Acute disease</u>: fever, sweating, chills, malaise, anorexia, headache, backache, and myalgia. Additionally, neurologic symptoms, arthritis, and infection of the liver or spleen may be present.
- 5. <u>Chronic disease</u>: may include depression, arthritis, and chronic fatigue syndrome-like symptoms.
- **ASSESSMENT** Exposure to *Brucellae* species (brucellosis) pathogenic to humans Symptomatic or asymptomatic.

PLAN DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC

PHARMACOLOGIC (Optimal antibiotic therapy remains under dispute. Several treatment options are provided below, but consultation with an infectious disease specialist is advised).

- 1. Case -- Combination therapy:
 - a. <u>Adult</u>
 - 1) Doxycycline 100 mg po BID for at least 6 weeks

PLUS

2) **[IND]** Rifampin 600 - 900 mg (15-20 mg/kg) po daily, in 1 or 2 divided doses for at least 6 weeks

AND/OR

Streptomycin 1 g IM once or twice daily for one week, then daily for one week.

NOTE: Several sources favor Streptomycin over Rifampin as the second agent, as it might result in fewer relapses.

- b. Child eight (8) years of age and younger:
 - [IND]Co-Trimoxazole (10 mg/kg Trimethoprim as Co-Trimazole, up to 480 mg/d) po daily in 2 divided doses for at least 4-6 weeks PLUS
 - 2) **[IND]** Rifampin 15-20 mg/kg (not to exceed 600 mg) po daily in 1 or 2 divided doses for at least 6 weeks.

OR

[IND] Gentamicin 5 mg/kg IM in equally divided doses q8h for 5 days. (For infants and children with normal renal function, this may be given as a single daily, undivided dose).

- c. <u>Child >8 years old</u>:
 - Doxycycline 2-4 mg/kg (up to 200 mg) po daily in 2 divided doses for at least 6 weeks PLUS

2) **[IND]** Rifampin 15-20 mg/kg (not to exceed 600 mg) po daily for at least 6 weeks.

OR

Streptomycin 20 mg/kg (up to 1 g) IM in 2 divided doses during the first 7-14 days of Doxycycline or Co-trimoxazole.

NOTE: Several sources favor Streptomycin over Rifampin as the second agent, as it might result in fewer relapses.

NOTE: Infections with complications (e.g., meningitis or endocarditis) require prolonged therapy with multiple agents. An infectious disease specialist should be consulted to select an appropriate regimen. Corticosteroids may also be indicated to reduce inflammation in patients with neurobrucellosis.

- 2. <u>Post-exposure Prophylaxis</u> (PEP)
 - a. <u>Adult</u>

Doxycycline 100 mg po BID for at least 3-6 weeks

PLUS

[IND] Rifampin 600-900 mg po daily for at least 3-6 weeks.

b. <u>Child >8 years</u>:

Doxycycline 2-4 mg/kg (up to 200 mg/d) po daily in 2 divided doses for at least 3-6 weeks **PLUS**

[IND] Rifampin 15-20 mg/kg (not to exceed 600 mg/d) po daily for at least 3-6 weeks.

c. Child eight (8) years of age and younger:

[IND]Co-Trimazole (10 mg/kg/d oral Trimethoprim as Co-Trimazole, up to 480 mg/d) po daily in 2 divided doses for at least 3-6 weeks

PLUS

[IND] Rifampin 15-20 mg/kg (not to exceed 600 mg) po daily for at least 3-6 weeks.

NOTE: If exposure was conjunctival, treatment should be given for 4-6 weeks.

CLIENT EDUCATION/COUNSELING

- 1. Report potential side effects of medication or suspicious symptoms.
- 2. Person-to-person transmission of the organism does not occur.
- 3. Complete the entire course of therapy; relapse is high when treatment is stopped prematurely.
- 4. Possible long-term or chronic signs and symptoms may occur after having brucellosis.
- 5. See Appendix A for Home Care Instructions and Appendix C for the Summary Chart for Biological Agents.
- 6. See attached FAQs for additional information.

FOLLOW-UP

Each person who begins PEP should be given a postcard to sign and mail back when treatment is completed.

CONSULTATION/REFERRAL

- 1. When Doxycycline and/or Rifampin are contraindicated for a client.
- 2. If a client develops suspicious symptoms.
- 3. Mental health services, as needed, for victims of bioterrorism.

REFERENCES

- 1. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 2. Mandell, Bennett, and Dolin (eds.), *Principles and Practice of Infectious Diseases*, 5th ed., Churchill Livingstone, Philadelphia, 2000.
- 3. *Physicians' Desk Reference*, 55th ed., Medical Economics Company, New Jersey, 2001.
- 4. *Infectious Diseases Handbook*, 3rd ed., Lexi-Comp, Inc., Hudson, Ohio, 1999.
- 5. American Hospital Formulary Service, 2004, pages 68,423,451,573,576.
- 6. Gerald E. Maloney, "CBRNE-Brucellosis", *eMedicine Journal*, October 15, 2001, Vol. 2 No. 10.
- 7. Abuhammour W, Nashar K. "Brucellosis", eMedicine.com, Sept 11, 2002.
- 8. Dire DJ. "CBRNE Biological Warfare Agents", eMEdicine.com, Feb 6, 2003.
- 9. Medical Management of Biological Casualties Handbook, 4th Ed, USAMRIID, Maryland, 2001.
- 10. American Pharmacological Association. "Pediatric Dosage Handbook", 9th Ed, 2002-2003, Lexi-Comp Inc, Hudson, OH.
- 11. Long S. "Principles and Practices of Pediatric Infectious Diseases", 2nd Ed, Elsevier Science, Philadelphia, 2003.
- 12. <u>www.bt.cdc.gov/agent/brucellosis/index.asp</u>.

Brucellosis – Frequently Asked Questions (FAQs)

What is Brucellosis?

The bacterium (germ) that causes brucellosis infection is generally transmitted (spread) to humans by contact with infected animals (cows and sheep) or drinking unpasteurized (contaminated) milk products.

Is brucellosis spread from person-to-person?

The infection is **NOT** spread from person-to-person.

How will I know if I was exposed to the germ?

It will depend on how the germ was released, where it was released and where you were in relation to the release site. The further away you were from the release site the less likely it will be that you were exposed.

How soon will the symptoms develop (incubation period)?

The symptoms start from 5 - 60 days after exposure.

What are the symptoms of infection?

Not all persons exposed to the germ will get sick. Symptoms may include: fever, headache, back pain, tiredness, chills, sweats, sore muscles, cough, pain in the lungs during a deep breath, loss of appetite, nausea, vomiting and diarrhea.

How is the infection treated?

Antibiotic medicines are available to treat symptomatic and exposed persons.

How is the infection prevented?

If the health department determines that you were exposed to the germ, you will be offered an antibiotic. Even if you take the antibiotic, you may develop the infection. If any symptoms occur, see your health care provider immediately.

How long should I take the antibiotic?

It is important to take the medicine exactly as directed. The dose and number of treatment days will depend on the antibiotic prescribed. If you develop side effects, call your health care provider immediately. Do not give your medicine to another person.

What should I do if I DO NOT have symptoms?

If you do not have any symptoms of the infection, you should continue with your routine daily activities. **DO NOT** go to the hospital emergency room unless you are feeling sick.

How can I get more information?

The local health department will make frequent public announcements about who should receive an antibiotic, how to take the antibiotic and where you can obtain the antibiotic. It is important that you listen to the radio or television for more information.

Adopted in part from the California Dept. of Health Services 2002
BRUCELLOSIS – SCREENING FORM

Current Date:///	Medical Record Number:		
Last Name:	First Name:		MI:
Street Address:	City:	State:	_Zip:
Home Phone:			
Occupation:	Work Phone:		
Work Address:	City:	State:	Zip:
Age: Date of Birth:	Sex: Date Sympt	oms Started:	

Question	No	Yes
Have you been camping in the past 3 weeks?		
Have you had any insect bites in the past 3 weeks?		
Have you had any contact with sick animals in the past 3 weeks?		
Are you or could you be pregnant?		

In the past 3 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 3 weeks, have you traveled to any foreign countries? If yes, identify them, and the cities: _____

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)? _____NO ____YES If Yes, to what medicines?

Have you had any of the following symptoms in the past 3 weeks?

Symptoms	Yes	No	Symptoms	Yes	No
Fever			Pain or tightness in the chest		
Headache			Feel cold all over or		
			shiver/shake		
Cough			Pain in the joints		
Sore muscles			Very tired		
Diarrhea (loose/runny			Vomiting		
stool)					
Pain in stomach			Upset stomach (nausea)		
Constipation			Lost of appetite		
Short of breath			Bad taste in the mouth		
Pain in the lumbar area			Stiff neck		

Adopted in part from the California Dept. of Health Services 2002

PROTOCOL FOR CYANIDE EXPOSURE

DEFINITION Cyanide is a highly lethal compound. It is not routinely considered a threat as an outdoor bioterrorism agent due to its high volatility, but in confined spaces it can rapidly be fatal.

MECHANISM OF Cyanide may be:

ACTION

- 1. Inhaled in gaseous form (hydrogen cyanide).
- 2. Absorbed through the skin in gaseous form, in pure liquid form, or as a solution of cyanide salts (potassium cyanide, sodium cyanide).
- 3. Ingestion may also occur.

Cyanide inhibits enzymes containing metal and disrupts normal cell functions, such as cell respiration. Cyanide poisoning commonly results in the buildup of lactic acid, causing metabolic acidosis.

- **SUBJECTIVE &** 1. Onset of symptoms is immediate or up to several hours following exposure, depending on the exposure dose and type. Inhalation exposure shows symptoms rapidly, while symptoms following ingestion may be delayed.
 - 2. Signs and symptoms of exposure to smaller concentrations of cyanide include increased respiratory rate leading to respiratory difficulty, restlessness, headache, palpitations, and later vomiting, convulsions, respiratory failure, unconsciousness, and possibly cardiac arrest.
 - 3. If the initial dose is extremely high, victims may show no symptoms, and suddenly collapse and die.
- **ASSESSMENT** Exposure to cyanide (gas, liquid or salts).
- PLAN Consultation with a toxicologist and/or the regional poison control center (1-800-222-1222) is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC

NON-PHARMACOLOGIC

Decontamination following exposure to liquid or gaseous cyanide is not usually needed due to cyanide's high volatility. However, if clothing is wet, remove it and wash affected skin with soap and water. Irrigate exposed or irritated eyes with plain water or a normal saline solution for 5 minutes.

PHARMACOLOGIC

- Symptomatic victims, especially those with severe manifestations, should be treated with 100% oxygen and specific cyanide antidotes as needed. Cyanide antidotes (amyl nitrite ampules and IV infusions of sodium nitrite and sodium thiosulfate) are packaged in a cyanide antidote kit. 100% oxygen should be provided throughout the treatment.
- Until an IV line is established: Break an ampule of amyl nitrite onto a gauze pad and hold the pad to client's nostril (or over the Ambu-valve intake or under the lip of the face mask) for 30 seconds every minute. Use a new ampule every three minutes until the sodium nitrite infusion is initiated.
- 3. <u>After an IV line is established</u>:
 - a. Sodium nitrite 3% solution,
 - Child <25 kg: 6 mg/kg (0.12-0.33 ml/kg) of a 3% solution, up to 10 ml (300 mg) IV over 5-20 minutes.
 - Child >25 kg and adult: 300 mg (10 ml of 3% solution) IV over 5-20 minutes.

NOTE: Slow the rate of infusion if hypotension develops. Adjust dose for persons with anemia.

FOLLOWED BY

- b. Sodium thiosulfate, 25% solution,
 - Initial dose for child <25 kg: 1.65 ml/kg (up to 50 ml) over 10 minutes at a rate of 2.5-5ml/minute.
 - Initial dose for child > 25 kg and adult: 12.5 g (50 ml of a 25% solution) over 10 minutes at a rate of 2.5-5 ml/minute.

If signs of cyanide poisoning reappear, give 50% of the initial doses of sodium nitrite and sodium thiosulfate one hour after the initial dose.

- c. Correct acidosis as needed.
- d. Benzodiazepines for seizure control as needed.

CLIENT EDUCATION/COUNSELING

See attached FAQs for additional information.

FOLLOW-UP

Clients who present with more than minimal symptoms may require a 24-48 hour observation period and supportive care.

REFERRAL

Mental health services, as needed, for victims of terrorism.

REFERENCES

- 1. *Medical Management of Chemical Casualties Handbook*, 3rd ed., Medical Research Institute of Chemical Defense, Maryland, 2000.
- 2. *Hydrogen Cyanide*, Organization for the Prohibition of Chemical Weapons. Available at <u>http://www.ocpw.nl/chemhaz/cwagents.htm.</u>
- 3. American Hospital Formulary Services, 2002, p. 1879.
- 4. Andre Pennardt, "CBRNE Cyanides, Hydrogen", *eMedicine.com*, January 9, 2003.
- 5. <u>http://www.bt.cdc.gov/agent/cyanide/index.asp.</u>
- 6. http://www.atsdr.cdc.gov/MHMI/mmg.html.
- 7. *Cyanide Toxicity,* Available at <u>http://www.emedicine.com/med/topic487.htm</u>.

CYANIDE - FREQUENTLY ASKED QUESTIONS (FAQs)

What is cyanide?

Cyanide is a colorless liquid that prevents cells from using oxygen, which results in death. Inhalation is the primary mode of exposure.

What are the health effects of cyanide exposure?

In moderate amounts, cyanide may produce headache, nausea, dizziness, weakness, or anxiety. A large amount of cyanide will produce loss of consciousness within seconds, and death may occur within minutes.

How might I be exposed to cyanide?

- Breathing air, drinking water, touching soil, or eating foods containing cyanide.
- Smoking cigarettes and breathing smoke-filled air during fires.
- Breathing air near a hazardous waste site containing cyanide.
- Eating foods containing cyanide compounds, such as cassava roots, lima beans, and almonds.
- Working in an industry where cyanide is used or produced, such as metallurgy, electroplating, metal cleaning, and photography.

How is exposure to cyanide diagnosed?

Cyanide exposure is diagnosed by clinical signs and symptoms suggestive of inadequate oxygen. Medical tests can measure blood and urine levels of cyanide; however, small amounts of cyanide are always detectable in blood and urine. Tissue levels of cyanide can be measured, but cyanide is rapidly cleared from the body, so the tests must be done soon after the exposure. An almond-like odor in the breath may be a suspicious sign that a person was exposed to cyanide.

What is the treatment for cyanide exposure?

Rapid treatment with oxygen and antidotes can provide success.

How likely is cyanide to cause cancer?

The EPA has determined that cyanide is not classifiable as to its human carcinogenicity (ability to cause cancer). There are no reports that cyanide can cause cancer in people or animals.

Source of Information

Agency for Toxic Substances and Disease Registry (ATSDR),1997. Toxicological profile for cyanide (update), Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

For more information: <u>www.atsdr.cdc.gov/toxfaq.html</u> <u>www.bt.cdc.gov/DocumentsApp/faq.asp</u>

PROTOCOL FOR NERVE AGENT EXPOSURE

DEFINITION	Nerve organ impuls manu The m agent • •	 re agents are chemical compounds classified as no-phosphates, which affect transmission of nerve ilses following exposure. They are easy to ufacture, highly toxic, stable, and easily dispersed. most important nerve agents as potential terrorism its are: Tabun (GA) Sarin (GB) Soman (GD) Cyclosarin (GF) VX 	
	See a inform	ttacheo nation c	d Frequently Asked Questions (FAQs) for on specific agents.
MECHANISM OF ACTION	Nerve or ingest cholin transr	e agenta ted in c esteras nission	s may be inhaled, absorbed through the skin, contaminated food or water. They inhibit se enzymes, which results in disrupted of nerve impulses.
SUBJECTIVE & OBJECTIVE	1.	Onset expos liquid.	t of symptoms ranges from a few seconds for sure to vapor, to <18 hours for exposure to
	2.	Signs	/symptoms
		a.	Exposure to small doses results in increased production of saliva, runny nose, feeling of

- production of saliva, runny nose, feeling of pressure in the chest, miosis, headache, tiredness, slurred speech, hallucinations, and nausea.
- b. Larger doses cause increased secretions (mucus, tears, saliva, sweat), abdominal cramping and vomiting, coughing and difficulty breathing, muscular weakness, convulsions and, possibly, involuntary urination and defecation.
- c. Extremely high doses exhibit more pronounced muscular symptoms and unconsciousness; if the dose is large enough

death precedes the development of many symptoms.

ASSESSMENT Exposure to a nerve agent (vapor or liquid).

PLAN If possible, consultation with a toxicologist and/or the regional poison control center (1-800-222-1222) is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC

NON-PHARMACOLOGIC

- 1. Remove clothing and treat it as toxic waste.
- 2. Decontaminate exposed person by washing with soap and water.

NOTE: Personnel performing decontamination procedures should dress in appropriate chemically protective equipment. In the absence of more specific information, this should be at OSHA Level B or higher, including a supplied air respirator or powered air-purifying respirator with appropriate cartridge filters for the agent(s) in question.

PHARMACOLOGIC

NOTE: Prolonged observation may be necessary to detect late effects of exposure needing treatment.

- 1. For excess secretions, miosis, and other muscarinic effects:
 - a. Atropine (Pregnancy Category C), initial dose
 - <u>Infant (<2 yrs)</u>:
 a) Mild to moderate symptoms,
 - 0.05 mg IM **or** 0.02 mg/kg IV;
 - b) <u>Severe symptoms</u>, 0.1 mg/kg IM or 0.02 mg/kg/IV.
 - 2) <u>Child (2-10 yrs</u>):

- a) <u>Mild to moderate symptoms</u>, 1 mg IM;
- b) <u>Severe symptoms</u>, 2 mg IM.
- 3) <u>Child >10 yrs and Adult</u>:
 - a) <u>Mild to moderate symptoms</u>, 2 - 4 mg IM **or** IV;
 - b) <u>Severe symptoms</u>, 6 mg IM **or** IV.
- 4) Elderly:
 - a) <u>Mild to moderate symptoms</u>, 1 mg IM **or** IV
 - b) <u>Severe symptoms</u>, 2 - 4 mg IM **or** IV.
- b. If an initial dose does not control secretions, repeat Q 2-5 minutes, titrated to effect.
- c. Additional doses of atropine may be given PRN until secretions have diminished and breathing is comfortable or airway resistance has returned to near normal.

NOTE: The client may require extremely large doses (e.g., up to 20 mg) in the first 3 hours.

- 2. For hypertension, muscle weakness, and other nicotinic effects:
 - a. Pralidoxime chloride [2PAM] (Pregnancy Category C), initial dose, IV infusion of 20-30 minutes or longer.
 NOTE: 2PAM is effective only when given with atropine.
 - 1) Infants and children < 10 years:
 - a) <u>Mild to moderate symptoms</u>, 15 mg/kg IM **or** IV;
 - b) <u>Severe symptoms</u>,
 25 mg/kg IM or 15 mg/kg IV.
 - 2) <u>Adults</u>:
 - a) <u>Mild to moderate symptoms</u>, 600 mg IM autoinjector **or** 15 mg/kg IV (maximum 1 g);
 - b) <u>Severe symptoms</u>, 1800 mg IM **or** 15 mg/kg IV (maximum 1 g).

- 3) Elderly:
 - a) <u>Mild to moderate symptoms</u>, 10 mg/kg IM **or** 5-10 mg/kg IV;
 - b) <u>Severe symptoms</u>, 25 mg/kg IM **or** 5-10 mg/kg IV.
- Repeat initial dose PRN, once or twice at intervals of 60-90 minutes.
 Maximum dose is 2.5 g within 60 to 90 minutes.
- c. If 2PAM-induced hypertension occurs, give phentolamine (child 1 mg IV, adult 5 mg IV).
- 3. For seizures_ Diazepam [e.g., Valium] (Pregnancy Category D),
 - a. <u>Neonates</u>:

0.1 - 0.3 mg/kg/dose IV over 3-5 minutes, every 15-30 minutes (maximum total dose 2 mg).

- b. <u>Infants and children <5 years</u>: 0.2 - 0.5 mg/dose IV every 2-5 minutes, (maximum total dose 5 mg); repeat in 2-4 hours PRN.
- c. <u>Children 5-12 years</u>: 1 mg/dose IV every 2-5 minutes, (maximum total dose 10 mg); repeat in 2-4 hours PRN.
- d. <u>Adults</u>: 5-10 mg IV every 10-15 minutes, up to 30 mg in an 8 hour period; may repeat in 2-4 hours PRN.
- 4. Mydriatic-cyclopegics, as needed, for ophthalmic care in adults:

Tropicamide 1-2 gtt of 0.5% solution to the eye; may repeat in 5 minutes. Persons with heavily pigmented irises may require larger doses.

(Pregnancy Category C).

CLIENT EDUCATION/COUNSELING

See attached FAQs for additional information.

REFERRAL

Mental health services, as needed, for victims of terrorism.

REFERENCES

- 1. *Nerve Agents*, Organization for the Prohibition of Chemical Weapons. Available at <u>http://www.pocw.nl/chemhaz/cwagents.htm</u>.
- 2. *Medical Management of Chemical Casualties Handbook*, 3rd ed., Medical Research Institute of Chemical Defense, Maryland, 2000.
- 3. *Physicians' Desk Reference*, 55th ed., Medical Economics Company, New Jersey, 2001.
- 4. American Hospital Formulary Service, 2004, pages 1208 & 3542.
- 5. American Pharmaceutical Association, *Pediatric Dosage Handbook*, 6th ed., Lexi-Comp, Inc., 1999-2000, p 287.
- 6. Jeffrey L. Arnold, "Nerve Agents, G-series: Tabun, Sarin, Soman", *eMedicine.com*, Jan 9, 2003.
- 7. Georgia Poison Center, "Brief Recommendations to Hospitals Regarding Nerve Agents", Sept 21, 2001.
- 8. <u>http://www.cdc.gov/agentlistschem-category.asp#nerve</u>.
- 9. Medical Management Guidelines (MMGs) for Nerve Agents: Tabun (GA); Sarin (GB); Soman (GD); and VX, Agency for Toxic Substances and Disease Registry (ATSDR). http.www.atsdr.cdc.gov/MHMImmg166.html

NERVE AGENTS - FREQUENTLY ASKED QUESTIONS (FAQs)

The effects of nerve agents often appear almost immediately. In a large group of exposed people, these effects will range from relatively minor effects to very severe effects that may lead to death.

Sarin (GB)

What is sarin?

Sarin is classified as a nerve agent that disrupts the transmission of nerve impulses in the body. It is a colorless, odorless liquid that mixes readily in water. Sarin can be ingested, inhaled, or absorbed through the skin.

What are the health effects of sarin exposure?

Depending on the dose, onset of clinical manifestations can vary from a few minutes to 1 hour, although most occur within minutes. Signs and symptoms include visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death.

How is exposure to sarin diagnosed?

Exposure to sarin is diagnosed by recognizing the signs and symptoms of exposure to nerve agents (visual disturbance, runny nose, chest tightness, nausea, vomiting, and convulsions).

How can sarin exposure be treated?

Treatment includes atropine, pralidoxime chloride, and diazepam. Using appropriate personal protective equipment, remove, bag, and seal contaminated clothing. Decontaminate skin by washing it twice with large amounts of soap and water. Secondary exposure can occur from contact with contaminated clothing; it can also occur when sarin evaporates from contaminated clothing. To protect health care workers and others exposed to a contaminated victim from secondary contamination, remove, bag, and seal the victim's clothing, and wash the victim's skin twice with large amounts of soap and water.

<u> Tabun (GA)</u>

What is tabun?

Tabun is classified as a nerve agent that interrupts the transmission of nerve impulses in the body. It is a colorless-to-brownish liquid. Under average weather conditions, tabun can persist for 1-2 days; it is primarily released as an aerosol or vapor.

What are the health effects of tabun?

Clinical signs and symptoms include visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death.

How is exposure to tabun diagnosed?

Tabun is detected on the basis of the history of exposure, clinical signs and symptoms, and confirmatory laboratory tests. The signs and symptoms of tabun exposure include visual disturbance, runny nose, chest tightness, nausea, vomiting, and convulsions.

How can exposure to tabun be treated?

Treatment includes atropine, pralidoxime chloride, and diazepam. Using appropriate personal protective equipment, remove, bag, and seal contaminated clothing. Decontaminate skin by washing it with large amounts of soap and water. Secondary exposure can occur from contact with contaminated clothing; it can also occur when tabun evaporates from contaminated clothing. To protect health care workers and others exposed to a contaminated victim from secondary contamination, remove, bag, and seal the victim's clothing, and wash the victim's skin with large amounts of soap and water.

Soman (GD)

What is soman?

Soman is classified as a nerve agent that disrupts the transmission of nerve impulses in the body. It is a colorless and tasteless liquid that mixes readily with water. Released soman evaporates rapidly, dissipates, and eventually breaks down in the environment.

What are the symptoms of soman exposure?

Clinical manifestations include visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death.

How is soman exposure diagnosed?

Diagnosis is based on history of exposure, clinical signs and symptoms, and confirmatory laboratory tests. Signs and symptoms of soman exposure include visual disturbance, runny nose, chest tightness, nausea, vomiting, and convulsions.

How is exposure to soman treated?

Treatment consists of decontamination; drugs such as atropine, pralidoxime chloride, and diazepam; ventilation to support respiratory function; and supportive care. Contaminated clothing must be removed, bagged, and sealed. Decontaminate skin by washing it with large amounts of soap and water. Secondary exposure can occur from contact with contaminated clothing; it can also occur when soman evaporates from contaminated clothing. To protect health care workers and others exposed to a contaminated victim from secondary contamination, remove, bag, and seal the victim's clothing, and wash the victim's skin with large amounts of soap and water.

What is VX?

VX is a nerve agent that disrupts the transmission of nerve impulses in the body. It is an amber-colored, oily liquid that will remain in the environment (persistent) until it has been properly cleaned through decontamination methods. VX can enter the body through ingestion, inhalation, or through the eyes or skin.

What are the health effects of VX exposure?

Health effects include constricted pupils, visual disturbance, runny nose, chest tightness, nausea, vomiting, convulsions, and death.

How is exposure to VX diagnosed?

Diagnosis is based on history of exposure, clinical signs and symptoms, and confirmatory laboratory tests. Signs and symptoms of VX exposure include visual disturbance, runny nose, chest tightness, nausea, vomiting, and convulsions.

How is exposure to VX treated?

Treatment includes atropine, pralidoxime chloride, and diazepam; ventilation to support respiratory function; and supportive care. Using appropriate personal protective equipment, remove, bag, and seal contaminated clothing. Decontaminate skin by washing it with large amounts of soap and water. Because of VX's persistent characteristics, take care to prevent secondary cases from contaminated clothing, ground, vegetation, or equipment.

For more information: www.bt.cdc.gov.

PROTOCOL FOR PNEUMONIC PLAGUE CASES AND EXPOSURE

- **DEFINITION** Naturally occurring bubonic or septicemic plague is transmitted to humans via bites from plague-infected fleas, and may progress secondarily to a pneumonic form. Pneumonic plague would be the most likely initial disease presentation of an intentional aerosol release of the organism. It is highly communicable and person-to-person transmission occurs via infected respiratory droplets.
- **ETIOLOGY** The Gram-negative bacillus *Yersinia pestis* is the causative organism. Wild rodents are the natural reservoir of the organism, which is found worldwide.
- **SUBJECTIVE &** 1. History of inhalation exposure to Yersinia pestis.
 - 2. Additional history per the Pneumonic Plague Screening Form.
 - 3. The incubation period is usually 2-4 days following inhalation exposure, with a range of 1-6 days.
 - 4. In cases of primary pneumonic plague, victims experience fever, headache, weakness, shortness of breath, chest pain, and cough with bloody and sometimes watery sputum. Gastrointestinal symptoms such as nausea, vomiting, diarrhea, and abdominal pain may also be present.
 - 5. Pneumonic plague may initially be indistinguishable from other respiratory illnesses in an outbreak. A presumptive diagnosis of pneumonic plague can be made based on the disease's rapid progression to respiratory failure, sepsis, and shock. The presence of hemoptysis also strongly indicates plague. If not treated within 24-48 hours of symptom onset, pneumonic plague may be up to 100% fatal.
- ASSESSMENT Exposure to pneumonic plague Symptomatic or asymptomatic
- PLAN If possible, consultation with an infectious disease specialist is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC

PHARMACOLOGIC

1. Cases

NOTE: Treat for at least 10-14 days.

- a. Adult, not pregnant
 - 1) <u>Preferred regimens</u>
 - a) Streptomycin 1 g IM BID OR
 - b)**[IND]**Gentamicin 5 mg/kg IM or IV daily, or 2 mg /kg loading dose followed by 1.7 mg/kg IM/IV TID.
 - 2) <u>Alternative non-pregnant adult regimens</u>
 - a) Doxycycline 100 mg IV BID or 200 mg IV daily OR
 - b) **[IND]**Ciprofloxacin 400 mg IV BID OR
 - c) **[IND]**Chloramphenicol 25 mg/kg IV QID.
- b. Pregnant women
 - Preferred regimen
 [IND] Gentamicin 5 mg/kg IM or IV daily, or 2 mg/kg loading dose followed by 1.7 mg/kg IM or IV TID.
 - 2) <u>Alternative regimens</u>
 - a) Doxycycline 100 mg IV BID or 200 mg IV daily OR
 - b) **[IND]**Ciprofloxacin 400 mg IV BID.
- c. <u>Children</u>
 - 1) <u>Preferred</u>
 - a) Streptomycin 15 mg/kg IM BID, maximum of 2 g daily OR
 - b) [IND]Gentamicin 2.5 mg/kg IM or IV TID.

NOTE: For neonates up to 1 week old and premature infants, give 2.5 mg/kg IV BID.

- 2) <u>Alternative regimens for children</u>
 - a) Doxycycline 2.2 mg/kg IV BID, maximum 200 mg daily, (If >44 kg, give adult dosage) OR
 - b) **[IND]**Ciprofloxacin 15 mg/kg IV BID, up to 1 g/day OR
 - c) If at least 2 years old,
 [IND]Chloramphenicol 25 mg/kg
 IV QID, up to 4 g/day.
- 2. Postexposure Prophylaxis (PEP)

NOTE: Treat for 7 days as follows:

- <u>Adults, including pregnant females</u>
 <u>Doxycycline 100 mg po BID</u>
 - OR
 - 2) [IND] Ciprofloxacin 500 mg po BID.
- b. <u>Children</u>
 - 1) Doxycycline 2.2 mg/kg po BID (if >44 kg give adult dosage) OR
 - 2) **[IND]** Ciprofloxacin 20 mg/kg po BID, up to 1 g/day.
- c. <u>Alternative PEP for all persons over 2 yrs</u> [IND]Chloramphenicol 25 mg/kg po QID, up to 4 g/day.

CLIENT EDUCATION/COUNSELING

- 1. If receiving PEP, seek immediate medical care if any symptoms of plague develop because different treatment must be given for actual disease.
- 2. Contacts who refuse PEP should seek immediate medical care if they develop a fever or cough within a week of exposure.
- 3. Report any side effects or other problems with medication.
- 4. When providing care to cases, use standard respiratory droplet precautions (surgical mask, gown, gloves and eye

protection) until the client has completed 48 hours of antibiotic therapy and shows improvement.

- 5. See Appendix A for Home Care Instructions and Appendix C for the Summary Chart for Biological Agents.
- 6. See attached FAQs for additional information.

FOLLOW-UP

Each person who begins PEP should be given a postcard to sign and mail back when treatment is completed.

CONSULTATION/REFERRAL

- 1. Clients with suspicious symptoms.
- 2. Mental health services, as needed, for victims of bioterrorism.

REFERENCES

- 1. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 2. Bioterrorism Readiness Plan: A Template for Healthcare Facilities, APIC and CDC, <u>http://www.cdc.gov/ncidod/hip/Bio/13apr99APIC-CDCBioterrorism.pdf</u>.
- 3. Mandell, Bennet, and Dolin (eds.), *Principles and Practice of Infectious Diseases*, 5th ed., Churchill Livingstone, Philadelphia, 2000.
- 4. *Physicians' Desk Reference*, 55th ed., Medical Economics Company, New Jersey, 2001.
- 5. *Medical Management of Biological Casualties Handbook.*, 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 6. American Hospital Formulary Services, 2004, page 68,370-371,451.
- 7. "Management of Plague Used as a Biological Weapon," *JAMA*, May 3, 2000, Vol.. 283, No. 17, page 2287.
- 8. <u>http://www.bt.cdc.gov/agent/plague/index.asp</u>.

PLAGUE - FREQUENTLY ASKED QUESTIONS (FAQs)

What is plague?

Plague is a bacterium (germ) that may intentionally be released into the air through acts of bioterrorism and inhaled (breathed) into people's lungs causing a severe pneumonia. The infection may also be spread to humans through the bite of infected fleas.

Is plague spread from person-to-person?

Yes. The infection is spread from person-to-person by close contact (within 3 feet) with the infected person who coughs the germ from the lungs into the air.

How will I know if I was exposed to the germ?

That will depend on how and where the germ was released into the air, and where you were relative to the release site. The further away you were, the less likely it will be that you were exposed. If you have close contact (within 3 feet) with an infected person the local health department may determine that you have been exposed.

How soon will symptoms develop (incubation period)?

The symptoms may start within 1 - 4 days after you breathe the germ into your lungs.

What are the symptoms of infection?

The symptoms include sudden onset of high fever, chills, headache, extreme fatigue, muscle aches, and a cough that may be bloody.

How is the infection treated?

If you have the infection, you will be given an antibiotic medicine.

How is the infection prevented?

If the local health department determines that you were exposed to the germ, you will be offered an antibiotic. Even if you take the antibiotic, you may develop the infection. If you develop symptoms of the infection, such as fever or bloody cough, you should go to the nearest emergency service center or hospital immediately.

How long should I take the antibiotic?

Take the antibiotic exactly as directed. The dose and the number of treatment days will differ depending on the antibiotic prescribed. If you develop side effects, call your health care provider immediately. Do not give your antibiotic to another person.

What should I do if I develop symptoms of infection while taking the antibiotic?

Take your temperature daily. If you have a fever of greater that 100°F or if you develop flu-like symptoms (cough, fatigue, muscle aches), or a headache, go immediately to the nearest emergency medical service or hospital.

What should I do if I DO NOT have symptoms?

If you do not have symptoms of the infection, continue with your routine daily activities. Please DO NOT go to the hospital emergency room unless you are feeling sick. The local health officer may suggest that you wear a mask over your nose and mouth if you have to go to public places.

How can I get more information?

The local health department will make frequent public announcements about who should receive an antibiotic and how to obtain and take it. Listen to the radio or television.

Adopted in part from the California Dept. of Health Services 2002

PLAGUE – SCREENING FORM

Current Date:/_	/ Medical Re	ecord Number:	
Last Name:	First	Name:	MI:
Street Address:	City:	State: _	Zip:
Home Phone :			
Occupation:		_ Work Phone:	
Work Address:	City:	State:	Zip:
Age: Date of Birth	: Sex:	Date Symptoms Sta	rted:

Questions	No	Yes
Have you been camping in the last 3 weeks?		
Have you had any insect bites in the past 3 weeks?		
Have you had contact with sick animals in the past 3 weeks?		
Are you or could you be pregnant?		

In the past 3 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 3 weeks, have you traveled to any foreign countries? If yes, identify them, and the cities:_____

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)? ____ NO ____YES If yes, to what medicine(s)?

Have you had any of the following symptoms in the past 3 weeks?

Symptoms	Yes	No	Symptoms	Yes	No
Fever			Headache		
Trouble breathing			Cough		
Cough up blood			Pain or tightness in the chest		
Sore muscles			Very tired		
Lump in the groin,			Pain in the groin, arm pit or		
armpit, or neck			neck		
Upset stomach			Vomiting		
Diarrhea			Confusion or disorientation		

Adopted in part from the California Dept. of Health Services 2002

PROTOCOL FOR Q FEVER CASES AND EXPOSURE

- **DEFINITION** Q fever is an infectious disease with variable manifestations, from an acute febrile illness to a lack of any clinical signs.
- **ETIOLOGY** The rickettsia *Coxiella burnetii*, which is extremely infectious to humans, is the causative organism. A single organism can cause infection. Transmission occurs through inhalation of aerosolized organisms, handling fluids or tissues from infected animals, or direct contact with fomites such as laundry. *C. burnetii* is not transmitted person-to-person except via contaminated blood products or bone marrow. Reservoirs are sheep, goats, cattle, cats, dogs, wild rodents, and birds. Infected animals are usually asymptomatic, but shed a large number of organisms in placental tissues at delivery, milk, urine, and feces.
- **SUBJECTIVE &** 1. History of exposure to *C. burnetii*. **OBJECTIVE**
 - 2. Additional history per the attached Q Fever Screening Form.
 - 3. The incubation period is usually 2-3 weeks, although has been reported as short as two days after exposure.
 - 4. May or may not have signs or symptoms. Only about half of infected persons show signs of clinical illness.
 - 5. May have sudden onset of fever, chills, retrobulbar headache, weakness, malaise and severe sweats. Severity and duration will vary.
 - 6. A pneumonitis may be seen on X-ray in about 50% of the cases. However, respiratory symptoms and signs like cough and rales only occur about 25% of the time.
 - 7. Abnormal liver function tests are common.
 - 8. Complications include acute and chronic granulomatous hepatitis and endocarditis, predominantly in the aortic valve.
- **ASSESSMENT** Exposure to *C. burnetii* (Q fever rickettsia) Symptomatic or asymptomatic
- PLAN If possible, consultation with an infectious disease specialist is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC

PHARMACOLOGIC

Clinical consult is needed for preexisting valvular heart disease.

- 1. <u>Acute Infection in Adults</u>
 - a. **[IND]** Doxycycline 100 mg po BID x 15-21 days OR
 - b. Tetracycline 500 mg po QID x 15-21 days OR
 - c. **[IND]** Chloramphenicol 500-750 mg po or IV, Q6h for 15-21 days (up to 4g/day).
- 2. <u>Acute Infection in Children</u>
 - a. [IND] Doxycycline
 - 1) >8 years or >45 kg, give adult dose
 - <u><8</u> years (<45 kg)
 3 mg/kg po BID for 15-21 days, up to 200 mg/day.
 OR
 - b. **[IND]** Chloramphenicol 50 mg/day po or IV, divided into 4 daily doses for 15-21 days, up to 4 grams/day.
- 3. <u>Post-exposure prophylaxis (PEP)</u>

In general PEP, is not necessary since outbreaks normally resolve quickly. Exposed persons should be observed and treated if symptoms appear.

For persons at risk of more serious illness (e.g., women of child-bearing age and persons with valvular heart disease), begin PEP 8-12 days after exposure. Chemoprophylaxis begun too early in the incubation period may delay but not prevent the onset of symptoms. a. Adults: **[IND]** Doxycycline 100 mg po BID x 7 days OR

Tetracycline 500 mg po QID x 7 days.

- b. Children:
 - 1) >8 years or >45 kg, give adult dose
 - ≤8 years (<45 kg)
 [IND] Doxycycline 3 mg/kg po BID for 7 days, up to 200 mg/day.

CLIENT EDUCATION/COUNSELING

- 1. Report potential side effects to medication or suspicious symptoms.
- 2. Person-to-person transmission of the organism does not occur.
- 3. See Appendix A for Home Care Instructions and Appendix C for the Summary Chart for Biological Agents.
- 4. See Attached FAQs for additional information.

FOLLOW-UP

Each person who begins PEP should be given a postcard to sign and mail back when treatment is completed.

CONSULTATION/REFERRAL

- 1. If client cannot tolerate medication.
- 2. Mental health services, as needed, for victims of bioterrorism.
- Infectious disease consult for treatment of chronic cases. Antibiotic therapy lasts a minimum of 2 years for chronic Q fever. A combination of Doxycycline PLUS an additional antibiotic (e.g., Rifampin, Fluoroquinolone, Trimethoprim-Sulfamethoxazole) has shown best results.

REFERENCES

- 1. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 2. Mandell, Bennett, and Dolin (eds.), *Principles and Practice of Infectious Diseases*, 5th ed., Churchill Livingstone, Philadelphia, 2000.
- 3. *Physicians' Desk Reference*, 55th ed., Medical Economics Company, New Jersey, 2001.
- 4. *Medical Management of Biological Casualties Handbook,* 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 5. Nochimson G. "CBRNE Q Fever", eMedicine.com, Aug 18, 2003.
- 6. http://www.cdc.gov/ncidod/dvrd/qfever/index.htm.

Q FEVER Frequently Asked Questions (FAQs)

What is Q fever?

The bacterium (germ) that causes Q fever is usually spread to humans by:

- Contact with infected animals (sheep, goat, cattle, cats, dogs, wild rodents, birds);
- Contact with contaminated straw or manure;
- Inhaling (breathing) airborne dust or soil contaminated with the germ;
- Ingesting (drinking) raw milk; or
- Skinning wild rabbits.

If the germ were intentionally released into the air, you could breathe it into your lungs and develop pneumonia.

Is Q fever spread from person- to- person?

The infection is **NOT** spread from person-to-person.

How will I know if I was exposed to the germ?

It will depend on how and where it was released, and where you were in relation to the release site. The further away you were from the release site, the less likely it will be that you were exposed.

How soon will the symptoms develop (incubation period)?

Not all persons exposed to the germ will get sick. The symptoms would start anywhere from 2 - 21 days after you were exposed.

What are the symptoms of infection?

The symptoms may include fever, dry cough, severe headache, tiredness, chills, sweats, sore muscles, nausea, vomiting, diarrhea, and pain when taking a deep breath.

How is the infection treated?

Antibiotics are available for persons who have symptoms of the infection or are determined by health officials to have been exposed to the germ.

How long should I take the antibiotic?

Take the antibiotic exactly as directed. Instructions will differ depending on the antibiotic prescribed. If you develop side effects, call your health care provider immediately. Do not give your medicine to another person.

What should I do if I DO NOT have symptoms?

You should continue with your routine daily activities. DO NOT go to the hospital emergency room unless you are feeling sick.

How can I get more information?

If an outbreak occurs, the local health officer will make frequent public announcements on the radio and television.

Adopted in part from the California Dept. of Health Services

Q FEVER - SCREENING FORM

Current Date://	Medical Record Number:			
Last Name:	First Name:		MI:	
Street Address:	City:	State:	_ Zip:	
Home Phone:				
Occupation:	Work Phone:			
Work Address:	City:	State:	Zip:	
Age: Date of Birth:	Sex: Date Sympto	ms Started	:	

Questions	No	Yes
Have you been camping in the past 2 weeks?		
Have you had contact with sick animals within the past 2 weeks?		
Are you or could you be pregnant?		
Have you had any insect bites in the past 2 weeks?		
Do you have a preexisting valvular heart disease?		

In the past 2 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 2 weeks, have you traveled to a foreign country(s)? If yes, identify them and the cities.

What prescription, over-the-counter medicine, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)? ____ NO ___YES If Yes, to what medicine?

Have you had any of the following symptoms in the past 2 weeks?

Symptoms	Yes	No	Symptoms	Yes	No
Fever			Sore throat		
Headache			Feel cold all over or shivers		
			and shakes		
Dry cough			Short of breath		
Sweating			Pain or tightness in the chest		
Sore muscles			Very tired		
Diarrhea			Vomiting		
Swollen fingers			Upset stomach (nausea)		
Loss of appetite			Rash on the skin		
Change in mental			Confusion		
status					

Adopted in part from the California Dept. of Health Services 2002

PROTOCOL FOR RICIN INHALATION, INGESTION OR INJECTION

- **DEFINITION** Ricin is a potent protein toxin produced from the castor plant, *Ricinus communis.* Castor beans are found worldwide, and the ricin toxin is easily derived from them. Ricin is considered a threat as a biological weapon primarily because it is widely available.
- MECHANISMRicin inhibits the synthesis of proteins by inactivating ribosomes.OF ACTIONThe toxin may be inhaled, ingested, or in some instances directly
introduced into the body such as by injection.

SUBJECTIVE & OBJECTIVE

1.

- Appearance of symptoms
 - a. When inhaled, within approximately 8 hours.
 - b. When ingested or injected, within a few hours.
- 2. Signs/symptoms of ricin intoxication (when inhaled) are similar to pneumonia and may be mistaken as bacterial infection. Signs/symptoms include: fever, tightness in the chest, cough, dyspnea, nausea, and arthralgia, followed by severe lung inflammation, cyanosis, and pulmonary edema in cases exposed to high doses. Death occurs within 36-72 hours due to respiratory failure and circulatory collapse.

NOTE: Ricin inhalation produces signs and symptoms similar to those caused by other potential biological weapons (such as anthrax, Q fever, tularemia, plague, and chemical agents such as phosgene) and Staphylococcal enterotoxin B (SEB). Ricin poisoning can be differentiated from these based on the following criteria:

- Ricin intoxication will not respond to antibiotics, as infectious agents will.
- Mediastinitis will not be present, as it would in the case of anthrax inhalation.
- SEB exposure would not progress to become lifethreatening, as ricin may.
- Phosgene or other chemically-induced lung injuries will progress more quickly than those caused by ricin intoxication.
- 3. When ingested, ricin intoxication leads to gastrointestinal hemorrhage with hepatic, splenic, and renal necrosis. Victims experience abdominal pain, vomiting, diarrhea, and dehydration.
- 4. When injected, ricin causes severe necrosis of tissues surrounding the affected region.

ASSESSMENT Exposure to ricin Ricin intoxication (inhalation), ingestion or injection

> **NOTE:** An individual risk assessment must be made to determine the need for treatment. The Georgia Department of Human Resources' *"Advice for First Responders Dealing with Suspicious Substances"* (Appendix B) provides some guidance on assessing the credibility of a threat from a suspicious substance. Additional guidance may be obtained by contacting your local or district health department, or the Georgia Division of Public Health.

PLAN If possible, consultation with a toxicologist and/or the regional poison control center (1-800-222-1222) is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC - Follow current CDC recommendation

NON-PHARMACOLOGIC

For gross contamination at the scene of a release or prior to entering a medical facility, use soap and copious amounts of water, or shower with liquid soap and warm water. Exposure via ingestion does not require skin decontamination.

For ricin ingestion, gastric lavage may be performed if the patient presents less than one hour after exposure and is not vomiting. If ricin powder was ingested, lavage with a nasogastric tube may be considered.

PHARMACOLOGIC

1. <u>Ricin inhalation</u>

Treat for pulmonary edema and give respiratory support as needed.

- 2. Ricin ingestion
 - a. Superactivated charcoal (shake well; if too concentrated it may clog airways).

NOTE: Should be given only if the patient is not vomiting and the airway is secure. Some clinicians

recommend inducing vomiting before giving charcoal, but activated charcoal may not be tolerated for 1-2 hours after emesis with ipecac syrup.

- 1) Adults
 - a) 30-100 g or 1-2 g/kg of activated charcoal suspended in 4-8 ounces of water, OR
 - b) 4.3 ml/kg of 70% sorbitol with 1 g/kg of activated charcoal.
- 2) Children 1-12 years
 - a) 1-2 g/kg or 25-50 g of activated charcoal suspended in 4-8 ounces of water, OR
 - b) 4.3 ml/kg of 35% sorbitol with 1 g/kg of activated charcoal or maximum dose of 2g/kg sorbitol with activated charcoal.
 NOTE: In young children, sorbitol should not be repeated more than 1-2 times a day.
- 3) <u>Infants <1 year</u>
 1 g/kg of activated charcoal suspended in 4-8 ounces of water.

(Sorbitol is not recommended for infants.)

- b. Supportive care, including IV fluid and vasopressors (e.g., dopamine) for hypotension, and electrolyte replacement.
- c. H2 Blockers
 - 1) Adults Famotidine (Pepcid) 20 mg IV q12h
 - Infants and children Famotidine (Pepcid)
 0.5 mg/kg IV q12h, up to 40 mg/day.

3. <u>Ricin injection</u>

- a. Give supportive treatment as needed.
- b. Antibiotics may be given to prevent infection resulting from the percutaneous mechanism.
- c. Tetanus immunization, if status unknown.
- 4. For dermal exposure, decontaminate with soap and water, or with a 0.1% solution of sodium hypochlorite.

CLIENT EDUCATION/COUNSELING

- 1. Ricin is not volatile, so other persons are not at risk of inhalation.
- 2. See attached FAQs for additional information.

FOLLOW-UP

Follow-up of persons treated for ricin intoxication is typically not needed.

REFERRAL

Mental health services, as needed, for victims of bioterrorism.

REFERENCE

- 1. *Medical Management of Biological Casualties Handbook*, 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 2. Ferdanando L. Mirarchi, "CBRNE-Ricin", *eMedicine.com*, Jan 8, 2003.
- 3. American Pharmaceutical Association, *Pediatric Dosage Handbook*, 9th ed., Lexi-Comp Inc., 2002-2003.
- 4. <u>http://www.bt.cdc.gov/agent/ricin/index.asp</u>.
- 5. "Investigation of a Ricin-Containing Envelope at a Postal Facility South Carolina, 2003", CDC, MMWR, Nov 21, 2003, Vol 52, No 46.
- 6. American Society of Health-Systems Pharmacists, American Hospital Formulary Services, 2004, pg. 2762.

RICIN Frequently Asked Questions (FAQs)

What is Ricin?

Ricin is a potent protein toxin produced from the castor plant, *Ricinus communis*. It could be intentionally released into the air or administered in acts of terrorism.

How soon after exposure to Ricin will symptoms develop?

Symptoms will develop within approximately 8 hours after ricin is inhaled, or within a few hours of when it is ingested (eaten) or injected.

What are the symptoms of exposure to Ricin?

When inhaled, ricin can cause: fever, tightness in the chest, cough, difficulty breathing, nausea, and arthralgia, followed by severe lung inflammation, cyanosis, and pulmonary edema in cases exposed to high doses. Death occurs within 36-72 hours due to respiratory failure and circulatory collapse.

When ingested, ricin can cause gastrointestinal hemorrhage with death of liver, spleen and kidney tissues. When ricin is injected it causes death of tissues in the area.

How is exposure to Ricin diagnosed?

Diagnosis is based largely on symptoms. A blood antibody test exists, but is not readily available.

How is exposure to Ricin treated?

When inhaled, treatment is given to lessen effects on the lungs. When ingested, a suspension of superactivated charcoal is given. When injected, the area is cleansed and decontaminated.

DHR

of

Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

May 11, 2004

MEMORANDUM

TO:	District Health Directors District Public Health Nursing and Clinical Directors District Emergency Preparedness Coordinators District Program Managers
FROM:	Kathleen E. Toomey, M.D., M.P.H. Director Division of Public Health
SUBJECT:	Revision of Guidelines/Procedures for Pre-Event Administration Smallpox Vaccine

Enclosed are the Guidelines/Procedures for Pre-Event Administration of Smallpox Vaccine that has been revised to include updated recommendations from the Centers for Disease Control and Prevention (CDC) and the Georgia Department of Human Resources, Division of Public Health. Appendix A is a letter from Dr. Julie Gerberding that must be distributed to potential vaccinees. CDC has consolidated most of its appendices into one *Vaccine Information Statement (VIS) Smallpox Vaccine What You Need to Know* (Appendix B). In lieu of the Georgia Medical History and Consent Form the new CDC *Smallpox Vaccination Patient Medical History and Consent Form* (Appendix E) will be used along with the Georgia supplement (Appendix E1). All Georgia supplements to CDC documents have been updated appropriately. All appendices have been reordered.

A Summary of the New and Revised Forms:

- Revised Guidelines/Procedures for Pre-Event Administration of Smallpox Vaccine (Phase 1)
- Appendix A (new) Dr. Gerberding's cover letter
- Appendix B CDC's revised VIS consolidates many of CDC's old appendices
- Appendix B1 Georgia's supplemental attachment detailing Georgia's more restrictive criteria
- Appendix C CDC's updated screening worksheet

- Appendix C1 Georgia's updated supplemental screening worksheet detailing the more restrictive criteria
- Appendix E CDC's new medical history and consent form
- Appendix E1 Georgia's new supplemental medical history and consent form

For clarification purposes, the entire revised and reordered smallpox packet is included with this memo. Please destroy previous revisions of the Guidelines/Procedures and all appendices dated prior to 5/10/04.

Please contact Camille DiClerico at 404-657-6015 with any questions.

Enclosures Cc: David Martin, Chief Financial Officer Branch Directors Smallpox Core Group

GUIDELINES/PROCEDURES FOR PRE-EVENT ADMINISTRATION OF SMALLPOX VACCINE (Phase 1)

ELIGIBILITY Candidates to receive the vaccine are from populations specified in the Georgia Pre-event Smallpox Vaccination Plan and have met **ALL** of the following criteria:

- 1. Have volunteered to receive the vaccine.
- 2. Have received and reviewed the Pre-Vaccination Information Package which includes the most current copies of the following publications from the Centers for Disease Control and Prevention (CDC) and the Department of Human Resources, a summary of the *Georgia Smallpox Vaccination Plan,* and a cover letter listing the required pre-screening materials:
 - Letter from Dr. Julie Gerberding to potential vaccinees (Appendix A)
 - CDC's Vaccine Information Statement (VIS) Smallpox Vaccine What you Need to Know (Appendix B) and Georgia's VIS Supplement (Appendix B1)
 - CDC's Pre-Event Screening Worksheet for Smallpox Vaccine (Appendix C), Georgia's Supplemental Worksheet (Appendix C1) with a Body Mass Index explanation (Appendix C2)
 - Someone You Are Close to May Get Smallpox Vaccine: What You Should Know and Do (Appendix D)
- 3. Have received and completed the self-assessment checklists:
 - CDC's Pre-Event Screening Worksheet for Smallpox Vaccine (Appendix C)
 - Georgia's Worksheet Supplements (Appendices C1 and C2)
- 4. Have reviewed the CDC video, *Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate,* March 11, 2003.
- 5. Have had the opportunity to discuss any medical concerns with a health care provider, and know of no contraindications to receiving the vaccine.
- 6. Have had their names pre-submitted by their referring agency.

SCREENING NOTE: The healthcare worker who provides the medical screening may or may not be the one who will provide the vaccination and/or post-vaccination counseling.

The process will stop and the candidate will be discharged at the point that any one of the following steps cannot be completed.

SUBJECTIVE/ OBJECTIVE

- 1. Verify the candidate's name on the pre-submitted list.
- 2. Provide the Pre-Vaccination Information Packet (Appendices A, B, B1, C, C1, C2, D) to the candidate again.
- 3. Ensure that the candidate has had the opportunity to view the video *Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate*.
- Using CDC's Pre-Event Screening Worksheet for Smallpox Vaccine (Appendix C) and Georgia's Supplemental Worksheet (Appendix C1) as a guide, screen the candidate for contraindications and complete CDC's Patient Medical History and Consent Form (Appendix E) and Georgia's Medical History Supplement (Appendix E1), NOTE: The worksheet itself does not need to be completed

and should not be collected. Determination of risk factors should be made by the volunteer utilizing information provided in the pre-event screening worksheets (Appendices C, C1, C2). Inform the volunteer that the screening process does not eliminate risk of vaccine adverse events.

 Discuss the Patient Medical History and Consent Form (Appendices E, E1) and the Smallpox Vaccine Information Statement - VIS (Appendices B, B1) with the candidate. Record the answers on Appendix E and document that there are no known contraindications.

Stress the following information from CDC's *Smallpox Vaccine VIS* (Appendix B, page 5), "A vaccine, like any medicine, can cause serious problems. There is a very small risk of smallpox vaccine causing serious harm, or death."

- 6. Ask the candidate...."how do you feel today?"...and determine that there are no signs/symptoms of a moderate or severe illness.
- 7. The candidate signs the consent forms (Appendices E and E1) to be vaccinated.
- **ASSESSMENT** Candidate has no known contraindications and is eligible to receive the smallpox vaccine.
- **PLAN NOTE:** If the vaccinator does not provide the screening, then the vaccinator must confirm that the candidate has completed the screening process, signed the consent form and had all concerns addressed before proceeding.

THERAPEUTIC

PHARMACOLOGIC

Smallpox Vaccine (Dryvax®, ACAM1000®, ACAM2000®)

- 1. At the time of reconstitution, record the date on the vial label. Reconstitute the smallpox vaccine, using protective gloves and aseptic technique, according to the package insert and any additional product materials included in the vaccine shipment.
- 2. Advisory Committee on Immunization Practices (ACIP) recommends 3 pricks for primary vaccinations and 15 pricks for revaccination.
- 3. Follow the step-by-step guidelines in the *Smallpox Vaccine Administration Procedure* (Appendix F).
- Document the site of the vaccination and other required information on CDC's Patient Medical History and Consent Form (Appendix E), CDC's Temporary Proof of Vaccination and Site Check Reminder Sheet (Appendix G) and Georgia's Smallpox Vaccination Card (Appendix H).
- 5. Store reconstituted Dryvax® at 2°- 8°C (35°- 46°F) when not in actual use (e.g., lull in clinic flow, breaks, absence of healthcare personnel, after clinic hours). The vaccine may be used for 90 days after being reconstituted, and may be taken in and out of refrigeration as many times as needed during the course of the 90 days.

EDUCATION/COUNSELING

- Review and discuss sections 6, 7, 8, and 9 of CDC's VIS (Appendix B) on caring for the vaccination site, risks from the vaccine and what to do for a moderate, severe or lifethreatening problem. Assure that the patient has a copy of Appendices B and B1.
- Explain and distribute CDC's Temporary Proof of Vaccination and Site Check Reminder Sheet (Appendix G) and Georgia's Smallpox Vaccination Site Photo Card (Appendix I) with the emergency contact telephone number and return appointment date.
- 3. Instruct the patient(s) on how to complete the *Pre-Event Post-Vaccination Patient Diary* (Appendix J) until the scab separates and to bring the diary to the "take" reading appointment.
Inform the patient(s) that after the "take" reading visit there will be weekly contacts until the scab falls off (Use Appendices K and K1 for all follow up contacts with patients).

FOLLOW-UP

- 1. Utilize Appendices L and L1 (Smallpox Guidelines and Recommendation Smallpox Vaccination Status and Procedures-Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine and the Georgia Supplemental Attachment) in assessing vaccination reactions and follow up.
- Read the vaccination site in 6 to 8 days and record "Take" or "No Take" and the date on the *Patient Medical History and Consent Form* Appendix E) and the *Georgia Smallpox Vaccination Card* (Appendix H). See Appendix L for detailed instructions on assessing vaccination reactions.
- 3. If the reading is a "take":
 - Review potential side effects, adverse reactions and emergency contact information.
 - Review the *Pre-Event Post-Vaccination Patient Diary* (Appendix J) and complete "week one" in the *Smallpox Vaccine Adverse Event Active Surveillance Worksheet* (Appendix K), using the instructions provided in Appendix K1.
 - After the successful "take" reading, telephone the patient weekly until the scab falls off. Complete the Smallpox Vaccine Adverse Event Active Surveillance Worksheet (Appendix K) for each telephone contact, using the instructions provided in Appendix K1. Information from this worksheet should be entered into the CDC Pre-Event Vaccination System (PVS) at <u>https://sdn.cdc.gov/</u> Please contact the Epidemiology Branch at 404-657-2588 with any questions.
 - Issue the *Georgia Smallpox Vaccination Card* (Appendix H) to the patient.
- 4. If the reading is "no take":
 - a. Reevaluate subjective and objective information and revaccinate (if possible, with a different batch of vaccine). Utilizing a new *Patient Medical History and Consent Forms* (Appendices E and E1) record all information as on the first visit. Review the instructions for caring for the vaccination site, side effects, adverse reactions and emergency contact information.
 - ALL "no takes" should be revaccinated a second time and receive 15 vigorous pricks. See Appendices L and L1 for specific instructions.
 - c. At the second take reading:

- For those who were originally revaccinees (15 pricks at both clinics) and had two "no takes" consider those patients immune.
- For those who were originally primary vaccinees (3 pricks first clinic; 15 pricks second clinic) contact the Division of Public Health Epidemiology Branch at 404-657-2588 for further consultation. See Appendix L1 for specific details.

REFERENCES

- 1. Centers for Disease Control and Prevention, <u>http://www.bt.cdc.gov/agent/smallpox</u>.
- 2. Centers for Disease Control and Prevention, *Smallpox Vaccine Administration Video*, December 2002.
- 3. Centers for Disease Control and Prevention, *Smallpox Vaccine Administration Training Manual*, December 2002.
- 4. Centers for Disease Control and Prevention, *Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program,* MMWR, April 4, 2003:52 (No. RR-7).
- 5. Centers for Disease Control and Prevention, *Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate Video,* March 2003.
- 6. Centers for Disease Control and Prevention, <u>http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-adult</u>.

Approved by:

Date:

Kathleen E. Toomey, M.D., M.P.H. Director Division of Public Health

District Health Director

District _____

Appendix Name	Title	Publication Date
• •	CDC Cover Letter from	
Appendix A	Dr. Julie Gerberding	November 10, 2003
DPH 04-122HW		
	CDC Smallpox Vaccine	
Appendix B	Information Sheet (VIS)	November 15, 2003
DPH 04-122HW		
	Georgia Supplemental	
Appendix B1	Attachment to CDC	February 1, 2004
DPH 04-122HW	Smallpox VIS	
	CDC Pre-Event Screening	
Appendix C	Worksheet for Smallpox	November 15, 2003
DPH 04-122HW	Vaccine	
Annon dive C1	Georgia Supplemental	February 1, 2004
	Screening Workshoot	reditiary 1, 2004
Appendix C2	What is Divil?	April 23, 2003
DPH 04-122HW		April 23, 2003
	CDC Smallpox Fact Sheet	November 15, 2003
Appendix D	(For Close Contacts of	
DPH 04-122HW	People Considering	
	Vaccination)	
Annon dia E	CDC Smallpox Vaccination	Neversher 15, 2002
	Patient Medical History and	November 15, 2003
DPH 04-122HW	Consent Form	
	Georgia Supplement to the	March 16, 2004
Appendix E1	CDC Smallpox Vaccination	
DPH 04-122HW	Patient Medical History and	
	Consent Form	
Appendix F	Georgia Smallpox Vaccine	January 30, 2003
DPH 04-122HW	Administration Procedure	N 45 0000
	CDC Temporary Proof of	November 15, 2003
Appendix G	Vaccination and Site Check	
Appendix H		
	Vaccination Card	January 30, 2003
Appendix I	Goorgia Smallpay	January 30, 2002
	Vaccination Site Photo	January 30, 2003
	Card (Red)	
	Laiu (Reu)	

Appendix Name	Title	Publication Date
Appendix J DPH 04-122HW	Georgia Smallpox Vaccination Clinic Pre- Event Post-Vaccination Patient Diary	April 8, 2003
Appendix K DPH 04-122HW	Georgia Smallpox Vaccine Adverse Event Active Surveillance (SVAEAS) Worksheet	April 8, 2003
Appendix K1 DPH 04- 122HW	CDC Instructions for Completing the SVAEAS Worksheet	April 23, 2003
Appendix L DPH 04-122HW	CDC Guidelines and Recommendations Smallpox Vaccination Status and Procedures- Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine	July 9, 2003
Appendix L1 DPH 04-122HW	Georgia Supplemental Attachment to Appendix L	February 1, 2004



Appendix A DPH 04-122HW Public Health Service

Centers for Disease Control and Prevention (CDC) Atlanta GA 30333



Dear Colleague:

We are at a crossroads in public health. In 1980, we eradicated smallpox as a naturally occurring disease. Now, this contagious, deadly disease may be brought back as a biological weapon. The most effective tool we have against the disease is the smallpox vaccine, which carries its own risks.

President Bush has initiated a national preparedness program to protect our citizens against smallpox as a biological weapon. Communities have been asked to form smallpox preparedness teams that are ready for a potential smallpox attack on our country. Some of you must now decide whether to participate in this effort and receive the vaccination so that you might protect others. You must weigh your decision carefully.

As you consider participating on a smallpox preparedness team, and before making any decision, please read the materials in the enclosed Smallpox Pre-Vaccination Information Packet. The packet includes the smallpox Vaccination Information Statement (VIS) and a screening worksheet. Please also view the brief video entitled "Decision Point for the Smallpox Vaccine Candidate." These materials are available on the CDC website at www.cdc.gov/smallpox, along with additional information about smallpox and smallpox vaccination.

If you have any questions, please consult your healthcare provider prior to vaccination. Your safety is our highest priority.

We recognize the decision about whether or not to participate in a smallpox preparedness team is difficult. Therefore, we urge you to read, understand, and weigh all the information concerning your personal risks against your ability to help protect those in your community against a potential attack.

On behalf of all of us in public health, we truly thank you for taking the time to make this important decision.

Sincerely,

Julie Louise Gerberdin

Enclosure

VACCINE INFORMATION STATEMENT (VIS)

Appendix B DPH 04-122HW

SMALLPOX VACCINE

WHAT IS SMALLPOX?

Smallpox is a serious disease that can kill up to 3 out of 10 people who get it.

Smallpox can also cause-

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

Smallpox is caused by a virus called "**variola**," which spreads from person to person. Usually, face-to-face contact lasting 3 or more hours is needed to spread smallpox from one person to another. Smallpox can also be spread through direct contact with infected body fluids or objects such as bedding or clothing that have smallpox virus on them.

Smallpox killed millions of people over the centuries. Smallpox vaccination was developed in 1796. As a result, the last outbreak of smallpox in the United States was in 1949. The world's last case of naturally occurring smallpox was in 1977. Routine vaccination of the American public against smallpox ended in 1972.

WHAT IS THE SMALLPOX VACCINE?

Smallpox vaccine is made from a living virus called "**vaccinia**." Vaccinia virus is like smallpox virus, but less harmful.

The smallpox vaccine can **NOT** give you smallpox.

The vaccine is not a shot like other vaccines. The needle is pricked into the skin a number of times in a few seconds (usually in the upper arm). The pricking is not deep, but will cause one or two small drops of blood to form. The place on the skin where the vaccine is given is called the "vaccination site." Getting the vaccine—

- before exposure will protect most people from smallpox (the vaccine is about 95% effective).
- up to 3 days after exposure can prevent the disease or at least make it less severe.
- 4-7 days after exposure can still make the disease less severe and decrease the chance of death.

Smallpox vaccine protects people from getting smallpox for 3 to 5 years. Protection from severe illness and death can last 10 years or more.

3 Why get vaccinated now?

Smallpox vaccine protects people from smallpox.

Some people should get the vaccine because they work with smallpox or related viruses in laboratories.

Others are being offered the vaccine so they can assist in responding to a smallpox outbreak. Smallpox virus is kept in two approved laboratories in the United States and Russia. There is concern that terrorists may have obtained the smallpox virus and could use it as a weapon. If this happened, many people could become ill and many could die.

The U.S. needs teams of health care providers and others to be vaccinated so they can respond quickly if a smallpox attack happens. These teams will do many things to help control a smallpox outbreak, including quickly vaccinating people who have been exposed to the disease.

WHO SHOULD GET SMALLPOX VACCINE AND WHEN?

When There is NO Smallpox Outbreak—

You should get the smallpox vaccine if you-

- Are a lab worker who works with smallpox or viruses like it.
- Are a member of a smallpox response team.

When There IS a Smallpox Outbreak—

You should get the smallpox vaccine if you—

Are directly exposed to smallpox virus.

If there is a smallpox outbreak, public health experts will say who else should get the vaccine.

Vaccinated persons may need to get the vaccine again at least every 3-10 years, depending on their risk of exposure to smallpox or related viruses.

5 Who should **NOT** get the smallpox vaccine, or should wait?

When There is NO Smallpox Outbreak—

You should NOT get the smallpox vaccine if you-

Have Skin Problems

People with skin problems are at risk of developing rashes which can be severe if they get the smallpox vaccine.

- Anyone who has atopic dermatitis (often called eczema) or had it in the past, should not get the smallpox vaccine.
- Anyone who has Darier's disease (a skin disease that usually begins in childhood) should not get the smallpox vaccine.
- Anyone who has a skin problem that has made many breaks in the skin (such as an allergic rash, bad burn, impetigo, psoriasis, pityriasis rosea, poison oak, poison ivy, chickenpox, shingles, herpes, or very bad acne) should not get the vaccine now. They should wait until the skin heals before getting the smallpox vaccine.

Have Immune System Problems

Rarely, when a person with a weakened immune system gets the smallpox vaccine, their vaccination site does not heal. Instead, it spreads to other parts of the body. This reaction can be life-threatening. Anyone with a weakened immune system should **NOT** get the smallpox vaccine, including anyone who:

- Has HIV/AIDS, primary immune deficiency disorders, humoral (antibody) immunity problems (such as agammaglobulinemia or lack of normal antibodies), or other diseases that affect the immune system.
- Has lupus or another severe autoimmune disease that weakens the immune system.
- ▶ Has leukemia, lymphoma, or most other cancers.
- Is taking cancer treatment with radiation or drugs, or has taken such treatment in the past 3 months.
- Is taking, or has recently taken, drugs that affect the immune system. These include high-dose steroids (for 2 weeks or longer within the past month), some drugs for autoimmune disease, or drugs taken for an organ or bone marrow transplant.

Have Heart Problems

Smallpox vaccination may cause heart inflammation that can be mild to life-threatening. It is not known who is at risk for this problem. As a precaution, anyone who has been told by a doctor that they have a heart condition should **NOT** get the smallpox vaccine, even if they feel well. This includes anyone who has:

- Known heart disease, such as past heart attack or angina (chest pain caused by lack of blood to the heart).
- Congestive heart failure
- Cardiomyopathy (heart muscle becomes enlarged and does not work as well as it should)
- Stroke or transient ischemic attack (a "mini-stroke" that causes stroke-like symptoms, but no lasting damage)
- Chest pain or shortness of breath with activity (such as walking up stairs)
- Other heart conditions that require the care of a doctor

In addition, anyone with **3 or more** of the following risk factors should **NOT** get the smallpox vaccine:

- Have been told by a doctor that you have high blood pressure.
- Have been told by a doctor that you have high blood cholesterol.
- Have been told by a doctor that you have diabetes or high blood sugar.
- Have a first degree relative (for example, mother, father, sister or brother) who had a heart condition before the age of 50.
- Smoke cigarettes now

Are Pregnant or Breastfeeding

Babies of mothers who have been vaccinated while pregnant or during the month before they become pregnant can get a very rare but serious infection from the vaccine.

- Do NOT get the smallpox vaccine if you are pregnant, think there is a chance you are pregnant, or think you might become pregnant within 4 weeks after vaccination.
- Sexually active women are encouraged to take a pregnancy test before getting the vaccine. The test should be done the day their vaccination is scheduled. But be aware that even the best tests may not detect early pregnancies (those less than 2 weeks).
- Take steps to prevent pregnancy during the month before and the month after vaccination:
 - Do not have sex, or
 - Use effective birth control every time you have sex. Effective birth control methods include male or female sterilization, hormonal methods (such as birth control pills, implants, patches or injections) and intrauterine devices (IUDs). Condoms and the use of spermicide with diaphragms, sponges, or cervical caps are also acceptable methods, although they are less effective. Do **NOT** rely solely on the rhythm or 'natural family' planning method.

- Do NOT get the smallpox vaccine if you are breastfeeding. Follow this advice even if you are pumping and then bottle-feeding breast milk. It is not known if smallpox vaccine virus or antibodies can be passed to babies through breast milk.
- Other Reasons—Do NOT Get the Smallpox Vaccine if You—
 - Are very allergic to polymyxin B, streptomycin, chlortetracycline, neomycin, or latex.
 - Had a bad reaction the last time you got the smallpox vaccine.
 - Are using steroid drops in your eyes.
 - Are moderately or severely ill the day of your vaccination appointment. Wait until you are better before getting the smallpox vaccine.
- You should NOT get the smallpox vaccine if you live with or have close physical contact with anyone (such as a sex partner) who—
 - ▶ Has any of the skin problems listed above.
 - Has any of the immune system problems listed above.
 - Is pregnant or may become pregnant within 4 weeks of your vaccination.

The smallpox vaccine may pose a similar risk to them.

Smallpox vaccine is not routinely recommended for anyone under 18 years of age or for older people. People age 65 or older who do not have any of the conditions listed above should talk to their health care provider before getting the vaccine.

If There IS a Smallpox Outbreak—

These restrictions may not apply. Public health experts will say who should get the vaccine at that time.

6

WHAT SHOULD YOU EXPECT AFTER VACCINATION?

Normal Reactions

Week I: Three or 4 days after vaccination, a red, itchy bump will form at the "vaccination site". Most times, this spot is about the size of a dime. It can be larger than 3 inches. The bump becomes a blister. It will fill with pus and then start to drain.

A health care provider should check your vaccination site 6–8 days after you get the vaccine to make sure the vaccination worked and everything is o.k.

Week 2: The blister will dry up and a scab will form.

Week 3: The scab will fall off. It will leave a small scar.



Day 4

∕₂ inch



Day 14

Day 21

The lymph nodes under your arm may swell and be sore. The vaccination site may itch. You may also feel tired, have a mild fever, headache, or muscle aches.

You may not get a blister if the vaccine did not work properly or if you are already immune to smallpox. In this case, you will need to get the vaccine again. If you still do not get a blister after getting the vaccine a second or third time, a health care provider will tell you if you are, or are not, considered immune.

What You Will Need to Do

The virus in the vaccine is alive. It can be spread from the vaccination site to other parts of your body or to other people through close physical contact. This can happen until the scab falls off.

In the past, the vaccine virus was spread from vaccinated people to others about 2 to 6 times out of every 100,000 people vaccinated for the first time (this usually happened between people who lived together).

To Help Prevent Spread of the Virus:

- Cover the area loosely with a gauze bandage held in place with first aid tape. While at work, health care workers should also cover the gauze with a semi-permeable bandage (this type of bandage allows air to flow through but not fluids).
- Change the bandage often (at least every 3 days).

Try not to touch your vaccination site.

- Do not let others touch the site or items that have touched it such as bandages, clothes, sheets, or towels.
- Always wash your hands with soap and water or alcohol-based hand wash if you touch the site or if you touch bandages, clothes, sheets, or towels that have touched the site.
- Keep the vaccination site dry. If the gauze bandage gets wet, change it right away. Cover your vaccination site with a waterproof bandage while bathing.
- Don't scratch or put ointment on the vaccination site.
- Don't touch your eyes, any part of your body, or another person after changing the bandage or touching the vaccination site until you have washed your hands.
- Wear a shirt that covers the vaccination site and bandage. This helps protect those you have close contact with such as young children or the person you share a bed with.
- Don't share towels.
- Do your own laundry. Use a separate laundry hamper for clothes, towels, sheets, and other items that may come into contact with your vaccination site or pus from the site. Machine wash items that have touched the vaccination site in hot water with detergent and/or bleach.
- Put used bandages in plastic zip bags, then throw them away in the regular trash.
- After the scab falls off, put it in a plastic zip bag and throw it away.

If you do not feel like you can follow these instructions, do not get vaccinated.



WHAT ARE THE RISKS FROM THE SMALLPOX VACCINE?

A vaccine, like any medicine, can cause serious problems. There is a very small risk of smallpox vaccine causing serious harm, or death.

The following information is about known reactions to smallpox vaccine. There may be other unknown side effects. People who did not get the vaccine can also have the side effects described below if they touch someone's vaccination site or items that have touched the site (like bandages, clothes, sheets, or towels). Following instructions on how to care for the vaccination site (such as covering the site and washing hands) can help prevent spread of the vaccine virus to others.

MILD TO MODERATE PROBLEMS	HOW OFTEN DID IT HAPPEN IN THE PAST?
Feel sick enough to miss work	About I out of 10 to 20 people vaccinated
Fever of over 100°F	About I out of 10 people vaccinated
Mild rash that gets better without medicine	About I out of I2 people vaccinated
Blisters on other parts of the body	About I out of 10,000 people vaccinated
MODERATE TO SEVERE PROBLEMS CALL OR VISIT A HEALTH CARE PROVIDER	HOW OFTEN DID IT HAPPEN IN THE PAST?
Eye infection from touching your eye if you have vaccine virus on your hand. This can lead to a loss of vision in the infected eye.	About I out of 45,000 people vaccinated
Rash on entire body which usually goes away without problems	About I per 15,000 people vaccinated
Inflamed heart (can be mild to life-threatening)	About I out of 10,000 people vaccinated for the first time
SEVERE OR LIFE-THREATENING PROBLEMS GET TO A HEALTH CARE PROVIDER IMMEDIATELY	HOW OFTEN DID IT HAPPEN IN THE PAST?
Severe rash on people with eczema or atopic dermatitis, which can lead to scarring or death.	About I out of 26,000 people vaccinated
Encephalitis (severe brain swelling), which can lead to permanent brain damage or death.	About I out of 83,000 people vaccinated
Skin and tissue destruction starting at the vaccination site and spreading to the rest of the body, which can lead to scarring or death (usually happens in people with very weakened immune systems).	About I out of 667,000 people vaccinated
Vaccinia virus infection in unborn child that can lead to premature delivery, skin rash with scarring, stillbirth, or death of the child after delivery	Very rare, less than 50 cases have been reported throughout the world in the last 100 years

For every million people vaccinated in the past, up to 52 people had a life-threatening reaction to smallpox vaccine and up to 2 people died.

The numbers provided above for severe or life-threatening problems are from studies done in the 1960's when the smallpox vaccine was still routinely used in the U.S. The numbers reflect how often the problems occurred in infants, children, and adults.

The numbers provided for all other problems are from recent studies and experiences vaccinating members of response teams and the military.

WHAT IF SOMEONE HAS A MODERATE, SEVERE OR LIFE-THREATENING PROBLEM?

Within a Few Minutes to a Few Hours of Getting the Vaccination, Watch For—

- Trouble breathing, hoarseness or wheezing.
- Hives, pale skin, weakness, a fast heart beat, or dizziness.

These could be signs that you are having an allergic reaction to the vaccine.

For the Next 3 to 4 Weeks, Keep Watching For—

- A vaccination site that is not healing.
- A rash or sore on other parts of your body.
- An eye infection.
- A lasting headache or fever.
- Confusion, seizures, or trouble staying awake.
- Chest pain, shortness of breath, rapid or unusual heartbeat or unusual fatigue.
- Any unexpected health problem.

What Should You Do?

If you or a close contact have any of these problems, or if you are concerned about any health problem that you have after vaccination—

- Call or go to a health care provider right away.
- Tell the health care provider that you received the smallpox vaccine and when.
- Ask your doctor or nurse to file a Vaccine Adverse Event Report (VAERS form) and contact the health department. You can also file a report yourself by visiting the VAERS website at www.vaers.org or by calling 1-800-822-7967.

Treating Serious Problems

There are two drugs that may help people who have certain serious side effects from the vaccine:Vaccinia Immune Globulin (VIG) and cidofovir.These drugs are not licensed for this purpose, and may also cause side effects.

Cost of Treating Serious Problems

In the rare event that you have a serious reaction to the smallpox vaccine, a federal program has been created to help pay for related costs of medical care and lost wages. This program was created to compensate certain people, such as health care workers and emergency responders, injured by the vaccine. It will also cover certain people injured as the direct result of exposure to vaccinia through contact with certain people who received the smallpox vaccine (or with the contacts of such vaccine recipients). The program covers related costs of medical care and lost wages (usually starting after the first five days of missed work) after other available coverage, such as workers' compensation or health insurance, has been used.

The Department of Health and Human Services will make more information about this program available soon, including how to request benefits and/or compensation. For more information contact Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Office of Special Programs, **888-496-0338** or go to **www.hrsa.gov/smallpoxinjury.**

9 How can you learn more?

- Ask your health care provider. They can give you more information, show you the vaccine package insert or suggest other sources of information.
 - Call your local or state health department.
 - Visit the Centers for Disease Control and Prevention (CDC) smallpox website at www.cdc.gov/smallpox
 - Contact the (CDC):
 - Call I-888-246-2675 (English)
 - Call 1-888-246-2857 (Español)
 - ► Call **I-866-874-2646** (TTY)

If you decide to get the smallpox vaccine, please **KEEP THIS DOCUMENT** for one month following vaccination.

Appendix B1 DPH 04-122HW



Maria Green, Acting Commissioner

Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

February 1, 2004 Georgia Division of Public Health Supplemental Attachment: CDC Smallpox Vaccine Information Statement (VIS):

CDC states in the Smallpox VIS: WHAT YOU NEED TO KNOW- 11/15/03, that

if you have been diagnosed by a doctor as having a heart condition with or without symptoms, you should NOT get the smallpox vaccine at this time, even if you are feeling well.

This includes anyone who has any of the following:

- Known heart disease, such as past heart attack or angina (chest pain caused by lack of blood to the heart)
- Congestive heart failure
- Cardiomyopathy (heart muscle becomes enlarged and doesn't work as well as it should)
- Stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)
- Chest pain or shortness of breath with activity (such as walking up steps)
- Other heart conditions that require the care of a doctor.

When there is no smallpox outbreak; The Georgia Division of Public Health has chosen to additionally exclude persons with any of the following conditions:

- History of hypertension (high blood pressure)
- History of diabetes (high blood sugar)
- Children under 12 months of age in the household.

CDC further recommends in the VIS supplemental statement you should NOT get the smallpox vaccine if you have three or more of the following risk factors:

- You have been told by a doctor that you have high blood cholesterol.
- You have a first degree relative (mother, father, brother, or sister) who had a heart condition before age of 50.
- You smoke cigarettes now.
- You have been told by a doctor that you have high blood pressure.
- You have been told by a doctor that you have diabetes or high blood sugar.

When there is no smallpox outbreak The Georgia Division of Public Health additionally recommends, you should NOT get the smallpox vaccine if you have <u>two or more</u> of the following risk factors:

- You have been told by a doctor that you have high blood cholesterol;
- You have a first degree relative (mother, father, brother, or sister) who had a heart condition before age of 50;
- You smoke cigarettes now; or
- You are obese. (See Appendix C2 on Body Mass Index to determine obesity).



SMALLPOX

Pre-Event Screening Worksheet for Smallpox Vaccine

You have received a smallpox Vaccine Information Statement ("VIS") called "Smallpox Vaccine: What You Need to Know." The VIS contains important information about smallpox vaccination. The VIS describes people who should not get the smallpox vaccine or should wait to get the vaccine because of their own health or the health of their "close contacts." ("Close contact" means a person who you live with. It also means a person you have close physical contact with, such as a sex partner or someone you share a bed with. Friends or people you work with are not "close contacts.")

Please read the VIS very carefully and then answer the questions in this worksheet. The VIS and the questions in this worksheet will help you decide if you should or should not get the smallpox vaccine. Answer each question the best you can. **Some questions in this worksheet are very personal.** You should **not** put your name on this worksheet. The worksheet is for you to keep. The staff at the smallpox vaccination clinic will not ask for or collect this sheet. If you wish, you may ask clinic staff questions concerning this sheet.

Ask a health care provider for help if you do not understand a question or if you have any concerns. If you need more information, visit <u>www.cdc.gov/smallpox</u>. You can also call (888) 246-2675 (English), (888) 246-2857 (español), or (866) 874-2646 (TTY). The calls are free.

- If you answer "NO" to **ALL** the questions on this sheet, then you may go to the vaccination clinic to get the vaccine.
- If you answer "YES" to one or more questions, follow the advice that is given.
- If you don't know, get answers from your health care provider (or your close contact's health care provider) before going to the vaccination clinic.

Please read the following important information about HIV infection before completing this form.

Up to 300,000 people in the United States may have HIV infection and do not know it. You can have HIV infection and feel fine. If you have HIV infection you can have very bad side effects from the smallpox vaccine. So, before getting the vaccine, it's important to know if you have HIV infection. If you do not know, get an HIV test. Below is a list of things that may place you at higher risk for having HIV infection. **If any of these apply to you, be sure to get tested for HIV before you get the smallpox vaccine.**

You should get tested for HIV if you

- Use needles to inject anything **NOT** prescribed by your doctor
- Were stuck by a needle by accident
- Had sex with someone who has HIV/AIDS or tested positive for HIV/AIDS
- Had sex with a prostitute or someone who takes money or drugs for sex
- Had sex with someone who has ever used needles to inject anything **NOT** prescribed by a doctor
- For women: Had sex with a man who has ever had sex with another man
- For men: Had sex with another man

(Version 3)	November 15, 2003	Page 1 of 7
	DEPARTMENT OF HEALTH AND HUMAN SERVICES	
CENTERS FOR DISEASE CONTROL AND PREVENTION		
	SAFER•HEALTHIER•PEOPLE [™]	

(continued from previous page)

A. Please answer these questions about your health and the health of your close contacts

Health Conditions	Do you have this condition?	Does a close contact have this condition?
Have cancer now, or have been treated for cancer in the past 3 months	☐ YES ☐ NO ↓ Do not get vaccinated	☐ YES ☐ NO ↓ Do not get vaccinated
Had an organ or bone marrow transplant	Do not get vaccinated	Do not get vaccinated
Have a disease that affects the immune system like HIV/AIDS, lymphoma, leukemia, or a primary immune deficiency disorder	☐ YES ☐ NO ↓ Do not get vaccinated	☐ YES ☐ NO ↓ Do not get vaccinated
Have lupus or another severe autoimmune disease that may weaken the immune system	YES □ NO VAIT to get the vaccine until AFTER you check with a doctor	☐ YES ☐ NO ↓ WAIT to get the vaccine until AFTER you check with your contact's doctor
Have Darier's disease, a skin disease that usually begins in childhood	YES NO ↓ Do not get vaccinated	☐ YES ☐ NO ↓ Do not get vaccinated
Have many breaks in the skin (such as those caused by bad burns, impetigo, psoriasis, pityriasis rosea, herpes, very bad acne, poison ivy, poison oak, chickenpox, shingles, or other rashes such as bad diaper rash and rashes caused by prescription medicines)	YES □ NO ↓ WAIT to get the vaccine until AFTER your skin is healed	YES □ NO ↓ WAIT to get vaccinated until AFTER your contact's skin is healed
Have ever been told by a health care provider you have atopic dermatitis (often called "eczema"), even if the condition is mild, not currently active, or you had it only as a baby or child	\square YES \square NO \downarrow Do not get vaccinated	☐ YES ☐ NO ↓ Do not get vaccinated

Some people may not know for sure if they ever had atopic dermatitis (or eczema). Answer thesequestions to help you find out if you or a close contact may have had atopic dermatitis or eczema.(Version 3)November 15, 2003Page 2 of 7

(continued from previous page)

1. Do you currently have an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or did you have such a rash as a baby or child?

\square YES \rightarrow	You likely have atopic dermatitis	(or eczema)	and should NOT	get vaccinated	at this time.
	Please be sure to answer questio	ns 2 and 3.			

 \Box Don't know \rightarrow You should discuss any rashes you have with your doctor.

If you can, please write down any information given to you by a doctor regarding this rash:

2. Did the itchy rash affect the creases of your **elbows** or **knees**?

\square YES \rightarrow You likely have eczema or atopic dermatitis and should NOT get vaccinated at this time
🗌 Don't know
Did you have food allergies as a baby or child?
🗌 Don't know
\square YES \rightarrow Do you also have asthma or hay fever ?
VES

You likely have eczema or atopic dermatitis and should **NOT** get vaccinated at this time

4. Does a close contact currently have an **itchy red rash** that comes and goes but usually lasts more than two weeks, or did a close contact have this condition as a baby or child?

\square NO \rightarrow SKIP TO Section	B
\Box YES or \Box Don't know \rightarrow	More information is needed about your close contact before you get the smallpox vaccine. Please answer questions 5-7 . If you do not know the answers to the questions below, please ask the right person to help you answer them. A parent should answer these questions if they apply to a child.

5. Ask your close contact if he or she has an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or if this person had such a rash as a baby or child?

 \square YES \rightarrow Your close contact may have eczema or atopic dermatitis. Please gather information so that questions 6 and 7 can be answered. Check with the contact's doctor about the rash.

3.

If you can, please write down any information given by a doctor regarding this rash:

6. Did the itchy rash affect the creases of the **elbows** or **knees**?

(Version 3)	November 15, 2003	Page 3 of 7
	BERARTHENT OF HEALTH AND HUMAN SERVICES	
	DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION	
	SAFER • HEALTHIER • PEOPLE [™]	

(continued from previous page)

 \square YES \rightarrow Your close contact likely has eczema or atopic dermatitis and you should **NOT** get vaccinated at this time

🗌 NO

Don't know

7. Did the person with the rash have **food allergies** as a baby or child?

🗌 Don't know	
\Box YES \rightarrow Does the person wit	h rash and food allergies also have asthma or hay fever?
\Box YES \rightarrow	Your close contact likely has eczema or atopic dermatitis and you should NOT get vaccinated at this time
🗌 NO	
🗌 Don't kno	w

B. Please answer these questions about treatments or medicines you or your close contact take

(Talk to a health care provider if you are not sure about answers to these questions)

Treatments or medicines	Are you getting this treatment or taking this medicine?	Is a close contact getting this treatment or taking this medicine?
Took steroids such as prednisone or related medicine either by mouth or intravenously for 2 weeks or longer in the past month	YES □ NO ↓ Do not get vaccinated Name and dose of medication:	YES □ NO ↓ Do not get vaccinated Name and dose of medication:
Took medicines in the last 3 months that affect the immune system (such as methotrexate, cyclophosphamide, cyclosporine). If you don't know whether or not your medicine affects your immune system, ask your doctor.	YES ☐ NO ↓ Do not get vaccinated Name and dose of medication:	YES □ NO ↓ Do not get vaccinated Name and dose of medication:
Had radiation therapy in the last 3 months	☐ YES ☐ NO ↓ Do not get vaccinated	☐ YES ☐ NO ↓ Do not get vaccinated
(Version 3)	November 15, 2003	Page 4 of 7

(continued from previous page)

Treatments or medicines	Are you getting this treatment or taking this medicine?	Is a close contact getting this treatment or taking this medicine?
Had chemotherapy for cancer in the last 3 months	☐ YES ☐ NO ↓ Do not get vaccinated	☐ YES ☐ NO ↓ Do not get vaccinated

C. Please answer these questions about pregnancy. The questions do not apply to women who are post-menopausal (have had no menstrual periods for over a year) or have had a hysterectomy or female sterilization.

Pregnancy status and pregnancy risk factors	Does this apply to you? (Women only)	Does this apply to a close contact?			
Are pregnant or think you might be pregnant. Sexually active women are encouraged to take a pregnancy test before getting the vaccine. The test should be done the day vaccination is scheduled. But be aware that even the best tests may not detect early pregnancies (those less than 2 weeks).	☐ YES ☐ NO ↓ Do not get vaccinated	☐ YES ☐ NO ↓ Do not get vaccinated			
Last menstrual period was not on time and/or was not normal	YES □ NO ↓ Do not get vaccinated until you check with your doctor to make sure you are not pregnant	YES □ NO ↓ Do not get vaccinated until your close contact checks with her doctor to make sure she is not pregnant.			
Had sexual intercourse in the past month and did not always use one or more types of effective birth control, including sterilization (such as vasectomy or tubes tied), birth control pills, implants, patches, injections, IUDs, condoms, and diaphragm with spermicide, cervical cap with spermicide, and contraceptive sponge with spermicide	☐ YES ☐ NO ↓ Do not get vaccinated at this time	YES □ NO ✓ Do not get vaccinated at this time			
Might have sexual intercourse during the (Version 3)	VES NO	Page 5 of 7			

Pre-Event Screening Worksheet for Smallpox Vaccine (continued from previous page)

Pregnancy status and pregnancy risk factors	Does this apply to you? (Women only)	Does this apply to a close contact?		
month after vaccination and might not always use an effective form of birth control	↓ Do not get vegeingted	YES NO ↓		
	Do not get vaccinated	Do not get vaccinated		
Think menstrual period might be late	□ YES □ NO ↓	□ YES □ NO		
	Do not get vaccinated until you check with your doctor to make sure you are not pregnant	Do not get vaccinated until your contact checks with her doctor to make sure she is not pregnant		

D. Please answer these questions about your own health (these questions do not apply to close contacts)

Health Conditio	Does this app	bly to you?	
 Have a heart condition, including any of a previous heart attack (also caller infarction), angina (chest pain cau flow to the heart), or other corona (disease in the vessels that bring cardiomyopathy (heart muscle be doesn't work as it should) congestive heart failure stroke or transient ischemic attack produces stroke-like symptoms be chest pain or shortness of breath walking up stairs) 	ne of the following: d myocardial used by lack of blood ary artery disease blood to the heart) comes enlarged and (a "mini-stroke" that it no lasting damage) with activity (such as	☐ YES ↓ Do not get vaccinate feel well)	□ NO ed (even if you
 any other heart condition under the any other heart condition under the following: Have been told by a doctor that y pressure 	ne care of a doctor	☐ YES ↓	
(Version 3)	November 15, 2003		Page 6

Pre-Event Screening Worksheet for Smallpox Vaccine (continued from previous page)

Health Conditions	Does this apply to you?
 Have been told by a doctor that you have high blood cholesterol Have been told by a doctor that you have diabetes or high blood sugar Have a first degree relative (for example mother, father, sister or brother) who had a heart condition before the age of 50 Smoke cigarettes now 	Do not get vaccinated
Using steroid drops in your eyes now	Do not get vaccinated
Have a moderate or serious illness	□ YES □ NO ↓ WAIT to get the vaccine until AFTER your are no longer sick
<i>Women only:</i> Are breastfeeding or pumping and then bottle-feeding breast milk	□ YES □ NO ↓ WAIT to get the vaccine until AFTER you stop breastfeeding
Have had a serious allergic reaction to polymyxin B, streptomycin, chlortetracycline, neomycin or latex	☐ YES ☐ NO ↓ Do not get vaccinated
Had a very bad reaction to smallpox vaccine in the past	YES □ NO ↓ Do not get vaccinated

For more information, visit <u>www.cdc.gov/smallpox</u>, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (español), or (866) 874-2646 (TTY)

(Version 3)	November 15, 2003	Page 7 of 7
	DEPARTMENT OF HEALTH AND HUMAN SERVICES	
	CENTERS FOR DISEASE CONTROL AND PREVENTION	

SAFER • HEALTHIER • PEOPLE[™]



Appendix C1 DPH 04-122HW

Maria Greene, Acting Commissioner

Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

February 1, 2004

Georgia Division of Public Health Supplemental Attachment: Pre-Event Screening Worksheet For Smallpox Vaccine

After reading and completing the attached CDC *Pre-Event Screening Worksheet for Smallpox Vaccine:* 11/15/03, please answer these additional questions to the best of your knowledge.

Have you been told by a doctor that you have hypertension (high blood pressure)?	YESNO
Have you been told by a doctor that you have diabetes (high blood sugar)?	□ YES □ N0
Do you live with an infant under 12 months old in your household?	YESNO
If you answered "Yes" to any of the above questions and there is no smallpox or Georgia Division of Public Health recommends that you <u>NOT</u> receive the small	utbreak, the pox vaccine.

Also:

Have you been told by a doctor that you have high blood cholesterol?	□ YES
	□ NO
Do you have a first degree relative (mother, father, brother, or sister) who had	□ YES
a heart condition before age of 50?	□ NO
Do you smoke cigarettes now?	□ YES
	□ NO
Are you very overweight (obese)? [See Appendix C2 for information on	□ YES
obesity.]	□ NO
If you answered "Ves" to two (2) or more of the above questions and there is n	o smallnov

If you answered "Yes" to two (2) or more of the above questions and there is no smallpox outbreak, the Georgia Division of Public Health additionally recommends that you should <u>NOT</u> get the smallpox vaccine.



CDC Home Search Health Topics A-Z

National Center for Chronic Disease Prevention and Health Promotion

Nutrition & Physical Activity

Home | About Us | Site Map | Visitor Survey | Contact Us

BMI: Body Mass Index

- Overview
- BMI for Adults
- <u>BMI-for-Age</u> (Children)
- BMI Web Calculator

<u>Obesity and</u>
 <u>Overweight</u>

Nutrition and Physical Activity

- What's New!!
- <u>Nutrition</u>
- <u>Physical Activity</u>
- Public Health
 Programs
- Publications
- <u>Recommendations</u>
- Data and Statistics
- <u>Training and</u> <u>Software Tools</u>
- <u>Related Links</u>

BMI for Adults What is BMI?

Body **M**ass **I**ndex or BMI is a tool for indicating weight status in adults.¹ It is a measure of weight for height. For adults over 20 years old, BMI falls into one of these categories:

ВМІ	Weight Status
Below 18.5	Underweight
18.5 - 24.9	Normal
25.0 - 29.9	Overweight
30.0 and Above	Obese

BMI for Adults

What is BMI?

BMI Myths

<u>BMI Formula</u>

BMI Calculator

What Does This All Mean?

Note: <u>BMI for Children and Teens</u> is based on gender and age specific charts.

BMI *correlates* with body fat. The relation between fatness and BMI differs with age and gender. For example, women are more likely to have a higher percent of body fat than men for the same BMI. On average, older people may have more body fat than younger adults with the same BMI.²

For more information about overweight among adults, see *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. Bethesda, MD: NHLBI, 1998.

How does BMI relate to health?

The BMI ranges are based on the effect body weight has on disease and death.³ As BMI increases, the risk for some disease increases. Some common conditions related to overweight and obesity include⁴

- Premature death
- Cardiovascular disease
- High blood pressure
- Osteoarthritis
- Some cancers
- Diabetes

BMI is only one of many factors used to predict risk for disease. BMI cannot be used to tell a person if he/she has a disease such as diabetes or cancer. It is important to remember that weight is only one factor that is related to disease.

BMI for Adults

- BMI Myths
- BMI Formula
- BMI Calculator
- What Does This All Mean? You have calculated your BMI — now what? This page helps you look at your BMI and find out what it may mean.

References

¹ Garrow JS and Webster J. Quetelet's index (W/H²) as a measure of fatness. *International Journal of Obesity* 1985;9:147–153.

² Gallagher D, et al. How useful is BMI for comparison of body fatness across age, sex and ethnic groups? *American Journal of Epidemiology* 1996;143:228–239.

³ World Health Organization. Physical status: The use and interpretation of anthropometry. Geneva, Switzerland: World Health Organization 1995. *WHO Technical Report Series*.

⁴ Calle EE, et al. BMI and mortality in prospective cohort of U.S. adults. *New England Journal of Medicine* 1999;341:1097–1105.



CDC Home Search Health Topics A-Z

National Center for Chronic Disease Prevention and Health Promotion

Nutrition <u>& Physical Activity</u>

Home | About Us | Site Map | Visitor Survey | Contact Us

BMI: Body Mass Index

- <u>Overview</u>
- BMI for Adults
- <u>BMI-for-Age</u> (Children)
- BMI Web Calculator
- <u>Obesity and</u>
 <u>Overweight</u>

BMI for Adults Body Mass Index Formula

If you are unable to use the BMI calculator, or if you are interested in how BMI is calculated, this page has the mathematical formulas. You can calculate BMI using wither feet, inches, and pounds, or meters, centimeters, and kilograms.

<u>What is BMI?</u> <u>BMI Myths</u> <u>BMI Formula</u>

BMI Calculator

Mean?

What Does This All

BMI for Adults

English Formula

Nutrition and Physical Activity

- What's New!!
- <u>Nutrition</u>
- <u>Physical Activity</u>
- Public Health
 Programs
- Publications
- <u>Recommendations</u>
- Data and Statistics
- <u>Training and</u>
 <u>Software Tools</u>
- <u>Related Links</u>

Body Mass Index can be calculated using pounds and inches with this equation

 $BMI = (\underbrace{Weight in Pounds}_{(Height in inches) \times (Height in inches)}) \times 703$

For example, a person who weighs 220 pounds and is 6 feet 3 inches tall has a BMI of 27.5.

($\frac{220 \text{ lbs.}}{(75 \text{ inches}) \text{ x } (75 \text{ inches})}$) x 703 = 27.5

What Does This All Mean?

Metric Formula

Body Mass Index can also be calculated using kilograms and meters (or centimeters).

$$BMI = \frac{\frac{\text{Weight in Kilograms}}{(\text{Height in Meters}) \times (\text{Height in Meters})}}$$
or
$$BMI = \frac{\text{Weight in Kilograms}}{(\text{Height in centimeters}) \times (\text{Height in} \atop centimeters})}) \times 10,000$$

For example, a person who weighs 99.79 Kilograms and is 1.905 Meters (190.50 centimeters) tall has a BMI of 27.5.

 $\frac{99.79 \text{ Kg}}{(1.905 \text{ m}) \text{ x (190.5 m)}} = 27.5$

Body	Mass	Index	(BMI)) Table
Duay	mass	maon	(

-												-		- Ob	ese		
BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Height Weight (in pounds)																	
4'10" (58")	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
4'11" (59")	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
5' (60")	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
5'1" (61")	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
5'2" (62")	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
5'3" (63")	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
5'4" (64")	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
5'5" (65")	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
5'6" (66")	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
5'7" (67")	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
5'8" (68")	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
5'9" (69")	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
5'10" (70")	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
5'11" (71")	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
6' (72'')	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
6'1" (73")	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
6'2' (74")	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272
6'3' (75")	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
												-		Ob	ese		\rightarrow

Source: Evidence Report of Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults, 1998. NIH/National Heart, Lung, and Blood Institute (NHLBI)



SMALLPOX

SMALLPOX FACT SHEET (FOR CLOSE CONTACTS OF PEOPLE CONSIDERING VACCINATION)

Someone You Are Close to May Get the Smallpox Vaccine: What You Should Know and Do

There are some things you should know and do if someone you have close contact with is thinking about getting the smallpox vaccine. ("Close contact" means anyone living in your household. It also means anyone you have close, physical contact with, like a sex partner or someone you share a bed with. Close contact does not mean friends or co-workers.)

BEFORE Vaccination: What You Should Know

The smallpox vaccine is made from a living virus called "vaccinia." Vaccinia virus is like smallpox virus, but less harmful. The vaccine does <u>not</u> contain the smallpox virus. It can <u>not</u> give you smallpox. The vaccine can protect people from smallpox. For most people, the smallpox vaccine works and is safe.

But, <u>people with certain health conditions</u> are more likely to have serious reactions to the smallpox vaccine. These people <u>should not be vaccinated</u> and they <u>should not be in close contact</u> with someone who has been vaccinated.

BEFORE Vaccination: What You Should Do

Tell your close contact if you have any of the conditions listed below, or even if you have concerns about any of them.

You should <u>NOT</u> be in close contact with someone who has been vaccinated if you:

- Ever had or now have atopic dermatitis, often called "eczema" (even if you had the condition as a baby or child and even if the condition is mild)
- Have many breaks in your skin such as those caused by chickenpox, shingles, bad burns, severe acne, poison oak, poison ivy, herpes, psoriasis, pityriasis rosea, impetigo, or other rashes.
- Have Darier's disease, a skin disease that usually begins in childhood
- Have a weakened immune system for whatever reason (HIV/AIDS, cancer and cancer treatment, lupus or other severe autoimmune diseases, primary immune deficiency disorder, or medicines that affect the immune system like high-dose steroids, some drugs for autoimmune disease, or drugs taken for an organ or bone marrow transplant)
- Are pregnant or might become pregnant within 4 weeks of your close contact's vaccination

Because of the risk to you (or your baby if you are pregnant), you should <u>not</u> be in close contact with someone who has gotten smallpox vaccine if any of these apply to you.

(Version 2)	November 15, 2003	Page 1 of 2
	DEPARTMENT OF HEALTH AND HUMAN SERVICES	
	CENTERS FOR DISEASE CONTROL AND PREVENTION	
	SAFER • HEALTHIER • PEOPLE™	

Someone You Are Close to May Get the Smallpox Vaccine: What You Should Know and Do (continued from previous page)

AFTER Vaccination: What You Should Know

There are things you should know if your close contact gets the smallpox vaccine (even if both you and your close contact don't have any health problems).

After vaccination, a bump will form at the place on your close contact's skin where the vaccine was given (called the "vaccination site"). The bump will turn into a blister. It will fill with pus and start to drain. The blister will dry up and form a scab. After about 2 to 3 weeks, the scab will fall off and leave a small scar.

The vaccinia virus in the vaccine (and on your close contact's vaccination site) is a live virus. Until their scab falls off, a person who has been vaccinated can spread vaccinia virus to other people. This can cause problems such as rash (mild to severe), fever, and head and body aches in the other person.

Vaccinia is spread by touching the vaccination site before the scab has fallen off, or by touching items like bandages, clothes, sheets, or towels that have touched the site.

In the past, the vaccine virus was spread from vaccinated people to others about 2 to 6 times out of every 100,000 people vaccinated for the first time. This usually happened between people who lived together.

AFTER Vaccination: What You Should Do

Until your close contact's scab falls off:

- Do <u>not</u> touch your close contact's vaccination site or any items that have touched it (such as bandages, clothes, sheets, towels, or washcloths used by the person who got the vaccine).
- Wash with soap and warm water right away if you accidentally touch the vaccination site or items that were in contact with it. Do not touch your eyes or any part of your body until you have washed your hands.
- If you share a bed with the vaccinated person, be sure that they wear a gauze bandage held in place with first aid tape. To be extra careful, the person who got the vaccine should wear a shirt or pajamas that cover the bandage. If they do not, you may choose to sleep in another bed.
- Don't share towels or clothing. Keep clothes, towels, sheets, or other items used by the vaccinated person separate. He or she should machine wash items that have touched the vaccination site using hot water with detergent and/or bleach.
- Remind the person who got the vaccine to follow the vaccination site care and hand washing instructions they have been given. The vaccination site often becomes itchy, which may lead to scratching, rubbing, or touching of the site. If their hand has vaccinia virus on it and they touch you, you can be infected.

For more information, visit <u>www.cdc.gov/smallpox</u>, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (español), or (866) 874-2646 (TTY)

(Version 2)	November 15, 2003	Page 2 of 2
	DEPARTMENT OF HEALTH AND HUMAN SERVICES	
	CENTERS FOR DISEASE CONTROL AND PREVENTION	

SAFER • HEALTHIER • PEOPLE[™]

Appendix E SMALLPOX VACCINATION PATIENT MEDICAL HISTORY AND CONSENT FORM

Initial Vaccination: Revaccination: Date: (Initial PVN)	Place Patient Vaccination Number (PVN) sticker here
PATIENT MUST COMPLETE SECTIONS A, B, C, D, SECTION A GENERAL PATIENT INFORMATION	, E and F. Please use pen and print.
Title: First Name: (Mr., Ms., Mrs., Dr., etc.) Last Name: Last Name: Social Security Number (optional): Social Security Number (optional):	Middle Name:
Home Phone: Work:	ext #:
Occupation:Ethnicity/Race (optional, you do not have to provide this information. If you choose to provide the provide	rovide this information, you may select more than one category): an American an or Alaska Native
SECTION B PATIENT VACCINATION HISTORY	
How many times have you already received smallpox vaccination' received since January 2003 as part of the National Smallpox Vac 0 1 2 More than 2 D Enter the year of the most recent vaccination prior to the NSVP if	? Do NOT count smallpox vaccinations you ccination Program (NSVP) Don't know known:
 Please indicate source of date: Document (e.g., vaccination can be indicate source of date: Document (e.g., vaccination can be indicated in childhood but can't recall the vaccinated in childhood but can't recall the date I was vaccinated in adulthood but can't recall the date 	ard) L self-recall (from memory)
Have you been told (for instance, by a doctor or a parent) that you Yes No Don't Know	ur vaccination was successful?
Do you have a vaccination scar? 🗌 Yes 🔲 No 🔲 Don't Know	
Did you have any bad reaction(s) to the vaccine?] Don't know
If yes, you should not get the vaccine at this time if the reaction(s) Please tell us about the reaction(s)) was serious.

CENTERS FOR DISEASE CONTROL AND PREVENTION



Date: _

mm dd yyyy

Patient Name:

PVN:

SECTION C PATIENT CONTACT AFTER VACCINATION

During the month following vaccination, you may be contacted for routine follow-up. May we also contact you in the future about participating in a survey? \Box Yes \Box No

SECTION D REFERRING ORGANIZATION

Please provide the following information about the organization that referred you for vaccination. Name:

Street Address: _____

City: ___

County: ______ Otale: _____ County: Phone: () -

_____ State: _____ Zip code: _____

SECTION E PATIENT MEDICAL HISTORY

Have you received chickenpox (varicella) vaccination in the last month? \Box Yes \Box No If yes, you should not get the smallpox vaccine at this time.

Are you currently taking medication? \Box Yes \Box No If yes, please list medications (also see questions 3, 4, and 17 below):

Are you sick today?
Yes No

If yes, please describe your illness, you may need to wait to get the vaccine

Do any of the following apply to <u>YOU</u>?

Weakened Immune System

- 1. Do you have any conditions that weaken the immune system such as HIV/AIDS; leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
- 2. Do you have a severe autoimmune disease such as lupus that may weaken the immune system?
- 3. Are you now taking, or have you recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), some medicines for autoimmune disease, or medicines taken after an organ transplant?
- 4. Are you now taking cancer treatment with drugs or radiation or have you taken such treatment in the past 3 months?

Skin Problems

- 5. Do you now have, or have you ever had atopic dermatitis, often called eczema (even as a baby or child and even if the condition is mild)?
- 6. Do you now have other skin problems that have made many breaks in your skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, or severe acne?
- 7. Do you have Darier's disease (a skin problem that usually begins in childhood)?

Heart Problems

- 8. Have you ever been diagnosed by a doctor as having a heart condition with or without symptoms such as previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure, or cardiomyopathy?
- 9. Have you ever had a stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)?
- 10. Do you have chest pain or shortness of breath when you exert yourself (such as when you walk up stairs)?
- 11. Do you have any other heart condition for which you are under the care of a doctor?
- 12. Do you have three of more of the following risk factors?
 - a. You have been told by a doctor that you have high blood pressure
 - b. You have been told by a doctor that you have high blood cholesterol.
 - c. You have been told by a doctor that you have diabetes or high blood sugar.
 - d. You have a first degree relative (for example mother, father, brother, or sister) who had a heart condition before the age of 50.
 - e. You smoke cigarettes now.

Date: _____ dd vyyy

Patient Name:

PVN:

SECTION E PATIENT MEDICAL HISTORY continued

Pregnant or Breastfeeding

- 13. Are you pregnant, might be pregnant, or might become pregnant in the next month?
- 14. In the past month, have you had any sex without using effective birth control or do you think you will have sex without using effective birth control during the month after vaccination?
- 15. Are you currently breastfeeding or pumping and then bottle-feeding breast milk?

Other

- 16. Have you ever had a life-threatening allergic reaction to smallpox vaccine, latex or the antibiotics polymixin B, streptomycin, chlortetracycline, or neomycin?
- 17. Are you now being treated with steroid eye drops?

IF YOU ANSWERED <u>YES</u> TO ANY OF THE QUESTIONS ABOVE, YOU SHOULD <u>NOT</u> GET THE SMALLPOX VACCINE AT THIS TIME.

If you answered NO, please continue with the following questions about your close contacts.

Do any of the following apply to your <u>CLOSE CONTACTS</u>?

(A close contact is someone you live with or have close physical contact with, such as a sex partner. Close contacts do not include friends or co-workers.)

Weakened Immune System

- 1. Do any of your close contacts have conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
- 2. Do any of your close contacts have a severe autoimmune disease such as lupus that may weaken the immune system?
- 3. Are any of your close contacts now taking, or have they recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), some medicines for autoimmune disease, or medicines taken after an organ transplant?
- 4. Are any of your close contacts taking cancer treatment with drugs or radiation or have they taken such treatment in the past 3 months?

Skin Problems

- 5. Do any of your close contacts now have, or have they ever had atopic dermatitis, often called eczema (even as a baby or child and even if the condition is mild)?
- 6. Do any of your close contacts now have other skin problems that have made many breaks in their skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, severe diaper rash, or severe acne?
- 7. Do any of your close contacts have Darier's disease (a skin problem that usually begins in childhood)?

Pregnancy

8. Are any of your close contacts pregnant, might be pregnant, or might become pregnant in the next month?

IF YOU ANSWERED <u>YES</u> TO ANY OF THE QUESTIONS ABOVE, YOU SHOULD <u>NOT</u> GET THE SMALLPOX VACCINE AT THIS TIME.

Screener comments/Notes for clarification (for clinic use only)

mm dd yyyy
Patient Name:

__ PVN:

SECTION F SIGNED CONSENT (TO BE KEPT BY THE VACCINATION CLINIC)

I have:

- received, read and understand the Smallpox Pre-Vaccination Information Package, including the Vaccine Information Statement (VIS) and the pre-event screening worksheet;
- considered my own health status as well as the health status of my close contacts;
- had the opportunity to discuss my medical concerns with my health care provider or a health care provider at the vaccination clinic;
- had the opportunity to obtain a referral to seek confidential laboratory testing for medical conditions that may increase my risk for adverse reactions from the vaccine;
- responded to the questions above to the best of my ability.

I understand that getting the vaccine is my choice. I agree to get the smallpox vaccine.

Patient signature

Date

Privacy Act Statement

The information requested on this form, including the Social Security Number (SSN), is collected under the authority of Section 311 of the Public Health Service Act (42 U.S.C. 243), the NCVIA (42 U.S.C. 300aa-2(a)), and Section 304 of the Homeland Security Act of 2002 (Pub. L. No. 107-296). The information will be used in the analysis and follow-up of significant events associated with smallpox vaccination and to assure availability of smallpox response teams. The SSN is being collected for identity verification purposes. Furnishing the requested information, including SSN, is voluntary; however, with more complete information, public health objectives, such as adequate monitoring and follow-up of potential adverse events, are more readily achievable. Individuals who do not provide all of the requested information (except items marked as optional) will not be eligible to receive the smallpox vaccine. Identifiable information may be shared by the Centers for Disease Control and Prevention with authorized U.S. Department of Health & Human Services' personnel and public health or cooperating medical authorities.

Date:		

mm dd yyyy
Patient Name:

PVN:

accination Clinic Info	rmation		
Name:			
Street Address:			
City:		_ State:	Zip code:
County:	Phone: (_)	Fax: ()
Disposition			
Referred for Vaccir	nation Deferred for	medical reasons	is 🗌 Vaccination refused
<i>Was a smallpox vaccir</i> Vaccinee status?	nation scar seen by clin Primary vaccinee 🔲 Rev	<i>ic staff?</i> □ Yes [vaccinee	□ No
accination Administr	ation Information		
Date of Vaccination: _	Arm	vaccinated: 🗌 L	Left 🗌 Right 🗌 Other:
Vaccine Administered	mm dd yyyy by:		
accine Batch Informa	Plea	se print first name, last r	name, and professional suffix (MD, RN, etc.)
Vaccine Type:		Batch #:	
Program:		External #:	k:
Dilution Strength:		Batch Date	te:
Diluent Lot #:		Vaccine Lo	.ot #:
Diluent Lot Manufacturer:		Vaccine Lo Manufactu	ot urer:
ake Evaluation and F	Response		
Name of the organizati	on/clinic where take wil	l be evaluated: _	
Street Address:			
City:		_ State:	Zip code:
County:	Phone: (_)	
Take response evaluati	ion performed by:		
Data of Evoluation (abo	auld be 6.9 days ofter u	Please print first n	name, last name, and professional suffix (MD, RN, etc.)
Jale of Evaluation (sho	buid be 6-8 days alter v		dd yyyy
ake Response (check	only one box)		
 Major (usually success surrounding a central l Equivocal (all other l 	esion, which might be a sc responses)	erized by a pustula ab or an ulcer; go t	to the CDC website listed below for more informatio
Not available , reaso	on:		
s the vaccinee consid) ered immune for respor	e.g., cannot be contacte nse team work?	led, died, hospitalized, refused, other)
☐ Yes (the vaccinee has a second	ad a Major response or	was a revaccine	ee and had two Equivocal responses)
□ No			
Additional comments:			

SAFER+HE



Maria Greene, Acting Commissioner

Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

GEORGIA DIVISION OF PUBLIC HEALTH SUPPLEMENTAL ATTACHMENT: CDC SMALLPOX VACCINATION PATIENT MEDICAL HISTORY AND CONSENT FORM

In addition to those conditions listed by the CDC in Section E of the "Patient Medical History and Consent Form", the Georgia Division of Public Health asks that you **consider the following:**

1) Have you ever been diagnosed by a doctor as having a heart condition with or without symptoms? Examples include:

- a. Previous myocardial infarction (heart attack)
- b. Angina (chest pain caused by lack of blood flow to the heart)
- c. Congestive heart failure (chest pain or shortness of breath when you exert yourself, such as when you walk up stairs)
- d. Cardiomyopathy (weakened heart muscle)
- e. Any other heart condition for which you are under the care of a doctor (including valve disease and dysrhythmias)
- 2) Have you ever had a stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)?
- 3) Have you been told by a doctor that you have high blood pressure?
- 4) Have you been told by a doctor that you have diabetes or high blood sugar?
- 5) Do you have two or more of the following conditions ?
 - a. A doctor has told you that you have high blood cholesterol
 - b. You smoke cigarettes now
 - c. You have an immediate family member with onset of a heart condition before age 50
 - d. You are very overweight (obese). [See Appendix C2 on obesity]
- 6) Do you live with or have close physical contact with an infant less than 12 months of age?
- 7) Have you received measles, mumps, rubella (MMR), chickenpox, yellow fever or nasal Live Attenuated Influenza Vaccine (LAIV) in the past 28 days?

Can you answer "yes" to any questions above? ____Yes ____ No (Please check one)

IF YOU CAN ANSWER "<u>YES</u>" TO ANY OF THE QUESTIONS ABOVE, YOU SHOULD <u>NOT</u> SIGN THE PATIENT MEDICAL HISTORY AND CONSENT FORM, AND SHOULD <u>NOT</u> GET THE SMALLPOX VACCINE AT THIS TIME. This policy is slightly more restrictive than CDC's to assure the greatest possible margin of safety while research on newly recognized vaccine adverse events continues.

	EMERGENCY CONTACT INFORMATION:	
Name:	Relationship	
Phone Number ()	Cell Phone Number ()	
Address:	City	State
Patient name (print)	Signature	Date
Screener name (print)	Signature	Date
Vaccinator name (print)	Signature	Date

SMALLPOX VACCINE ADMINISTRATION PROCEDURE

Step-by-Step Procedure	Method
1. Prepare Worksite	Collect all materials needed for your clinic.
2. Vaccine Preparation	• Prepare the vaccine by consulting the protocol provided or consulting the package insert.
	• Place the rubber stopper in a clean container.
	• Use an appropriate vial holder to stabilize the vaccine vial on a flat surface.
3. Vaccinator Preparation	• Assure that the candidate has been screened by a medical screener and has signed consent.
	• <u>DO NOT</u> proceed if the candidate has any contraindications!
	Disinfect hands, don clean gloves.
4. Skin Preparation	• <u>NO</u> skin preparation is required, unless grossly visible dirt is present.
	• If soap and water are used, the skin must be allowed to dry thoroughly.
	• <u>DO NOT</u> use alcohol or acetone under any circumstances as they inactivate the vaccine virus.
	• Remove the bifurcated needle appropriately from its package.
	• <u>DO NOT</u> touch the pointed end of the needle!
	• Hold the bifurcated needle between your thumb and forefinger perpendicular to the floor.
	• Dip the point of the needle straight down into the vaccine solution.
	• Withdraw the needle from the solution; it will contain a drop of vaccine in the space between the two prongs.
	• Caution: Needles should never be dipped back into the vaccine vial if it has touched the skin, to avoid contamination of the vial.
	• Hold the skin taut on the deltoid region of the recipient's non-dominant arm.
	• Stabilize your wrist on the arm of the recipient.
	• Position the needle perpendicular to the site of insertion, with the prongs in a parallel position to the ground.
	• Rapidly prick an area 5 mm in diameter (the size of a pencil eraser head) 3 times for primary vaccinations, 15 times for revaccinations. This should draw a trace of blood after 15 to 20 seconds. If no blood is drawn, reprick 3 times (no additional vaccine is needed). Use a robust technique when vaccinating.
	• If excess vaccine is noted at the site, dab the site with a piece of gauze.
	• Discard the used needle and any empty vaccine vials in a sharps container; discard used gauze in a biohazard waste container.
	• Loosely cover the vaccination site with a porous gauze bandage and tape.
	• If the patient is reporting to work in the healthcare setting, the gauze should be covered with a semi-permeable dressing.
8. Post Vaccination	• Remove gloves and discard in a biohazard waste container.
	• Disinfect hands.
	• Document on the medical record and vaccination card.
9. Education and follow up	Caution and instruct the recipient on site care.
	• Review all handouts with the vaccinee.
	Review emergency information.
	• <u>DO NOT</u> allow an unvaccinated person to come in contact with the site or contaminated materials from the site!
	• Schedule a "TAKE" evaluation appointment in 6-8 days.



SMALLPOX

Temporary Proof of Vaccination and Site Check Reminder Sheet (To be Completed by Clinic Staff and Kept by the Vaccinee)

IMPORTANT: KEEP THIS FORM. BRING IT WITH YOU TO YOUR VACCINATION SITE CHECK.

Please bring this sheet with you to your vaccination site check appointment and keep it for the next 4 weeks. This sheet contains the phone number you should call if you think you are having a bad reaction to the vaccine. This sheet is also your proof of vaccination until you come back to the clinic for your vaccination site check. On that date, you will get your permanent immunization card.

TEMPORARY PROOF OF SMALLPOX VACCINATION:

Name:			Date vaccinated:	/
PVN:	_ Clinic:			mm/dd/yyyy
Clinic Telephone No.: ()	=	Arm Vaccinated: 🗌 Left	🗌 Right
APPOINTMENT FOR RE You will need to get your va	QUIRED V	ACCINATIO	N SITE CHECK: the date below to make sure the	vaccination worked.

Date of Appointment:		Time:		
Clinic Name:	mm/dd/yyyy			
Street Address				
City		State	Zip	
Clinic Telephone No.: (_)			

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

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

IMPORTANT: DO NOT DISCARD THIS FORM. BRING IT WITH YOU WHEN YOU RETURN FOR YOUR VACCINATION SITE CHECK.

For more information, visit <u>www.cdc.gov/smallpox</u>, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (español), or (866) 874-2646 (TTY) (Version 2) November 15, 2003 Page 1 of 1

Appendix H DPH 04-122HW_ January 30, 2003



















SMALLPOX VACCINATION HISTORY

Clinic Location		
Vaccination Date	Reading Date	
Take Response: 🗆 Take	🗆 No Take	
Revaccination Clinic Loca	tion	
Revacc. Date	Reading Date	· · · · · · · · · · · · · · · · · · ·
Take Response: 🗆 Take	🗆 No Take	
		DPH 04-

SMALLPOX VACCINATION HISTORY

Clinic Location		
Vaccination Date	Reading Date	
Take Response: 🗆 Take	🗆 No Take	
Revaccination Clinic Loca	tion	
Revacc. Date	Reading Date	
Take Response: 🗆 Take	🗆 No Take	
		DPH 04-

SMALLPOX VACCINATION HISTORY

Clinic Location		
Vaccination Date	Reading Dat	e
Take Response: 🗆 Take	No Take	
Revaccination Clinic Loca	tion	
Revacc. Date	Reading Date _	
Take Response: 🗆 Take	🗆 No Take	
•		DPH 04-

SMALLPOX VACCINATION HISTORY

Clinic Location		
Vaccination Date	Reading Date	
Take Response: 🗆 Take	🗆 No Take	
Revaccination Clinic Locat	tion	
Revacc. Date	Reading Date	
Take Response: 🗆 Take	🗆 No Take	
		DPH 04-

SMALLPOX VACCINATION HISTORY

Clinic Location			
Vaccination Date	Reading Date		
Take Response: Take	No Take		
Revaccination Clinic Location			
Revacc. Date	Reading Date		
Take Response: 🗆 Take	🗆 No Take		

DPH 04-

SMALLPOX VACCINATION HISTORY

Clinic Location				
Vaccination Date	Reading Date	e		
Take Response: 🗆 Take	🗆 No Take			
Revaccination Clinic Location				
Revacc. Date	Reading Date _			
Take Response: 🗆 Take	🗆 No Take			
		DPH 04-		

SMALLPOX VACCINATION HISTORY

Clinic Location ______ Vaccination Date _____ Reading Date _____ Take Response: □ Take □ No Take

Revaccination Clinic Location

Revacc. Date ______ Reading Date ______

Take Response: □ Take □ No Take

DPH 04-

SMALLPOX VACCINATION HISTORY

Clinic Location				
Vaccination Date	Reading Date			
Take Response: 🗆 Take	No Take			
Revaccination Clinic Location				
Revacc. Date	Reading Date			
Take Response: 🗆 Take	🗆 No Take			
		DPH 04-		
Appendix I DPH 04-122HW January 30, 2003



DPH-04	
* If you have questions or concerns about your vaccination, call: <u>1-866-782-4584</u>	
Next appointment:	
* In life threatening situations dial 911	DHR

DPH	1-04-
* If you have questions or concerns about your vaccination, call: <u>1-866-782-45</u>	84
Next appointment:	
* In life threatening situations dial 911	DHR





Smallpox Vaccination Clinic Pre-Event Post-Vaccination Patient Diary

Patient Demographic Information

Name:

Vaccination date:

Clinic Site:_____

Contact/Information Phone #: 1-866-782-4584

* In Life Threatening Situations - Dial 911

Symptom(s) Day 1			Days 2 through 21												Week							
Please check off any symptoms Present on each indicated day	Day of Vaccine	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	4
No symptoms																						
Fever (write down temperature)																						
Joint pain																						
Muscle pain																						
Headache																						
Backache																						
Fatigue																						
Difficulty sleeping																						
Loss of appetite																						
Difficulty breathing																						
Extreme weakness																						
Chest pain																						
Palpitations																						
Swelling/tender lymph nodes																						
Pain at vaccination site																						
Itching at vaccination site																						
Vaccination site rash/lesion (describe):																						
Vaccinia lesions other than at vaccination site (describe on back of form)																						
Rash elsewhere (describe):																						
Other (describe on back of form)																						
Did not work																						
Was medical care sought? (describe on back of form)																						

Smallpox Vaccine - Pre-event Post-Vaccination Patient Diary

Description of vaccinia lesions other than at vaccination site:

Description of other symptoms: Other notes: If medical care was sought, where? (Name of facility/MD):_____ Phone:_____ Address:_____

Vaccinee's Name:_____

Smallpox Vaccine Adverse Event Active Surveillance Worksheet (GDPH Policy – complete at "take" reading and weekly by phone until scab falls off											
– and document findin	gs in PVS once s	scab sep	arates)								
Section 1.											
Facility Name	Public Health Er	ntity	. (D) (
Worksheet Completed By (Last name, First name)	Patient Vaccinat	tion Num	iber (PV	N) or State As	signe	ed ID	:				
Phone Number	Date Worksheet Week 1	Comple: Week 2_	ted: (mn	n/dd/yyyy) Veek 3	Wee	k 4		_			
E-mail Address Date of Vaccination: (mm/dd/yyyy)											
Date of Vaccinee Follow-up: (mm/dd/yyyy) If you were unable to contact vaccinee for follow-up, check here.											
Section 2. Contraindications in vaccinee	Section 2. Contraindications in vaccinee										
 Has the vaccinee been identified as having any of the following contraindications to vaccination that were not identified during pre-vaccination screening? Check appropriate answer: (Yes, No, or Unk=Unknown) Week 1 Yes No Unk Week 2 Yes No Unk Conditions that weaken immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g. prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months 											
Did the vaccinee have any of the following cardiovascular conditions or risk factors diagnosed by a physician? If yes, was it before or after vaccination? (Please provide answers to each question below.) If yes, please check if it was diagnosed Wes No Unk								IS			
			Unk	vaccination	vac	cina We	ek				
			Unk	vaccination	vac 1	cina We 2	ek 3	4			
 Heart disease or ischemic cardiovascular disease with without symptoms 	or 🗌				vac	cinat We 2	3	4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction 	or				1	cina We 2	3	4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina 	or				1	Cina We 2	3 □ □	4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina Congestive Heart Failure 	or					2	3 □ □ □ □	4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina Congestive Heart Failure Stroke 	or							4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina Congestive Heart Failure Stroke Transient Ischemic Attack (TIA) 	or							4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina Congestive Heart Failure Stroke Transient Ischemic Attack (TIA) Diabetes 	or							4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina Congestive Heart Failure Stroke Transient Ischemic Attack (TIA) Diabetes Hypercholesterolemia 	or			vaccination				4			
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina Congestive Heart Failure Stroke Transient Ischemic Attack (TIA) Diabetes Hypercholesterolemia Family member with onset of heart condition before age 	or			vaccination							
 Heart disease or ischemic cardiovascular disease with without symptoms Myocardial infarction Angina Congestive Heart Failure Stroke Transient Ischemic Attack (TIA) Diabetes Hypercholesterolemia Family member with onset of heart condition before age Hypertension 	or			vaccination							

Section 4. New Health Events
Did the vaccinee receive medical care for any new health condition (including recognized adverse events)?
Check appropriate answer(s):
Week 1 If \Box Yes: (Check boxes that apply) \Box Hospital \Box Outpatient (e.g., doctor's office, ER, or clinic) \Box No
Week 2 If \Box Yes. (Check boxes that apply) \Box Hospital \Box Outpatient (e.g., doctor's office, ER, or clinic) \Box No
Week 5 If \Box res. (Check boxes that apply) \Box rospital \Box Outpatient (e.g., doctor's office, ER, or clinic) \Box roo
Did the vessions experience an enset of a new health condition (including recognized adverse events) post vaccination?
Week 1 🗌 No (Proceed to Section 5) 🗌 Yes(Specify below which adverse event. Check all that apply) 🗌 Unknown
Week 2 No (Proceed to Section 5) Yes(Specify below which adverse event. Check all that apply) Unknown
Week 3 No (Proceed to Section 5) Yes(Specify below which adverse event. Check all that apply) Unknown
Week 4 No (Proceed to Section 5) Yes(Specify below which adverse event. Check all that apply) Unknown
□ Local reaction at vaccination site □ Erythema multiforme major (Stevens-Johnson Syndrome)*
Eczema vaccinatum* Pyogenic infection of vaccination site*
Progressive vaccinia* Inadvertent inoculation (non-ocular)*
Post-vaccinal encephalitis or encephalomyelitis*
□ Generalized vaccinia* □ Non-specific rash (e.g., roseola-like)
□ Myopericarditis/Pericarditis* □ Myocardial infarction*
□ Angina* □ Other cardiac events (describe)
Immediate hypersensitivity reaction* Other* (describe)
□ Death*
*A VAERS report is requested for this adverse event and for other serious adverse events (hospitalization, permanent
disability, life threatening illness, or death). Please provide the VAERS Number: or E-report Number:
Section 5. Contraindications in contact(s) of vaccinee
Have any contact(s) of the vaccinee been identified as having any of the following contraindications that were not identified
during pre-vaccination screening? Week 1 No Yes Unknown Week 2 No Yes Unknown Week 4 No Yes Unknown
during pre-vaccination screening?Week 1NoYesUnknownWeek 3NoYesUnknownWeek 4NoYesUnknownWeek 4NoYesUnknown
during pre-vaccination screening? Week 1 No Yes Unknown Week 3 No Yes Unknown Week 3 No Yes Unknown • Conditions that weaken the immune system • Taking cancer treatment with drugs or radiation or have taken
during pre-vaccination screening? Week 1 No Yes Unknown Week 2 No Yes Unknown Week 3 No Yes Unknown Week 4 No Yes Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months
during pre-vaccination screening? Week 1 No Yes Unknown Week 3 No Yes Unknown Week 3 No Yes Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • Eczema or atopic dermatitis or a history of these conditions,
 during pre-vaccination screening? Week 1 No Yes Unknown Week 2 No Yes Unknown Week 3 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy
 during pre-vaccination screening? Week 1 No Yes Unknown Week 2 No Yes Unknown Week 3 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as an exertemic lurgue on thematosus (SLE) that movies
 during pre-vaccination screening? Week 1 No Yes Unknown Week 2 No Yes Unknown Week 3 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system
 during pre-vaccination screening? Week 1 No Yes Unknown Week 2 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system Currently taking, or have recently been treated Week 2 No Yes Unknown Week 4 No Yes Unknown Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne Currently pregnant
 during pre-vaccination screening? Week 1 No Yes Unknown Week 3 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids Week 2 No Yes Unknown Week 2 No Yes Unknown Week 4 No Yes Unknown Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne Currently pregnant
 during pre-vaccination screening? Week 1 No Yes Unknown Week 3 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune Week 2 No Yes Unknown Week 4 No Yes Unknown Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Taking cancer treatment with drugs or a history of these conditions, even in childhood or infancy Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne Currently pregnant
 during pre-vaccination screening? Week 1 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant Week 2 No Yes Unknown Week 4 No Yes Unknown Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne Currently pregnant
 during pre-vaccination screening? Week 1 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant Section 6. Transmission to contact(s) of vaccinee
 during pre-vaccination screening? Week 1 No Yes Unknown Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant Section 6. Transmission of vaccinia (inadvertent inoculation of smallpox vaccine) to contact(s) of the vaccinee occur? Waek 2 No Yes Unknown Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne Currently pregnant Section 6. Transmission to contact(s) of vaccinee
during pre-vaccination screening? Week 1 No Yes Unknown Week 1 No Yes Unknown Week 2 No Yes Unknown Week 3 No Yes Unknown Week 4 No Yes Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system • Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant • Currently pregnant Section 6. Transmission to contact(s) of vaccinee • Other skin contact(s) of the vaccinee occur? Week 1 No Yes* Unknown Week 2 No Yes* Unknown
during pre-vaccination screening? Week 1 \overline No Yes Unknown Week 3 \overline No Yes Unknown Week 2 \overline No Yes Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system • Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne • Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant • Currently pregnant Section 6. Transmission to contact(s) of vaccinee • Other skin contact(s) of the vaccinee occur? Week 1 \overline No Yes* Unknown Week 2 \overline No Yes* Unknown * A VAFRS report is requested which describes how transmission occurred and clinical manifestations in contact(s) of the
during pre-vaccination screening? Week 1 No Yes Unknown Week 3 No Yes Unknown Week 4 No Yes Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system • Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne • Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant • Currently pregnant Section 6. Transmission to contact(s) of vaccinee • No Yes* Unknown Week 3 No Yes* Unknown Week 4 No Yes* Week 3 No Yes* Unknown Week 4 No Yes* Unknown * A VAERS report is requested which describes how transmission occurred and clinical manifestations in contact(s) of the vaccinee. If transmission to more than one contact of the vaccinee was identified, a VAERS report should be filed for each
during pre-vaccination screening? Week 1 □ No □ Yes □ Unknown Week 2 □ No □ Yes □ Unknown Week 3 □ No □ Yes □ Unknown Week 4 □ No □ Yes □ Unknown Week 4 □ No □ Yes □ Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant • Currently pregnant Section 6. Transmission to contact(s) of vaccinee • Olknown Week 2 □ No □ Yes* □ Unknown Week 1 □ No □ Yes* □ Unknown Week 2 □ No □ Yes* □ Unknown Week 4 □ No □ Yes* □ Unknown Week 3 □ No □ Yes* □ Unknown Week 4 □ No □ Yes* □ Unknown Week 4 □ No □ Yes* □ Unknown * A VAERS report is requested which describes how transmission occurred and clinical manifestations in contact(s) of the vaccinee was identified, a VAERS report should be filed for each contact. Please list the VAERS or E-report Number for each contact for which a VAERS report should be filed for each contact.
during pre-vaccination screening? Week 1 No Yes Unknown Week 3 No Yes Unknown Week 4 No Yes Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant • Currently pregnant Section 6. Transmission to contact(s) of vaccinee • Currently pregnant Meek 3 No Yes* Unknown Week 2 No Yes* Did transmission of vaccinia (inadvertent inoculation of smallpox vaccine) to contact(s) of the vaccinee occur? Week 4 No Yes* Unknown * AzerS report is requested which describes how transmission courcer and clinical manifestations in contact(s) of the vaccinee. If transmission to more than one contact of the vaccinee was identif
during pre-vaccination screening? Week 1 □ No □ Yes □ Unknown Week 1 □ No □ Yes □ Unknown Week 2 □ No □ Yes □ Unknown Week 3 □ No □ Yes □ Unknown Week 4 □ No □ Yes □ Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant • Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne Did transmission of vaccinia (indvertent inoculation of smallpox vaccine) to contact(s) of the vaccinee occur? Week 1 □ No □ Yes* □ Unknown Week 2 □ No □ Yes* □ Unknown Week 3 □ No □ Yes* □ Unknown Week 4 □ No □ Yes* □ Unknown * A SERS report is requested which describes how transmission ocurred and clinical manifestations in contact(s) of the vaccinee. If transmission to more than one contact of the vaccinee was identified, a VAERS report should be filed for each contact. Please list the VAERS or E-report Number for each contact for which a VAERS report was filed: Contact 1: VAERS Number:
during pre-vaccination screening? Week 1 No Yes Unknown Week 1 No Yes Unknown Week 2 No Yes Unknown Week 3 No Yes Unknown Week 4 No Yes Unknown • Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia • Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months • A severe autoimmune disease, such as systemic lupus erythematosus (SLE), that may significantly suppress the immune system • Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne • Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g., prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant • Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo, chickenpox, shingles, or severe acne Did transmission of vaccinia (indvertent inoculation of smallpox vaccine) to contact(s) of the vaccinee occur? • Currently pregnant *A VAERS report is requested which describes how transmission occurred and clinical manifestations in contact(s) of the vaccinee. If transmission to more than one contact of the vaccinee was identified, a VAERS report should be filed for each contact. Please list the VAERS or E-report Number for each contact for which a VAERS report was filed: Contact 1: VAERS N

Smallpox Vaccine Adverse Event Active Surveillance System (SVAEAS)

Instructions for Completing the SVAEAS Worksheet Vers. 1.1 and Entering Records via the Secure Data Network (SDN) (Electronic Reporting)

Topics Included in These Instructions: 1 Accessing the Secure Data Network (SDN). 2 Specific Instructions by Section 2 Section 1. 2 Section 2: Contraindications in Vaccinee. 4 Section 3: Cardiac Risk Factors. 4 Section 4: New Health Events. 5 Section 5: Contraindications in Contact(s) of Vaccinee. 7 Section 6: Transmission to Contact(s) of Vaccinee. 8 Updating Previously Submitted Records. 8 Inactivating (Deleting) Previously Submitted Records. 8

General Instructions

Please Note: *Each smallpox vaccine recipient, regardless of the outcome of their vaccination,* should be entered into the Active Surveillance system when site care follow-up is completed at the time of, or after, the scab falls off. This generally occurs 21 to 28 days after vaccination.

Use the worksheet to assemble all the relevant information for each and every recipient of smallpox vaccine. Instructions that pertain specifically to electronic reporting are marked with a ► character. The following information should be obtained especially **before** entering a vaccinee into the Active Surveillance system via SDN:

- 1. The **PVN** or **state identifier** for the vaccinee.
- 2. Whether or not contraindications to vaccination among the vaccinee or contacts of the vaccinee were identified since the time of vaccination.
- 3. Whether the vaccinee experienced an adverse event that required hospitalization or outpatient care.
- 4. Information on cardiac disease conditions and/or risk factors that occurred postvaccination and whether these were present prior to vaccination.
- 5. Whether vaccinia transmission to contacts of the vaccinee occurred.
- The VAERS number or e-report number of the VAERS report (for vaccinees or contacts whenever an adverse event requiring medical care is reported). This applies both to vaccinees newly reported to VAERS and to those for whom a VAERS report has already been submitted.

Accessing the Secure Data Network (SDN)

► Entry to Active Surveillance for electronic reporting can be accomplished through PVS or directly through the Secure Data Network. You must have obtained and installed your digital certificate prior to attempting access to SDN. If you have not obtained your certificate or if you have trouble with your installation, please contact the Smallpox Adverse Events Response Activity State Team at (404) 639-6045 or nipsptech@cdc.gov.

► After obtaining and installing the digital certificate, the SDN website can be accessed by going to the following URL: <u>https://sdn.cdc.gov</u>. Depending on the security level of the digital certificate used to access SDN, a user prompt may appear. Select your name from the prompt and click OK. A screen will display with the following text: "Application is requesting access to a protected item." Click OK. You will then be prompted to enter the challenge phrase you selected as part of the digital certificate application process. Enter your phrase and then click OK. Once the challenge phrase has been verified, the main SDN page will be displayed providing a list of available activities. Select the Smallpox Vaccine Adverse Event Active Surveillance System. You are now ready to begin.

► If the Smallpox Vaccine Adverse Event Active Surveillance is not listed, please go to "Request Additional Activities." Click on Smallpox Vaccination Activities and then on to Active Surveillance. You will need to wait until you receive approval to begin the activity. Please contact the Smallpox Adverse Events Response Activity State Team at (404) 639-6045 or <u>nipsptech@cdc.gov</u> to notify us that you have applied for the activity.

Specific Instructions by Section

Section 1.

▶ Please Note: The following data items in this section that are marked with an asterisk (*) will be filled in automatically if the Active Surveillance system is accessed from either PVS or HSVMS. The data items marked with a dagger (†) will be filled in automatically from the registration information of the user whose digital certificate is being used to access the system.

Facility Name:* Enter the name of the facility where the smallpox vaccine was received.

Form Completed By†: Enter the name of the individual completing the active surveillance worksheet.

Phone Number†: Enter the area code and phone number of the individual completing the active surveillance worksheet.

E-mail Address†: Enter the e-mail address of the individual completing the active surveillance worksheet.

Public Health Entity*: Enter the two-digit code for the public health entity where vaccination occurred. The code for Georgia is GA.

► Be sure to scroll down and select the correct public health entity. This will correspond to your state's abbreviation. CDC, Chicago, Los Angeles and New York City have unique abbreviations separate from their states.

Patient Vaccination Number (PVN) or State Assigned ID*: Enter the vaccinee's 10digit PVN. (Please Note: For PVN numbers, please make sure PVN is entered, along with all 10 digits of the PVN (including all zeros). Do not enter a space between PVN and the digits. A correct PVN number will consist of 3 letters and 10 numbers.)

Date Worksheet Completed: Enter the date (mm/dd/yyyy) the Active Surveillance worksheet is completed. (**Please Note:** The date when the worksheet is completed may differ from that of vaccinee follow-up. However, it is preferable that the worksheet be completed on the same day as follow-up.)

► Please Note: This date may be filled in automatically from the current system date, but it can be edited.

Date of Vaccination*: Enter the date (mm/dd/yyyy) the vaccinee received the smallpox vaccination.

Date of Vaccinee Follow-up: Enter the date (mm/dd/yyyy) that patient follow-up for Active Surveillance occurred (e.g. date the vaccinee was examined or contacted to obtain information to be entered onto the Active Surveillance worksheet). If the vaccinee cannot be contacted for follow-up, enter the date on which the last follow-up attempt was made and check the box next to "**Unable to contact vaccinee for follow-up**."

Unable to contact vaccinee for follow-up: If the vaccinee could not be contacted for follow-up, check the box provided for this question. (Please Note: This should only be checked when no follow-up data is available on the vaccinee [e.g., none of the questions of the Active Surveillance worksheet could be answered]. Several attempts (e.g., at least 3 unsuccessful attempts) to contact the vaccinee should occur before selecting this option.) If a vaccinee is lost to follow-up, this question still needs to be answered. If using the worksheet and the box for this question is checked, stop here. The record for the vaccinee is completed.

▶ **Please Note:** Once this option is selected in electronic reporting, the vaccinee record will be saved and no further data on the vaccinee can be entered.

Section 2. Contraindications in vaccinee

Indicate whether a contraindication to vaccination was identified in the vaccinee that was **not identified at the time of vaccination**.

- **No.** Check "**No**" if a contraindication is reported during the follow-up interview that was already known at the time of vaccination or if no contraindication is identified. Proceed to Section 3.
- **Yes.** Check "**Yes**" if a contraindication that was not identified at the time of vaccination is identified during the follow-up interview.
- **Unknown.** Check "**Unknown**" if it is unclear whether or not any contraindication existed prior to vaccination. Proceed to Section 3.
- ▶ Please Note: This question must not be left blank.

Section 3. Cardiovascular risk factors (see MMWR 4/4/2003 for case definitions)

This section summarizes the cardiac conditions and/or risk factors that may be present in the vaccine recipient. Check the appropriate box(es) for the first question as to when the vaccinee was asked about cardiac conditions or risk factors. The addition of the "after vaccination" box is for the benefit of vaccinees who were immunized in Phase I prior to 04/04/2003 and who experienced any of these adverse events after vaccination. For vaccine recipients after 04/04/2003, it is possible that both "**Yes**" boxes can be checked as appropriate.

▶ Please Note: In electronic reporting, either "Yes – before vaccination" or "Yes – after vaccination" will inactivate the boxes for No" or "Unknown" in this first question.

In the second portion of this section, please inquire as to the presence of each of the conditions or risk factors listed. A physician's diagnosis is necessary for all of the conditions and risk factors listed with the exception of "currently smoking." Acceptable responses for conditions or risk factors assessed by a physician are "**Yes – before vaccination**," "**Yes – after vaccination**," or "**No**." A history of cardiac conditions in a family member also needs to be determined by a physician. Check "**Unknown**" if the vaccinee has not been to a physician for cardiac disease evaluation or has not been evaluated for any of the risk factors. (**Please Note**: If any of the boxes under "**Yes**" and "**After vaccination**" are checked, go to Section 4 and fill in the information as appropriate. A VAERS report may be needed. See Section 4 for VAERS indications.)

Section 4. New health events

For the first question, indicate whether or not the vaccinee was hospitalized or received care in an outpatient setting (e.g., a doctor's office, a clinic, health department service, emergency room [no hospital admission]) for evaluation of a new or worsening health condition (including adverse events) as a result of vaccination.

- *No.* Check "**No**" if medical care was not received for an adverse event as a result of vaccination. Proceed to Section 5.
- **Yes.** Check "**Yes**" if medical care was received, and indicate if care was received at a hospital or outpatient/emergency room. Then, indicate for which type of adverse event(s) the vaccinee received medical care. Check all that apply.

Please Note: Adverse events for which a VAERS report is requested are indicated with an asterisk (*). If the vaccinee experienced an adverse event for which a VAERS report is requested, please write-in the VAERS or E-report number in the space provided and ensure that the VAERS report is filled out.

A newly added question in this section documents the onset of a new or worsening health condition (including all adverse events).

- **No.** Check "**No**" if the vaccinee did not experience a new or worsening health condition. If this box is checked, proceed to Section 5.
- **Yes** Check "**Yes**" if a new or worsening condition is identified, and check the appropriate box that describes the condition/adverse event.
- **Unknown** Check "**Unknown**" if it cannot be determined that a new or worsening condition exists. Proceed to Section 5.

Description of adverse events:

- **Local reaction at vaccination site**. Reactions include contact dermatitis due to allergic reactions to bandage and tape adhesives, robust takes, and bacterial infections of the vaccination site. The reaction involves local pruritus and can occur in the absence of other systemic symptoms.
 - Please Note: In the electronic reporting, there is an additional box for this reaction that permits a description of this condition to be added.
- *Eczema vaccinatum (EV).** EV is a localized or generalized popular, vesicular, or pustular rash, which can occur anywhere on the body, with a predilection for

areas of previous atopic dermatitis lesions. EV can be associated with systemic illness that includes fever and malaise.

- **Progressive vaccinia (PV).*** PV is also referred to as vaccinia necrosum, vaccinia gangrenosa, prolonged vaccinia, and disseminated vaccinia. PV is a rare, severe, and often lethal complication that occurs among persons with immunodeficiencies. PV is characterized by painless progressive necrosis at the vaccination site with or without metastases to distant sites (e.g. skin, bones, and other viscera). The vaccination lesion does not heal, presumably secondary to an immune derangement, and progresses to an ulcerative lesion, often with central necrosis.
- **Post-vaccinial encephalitis or encephalomyelitis.*** If this box is checked, please contact the CDC Smallpox Vaccination Adverse Events Clinical Team for consultation and evaluation of the case.
- **Generalized vaccinia (GV).*** GV is characterized by a disseminated maculopapular or vesicular rash, frequently on an erythematous base. The rash spans the spectrum of vaccinial lesions, from maculopapules to vesicles. Lesions can present anywhere on the body, including the palms and soles and can be numerous or limited. GV can appear as a regional form that is characterized by extensive satellite vesiculation around the vaccination site, or as an eruption localized to a body part (e.g. arm or leg) with no evidence of inadvertent inoculation. A mild form of GV also exists, which appears with only a limited number of scattered lesions.
- *Immediate hypersensitivity reaction.** Check with the CDC Smallpox Vaccination Adverse Event Clinical Team for the most recent definition of this reaction.
- Erythema multiforme (EM) or Stevens-Johnson Syndrome (SJS).* (Also known as roseola vaccinia or toxic urticaria). EM includes rashes that appeared as lesions, including macules, papules, urticaria, and typical bull's eye (targetoid or iris) lesions. SJS typically includes systemic symptoms with involvement of ≥2 mucosal surfaces or 10% of body surface area.
- **Pyogenic infection of vaccination site.*** Please check with the CDC Smallpox Vaccination Adverse Event Clinical Team for more information about this reaction.
- *Inadvertent inoculation (in vaccinee).** Inadvertent inoculation refers to the transmission of vaccinia virus from the vaccination site to a second location on the vaccinee. (Inadvertent inoculation in contacts of the vaccinee should be reported in Section 5 of the active surveillance worksheet). The most common sites involved are the face, eyelid, nose, mouth, lips, genitalia, and anus. However, if inoculation of the eye occurs, this should be reported as ocular vaccinia rather than inadvertent inoculation).

Ocular vaccinia.* Ocular vaccinia (also known as periocular and ocular implantation) results from transplantation of vaccinia to the eye. Ocular vaccina can occur in different forms, including blepharitis (inflammation of the eyelid), conjunctivitis, keratitis (inflammation of the cornea, including epithelial and stromal forms), iritis, or combinations thereof.

Please Note: CDC will finalize case definitions for the cardiac conditions. Please refer to the 4/4/03 issue of the MMWR for current information. All cardiac events must also be reported to VAERS.

- *Non-specific rash.* Common nonspecific rashes associated with smallpox vaccination include fine reticular maculopapular rashes, lymphangitic streaking, generalized urticaria, and broad, flat, roseola-like erythematous macules and patches.
- **Other*** (describe). Please describe any reaction post vaccination that has not been mentioned in any of the adverse events listed above. A VAERS report will be needed if the box for this item is checked.
- **Death.*** If a vaccine recipient dies at some point after being vaccinated, this event must be reported in Active Surveillance and VAERS. The end point of the surveillance period for this adverse event has not yet been determined.

Section 5. Contraindications in contact(s) of vaccinee

Indicate whether any contact(s) of the vaccinee were identified during the follow-up interview as having a contraindication to vaccination that was not identified at the time of vaccination. Check the appropriate box:

- **No.** Check "**No**" If a contraindication in a contact was not identified or if the contact's contraindication(s) **was already known** at the time of vaccination. Proceed to Section 6.
- **Yes.** Check "**Yes**" if any of the contraindications listed has been identified in one or more contacts. Put a check mark next to the contraindication(s) that was/were identified from the list. Please check all that apply. If "**Other skin conditions that cause breaks in the skin**" is selected, provide a brief description of the contraindication on a separate sheet.
- **Unknown.** Check "**Unknown**" if the vaccinee has no knowledge of any of the conditions listed in any of their contacts.

► Please Note: This question must not be left blank. For states not collecting this information, please check "Unknown."

Section 6. Transmission to contact(s) of vaccinee

Indicate whether transmission of vaccinia to contact(s) of the vaccinee occurred. (This is also known as inadvertent inoculation in vaccinee contacts).

- **No.** Check "**No**" if transmission of vaccinia (inadvertent inoculation) did not occur to one or more contacts of the vaccinee.
- Yes. Check "Yes" if transmission of vaccinia (inadvertent inoculation) to contact(s) of the vaccinee occurred. A VAERS report is requested for the contact(s) of the vaccinee in which inadvertent inoculation occurred. For each contact where inadvertent inoculation occurred, please list the VAERS or E-Report number.
- **Unknown.** Check "**Unknown**" if it is not known whether transmission of vaccinia (inadvertent inoculation) occurred in contact(s) of the vaccinee."

▶ Please Note: This question must not be left blank. For states not collecting this information, please check "Unknown." If the "Yes" response is checked for this section, a screen will appear with directions to input the VAERS or E-Report number.

Updating Previously Submitted Records

Because of software security issues, previously submitted Active Surveillance records cannot be edited through the Web application. If a user needs to edit previously submitted information, the user should complete a new record with all information for that vaccinee, including the still correct prior information as well as any additions or changes. Upon completion of all information, the user should click the **Submit** button to send the information to CDC. CDC will then replace any originally submitted records with the latest information.

Inactivating (Deleting) Previously Submitted Records

To inactivate a previously submitted record, the user should complete all information on the first screen through the **PVN or State-Assigned ID** field, and then check the **"Unknown (unable to contact vaccinee for follow-up)"** box. CDC will process duplicate records with **"Unknown (unable to contact vaccinee for follow-up)"** box checked as de-activated records. Click on the **"Continue"** button, as there is no other information to provide. The Web-based application will submit the records to CDC and prompt the user for data entry on additional vaccinees. **Please Note:** If this is the

Appendix K1 DPH 04-122HW April 23, 2003

original (first) record received by CDC with "**Unknown (unable to contact vaccinee for follow-up)**", box checked, CDC will process the record as standard information provided on a vaccinee.

Upon completion of the SVAEAS Worksheet, please enter information in the PVS or contact Alison Han @ 404-463-4626 (or <u>ahan@dhr.state.ga.us</u>) regarding submission so that an entry can be made to Active Surveillance system. If you have any questions about the completion or use of this worksheet, or have questions about entry of information into Active Surveillance, please contact Alison Han. Thank you for participating in the Smallpox Vaccination Adverse Event Active Surveillance system!

Appendix L DPH 04-122HW

SMALLPOX



GUIDELINES AND RECOMMENDATION

Smallpox Vaccination Status and Procedures – Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine

I. Determining Prior Smallpox Vaccination Status

Factors to consider:

- 1) Vaccination record,
- 2) Vaccination scar,
- 3) Age of the vaccinee,
- 4) Prior military service.

Revaccinee:

Consider as a revaccinee if:

- 1) Written record of vaccination, or
- 2) Visible vaccination scar (determine if foreign born since BCG vaccine also leaves a scar), or
- 3) Born before 1972, or
- 4) Served in the military before 1984*.

*If in the military between 1984 and 1990, must show a scar or vaccination record to be considered as revaccinee.

First-time (primary) vaccinee

Has none of the above factors that determine revaccinee status and/or definitive history of not having received a vaccination.

II. Vaccination procedures

For first-time (primary) vaccinees, give three vigorous insertions with potent vaccine and proper technique. If no trace of blood, without reinserting the needle into the vaccine vial, give three additional insertions in the same spot. Even if there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination.

For revaccinees, give fifteen vigorous insertions with potent vaccine and proper technique. If no trace of blood, without reinserting the needle into the vaccine vial, give three additional insertions. Even if there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination.

For both those vaccinees who were primary vaccinees or revaccinees, if no major reaction, at day 6-8, repeat the vaccination by giving fifteen vigorous insertions with potent vaccine and proper technique. If no trace of blood on revaccination, give three additional insertions. Even if there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination. The repeat vaccination should be done on the same day as the take reading so as to not miss an opportunity. In addition, one can use the same arm, one to two centimeters away from the previous vaccination spot.

(Version 1)	July 9, 2003	Page 1 of 3
	DEPARTMENT OF HEALTH AND HUMAN SERVICES	
	CENTERS FOR DISEASE CONTROL AND PREVENTION	
	SAFER · HEALTHIER · PEOPLE [™]	

Smallpox Vaccination Status and Procedures - Guidelines for Grantees using Licensed Undiluted Wveth Drvvax Vaccine

(continued from previous page)

Assessing vaccination reaction 6-8 days after vaccination

Vaccination site reactions are classified into two categories, "major reactions" and "equivocal reactions". A major reaction indicates a successful vaccination, and is characterized by a pustular lesion or an area of definite induration or congestion surrounding a central lesion, which might be a scab or an ulcer. All other responses are equivocal reactions and are not successful vaccinations. Equivocal reactions may be due to poor vaccination technique, use of subpotent vaccine, or residual vaccinial immunity in previously vaccinated individuals. Persons with an initial equivocal reaction cannot be presumed to be immune to smallpox and revaccination is recommended. If a second equivocal reaction occurs after revaccination with fresh vaccine and vigorous technique, if a revaccinee, the vaccinee can be considered immune, if a first time vaccinee, a third vaccination should be given. (See criteria for considering a vaccinated person immune for persons with two consecutive equivocal reactions.)

The World Health Organization (WHO) has recommended that response to vaccination be evaluated on post-vaccination day 6, 7, or 8 (Fenner and Henderson, WHO 1988). These are the days of peak viral replication in primary vaccinees, and the period during which vaccination reaction should be assessed in both first-time vaccinees and re-vaccinees. If the response to vaccination is evaluated too early, <6 days post-vaccination, some equivocal responses will look reactive due to dermal hypersensitivity to vaccinial proteins. These were sometimes called "immediate reactions" but are not caused by viral replication, i.e., not successful vaccination. If the response to vaccination is evaluated too late, >8 days post-vaccination, the major reaction may be missed in those individuals with prior immunity to vaccinia who may experience a more rapid progression of the vaccination lesion. Responses in revaccinees that resolve in fewer than 6 days are not successful vaccinations.

Assessing vaccination reaction more than 8 days after vaccination

If a vaccinee is not seen at 6-8 days post vaccination for an assessment of his/her vaccination site, but shows up at a later time, visually observing that the vaccination site reaction is at that time characteristic of a major reaction (pustule, and/or scab or ulcer surrounded by definitive induration or congestion) confirms it to be a successful vaccination. At even a much later time, if the vaccination site has a scar and the receipt and date of the pertinent dose of vaccine can be documented through the vaccinee's vaccination card, clinic record or PVS, the observer may confirm a successful vaccination. The observer should rely on his/her direct visual observation and not on the vaccinee's history of the evolution of the vaccination site reaction.

Criteria for Considering a Vaccinated Person Immune

Revaccinees

If a revaccinee has some degree of visible or palpable erythema or induration and there is an indication of a central lesion at day 6, 7, or 8, it is a major reaction and the vaccinee should be considered immune.

If a revaccinee has had 2 additional vaccinations, both with equivocal reactions, consider that person immune. This person may serve on a smallpox response team.

Smallpox response readiness is an on-going, long-term endeavor. It will require that all smallpox response team members maintain an up-to-date smallpox vaccination status. The appropriate interval for revaccination of response team members is currently under review and will be made available in the near

(Version 1)	July 9, 2003	Page 2 of 3
	DEPARTMENT OF HEALTH AND HUMAN SERVICES	
	CENTERS FOR DISEASE CONTROL AND PREVENTION	
	SAFER • HEALTHIER • PEOPLE [™]	

Smallpox Vaccination Status and Procedures - Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine

(continued from previous page)

future. In addition, upon confirmation of a smallpox outbreak, a repeat vaccination to boost the immune system response may be indicated for all team members to ensure their greatest protection.

Primary Vaccinees

If a first time vaccinee (primary vaccinee) has not had a successful vaccination (major reaction) after two vaccinations (the first with 3 insertions; the 2nd with 15 insertions), a 3rd vaccination should be given with 15 insertions using fresh vaccine and vigorous technique.

If the 3rd vaccination is not successful, the vaccinee may not have been a true first time vaccinee. If it can be confirmed that the individual actually was vaccinated prior to the recent vaccinations, this person can be considered immune and can serve on a smallpox response team. However, if it can't be confirmed that the individual is actually a re-vaccinee, then this person should not be considered immune and should not serve on a smallpox response team in a capacity in which exposure to smallpox might occur.

Smallpox response readiness is an on-going, long-term endeavor. It will require that all smallpox response team members maintain an up-to-date smallpox vaccination status. The appropriate interval for revaccination of response team members is currently under review and will be made available in the near future. In addition, upon confirmation of a smallpox outbreak, a repeat vaccination to boost the immune system response may be indicated for all team members to ensure their greatest protection.

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)



Maria Greene, Acting Commissioner

Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

February 1, 2004

Georgia Division of Public Health Supplemental Attachment: Pre-Event Guidelines and Recommendations on Status and Procedures when there is no Smallpox Outbreak

The Appendix L criteria (The Guidelines and Recommendation *Smallpox Vaccinations Status and Procedures – Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine*) should be followed to classify patients as primary vaccinees or revaccinees, to assess a smallpox vaccination, and to revaccinate after a "no take."

The Division of Public Health **also recommends the following for primary vaccinees only**:

- 1) If a primary vaccinee has been vaccinated the 1st time with 3 pricks and has a "no take" response, then revaccinate no earlier than 7 days after the first vaccination, administering 15 pricks.
- 2) If the vaccinee has a "no take" response after the second vaccination, do not vaccinate a 3rd time. Contact the Division of Public Health Epidemiology Branch, at 404-657-2588 for further consultation.

GUIDELINES/PROCEDURES FOR PRE-EVENT ADMINISTRATION OF SMALLPOX VACCINE (Phase 1)

ELIGIBILITY Candidates to receive the vaccine are from populations specified in the Georgia Pre-event Smallpox Vaccination Plan and have met **ALL** of the following criteria:

- 1. Have volunteered to receive the vaccine.
- 2. Have received and reviewed the Pre-Vaccination Information Package which includes the most current copies of the following publications from the Centers for Disease Control and Prevention (CDC) and the Department of Human Resources, a summary of the *Georgia Smallpox Vaccination Plan*, and a cover letter listing the required pre-screening materials:
 - Letter from Dr. Julie Gerberding to potential vaccinees (Appendix A)
 - CDC's Vaccine Information Statement (VIS) Smallpox Vaccine What you Need to Know (Appendix B) and Georgia's VIS Supplement (Appendix B1)
 - CDC's Pre-Event Screening Worksheet for Smallpox Vaccine (Appendix C), Georgia's Supplemental Worksheet (Appendix C1) with a Body Mass Index explanation (Appendix C2)
 - Someone You Are Close to May Get Smallpox Vaccine: What You Should Know and Do (Appendix D)
- 3. Have received and completed the self-assessment checklists:
 - CDC's Pre-Event Screening Worksheet for Smallpox Vaccine (Appendix C)
 - Georgia's Worksheet Supplements (Appendices C1 and C2)
- 4. Have reviewed the CDC video, *Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate,* March 11, 2003.
- 5. Have had the opportunity to discuss any medical concerns with a health care provider, and know of no contraindications to receiving the vaccine.
- 6. Have had their names pre-submitted by their referring agency.

SCREENING NOTE: The healthcare worker who provides the medical screening may or may not be the one who will provide the vaccination and/or post-vaccination counseling.

The process will stop and the candidate will be discharged at the point that any one of the following steps cannot be completed.

SUBJECTIVE/ OBJECTIVE

- 1. Verify the candidate's name on the pre-submitted list.
- 2. Provide the Pre-Vaccination Information Packet (Appendices A, B, B1, C, C1, C2, D) to the candidate again.
- 3. Ensure that the candidate has had the opportunity to view the video *Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate*.
- Using CDC's Pre-Event Screening Worksheet for Smallpox Vaccine (Appendix C) and Georgia's Supplemental Worksheet (Appendix C1) as a guide, screen the candidate for contraindications and complete CDC's Patient Medical History and Consent Form (Appendix E) and Georgia's Medical History Supplement (Appendix E1), NOTE: The worksheet itself does not need to be completed

and should not be collected. Determination of risk factors should be made by the volunteer utilizing information provided in the pre-event screening worksheets (Appendices C, C1, C2). Inform the volunteer that the screening process does not eliminate risk of vaccine adverse events.

 Discuss the Patient Medical History and Consent Form (Appendices E, E1) and the Smallpox Vaccine Information Statement - VIS (Appendices B, B1) with the candidate. Record the answers on Appendix E and document that there are no known contraindications.

Stress the following information from CDC's *Smallpox Vaccine VIS* (Appendix B, page 5), "A vaccine, like any medicine, can cause serious problems. There is a very small risk of smallpox vaccine causing serious harm, or death."

- 6. Ask the candidate...."how do you feel today?"...and determine that there are no signs/symptoms of a moderate or severe illness.
- 7. The candidate signs the consent forms (Appendices E and E1) to be vaccinated.
- **ASSESSMENT** Candidate has no known contraindications and is eligible to receive the smallpox vaccine.
- **PLAN NOTE:** If the vaccinator does not provide the screening, then the vaccinator must confirm that the candidate has completed the screening process, signed the consent form and had all concerns addressed before proceeding.

THERAPEUTIC

PHARMACOLOGIC

Smallpox Vaccine (Dryvax®, ACAM1000®, ACAM2000®)

- At the time of reconstitution, record the date on the vial label. Reconstitute the smallpox vaccine, using protective gloves and aseptic technique, according to the package insert and any additional product materials included in the vaccine shipment.
- 2. Advisory Committee on Immunization Practices (ACIP) recommends 3 pricks for primary vaccinations and 15 pricks for revaccination.
- 3. Follow the step-by-step guidelines in the *Smallpox Vaccine Administration Procedure* (Appendix F).
- Document the site of the vaccination and other required information on CDC's Patient Medical History and Consent Form (Appendix E), CDC's Temporary Proof of Vaccination and Site Check Reminder Sheet (Appendix G) and Georgia's Smallpox Vaccination Card (Appendix H).
- 5. Store reconstituted Dryvax® at 2°- 8°C (35°- 46°F) when not in actual use (e.g., lull in clinic flow, breaks, absence of healthcare personnel, after clinic hours). The vaccine may be used for 90 days after being reconstituted, and may be taken in and out of refrigeration as many times as needed during the course of the 90 days.

EDUCATION/COUNSELING

- Review and discuss sections 6, 7, 8, and 9 of CDC's V/S (Appendix B) on caring for the vaccination site, risks from the vaccine and what to do for a moderate, severe or lifethreatening problem. Assure that the patient has a copy of Appendices B and B1.
- Explain and distribute CDC's Temporary Proof of Vaccination and Site Check Reminder Sheet (Appendix G) and Georgia's Smallpox Vaccination Site Photo Card (Appendix I) with the emergency contact telephone number and return appointment date.
- 3. Instruct the patient(s) on how to complete the *Pre-Event Post-Vaccination Patient Diary* (Appendix J) until the scab separates and to bring the diary to the "take" reading appointment.

 Inform the patient(s) that after the "take" reading visit there will be weekly contacts until the scab falls off (Use Appendices K and K1 for all follow up contacts with patients).

FOLLOW-UP

- 1. Utilize Appendices L and L1 (Smallpox Guidelines and Recommendation Smallpox Vaccination Status and Procedures-Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine and the Georgia Supplemental Attachment) in assessing vaccination reactions and follow up.
- Read the vaccination site in 6 to 8 days and record "Take" or "No Take" and the date on the *Patient Medical History and Consent Form* Appendix E) and the *Georgia Smallpox Vaccination Card* (Appendix H). See Appendix L for detailed instructions on assessing vaccination reactions.
- 3. If the reading is a "take":
 - Review potential side effects, adverse reactions and emergency contact information.
 - Review the *Pre-Event Post-Vaccination Patient Diary* (Appendix J) and complete "week one" in the *Smallpox Vaccine Adverse Event Active Surveillance Worksheet* (Appendix K), using the instructions provided in Appendix K1.
 - After the successful "take" reading, telephone the patient weekly until the scab falls off. Complete the Smallpox Vaccine Adverse Event Active Surveillance Worksheet (Appendix K) for each telephone contact, using the instructions provided in Appendix K1. Information from this worksheet should be entered into the CDC Pre-Event Vaccination System (PVS) at <u>https://sdn.cdc.gov/</u> Please contact the Epidemiology Branch at 404-657-2588 with any questions.
 - Issue the *Georgia Smallpox Vaccination Card* (Appendix H) to the patient.
- 4. If the reading is "no take":
 - a. Reevaluate subjective and objective information and revaccinate (if possible, with a different batch of vaccine). Utilizing a new *Patient Medical History and Consent Forms* (Appendices E and E1) record all information as on the first visit. Review the instructions for caring for the vaccination site, side effects, adverse reactions and emergency contact information.
 - ALL "no takes" should be revaccinated a second time and receive 15 vigorous pricks. See Appendices L and L1 for specific instructions.
 - c. At the second take reading:

- For those who were originally revaccinees (15 pricks at both clinics) and had two "no takes" consider those patients immune.
- For those who were originally primary vaccinees (3 pricks first clinic; 15 pricks second clinic) contact the Division of Public Health Epidemiology Branch at 404-657-2588 for further consultation. See Appendix L1 for specific details.

REFERENCES

- 1. Centers for Disease Control and Prevention, <u>http://www.bt.cdc.gov/agent/smallpox</u>.
- 2. Centers for Disease Control and Prevention, *Smallpox Vaccine Administration Video*, December 2002.
- 3. Centers for Disease Control and Prevention, *Smallpox Vaccine Administration Training Manual*, December 2002.
- 4. Centers for Disease Control and Prevention, *Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program,* MMWR, April 4, 2003:52 (No. RR-7).
- 5. Centers for Disease Control and Prevention, *Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate Video,* March 2003.
- 6. Centers for Disease Control and Prevention, <u>http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-adult</u>.

Approved by:

Date:

Kathleen E. Toomey, M.D., M.P.H. Director Division of Public Health

District Health Director

District _____

Table of Appendices

Appendix Name	Title	Publication Date
Appendix A DPH 04-122HW	Dr. Julie Gerberding	November 10, 2003
Appendix B	CDC Smallpox Vaccine	November 15, 2003
DPH 04-122HW	Information Sheet (VIS)	
Appendix B1	Attachment to CDC	February 1, 2004
DPH 04-122HW	Smallpox VIS	
Annondiv C	CDC Pre-Event Screening	Nevember 15, 2002
DPH 04-122HW	Vorksneet for Smallpox Vaccine	November 15, 2003
	Georgia Supplemental	
Appendix C1	Attachment to CDC	February 1, 2004
D11104-12211W	What Is BMI?	
Appendix C2		April 23, 2003
DPH 04-122HW		Nevershar 45, 0000
Appendix D	(For Close Contacts of	November 15, 2003
DPH 04-122HW	People Considering	
	Vaccination)	
Appendix E	CDC Smallpox Vaccination	November 15, 2003
DPH 04-122HW	Consent Form	
	Georgia Supplement to the	March 16, 2004
Appendix E1	CDC Smallpox Vaccination	
DPH 04-122HW	Consent Form	
Appendix F	Georgia Smallpox Vaccine	January 30, 2003
DPH 04-122HW	Administration Procedure	November 15, 2003
Appendix G	Vaccination and Site Check	100vember 13, 2003
DPH 04-122HW	Reminder Sheet	
Appendix H	Georgia Smallpox	January 30, 2003
DPH 04-122HW	Vaccination Card	January 30, 2003
DPH 04- 122HW	Vaccination Site Photo	January 30, 2003
	Card (Red)	

Appendix Name	Title	Publication Date
Appendix J DPH 04-122HW	Georgia Smallpox Vaccination Clinic Pre- Event Post-Vaccination Patient Diary	April 8, 2003
Appendix K DPH 04-122HW	Georgia Smallpox Vaccine Adverse Event Active Surveillance (SVAEAS) Worksheet	April 8, 2003
Appendix K1 DPH 04- 122HW	CDC Instructions for Completing the SVAEAS Worksheet	April 23, 2003
Appendix L DPH 04-122HW	CDC Guidelines and Recommendations Smallpox Vaccination Status and Procedures- Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine	July 9, 2003
Appendix L1 DPH 04-122HW	Georgia Supplemental Attachment to Appendix L	February 1, 2004



Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

TO:Smallpox Vaccine Administration Training ParticipantFROM:Kathleen E. Toomey, M.D., M.P.H.
Director
Division of Public HealthDATE:August 25, 2003RE:Pre-Event Smallpox Vaccine Administration Training

Dear Training Participant:

Thank you for taking time out from your busy schedule to attend the Smallpox Vaccine Administration training. The purpose of this workshop is to teach participants how to administer smallpox vaccine with a bifurcated needle. At the end of the workshop, you should be able to properly administer the vaccine and teach others to do the same. As a participant in this workshop, you are agreeing to train others in Georgia to administer the vaccine, as requested. **Once trained, you may only administer the vaccine if you are legally authorized to do so in Georgia, and you do not have a contraindication to smallpox vaccine.**

During the workshop, you will practice on other participants using a bifurcated needle and MMR vaccine diluent or normal saline. Smallpox vaccine will not be administered to attendees at the workshop. Attached is a consent form that you will be asked to sign when you arrive at the workshop. The consent form explains that during the practice sessions your skin will be pricked a number of times with a bifurcated needle and that this is not risk free. If you have any questions about the workshop requirements or the consent form, you may contact Camille DiClerico, RN at (404) 657-2873 or via e-mail at cbdiclerico@dhr.state.ga.us.

Georgia Department of Human Resources (GA DHR)

Division of Public Health

Pre-Event Smallpox Vaccination Training

CONSENT FORM FOR PARTICIPANTS

I have read and understand the information contained in the "Training Participant" letter from Dr. Toomey.

- I understand that as a participant in the Division of Public Health Smallpox Vaccination Training, I will be practicing the smallpox vaccination technique with a bifurcated needle using MMR vaccine diluent or normal saline.
- I understand that I will be practicing the multiple puncture technique on a colleague and allowing a colleague to practice on me, and hereby consent to this training.
- 3) While I understand that the smallpox vaccine will not be administered during this session, I acknowledge that vaccination training with a bifurcated needle involves a risk of skin puncture and is therefore not risk free.
- 4) I understand that upon my successful completion of the Smallpox Clinic Operations and Vaccine Administration training courses provided by the Division of Public Health, my name will be entered into a statewide database that is shared with the health districts, and that I may be called to assist with training others, whether in a pre-event setting or in the event of a suspected or actual case of smallpox potentially requiring mass vaccination of the population of Georgia.

- 5) I understand that as a certified trainer, I must:
 - Notify the Georgia State Public Health Pharmacy Office prior to providing any training sessions;
 - Coordinate with the Georgia State Public Health Pharmacy Office to obtain training needles and diluent needed to conduct the training;
 - Utilize only the standardized training materials that are provided by the Georgia State Public Health Office of Training;
 - Submit a list of all individuals certified in such a training session using the database form supplied by the Georgia State Public Health Office of Training; and
 - Distribute and submit all completed evaluations to the Public Health State Training Office.

Name (printed):	 	
Signature:	 	
Date:		



Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

SMALLPOX VACCINEE VOLUNTEER PRE-SCREENING MATERIALS

The information in this packet will inform you of **known** risks of reactions to the smallpox vaccine. The smallpox vaccine, like all medications, can cause serious problems or allergic reactions. There is a known low risk of smallpox vaccination causing serious side effects or death, and the vaccine may have risks that are not yet known.

Please consider the risks while reviewing all the information included in the appendices listed below and in making your decision on whether or not to be vaccinated at this time.

- □ Appendix A: CDC Cover Letter from Dr. Julie Gerberding
- □ Appendix B: CDC Smallpox Vaccine: What You Need to Know, Vaccine Information Statement (VIS) 11/15/03
- □ Appendix B1: Georgia Supplemental Attachment to CDC VIS 2/1/04
- □ Appendix C: CDC Pre-Event Screening Worksheet for Smallpox Vaccine 11/15/03
- □ Appendix C1: Georgia Supplemental Attachment to CDC Screening Worksheet 2/1/04
- □ Appendix C2 What is BMI? 4/23/03
- □ Appendix D: CDC Smallpox Fact Sheet (For Close Contacts of People Considering Vaccination), 11/15/03



Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 404-657-2700 • FAX: 404-657-2715

Georgia Smallpox Vaccination Plan Summary

On December 9, 2002 the Georgia Department of Human Resources Division of Public Health (GDPH) submitted its smallpox pre-event vaccination plan to the Centers for Disease Control and Prevention (CDC). The four-phased approach outlined in the plan follows the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the President of the United States to start with voluntary vaccination of healthcare providers and public health teams. It also limits the potential for complications from the vaccine, which can cause serious illness, and in rare cases, death. On December 12, 2002 GDPH submitted an addendum that went into greater detail on implementing Phase I of the vaccination plan.

Update:

As each part of the plan is implemented, the smallpox vaccination program evolves. As of July 11, 2003 there have been more than 150 people vaccinated and no reports of severe adverse reactions in Georgia.

Phase I:

Offering the smallpox vaccine to healthcare providers and public health teams:

- Step 1 "Smallpox Public Health Response Teams" from across the state, with emphasis on those in metro Atlanta and "Smallpox Healthcare Teams" from trauma hospitals in metro Atlanta.
- Step 2 "Smallpox Public Health Response Teams" from across Georgia and "Smallpox Healthcare Teams" from trauma hospitals across Georgia.
- Step 3 Full complement of staff (up to 45 people/hospital) from trauma hospitals in metro Atlanta, as well as volunteers from any other metro Atlanta hospitals.
- Step 4 Full complement of staff (up to 45 people/hospital) from the non-metro Atlanta trauma hospitals, as well as volunteers from any other non-metro Atlanta hospitals, emphasizing hospitals with isolation units.

Phase II:

Offering the smallpox vaccine to first responders including EMS, fire, police and other public safety officers.

Phase III:

Offering the smallpox vaccine to general public volunteers, in the absence of a known smallpox case.

Phase IV:

In the event of a known case, administering the smallpox vaccine to people who come in contact with smallpox cases and others in conjunction with a disease investigation.

Georgia's Trauma Hospitals:

Metro Atlanta:

• Atlanta Medical Center, Children's Healthcare of Atlanta at Egleston, Children's Healthcare of Atlanta at Scottish Rite, Grady Memorial Hospital, Gwinnett Medical Center, North Fulton Regional Hospital and DeKalb Medical Center.

Outside of Metro Atlanta:

 Medical Center of Central Georgia (Macon), Memorial Health University Medical Center (Savannah), Medical College of Georgia (Augusta), Floyd Medical Center (Rome), Medical Center-Columbus, Hamilton Medical Center (Dalton), John D. Archibold Memorial Hospital (Thomasville), and Morgan Memorial Hospital (Madison).

Implementation of each part of the plan is contingent upon federal guidance and successful completion and assessment of the preceding phase or step.

An Equal Opportunity Employer www.dhr.georgia.gov

PROTOCOL FOR SMALLPOX CASES AND EXPOSURE

- **DEFINITION** Smallpox is an acute viral disease that causes febrile rash illness with up to 30% mortality. It was eradicated worldwide in 1977 through patient isolation and vaccination of contacts. Routine smallpox vaccinations were stopped in the United States during the 1970s, and in all countries by 1980. This leaves most of the population susceptible to infection if smallpox virus should be intentionally released as an aerosol in acts of bioterrorism. Multiple primary exposures could subsequently result in a larger number of secondarily exposed persons if the disease is not recognized quickly.
- **ETIOLOGY** The variola virus, also referred to as the smallpox virus, is transmitted only from person-to-person. There is no animal reservoir, and the virus is inactivated in air within 24 hours. Infection normally results from inhalation of virus-containing droplets of saliva from an infected person, following direct and fairly prolonged face-to-face contact. The virus can also be transmitted by contact with draining skin lesions and with surfaces and articles, such as clothing and bed linens, contaminated with drainage. Smallpox is most infectious during the first 7 to 10 days following the onset of fever and rash. Infected non-immune contacts may avoid serious illness if vaccinated within 7 days after infection.
- **SUBJECTIVE &** 1. Initial symptoms usually occur 12-14 days following exposure, with a range of 7-17 days.
 - 2. Additional history per the attached Smallpox Screening Form.
 - 3. Typical initial symptoms include: high fever, malaise, prostration, headache, and backache.
 - 4. The maculopapular rash begins shortly after the initial symptoms, erupting first on the face and forearms and then spreading to the trunk and legs. The rash becomes vesicular within 24-48 hours, then progresses to pustular. Eventually scabs form over the pustules and pitted scarring results.
 - 5. Death occurs due to extremely high levels of immune complexes and soluble antigens leading to toxemia in 30 percent of the cases.

- 6. Other manifestations:
 - a. <u>Hemorrhagic smallpox</u> exhibits as high fever, headache, severe prostration, backache, and abdominal pain, followed by development of erythema, petechiae, then frank hemorrhages in the skin and mucous membranes. It is believed to be 100% fatal. It is more common in pregnant women.
 - b. <u>Malignant smallpox</u> is characterized by symptoms similar to a typical smallpox infection, yet the skin lesions never develop into pustules and resolve without scabbing. It is often fatal.
- 7. Lesions of smallpox are all seen in the same stage. In comparison, the lesions of chickenpox occur in crops that are in different stages of development. Chicken pox eruptions are also generally more numerous on the trunk than on the face and extremities.
- **ASSESSMENT** Smallpox / suspected smallpox / exposure to smallpox

(Differential diagnoses include chicken pox, allergic contact dermatitis, erythema multiforme with bullae, secondary syphilis, and atypical measles.)

NOTE: A single case of smallpox is considered a public health emergency and must be reported immediately through appropriate channels.

PLAN If possible, consultation with an infectious disease specialist is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC - Follow current CDC Recommendations

PHARMACOLOGIC

1. <u>Antivirals</u>

[IND]Cidofovir may be effective in preventing infection if administered within 1-2 days of exposure; however, it may have severe side effects.

- 2. Antibiotic treatment of secondary bacterial infections may be necessary.
- 3. <u>Vaccine</u>

Smallpox vaccination may prevent serious illness if given within 7 days of infection. Decisions about vaccinations must be made in consultation with the Division of Public Health (1-866-PUB-HLTH).

ISOLATION

Clients with confirmed or suspected smallpox should be isolated in negative-pressure rooms with respiratory precautions (See CDC Guidelines on Isolation and Quarantine). All persons (healthcare workers) entering smallpox patient rooms should have documented successful recent smallpox vaccinations (within 3 years), or receive smallpox vaccination within 72 hours of exposure to smallpox patients.

CLIENT EDUCATION/COUNSELING

- 1. Early symptoms of smallpox infection.
- 2. Seek immediate medical attention if symptomatic.
- 3. Can be transmitted by contact with vaccination site, draining skin lesions, clothing, and bed linens.
- 4. Necessary isolation procedures.
- 5. How to care for a vaccination site.
- 6. See attached FAQs for additional information, and Appendix A for Home Care Instructions.

REFERRAL

Mental health services, as needed, for victims of bioterrorism.

REFERENCES

- 1. ACIP and CDC, *Bioterrorism Readiness Plan: A Template for Healthcare Facilities*. Available at <u>http://www.cdc.gov/ncidod/hip/Bio/13apr99APIC-CDCBioterrorism.pdf.</u>
- 2. CDC Smallpox Response Plan and Guidelines, Version 3.0, Sept 23, 2003, http://www.bt.gov/agent/smallpox/response-plan/index.asp.
- 3. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 4. Mandell, Bennett, and Dolin (eds.), *Principles and Practice of Infectious Diseases*, 5th ed., Churchill Livingstone, Philadelphia, 2000.
- 5. *Medical Management of Biological Casualties Handbook*, 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 6. Christopher J. Hogan, "CBRNE-Smallpox", *eMedicine Journal*, February 5, 2002, Vol. 3, No. 2.
- 7. <u>http://www.bt.cdc.gov/agent/smallpox/index.asp</u>.

SMALLPOX - Frequently Asked Questions (FAQs)

What is smallpox?

Smallpox is a virus (germ) that causes a high fever and a rash with draining lesions over the whole body. No person in the world has been diagnosed with smallpox since 1977. For that reason, vaccination programs were discontinued in all countries including the U.S. in 1980. Adults vaccinated prior to 1980 may have some immunity, but the level of protection is unknown.

How is smallpox spread from person-to-person?

When an infected person breathes or coughs the germ is forced out of the mouth into the air on droplets that settle within a few feet. A non-infected person gets the infection through prolonged close contact by inhaling (breathing) the virus into their lungs. The infection can also be spread by skin-to-skin contact with the rash or by contact with contaminated items such as sheets, towels, and clothes. Intentional release of smallpox virus into the air may result is widespread infection.

How will I know if I was exposed to the germ?

The further away you were from a sick smallpox patient or an intentional release site, the less likely it is that you were exposed. Public health investigators will help determine if you may be at risk and if you require vaccination.

What are the symptoms of the infection?

Initial symptoms usually begin 12-14 days after infection (range: 7-17 days), and include: high fever, severe tiredness, headache, backache, and vomiting. A person may become confused and disoriented. The rash (raised, discolored spots) begins on the face and arms, and then spreads to the body and legs. The rash starts as fluid-filled bumps and progresses to pus-filled bumps. Scabs will begin to form on the skin about 8 - 9 days after the onset of the rash.

How is the infection treated?

Smallpox vaccine may prevent serious illness if given within 7 days of exposure to the virus, before symptoms develop. There is no medicine to treat smallpox after the onset of symptoms. Medication may be given to control the fever and to keep the person calm (sedative).

How is the infection prevented?

Infection is prevented by avoiding exposure to smallpox patients or areas of intentional release of smallpox virus. If a smallpox outbreak is confirmed, the health department will provide vaccine to all those who may have been exposed.

How will I know if I need to be vaccinated and where to go to get the vaccination?

If you were in the location where the germ was originally released, or if you were exposed to a person who developed the symptoms of infection, you will be offered the vaccination. The local health department will provide information on the radio and television about the locations of the vaccination sites in your area.
Do people get sick from the vaccination?

Complications are not common, but they do occur. You will be given information and asked to sign a consent form before you receive the vaccine.

What can I do to keep from getting infected?

If a smallpox outbreak is identified, the most important thing you can do is stay at home. Listen to the local radio or television station for special instructions. The local health officer may ask you to wear a mask over your nose and mouth if you have to go to out. DO NOT go to a hospital emergency room unless you are sick.

SMALLPOX - SCREENING FORM

Current Date:///	Medical Red	cord Number: _		
Last Name:	First	Name:		MI:
Street Address:	City	Zip:		
Home Phone:		-		
Occupation:		Work Phone:		
Work Address:	_ City:		State:	_Zip:
Age: Date of Birth:	Sex:	_ Date Sympto	oms Starteo	J:

Question	No	Yes
In the past 3 weeks, have you had contact with any person		
with a high fever and a rash?		
Are you or could you be pregnant?		

In the past 3 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 3 weeks, have you traveled to a foreign country(s)? If yes, identify them and the cities.

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)? ____ NO ___YES If yes, to what medicines?

Have you had any of the following symptoms in the past 3 weeks?

Symptoms	Yes	No	Symptoms	Yes	No
Fever			Backache		
Headache			Sore muscles		
Cough			Vomiting		
Very tired			Rash on the face		
Pain in the stomach			Rash on the arms or legs		
Sore mouth or			Feel cold all over or		
bumps in the mouth			shivers and shakes		
Confusion					

PROTOCOL FOR TULAREMIA CASES AND EXPOSURE

- **DEFINITION** Tularemia (also known as rabbit or deerfly fever) is a bacterial illness typically acquired by humans after skin or mucous membrane exposure to infected animals.
- **ETIOLOGY** *Francisella tularensis,* a small non-motile gram-negative coccobacillus. Numerous wild animals are reservoirs, including rabbits, hares, voles, muskrats, beavers, and various hard ticks.

Transmission can occur by insect vector, inoculation of oropharyngeal or conjunctival tissue with contaminated water, blood or tissue while skinning animals, or by inhalation of dust while handling infected animal carcasses. Bites from animals (e.g., skunks, squirrels, cats or dogs) that may have eaten another infected animal, are rarely implicated as causes. Laboratoryacquired infections are common and usually result in typhoidal or pleuropneumonic disease.

- **SUBJECTIVE &** 1. History of exposure to *F. tularensis*. **OBJECTIVE**
 - 2. Additional history per the Tularemia Screening Form.
 - 3. The average incubation period is 3-5 days, with a range of 1-14 days.
 - 4. Initial symptoms are: fever, headache, malaise, and anorexia.
 - 5. Later signs/symptoms fall into six categories:
 - a. <u>Ulceroglandular disease</u> is characterized by an indolent ulcer appearing at the site of infection, accompanied by lymphadenopathy.
 - b. <u>Glandular disease</u> causes suppurative lymphadenopathy that follows infection without an ulcer or in which the ulcer was not recognized.
 - c. <u>Typhoidal disease</u> primarily causes septicemia, with a highly fatal course.
 - d. <u>Pleuropneumonic disease</u> occurs when organisms localize in the lungs and pleura.
 - e. <u>Oropharyngeal disease</u> is typified by a painful cough and sore throat, accompanied by a watery diarrhea.
 - f. <u>Oculoglandular disease</u> occurs when conjunctivae are the site of invasion; disease is usually unilateral, with painful purulent conjunctivitis and regional lymphadenopathy.

ASSESSMENT	Exposure to <i>F. tularensis</i>
	Symptomatic or asymptomatic

PLAN If possible, consultation with an infectious disease specialist is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

THERAPEUTIC- Follow current CDC recommendation

PHARMACOLOGIC

NOTE: A Streptomycin-resistant (Gentamicin-sensitive) strain of this organism has previously been developed. Antimicrobial susceptibility testing should be performed as quickly as possible.

NOTE: In a mass casualty situation, Doxycycline and Ciprofloxacin, administered orally, are the preferred choices for treatment of both adults and children.

- 1. <u>Adult cases</u>
 - a. Streptomycin 1 g IM BID x 10-14 days OR
 - b. **[IND]**Gentamycin 5 mg/kg IM or IV QD x 10-14 days **OR**
 - c. Doxycycline 100 mg IV BID x 14-21 days OR
 - d. [IND]Ciprofloxacin 400 mg IV BID x 10-14 days OR
 - e. If client is not pregnant,
 [IND] Chloramphenicol 15 mg/kg IV QID x 14-21 days.
- 2. <u>Cases in children</u>
 - a. Streptomycin 15 mg/kg IM BID (maximum of 2g/day) x 10-14 days
 - b. [IND]Gentamicin 2.5 mg/kg IM or IV TID x 10-14 days

OR

c. Doxycycline, IV x 14-21 days, >45 kg: 100 mg <45 kg: 2.2 mg/kg OR

- d. If at least 2 years of age,
 [IND] Chloramphenicol 15 mg/kg IV QID x 14-21 days
- d. **OR [IND]**Ciprofloxacin 15 mg/kg IV (maximum 1 g/day) BID x 10-14 days.

NOTE: Persons beginning treatment with IM or IV Doxycycline, Ciprofloxacin or Chloramphenicol can switch to oral administration when clinically indicated.

- 3. Post-exposure Prophylaxis (PEP)
 - a. Adults, including pregnant women
 - 1) Doxycycline 100 mg po BID x 14 days OR

2) **[IND]**Ciprofloxacin 500 mg po BID x 14 days.

- b. <u>Children</u>
 - 1) Doxycycline, BID x 14 days >45 kg: Adult dose po > > >

2) **[IND]**Ciprofloxacin 15 mg/kg po (maximum of 1 g /day) BID x 14 days.

CLIENT EDUCATION/COUNSELING

- 1. Reassure clients that person-to-person transmission of tularemia does not occur.
- 2. Report potential side effects to medication, or suspicious symptoms.
- 3. Avoid bites from flies, ticks, and mosquitoes in an area where *F. tularensis* may have been introduced.
- 4. Contact precautions for clients with ulceroglandular or oculoglandular cases, if lesion drainage is not contained within a dressing.
- 5. See Appendix A for Home Care Instructions and Appendix C the Summary Chart for Biological Agents.
- 6. See attached FAQs for additional information.

FOLLOW-UP

Each person who begins PEP should be given a postcard to sign and mail back when treatment is completed.

CONSULTATION/REFERRAL

- 1. If PEP client cannot take Tetracyclines or Ciprofloxacin.
- 2. If client develops side effects or suspicious symptoms.
- 3. Mental health services, as needed, for victims of bioterrorism.

REFERENCES

- 1. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 2. Mandell, Bennett, and Dolin, (eds.) *Principles and Practice of Infectious Diseases*, 5th ed. Churchill Livingstone, Philadelphia, 2000.
- 3. *Physicians' Desk Reference*, 55th ed., Medical Economics Company, New Jersey, 2001.
- 4. *Medical Management of Biological Casualties Handbook,* 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 5. *American Hospital Formulary Service*, 2004,pp. 64-69, 214, 370, 451.
- 6. David T. Dennis, et al., for the Working Group on Civilian Biodefense, *Tularemia* as a Biological Weapon, JAMA, June 6, 2001, Vol. 285 No. 21.
- 7. http://www.bt.cdc.gov/agent/tularemia/index.asp.

TULAREMIA – Frequently Asked Questions (FAQs)

What is tularemia?

The bacterium (germ) that causes tularemia infection is normally spread from insects such as flies and ticks to other animals such as rabbits, squirrels, and birds. Humans can get the infection by: contact with dead, infected animals; flea and tick bites; breathing airborne contaminated dust and soil, or an intentionally-released germ; or drinking contaminated water and eating undercooked meat.

Is tularemia spread from person-to-person?

The infection is **NOT** spread from person-to-person.

How will I know if I was exposed to the germ?

It will depend on how and where the germ was released, and where you were in relation to the release site. The further away you were, the less likely that you were exposed.

How soon will symptoms develop (incubation period)?

The incubation period may be 1 day to 14 days, depending on how close you were to where the germ was released into the air. Not everyone that is exposed will develop symptoms.

What are the symptoms of infection?

The symptoms may include a sudden onset of fever, chills, headache, tiredness, sore muscles, loss of appetite, cough, and chest pain. You may also develop vomiting, stomach pain, and watery diarrhea. Although rare, you may develop a sore throat or an ulcer on your face, neck or arms and have painful, swollen glands.

How is the infection treated?

If you have symptoms of the infection, a health care provider will give you an antibiotic.

How is the infection prevented?

If the local health officer determines that you were exposed, you will be offered an antibiotic medicine. Even if you take the medicine, you may develop the infection. If symptoms develop while you are taking the medicine, see the health care provider.

How long should I take the antibiotic?

Take the antibiotic exactly as directed. The dose and number of treatment days will differ depending on the antibiotic prescribed. If you develop side effects, call your health care provider immediately. Do not give your antibiotic to another person.

What should I do if I DO NOT have symptoms?

If you do not have any symptoms of the infection, you should continue with your routine daily activities. **DO NOT** go to the emergency room unless you have symptoms

How can I get more information?

The local health department will make frequent radio and TV announcements about who should receive an antibiotic, how to take it, and where you can obtain it.

TULAREMIA - SCREENING FORM

Current Date://	Medical Record Number	r:	
Last Name:	First Name:		MI:
Street Address:	City:	State: _	Zip:
Home Phone :			
Occupation:	Work Phone:		
Work Address:	City:	State:	Zip:
Age: Date of Birth:	Sex: Date Sym	ptoms Starte	d:

Questions	No	Yes
Have you been camping in the last 3 weeks?		
Have you had any insect bites in the past 3 weeks?		
Have you had contact with sick animals in the past 3 weeks?		
Are you or could you be pregnant?		

In the past 3 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 3 weeks, have you traveled to any foreign countries? If yes, identify them, and the cities:_____

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)? _____NO ____YES If yes, to what medicine(s)?

Have you had any of the following symptoms in the past 3 weeks:

Symptoms	Yes	No	Symptoms	No	Yes
Fever			Sore throat		
Headache			Feel cold all over or		
			shiver/shake		
Dry cough			Cough up blood		
Sore muscles			Pain or tightness in the chest		
Diarrhea (loose, runny			Very tired		
stool)					
Bloody diarrhea			Vomiting		
Pain in stomach			Upset stomach (nausea)		
Loss of appetite			Swollen glands		
Short of breath			Red, painful bumps on the skin		

PROTOCOL FOR VIRAL HEMORRHAGIC FEVERS (VHF)

DEFINITION Viral hemorrhagic fevers are a diverse group of naturally-occurring illnesses ranging from mild to life threatening. All (except dengue) are infectious by aerosol and could conceivably be used as bio-terrorism agents.

ETIOLOGY Viral hemorrhagic fevers are caused by viruses belonging to four distinct families:

- 1. Arenaviruses include Argentine, Bolivian, Venezuelan and Lassa hemorrhagic viruses. These are transmitted to humans by inhalation of dust contaminated with rodent feces.
- 2. Bunyaviruses include Rift Valley fever, Crimean-Congo fever and Hantaviruses. These are transmitted to humans from a variety of reservoirs, including mosquitoes, ticks, rodents and domestic animal slaughter.
- 3. Filoviruses include Marburg and Ebola viruses. Their natural reservoir is unknown.
- 4. Flaviviruses include yellow fever and dengue fever. Both are mosquito-borne.

NOTE: Humans are not the natural host for any VHF yet, once infected, humans can transmit some of the viruses to other humans.

SUBJECTIVE & 1. History of exposure.

OBJECTIVE

- 2. Additional history per the attached VHF Screening Form.
- 3. The incubation period varies depending on the causative Virus. It may be as short as 1 day or as long as 6 weeks. Most VHF exhibit symptoms within 3 weeks of exposure.
- 4. VHF should be suspected in any client presenting with severe febrile illness and evidence of vascular involvement (e.g., subnormal blood pressure, postural hypotension, petechiae, flushing of the face and chest, and non-dependent edema.)
- 5. Symptoms of additional organ involvement may include: photophobia, pharyngitis, cough, nausea, vomiting, diarrhea, constipation, abdominal pain, hyperesthesia, dizziness, confusion and tremor.
- 6. Vascular involvement leads to bleeding under the skin, in internal organs, or from body orifices.

- 7. Severely ill persons may exhibit shock, nervous system malfunction, coma, delirium, and seizures.
- 8. Laboratory findings vary from disease to disease.

Type of	
Viral Hemorrhagic Fever	Prominent Clinical Variables
Argentine and Bolivian HF	Epigastric, retroorbital and low back pain, vesicles on palate, hyporeflexia with gait abnormalities, tremors of tongue and upper extremities, hematuria, proteinuria
Lassa fever	Retrosternal chest pain, back pain, sore throat, peripheral edema, proteinuria, hemorrhage uncommon, hearing loss, elevated AST
Rift Valley fever	Retinitis, loss of vision (delayed), jaundice, Disseminated Intravascular Coagulation (DIC).
Crimean-Congo fever	DIC, thrombocytopenia, jaundice
Hantavirus HF with Renal Syndrome	Renal failure, proteinuria, hematuria, oliguria, polyuria, blanching erythemic rash
Hantavirus Pulmonary Syndrome	Pulmonary vascular permeability, Adult Respiratory Distress Syndrome, hypoxia, dyspnea, hemorrhage and renal failure rare
Marburg and Ebola HF	Photophobia, lymphadenopathy, jaundice, pancreatitis, delirium, coma, maculopapular rash on trunk, DIC
Yellow fever	Jaundice

VHF Differential Diagnostic Variables

ASSESSMENT Possible viral hemorrhagic fever (VHF)

NOTE: Any suspected case of VHF must be treated as a Public Health emergency and reported through established channels.

PLAN

If possible, consultation with an infectious disease specialist is advised.

DIAGNOSTIC STUDIES

Diagnostic information to be determined based on current standards of care at the time of exposure.

PRECAUTIONS

- 1. Because some viruses are extremely deadly, strict barrier isolation should be employed until the causative agent has been conclusively identified.
- 2. Everything in contact with the patient should be disinfected with 0.5% sodium hypochlorite and if possible autoclaved, incinerated, or boiled.

- 3. Dead bodies should not be embalmed, but promptly sealed and buried or cremated.
- 4. Persons coming within 3 feet of the patient should wear face shields or surgical masks with eye protection (including side shields) and any other necessary coverings.
- 5. A negative pressure room and airborne isolation precautions, including use of a fit-tested HEPA filter respirator or more protective respirator may be necessary if patient(s) have prominent cough, vomiting, diarrhea or hemorrhage.

THERAPEUTIC - Follow current CDC recommendation

- 1. Provide intensive supportive therapy for bleeding, hypotension, and shock.
- 2. Avoid intramuscular injections and the use of aspirin or other anticoagulants.
- 3. **[IND]** Ribavirin IV (available from CDC) has been effective at treating some individuals with Lassa Fever and with Hemorrhagic Fever with Renal Syndrome (HFRS), which is caused by old world hantaviruses. Ribavirin may also be useful for treatment of the other Arenaviruses and Bunyaviruses, with the exception of Hantavirus Pulmonary Syndrome (HPS), for which it is **not** effective and **not** recommended. Ribavirin is **not** useful for the treatment of Filoviruses or Flaviviruses.
 - a. Adults (including pregnant woman*) and children in a Contained-Casualty Setting:
 - i. Loading dose of 30 mg/kg (maximum 2 g) IV, **followed by**
 - ii. 16 mg/kg (maximum 1 g) IV q6h for 4 days, **followed by**
 - iii. 8 mg/kg (maximum 500 mg) IV q8h for 6 days.
 NOTE: If IV not available, give oral Ribavirin in a mass casualty setting.
 - b. Adults (including pregnant women*) in a mass casualty setting using oral Ribavirin:
 - i. Loading dose of 2,000 mg once.
 - ii. If weighing > 75 kg, give 1,200 mg/daily in 2 divided doses for 10 days.
 - iii. If weighing ≤ 75 kg give 1,000 mg/daily in 2 divided doses (400 mg in the AM and 600 mg in the PM) for 10 days.

- c. Children in a mass casualty setting using oral Ribavirin:
 - i. Loading dose 30 mg/kg (maximum 2g) Followed by
 - ii. 5 mg/kg/day (maximum 1g) given in 2 divided doses for 10 days.

*Ribavirin is contraindicated in pregnant women however, the Working Group of Civilian Biodefense believes that the benefits appear to outweigh the fetal risk of ribavirin therapy. Also, the mortality of VHF appears to be higher in pregnancy.

- 4. Convalescent phase plasma has shown some success in treating patients with Argentinian Hemorrhagic Fever, and small studies have shown it to be promising for treating Bolivian Hemorrhagic Fever. It may also have limited efficacy for treating Lassa Fever, Crimean-Congo Fever, and Rift Valley Fever. Convalescent phase serum is contraindicated for the treatment of HFRS, as an active immune response is already occurring by the time initial symptoms are recognized. (However, convalescent phase plasma has been used empirically as post-exposure prophylaxis for HFRS).
- 5. Post-exposure Prophylaxis (PEP): Preemptive administration of ribavirin or post exposure prophylaxis in the absence of clinical signs of infection with known or presumed exposure is not currently recommended. Individuals with known or presumed exposure and all high-risk contacts and close contacts should be placed under medical surveillance for 21 days. If symptoms suggestive of VHF occur or if a temperature of 38.3 °C (100.94°F) or higher occurs presumptive treatment should begin, unless there is an alternative diagnosis or the etiologic agent is filovirus, or flavivirus. However, The Department of Defense has a compassionate use protocol for oral ribavirin for high-risk contacts of patients with Crimean-Congo Fever, and a similar PEP strategy has been suggested for Lassa Fever. Ribavirin may also be useful as PEP for other arenaviruses and bunyaviruses.
 - a. Non-pregnant adults and children >9 years:
 i. [IND] Ribavirin 500-600 mg po q6h x 7-10 days.
 - b. Children 6-9 years:
 - i. **[IND]** Ribavirin 400 mg po q6h x 7-10 days.
- 6. Other agents that may have a role in treating some of the viral hemorrhagic fevers include interferon (Rift Valley Fever) and exogenous interferon gamma (Arenaviral infections).

CLIENT EDUCATION/COUNSELING

- 1. Varies depending on the exact agent.
- 2. If strict isolation is required this should be explained to clients and contacts.
- 3. Persons potentially exposed should be advised of the symptoms of early infection and encouraged to seek immediate medical attention if they become symptomatic.

NOTE: In some cases, exposed persons may need to be under close surveillance during the incubation period.

- 4. See Appendix A for Home Care Instructions and Appendix C the Summary Chart for Biological Agents.
- 5. See attached FAQs for additional information.

FOLLOW-UP

Depends on type and severity of illness.

REFERRAL

Mental health services, as needed, for victims of bioterrorism.

REFERENCES

- 1. James Chin (ed.), *Control of Communicable Diseases Manual*, 17th ed., American Public Health Association, Washington, DC, 2000.
- 2. Mandell, et al. (eds.), *Principles and Practice of Infectious Diseases*, 5th ed., Churchill Livingstone, Philadelphia, 2000.
- 3. *Medical Management of Biological Casualties Handbook*, 4th ed., U.S. Army Medical Research Institute of Infectious Diseases, Maryland, 2001.
- 4. David C. Pigott, "CRBNE Viral Hemorrhagic Fevers", *eMedicine.com*, July 26, 2002.
- 5. American Hospital Formulary Service, 2004, pp. 795-808.
- 6. <u>http://www.bt.cdc.gov/agent/vhf/index.asp</u>.
- Jahrling PB, "Viral Hemorrhagic Fevers", in Medical Aspects of Chemical and Biological Warfare, Office of the Surgeon General at TMM Publications, Washington, D.C., 1997.

VIRAL HEMORRHAGIC FEVERS (VHF)

FREQUENTLY ASKED QUESTIONS (FAQs)

What are viral hemorrhagic fevers?

The viruses (germs) that cause viral hemorrhagic fevers are common in Africa and in South America, but very rare in the United States.

Is VHF spread from person-to-person?

Yes. VHF are commonly spread from person- to-person by contact with infected blood and other infected body fluids such as urine, feces, vomitus, and droplets coughed into the air by the infected person.

How soon will symptoms develop (incubation period)?

Normally the symptoms start 5 days or longer after exposure to the germ. Not all persons exposed to the germ will develop symptoms.

What are the symptoms of infection?

The symptoms of VHF generally include high fever, sore muscles and extreme weakness. The eyes may become red and the skin may appear to be red (flushed). In the advanced stages of the infection there may be bleeding from the nose, mouth, bowel or bladder.

How is the infection treated?

While there is no specific therapy available, the antiviral medication ribavirin may be useful for treatment of some forms of the disease.

What should I do if I DO NOT have symptoms?

If you do not have any symptoms of the infection, you should continue with your routine daily activities. Please DO NOT go to the hospital emergency room unless you have a fever or other symptoms of the infection.

How can I get more information?

The local health department will make frequent public announcements. It is important that you listen to the radio or television for more information.

Viral Hemorrhagic Fevers (VHF) - SCREENING FORM

Current Date://_	Medical Record Nur	mber:	_
Last Name:	First Name:	MI:	
Street Address:	City:	State: Zip:	
Home Phone :			
Occupation:	Work P	hone:	
Work Address:	City:	State: Zip:	_
Age:Date of Birth:	Sex: Date	Symptoms Started:	_

Questions	No	Yes
Have you been camping in the last 3 weeks?		
Have you had any insect bites in the past 3 weeks?		
Have you had contact with sick animals in the past 3 weeks?		
Do you have any hepatic or renal impairment?		
Are you or could you be pregnant?		

In the past 3 weeks, have you traveled to other USA cities? If yes, identify them:

In the past 3 weeks, have you traveled to any foreign countries? If yes, identify them, and the cities:_____

What prescription and/or over-the-counter medicines, supplements (including iron supplements) or herbal products are you currently taking?

Are you allergic to any medicine(s)? _____NO ____YES If yes, to what medicine(s)?

Have you had any of the following symptoms in the past 3 weeks?

Symptoms	Yes	No	Symptoms	Yes	No
Fever			Bleeding from the nose or mouth		
Headache			Bleeding from the rectum		
Cough, cough up blood			Bleeding from the bladder		
Sore muscles			Extreme weakness		
Trouble walking			Very tired		
Bloody diarrhea			Vomiting blood		
Red eyes			Red spots on the skin		
Yellow eyes			Change in mental status		
Reduced urination			Excessive urination		
Pain in the eyes			Low back pain		
Chest pain			Loss of vision		
Difficulty breathing			Light hurts the eyes		
Swelling of legs, fingers, hands					

HOME CARE INSTRUCTIONS FOR SELECTED BIOLOGIC AGENTS

In the event of an intentional release of the germ that causes the following conditions, many people may require hospitalization within a few days. Hospitals could become overcrowded and it may become necessary for many sick people to be cared for in their homes by relatives or friends. The following information would be helpful in providing care to sick persons at home. The information that follows is for the care of people with suspected or confirmed conditions of:

- Anthrax
- **Botulism** (See Additional Home Care Instructions)
- Brucellosis
- **Plague** (See Additional Home Care Instructions)
- Q Fever
- **Smallpox** (See Additional Home Care Instructions)
- Tularemia
- Viral hemorrhagic fevers (See Additional Home Care Instructions)
- Wash your hands with soap and water before you eat or drink, after using the bathroom and after contact with the sick person.
- Wear gloves (vinyl or latex) when you have contact with the sick person's blood and other body fluids (urine, feces, vomit, wound drainage, mucous or saliva). Wash your hands after removing the gloves. If gloves are not available, wash your hands with soap and water after contact with the sick person's blood and other body fluids.
- Wash the sick person's hands after using the bathroom, before eating or drinking and after contact with pets.
- If an antibiotic is recommended, give it exactly as prescribed by the doctor or nurse. If an allergic reaction develops, seek medical advice immediately.
- Take the person's temperature at least twice a day. If the temperature goes above 100° F, consult a health care provider.
- If the person is having trouble breathing, go immediately to the nearest designated emergency center or hospital.
- Give the person plenty of fluids such as water or juice. Allow the person to eat solid food as tolerated.
- Change the sick person's clothes and bed linens frequently especially if soiled with blood or other body fluids.
- Wash soiled clothes and bed linens in warm water using any commercial laundry product.
- Disinfect the bathroom and kitchen with a disinfectant such as Lysol[®] every day or when surfaces become soiled with blood or other body fluids. Household bleach (mixed daily at a dilution of 1 part bleach to 10 parts water = 1:10) can also be used as a disinfectant.
 - = 1:10) can also be used as a disinfectant.

As a caregiver, you must take care of yourself. Get plenty of rest, drink fluids frequently, and eat a healthy diet. Even if you are not taking an antibiotic, take your temperature in the morning and afternoon for 3 weeks. If you develop a fever above 100° F or if you have shortness or breath, seek medical attention immediately.

Additional Home Care Instructions for SMALLPOX and PLAGUE

- Follow all of the instructions above.
- Advise friends and relatives not to visit.
- Wear a mask when you are in close contact (within 3 feet) with an infected person.

Additional Home Care Instructions for VIRAL HEMORRHAGIC FEVERS

- Follow all of the instructions above.
- Advise friends and relatives not to visit.
- Wear a mask when you are in close contact (within 3 feet) with an infected person who is coughing or bleeding from any site.
- Wear a plastic apron or gown to protect clothes from becoming soiled with blood or other body fluids.
- After the sick person uses the toilet or after pouring blood or other body fluids into the toilet, pour 1-cup of household bleach into the toilet. Wipe down both sides of the toilet seat and toilet bowl inside and out with the bleach solution. Let the bleach sit in the toilet for 20 minutes and then flush the toilet.
- Take the person's temperature at least twice a day. If the temperature goes above 100° F, consult a health care provider.
- As a caregiver, take your temperature in the morning and afternoon for 3 weeks. If you develop a fever above 100° F or if you begin to bleed from the mouth, bladder or bowel see a health care provider immediately.

Additional Home Care Instructions for BOTULISM

Do not attempt to care for anyone at home who shows symptoms of botulism. If you or any member of your family has any of the following symptoms, go to the nearest hospital emergency room immediately:

- Blurred vision
- Double vision

- Dry mouth
- Trouble speaking
- Trouble swallowing foods or liquids
- Trouble breathing

If you do not have any symptoms, you should practice good personal hygiene as follows:

- Wash your hands with soap and water before you eat or drink, after using the bathroom, and after contact with any sick person.
- Wash soiled clothes and bed linens in warm water using any commercial laundry product.
- Disinfect the bathroom and kitchen with a disinfectant (Bleach, Lysol[®]) every day or when surfaces become soiled.

Adopted with permission from the *California Hospital Bioterrorism Response Planning Guide* (2002), California Department of Health Services.



B.J. Walker, Commissioner

Georgia Department of Human Resources • Division of Public Health • Kathleen E. Toomey, M.D., M.P.H., Director 2 Peachtree Street NW • Suite 15.470 • Atlanta, Georgia 30303-3142 TEL: 404-657-2700 • FAX: 404-657-2715

Advice for First Responders (911, EMS, EMA Personnel, Police, State Patrol, Fire, Sheriffs) Dealing with Suspicious Substances

(February 6, 2004)

The threat posed by suspicious substances ranges from none to credible, and no set of guidelines can cover every possible variation. Every situation will have unique features and the responder must use his or her own judgment in applying these guidelines.

A. SUSPICIOUS SUBSTANCES ASSOCIATED WITH PACKAGES AND LETTERS:

As there is no reliable way to determine visually whether a suspicious powder or substance contains a biological agent like anthrax or a toxin like ricin, it is important to assess the threat of the possible exposure. Factors that need to be assessed include the credibility of the exposure and whether the exposure might result in inhalational anthrax or cutaneous anthrax, or inhalation or ingestion of ricin.

Threat Credibility Assessment

Notify local law enforcement personnel who will conduct a threat credibility assessment. Whether or not the assessment should be conducted at the scene can be decided on a case-by-case basis at the discretion of the law enforcement personnel.

Credible Threat

- 1. Either one or both of the following circumstances may indicate a credible threat:
 - A letter/package (either opened or unopened) with material present. For example, it could be covered with powder, or have a substance staining the letter or leaking from it.
 - A threat accompanies the letter or package (substance need not be present).

- 2. If the above criteria for credible threats are met, the Federal Bureau of Investigation (FBI) should be notified at 404-679-9000 (24/7). If the FBI accepts the situation as a credible threat, follow the steps below:
 - Notify local or district public health
 - and/or notify state public health
 - For State Public Health call:
 - i. During business hours: 404-657-2588
 - ii. Non-business hours (24/7 answering service): 770-578-4104

No credible threat

A suspicious substance associated with packages or letters may have no threat credibility if any of the following apply:

- Neither of the two criteria for credible threats involving letters or packages is met.
- The FBI does not accept the situation as a credible threat.
- The substance in the letter/package is known to be harmless (e.g., crushed candy, crushed Tylenol, laundry soap, etc.).
- The setting is low profile and low-risk (e.g., not news media, not government, not public setting or event).

Substances associated with packages or letters with no threat credibility should be handled as follows:

- Place the letter/package in a plastic bag and discard as routine trash.
- Any substance not in the letter/package should be cleaned up like a routine household spill.

Substances in letters or packages with no threat credibility are very unlikely to contain anthrax or ricin and <u>do not need to be tested</u>. Public safety and public health officials <u>do not need to provide on-scene response</u>.

If the level of threat is uncertain

- Clean and disinfect with a bleach solution (one part household bleach to 10 parts water) using minimal protective gear (e.g., NIOSH-approved disposable mask, gloves).
- Place in plastic bag and discard as routine trash.

If further information is gathered that suggests that the FBI's initial appraisal (not a credible threat) was incorrect, go back to the steps under "Credible Threat" above.

Respiratory Protection Information

The basic purpose of any respirator is to protect an individual from inhalation of hazards (chemical, biological, etc.). Respirators provide protection either by removing contaminants from the air before it is inhaled (air-purifying) or by supplying an independent source of respirable air (air-supplying). Respirators providing protection against inhalation of **biological** organisms (in relative order of protection ranging from air-purifying to air-supplying) include disposable quarter-masks, half-mask respirators, full-facepiece respirators, powered air-purifying respirators (PAPR), air-supplied respirators, and self-contained breathing apparatus (SCBA). Among NIOSH approved air-purifying respirators, there are three categories of filter (N, R, and P) type based on resistance to oil. All will filter particles 0.3 microns or larger, but at various levels of filter efficiency (95%, 99%, and 99.97%). For example, in the hospital setting, disposable N95 masks are used to protect healthcare workers against hazards such as pulmonary tuberculosis (95% efficient), and P100 respirators are used for hazards such as hantavirus (99.97% efficient).

Individual anthrax spores are reported to be 2-6 microns in diameter, so would presumably be filtered at a 95% efficiency rate by a properly fitting N95 respirator Current data suggest that the SCBA which first responders currently use for entry into potentially hazardous atmospheres will provide responders with respiratory protection against biological exposures associated with a suspected act of biological terrorism. Protective clothing, including gloves and booties, also may be required for the response to a suspected act of biological terrorism.

The CDC recommendations, "Interim Recommendations for Firefighters and Other First Responders for the Selection and Use of Protective Clothing and Respirators Against Biological Agents" indicate that responders should use a NIOSH-approved, pressure demand SCBA in conjunction with a Level A protective suit in responding to a suspected biological incident where the agent and/or the dissemination method is unknown. In situations where dissemination was by a letter or package that can be easily bagged, the CDC guidelines indicate that responders should use a full-facepiece respirator with a P100 filter or powered air-purifying respirator (PAPR) with high efficiency particulate air (HEPA) filters.

However, this level of respiratory protection may not be available, practical, or feasible in all jurisdictions or response situations, especially when risk levels are deemed to be low. As such, a **minimum level of protection would consist of wearing a N95 mask and gloves when handling suspicious letters, packages, or substances**, although individual response scenarios may be judged to warrant a higher level of respiratory protection. The choice of glove material (e.g., nitrile, vinyl, latex) should be based on safety, fit, durability, and comfort. Sterile gloves (e.g., surgical gloves) are not necessary.

Care of Exposed Persons

- Ensure that all persons with possible exposure to the package, letter, or substance remain on site until emergency personnel arrive; list all persons who physically handled the letter (package) and provide the list to authorities.
- Persons with exposure to the package, letter, or substance should wash their hands and/or exposed skin with soap and water. If a substance from the letter or package has visibly contaminated a person's clothing, the clothing should be removed and laundered with usual cleaning methods appropriate for the clothing affected.
- Preventive antibiotics for exposed individuals may be indicated if a substance contains anthrax spores (but not if ricin is present). However, decisions about the need to begin preventive antibiotics should be made in consultation with public health officials. In most circumstances, the decision to begin preventive antibiotics can be delayed until the presence or absence of anthrax spores is determined.
- Note: CDC currently does NOT recommend use of nasal swab specimens as part of evaluating anthrax threats/implied threats or evaluating concerned citizens who think they may have been exposed to anthrax.

Laboratory Testing

Prompt laboratory testing of suspicious letters, packages, or substances provides responders with rapid information about exposure risk such that appropriate preventive treatment can be offered.

- HazMat personnel (if a substance is present) or law enforcement personnel (if a substance is NOT present) should triple-bag the letter or package in plastic bags using personal protective equipment (including respiratory protection and protective clothing) based upon the anticipated level of exposure risk associated with the response situation.
- Care should be taken when bagging letters and packages to minimize creating a puff of air that could spread pathogens. It is best to avoid large bags and to work very slowly and carefully when placing objects in bags.
- Do not smell, touch, taste, look closely at, or shake the contents of the package or letter. Wash hands with soap and water.
- For credible threats, substances in letters/packages can be submitted for testing at the Georgia Public Health Laboratory (GPHL) according to the Packaging/Transport protocol below. Competent, trained and properly equipped personnel, including HazMat teams, should appropriately prepare the letter/package for transport. Unopened packages should be screened for other hazards by local HazMat personnel or the FBI officer on scene.

 In addition to testing for anthrax and ricin, the GPHL will also test for other biologic or chemical agents as indicated by request or by preliminary test results.

Packaging/Transport Protocol

- Prior to transport, coordinate with the GPHL at **404-327-7900.**
- Place the double or triple-bagged suspicious letter or package into a leakproof container with a tight cover that is labeled "biohazard." If ricin testing is proposed, do NOT use glass containers.
- Place this container into a second leak proof container with a tight cover that is labeled "biohazard." The size of the second container should be no larger than a one-gallon paint can. No ice packs are needed.
- Place the second container into a third leak proof container with a tight cover that is labeled "biohazard." The third container should be no larger than five-gallon paint can.
- All three containers should meet state and federal regulations for transport of hazardous material, and be properly labeled.
- Local Law Enforcement personnel (or, if needed, State Patrol or Department of Natural Resources officers) should **immediately** transport specimens to the GPHL in Atlanta according to appropriate "chain of custody" protocols. Do NOT batch specimens for transport.

Decontamination of Responders

• Decontamination of protective equipment and clothing is an important precaution to make sure that any particles that might have settled on the outside of protective equipment are removed before taking off gear. Decontamination sequences currently used for hazardous material emergencies should be used as appropriate for the level of protection employed. Equipment can be decontaminated using soap and water, and a bleach solution (one part household bleach to 10 parts water) can be used as appropriate or if gear had any visible contamination. Note that bleach may damage some types of firefighter turnout gear. After taking off gear, response workers should shower using copious quantities of soap and water.

B. SUSPICIOUS SUBSTANCES <u>NOT</u> ASSOCIATED WITH LETTERS OR PACKAGES:

<u>Credible threat</u> (examples: substance plus threat, or no threat but high profile target—news media, government, sporting event, abortion clinic)

- The Federal Bureau of Investigation (FBI) should be notified at 404-679-9000 (24/7).
- Notify local or district public health
- and/or notify state public health
- For State Public Health call:
 - i. During business hours: 404-657-2588
 - ii. Non-business hours (24/7 answering service): 770-578-4104
- Ensure that all persons with possible exposure to the substance remain on site until emergency personnel arrive; list all persons who physically handled the substance and provide the list to authorities.

Laboratory Testing

- Competent, trained and properly equipped personnel, including HazMat teams, should appropriately prepare the substance for transport according to above "Packaging/Transport Protocol".
- HazMat personnel should double or triple-bag the substance in plastic bags using personal protective equipment (including respiratory protection and protective clothing) based upon the anticipated level of exposure risk associated with the response situation. Please refer to the section "Respiratory Protection Information" above to assist responders in selection of appropriate respiratory protection. At a minimum, gloves and a N95 respirator mask should be used. The choice of glove material (e.g., nitrile, vinyl) should be based on safety, fit, durability, and comfort. Sterile gloves (e.g., surgical gloves) are not necessary.
- **Do not smell, touch, taste, look closely at, or shake the substance.** Care should be taken when bagging substances to minimize creating a puff of air that could spread pathogens or toxins. It is best to avoid large bags and to work very slowly and carefully when placing objects in bags.
- Law enforcement personnel (or, if needed, State Patrol or Department of Natural Resources officers) should **immediately** transport the bagged letter/package to the Georgia Public Health Laboratory (GPHL) in Atlanta under chain-of-custody protocols. Prior to transport, phone the GPHL at 404-327-7900. Do NOT batch specimens for transport.
- In addition to testing for anthrax and ricin, the GPHL will also test for other biologic or chemical agents as indicated by request or by preliminary test results.

Care of Exposed Persons

- Persons with exposure to the substance should wash their hands and/or exposed skin with soap and water. If the substance has visibly contaminated a person's clothing, the clothing should be removed and laundered with usual cleaning methods appropriate for the clothing affected.
- Preventive antibiotics for exposed individuals may be indicated if a substance contains anthrax spores (but not if ricin is present). However, decisions about the need to begin preventive antibiotics should be made in consultation with public health officials. In most circumstances, the decision to begin preventive antibiotics can be delayed until the presence or absence of anthrax spores is determined.
- Note: CDC currently does NOT recommend use of nasal swab specimens as part of evaluating anthrax threats/implied threats or evaluating concerned citizens who think they may have been exposed to anthrax.

Decontamination of Responders

 Decontamination of protective equipment and clothing is an important precaution to make sure that any particles that might have settled on the outside of protective equipment are removed before taking off gear.
 Decontamination sequences currently used for hazardous material emergencies should be used as appropriate for the level of protection employed. Equipment can be decontaminated using soap and water, and a bleach solution (one part household bleach to 10 parts water) can be used as appropriate or if gear had any visible contamination. Note that bleach may damage some types of firefighter turnout gear. After taking off gear, response workers should shower using copious quantities of soap and water.

Other Resources:

Georgia Division of Public Health bioterrorism webpages at http://health.state.ga.us/programs/emerprep/bioterrorism.asp http://health.state.ga.us/programs/emerprep/links.asp http://health.state.ga.us/pdfs/publications/factsheets/ricin.03.pdf

Contact telephone numbers:

FBI: 404-679-9000
State public health: During business hours: 404-657-2588 Non-business hours (24/7 answering service): 770-578-4104
Georgia Public Health Laboratory: 404-327-7900

APPENDIX C

SUMMARY CHART FOR BIOLOGICAL AGENTS

Disoaso	Usual	Transmitted	Usual Treatment	Post-
DISEase	Period	person?		prophylaxis?
	Inhalational 2-60 days	.	[IND] Ciprofloxacin OR	
Anthrax	Cutaneous or Gastrointestinal	No	Doxycycline, AND	Yes
	Inhalational			
	24 hrs to a few			
Botulism	days <u>Ingestion</u> 6 hrs to 10 days	No	Trivalent equine antitoxin (from the CDC)	No
			Adult and child >8 years:	
Brucellosis	5 to 60 days	No	[IND] Rifampin OR Streptomycin	Yes
			[IND] Co-Trimazole AND [IND] Rifampin OR Gentamicin	
			Adult and child, preferred:	
	1 to 6 dove	Voc	Streptomycin OR	Vac
Pheumonic	usually 2-4 days	163	Other antibiotics:	163
i lague			Doxycycline,	
			[IND] Ciprofloxacin,	
			[IND] Doxycycline,	
Q Fever	2-3 weeks; but	No	Tetracycline, OR	Yes
	2 days possible		[IND] Chloramphenicol	
			Supportive	Immunization;
	7-17 days,	Vaa		Antiviral –
Smallpox	davs	165		cidofovir but
				may cause
				severe side
			Streptomycin,	6116012
			[IND] Gentamicin,	
Tularemia	1-14 days, usually 3-5 days	No	Doxycycline,	Yes
			Chloramphenicol	
Virol	Depends on	Yes some	Lassa HERS and possibly	For agents in
Hemorrhagic	specific virus;	viruses	other arenaviruses AND	previous box
Fevers	mostly within 3 weeks		<u>bunyaviruses (except HPS)</u> : [IND] Ribavirin	