This policy has been adopted by UNC Health Care for its use in infection control. It is provided to you as information only.

Infection Control Manual				
UNC HEALTH CARE	Policy Name	Infection Control Response to the Intentional Use of a Biothreat Agent		
	Policy Number	IC 0004		
	Date this Version Effective	August 2016		
	Responsible for Content	Hospital Epidemiology		

I. Description

Describes the policies and procedures for management of biothreat acts.

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II. Rationale

A rapid and appropriate response to a potential biothreat act is critical for patient management and the potential spread of infectious disease. This policy provides information on potential agents of biothreat and a framework for management.

III. Policy

A. Detection of Outbreaks Caused by Biothreat Agents (source of outbreak NOT at UNC; see B3 for management of a biothreat agent on UNC Health Care property)

Rapid response to a biothreat-related outbreak requires prompt identification of its onset. Because of the rapid progression to illness and potential for dissemination of some of these agents, it may not be practical to await diagnostic laboratory confirmation. Instead, it may be necessary to initiate a response based on the recognition of high-risk syndromes. Each of the agent-specific case definitions in Appendix 4 includes a syndrome description (i.e., typical combination of clinical features of the illness at presentation) that should alert health care practitioners to the possibility of a biothreat-related outbreak.

Healthcare personnel (HCP) should contact Hospital Epidemiology (4-7500) immediately if they detect an outbreak or suspected outbreak related to a biothreat agent. After hours and weekends, the Infection Preventionist may be reached via pager #123-7427.

A biothreat event may be recognized in the following ways:

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- 1. Covert event: Persons are unknowingly exposed and an outbreak is suspected only upon recognition of unusual disease clusters or symptoms.
- 2. Announced event: Persons are warned that an exposure has occurred. A number of these have occurred in the US, however, they were determined to be hoaxes, that is, no true exposure to biothreat agents occurred. The Emergency Department (ED) would likely be notified by Emergency Management Service or Police. In the event a biothreat event is suspected, UNC Health Care System (UNCHCS) personnel will follow the UNCHCS Biothreat Disaster Plan located in the UNCHCS Disaster Manual / HEICS (Hospital Emergency Incident Command System)

B. Potential Agents

- 1. Key diseases with recognized biothreat potential (e.g., anthrax, botulism, plague, and smallpox) and the agents responsible for them are described in Appendices 2 and 3 of this document. These appendices contain brief descriptions of certain agents, modes of transmission and risks of human to human transmission.
- 2. Epidemiologic principles must be used to assess whether a patient's presentation is typical of an endemic disease or is an unusual event that should raise concern. Features that should alert health care providers to the possibility of a biothreat-related outbreak include:
 - a. A rapidly increasing disease incidence (e.g., within hours or days) in a normally healthy population.
 - b. An epidemic curve that rises and falls during a short period of time.
 - c. An unusual increase in the number of people seeking care, especially with fever, respiratory, or gastrointestinal complaints (see Appendix 4 for syndromic case definitions). In addition, people seeking care with lesions consistent with plague, anthrax, or smallpox.
 - d. An endemic disease rapidly emerging at an uncharacteristic time or in an unusual pattern.
 - e. Lower attack rates among people who had been indoors, especially in areas with filtered air or closed ventilation systems, compared with people who had been outdoors.
 - f. Clusters of patients arriving from a single locale.
 - g. Large numbers of rapidly fatal cases.
 - h. Any patient presenting with a disease that is relatively uncommon and has biothreat potential (e.g., pulmonary anthrax, tularemia, viral hemorrhagic fever, smallpox, botulism or plague).
- 3. For management of a suspicious letter/package/container as a biothreat, call Hospital Police to initiate the UNC Healthcare policy on suspicious letters/packages/containers. In addition, in situations involving suspicious substances, including liquids or powders, the state-wide Suspicious Substance Response Guidelines must also be followed. Do not touch or move the suspicious letter/package/container evacuate the immediate area but remain in the vicinity until Hospital Police arrive. If there is suspicion of an explosive device, follow the policy for potential explosives.

C. Infection Control Practices for Patient Management

The management of patients following suspected or confirmed biothreat events must be well organized and rehearsed. Strong leadership and effective communication are paramount.

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1. Isolation Precautions

All patients in healthcare facilities, including symptomatic patients with suspected or confirmed biothreat-related illnesses, should be managed utilizing Standard Precautions. Standard Precautions are designed to reduce transmission from both recognized and unrecognized sources of infection in health care facilities, and are recommended for all patients receiving care, regardless of their diagnosis or presumed infection status. For certain diseases or syndromes (e.g., smallpox and pneumonic plague), additional transmission-based precautions may be needed to reduce the likelihood for transmission. See Appendix 2 for specific diseases and requirements for additional isolation precautions. Additional information can be found in the Isolation Precautions policy.

Standard Precautions prevent direct contact with all body fluids (except sweat), including blood, secretions, excretions, non-intact skin (including rashes), and mucous membranes. Standard Precautions routinely practiced by health care providers include:

a. Hand Hygiene

Hand hygiene is performed after touching blood, body fluids, excretions, secretions, or items contaminated with such body fluids, whether or not gloves are worn. Hand hygiene is performed immediately after gloves are removed, between patient contacts, and as appropriate to avoid transfer of microorganisms to other patients and the environment. Soap and water should be used if contamination with anthrax spores is possible. An antiseptic handwash or a waterless alcohol-containing agent may be used for other potential biothreat pathogens.

b. Gloves

Clean nitrile gloves are worn when touching blood, body fluids, excretions, secretions, or items contaminated with such body fluids. Clean gloves are put on before touching mucous membranes and non-intact skin. Gloves are changed between tasks and between procedures on the same patient if contact occurs with contaminated material. Hand hygiene is performed promptly after removing gloves and before leaving a patient care area.

c. Masks/Eye Protection or Face Shields

A mask and eye protection (or face shield) are worn to protect mucous membranes of the eyes, nose, and mouth while performing procedures and patient care activities that may cause splashes of blood, body fluids, excretions, or secretions. For some airborne transmitted agents (e.g., viral hemorrhagic fever agents, smallpox, monkeypox) an N-95 (must have prior fit-testing) respirator should be worn.

d. Gowns

A fluid resistant gown is worn to protect skin and prevent soiling of clothing during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, excretions, or secretions. Selection of gowns and gown materials should be suitable for the activity and amount of body fluid likely to be encountered. Soiled gowns are removed promptly and hand hygiene is performed to avoid transfer of microorganisms to other patients and environments.

e. Patient Placement

In small-scale events, routine facility patient placement and infection control practices should be followed. However, when the number of patients presenting to a health care facility is too large to allow routine triage and isolation strategies (if required), it will be necessary to apply practical alternatives. These may include cohorting patients who

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present with similar syndromes, i.e., grouping affected patients into a designated section of a clinic or emergency department, or a designated ward or floor of a facility, or even setting up a response center at a separate building. Designated cohorting sites should be chosen in advance by the Hospital Infection Control Committee (or other appropriate decision-making body), in consultation with Plant Engineering staff, based on patterns of airflow and ventilation, availability of adequate plumbing and waste disposal, and capacity to safely hold potentially large numbers of patients. The triage or cohort site should have controlled entry to minimize the possibility for transmission to other patients at the facility and to staff members not directly involved in managing the outbreak. At the same time, reasonable access to vital diagnostic services (e.g., radiography departments) should be maintained.

f. Patient Transport

Most infections associated with biothreat agents cannot be transmitted from patient-to-patient. Patient isolation requirements for specific potential biothreat agents are listed in Appendix 2. In general, the transport and movement of patients with biothreat-related infections that have the potential for person-to-person transmission, as for patients with any epidemiologically important infections (e.g., pulmonary tuberculosis, chickenpox, measles), should be limited to movement that is essential to provide patient care, thus reducing the opportunities for transmission of microorganisms within health care facilities.

- g. Cleaning, Disinfection, and Sterilization of Equipment and Environment Principles of Standard Precautions should be generally applied for the management of patient-care equipment and environmental control.
 - i. Refer to the <u>"Cleaning, Disinfection and Sterilization Infection Control Policy"</u> for procedures for the routine care, cleaning, and disinfection of environmental surfaces, beds, bedrails, bedside equipment, and other frequently touched surfaces and equipment, and ensure that these procedures are being followed.
 - ii. Facility-approved EPA registered cleaning agents are available in patient care areas to use for cleaning spills of contaminated material and disinfecting non-critical equipment.
 - iii. Used patient-care equipment soiled or potentially contaminated with blood, body fluids, secretions, or excretions should be handled in a manner that prevents exposures to skin and mucous membranes, avoids contamination of clothing, and minimizes the likelihood of transfer of microbes to other patients and environments.
 - iv. Policies are in place to ensure that reusable equipment is not used for the care of another patient until it has been appropriately cleaned and reprocessed, and to ensure that single-use patient items are appropriately discarded.
 - v. Sterilization is required for all instruments or equipment that enter normally sterile tissues or sites through which blood flows.
 - vi. Rooms and bedside equipment of patients with biothreat-related infections must be cleaned using the same procedures that are used for all patients as a component of Standard Precautions, unless the infecting microorganism and the amount of environmental contamination indicates special cleaning. In addition to adequate cleaning, thorough disinfection of bedside equipment and environmental surfaces may be indicated for certain organisms that can survive in the inanimate environment for extended periods of time. The methods and frequency of cleaning and the products used will be determined by Infection Control.

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- vii. Patient linens are handled in accordance with Standard Precautions, unless the infecting microorganism (e.g. smallpox virus) indicates special handling, transporting, and laundering. In most cases, although linen may be contaminated, the risk of disease transmission is negligible if it is handled, transported, and laundered in a manner that avoids transfer of microorganisms to other patients, personnel and environments. If special handling, transporting, and laundering is indicated, specific procedures will be determined by Infection Control. In all other cases, facility policy and local/state regulations should determine the methods for handling, transporting, and laundering soiled linen.
- viii. Contaminated waste is sorted and discarded in accordance with the Guidelines for Disposal of Regulated Medical Waste, which complies with federal, state and local regulations.
- ix. Policies must be followed for the prevention of occupational injury and exposure to bloodborne pathogens in accordance with the <u>"Exposure Control Plan for Bloodborne Pathogens."</u>

h. Reporting

Any patient with a suspected or known exposure to or infection from a biothreat agent must be reported immediately to the local health department of the patient's county of residence. Specific instructions for reporting can be found in the <u>Reporting of Communicable Disease policy</u>. For questions regarding reporting call Hospital Epidemiology at 4-7500.

i. Discharge Management

Ideally, patients with biothreat-related infections will not be discharged from the facility until they are deemed noninfectious. However, consideration should be given to developing home care instructions in the event that large numbers of persons exposed may preclude admission of all infected patients. Depending on the exposure and illness, home care instructions may include recommendations for the use of appropriate barrier precautions, hand hygiene, waste management, and cleaning and disinfection of the environment and patient-care items. Discharge of any patient infected with a biothreat agent who remains potentially communicable should be coordinated with the local health department of the patient's county of residence.

Post-Mortem Care

McLendon Labs and the Department of Pathology must be informed of a potentially infectious outbreak prior to submitting any specimens for examination or disposal. All autopsies must be performed carefully using all personal protective equipment and standards of practice in accordance with Standard Precautions, including the use of masks and eye protection whenever the generation of aerosols or splatter of body fluids is anticipated. If the agent is suspected or known to be spread by the airborne route, personnel should follow Airborne Precautions.

D. Post-Exposure Management

1. Decontamination of Patients and Environment

The need for decontamination depends on the suspected exposure and in most cases will not be necessary. The goal of decontamination after a potential exposure to a biothreat agent is to reduce the extent of external contamination of the patient and contain the contamination to prevent further spread. Decontamination should only be considered in instances of gross contamination. Decisions regarding the need for decontamination should be made in consultation with state and local health departments. Decontamination of

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exposed individuals prior to receiving them in the health care facility may be necessary to ensure the safety of patients and staff while providing care. If decontamination is required, the patient should enter through the outside door into the decontamination room in the ED where removal of clothing and showering will take place.

Depending on the agent, the likelihood for re-aerosolization, or a risk associated with cutaneous exposure, clothing of exposed persons may need to be removed. Potentially harmful practices, such as bathing patients with bleach solutions, are unnecessary and should be avoided. Clean water, saline solution, or commercial ophthalmic solutions are recommended for rinsing eyes. If indicated, after removal at the decontamination site, patient clothing should be handled only by personnel wearing appropriate personal protective equipment, and placed in an impervious bag (e.g., sealed plastic patient clothing bag) to prevent further environmental contamination. The SBI or FBI may require collection of exposed clothing and other potential evidence for submission to SBI, FBI or Department of Defense laboratories to assist in criminal investigations.

2. Prophylaxis and Post-Exposure Immunization

Recommendations for prophylaxis are subject to change. Current recommendations for post-exposure prophylaxis and immunization are provided in Appendix 3 for relevant potential biothreat agents. However, up-to-date recommendations should be obtained in consultation with Orange County Health Department, North Carolina State Health Department and CDC. Facilities should ensure that policies are in place to identify and manage healthcare personnel exposed to infectious patients. In general, maintenance of accurate occupational health records will facilitate identification, contact, assessment, and delivery of post-exposure care to potentially exposed healthcare personnel.

Triage and Management of Large Scale Exposures and Suspected Exposures

Triage and management of large scale exposures and suspected exposure events will be coordinated by the Incident Command Team in consultation with Infection Control/Hospital Epidemiology and in accordance with the Emergency Operations Plan. Actions may include:

- a. Establishing networks of communication and lines of authority required to coordinate onsite care.
- b. Planning for cancellation of non-emergency services and procedures.
- c. Identifying source(s) able to supply available vaccines, immune globulin, antibiotics, and botulinum anti-toxin (with assistance from local and state health departments, and local and state emergency management).
- d. Planning for the efficient evaluation and discharge of patients.
- e. Developing discharge instructions for patients determined to be non-contagious or in need of additional on-site care, including details regarding if and when they should return for care or if they should seek medical follow-up.
- f. Determining availability and sources for additional medical equipment and supplies (e.g., ventilators) that may be needed for urgent large-scale care.
- g. Planning for the allocation or re-allocation of scarce equipment in the event of a large-scale event (e.g., duration of ventilator support of terminally afflicted individuals).
- h. With assistance from the Department of Pathology, identifying the institution's ability to manage a sudden increase in the number of cadavers on site.

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- 4. Exposure Reporting and Evaluation for Healthcare Personnel
 - a. An occupational exposure to a biothreat agent is an exposure that occurs within the healthcare facility while the employee is on duty. Criteria for an exposure depend on the biothreat agent and will be defined by Hospital Epidemiology using standardized CDC case definitions when available.
 - b. All occupational exposures must be reported to the appropriate occupational health service provider immediately.
 - i. Occupational Health Service: UNC Health Care personnel
 - ii. University Employee Occupational Health Clinic: UNC University employees
 - iii. Campus Health Service: UNC students
 - iv. Contract workers who are not UNC Health Care or UNC personnel but are providing medical services within our facilities and students who are not UNC students but who are working within our facilities should notify their assigned occupational health provider and be evaluated in the UNC Emergency Department if immediate care is required.

The occupational health service providers will notify the local health department of all employee exposures.

- c. Management of asymptomatic healthcare personnel exposed to a contagious biothreat agent (e.g., pneumonic plague, smallpox, viral hemorrhagic fever).
 - i. Persons who have been exposed to a communicable biothreat agent should notify their occupational health service provider immediately. They should also be vigilant for fever, rash, respiratory symptoms, or other signs and symptoms as directed by Hospital Epidemiology following exposure for a period of time that varies depending on the pathogen (time period to be defined by Hospital Epidemiology using standard CDC case definitions when available). Those who develop symptoms should limit interactions outside the home and should not go to work, school, out-of-home child care, church, or other public areas per public health recommendations.
 - ii. Exposed unprotected healthcare personnel who are asymptomatic, depending upon the disease, may be furloughed at the discretion of the Medical Director of the applicable occupational health service during the incubation period of the disease (time period to be defined by Hospital Epidemiology using standard CDC case definitions when available).
 - iii. Exposed unprotected healthcare personnel who are asymptomatic and who are allowed to work must be evaluated prior to work each day by the appropriate occupational health service.
 - iv. Such examinations will be performed for a period of time that varies depending on the pathogen following the last unprotected exposure (time period to be defined by Hospital Epidemiology using standard CDC case definitions when available). In addition, exposed asymptomatic healthcare personnel should take their own temperature 2x per day and report any elevated temperatures (i.e., ≥38.0°C) to their occupational health provider.
- d. Management of asymptomatic healthcare personnel with a *high-risk exposure* to a contagious biothreat agent (e.g., pneumonic plague, smallpox, viral hemorrhagic fever).

To manage an unprotected high-risk exposure of a [provider (i.e., healthcare provider in the same room as a patient infected with a highly communicable biothreat agent during a

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high-risk aerosol-generating procedure and infection control precautions are either absent or breached) with no symptomatic disease, the provider:

- i. Should be excluded from duty for a time period that depends on the specific pathogen (time period to be defined by Hospital Epidemiology using standard CDC case definitions when available) following the date of the last high-risk exposure.
- ii. Should limit activities outside the healthcare setting per public health recommendations and should be vigilant for development of fever, rash, and/or respiratory symptoms or other signs and symptoms as directed by Hospital Epidemiology.
- iii. Will document active surveillance for the development of symptoms, and the frequency of recording health status measures will be determined by occupational health service providers.
- e. Management of symptomatic healthcare personnel exposed to a contagious biothreat agent (e.g., pneumonic plague, smallpox, viral hemorrhagic fever).
 - i. Exposed healthcare providers who develop fever, rash and/or respiratory tract symptoms or other signs and symptoms as directed by Hospital Epidemiology should not report to work. Rather they should immediately report by phone to their appropriate occupational health provider the development of fever, rash, respiratory tract, and/or other symptoms. An appropriate health provider will evaluate symptomatic persons as medically necessary in the Infectious Disease Clinic. Alternatively, symptomatic healthcare personnel could be medically evaluated in alternative locations as directed by the Incident Commander. For serious symptoms, employees should be evaluated immediately in the Emergency Department, but must the ED must be notified in advance of the disease exposure.
 - ii. If symptoms do not progress to meet the suspect biothreat agent case definition within the time period to be determined by specific infectious agent (time period to be defined by Hospital Epidemiology using standard CDC case definitions when available), the person following permission from their appropriate occupational health provider may be allowed to return to work (depending on the pathogen), school, out-of-home child-care, church or other public areas per public health recommendations, and infection control precautions may be discontinued per Hospital Epidemiology recommendations.

5. Psychological Aspects of Biothreats

Following a biothreat-related event, fear and panic can be expected from both patients and healthcare providers. Psychological responses following a biothreat event may include horror, anger, panic, unrealistic concerns about infection, fear of contagion, paranoia, social isolation, or demoralization. Mental health support personnel (e.g., psychiatrists, psychologists, social workers, clergy, Critical Incidence Stress Management Team (CISM), and volunteer groups) may be asked to assist the Director On Call and/or Public Affairs office. Local, state, and federal media experts can provide assistance with communications needs.

Fearful or anxious healthcare personnel may benefit from their usual sources of social support (e.g., CISM, Occupational Health Service, Employee Relations).

E. Laboratory Support and Confirmation

The current McLendon Clinical Laboratories plan for management of potential biothreat agents should be followed (see McLendon Clinical Laboratories Disaster Preparedness Plan).

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1. Obtaining Diagnostic Samples

See specific recommendations for diagnostic sampling for each agent. Sampling should be performed in accordance with Standard Precautions. In all cases of suspected biothreat, collect an acute phase serum sample to be analyzed, aliquotted, and saved for comparison to a later convalescent serum sample. Send samples to McLendon Labs. McLendon Labs will coordinate with state and federal authorities as needed. Refer to the McLendon Labs on-line resource, "Laboratory Specimens for Suspected Bioterrorism Agents," for information regarding testing procedures.

2. Transport Requirements

Specimen packaging and transport must be coordinated with McLendon Labs. Advance planning should include identification of appropriate packaging materials and transport media in collaboration with the clinical laboratory at individual facilities.

F. Patient, Visitor, and Public Information

Clear, consistent, understandable information should be provided (e.g., via fact sheets) to patients, visitors, and the general public. Visitors may be strictly limited. Failure to provide a public forum for information exchange may increase anxiety and misunderstanding, increasing fear among individuals who attribute non-specific symptoms to exposure to the biothreat agent. All communication with the public will be provided by Public Affairs (and coordinated with Hospital Epidemiology and senior hospital management).

G. Policy Implementation

Implementation of this policy is the responsibility of Hospital Epidemiology, Occupational Health, and the Medical Staff.

IV. Reviewed/Approved by

Hospital Infection Control Committee

V. Original Policy Date and Revisions

Revised on July 2005, Aug 2007, July 2010, Aug 2013, Aug 2016

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Appendix 1: Important Contact Information

Federal Bureau of Investigation (FBI) Field Offices

FIELD OFFICE	STREET ADDRESS	ZIP CODE	TELEPHONE NUMBER
Charlotte, NC	7915 Microsoft Way	28273	704/672-6100
Washington, D.C.	601 4 th Street, NW	20535	202/278-2000

Telephone Numbers for NC Public Health Director and Local Health Department

NC Department of Health and Human Services State Health Director Phone No. (919) 707-5001 Fax No. (919) 870-4829

General Communicable Disease Branch (24 hour number)

Phone No. (919) 733-3419

Public Health Command Center (activated during disasters)

Phone No. (919) 715-0988 or 1-888-820-0520

Email: phpr.nc@dhhs.nc.gov

Orange County Health Department

Phone No. (919) 245-2400 (x3 Chapel Hill office; x4 Hillsborough office)

University Biological Safety Officer

For information on: Standard Operating Protocols for post exposure follow-up of University researchers to select agents

Biological Safety Officer: office (919)962-5722 cell (919)883-7021
Associate Biological Safety Officer: office (919)962-5726 cell (919)883-7020

24-hour pager for Biological Safety Officer pager (919)216-3963

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Appendix 2: Epidemiologic Characteristics of Key Biothreat Agents

Disease	Pathogen	Mode(s) of Transmission	Risk of Human-to- Human Transmission	Isolation Precautions
Anthrax (A)#	Bacillus anthracis	Direct contact with contaminated animal products (e.g., hides), inhalation of spores, or ingestion of contaminated food.	Rare cases of human- to-human transmission via direct contact with cutaneous lesions. Risk of infection via inhalation from contaminated clothes/patient items.	Cutaneous: Contact Pulmonary: Standard
Hemorrhagic fever viruses (A)	Multiple agents*	Direct contact with potentially infective material (blood, vomitus stool, tissue).	Highly contagious via direct contact and droplet; possible sexual transmission; airborne transmission unclear	Special Precautions
Botulism (A)	Clostridium botulinum	Ingestions, aerosolization	None	Standard
Plague (A)	Yersinia pestis	Flea bite, cat scratch, inhalation.	High for pneumonic plague; theoretical for cutaneous plague (via inhalation from aspiration or irrigation). Risk of infection via inhalation from contaminated clothes/patient items.	Bubonic: Droplet for 72 hours after initiation of therapy Pneumonic: Droplet for 72 hours after initiation of therapy
Q fever (B)	Coxiella burnetii	Contact with product of conception, inhalation.	Rare. Risk of infection via inhalation from contaminated clothes/patient items.	Contact for delivery procedures; Standard for all other patient care
Smallpox (A)	Variola	Contact with lesions, droplet and airborne	Highly contagious via direct contact and airborne	Special Airborne and Contact
Tularemia (A)	Franciscella tularensis	Contact, ingestion, or inhalation of contaminated products	None	Draining lesion: Standard Pulmonary:
				Standard

[#] CDC classification of biothreat agents

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^{*} Includes Ebola, Marburg, Lassa, Congo-Crimean fever, Argentinean, and Bolivian hemorrhagic fever

Appendix 3: Treatment Recommendations for Key Biothreat Agents

Pathogen	Pre-exposure prophylaxis	Post-exposure prophylaxis	Therapy
Bacillus anthracis	Vaccine (Follow ACIP/CDC recommendations for use)	Doxycycline 100 mg PO Bid x 60 days Or Ciprofloxacin 500 mg PO BID x 60 days Vaccine may be advised. OR Levofloxacin 500 mg PO Qd x 60 days (adults only) AND Anthrax vaccine	Inhalation disease: Doxycycline or Ciprofloxacin IV AND 1 other active drug (vancomycin, imipenem, rifampin) Vaccine may be advised.
Viral hemorrhagic fever viruses	None	None	Ribavirin (Lassa, Venezuelan, Korean, Savia, Argentinean, Bolivian, Junin, Machupa HF){not FDA approved for these diseases}
Yersinia pestis	None	Doxycycline 100 mg PO Bid Or Ciprofloxacin 500 PO Bid (2 nd line)	Streptomycin or gentamicin Alternatives: doxycycline 100 mg PO Bid or ciprofloxacin 400 Bid
Coxiella burnetii	None	Doxycycline 100 mg PO Bid	Doxycycline 100 mg PO Bid
Variola	Vaccinia vaccine (Follow ACIP/CDC recommendations for use)	Vaccinia vaccine	Cidofovir? {not FDA approved}
Franciscella tularensis	None	Doxycycline 100 mg PO Bid x 14 days Or Ciprofloxacin 500 PO Bid x 14 days (2 nd line)	Streptomycin or gentamicin Alternatives: doxycycline 100 mg PO Bid or ciprofloxacin 400 Bid

^{*} Include Ebola, Marburg, Lassa, Congo-Crimean fever, Argentinean, and Bolivian hemorrhagic fever

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Appendix 4: Syndromic Surveillance Case Definitions

Case Definition for Fever and Rash

Clinical Description

Acute (</= 2 days) onset of generalized (predominantly on face, arms, legs) rash and fever of unknown origin (FUO) (>/= 38 $^{\circ}$ C).

Specific Signs & Symptoms

- ***Must have at least one rash sign or symptom AND one constitutional sign or symptom. May also have other symptoms.***
 - 1. <u>Rash</u>: blister, bumps, chickenpox, dot, erythema, hives, itchiness, measles, mouth sores, petechial rash, hemorrhagic rash, maculopapular rash, monkeypox, pox, pocks, pustule, red spots (tongue, mouth, skin), RMSF, shingles, skin inflammation, skin irritation, skin redness, skin sores, varicella, variola, welps, welts
 - 2. <u>Constitutional</u>: achy, backache, body aches, chills/shivers/rigors, diaphoresis/sweaty, dizziness, drowsy/exhausted/fatigue/tired, fever (>/= 38°C)/febrile/fever of unknown origin (fuo)/temperature, headache, H/A, hurts all over, joint pain, lightheaded, loss of appetite/poor/decreased/no appetite, malaise, muscle aches, myalgias, prostration, weariness, wooziness...Pediatric cases: fussiness, cranky, irritable
 - ** OR any of these diagnoses by themselves: **
 - 3. Anthrax, (Bubonic) Plague, Smallpox, Tularemia

Comments:

- This syndrome represents many possible diagnoses both specific and non-specific.
 Included conditions: fever and septicemia**** (not otherwise specified), unspecified viral illness
- Excluded conditions: allergic or inflammatory skin conditions such as contact or seborrheaic dermatitis, rosacea, rash due to poison ivy or sunburn, eczema
- Diagnoses of particular concern:
 - Category A agents: plague, smallpox, viral hemorrhagic fevers (Ebola, Marburg, Old World Lassa, Junin, Machupo)
 - Other diagnoses of public health priority: vaccine preventable diseases (rubella, varicella, measles)

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Case Definition for Gastrointestinal Illness (GI)

Clinical Description

Acute (</= 7 days) onset of upper or lower gastrointestinal tract disease. Excludes chronic conditions.

Specific Signs and Symptoms

- ***Must have at least one gastrointestinal AND one constitutional sign or symptom. May also have other symptoms.***
 - 1. <u>Gastrointestinal:</u> abdominal bloating, abdominal pain, anorexia, loss of appetite, poor/decreased/no appetite, ascites, bloody stool/diarrhea, bloody vomiting/hematemesis, diarrhea, emesis, flatus, gassiness, nausea, vomiting
 - 2. <u>Constitutional:</u> achy, backache, body aches, chills/shivers/rigors, diaphoresis/sweaty, dizziness, drowsy/exhausted/fatigue/tired, fever (>/= 38°C), febrile, temperature, fever of unknown origin (fuo), headache, H/A, hurts all over, joint pain, lightheaded, loss of appetite, poor/decreased/no appetite, malaise, muscle aches, myalgias, prostration, weariness, wooziness

Pediatric cases: fussiness, cranky, irritable

OR Any of these diagnoses by themselves:

3. Anthrax

Comments:

- This syndrome represents many possible diagnoses both specific and non-specific.
- Patients may exhibit other symptoms: cyanosis, edema, toxemia.
- Excluded conditions: IBS, Crohn's
- Diagnoses of particular concern:
 - Category A agents: anthrax (gastrointestinal)
 - Other diagnoses of public health priority: foodborne diseases, Shigella, Salmonella, E.coli, O157:H7
- Chemical agents:
 - Vesicants/Blister Agents: sulfur mustard, lewisite, nitrogen mustard, mustard lewisite, phosgene-oxime
 - Ricin (Castor bean oil extract)
 - T-2 mycotoxins: Fusarium, Myrotecium, Trichoderma, verticimonosporium, Stachybotrys

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Case Definition for Respiratory Illness

Clinical Description

Acute (</= 14 days) onset of lower respiratory tract disease (from larynx to lungs). Excludes certain chronic conditions

Specific Signs & Symptoms

Must have at least one respiratory AND one constitutional sign or symptom. May also have other symptoms.

1. Respiratory:

cough, cyanosis, difficulty breathing, hemoptysis, hypoxia, pleural effusion, pleurisy, pneumonia, respiratory stridor, shortness of breath/SOB/dyspnea, tachypnea/increased respiratory rate

2. Constitutional:

achy, body aches, chills/shivers/rigors/shakes, diaphoresis/sweaty, dizziness, drowsy/sleepy/tired/ exhausted/fatigue, fever (>/= 38°C)/febrile/FUO/temperature, hurts all over, joint pain, light headed, loss of appetite/ poor/decreased/no appetite, malaise, muscle aches, myalgia, prostration, weariness, wooziness

Pediatric cases: cranky, fussiness, irritable

OR Any of these conditions by themselves:

3. Anthrax, Plague, SARS, Tularemia, influenza

Comments:

- This syndrome represents many possible diagnoses both specific and non-specific.
- Excluded conditions: CHF
- Diagnoses of particular concern:
 - o Category A agents: anthrax, plague, tularemia
 - Other diagnoses of public health priority: SARS, influenza
- Chemical Agents:
 - Vesicants/Blister Agents: sulfur mustard, lewisite, nitrogen mustard, mustard lewisite, phosgene-oxime
 - Pulmonary/Choking Agents: phosgene, chlorine, diphosgene, chloropicrin, oxide of nitrogen, sulfur dioxide
 - Ricin (Castor bean oil extract)
 - o T-2 mycotoxins: Fusarium, Myrotecium, Trichoderma, verticimonosporium, Stachybotrys

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Case Definition for Neurological Illnesses

Clinical Description

Acute (</= 14 days, typically </= 48 hours) onset of neurological disease of the CNS. Excludes chronic conditions

Specific Signs & Symptoms

Must have at least one neurological AND one constitutional sign or symptom.

1. Neurological:

altered mental status/AMS, blurred vision, coma, convulsions/seizures, cranial palsy, descending flaccid paralysis, difficulty focusing to near point, difficulty swallowing, diplopia/double vision, dizziness, dysarthria/slurred speech, dysphagia/difficulty swallowing, forgetfulness, headache, H/A, lack of feeling/sensation, loss of consciousness/unconscious, muscle weakness, nuchal rigidity/stiff neck, numbness/facial numbness, prostration, ptosis/drooping eyelids, respiratory paralysis, shake, somnolence, spasm, stiff neck, stupor, tingling, tremor

2. Constitutional:

achy, backache, body aches, chills/shivers/rigors, diaphoresis/sweaty, exhausted/fatigue/tired, fever (>/= 38°C)/febrile/fever of unknown origin (fuo)/temperature, hurts all over, lightheaded, loss of appetite/poor/decreased/no appetite, malaise, muscle aches, myalgias, prostration, weariness, wooziness Pediatric cases: fussiness, cranky, irritable

Comments:

- This syndrome represents many possible diagnoses both specific and non-specific.
- Patients may exhibit other symptoms: constipation, nausea, vomiting, eye pain, rash, dry mouth.
- Excluded conditions: chronic, hereditary, or degenerative conditions of the CNS (obstructive hydrocephalus, Parkinson's, Alzheimer's), head injuries.
- Diagnoses of particular concern:
 - Diagnoses of public health priority: meningococcal/pneumococcal meningitis, viral encephalitis (WNV, EEE, CAL)
 - Chemical agents:

Nerve: Sarin (GB), Tabun (GA), Soman (GD), Cyclohexyl Sarin (GF), VX, Novichok agents, organophosphorous compounds (carbamates & pesticides)

Cyanides: hydrogen cyanide (HCN), cyanogen chloride

<u>T-2 mycotoxins</u>: Fusarium, Myrotecium, Trichoderma, verticimonosporium, Stachybotrys

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Case Definition for Botulism-Like Illness

Clinical Description

Acute (</= 14 days, typically </= 48 hours) onset of neurological disease of the CNS. Excludes chronic conditions

Specific Signs & Symptoms

Must have at least one neurological AND one constitutional sign or symptom.

1. Neurological:

altered mental status/AMS, aphasia, areflexia/hyporeflexia/decreased reflexes, ataxia, blurred/blurry vision, coma, difficulty focusing to near point, difficulty reading, difficulty seeing, dry mouth, dysphagia/difficulty swallowing, difficulty walking/unsteady gait, diplopia/double vision, drooping/droopy eyelids, drooling/difficulty handling secretions, dysarthria/slurred speech/difficulty speaking, facial droop, hypotonia/decreased tone, lethargy, loss of consciousness/LOC, loss of head control, numbness, nystagmus, palsy, ptosis, pupils dilated, pupils fixed, paralysis (descending flaccid, gaze, & respiratory muscle), somnolence, stupor, unconscious, visual changes, weakness (arm, leg, muscle)

2. Constitutional:

anorexia/poor/decreased/loss of/no appetite/not eating, constipation, difficulty breathing, diarrhea, drowsy, dyspnea, emesis/vomiting, exhausted/exhaustion, fatigue, hypoxia, malaise, nausea, prostration, SOB/shortness of breath, sleepy, tired, tremor, weariness, wooziness

Pediatric cases: fussiness, cranky, irritable

** Or any of these diagnoses by themselves: **

3. Botulism

Comments:

- Diagnoses of particular concern: Category A agent Botulism
- Excluded conditions: myasthenia gravis, head injuries

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Case Definition for Meningoencephalitis Illnesses

Clinical Description

Acute (</= 14 days, typically </= 48 hours) onset of neurological disease of the CNS.

Specific Signs & Symptoms

1. Neurological:

altered mental status/AMS, back ache/back pain, blurred/blurry vision, coma, confusion, convulsion, disoriented/disorientation, drowsy/sleepy, eye pain, bulging fontanel/soft spot, forgetfulness, headache, irritable/irritability, lethargy, light sensitivity/sensitivity to light, loss of consciousness/LOC, meningismus, muscle weakness, neck pain, nuchal rigidity, numbness, photophobia, seizures, shake/shaking, somnolence, spasm, stupor, stiff neck, tingling, tremor, unconscious

2. Constitutional:

achy, backache, body aches, chills/shivers/rigors, diaphoresis/sweaty, dizziness, exhausted/fatigue/tired, fever (>/= 38°C)/febrile/fever of unknown origin (fuo)/temperature, hurts all over, lightheaded, loss of appetite/poor/decreased/no appetite, malaise, muscle aches, myalgias, prostration, weariness, wooziness Pediatric cases: fussiness, cranky, irritable

Comments:

- This syndrome represents many possible diagnoses both specific and nonspecific.
- Excluded conditions: head injuries
- Diagnoses of particular concern
 - Diagnoses of public health priority: meningococcal/pneumococcal meningitis, viral encephalitis (WNV, EEE, CAL)
 - o Chemical agents:

Nerve: Sarin (GB), Tabun (GA), Soman (GD), Cyclohexyl Sarin (GF), VX, Novichok agents, organophosphorous compounds (carbamates & pesticides)

Cyanides: hydrogen cyanide (HCN), cyanogen chloride

T-2 mycotoxins: Fusarium, Myrotecium, Trichoderma, verticimonosporium, Stachybotrys

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