

Track 1 – Outbreak/Public Health

Urgent Prophylaxis and Treatment of Diseases Caused by Biological Weapons

Friday, February 4, 2005

2:30pm ~ 3:30pm

Response to a Bioweapons Event: Mass Immunization, Prophylaxis, and Restriction

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Objectives

- To understand the elements necessary in planning for response to a bioweapons event
- To discuss the role of the FBI and Public Health in biological terrorist events
- To demonstrate the need for preplanning activities in your community

Variable Determinants of Response

- Covert or Overt
- Infectious vs. non-infectious
- Prophylaxis or vaccine available?
- Estimated scale of exposure

Covert vs. Overt Bioweapons Attack

- In an overt attack, law enforcement will respond and notify public health of the possibility of health threat to the public.
- In a covert attack, public health will first become aware of the possibility of attack, and alert law enforcement.

What are the roles of law enforcement and the health department in dealing with the release of a bioweapon?

The FBI has authority and jurisdiction over any terrorist event.

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The Public Health Department has authority and jurisdiction over any situation threatening the health of the public.

Example: Anthrax attacks in US

- The covert attack in Florida was picked up by physician/health department interaction, and referred to the FBI. No crime scene was immediately identified, leading to continued exposure of unaware individuals.
- The letter to the Hart office in DC announced contamination, and the FBI was first to respond, notifying the health department. This was clearly a crime scene. Further exposure was curtailed.

Similarities between law enforcement and public health.

- Both protect the public.
- Both are involved in investigation of potential bioweapons attacks.
- Both depend on laboratory investigation to support their primary functions.
- The approach and nature of the work done by each is quite different.

Public Health Investigation – an Inductive Approach

- Patients and involved/exposed persons are interviewed
- Data is collected
- A Hypothesis is developed to explain transmission
- Epidemiologic and laboratory studies test the Hypothesis
- If the Hypothesis is supported, prevention and control strategies are implemented, then evaluated.
- Work is held to a scientific standard.

Law Enforcement – a Deductive Approach

- Witnesses and potential suspects are interviewed.
- Leads are developed and pursued.
- Evidence is collected and carefully identified.
- The perpetrator is identified and prosecuted if the evidence is sufficient to obtain a conviction.

Joint investigations can be problematic

- Public health has not encouraged participation of law enforcement in the past.
- Law enforcement must follow due process.
- Access to health care information is regulated by multiple different laws.
- Laboratory testing was developed to meet the needs of public health, but did not withstand legal challenges.

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Laboratory Response Network (LRN)

- CDC and FBI joint effort to standardize laboratory protocols and security, to meet the needs of both agencies.
- The LRN is a network connecting state and local labs with federal and military labs, standardizing analyses and reporting.

Challenges that remain

- Interviews of affected persons should be conducted jointly, when possible.
- Secure communication must be established between law enforcement and public health.
- Public information should come jointly, to avoid the perception of confusion.
- These partnerships must be in place at all levels to minimize the effect of a bioweapons assault.

Public Health Response

- Providing information to health care workers and the public (timely and accurate)
- Disease surveillance
- Contact tracing
- Administer vaccines/prophylaxis
- Restrictive measures (quarantine, isolation)
- Laboratory testing of specimens
- Protecting the quality of air, water, food

Impediments to timely response

- Will a sufficient number of public health workers show up for work?
- Is secure and reliable communication between central offices and local offices and hospitals in place?
- Can public health work within an incident command structure, with elected political leadership? (national security issue, crime, and health threat)

What is the magnitude of the response?

Smallpox outbreak 1947, New York

- In response to a few cases of smallpox, over 6 million people were vaccinated by the public health department, using volunteers
- This effort took three weeks, running 179 clinics from 9am to 10pm, 7 days a week.

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Legal barriers to response

- Regulations concerning transfer of patients from one facility to another.
- Regulations concerning dispensing of medications. (Pharmacy)
- Use of volunteers, retired or out of state health care professionals, for mass prophylaxis and vaccination.

Efforts to allow timely interventions within the law have been developed at the state level, most commonly by drafting emergency executive orders.

Disease Control Measures

- Symptomatic victims will often die.
- Early implementation of specific disease control measures can stop an epidemic and save lives.
- Case fatality rates will depend upon the specific microbial agent, the dose delivered, and the susceptibility of the exposed population.

Specific Disease Control Measures

- Restriction
- Mass Immunization
- Mass Prophylaxis

Restrictive Measures

- Current public health authority allows restriction of personal behavior for persons with specific illness (eg., TB), though these vary from state to state in the US.
- We have limited experience with large scale quarantine.
- Restrictive measures must be specific to the circumstances, and are hard to draft in planning stages.

Restriction

- **Decentralized quarantine** – at home. Reduces the risk of passing on infection; requires a lot of community support.
- **Centralized quarantine** – all persons are quarantined together in a large facility. Easier to care for (less community support), but allows contagious and non contagious persons to come into contact.
- **Restriction of Travel**, essentially geographic quarantine of an entire area.

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Plague in Los Angeles, 1924

- 15 cases discovered, with person to person transmission highly suspected.
- Eight city blocks, housing 2,500 Mexican immigrants, was quarantined.
- Health department nurses made house to house visits to discover new cases, which were sent to the county hospital
- 7 day rations of food were given to each household
- All persons living at addresses where cases had occurred were quarantined in the county hospital.

Large Tabletop Exercises

- Operation Topoff (Denver)
- Operation Topoff 2 (Seattle and Chicago)
- Dark Winter (Oklahoma City)

- Underscored the need for rethinking restriction of transport and quarantine.

Mass Immunization and Prophylaxis

- Prompt epidemiologic investigation by the Health Department will define the bounds of the outbreak, in order to identify the most effective intervention to save people not yet symptomatic.
- First responders, emergency workers, those involved in the investigation and care of these patients, and their families, must be among the first to be treated.

When to activate the plan:

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

Current prophylaxis assumptions:

- Bacteria that cause anthrax, plague and tularemia are susceptible to antibiotics; therapy and prophylaxis with antibiotics are recommended.
- Botulism toxin therapy is primarily supportive; passive immunization with antitoxin is effective only if given early.
- No preventive antiviral drugs against smallpox or viral hemorrhagic fevers exist.

Current prophylaxis assumptions (cont.)

- Smallpox vaccine supplies are adequate; anthrax vaccines are not. No other vaccines are available.
- No treatment, prophylaxis nor vaccines are available for Ricin, SEB, or Tricothecene mycotoxins.
- No vaccines used to prevent or limit disease severity to biological weapons are currently available to civilians.

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Current agent specific recommendations are included in your handout.

Planning for Mass Prophylaxis and Immunization

- Define levels of response.
- Plan for specific agents where possible.
- Define indications for antibiotics, and a priority list for distribution of preventive medications.
- Predetermine distribution sites locally, and identify and prepare workforce personnel.
- Identify supplies of vaccines and antibiotics.

Example – define levels of response

- Level 1 response – 1 to 100 people.
- Level 2 response – 101 to 1000 people.
- Level 3 response – 1001 to 10,000 people.
- This allows for modular expansion of the health care system, dependent on local capabilities and needs.

Plan for specific agents

- Keep current with CDC recommendations for “most likely” bioweapons.
- Allow for flexibility based on occurrence.
- Current recommendations include Anthrax, Brucellosis, Tularemia, Pneumonic Plague, Smallpox, Viral Hemorrhagic Fevers, Botulinum toxin, and Ricin.
- Prepare standing order documents where possible.

Highly Communicable Diseases

- It is best to avoid mass gatherings
- Provide for home distribution of medications to affected individuals.
- Public education, and public service announcements must be provided.
- Provision of emergency medical care must be accomplished.

Predetermine distribution sites

- Explore regional possibilities
- Consider accessibility, parking, client comfort.
- Examples include schools, colleges, local amphitheatres, shopping malls, grocery stores.

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Workforce considerations

- Identify and educate potential workforce for all levels of response.
- Consider that public service professionals will likely have other duties in response to level 2 or level 3 incident, and will not be available to assist.
- Be prepared to rapidly educate new volunteers for specific functions.

Identify source of antibiotics and vaccines

- Consider a local cache of antibiotics for all emergency responders, law enforcement, and health care providers, and their families, to protect the workforce.
- Consider a local cache for Level 1 and Level 2 incidents, to cover 1 to 3 days.
- Identify local resources (pharmaceutical companies, hospitals, clinics, etc.)
- Become familiar with the state and local plans for accessing and distributing the SNS

Strategic National Stockpile

- Cities Readiness Initiative
 - Begun in 1999 by CDC to fund readiness to receive and rapidly disperse contents of SNS.
 - Intent is to be able to provide oral medications to 100% of the population.
 - Initial work was CDC with individual states, 21 cities have been identified and funded as pilot projects.

Consider the impact of Disease Control Measures on the other parts of the biological incident response plan.

Operational Issues

- Authority to initiate the plan
- Ability to change response dependent on on-going evaluation
- Investigational new drug requests
- Public information access
- Security and transportation of personnel and supplies

Other considerations

- Record keeping and patient tracking
- Reliable and secure communications.
- Infection control, and PPE
- Reimbursement
- Training
- Exercises

Bibliography: Response to a Bioweapons Event
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BIOLOGICAL AGENT POST-EXPOSURE PROPHYLAXIS

NOTE: The information that follows is for informational and planning purposes only. Actual treatment of patients and exposed individuals should follow the most current guidelines issued by the Center for Disease Control or other recognized experts. The agents discussed in this annex are only the most likely agents. There are numerous other agents that may occur either naturally or as a result of bioterrorism. Recommendations for prophylaxis and post-exposure immunization are subject to change. If required, current recommendations will be obtained in consultation with local and state health departments and the CDC.

1. Anthrax

Recommended post-exposure prophylaxis:

ANTIMICROBIAL AGENT	ADULTS	CHILDREN
Ciprofloxacin	500 mg twice daily	20-30 mg/kg/day, divided into two doses
Levofloxacin	500 mg once daily	Not recommended
Ofloxacin	400 mg twice daily	Not recommended
Doxycycline (Only if above three unavailable)	100 mg twice daily	5 mg/kg/day divided into two doses

Pediatric use of fluoroquinolones and tetracycline is associated with adverse effects that must be weighed against the risk of developing a lethal disease. If *Bacillus anthracis* exposure is confirmed, the organism will be tested for penicillin susceptibility. If susceptible, exposed children will be treated with oral amoxicillin 40 mg per kg of body mass per day divided every 8 hours (not to exceed 500 mg three times daily).

Prophylaxis will continue until *Bacillus anthracis* exposure has been excluded. If exposure is confirmed, prophylaxis will continue for 8 weeks. In addition to prophylaxis, post-exposure immunization with an inactivated, cell-free anthrax vaccine is also indicated following anthrax exposure. If available, post-exposure vaccination will consist of three doses of vaccine at 0, 2, and 4 weeks after exposure. With vaccination, post-exposure antimicrobial prophylaxis can be reduced to 4 weeks.

2. Plague

Post-exposure prophylaxis will be initiated following confirmed or suspected bioterrorism *Yersinia pestis* exposure, and for post-exposure management of healthcare workers and others who had unprotected face-to-face contact with symptomatic patients.

Recommended post-exposure prophylaxis:

ANTIMICROBIAL AGENT	ADULTS	CHILDREN
Doxycycline (First choice)	100 mg twice daily	5 mg/kg/day divided into two doses
Ciprofloxacin (Second choice)	500 mg twice daily	20-30 mg/kg/day, divided into two doses

Pediatric use of tetracycline and fluoroquinolones is associated with adverse effects that must be weighed against the risk of developing a lethal disease.

Prophylaxis will continue for 7 days after last known or suspected *Yersinia pestis* exposure, or until exposure has been excluded.

3. Tularemia

The recommended post-exposure prophylaxis:

ANTIMICROBIAL AGENT	ADULTS	CHILDREN
Tetracycline	500 mg 4 times a day	Not recommended
Gentamicin	3-5 mg/kg/day in divided doses	3-5 mg/kg/day, in divided doses
Streptomycin	1 gm every 12 hours	30-40 mg/kg/day twice daily

The therapeutic response to effective antibiotic therapy is rapid. Patients with all forms of tularemia respond to the antibiotics streptomycin, gentamicin, tetracycline, and chloramphenicol.

In addition to prophylaxis, post-exposure immunization with a live attenuated strain of *Francisella tularensis* is also indicated following exposure. Recovery from tularemia is thought to confer protective immunity for life, although a few recurrent infections have been documented. Therefore, previously infected individuals are not candidates for vaccination or preemptive antibiotic therapy after a known exposure.

4. Brucellosis

For pre-exposure prophylaxis, vaccines are not currently available for human use; attenuated vaccines for veterinary use have caused brucellosis following accidental percutaneous or mucous membrane exposures. Chemoprophylaxis has not been proven to be effective and may delay or mask the onset of the disease

Post-exposure prophylaxis consists of a 3- to 6-week course of therapy and will follow any patient exposed to a proven brucellosis attack. Post-exposure chemoprophylaxis will not be administered following possible natural exposures to endemic disease.

Brucellosis is treated with antibiotics but, due to the intracellular nature of the infectious process, treatment usually requires combination therapy over a long duration. Doxycycline plus rifampin for 6 weeks will be administered for uncomplicated disease in adults. Ofloxacin plus rifampin has also been reported to be effective. For complications, such as endocarditis or meningoenophalitis, triple therapy including rifampin, a tetracycline, and an aminoglycoside will be provided.

ANTIMICROBIAL AGENT	ADULTS	CHILDREN
Doxycycline PO plus Rifampin PO x 6 wk	200 mg/day 600-900 mg/day	Not recommended
Ofloxacin Rifampin	400 mg/day 600 mg/day for 6 weeks	

5. Smallpox

Recommendations for prophylaxis are subject to change. Up-to-date recommendations should be obtained in consultation with local and state health departments and CDC.

Post-exposure immunization with smallpox vaccine (vaccinia virus) is available and effective. Vaccination alone is recommended if given within 3 days of exposure. Passive immunization is also available in the form of vaccinia immune-globulin (VIG) (0.6ml/kg IM). If greater than 3 days has elapsed since exposure, both vaccination and VIG are recommended.

VIG is maintained at USAMRIID, 301/619-2833.

Vaccination is generally contraindicated in pregnant women, and persons with immunosuppression, HIV–infection, and eczema, which are at risk for disseminated vaccinia disease. However, the risk of smallpox vaccination should be weighed against the likelihood for developing smallpox following a known exposure. VIG should be given concomitantly with vaccination in these patients.

6. Viral Hemorrhagic Fevers

Post-exposure immunization:

Intensive supportive care may be required. Antiviral therapy with ribavirin may be useful in several of these infections. Convalescent plasma may be effective in Argentine hemorrhagic fever. The only licensed VHF vaccine is yellow fever vaccine. Prophylactic ribavirin may be effective for Lassa fever, Rift Valley fever, CCHF, and possibly HFRS. Contact Precautions for healthcare workers. Decontamination is accomplished with hypochlorite or phenolic disinfectants. Isolation measures and barrier nursing procedures are indicated.

7. Botulism

Post-exposure immunization:

Post-exposure immunization is available as a trivalent botulinum antitoxin by contacting the State DOH or by contacting CDC (404/639-2206 during office hours, 404/639-2888 after hours). This horse serum product has a <9% percent rate of hypersensitivity reactions, so skin testing will be performed according to the package insert prior to administration.

8. Investigation New Drug Requests

The NCDHHS Human Research and Evaluation Committee (the Health Department’s institutional review board) will convene to review all investigational new drug (IND) or vaccine requests for the prevention and treatment of diseases due to bioterrorism agents, and will be the approving authority for use of these drugs or vaccines during DOH operations.

ANNEX B: TABLE OF CHARACTERISTICS AND MANAGEMENT OF SELECTED BIOTERRORISM AGENTS

(Data for this chart was compiled from various *Journal of the American Medical Association* and University of South Florida resources, and is intended for planning and informational purposes only. Medication information should be researched and verified before initiation of patient treatment)

Disease/ Agent	Incubation Period	Clinical Syndrome	Lethality	Mode of Tx	PPE	Diagnostic Tests	Treatment	Vaccine	Chemo prophylaxis	Local cache
BACTERIAL AGENTS										
Anthrax	1-5 days, possibly up to 60 days	<p>Cutaneous: Evolving skin lesion (face, neck, arms), progresses to vesicle, depressed ulcer, and black necrotic lesion</p> <p>Gastrointestinal: Nausea, vomiting, abdominal pain, bloody diarrhea, sepsis</p> <p>Inhalational: Abrupt onset of “flu-like” symptoms, fever with or without chills, sweats, fatigue or malaise, non- or minimally productive cough, nausea and vomiting, dyspnea, headache, chest pain, followed in 2 to 5 days by severe respiratory distress, mediastinitis, hemorrhagic meningitis, sepsis, shock.</p>	<p>20% if untreated, otherwise rarely fatal</p> <p>Approaches 100% if untreated. Rapid, aggressive treatment may reduce mortality</p> <p>Once respiratory distress develops, mortality rates approach 90%. Early treatment significantly decreases the mortality rate</p>	Aerosol, Direct	Gloves, gown, mask	<p>Gram stain and culture of blood, pleural fluid, CSF, ascitic fluid, vesicular fluid or lesion exudates. Sputum rarely positive.</p> <p>Confirmatory serological and PCR tests available through public health laboratory network.</p> <p>Widened mediastinum or chest x-ray for inhalational and occasionally, gastrointestinal anthrax.</p>	<p>Ciprofloxacin; doxycycline</p> <p>Combination therapy of ciprofloxacin or doxycycline plus one or two other antimicrobials should be considered with inhalational anthrax.</p> <p>Penicillin should be considered if strain is susceptible and does not possess inducible beta-lactamases If meningitis is suspected, doxycycline may be less optimal because of poor CNS penetration.</p> <p>Steroids may be considered for severe edema and for meningitis.</p>	6 injections and annual booster	Ciprofloxacin or doxycycline with or without vaccination; if strain is susceptible, penicillin or amoxicillin should be considered.	YES
Brucellosis	5-60 days (usually 1-2 months)	Non-specific “flu-like” symptoms, fever, headache, profound	Less than 5% even if untreated.	Aerosol	Gloves, gowns, and	Blood and bone marrow culture (may require 6 weeks to	Doxycycline plus streptomycin or rifampin.	None. Only animal vaccine	Doxycycline plus streptomycin or rifampin	YES

Disease/ Agent	Incubation Period	Clinical Syndrome	Lethality	Mode of Tx	PPE	Diagnostic Tests	Treatment	Vaccine	Chemo prophylaxis	Local cache
		weakness and fatigue, gastrointestinal symptoms such as anorexia, nausea, vomiting, diarrhea or constipation. Osteoarticular complications common	Tends to incapacitate rather than kill		mask	grow <i>Brucella</i>)	Alternative therapies: ofloxacin plus rifampin; doxycycline plus gentamicin; TMP/SMX plus gentamicin.	exists		
Inhalational (pneumonic) tularemia	3-5 days (range of 1-21 days)	Sudden onset of acute febrile illness, weakness, chills, headache, generalized body aches, elevated WBCs. Pulmonary symptoms such as dry cough, chest pain or tightness with or without objective signs of pneumonia, are present. Progressive weakness, malaise, anorexia, and weight loss occurs, potentially leading to sepsis and organ failure.	About 30 – 60 % if untreated	Aerosol	Gloves, gown, mask	Largely clinical diagnosis. Culture of blood, sputum, biopsies, pleural fluid, bronchial washings (culture is difficult and potentially dangerous). Confirmatory serological testing available through public health laboratory network.	Streptomycin; gentamicin. An alternative is ciprofloxacin	Live attenuated vaccine (USAMRIID investigational) given by scarification; currently under review by FDA, limited availability	Tetracycline; doxycycline; ciprofloxacin	YES
Pneumonic Plague	1-10 days (typically 2-3 days)	Acute onset of “flu-like” prodrome: fever, myalgia, weakness, and headache. Within 24 hours of prodrome, chest discomfort, cough, and dyspnea appear. By day 2-4 of illness, symptoms progress to cyanosis, respiratory distress and hemodynamic instability.	Almost 100% if untreated. 20-60% if appropriately treated within 18-24 hours of symptoms. Begin treatment when diagnosis of plague is suspected, do not wait for confirmatory testing.	Aerosol and person-to-person	Gloves, gowns, and mask. HEPA mask should be used	Gram stain and culture of blood, CSF, sputum, lymph node aspirates, bronchial washings. Confirmatory serological and bacteriological tests available through public health laboratory network.	Streptomycin; gentamicin. Other alternatives include doxycycline, tetracycline, ciprofloxacin, and chloramphenicol. Chloramphenicol is 1 st choice for meningitis except in pregnant or lactating women.	Inactivated whole cell vaccine licensed but not readily available. Injection with boosters. Vaccine not protective against aerosol in animals.	Tetracycline; doxycycline; ciprofloxacin	YES
VIRAL AGENTS										
Smallpox	7-17 days	Prodrome of high fever,	30% in un-	Aerosol	Gloves,	Pharyngeal swab,	Supportive care; cidofovir	Attenuated-	Vaccination given	NO

Disease/ Agent	Incubation Period	Clinical Syndrome	Lethality	Mode of Tx	PPE	Diagnostic Tests	Treatment	Vaccine	Chemo prophylaxis	Local cache
		malaise, prostration, headache, vomiting, delirium followed in 2-3 days by masculopapular rash uniformly progressing to pustules and scabs, mostly on extremities and face. Requires astute clinical evaluation; may be confused with chickenpox, erythema multiform with bullae, or allergic contact dermatitis.	vaccinated persons	and person-to-person	gowns, and mask. HEPA mask should be used	vesicular fluid, biopsies, scab material for definitive testing through public health laboratory network. Notify CDC Poxvirus Section at 404-639-2184	has been effective in vitro, and in experimental animals infected with surrogate orthopox virus.	strain vaccinia vaccine derived from calf lymph; given by scarification (licensed, limited supply). Vaccination may be effective within 3-4 days of exposure.	within 3-4 days following exposure can prevent, or decrease the severity of, disease.	
Viral Hemorrhagic Fevers	4-21 days	Fever with mucous membrane bleeding, petechiae, thrombocytopenia and hypotension in patients w/o underlying malignancies. Malaise, myalgias, headache, vomiting, diarrhea may occur.	Variable depending on strain. 15 to 25% with Lassa fever to as high as 90% with Ebola.	Aerosol and person-to-person Direct	Gloves, gowns, and mask. HEPA mask should be used.	Confirmatory serological testing and viral isolation available through public health laboratory. Notify CDC Special Pathogens Office at 404-639-1115.	Supportive therapy. Ribavirin may be effective for Lassa fever, Argentine hemorrhagic fever, and Congo-Crimean hemorrhagic fever.	Yellow Fever vaccine is the only licensed vaccine available.	Ribavirin is suggested for Congo-Crimean hemorrhagic fever and Lassa fever.	NO
BIOLOGICAL TOXINS										
Botulinum toxin	1-5 days (typically 12-36 hours)	Blurred vision, diplopia, dry mouth, ptosis, fatigue. As disease progresses, acute bilateral descending flaccid paralysis, respiratory paralysis resulting in death	60% without ventilator support	Aerosol PO	Gloves, gowns, and mask.	Treatment and reporting is based on clinical diagnosis. Serum and stool should be assayed for toxin by mouse neutralization bioassay, which may require several days.	Supportive care – ventilation may be necessary. Trivalent equine antitoxin (serotypes A,B,E – licensed, available from the CDC) should be administered immediately following diagnosis. Anaphylaxis and serum sickness are potential antitoxin complications. Do not use Aminoglycosides and clindamycin.	Pentavalent toxiod (A-E), yearly booster (investigational, CDC) Not available to the public.	Antitoxin might prevent illness following exposure but is not recommended until patient is showing symptoms.	NO