

Disclaimer: This case study is solely an educational exercise and does not necessarily reflect the position of Centers for Disease Control and Prevention on this issue.

Ensuring Biosafety/Biosecurity during a Public Health Emergency

Background

In 2002 in the wake of the 9/11 attack and anthrax scare, the Public Health Security and Bioterrorism Preparedness and Response Act (the Act) was enacted. The Act authorizes the U.S. Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of a select biological agent or toxin (SAT) that has the potential to pose a severe threat to public health and safety. Authority to establish regulations to implement the Act was delegated to the Centers for Disease Control and Prevention (CDC). CDC promulgated the select agent and toxin regulations and implemented robust oversight of entities that possess, use, or transfer SAT (1). The list below details some regulatory requirements that an entity must fulfill:

- To ensure adherence to appropriate biosafety and security measures, an entity must register with and be inspected by CDC.
- All individuals who will have access to SATs must undergo a security risk assessment conducted by the FBI's Criminal Justice Information Services.
- To transfer a SAT, entities must seek prior approval from CDC.
 - Diagnostic laboratories that do not routinely possess SAT, but might encounter these materials in the routine analysis of samples, are exempted from most of the requirements of the select agent regulations. For these exempted laboratories, the following SAT regulatory requirements apply: the transfer of the select agent or toxin to a registered entity or destruction of the select agent or toxin, within seven calendar days;
 - The select agent or toxin is secured against theft, loss, or release; the identification of the select agent or toxin is reported to CDC

In the past, tensions between the scientific community and the regulatory community have arisen regarding the impact of the SAT regulations on the important and legitimate use of these materials (2, 3). Critics of the SAT regulations argue that increased biosafety and security oversight requirements delay scientific and diagnostic investigations and adversely impact the efficient allocation of scarce resources. They posit that the adverse impact of such delays would be especially critical in emergency response to disease outbreaks. However, the Act also authorizes the HHS Secretary to exempt an entity from some or all SAT regulations in cases of a declared public health emergency. This exemption provision could cover emergencies that involved either a significant outbreak of infectious disease or a bioterrorist attack, allowing a response to proceed as efficiently as possible.

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The laboratory response network (LRN) is a key component of a national system of response to a significant outbreak of infectious disease, bioterrorist attack, or other public health emergencies. The LRN consists of an infrastructure of local, state and federal laboratories that includes public health, food testing, veterinary diagnostic, and environmental testing laboratories. Most state public health laboratories participate as LRN reference laboratories to which samples are referred and that will investigate samples. More than 150 state and local public health, military, international, veterinary, agriculture, food, and water testing laboratories comprise the LRN. These facilities support hundreds of sentinel laboratories, which are hospital-based, clinical institutions, or commercial diagnostic laboratories. Sentinel laboratories play a key role in the early detection of biological agents. While sentinel laboratories may not be equipped to perform the same tests as LRN reference laboratories, they can test samples in a limited capacity and to rule out or refer suspect SAT samples (4). Although reference laboratories generally are registered with the CDC, many sentinel laboratories are not.

Case Description

Due to a human outbreak of a viral respiratory illness in the Los Angeles-San Francisco corridor, the HHS Secretary is considering exempting a subset of the SAT regulatory requirements. The intelligence/law enforcement community has reason to believe that this outbreak is due to an intentional release by terrorists of a bio-engineered strain of SARS. As a result, they would like to pursue a criminal investigation that would entail tightly tracking all the samples as forensic evidence. The possibility of terrorist bioengineering also raises the concern that the new strain possesses increased virulence and transmissibility in humans, which would exponentially increase the threat posed to both the public and laboratorians by this outbreak. So far the outbreak has involved multiple elementary schools in Los Angeles and San Francisco.

Initial analysis has determined that the illness is due to Severe Acute Respiratory Syndrome (SARS). Since the 4 local sentinel laboratories involved are not registered with the CDC for possession of SARS virus, and they do not want to destroy their hundreds of samples, they are required by regulation to transfer confirmed SARS samples to a CDC registered reference laboratory within 7 days. As a result, the sent samples are overwhelming CDC SARS-registered reference laboratories. To handle the sample surge, the overwhelmed CDC registered laboratories would need to augment their staff with laboratory technicians who have not undergone a security risk assessment. In the meantime, they would like sentinel laboratories to keep their samples as the registered laboratories are running out of storage space. The LRN would like to transfer their samples to laboratories that can perform more detailed analysis of the SARS strains to determine the exact genetic sequence of critical marker genes. Not all of these laboratories, however, are registered with the CDC. Further, in order to transfer the confirmed SARS samples, the LRN needs permission from the CDC, which will add to the response time. The LRN is concerned that regulatory related delays are extending critical response times and therefore treatment of patients, especially vulnerable patients like children.

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While the CDC understands the LRN's concerns, they must also begin planning now for the follow-up that will be conducted once the outbreak has ended. Depending on the type of exemption granted by the Secretary, the CDC could be responsible for following up with hundreds of previously unregistered and uninspected laboratories that would have participated in the outbreak and still possess SARS, tracking down thousands of SARS samples, and performing hundreds of background checks on individuals who have access to the select agent.

To assist the LRN in their response, the HHS Secretary has invited you, the State Health Department Director, to provide input on the following proposed options for exemption of regulatory provisions:

1. Allow unregistered entities and laboratory technicians without a security risk assessment to immediately possess, use, and transfer SAT.
2. Allow an entity to possess, use, and transfer a SAT before the entity met the biosafety and security requirements of the SAT regulations.
3. Allow the transfer of SAT without prior approval from CDC.

Discussion Questions

1. Who are the stakeholders in this case and what values and perspectives do they bring to the issue about the implementation of the national strategy?
2. Allowing access to SAT by individuals without a security risk assessment could potentially allow access to SAT for individuals who would otherwise be denied such access. How would this influence your decision?
3. Allowing the transfer of SAT without prior approval could hamper the tracking of those who possess SAT within the United States. How would this influence your decision?
4. Would it impact your decision if the attack did not involve a vulnerable population such as children?
5. How does the existence or lack of scientific evidence regarding the impact of biosafety and security concerns in laboratory processing time influence your decision?
6. What would your recommendation to the Federal government be? In explaining why you have come to this recommendation, indicate what consideration or values you

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have prioritized.

7. Further study of the virus has determined that only the transmissibility of the SARS strain was increased but the virulence was not. Does this change your thinking? Why or why not?
8. Initial investigations by the intelligence/law enforcement community suggest that this attack may have been carried out by an insider who has expert knowledge of the biology of the organism and has access to the organism, who has the means to launch similar attacks elsewhere. Does this change your thinking? Why or why not?
9. The outbreak has spread beyond the initial schools and now includes members of the general population in Los Angeles and San Francisco, but also two reported cases in separate locations outside these two cities. Does this change your thinking? Why or why not?

References

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4. <http://www.bt.cdc.gov/lrn/biological.asp>

Acknowledgements

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