State of Hawaii
Department of Health
Emergency Medical Services System

Mobile Intensive Care Technician

ANNEX

Biological Outbreak/Exposure Mass Prophylaxis & Immunization Standing Orders

First Edition
November 2001

Approved:

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Donald C. Fancher, M.D.
State EMS Medical Director

Mobile Intensive Medical Technician
Biological Outbreak/Exposure
Mass Prophylaxis and Immunization
Standing Orders

November 1, 2001

TO: EMS Providers
EMS Training Programs

FROM: Donald C. Fancher, M.D.
State EMS Medical Director

SUBJECT: **Mobile Intensive Care Technician Standing Orders for Mass Prophylaxis Following a Bioterrorism Incident**

The document, *Mobile Intensive Care Technician Biological Outbreak/Exposure Mass Prophylaxis & Immunization Standing Orders*, is the first edition of a manual that provides the Department of Health with standing orders for preventive antibiotic therapy and/or immunizations in the event of a bioterrorism attack due to anthrax, brucellosis, plague, smallpox, or tularemia.

The document contains 1) an overview of the bioterrorism preparedness response plans regarding mass prophylaxis and immunization; 2) standing order protocols for anthrax, brucellosis, plague, smallpox, and tularemia; 3) antibiotic information for practitioners; 4) antibiotic information brochures for patients; and 4) data management and consent forms.

This document should be considered an annex to the *State of Hawaii EMS MICT Standing Orders and Extended Standing Orders*.

The standing orders contained within this document become activated when the Director of Health declares a state of emergency due to a specific bioterrorism incident, and issues a memorandum ordering the EMS prehospital providers to begin mass prophylaxis. The memorandum would contain information regarding the nature of the bioterrorism incident, the causative microorganism, the population at risk, and the mass prophylaxis protocol to be followed.

This document may be reviewed annually to ensure that the standing orders are up to date, and reflect the latest available recommendations from the Centers for Disease Control and Prevention for Bioterrorism Preparedness and Response.

cc: EMS Medical Directors

Mobile Intensive Care Technician
Biological Outbreak/Exposure
Mass Prophylaxis and Immunization Standing Orders

OVERVIEW

INTRODUCTION

An intentional biological agent release may produce thousands of casualties. Victims of a bioterrorism (BT) incident may die despite the best medical management. Case fatality rates will depend upon the specific microbial agent released, and the susceptibility of the exposed population.

The rapid implementation of a mass prophylaxis program is the most effective method of countering the consequences of a biological incident. The best chance to save lives following such an event is through early recognition and prompt administration of appropriate antibiotic therapy and, if available, vaccines to exposed (infected) individuals before symptoms occur.

The standing orders in this manual are specific for the mass prophylaxis and immunization for BT incidents involving anthrax, brucellosis, plague, smallpox, and tularemia. They can be adapted for other BT agents that might be used in a BT attack. The bacteria that cause anthrax, plague, tularemia, and brucellosis are susceptible to antibiotics. Antibiotic therapy of exposed, or potentially exposed, individuals will prevent or mitigate these diseases and save lives. No preventive antiviral drugs against smallpox currently exist.

Vaccine supplies for smallpox and anthrax are currently limited. Food and Drug Administration (FDA) approved vaccines against aerosol exposure to plague, brucellosis, and tularemia either do not exist, or are ineffective.

POLICIES

1. A mass prophylaxis program will be implemented within 24 hours of recognition of a BT incident.

2. The Department of Health (DOH) has the legal authority to adopt rules requiring and governing immunizations against any communicable disease if a suitable immunizing agent is available for the disease, and a need for immunization against it exists within

the State. The department may also provide vaccines and other immunizing agents to private and public health care providers for administration to the general public (§325-32, Hawaii Revised Statutes). The DOH will establish standing orders for the administration of antibiotics and vaccines, and establish a priority list for the distribution of these prophylactic pharmaceuticals.

3. If a BT event occurs, the DOH will define the distribution and determinants of the disease event, including the case definition, etiology, source, time, person, place, disease pattern, risk factors, exposed populations, and mass prophylaxis recommendations.

OPERATIONS

1. The State Epidemiologist will investigate suspected or confirmed outbreaks involving BT organisms (e.g., anthrax, brucellosis, plague, smallpox and tularemia); and other mysterious or undiagnosed disease outbreaks that threaten the public's health. The State Epidemiologist will determine appropriate disease control measures, and report findings and recommendations to the Director of Health.

2. The Director of Health activates the DOH Emergency Operations Center (EOC), as outlined in the *State of Hawaii DOH Emergency Operations Plan*, when notified by law enforcement agencies of a credible BT threat, or by recommendations of the State Epidemiologist that a true state, or county-wide, infectious disease emergency exists.

3. The Director of Health may order DOH personnel and EMS providers to activate plans for mass prophylaxis and/or immunization when:

    a. A single confirmed case is identified in the community that can't be attributed to a natural infection.
    b. Multiple confirmed or highly suspected cases have occurred within a short period of time, and the source of the infection is unknown.
    c. Law enforcement or public health officials have determined that a definite or highly probable release of a virulent biological agent has occurred within the community.

4. The Public Health Nursing Branch (PHNB) and EMS providers will conduct mass prophylaxis at Public Health Clinics identified and activated by the Director of Health following a BT event. Other clinic sites may be activated, if necessary, at neighborhood fire stations, additional city and county locations, or other state government facilities depending upon the magnitude and location of the exposure or outbreak. These clinics will be referred to as Neighborhood Assistance Centers (NAC).

5. The NAC will provide basic information to the public, provide preventive medications and/or immunizations, and direct victims to appropriate treatment centers. Public health nurses and other DOH employees together with community volunteers will staff NAC sites as outlined in the *State of Hawaii DOH Emergency Operations Plan*.

6. The EMS Administration will be the central point of communication, mobilization, and staffing for DOH prophylaxis sites during a BT event. The Deputy Director for the Health Resources Administration will determine the nursing personnel that will report for duty, and their distribution in the field to include: nursing offices, emergency units, shelters, public health clinic sites, and field operations.

7. NAC will administer antibiotics and/or vaccines to exposed asymptomatic individuals. Symptomatic, or ill individuals will be referred to hospitals, private physicians, or mass care centers depending upon the severity of the symptoms and magnitude of the BT event.

8. NAC personnel which may include EMS personnel are responsible for client registration, informed consent, maintaining client health records, and tracking individuals.

9. NAC personnel will collect the following data on a daily basis and report theses findings to the EMS provider administration which will be transmitted to the Director of Health:

    a. The number of clients starting antibiotic prophylaxis or vaccination.
    b. The number of clients completing antibiotic prophylaxis or vaccination.
    c. The number of clients presenting with symptoms.
    d. The number of clients developing symptoms during or after prophylaxis and/or vaccination.
    e. The number of clients referred to an in-patient medical facility for treatment.
    f. The number of clients developing adverse reactions to prophylaxis or immunization.

10. NAC personnel will report the names of clients who are infected with identified BT agents, people directly exposed to these cases, or people environmentally exposed to these microbial agents and transmit information to the Director of Health.

11. Each client will receive a one-week supply of antibiotics. This will require that clients return to the NAC for refills.

12. Infection control procedures will follow recommendations outlined in the document written by the Association for Professionals in Infection Control and Epidemiology (APIC) and the CDC entitled *Bioterrorism Readiness Plan, a Template for Healthcare Facilities.*

13. Public Health Nursing sections are responsible for maintaining adequate infection control supplies and protective clothing for the clinic staff.

REFERENCES

1. City and County of Honolulu Emergency Operations Plan, Annex S, Appendix 7, Tab A: *Honolulu Biological Incident Response Plan, June 2000*.

2. State of Hawaii Department of Health Emergency Operations Plan.

3. Oahu Disaster Plan for HRA Nursing Personnel.

4. Public Health Nurses Policy and Procedures Clinic Manual.

5. APIC. Bioterrorism Readiness Plan, a Template for Healthcare Facilities, April 13, 1999. URL: www.apic.org.

6. CDC. Vaccinia (Smallpox) Vaccine; Recommendations of the ACIP. MMWR 1991; 40(No. RR-14): 1-10. MMWR:

7. Franz DR, Jahrling PB, Friedlander AM, et al: *Clinical Recognition and Management of Patients Exposed to Biological Warfare Agents.* JAMA. 1997, 278: 399-411.

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9. Inglesby TV, Dennis DT, Henderson DA, et al: *Plague as a Biological Weapon. Medical and Public Health Management.* JAMA. 2000, 283: 2281-2290.

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12. CDC. Use of anthrax vaccine in the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2000; 49(No. RR-15): 1-20.

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CLINIC FUNCTIONS AND OPERATIONAL ACTIVITIES	TYPE OF STAFFING AND NUMBER NEEDED	TRAINING NEEDS
► **REGISTRATION** *Welcome clients *Provide written information; brochures *Assist with completion of registration form *Provide information *Oversee registration area for questions; response to urgent needs	► Volunteers ► Clerical workers ► 34 workers covering four (4) stations ► One PHN/RN/MICT/EMT	► Overview ► Reception of clients as first contact; importance of relationship building; trust and support; how to handle anxious clients; managing conflicts ► Specific information as to the event; symptoms ► Brochures/Registration forms completion ► Common questions that will be asked and responses ► Triage processes
► **INTAKE PROCESSES** *Interview – assessment as to contact; length, type of contact; presence of symptoms; type and severity of symptoms *Medical history and documentation *Triage for services- no services and provide information only; referral to in-patient facility; need for prophylaxis or vaccinations *Documentation and completion of forms	► 1-PHN Coordinator ► 4- PHNs/RNs/MICT/EMT to set up four stations ► 2- LPNs to assist PHNs with clients with acute symptoms and need for inpatient referral and arrangements ► 1-Clerical ► Paramedics	► Same as above PLUS ► Disease processes; course of disease; symptomatology; treatment options- risks and benefits; communicability ► Preventive measures in home and environment; personal self care measures ► Emphasis on treatment modalities and follow-up required ► Training in use of forms and data collection
► **ANTIBIOTIC PROPHYLAXIS OR VACCINATION** *Informed Consent Process, including signing of consents *Risks and Benefits of treatment options *Anthropometric measurements *Instructions and written materials about treatment *Administration of Medications or vaccination *Assess for knowledge acquisition and understanding *Return timeframe *Documentation and data collection processes	► One PHN overseeing the entire station ► 4- PHNs/RNs/MICT ► 4-LPNs/EMT ► 2-clerical to give specific return appointment ► American Red Cross Representative ► Mental Health Counselor	Same as above

PUBLIC HEALTH CLINIC ORGANIZATION
FOR MASS PROPHYLAXIS AND IMMUNIZATION
PAGE 2

CLINIC FUNCTIONS AND OPERATIONAL ACTIVITIES	TYPE OF STAFFING AND NUMBER NEEDED	TRAINING NEEDS
► **DATA ENTRY AND OTHER CLERICAL FUNCTIONS** *Verification with client of all demographic information, including accuracy of contact phone numbers *Provide return appointment card; enter return appointment in clinic book *Data entry of all information *Generate data report at the end of the clinic	► 1-Secretary or office manager type personnel to oversee this station ► 5-Clerical workers ► Volunteers	► Similar to training listed above for the Registration Station ► Use of Computer and software ► Communication with clients in verification of information ► Data entry functions ► Maintenance of appointment books ► Generate report for data reporting
► **MAINTENANCE OF MEDICAL/CLINIC RECORDS** *Proper filing of records *Proper handling of consent forms within each client's record *Organization of all forms *Set up system to have records available for next clinic	► 2-clerical	
► **FIRST AID STATION/HOLDING AREA** *Provide first aid and other emergency measures *Allay extremely anxious clients or those with challenging behaviors *Observation for any untoward reactions	► EMS Personnel ► Mental Health Counselor ► DMAT ► Military	
► **SECURITY**	Honolulu Police Department; Public Safety; National Guard – need to follow-up	Managing potential infectious disease patients. Safety precautions at the clinic. Coordination with DOH, and ARC
► **LOGISTICS FOR TRANSPORTATION**	Follow-up needed.	

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Approved By: Donald C. Fancher, M.D.		Effective Date: November 1, 2001
Subject: Mobile Intensive Care Technician Standing Orders for Administration of Immunizations		Review Date: November 30, 2002

CONTRAINDICATIONS & PRECAUTIONS TO IMMUNIZATION

See individual vaccines for contraindications and precautions.

NOTE:

If a contraindication or precaution to <u>any</u> immunization exists, do <u>NOT</u> administer vaccine. Refer patient to their primary care provider.

PROTOCOL FOR THE MANAGEMENT OF ADVERSE REACTIONS TO VACCINES & MEDICATIONS

GENERAL GUIDELINES

All those who administer medications or vaccines must be aware that the recipient could experience an adverse reaction following the injection. Adverse reactions to vaccines are infrequent, but if an allergic reaction does occur, it can be life threatening.

Staff need to be prepared to respond immediately and appropriately to such emergencies. All clinic personnel must familiarize themselves with the management protocols contained herein and know where the emergency supplies are kept.

TYPES OF ADVERSE REACTIONS

Adverse reactions to an injection can range from a general feeling of faintness to a severe allergic reaction. Faintness or syncope are the more common of adverse reactions and are usually self limited; true allergic reactions are rare.

Symptoms of an allergic reaction may be *mild*, such as itching and hives, or *severe*, with shortness of breath, wheezing, and/or anaphylactic shock. Allergic reactions may begin almost immediately after the injection is given. Anaphylaxis is characterized by acute, progressive, respiratory distress and cardiovascular collapse (shock). Early recognition of an anaphylactic reaction is important because death can occur within minutes following the first symptoms.

It is important to distinguish between faintness/syncope and anaphylaxis. Should an adverse reaction occur, assess the patient and FOLLOW THE PROCEDURES PROVIDED IN THE ATTACHED PROTOCOL.

BASIC FIRST AID AND INITIAL ASSESSMENT PROCEDURES

Airway: Ensure the airway is clear; remove dentures and keep tongue from obstructing the oropharynx.

Breathing: Check for breathing; auscultate (listen for sounds at the chest), if necessary. When required, assist with breathing by using the ambubag or perform mouth-to-mouth resuscitation.

Circulation: Check carefully for a pulse; in case of cardiac arrest, initiate CPR.

Document any occurrence of an allergic reaction and report the incident to the Chief, Communicable Disease Division.

MANAGEMENT OF ANAPHYLAXIS or SHOCK-LIKE STATE IN ADULTS

DESCRIPTION

Signs and symptoms include flushing of the face, shortness of breath, difficulty breathing with audible wheezing or stridor. The pulse may be weak, irregular, or non-palpable.

This is a true emergency.

ACTION

1. Place the patient in recumbent position. Make sure the airway is clear. Use ambubag or other forms of assisted respiration if necessary. If no pulse, begin CPR.

2. ADMINISTER EPINEPHRINE

   Administer 0.3 ml of 1:1,000 epinephrine subcutaneously.

3. ADMINISTER BENADRYL

   Administer 50 mg. of BENADRYL IM at a different site than that given for the epinephrine.
   Maximum dose is 50 mg.

4. REPEAT EPINEPHRINE

   Administer 0.5 ml dose of 1:1,000 epinephrine subcutaneously 20 minutes after first dose if necessary.

5. REFER TO HOSPITAL OR PHYSICIAN

   Refer the patient to a hospital or physician, even if the patient appears stable.

MANAGEMENT OF ANAPHYLAXIS or SHOCK-LIKE STATE IN INFANTS AND CHILDREN

DESCRIPTION

Signs and symptoms include flushing of the face, shortness of breath, difficulty breathing with audible wheezing or stridor. The pulse may be weak, irregular, or non-palpable.

This is a true emergency.

ACTION

1. Place client in recumbent position. Make sure the airway is clear. Use ambu bag or other forms of assisted respiration if necessary. If no pulse, begin CPR.

2. ADMINISTER EPINEPHRINE

   INFANTS (Birth to 12 months old)
   Administer 0.03 - 0.1 ml of 1:1,000 epinephrine subcutaneously. Repeat every 10-20 minutes as necessary. See attached table for exact dosage.

   CHILDREN
   Administer 0.1 to 0.3 ml of 1:1,000 epinephrine subcutaneously. Repeat every 10-20 minutes as necessary. See attached table for exact dosage. Maximum dose is 0.3 ml.

3. ADMINISTER BENADRYL

   Administer one dose of BENADRYL at a different site than that given for epinephrine. See attached table for exact dosage. Maximum dose of Benadryl in children is 25 mg.

   DO NOT ADMINISTER BENADRYL TO INFANTS LESS THAN 1 YEAR OLD.

MANAGEMENT OF ANAPHYLAXIS or SHOCK-LIKE STATE IN INFANTS AND CHILDREN

DESCRIPTION	ACTION
	4. REFER TO HOSPITAL OR PHYSICIAN Refer the patient to a hospital or physician, even if the patient appears stable.

MANAGEMENT OF FAINTING, DIZZINESS OR EXCITABILITY IN ADULTS AND CHILDREN

SYNCOPE (Fainting)

DESCRIPTION	ACTION
Patient is breathing normally, although respiration may be shallow. There is no respiratory distress (i.e., wheezing, tightness, or other impairment with breathing). The pulse is regular, but patient is unresponsive.	Place the patient in the recumbent position and check the pulse and respirations. Provide ammonia inhalant if consciousness is not regained in one minute. Allow to remain in quiet area for 15 minutes once conscious and observe.

"LIGHT-HEADEDNESS"

DESCRIPTION	ACTION
Patient complains of feeling faint, dizzy, or tired. Appears pale and may yawn. Pulse and respirations are generally steady. There is no respiratory distress (wheezing, tightness or other impairment with breathing).	Allow client to lie down and elevate lower extremities, or have client sit in a head-down position for several minutes. Make sure breathing is clear. Monitor to ensure patient is improving.

MANAGEMENT OF FAINTING, DIZZINESS OR EXCITABILITY IN ADULTS AND CHILDREN

HYPERVENTILATION OR EXCITABILITY

DESCRIPTION	ACTION
Rapid breathing with good air movement and no wheezing or stridor. Patient appears anxious, not tired or pale. May complain of light-headedness.	Make sure airway is clear. Instruct client to sit or lie down and slow down breathing. Have patient breathe into a paper bag to correct for hyper-ventilation. Provide support and reassurance. Monitor until the episode subsides to ensure patient is improving.

State of Hawaii Department of Health	Emergency Medical Services System	
Approved By: Donald C. Fancher, M.D.		Effective Date: November 1, 2001
Subject: Summary of Bioterrorism Incident Mass Prophylaxis Recommendations		Review Date: November 30, 2002

Summary of Bioterrorism Incident Mass Prophylaxis Recommendations

DISEASE	**PROPHYLAXIS OF CHOICE**	**ALTERNATIVE #1**	**ALTERNATIVE #2**	**DURATION**
Anthrax	Ciprofloxacin plus Anthrax Vaccine	Doxycycline plus Anthrax Vaccine	Amoxicillin* plus Anthrax Vaccine	60 days with antibiotic alone; or 30 days with antibiotic plus vaccine
Brucellosis	Doxycycline plus Rifampin	Trimethoprim-sulfamethoxazole plus Rifampin	Ofloxacin plus Rifampin	3 to 6 weeks
Plague	Doxycycline	Ciprofloxacin	None	7 days
Smallpox	Vaccinia Virus Vaccine			One Vaccination
Tularemia	Doxycycline	Ciprofloxacin	None	14 days

*If anthrax strain is proven susceptible to penicillin

INDICATIONS

1. The person has had a confirmed or highly suspected exposure to aerosolized *Bacillus anthracis* spores following a BT incident as determined by the Director of Health;

2. The Director of Health has activated the DOH Emergency Operations Plan for mass antibiotic prophylaxis and immunization; and

3. Issues a signed memorandum ordering anthrax antibiotic prophylaxis and vaccination.

MANAGEMENT OF EXPOSED PEOPLE

1. All exposed people should be identified, and interviewed to detect any additional cases.

2. People having symptoms attributable to anthrax should be sent to Triage and Referral Centers for definitive treatment.

3. People eligible for antibiotic prophylaxis and vaccination should sign an informed consent form, and receive a patient information sheet about the antibiotics or vaccine before the medication or vaccine is administered.

4. **Antibiotics**

   a. Prophylaxis for asymptomatic patients with confirmed or suspected exposure to *Bacillus anthracis* spores can be achieved with a 60 day course of either ciprofloxacin or doxycycline.

   b. Ciprofloxacin is the treatment of choice for initial anthrax post-exposure prophylaxis during a BT event for adults, children, and pregnant women. If ciprofloxacin administration is contraindicated, then doxycycline is the alternative choice. If the specific *B. anthracis* strain used in the BT event is proven to be susceptible to penicillin, then amoxicillin may be used. Refer to section 4-d for antibiotic prophylaxis choices.

c. Exposed persons will be provided with a one-week supply of ciprofloxacin (14 doses), or an alternative antibiotic, and instructed to return in one week to receive additional antibiotic supplies. Antibiotics will be dispensed in one-week increments until it is certain that enough antibiotics are available to treat all exposed individuals. Each week the person will be monitored for the presence of anthrax symptoms, adverse reactions to the antibiotic, and any needed modifications made in the antibiotic choice, dose, or schedule.

d. Antibiotic Prophylaxis Following the Intentional Release of Anthrax Spores in a Community (Source: Reference #11)

PATIENT CATEGORY	**PROPHYLACTIC ANTIBIOTIC THERAPY OF CHOICE ***	**ALTERNATIVE THERAPY†**	**DURATION (DAYS)**
Adult	**Ciprofloxacin** 500 mg by mouth every 12 hours	**Amoxicillin** 500 mg every 8 hours; or **Doxycycline** 100 mg by mouth ever 12 hours	60
Children§	**Ciprofloxacin** 10-15 mg/kg by mouth every 12 hours. Do not to exceed 1 gram/day.	Weight ≥ 20 kg: A **moxicillin** 500 mg by mouth every 8 hours. Weight < 20 kg: A **moxicillin** 25 mg/kg every 8 hours. or **Doxycycline**§	60
Pregnant women ‡	**Ciprofloxacin** 500 mg by mouth every 12 hours	**Amoxicillin** 500 mg by mouth every 8 hours	60
Immunosuppressed	**Same as above**	**Same as above**	60

* For people with chronic renal failure or people > 65 years of age, reduce the dose of ciprofloxacin by 50% and consult the patient's personal physician for monitoring of drug therapy.

† Do not use amoxicillin until antibiotic susceptibility tests confirm that the anthrax strain is susceptible to penicillin.

§ Doxycycline can be used in children during an anthrax outbreak if antibiotic susceptibility tests, exhaustion of drug supplies, or history of allergy preclude use of amoxicillin and ciprofloxacin. For children heavier than 45 kg, use adult dosage. For children less than or equal to 45 kg, use 2.5 mg/kg of doxycycline by mouth every 12 hours.

‡ Balancing the risks of an anthrax infection with those of antibiotic use in pregnancy, it is recommended to use ciprofloxacin until antibiotic susceptibility tests confirm amoxicillin (penicillin) sensitivity of the anthrax strain.

5. **Anthrax Vaccine**

   a. Post-exposure anthrax vaccination is indicated for individuals exposed to aerosolized *B. anthracis* spores following a bioterrorism event.

   b. Post-exposure vaccination following an anthrax BT event along with antibiotic administration is recommended to protect against residual retained spores.

   c. If a person has received 3 doses of anthrax vaccine, then the total duration of antibiotic prophylaxis can be reduced to 30 days.

   d. Priority List:

      1. Exposed individuals
      2. Essential service personnel
      3. General population (if warranted)

   e. Dosage, Route, and Schedule of Administration for Primary Immunization (Reference 12):

DOSE	**ROUTE**	**SCHEDULE**	**MINIMUM INTERVAL**
0.5 mL	**Subcutaneously**	**SIX DOSES** **0, 2, and 4 weeks**; **6, 12,and 18 months**	 **2 weeks** **6 months**

   f. Individuals previously vaccinated with fewer than three doses will receive a single 0.5 mL booster subcutaneously.

   g. Dosage forms:

      1. Injection: 5 mL (10 doses each)

      2. The only human anthrax vaccine in current use in the U.S. is manufactured by BioPort Corporation, 3500 N. Martin Luther King , Jr. Boulevard, Lansing MI 48909.

      3. The anthrax vaccine is a sterile cell free filtrate of cultures from an avirulent nonencapsulated anthrax strain.

h. Contraindications:

1. Hypersensitivity to the vaccine or its components.
2. Previous history of anthrax infection

i. Precautions:

1. Pregnancy: (In the event of known or highly suspected exposure to aerosolized anthrax spores, the benefit of anthrax immunization far outweighs any potential risk to mother and fetus).
2. Moderate or severe acute illness

j. Adverse Reactions:

1. Local pain, pruritis, nodules, or inflammation at the site of injection
2. Malaise, chills, fever, and lassitude
3. Myalgia, nausea, arthralgia, headache
4. Anaphylaxis (rare)

k. Reporting of Adverse Events:

1. Adverse events occurring after administration of anthrax vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS).
2. VAERS forms can be obtained by calling 800-822-7967
3. VAERS information is available at http://www.vaers.org.

Anthrax Vaccine Information Brochure For Health Care Professionals

What is the threat?

Several countries around the world maintain biological weapons. Use of these weapons could cause widespread illness among unprotected groups of people. Anthrax is the biological weapon most likely to be encountered because it is highly lethal, easy to produce in large quantities, relatively easy to develop as a weapon, easily spread over a large area, and easily stored and dangerous for a long time. There is reason to believe that you may have been exposed to anthrax either through a natural exposure, or through an act of biological terrorism or war.

What is anthrax?

Anthrax is a disease normally associated with plant-eating animals such as sheep, goats, cattle, and swine. It is caused by the bacteria *Bacillus anthracis.* Once common where livestock were raised, it is now controlled through animal vaccination programs. Anthrax still occurs in countries where animals are not vaccinated, mainly in Africa and Asia. It does occur infrequently in the United States. Human infection with anthrax usually results from direct contact with infected animals, or animal products such as wool, meat or hides. However, when anthrax is used as a biological weapon, breathing anthrax that is released into the air infects people. Inhalational anthrax is the disease that results from breathing anthrax. Symptoms of inhalation anthrax can begin as early as 24 hours after breathing anthrax spores. Initial symptoms include: fever, cough, and weakness and usually progress to breathing problems, shock, and death.

Why Vaccinate?

Vaccines prevent illness by stimulating the body's natural disease-fighting abilities. They are among the most powerful tools developed by modern medicine for keeping people healthy. Vaccines are routinely used in the United States to protect against diseases such as mumps, measles, whooping cough, and polio.

What is the anthrax vaccine?

Anthrax vaccine is a sterile product made from filtrates of cultures of a strain of the anthrax organism that does not cause disease. The vaccine contains no living or dead anthrax organisms. The anthrax vaccine is not new. Human anthrax vaccines were developed in England and the U.S. in the 1950s and early 1960s. The anthrax vaccine you will receive was licensed by the FDA in 1970 and has been manufactured by the Michigan Biologic Products Institute (MBPI) under Establishment License No. 99. BioPort purchased MBPI in September of 1998 and will continue to manufacture the anthrax vaccine.

It has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers for more than twenty-five years.

Anthrax Vaccine Information Brochure For Health Care Professionals Page 2

Facts about the anthrax vaccine?

- Vaccination is a critical part of protection against infection and disease.
- Manufactured in the United States.
- Safely used for more than 25 years.
- As with other vaccinations, pain may occur at the site of injection.
- Temporary side effects (sore arm, redness, slight swelling, and a small nodule or knot under the skin) may occur.
- No known long term side effects.
- Six shots are required over 18 months, followed by an annual booster for routine prevention.
- In a post-exposure situation, people that have never received an anthrax vaccine will receive a primary series of immunization consisting of three shots given at 0, 2, and 4 weeks administered subcutaneously.
- Individuals previously vaccinated with fewer than three doses will receive a single 0.5 ml booster dose subcutaneously.

Is this an experimental vaccine?

No, anthrax vaccine has been FDA approved since 1970.

Is the vaccine safe?

Yes, this vaccine has been safely and routinely administered in the U.S. to veterinarians, laboratory workers, and livestock handlers since 1970. The manufacturer, the Michigan Biologic Products Institute, has received no reports of serious adverse effects.

Is there anyone who should not receive the vaccine?

Anthrax vaccine should not be administered to anyone who has a known history of allergic reaction to a prior anthrax shot.

What about pregnancy?

There is no scientific evidence to suggest that the vaccine is harmful during pregnancy. The vaccine is usually not administered during pregnancy during routine situations. However, if a pregnant woman is exposed to aerosolized anthrax spores, the benefits of anthrax immunization far outweighs any potential risk.

What other medical conditions could affect the use of this vaccine?

In the event of an exposure to aerosolized anthrax spores, only allergy to the vaccine would be a reason not to receive the protection from the vaccine.

Anthrax Vaccine Information Brochure For Health Care Professionals Page 3

How many shots will be given?

- Six shots are required over 18 months, followed by an annual booster for routine prevention.
- In a post-exposure situation, people that have never received an anthrax vaccine will receive a primary series of immunization consisting of three shots given at 0, 2, and 4 weeks administered subcutaneously.
- Individuals previously vaccinated with fewer than three doses will receive a single 0.5 ml booster dose subcutaneously.

What are the side effects?

As with other vaccinations, pain may occur at the site of injection. Temporary side effects (sore arm, redness, and slight swelling may occur. The vaccine has been in use since 1970 with no known long-term side effects.

THE ORDER TO ADMINISTER VACCINIA VIRUS VACCINE IS VALID WHEN THE DIRECTOR OF HEALTH:

1. Declares that a mass casualty bioterrorism incident involving smallpox has occurred;
2. Has identified the population at risk for exposure to smallpox for vaccination;
3. Has activated the State of Hawaii DOH Emergency Operations Plan and bioterrorism mass prophylaxis and immunization plans;
4. Confirms that a supply of smallpox vaccine is available for civilian use;
5. And issues a signed memorandum ordering smallpox vaccination.

INDICATION

Post-exposure vaccination for individuals exposed to a case of smallpox or aerosolized variola virus following a bio-terrorism event.

PRIORITY LIST

1. Exposed individuals
2. Essential Service Personnel
3. General Population (if warranted)

DOSAGE, ROUTE, AND METHOD OF ADMINISTRATION

1. Vaccination is performed by cutaneous inoculation of vaccinia virus and scarification using the multiple-puncture technique with a bifurcated needle.

2. A sterile bifurcated needle is inserted into an ampoule of reconstituted vaccine and, on withdrawal, a droplet of vaccine sufficient for vaccination containing an infectious dose of about 2×10^5 plaque forming units of vaccine strain vaccinia virus is held by capillarity attraction between the two tines of the needle.

3. The needle is held at right angels to the skin.
4. The wrist of the vaccinator rests against the arm.
5. Fifteen perpendicular strokes of the needle are rapidly made in an area of about 5 mm in diameter that penetrates into the epidermis of the deltoid region of the arm.
6. The strokes should be vigorous enough that a trace of blood appears at the vaccination site after 15 to 30 seconds.
7. After vaccination, excess vaccine should be wiped from the site with sterile gauze. The gauze should then be discarded in a hazardous waste receptacle.
8. The site should be covered with a loose, non-occlusive bandage to deter the individual from touching the site and perhaps transferring virus to other parts of the body. The vaccination site should be covered at all times with a porous bandage until the scab has separated and the underlying skin has healed. An occlusive bandage should not be used. The site should be kept dry. When the client bathes, the site should be covered with an impermeable bandage.
9. Two to five days after primary vaccination, a papule forms and then becomes a vesicle two to three days later. The vesicle reaches a maximum size by day 8 to 10. A scab forms within two weeks leaving behind a scar when healing is complete. Mild fever and localized (regional) swollen lymph glands are often present during the first two weeks after vaccination.

Precautions

1. Before administering the vaccine, a careful history should be performed to document the absence of contraindications to vaccination among both clients and their household contacts.
2. Eczema, a history of eczema, or immunodeficiency are contraindications to smallpox vaccination.
3. Vaccinia vaccine should not be administered if the above conditions are present among clients or their household contacts.

Contraindications

1. Hypersensitivity to the vaccine or its components including persons allergic to polymyxin B sulfate, streptomycin sulfate, chlortetracycline hydrochloride, or neomycin sulfate.
2. Immunodeficiency including HIV infection, and transplant recipients.
3. A history or presence of eczema, or presence of active skin conditions such as burns, atopic dermatitis, impetigo, or varicella zoster.
4. Pregnancy.

Complications of Vaccination:

1. Postvaccinial encephalitis.
2. Vaccinia necrosum (progressive vaccinia).
3. Eczema vaccinatum.
4. Generalized vaccinia.
5. Accidental inoculation of vaccine to other sites or unvaccinated contacts.
6. Bullous erythema multiforme and uriticarial and erythematous eruptions.

Treatment of Vaccine Complications

1. Vaccinia Immune Globulin (VIG): 0.6 mL/kg IM
2. The standard VIG dose may be large (a total dose of about 40 mL in 70 kg adults). Therefore, the dose may need to be divided and given over a 24 to 36 hour period. Doses may be repeated, usually at intervals of 2-3 days, until recovery begins. VIG is effective in reducing the morbidity and mortality from vaccinia necrosum, eczema vaccinatum, severe cases of generalized vaccinia, and possibly ocular inoculation. It is of no benefit for the treatment of postvaccinial encephalitis.

VIG and Vaccinia Virus Vaccine are only available through the CDC (404-639-3670).

Vaccinia (Smallpox) Vaccine
What You Need To Know

WHAT IS SMALLPOX?

Smallpox is a serious highly infectious disease that affects humans. A virus called variola causes smallpox. This disease was eradicated from the world through a worldwide vaccination program. There has been no natural case of smallpox reported on earth since 1977.

Smallpox is initially characterized by the sudden onset of chills, high fever, headache, backache, and muscle aches with the subsequent development of a widespread skin rash. The rash consists of pimples that eventually blister, produce pus, and form pockmarks.

Smallpox is spread from person to person. The attack rate (spread) among contacts of smallpox is about 50%. Today, the only way a person could "catch" smallpox is by accidental exposure with the virus in a smallpox research laboratory; intentional release of an aerosol containing the smallpox virus as a result of a bio-terrorism event; or from contact with a person that developed smallpox following such an exposure.

If the smallpox virus is used in a bio-terrorism incident, the virus would most likely be disseminated in an aerosol cloud, and exposed individuals would breathe the virus into their lungs, and be spread throughout the body eventually producing smallpox disease. Secondary cases would arise in the community from person to person spread of the virus. Smallpox is deadly, and up to 40 % of smallpox cases will die. There is no known treatment for smallpox.

WHAT IS THE VACCINIA (SMALLPOX) VACCINE?

Vaccinia vaccine, previously known as smallpox vaccine, is highly effective in producing immunity (protection) to smallpox. Because of the low risk of contracting smallpox, the routine use of vaccinia vaccine in the United States was discontinued after 1971.

The vaccinia vaccine protection against smallpox lasts about 10 years. The opinion of public health experts is that almost all of the United States population is now susceptible to the smallpox virus.

The vaccinia vaccine licensed in the United States contains live vaccinia virus, derived from the New York City Board of Health strain of vaccinia. Vaccine is administered using the multiple puncture technique with a bifurcated needle. It produces a usually harmless vaccinia virus infection in the vaccine recipient that also leads to greater than 95% protection against the deadly smallpox virus.

YOU ARE BEING OFFERED IMMUNIZATION WITH VACCINIA VIRUS BECAUSE THERE IS EITHER CONFIRMATION OR STRONG EVIDENCE THAT YOU HAVE BEEN EXPOSED TO SMALLPOX!

WHO SHOULD RECEIVE VACCINIA VIRUS?

The United States Public Health Service recommends vaccinia vaccine for the following persons:

1. Laboratory workers who directly handle animals, or microbial cultures contaminated or infected with vaccinia virus, or other smallpox-related viruses;

2. Individuals exposed to aerosols containing variola virus (smallpox) virus, or exposed to cases of smallpox as the result of a bioterrorism incident.

WHAT ARE THE BENEFITS OF VACCINIA VACCINATION?

The vaccine will be highly successful in preventing smallpox infection in people exposed to the smallpox virus, and in stopping a community wide smallpox outbreak.

WHAT ARE THE RISKS OF VACCINATION?

Successful vaccination, particularly in persons receiving their first dose of vaccine, is associated with tenderness, redness, swelling, and a lesion at the vaccination site, and may cause fever for a few days. The lymph nodes in the armpit of the vaccinated arm may become enlarged and tender. These symptoms are more common in persons receiving their first dose of vaccine than in persons being revaccinated.

The overall risks of serious complications of smallpox vaccination are low, and occur more frequently in persons receiving their first dose of vaccine, and among young children. The most frequent serious complications of vaccination are encephalitis (brain inflammation), vaccinia necrosum (progressive destruction of skin and other tissues at the vaccination site), and eczema vaccinatum (severe and destructive infection of skin affected by eczema or other chronic skin disorder caused by spread of vaccinia virus).

Among persons receiving their first dose of vaccine, the following serious complications have been observed:

1. encephalitis - about one in 300,000 doses.

2. vaccinia necrosum - this complication has been limited to recipients who have abnormalities of their immune system, for whom the vaccine is contraindicated.

3. eczema vaccinatum - this complication has been limited to recipients who have eczema or other chronic skin conditions, for whom the vaccine is contraindicated.

Among persons being revaccinated, the following serious complications have been observed:

1. encephalitis - about one in 200,000 doses.

2. vaccinia necrosum - this complication has been limited to recipients who have abnormalities of their immune system, for whom the vaccine is contraindicated.

3. eczema vaccinatum - this complication has been limited to recipients who have eczema or other chronic skin conditions, for whom the vaccine is contraindicated.

Other less serious complications include:

1. Generalized vaccinia -vaccination lesions developing away from the vaccination site. This occurs in one in 5,000 primary vaccinations and one in 110,000 revaccinations.

2. Accidental transfer of vaccinia from the vaccination site to other parts of the body. This occurs in one in 1,700 primary vaccinations and one in 40,000 revaccinations.

Generalized vaccinia in persons without underlying illness (such as immune deficiency) is generally self limited and requires little or no therapy. Accidental transfer of vaccinia from the vaccination to other parts of the body can be prevented by handwashing after touching the vaccination site.

On rare occasions, almost always after primary vaccination, vaccinia virus has been reported to cause fetal infection after vaccination of a pregnant woman. Fewer than 50 instances of fetal vaccinia are known, but cases have been observed as recently as 1978. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Vaccinia vaccine is not known to cause congenital malformations.

Because the vaccinia virus is present at the vaccination site, other persons can become infected if they come in direct contact with the vaccinee's lesions. Vaccinees can also transfer virus from the vaccination site to another person by touching the lesion and then touching the other person. The exact risk of infection by such routes of transmission is unknown; however, virus can be cultured from the vaccination site until the skin heals. Most instances of contact transmission of vaccinia do not lead to serious illness in the contact. However, about 30% of contact transmission results in eczema vaccinatum.

WHO SHOULD NOT BE VACCINATED?

1. Persons who have **ever** been diagnosed as having **eczema**, even if the condition is mild or is not presently active.

2. Persons whose **household contacts** have **eczema**, or a **history of eczema**.

3. Persons with diseases or conditions which cause **immunodeficiency**, such as **HIV infection**, leukemia, lymphoma, generalized malignancy, agammaglobulinemia, or therapy with alkylating agents, antimetabolites, radiation, or large doses of corticosteroids.

4. Persons whose **household contacts** have an immunodeficiency disease or therapy listed above.

5. Persons with other acute or chronic skin conditions, such as **atopic dermatitis**, **burns, impetigo, or varicella zoster (shingles)** should not be vaccinated until the condition resolves.

6. Women who are **pregnant**, or who are **planning to become pregnant** within a month following vaccination.

7. Persons with serious, life-threatening allergies to the antibiotics **polymyxin B**, s**treptomycin**, **tetracycline**, or **neomycin**.

WHAT TO LOOK FOR AND DO AFTER THE VACCINATION ?

1. Three to five days following primary vaccination, a small bump develops at the site of vaccination. The bump becomes a blister, which then becomes pus-filled, and reaches its maximum size by 8-10 days. The pus-filled blister dries and forms a scab, which separates by 14-21 days after vaccination, leaving a distinct scar. Vaccinia virus is shed from the site from 4 days following vaccination until the scab separates from the skin. Persons being revaccinated may not develop a blister, and the progression of the lesion at the site of vaccination may be shorter.

2. The objectives in caring for a smallpox vaccination site are to avoid spread of virus from the vaccination site to another area of the body (such as the eyes), to avoid spread to another person, and to keep the area clean and dry.

3. Keep the site covered with a bandage, at all times until the scab has fallen off and the underlying skin is healed. An occlusive (air-tight) bandage should **not** be used.

4. Keep the site dry. When showering, cover the site with plastic and rubber bands or tape the plastic down with adhesive tape to prevent wetting. Do not direct shower water to the vaccinated area. After drying off, replace the plastic cover with a simple bandage.

5. After changing the bandage, or any time the vaccination site is touched, wash your hands thoroughly with soap and water. **This is the most important measure to prevent transmission of vaccinia to another person, or to another part of the body.**

6. Avoid contact with anyone at risk of complications of smallpox vaccination listed above until the scab has fallen off.

WHERE CAN I GET MORE INFORMATION ABOUT VACCINIA VACCINE?

If you have questions about vaccinia vaccination, you should ask your doctor, or the person responsible for vaccination at your health care facility. In December 1991, the United States Public Health Service published its recommendations for the use of vaccinia vaccine in *the Recommendations and Reports* series *of Morbidity and Mortality Weekly Report*. A copy of these recommendations may be obtained by writing to Information Services, National Center for Prevention Services, Mailstop E-06, Centers for Disease Control, Atlanta, Georgia 30333, or by calling (404) 639-1819.

VACCINIA IMMUNIZATION FORM

Form to Consent to Receive Vaccinia Immunization

I have been informed that due to my exposure history, activities or occupation, I am at risk of contracting smallpox. Having been provided information about being immunized against vaccinia and the opportunity to discuss the vaccinia immunization with the public health nurse or physician, I hereby request that I receive vaccinia immunization.

I have thoroughly read the attached materials about vaccinia and the smallpox vaccine, and I understand the contents of these materials. I am satisfied and have no further questions.

I understand that vaccinia immunization: (1**) may** protect me against smallpox only, **not** against other diseases; (2) **does not guarantee** protection against smallpox; (3) may possibly have as-yet undiscovered reactions or long-term effects, some of which could be serious and even life-threatening; (4) may have some as-yet **unknown** or **unproven association** with another disease, or deficiency; (5) may cause side effects including, but not limited to, those described in the attached materials.

I understand that if I request vaccinia immunization, and I am medically eligible to receive it, it will be provided without any cost to me. By signing below, I hereby indicate my desire to be immunized. If I experience complications or side effects, I understand that I should report them immediately to my personal physician or to the Public Health Nursing Branch at 808-_____.

I understand that copies of this form may be kept on file in the Public Health Nursing Branch.

No one has forced me to be immunized or to sign this consent against my will. I do so voluntarily and with full knowledge of its content and meaning. I understand that I may change my mind at any time prior to or during the immunization by signing a Form to Decline Vaccinia Immunization.

Signature:_____ I.D.#:_____

Printed Name:_____

Witness to
Signature:_____Date:_____

VACCINIA (SMALLPOX) IMMUNIZATION FORM

Form to Decline Vaccinia Immunization

I have been informed that I have either been exposed to air-borne variola (smallpox) virus particles, or to an active case of smallpox disease as the result of a bioterrorism event. Having been provided information about being immunized against smallpox and the opportunity to discuss vaccinia immunization with a public health nurse or physician, I choose not to receive vaccinia immunization at this time. The reason I choose not to receive vaccinia immunization is

_____.

I understand that if I request vaccinia immunization, and I am medically eligible to receive it, it will be provided without cost to me. I have read thoroughly the attached materials about the smallpox vaccine and I understand the contents of these materials. I have no further questions.

By signing below, I am confirming either: (a) my desire not to receive vaccinia immunization, or (b) my understanding that based on my medical condition, I am not eligible to receive vaccinia immunization. By signing below, I am also acknowledging that I understand that because I have chosen not to receive immunization or that I have a medical condition that makes me ineligible for immunization, I am at higher risk of contracting smallpox if I am exposed to it. Accordingly, I hereby release The State of Hawaii Department of Health, its officers, employees, and agents, including any physicians or other health care providers, from any liability related to any subsequent exposure I have to the smallpox virus.

I acknowledge that I am signing this Form to Decline Vaccinia Immunization voluntarily and with full knowledge of its contents and meaning. I understand that if I change my mind at any time and decide to receive immunization, and I am medically eligible to receive it, it will be provided at no cost to me.

Signature:_____ I.D.#:_____

Printed Name:_____

Witness to
Signature:_____Date:_____

State of Hawaii Department of Health	Communicable Disease Division Page 1 of 2	
Approved By: Donald C. Fancher, M.D.		Effective Date: November 1, 2001
Subject: **Brucellosis Prophylaxis Protocol**		Review Date: November 30, 2002

INDICATIONS

1. The person has had a confirmed or highly suspected exposure to *Brucella* species following a BT incident as determined by the Director of Health;

2. The Director of Health has activated the DOH Emergency Operations Plan for mass antibiotic prophylaxis; and

3. Issues a signed memorandum ordering brucellosis antibiotic prophylaxis.

MANAGEMENT OF EXPOSED PEOPLE

6. All exposed people should be identified, and interviewed to detect any additional cases.

7. People having symptoms attributable to brucellosis should be sent to Triage and Referral Centers for further diagnosis and treatment.

8. People eligible for antibiotic prophylaxis should sign an informed consent form, or declination form, and receive a patient information sheet about the preventive antibiotics prior to administration.

9. **Antibiotics**

   a. Prophylaxis for asymptomatic adult patients with confirmed or suspected exposure to *Brucella* species can be achieved by administering a combination of **doxycycline plus rifampin** for three week to six weeks.

   b. For pregnant women, and children < 9 years of age **trimethoprim-sulfamethoxazole plus rifampin** for at least three to six weeks is recommended. Refer to section 4-d for antibiotic choices, doses, and schedule.

   c. Exposed persons will be provided with a one-week supply of antibiotics, and instructed to return in one week to receive additional antibiotic supplies. Antibiotics will be dispensed in one-week increments until it is certain that enough antibiotics are available to treat all exposed individuals. Each week the person will be monitored for the presence of symptoms, adverse reactions to the antibiotic, and any needed modifications made in the antibiotic choice, dose, or schedule.

d. Management of cases/contacts/exposed individuals (reference #7)

PATIENT CATEGORY	**PROPHYLAXIS†**
Adult	Option 1: **Doxycycline** 100 mg orally bid and **rifampin** 600 orally daily for three to six weeks; Or Option 2: **Ofloxacin** 400mg plus **rifampin** 600mg daily for three to six weeks.
Children§	For children > 9 years of age **use adult regimen**. For children < 9 years of age, **trimethoprim-sulfamethoxazole** 5mg / 25 mg /kg every 12 hours daily plus **rifampin** 10 mg/kg (maximum 300 mg every 12 hours) for at least 3 weeks to 6 weeks.
Pregnant women	**Trimethoprim-sulfamethoxazole** 5mg / 25 mg plus **rifampin** 600 mg every 12 hours for at least three to six weeks.
Immuno-suppressed	Same as for normal adults

§Doxycycline could be used in children younger than 9 years of age during a bioterrorism attack if antibiotic susceptibility testing, exhaustion of drug supplies, or allergic/adverse reaction preclude the use of alternative agents. For children < 45 kg, use 2.5 mg /kg doxycycline every 12 hours. For children heavier than 45 kg use an adult dose. Pediatric use of tetracyclines and flouroquinolones is associated with adverse effects that must be weighed against the risk of developing a lethal disease.

† All regimens are administered orally. Reference #7.

INDICATIONS

1. The person has had a confirmed or highly suspected exposure to *Yersinia pestis* following a BT incident as determined by the Director of Health;

2. The Director of Health has activated the DOH Emergency Operations Plan for mass antibiotic prophylaxis; and

3. Issues a signed memorandum ordering plague antibiotic prophylaxis.

MANAGEMENT OF EXPOSED PEOPLE

1. All exposed people, or contacts of a case of plague should be identified, and interviewed to detect any additional cases.

2. People having symptoms should be sent to Triage and Referral Centers for further diagnosis and treatment.

3. All contacts of plague patients should be instructed to have their temperature taken twice daily and to report fever or other symptoms. Surveillance may terminate seven days after the last contact with the patient.

4. People eligible for antibiotic prophylaxis should sign an informed consent form or declination form, and receive a patient information sheet about the preventive antibiotics prior to administration.

5. <u>Antibiotics</u>

   a. The choice of antibiotic for prophylaxis or for use in face-to-face contacts of patients with pneumonic plague, or after a suspected or confirmed plague bioterrorism attack, is **doxycycline** 100 mg orally twice daily, for 7 days, or for the duration of risk exposure, whichever is longer.

   b. **Ciprofloxacin** 500 mg orally twice daily, for 7 days, or for the duration of the exposure, whichever is longer is an acceptable alternative agent for prophylaxis.

c. Post-exposure prophylaxis for plague: (Reference #9)

Patient Category	Post-Exposure Prophylaxis
Adult	**Doxycycline** 100 mg orally twice daily for 7 days, or **Ciprofloxacin** 500 mg orally twice daily for 7 days.
Children§	**Doxycycline** §, or **Ciprofloxacin** 10-15 mg/kg every 12 hours not to exceed 1 gram per day. Prophylaxis duration is 7 days
Pregnant women†	**Doxycycline** 100 mg orally twice daily for 7 days, or **Ciprofloxacin†** 500 mg orally twice daily for 7 days.
Immuno-suppressed	Same as for normal adults

§ Doxycyline could be used in children during a bioterrorism attack of plague. For children < 45 kg use 2.2 mg/kg orally twice daily with a maximum dose of 200mg/day. For children > 45 kg give adult dose. Pediatric use of tetracyclines and fluoroquinolones may be associated with adverse effects that must be weighed against the risk of developing a lethal disease.

† Ciprofloxacin may be used in pregnant women and children during or following a bioterrorism attack due to plague when in the judgement of the attending physician the risk of acquiring or dying from plague is greater than the unknown consequences of the use of ciprofloxacin.

Reference #9.

INDICATIONS

1. The person has had a confirmed or highly suspected exposure to *Francisella tularensis* following a BT incident as determined by the Director of Health;

2. The Director of Health has activated the DOH Emergency Operations Plan for mass antibiotic prophylaxis; and

3. Issues a signed memorandum ordering tularemia antibiotic prophylaxis.

MANAGEMENT OF EXPOSED PEOPLE

1. All exposed people should be identified, and interviewed to detect any additional cases.

2. People having symptoms attributable to tularemia should be sent to Triage and Referral Centers for further diagnosis and treatment.

3. People eligible for antibiotic prophylaxis should sign an informed consent form, and receive a patient information sheet about the preventive antibiotics prior to administration.

4. <u>Antibiotics</u>

a. Prophylaxis for asymptomatic patients with suspected exposure to aerosolized *F. tularensis* can be achieved with a 14 day course of doxycycline 100 mg orally twice daily.

b. Post-exposure prophylaxis for tularemia (reference #7):

PATIENT CATEGORY	**PROPHYLAXIS**
Adult	Doxycyline 100 mg orally twice daily for 14 days, or Tetracycline 500 mg orally qid for 14 days.
Pediatric§	Doxycycline § Ciprofloxacin† 10-15 mg/kg orally every 12 hours not to exceed 1 gram per day.
Pregnancy†	Ciprofloxacin† 500 mg orally twice daily for 14 days.
Immunosuppressed	Same as above
§ The use of doxycycline in pediatric patients < 7 years of age may be associated with adverse effects. In a bioterrorism incident the use of doxycycline to prevent a potentially lethal disease must be weighed against the potential side effects of the antibiotic. For children < 45 kg use 2.2 mg/kg orally twice daily with a maximum dose of 200mg/day. For children > 45 kg give the adult dose.	
† Use of ciprofloxacin is based on successful use in treating 6 cases in adults. The use of ciprofloxacin in pregnancy or pediatrics is not usually recommended, and the potential benefit in preventing a potentially lethal disease must be weighed against the unknown risk in pregnancy or the pediatric age group. Tetracyclines are contraindicated in pregnancy.	

Reference #7.

A. Indications

1. Post-exposure antibiotic mass prophylaxis antibiotic of choice for individuals exposed to aerosolized *B. anthracis* spores following a bioterrorism incident;
2. Alternative post-exposure antibiotic mass prophylaxis antibiotic of choice for individuals exposed to aerosolized *Brucella species* (brucellosis), *Yersinia pestis* (plague), and *Francisella tularensis* (tularemia).

B. Dosage, Route, and Schedule of Administration of Ciprofloxacin

Adults: Ciprofloxacin 500 mg by mouth every 12 hours.

Children: Ciprofloxacin 20-30 mg/kg per day by mouth divided into two daily doses not to exceed 1 gram per day.

Pregnant Women: Ciprofloxacin 500 mg by mouth every 12 hours.

C. Duration of Ciprofloxacin Prophylaxis

DISEASE	DURATION
Anthrax with < 3 doses of Anthrax vaccination	60 days
Anthrax with at least 3 doses of Anthrax vaccination	30 days
Brucellosis	3 weeks to 6 weeks
Plague	7 days
Tularemia	14 days

D. Contraindication

Hypersensitivity to ciprofloxacin or other quinolones.

E. Precautions

1. Usually not recommended in **children < 18 years of age**, but can be administered in the face of a life-threatening exposure to a potentially fatal biological pathogen or disease.

2. Children and adults with **chronic renal disease**, **psychiatric disorders** on psychotropic drugs, or **patients taking theophylline** preparations should be referred to a physician if at all possible for further management in treatment prior to starting ciprofloxacin prophylaxis.

3. Use with caution in known or suspected **central nervous system disorders** (e.g. **seizure disorders)**

4. Prolonged use may result in **superinfections**.

5. Discontinue use immediately with signs of **tendon inflammation or tendon pain**.

6. Patients taking **theophylline preparations** concurrently with ciprofloxacin must either reduce the dose of theophylline or have serum levels of theophylline monitored. In this case, consult with the person's private physician before administering ciprofloxacin.

7. **Chronic Renal Failure**: Consult with the person's physician. Dosage needs to be reduced depending upon the degree of renal failure.

8. Avoid drinking or eating **caffeine**-containing products while taking ciprofloxacin.

9. Use cautiously with **clozapine** and other **psychotropic drugs**; monitor closely for adverse effects.

10. **Age >65 years**: Geriatric patients may have reduced renal function. Therefore, reduce the ciprofloxacin dose to 500 mg every 24 hours.

F. Adverse Reactions

1. One percent to ten percent of patients will experience headache, restlessness, nausea, diarrhea, vomiting, abdominal pain, or rash.

2. Less than 1% of patients will experience dizziness, confusion, seizures, anemia, increased liver enzymes, tremor, arthralgia, ruptured tendons, or acute renal failure.

G. Drug Interactions

1. Enteral feedings may decrease ciprofloxacin plasma concentrations. Ciprofloxacin should not be administered with enteral feedings. The feedings need to be discontinued for two hours prior to, and after, ciprofloxacin administration.

2. Aluminum/magnesium products, didanosine, and sucralfate may decrease absorption of ciprofloxacin if administered concurrently. Administer ciprofloxacin two hours before, or 4 hours after, the dose of these agents. Withhold antacids for two hours after giving ciprofloxacin.

3. Calcium, iron, zinc, and multivitamins with minerals may decrease absorption of ciprofloxacin significantly if administered concurrently. Administer ciprofloxacin two hours before, or at least two hours after the dose of these agents.

4. Caffeine and theophylline can increase central nervous system stimulation when administered concurrently with ciprofloxacin.

5. Cyclosporine may increase serum creatinine levels when administered concurrently with ciprofloxacin. Cyclosporine serum levels need to be monitored when the patient is taking ciprofloxacin. Consult with the patient's personal physician.

J. Dosage Adjustment in Renal Impairment

For people with chronic renal failure, the dose of ciprofloxacin must be reduced to 500 mg every 24 hours, or as prescribed by the patient's personal physician.

K. Dosage Forms For Use in Mass Prophylaxis

Suspension, oral, as hydrochloride: 250 mg/5mL (100 mL); 500 mg/5mL (100 mL)
Tablet, as hydrochloride: 100 mg, 250 mg, 500 mg, 750 mg.

State of Hawaii Department of Health	Emergency Medical Services System Page 1 of 3	
Approved By: Donald C. Fancher, M.D.		Effective Date: November 1, 2001
Subject: **Antibiotic Information For Practitioners:** **DOXYCYCLINE**		Review Date: November 30, 2002

A. Indications

1. Post-exposure antibiotic mass prophylaxis agent of choice for individuals exposed to aerosolized *Brucella* species (brucellosis), *Yersinia pestis* (plague), and *Francisella tularensis* (tularemia).

2. Alternate post-exposure antibiotic mass prophylaxis agent of choice for individuals exposed to aerosolized *B. anthracis* spores following a bioterrorism incident.

B. Dosage, Route, and Schedule of Administration of Doxycycline

PATIENT CATEGORY	PROPHYLAXIS
Adults	Doxycycline 100 mg by mouth every 12 hours
Children ≥ 8 years of age	Doxycycline 100 mg by mouth every 12 hours
Children ≤ 8 years of age	Ordinarily contraindicated*
Pregnant women	Ordinarily contraindicated†

* Doxycycline can be used in children < 8 years of age for treatment or prophylaxis during a bioterrorism attack. Pediatric use of tetracyclines may be associated with adverse effects that must be weighed against the risk of developing a lethal disease if alternative antibiotics are not available. If doxycycline is determined to be necessary, the dose in children < 8 years of age is 2.5 mg/kg by mouth every 12 hours, not to exceed 100 mg every 12 hours.

† Doxycycline can be used in pregnant women during a bioterrorism attack if it is determined that the risk of dying from a potentially lethal disease outweighs the risk of adverse reactions to the pregnant woman or the fetus if alternative agents are not available. If doxycycline is determined to be necessary, the dose is 100 mg every 12 hours by mouth.

C. Duration of Doxycycline Prophylaxis

Disease	Duration
Anthrax with < 3 doses of Anthrax vaccination	60 days
Anthrax with at least 3 doses of Anthrax vaccination	30 days
Brucellosis	3 weeks to 6 weeks
Plague	7 days
Tularemia	14 days

D. Contraindication

1. Hypersensitivity to doxycycline, tetracycline, or any component.
2. Children < 8 years of age unless determined to be necessary during a bioterrorism attack.
3. Severe hepatic dysfunction.

E. Precautions

1. Tetracyclines use during tooth development may cause permanent discoloration of the teeth and enamel hypoplasia.
2. Prolonged use may result in superinfection.
3. Photosensitivity reactions may occur with this drug so avoid prolonged exposure to sunlight or tanning equipment.

F. Adverse Reactions

1. Discoloration of teeth in children < 8 years of age.
2. Esophagitis in less than ten percent of people..
3. Increased intracranial pressure, bulging fontanels in infants, rash, photosensitivity, nausea, diarrhea, neutropenia, eosinophilia, hepatotoxicity, or phlebitis in < 1% of patients.

G. Drug Interactions

1. Decreased effect with antacids containing aluminum, calcium, or magnesium.
2. Iron and bismuth subsalicylcate may decrease doxycycline bioavailability.
3. Barbiturates, phenytoin, and carbamazepine decrease doxycycline's half-life.
4. There is an increased effect of warfarin with doxycycline use.
5. Absorption from the gastrointestinal tract can be reduced by food or milk by 20%.

H. Dosage Adjustment in Renal Impairment

For people with chronic renal failure and a creatinine clearance of < 10 mL/min, the dose of doxycycline is 100 mg every 24 hours.

I. Dosage Forms (Oral):

1. Capsule, as hyclate:
    a. Doxychel®, Vibramycin®: 50 mg
    b. Doxy®, Doxychel®, Vibramycin®: 100 mg
    c. Periostat™: 20 mg

2. Capsule, as monohydrate (Mododox®): 50 mg, 100 mg

3. Capsule, coaged pellets, as hyclate (Doryx®): 100 mg

4. Powder for oral suspension, as monohydrate (raspberry flavor) (Vibramycin®): 25 mg/5mL (60 ML)

5. Syrup, as calcium (raspberry-aplle flavor) (Vibramycin®): 50 mg/mL (30 mL, 473 mL)

6. Tablet, as hyclate:
    a. Doxychel®: 50 mg
    b. Bio-Tab®, Doxychel®, Vibra-Tabs®: 100 mg

A. Indications

Amoxicillin is an alternate post-exposure antibiotic mass prophylaxis antibiotic of choice for individuals exposed to *confirmed* penicillin susceptible aerosolized *B. anthracis* spores following a bioterrorism incident.

B. Dosage, Route, and Schedule of Administration

PATIENT CATEGORY	PROPHYLAXIS
Adults	Amoxicillin 500 mg by mouth every 8 hours.
Children $\geq$ 20 kg.	Amoxicillin 500 mg by mouth every 8 hours.
Children < 20 kg.	Amoxicillin 25 mg/kg by mouth every 8 hours.
Pregnant Women	Amoxicillin 500 mg by mouth every 8 hours.

C. Duration of Amoxicillin Prophylaxis

DISEASE	DURATION
Anthrax with < 3 doses of Anthrax vaccination	60 days
Anthrax with at least 3 doses of Anthrax vaccination	30 days

D. Contraindication

Hypersensitivity to amoxicillin, penicillin, or the penicillin class of antibiotics.

E. Precautions

1. A low incidence of cross-allergy exists with other beta-lactam antibiotics and cephalosporins.
2. A high percentage of patients with infectious mononucleosis have developed rash during therapy with amoxicillin.

F. Adverse Reactions

1. Fever, urticaria, rash, and allergic reactions occur in 1% to 10% of patients.

2. Seizures, anxiety, confusion, hallucinations, depression, nausea, vomiting, leukopenia, neutropenia, thrombocytopenia, jaundice, and/or interstitial nephritis occur in < 1% of patients.

G. Drug Interactions

1. Efficacy of oral contraceptives may be reduced.
2. Disulfiram, or probenecid may increase amoxicillin levels.
3. Allopurinol theoretically has an additive potential for causing an amoxicillin rash.

H. Stability

Oral suspension remains stable for 7 days at room temperature or 14 days if refrigerated. Unit dose antibiotic oral syringes are stable for 48 hours.

I. Dosing Interval in Renal Impairment

1. For patients having chronic renal failure with creatinine clearance between 10-50 mL/minute, lengthen the dosing interval of the standard amoxicillin dose to every 12 hours.

2. For patients having chronic renal failure with creatinine clearance < 10 mL/minute, lengthen the dosing interval of the standard amoxicillin dose to every 24 hours.

J. Dosage Forms

1. Capsule, as trihydrate: 250 mg, 500 mg.

2. Powder for oral suspension, as trihydrate: 125 mg/5mL (5 mL, 80 mL, 100 mL, 150 mL, 200 mL); 250 mg/5mL (5 mL, 80 mL, 100 mL, 150 mL, 200 mL).

3. Powder for oral suspension, drops, as trihydratae: 50 mg/mL (15 mL, 30 mL).

4. Tablet, chewable, as trihydrate: 125 mg, 250 mg.

5. Tablet, film coated: 500 mg, 875 mg.

A. Indications

The combination of **trimethoprim-sulfamethoxazole** and **rifampin** is the post-exposure antibiotic mass prophylaxis of choice for children < 9 years of age as well as pregnant women exposed to aerosolized *Brucella* species (brucellosis).

B. Dosage, Route, and Schedule for Brucellosis Prophylaxis

Patient Category	Trimethoprim-Sulfamethoxazole Dosage	Duration
Adults	One double-strength tablet P.O. every 12 hours.	3 weeks to 6 weeks.
Children > 2 months of age	5 mg (trimethoprim component)/kg P.O. every 12 hours. Do not exceed adult dose.	Same as above.
Pregnant Women	Same as adult dose.	Same as above.

C. Contraindications

1. Hypersensitivity to any sulfa drug.
2. Porphyria.
3. Megaloblastic anemia due to folate deficiency.
4. Infants <2 months of age.
5. Marked hepatic damage.

D. Precautions

1. Do not use near the end of pregnancy (at term) to avoid kernicterus in the newborn.
2. Use during pregnancy only if risks outweigh the benefits. Folic acid metabolism may be inhibited.
3. Use with caution in patients with G-6-PD deficiency, impaired renal function, or hepatic function.
4. Maintain adequate hydration to prevent crystalluria.
5. Adjust dosage in patients with renal impairment.
6. Discontinue use at first sign of rash.
7. Elderly patients appear at greater risk for more severe adverse reactions.

E. Adverse Reactions

1. Allergic skin reactions including rashes and urticaria, photosensitivity, nausea, vomiting, and anorexia occur in >10% of patients.

2. Stevens-Johnson syndrome, toxic epidermal necrolysis (rare), agranulocytosis, aplastic anemia, and hepatitis occur in less than 10% of patients.

3. Confusion, depression, hallucinations, seizures, fever, ataxia, kernicterus in neonates, erythema multiforme, stomatitis, diarrhea, pseudomembranous colitis, pancytopenia, pancreatitis, rhabdomyolysis, thrombocytopenia, megaloblastic anemia, granulocytopenia, aplastic anemia, hemolysis (with G-6-PD deficiency), cholestatic jaundice, interstitial nephritis, and serum sickness have been reported in <1% of patients.

F. Drug Interactions

1. Trimethoprim-sulfamethoxazole decrease the effect of cyclosporines.

2. Phenytoin, cyclosporines, methotrexate, dapsone, sulfonylureas, digoxin, and oral anticoagulants may have increased effects or toxicity.

G. Dosing Adjustment in Renal Failure

1. Creatinine clearance 15-30 mL/minute: Administer 1 double strength tablet every 24 hours or 1 single strength tablet every 12 hours.

2. Creatinine clearance <15 mL/minute: Not recommended.

H. Dietary Considerations

1. Take with a glass of water on an empty stomach.

2. Maintain adequate fluid intake to prevent crystalluria.

I. Dosage Forms

1. The 5:1 ratio of sulfamethoxazole to trimethoprim remains constant in all dosage forms.

2. Suspension, oral: sulfamethoxazole 200 mg and trimethoprim 40 mg per 5 mL (20 mL, 100 mL, 150 mL, 200 mL, 480 mL).

3. Tablet: sulfamethoxazole 400 mg and trimethoprim 80 mg .

4. Tablet, double strength: sulfamethoxazole 800 mg and trimethoprim 160 mg.

State of Hawaii Department of Health	Emergency Medical Services System Page 1 of 2	
Approved By: Donald C. Fancher, M.D.		Effective Date: November 1, 2001
Subject: **Antibiotic Information For Practitioners:** **RIFAMPIN**		Review Date: November 30, 2002

A. Indications

The combination of **trimethoprim-sulfamethoxazole** and **rifampin** is the post-exposure antibiotic mass prophylaxis of choice for children < 9 years of age as well as pregnant women exposed to aerosolized *Brucella* species (brucellosis).

B: Dosage, Route, and Schedule for Brucellosis Prophylaxis

PATIENT CATEGORY	DOSAGE	DURATION
Adults:	Rifampin 300 mg by mouth every 12 hours	3 weeks to 6 weeks
Infants ≤ 1 month old:	Rifampin 5 mg/kg by mouth every 12 hours (maximum 600 mg per day)	Same as above
Infants and children > 1 month of age:	Rifampin 5 mg/kg by mouth every 12 hours (maximum 600 mg per day)	Same as above
Pregnant Women:	Rifampin 300 mg by mouth every 12 hours	Same as above

.

C. Contraindications

History of hypersensitivity to rifampin or any rifamycins.

D. Precautions

1. Use with caution and modify dosage in patients with liver impairment; observe for hyperbilirubinemia; discontinue therapy if clinical symptoms or any signs of significant hepatocellular damage develop.
2. Porphyria exacerbation is possible; use with caution in patients with porphyria.
3. Monitor for compliance and effects including hypersensitivity, and thrombocytopenia.
4. Urine, feces, saliva, sweat, and tears may be discolored to red/orange.
5. Remove soft contact lenses during therapy since permanent staining may occur.
6. Rifampin 600 mg once or twice weekly have been associated with a high incidence of adverse reactions including a flu-like syndrome.
7. Rifampin is best taken on an empty stomach since food decreases the extent of absorption.
8. In patients having hepatic impairment, dose reductions may be necessary to reduce
hepatotoxicity.

E. Adverse Reactions

1. Increased hepatocellular enzymes (liver function tests) occur in as many as 14% of patients.

2. Rash, epigastric distress, anorexia, nausea, vomiting, diarrhea, cramps, pseudomembranous colitis, or pancreatitis occurs in 1% to 10% of patients.

3. Other symptoms occur rarely and include flushing, edema headache, drowsiness, dizziness, confusion, numbness, behavioral changes, pruritus, urticaria, pemphigoid reaction, eosinophilia, leukopenia, hemolysis, hemolytic anemia, thrombocytopenia (especially with high-dose therapy), hepatitis, ataxia, myalgia, weakness, osteomalacia, visual changes, and exudative conjunctivitis.

F. Drug Interactions

1. Rifampin induces liver enzymes which may decrease the plasma concentration of verapamil, diltiazem, nifedipine, methadone, digitalis, cyclosporine, corticosteroids, oral anticoagulants, haloperidol, theophylline, barbiturates, chloramphenicol, imidazole antifungals, oral or systemic hormonal contraceptives, acetaminophen, benzodiazepines, hydantoins, sulfa drugs, enalapril, beta-blockers, chloramphenicol, clofibrate, dapsone, disopyramide, mexiletine, quinidine, tocainide, diazepam, doxycycline, fluoroquinolones, levothyroxine, nortriptyline, progestins, tacrolimus, zidovudine, protease inhibitors, and non-nucleoside reverse transcriptase inhibitors.

2. Coadministration with INH or halothane may result in additive hepatotoxicity.

3. Probenecid and trimethoprim-sulfamethoxazole may increase rifampin levels.

4. Antacids may decrease rifampin absorption.

5. Rifampin may cause leukopenia; use caution with clozapine and carbamazepine;

6. Monitor for altered effects when used concurrently with psychotropic drugs.

I. DOSAGE FORMS:

Capsule: 150 mg, 300 mg

A. Indications:

1. The combination of **ofloxacin plus rifampin** is an alternative post-exposure antibiotic mass prophylaxis of choice for individuals exposed to aerosolized *Brucella* species (brucellosis).

2. **Ofloxacin** is an alternative quinolone antibiotic that can be used in lieu of ciprofloxacin in any of the bioterrorism mass prophylaxis protocols if ciprofloxacin is not available.

B. Dosage, Route, and Schedule of Administration:

Standard adult dose: Ofloxacin 400 mg by mouth every 24 hours

C. Duration of Ofloxacin Prophylaxis

DISEASE	DURATION
Anthrax with < 3 doses of Anthrax vaccination	60 days
Anthrax with at least 3 doses of Anthrax vaccination	30 days
Brucellosis	3 weeks to 6 weeks
Plague	7 days
Tularemia	14 days

D. Contraindications

Hypersensitivity to ofloxacin or other members of the quinolone group (e.g. nalidixic acid, oxolinic acid, cinoxacin, norfloxacin, and ciprofloxacin).

E. Precautions

1. Use with caution in patients with epilepsy or other **CNS diseases** that could predispose **seizures.**
2. Use caution with systemic preparation in children <18 years of age due to association of other quinolones with transient **arthropathy**.

3. Discontinue immediately with signs of **tendon inflammation or tendon pain**.
4. Reduce dose in **renal impairment**:

    a. For a creatinine clearance of 10-50 mL/minute administer 200-400 mg every 24 hours.
    b. For a creatinine clearance of <10 mL/minute administer 100-200 mg every 24 hours.

5. Hold **antacids** for 2-4 hours before and after administering ofloxacin.
6. Use caution with **clozapine** and other **psychotropics**; monitor for adverse effects.
7. May cause drowsiness, dizziness, nervousness, insomnia, restlessness, hallucinations, euphoria, depression, panic, and paranoia.

F. Adverse Reactions

1. Chest pain, headache, insomnia, dizziness, fatigue, somnolence, sleep disorders, nervousness, pyrexia, rash/pruritus, diarrhea, vomiting, abdominal cramps, flatulence, abnormal taste, xerostomia , decreased appetite, and/or nausea occurs in 1% to 10% of patients.

2. Syncope, vasculitis, anxiety, cognitive change, depression, dream abnormality, euphoria, hallucinations, vertigo, chills, malaise, extremity pain, weight loss, paresthesia, ruptured tendons, Tourette's syndrome, weakness, photophobia, photosensitivity, hepatitis, decreased hearing acuity, tinnitus, cough, and thirst occur in <1% of patients.

G. Drug Interactions

1. There is decreased absorption of ofloxacin with antacids containing aluminum, magnesium, and/or calcium.

2. Quinolones cause increased caffeine, warfarin, cyclosporine, procainamide, and possibly theophylline levels. Cimetidine and probenecid increase quinolone levels.

H. Dosage Forms

Tablet: 200 mg, 300 mg, 400 mg

PATIENT INFORMATION

Ciprofloxacin

Ciprofloxacin is an antibiotic. You are taking this antibiotic in order to prevent or treat a serious infection.

Take all of your medicine as directed by your doctor or nurse. Do not skip doses. Take all the medicine as directed even if you are feeling better.

Take the medicine on an empty stomach (30 minutes before or 2 hours after meals, dairy products, antacids, or other medication).

Drink at least 6 glasses of water per day unless your health care provider has instructed you to restrict fluid intake.

You may experience nausea, vomiting, or loss of appetite. Small frequent meals, frequent mouth care, sucking lozenges, or chewing gum may help.

Report immediately to your doctor or nurse any signs of skin rash, joint or back pain, or difficulty breathing.

Report immediately to your doctor or nurse any unusual fever or chills; vaginal itching or foul-smelling vaginal discharge; easy bruising or bleeding; or pain, inflammation, or rupture of a tendon.

Inform your doctor or nurse if you are or intend to be pregnant. Do not breast-feed.

PATIENT INFORMATION
Doxycycline

Doxycyline is an antibiotic in the tetracycline family. You are taking this medicine to prevent or treat a serious infection. Take all the medicine as directed, even if you are feeling better.

Avoid alcohol and drink plenty of water (at least 6 glasses of water each day) unless instructed by your doctor to restrict fluid intake.

You may be very sensitive to sunlight; use sunblock, wear protective clothing and eyewear, or avoid exposure to direct sunlight.

You may experience lightheadedness, dizziness, or drowsiness (use caution when driving or engaging in tasks that require alertness until response to drug is known); nausea or vomiting (small frequent meals, frequent mouth care, sucking lozenges, or chewing gum may help); or diarrhea (buttermilk, boiled milk, or yogurt may help).

If you are diabetic, the drug may cause false tests with Clinitest® urine glucose monitoring; use of glucose oxidase methods (Clinistix®) or serum glucose monitoring is preferable.

Immediately report to your doctor or nurse any skin rash or itching, easy bruising or bleeding, yellowing of skin or eyes, pale stool or dark urine, unhealed sores of mouth, itching or vaginal discharge, fever or chills, or unusual cough.

Inform your doctor or nurse if you are or intend to be pregnant. Do not breast-feed. Oral contraceptives effectiveness may be reduced; use appropriate barrier contraceptive measures.

PATIENT INFORMATION

Amoxicillin

Amoxicillin is an antibiotic related to penicillin. You are taking this medicine to prevent, or treat, a serious infection. Take all the medicine as directed, even if you are feeling better.

If you are allergic to penicillin you are also allergic to amoxicillin. Tell your doctor or nurse if you are allergic to penicillin before you start to take the amoxicillin so that a different type of antibiotic can be prescribed for you.

Amoxicillin may be taken with milk, juice, or food.

You may experience nausea or vomiting (small frequent meals, frequent mouth care, sucking lozenges, or chewing gum help).

If you are diabetic, amoxicillin may cause false tests with Clinitest® urine glucose monitoring; use of glucose oxidase methods (Clinistix®) or serum glucose monitoring is preferable.

This drug may interfere with oral contraceptives; an alternate form of birth control should be used.

Immediately report to your doctor or nurse any rash; unusual diarrhea; vaginal itching, burning, or pain; unresolved vomiting or constipation; fever or chills; unusual bruising or bleeding; or if your condition worsens or does not improve by the time prescription is completed.

PATIENT INFORMATION

Trimethoprim-Sulfamethoxazole

Trimethoprim-Sulfamethoxazole is a sulfa drug. You are taking this antibiotic in order to prevent or treat a serious infection. You should not take this medication if you have an allergy to sulfa drugs.

Swallow this medicine with 8 oz of water on an empty stomach (1 hour before or 2 hours after meals).

Finish all medication; do not skip doses.

You may experience increased sensitivity to sunlight. Use sunblock, wear protective clothing and dark glasses, and/or avoid direct exposure to sunlight.

By eating small frequent meals, frequent mouth care, sucking lozenges, or chewing gum you may reduce nausea or vomiting.

Report skin rash, sore throat, blackened stool, or unusual bruising or bleeding immediately to your health care provider.

Inform your health care provider if you are or intend to be pregnant.

PATIENT INFORMATION

Rifampin

Rifampin is an antibiotic. You are taking this antibiotic in order to prevent or treat a serious infection.

Take all the medicine as directed. Do not skip doses. Finish all medicines.

Take the medicine on an empty stomach (1 hour before or 2 hours after meals).

Drink plenty of water (at least 6 glasses of water each day) unless instructed by your doctor to restrict fluid intake.

Rifampin will discolor urine, stool, saliva, tears, sweat, and other body fluids reddish-brown. Rifampin can permanently stain clothing or contact lenses. Wear eyeglasses instead of contact lenses while taking rifampin.

Report any of the following symptoms to your doctor or nurse immediately: persistent vomiting; fever, chill, or flu-like symptoms; unusual bruising or bleeding; or other problems you think might be caused by the medicine.

Inform your doctor or nurse if you are or intend to be pregnant or if you are using oral contraceptives (rifampin may reduce the effectiveness of certain oral contraceptives).

PATIENT INFORMATION

Ofloxacin

Ofloxacin is an antibiotic. You are taking this antibiotic in order to prevent or treat a serious infection.

Take all of your medicine as directed. Do not skip doses.

Take the medicine on an empty stomach (1 hour before or 2 hours after meals, dairy products, antacids, or other medication).

Drink at least 6 glasses of water per day unless your doctor has instructed you to restrict fluid intake.

You may experience dizziness, or lightheadedness. Use caution when driving or performing tasks that require alertness until your response to ofloxacin is known.

Nausea, vomiting, or change in taste may be a problem. Small frequent meals, frequent mouth care, sucking lozenges, or chewing gum may help.

Photosensitivity (sunburn or sunrash) is a common problem with this medicine. Use sunscreen, wear protective clothing and eyewear, and avoid direct sunlight while taking this medication.

Report stomach upset or diarrhea, excessive sleepiness, agitation, or tremors, skin rash, changes in vision, difficulty breathing, sore throat, chills, fever, burning, itching on urination, vaginal discharge, mouth sores, or worsening of your condition.

Inform your doctor or nurse if you are or intend to be pregnant. Do not breast-feed.

Form to Decline Antibiotic Preventive Treatment

I have been informed that I have been exposed to a life-threatening germ or germs, or an active case of a communicable disease as the result of a bioterrorism event. Having been provided information about being protected from the germ or communicable disease, and the opportunity to discuss antibiotic treatments with a public health nurse or physician, I elect not to receive the antibiotic treatments. The reason I am electing not to receive the antibiotic treatment is

_____.

I understand that if I request antibiotic treatment, and I am medically eligible to receive it, it will be provided without cost to me. I have read thoroughly the attached materials about the antibiotic(s) and I understand the contents of these materials. I am satisfied and have no further questions.

By signing below, I am confirming either: (a) my desire not to receive, or (b) my understanding that based on my medical condition, I am not eligible to receive the antibiotic(s). By signing below, I am also acknowledging that I understand that because I have elected not to receive the antibiotic(s) or I have a medical condition that makes me ineligible for antibiotics, I am at higher risk of contracting the communicable disease if I am exposed to it. Accordingly, I hereby release The State of Hawaii Department of Health, its officers, employees, and agents, including any physicians or other health care providers, from any liability related to any subsequent exposure I have to the germ causing the communicable disease.

I acknowledge that I am signing this Form to Decline Antibiotic Preventive Treatment voluntarily and with full knowledge of its contents and meaning. I understand that if I change my mind at any time and decide to receive antibiotic treatment, and I am medically eligible to receive it, it will be provided at no cost to me.

Signature:_____ I.D.#:_____

Printed Name:_____

Witness to
Signature:_____Date:_____

Form to Decline Immunization

I have been informed that I have either been exposed to a germ(s), or an active case of a communicable disease as the result of a bioterrorism event. Having been provided information about being immunized against the communicable disease and the opportunity to discuss immunization with a public health nurse or physician, I elect not to receive immunization at this time. The reason I am electing not to receive immunization is _____.

I understand that if I request immunization, and I am medically eligible to receive it, it will be provided without cost to me. I have read thoroughly the attached materials about the vaccine and I understand the contents of these materials. I am satisfied and have no further questions.

By signing below, I am confirming either: (a) my desire not to receive immunization, or (b) my understanding that based on my medical condition, I am not eligible to receive immunization. By signing below, I am also acknowledging that I understand that because I have elected not to receive immunization or I have a medical condition that makes me ineligible for immunization, I am at higher risk of contracting the communicable disease if I am exposed to it. Accordingly, I hereby release The State of Hawaii Department of Health, its officers, employees, and agents, including any physicians or other health care providers, from any liability related to any subsequent exposure I have to the germ(s).

I acknowledge that I am signing this Form to Decline Immunization voluntarily and with full knowledge of its contents and meaning. I understand that if I change my mind at any time and decide to receive immunization and I am medically eligible to receive it, it will be provided at no cost to me.

Signature:_____ I.D.#:_____

Printed Name:_____

Witness to
Signature:_____Date:_____

BIOLOGICAL OUTBREAK/EXPOSURE
MASS PROPHYLAXIS & IMMUNIZATION RECORD

REGISTRATION FORM

OFFICE USE ONLY	
Event or Exposure:	**Date:**
Clinic Site:	**ID #:**

Last Name:_____ First Name:_____ MI____

Date of Birth:_____ Age:_____ Sex:_____ Ethnicity:_____

Occupation/School &grade:_____

Emergency Contact_____ Relationship;_____ Phone:_____

(For Children): Mother:_____ Father:_____ Guardian:_____

Residential Address:_____
Number Street Apt #

_____
City State Zip Code

Mailing Address:_____
Number Street Apt #

_____
City State Zip Code

Home Phone:_____ Business Phone:_____

Cell Phone:_____ Pager: _____ E-mail:_____

Personal Physician:_____ Phone:_____

This information will remain confidential and will only be used by Public Health Officials to assist in contacting you with follow-up information. Thank you for your cooperation.

Client's or Guardian's Signature:_____ Date:_____

BIOLOGICAL OUTBREAK/EXPOSURE
MASS PROPHYLAXIS & IMMUNIZATION RECORD

MEDICAL HISTORY

OFFICE USE ONLY Date: _____

Name: _____ I.D. # _____

Sex: Male ? Female ? Age: _____ Weight: _____

Date, time, location and nature of the exposure? _____

_____

Decontamination at the scene required? ? Yes ? No

Pregnant? ? Yes ? No

Allergies? ? Yes ? No

_____

_____

Current or Past Illness? ? Yes ? No

_____

_____

_____

Current Medications? ? Yes ? No

_____

_____

_____

Symptoms? ? Yes ? No

_____

_____

_____

Referral to Triage? ? Yes ? No
Referral to Hospital? ? Yes ? No

Comments: _____

_____

_____

Practitioner's Signature: _____ Date: _____

BIOLOGICAL OUTBREAK/EXPOSURE
MASS PROPHYLAXIS & IMMUNIZATION RECORD

OFFICE USE ONLY Date:_____

Name:_____ I.D. # _____

Sex: Male ? Female ? Age:_____ Weight:_____

ANTIBIOTIC PROPHYLAXIS RECORD

1. I have read and understand the patient information statements about the antibiotic(s) that I am about to receive.
2. I understand why I should receive this medication.
3. I understand the possible side effects of such treatment.
4. I have been given the opportunity to ask questions about the antibiotics prior to receiving the medication.
5. I agree to receive the antibiotics. YES ? NO ? (Declination Form is attached)
6. SIGNATURE:_____

ANTIBIOTIC PROPHYLAXIS RECORD

Antibiotic	**Dose**	**Duration**	**Weekly Quantity of Antibiotic Dispensed**								**Adverse Reaction**	**Completed Rx**
			1st	2nd	3rd	4th	5th	6th	7th	8th		
Practitioner's Signature:												

BIOLOGICAL OUTBREAK/EXPOSURE
MASS PROPHYLAXIS & IMMUNIZATION RECORD

OFFICE USE ONLY	Date:_____
Name:_____	I.D. # _____
Sex: Male ? Female ? Age:_____	Weight:_____

ANTHRAX VACCINE IMMUNIZATION RECORD

1. I have been given an anthrax vaccine information brochure.
2. I have been given the opportunity to ask questions about anthrax vaccine prior to receiving the immunization.
3. I agree to receive the anthrax vaccine. YES ? NO ? (Declination Form is attached)
4. SIGNATURE_____

Date Given	Dose Number	Dosing Schedule	Dose (ml)	Site (left or right arm)	Manufacturer And Lot Number	Administered By: (Printed or stamped signature block)
	1	Day 0				
	2	14 days after dose 1				
	3	14 days after dose 2				
	Booster	5 months after dose 3				

BIOLOGICAL OUTBREAK/EXPOSURE
MASS PROPHYLAXIS & IMMUNIZATION RECORD

OFFICE USE ONLY	Date:_____
Name:_____	I.D. # _____
Sex: Male ? Female ? Age:_____	Weight:_____

SMALLPOX (VACCINIA) IMMUNIZATION RECORD

1. I have been given a smallpox (vaccinia) vaccine information brochure.
2. I have been given the opportunity to ask questions about the smallpox (vaccinia) vaccine prior to receiving the immunization.
3. I agree to receive the smallpox vaccine. YES ? NO ? (Declination Form is attached)
4. SIGNATURE_____

Date Given	Dose Number	Dosing Schedule	Dose (ml)	Site (left or right arm)	Manufacturer And Lot Number	Administered By: (Printed or stamped signature block)
		One Dose				

BIOLOGICAL OUTBREAK/EXPOSURE
MASS PROPHYLAXIS & IMMUNIZATION RECORD

OFFICE USE ONLY	Date:_____
Name:_____	I.D. # _____
Sex: Male ? Female ? Age:_____	Weight:_____

Client Disposition

Was the patient decontaminated at the site of exposure?	☐ Yes	☐ No
If yes, what is the status of patient's clothing & personal effects?	☐ Decontaminated ☐ Retained by Hazmat ☐ Releases to client	
If no, is the patient declining decontamination?	☐ Yes	☐ No;
If no, is the patient declining prophylaxis, or treatment?	☐ Yes	☐ No
Antibiotic prophylaxis indicated:	☐ Yes	☐ No
Vaccination indicated:	☐ Yes	☐ No
Client declined antibiotic(s):	☐ Yes	☐ No
Antibiotic received during the current event:	☐ Yes	☐ No
Client received appropriate vaccination:	☐ Yes	☐ No
Client declined appropriate vaccination:	☐ Yes	☐ No
Adverse Reactions to prophylaxis or immunization:	☐ Yes	☐ No

Describe:_____

Disease developed despite immunization and antibiotic prophylaxis: ☐ Yes ☐ No
Client referred to medical center/field hospital for treatment: ☐ Yes ☐ No
Name and Location of Facility:_____

Client has been provided with pertinent medical information: ☐ Yes ☐ No

Client died: ☐ Yes ☐ No

Practitioner's Signature:_____Date:_____

State of Hawaii
Department of Health
Biological Outbreak/Exposure Incident
Summary Data (All Sites)

Day of_____

CATEGORY	NUMBER
Total number of persons served	_____
Persons exposed	_____
Concerned persons presenting for treatment (not exposed)	_____
Persons dead	_____
Persons treated for disease	_____
Symptomatic persons recovered	_____
Persons starting antibiotics	_____
Persons completing antibiotics	_____
Persons receiving vaccination	_____
Persons completing vaccination schedule	_____
Adverse reactions to antibiotics	_____
Adverse reactions to vaccination	_____
Persons developing illness despite prophylaxis	_____

State of Hawaii
Department of Health
Biological Outbreak/Exposure Incident
Daily Summary (Individual NAC Site)

Day of_____

CATEGORY	**NUMBER**
Total number of people served	_____
Referred to triage center	_____
Referred to hospital	_____
People presenting with symptoms	_____
People started on antibiotics	_____
People completing antibiotic prophylaxis	_____
People receiving vaccination	_____
People completing the vaccination schedule	_____
People developing symptoms after prophylaxis	_____
People having adverse reactions to antibiotics or vaccination	_____

Signature of NAC site supervisor_____

REFERRAL TO EMERGENCY FACILITY

DATE: ___/___/___ LOCATION OF INCIDENT:

NAME: _____ BIRTHDATE: ___/___/

IMMUNIZATIONS ADMINISTERED: _____

_____

REACTION(S

- ✍✍Mild itching & hives
- ✍✍Wheezing
- ✍✍Difficulty breathing
- ✍✍Swelling of Mouth & Throat
- ✍✍Hypotension: BP: _____ Pulse: _____ Respiration:
- ✍✍Other:

ACTIONS:

1. Administration of epinephrine 1:1,000 subcutaneously
   _____ ml at ____:____a.m./p.m. (Time), _____(Site).

   Repeated at ____:____a.m./p.m. (Time), _____ml _____(Site).

2. EMERGENCY PERSONNEL CONTACTED: TIME: ____:____a.m./p.m.

3. If Benadryl is administered:

   Diphenhydramine (Benadryl) _____ mg _____ cc, Intramuscular given at ____:____a.m./p.m. (Time), _____(Site).

4. Referral (Name of Facility):

5. Time departed for Emergency Facility: ____:____a.m./p.m.

MICT (signature)_____Date:_____