Historical Perspective of Bioterrorism and Clinical Laboratory Preparedness

Bioterrorism is the intentional or threatened use of viruses, bacteria, fungi, or toxins of living organisms to produce death or disease in humans, animals, or plants. Often, the purpose of the bioterrorist is to inflict harm, create fear, or kill large numbers of people to accomplish political or social objectives. Sometimes the motive of bioterrorists is unknown.

Biological warfare dates back to at least the 14th century when plague was used in the city of Kaffa. Kaffa is an ancient city on the Crimean Peninsula situated on the ancient silk route between China and Europe. Rival merchants were at war with Tartar tribesmen, who brought plague from the East. As the epidemic spread, plague bodies were catapulted over the walled city; soon plague broke out to force a retreat to the East.

In the 18th century, the British used smallpox infested scabs in blankets and clothing during the War with the Indians, which led to an epidemic that so weakened the opposition that the British won the war. Chemical agents were used in the 20th century when mustard gas was used during World War I. In 1943, after learning that the Japanese were developing biological warfare for use against China and Mongolia, the United States launched a biological warfare program.

In 1953, the Department of Defense began a bioweapons program at Fort Detrick. However, in 1969, President Nixon signed a treaty to ban biological weapons, and the Fort Detrick facilities ceased its development of biological warfare agents. Because of atrocities against people and prisoners of war, the Geneva Protocol was signed to reduce or eliminate these occurrences. However, the United Nations did not sign a biological weapons convention until 1972, and the Geneva Convention was not ratified until 1975.

In the 1990’s the World Trade Center in New York City and the Federal Building in Oklahoma City were bombed by terrorists to garner attention for particular purposes.

Bioterrorism is first and foremost a law enforcement event, and our public health response must be integrated with law enforcement agencies.

There are several reasons why biological weapons are selected by terrorists. They offer advantages such as they are easy to obtain and inexpensive to produce, infection can be achieved by aerosols, and the organisms are fairly stable in the environment. Biological weapons easily spread person-to-person as the civilian population is susceptible. Such diseases are difficult to diagnose and treat, and the result is high morbidity and mortality. Also, the incubation period is long enough for the perpetrator to get away before the first case of the disease appears, even before anyone realizes a bioterrorist event has occurred.
How to Distinguish a Hoax from a Real Event

Diagnosis and confirmation of a bioterrorism agent by the clinical laboratory is absolutely essential for early recognition and proper response to a covert bioterrorist incident. The hospital clinical laboratory will be among the first responders. The laboratory must be able to respond rapidly to identify the agent or to refer the agent to the State Public Health Laboratory without delay.

Most anthrax threats are hoaxes, but they have a significant disruptive effect on society. In the first four months of 1999, Federal and local officials responded to 261 anthrax hoaxes. Federal agencies responded to between 750 and 800 anthrax and other hoaxes that year.

Hoaxes create panic, but if there is actual release of a bioterrorism agent it would potentially disseminate over a large geographic area, overwhelming medical care services. Some of the first responders to such an incident are primary health care personnel, hospital ER staff, EMS personnel, other emergency preparedness personnel, laboratory personnel and law enforcement.

Federal agencies have created a critical agents list of potential bioterrorism agents. They include Bacillus anthracis, Yersinia pestis, Francisella tularensis, Brucella spp, Vibrio cholerae, Coxiella burnetii (Q-fever), Variola major (smallpox), Viral hemorrhagic fevers, Eastern equine encephalitis, Botulinum toxin, Staphylococcus Enterotoxin-B, Ricin and T-2 Mycotoxins. Person-to-person transmission of these agents occurs only for smallpox, plague bacillus, and viral hemorrhagic fevers.

The agents of greatest concern are smallpox, tularemia, plague, anthrax and botulinum toxin. Rapid diagnostic tests to detect these agents are currently being developed by the Centers for Disease Control and Prevention (CDC) and selected State Public Health Laboratories. Rapid diagnostic methods include amplification of genetic material in the nucleic acid or chromosome of these bioterrorism agents, and the use of antigen detection tests to detect the presence of these agents in clinical material.

Chemical and Biological Terrorism Events: Historical

Several incidents of terrorism have occurred in the recent past.

- **1979 - Sverdlovsk Russia, Anthrax outbreak:** U.S. intelligence reported hundreds of fatalities of both civilian and military personnel due to pulmonary anthrax. The facility at Sverdlovsk was suspected of being a germ-warfare facility.
- **1984 - Dalles, Oregon:** Rajneesh followers attempted to influence a local election by contaminating local salad bars with Salmonella, to hopefully sicken voters and keep them away from the polls. 751 cases of Salmonellosis occurred. It was almost a year before the State Health Department in Oregon discovered this event was a purposeful attack by the Rajneesh, who grew the Salmonella in a special laboratory. A culture of the organism was recovered from the Rajnees lab by the Oregon State Public Health Laboratory and the lab genetically compared this culture with isolates from several patients to demonstrate identical genetic types.
- **1995 - Arkansas:** A Ricin toxin threat occurred, which turned out to be a hoax.
- **1996 - Dallas, Texas:** A disgruntled employee contaminated the muffins and doughnuts in the laboratory employee’s break room with a Shigella culture. Several diarrheal illnesses occurred in 12 of 45 lab workers in a large medical center. The organism recovered was Shigella dysenteria type 2.
- **1997 - Washington, D.C.:** At B’nai Brith headquarters in Washington, an anthrax hoax occurred by Counter Holocaust Lobbyists of Hillel.
- **1998 - 1999:** There was a series of bioterrorist threats of anthrax exposure, including letter threats and telephone threats.

The FBI has been designated by the President to be the lead agency during the crisis management phase of a terrorist incident. It is a law enforcement event, and it is critical to protect the evidence and document a chain of custody. Federal Emergency Management Agency (FEMA) is responsible for coordinating the consequence management phase to assist in recovery from an event. State and local governments can request this support.

Select Agent Rule

National concern over the use of microorganisms and toxins as agents of bioterrorism led to the Antiterrorism and Effective Death Penalty Act of 1996. Section 51.1 of the legislation resulted in the final rule. “Additional requirements for facilities transferring or receiving
select agents” (42 CFR Part 72.6, Federal Register, Oct. 24, 1996), commonly referred to as the Select Agent Rule. This Rule is designed to ensure that infectious agents and toxins are shipped to institutions or individuals that have legitimate reason to use them and are equipped to handle them appropriately.

A system of safeguards was created by the Select Agent Rule, which provides information on the location of potentially hazardous agents as they are transferred, tracks the acquisition and transfer of these agents, and establishes a process for alerting the proper authorities if an unauthorized attempt is made to acquire these agents. A component of the Rule is a comprehensive list of Select Agents. (See chart).

The Rule also includes a mechanism for registering facilities, the transfer requirements, verification procedures, agent disposal, and research and clinical exemptions.

Clinical laboratories utilizing these agents for diagnostic, reference, verification or proficiency testing are exempt from the provisions of the Select Agent Rule. Testing laboratories involved in food safety, animal health, or evidence for law enforcement are also exempt from the Select Agent Rule.

Select Agents must be transferred in accordance with federal regulations for shipping infectious substances. Appropriate packaging material and completion of the “Shippers Declaration for Dangerous Goods” are required. If a CLIA certified laboratory transfers specimens to a non-exempt facility, the CLIA laboratory must complete form EA101, using their CLIA certification number in lieu of a Select Agent Registration number.

### Select Agents

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What Can the Clinical Laboratory Do For Bioterrorism Preparedness?

1. **Increase Awareness of the Potential for a Bioterrorist Occurrence**
   During 1999, over 750 bioterrorism hoaxes or threats occurred in the United States. Some occurred in hospitals and were initiated by disgruntled employees with access to laboratory cultures. Remember, when a bioterrorism incident is least expected is when it is most likely to occur.

2. **Develop Laboratory Preparedness for Bioterrorism Incidents**
   Have laboratory procedures in place to rule-in or rule-out the critical bioterrorism agents. Procedures can be obtained from the State Public Health Laboratory. Refer all isolates of critical bioterrorism agents to the State Public Health Laboratory.

3. **Have a Response Plan in Place**
   Have a plan so that all laboratory employees know how they are to respond to a bioterrorism event.

4. **Have Individual and Collective Protection Available**
   Garments that provide individual barrier protection should be available for all laboratory employees (gloves, gowns, face shields, eye protection). Physical barrier protection (isolation rooms for cultures, safety cabinets, proper airflow) must also be available.

5. **Have the Capacity to Detect and Characterize Microorganisms**
   Level A laboratories should have the capability to rule-out the critical bioterrorism agents, and refer agents they are unable to rule-out to a Level B/C public health laboratory. This process must occur with minimal delay.

References

1. Biological warfare and bioterrorism: the military and public health response. US Army Medical Research Institute of Infectious Diseases, Center for Disease Control and Prevention, September 1999.

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![Select Agents Chart](chart.png)
# Laboratories Administration -- Important Contacts

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<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Office</th>
<th>Home</th>
<th>Fax</th>
<th>E-mail</th>
</tr>
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<tbody>
<tr>
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<td>410-333-5312</td>
<td><a href="mailto:myersr@dhmh.state.md.us">myersr@dhmh.state.md.us</a></td>
</tr>
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</table>

**STATE EMERGENCY NUMBER**

410-795-7365

Cut and Post for future reference.