

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.

Emergency Preparedness: Impact of Regulatory Compliance and Resource Allocation Decisions on Laboratory Capacity

Background

Laboratory capacity is a critical component of national emergency preparedness for bioterrorism, chemical emergencies, and natural disasters. In the event of an emergency, rapid and effective analysis of both environmental samples and human specimens (e.g., blood and urine) is imperative to determine the toxin(s) or chemical agent(s) released, the area and extent of contamination, persons who have been exposed and the extent of their exposure. These analyses help guide emergency medical care, public health management, and follow-up actions (1).

Environmental laboratories analyze environmental samples such as air, water, and soil for microbiological and chemical contamination of both public and environmental health concerns. These testing activities may be conducted within state public health laboratories, covered under departments of environmental quality or natural resources, or performed by separate environmental laboratories. Environmental laboratories usually operate under various laws and regulations at both the federal and state levels, addressing waste disposal, water quality, air quality, food safety, and other environmental protection issues (2).

The Clinical Laboratory Improvement Amendments (CLIA) regulations are U.S. federal regulations for laboratories that test samples obtained from the human body for health care and health assessment purposes (3). All facilities that conduct “biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings” (42 CFR 493.2) are required to comply with CLIA regulations (3). Facilities that only conduct specimen collection, packaging and shipping, but do not perform testing procedures do not need to be CLIA-certified. In addition, FDA regulations apply to in vitro diagnostic (IVD) devices including test kits and analyte-specific reagents (ASRs) (4).

At the state level, CLIA requirements are frequently used to regulate clinical laboratories while some states have additional oversight of the practice of clinical laboratory medicine (5). New York and Washington independently operate their own state laboratory certification programs, which are exempt from CLIA because the Centers for Medicare and Medicaid Services (CMS) has deemed their requirements as equal to or more stringent than CLIA requirements (6,7). Environmental laboratories are not subject to CLIA regulations or state requirements for clinical laboratories when they do not perform testing on samples derived from the human body (8).

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Case Description

As part of the state's emergency preparedness and planning, state X is considering strengthening its capacity to prepare for and respond to all hazards, including bioterrorism, chemical emergencies, and natural disasters. A taskforce is formed to develop a proposal for a statewide laboratory network that includes public health laboratories, environmental laboratories and other testing facilities. The laboratory network is expected to participate in the CDC Laboratory Response Network (LRN) that consists of three levels of laboratories (1):

- Level 3 laboratories have chemists and/or medical technologists on staff to work with hospitals and other first responders within their jurisdiction and are capable of specimen collection, storage, and shipment;
- Level 2 laboratories are staffed with one Ph.D. chemist, or an individual with equivalent experience, and multiple laboratory support personnel who are competent in analytical and clinical chemistry plus laboratory quality assurance in measuring and detecting exposure to a number of toxic chemical agents and will test human samples; and
- Level 1 laboratories are able to detect a broader range of toxic chemicals and also expand CDC's ability to analyze large numbers of patient samples when responding to large-scale exposure incidents.

As a local health director for a jurisdiction in State X where several environmental laboratories are located, you are serving on this taskforce to evaluate the proposed laboratory network and options for designating your state's laboratories at each specific response level. The taskforce must also consider resource allocation needs associated with each option because your state is experiencing significant budget constraints. Some funding is available from the CDC to support participation in the LRN, but the state will subsidize part of the costs. The following options are presented for the taskforce to consider:

1. Designate all public health and environmental laboratories at the state and county levels to be Level 2 laboratories, to enable these laboratories to test human specimens during emergency responses and rapidly produce accurate test results. These laboratories would be required to apply for and maintain CLIA certification including compliance with the CLIA quality system requirements and personnel requirements for high complexity testing. Hiring additional staff, providing training and documenting competency, participating in proficiency testing, additional facility needs, and the costs that could be incurred are among the budgetary and logistic concerns.
2. Designate laboratories that already have a CLIA certificate as Level 2 laboratories and the public health and environmental laboratories that are not CLIA-certified as level 3 laboratories. This option would allow the laboratories to enhance their capabilities based on their current capacity; however, you are concerned about the geographic locations of some potential Level 3 laboratories. These would include the environmental laboratories in your jurisdiction which are located a significant distance from the nearest Level 2-designated laboratories. You think the ideal way to ensure rapid detection and determination of possible human exposure would be for these environmental laboratories to have the capability of testing human specimens, but this

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would require these laboratories to meet all the requirements to attain CLIA certification for high complexity testing. You are also aware that the environmental laboratories in your jurisdiction do not have the training or experience with testing human samples.

3. Designate selected public health and environmental laboratories at the state and county levels to be Level 2 laboratories. Based on their geographic locations and distances from the nearest hospitals, you would like to suggest that all the environmental laboratories in your jurisdiction should be Level 2 laboratories. A manufacturer that develops test kits and reagents is located within your jurisdiction and has an interest in developing a test system that can accommodate testing of both environmental samples and human specimens while advocating for use of its products for routine surveillance and emergency preparedness.
4. Enact a new state law to give the governor the authority to declare state emergencies, during which a waiver can be granted to Level 3 laboratories to not only collect and ship specimens, but also to perform testing of human specimens if needed.

Discussion Questions

1. Who are the main stakeholders in this case and how will they react to each option?
2. How would you assess the four options presented to your Taskforce? What are the advantages and disadvantages, and the ethical issues associated with them?
3. Are there other legal and ethical issues associated with each option?

References

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