DEPARTMENT OF HEALTH & HUMAN SERVICES

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Director
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FROM: Daniel R. Levinson
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SUBJECT: Memorandum Report—Laboratory Preparedness for Pandemic Influenza, OEI-04-07-00670

This memorandum report provides information on laboratory pandemic influenza preparedness as requested in April 2007 by officials at the Centers for Disease Control and Prevention (CDC).

The Office of Inspector General (OIG) surveyed State public health laboratory officials in June 2007 about the extent to which they conducted the eight critical tasks for public health laboratory testing as required by the Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement, Phase II (the Guidance).[1]

All States reported that their public health laboratories performed the first two critical tasks, to conduct year-round influenza testing and to detect and subtype influenza viruses.[2] Although not specifically required by the Guidance, all States reported public health laboratory capability to subtype H5 influenza.[3] The H5 subtyping test is currently only available to public health laboratories. Consistent with this, most States reported that they have no sentinel laboratory capability to subtype H5 influenza.[4] However, this capability may be necessary to meet increased testing needs during an H5 influenza pandemic.

All States reported that their public health laboratories did not perform at least one of the six remaining critical tasks. For the tasks involving both public health and clinical laboratories,

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[1] The eight critical tasks are outlined in Attachment B under Pandemic Influenza Preparedness Goal 3: Detect and Report, Target Capability 3B. The Guidance is available online at http://www.bt.cdc.gov/planning/coopagreement/pdf/phase2-panflu-guidance.pdf. Accessed August 27, 2007.

[2] There are different types of influenza viruses (e.g., H1, H3, H5). Subtyping refers to the ability to distinguish one type of influenza from another.

[3] The H5 strain of influenza normally infects birds, but it has the potential to cause a human pandemic.

[4] Sentinel laboratories conduct initial screenings of biological specimens and refer suspicious specimens to public health laboratories.

States reported performing the required activities for public health laboratories to a greater extent than for clinical laboratories.[5]

BACKGROUND

Funding for Pandemic Influenza Preparedness and Response

In 2005, Congress appropriated $350 million for upgrading State and local capacity to prepare for and respond to an influenza pandemic. These funds have been awarded by the Department of Health and Human Services (HHS) in phases.[6] In March 2006, CDC awarded $100 million (Phase I) to 62 jurisdictions to identify gaps in their preparedness based on 60 critical tasks.[7][8] An updated version of these critical tasks is included in Attachment B of the Guidance. As of July 2006, CDC had awarded an additional $225 million to the same jurisdictions to address these preparedness gaps (Phase II). CDC plans to award the remaining $25 million through competitive grants to eligible recipients. Awardees are expected to complete tasks supported by the Guidance in 3 years, ending in 2009. By 2009, CDC expects that awardees should be fully prepared to respond to and control an influenza pandemic.[9]

In August 2007, the Secretary of HHS announced another $75 million for pandemic influenza preparedness.[10] These grants will supplement funds dedicated to strengthen the ability of the Nation's health care community to respond to bioterrorism, infectious diseases, and natural disasters.

Public Health Laboratory Testing Requirements for Pandemic Influenza Preparedness

The eight required critical tasks for public health laboratory testing as specified by the Phase II Guidance are to:

1. maintain the ability to test for influenza viruses year-round;

2. perform polymerase chain reaction (PCR) testing for rapid detection and subtyping of influenza viruses;

3. electronically exchange specimen-level data among clinical laboratories, the State public health laboratory, and CDC;

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[5] The tasks involving both clinical and public health laboratories are critical tasks 3, 5, 6, and 7.

[6] Emergency Supplemental Appropriations Act To Address Hurricanes in the Gulf of Mexico and Pandemic Influenza Act, 2006, Pub. L. No. 109-148, Division B, Title II, Chapter 6 (Dec. 30, 2005).

[7] These funds supplement the 2006 Public Health Emergency Preparedness Cooperative Agreement. Available online at http://www.bt.cdc.gov/planning/coopagreement/pdf/fy06announcement.pdf. Accessed August 27, 2007.

[8] The 62 jurisdictions are the 50 States, the District of Columbia, the cities of Chicago and New York, Los Angeles County, Puerto Rico, the U.S. Virgin Islands, and the 6 Pacific Basin jurisdictions.

[9] The Guidance, page 4, available online at http://www.bt.cdc.gov/planning/coopagreement/pdf/phase2-panflu-guidance.pdf. Accessed August 27, 2007.

[10] News Release available online at https://www.hhs.gov/news/press/2007pres/08/pr20070830a.html. Accessed September 3, 2007.

4. institute surveillance for influenza-like illness among laboratory personnel working with novel influenza viruses;

5. develop and exercise an operational plan to augment the capacity of public health and clinical laboratories to meet the needs of the jurisdiction during an influenza pandemic;

6. assess all public health and clinical laboratory influenza diagnostic testing proficiency and adherence to biosafety containment and biomonitoring protocols at least annually;

7. test the knowledge and competency of frontline clinicians and laboratory personnel with regard to:

    a. protocols for safe specimen collection and testing,
    b. the way in which and the person to whom a potential case of novel influenza should be reported, and
    c. mechanisms for submitting specimens to referral laboratories; and

8. determine how hospitals and health care systems will use systems and communication tools to report information to public health and response partners with an emphasis on regional hospital coordination.

Role of Clinical Laboratories in Public Health Preparedness and Response

As of June 2007, there were 210 public health laboratories in the U.S.[11] According to the Association of Public Health Laboratories, disease prevention, control, and surveillance should collectively represent a core function of State public health laboratories.[12] [13] However, privately owned clinical laboratories, which are not under the control of State public health laboratories, play a key role in States' ability to perform these activities, especially surveillance.

Clinical laboratories are often the first line of defense in a public health response because they perform diagnostic tests ordered by physicians and may be the first to identify the causes of illnesses in communities. However, not all clinical laboratories have the capacity to conduct initial screenings and refer suspicious specimens to a reference laboratory, usually the State public health laboratory, to confirm the presence of public health threats. Clinical laboratories that do have these capabilities are known as sentinel laboratories.[14]

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[11] Clinical Laboratory Improvement Amendments (CLIA) Update, Division of Laboratory Services, Centers for Medicare & Medicaid Services, Laboratories by Type of Facility, June 2007. Available online at http://www.cms.hhs.gov/CLIA/downloads/factype.pdf. Accessed September 17, 2007.

[12] "Core Functions and Capabilities of State Public Health Laboratories," p. 6. Available online at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.htm. Accessed August 29, 2007.

[13] Public health surveillance is the ongoing collection, analysis, and interpretation of health data to improve health and safety.

[14] Forty-nine States use this definition of sentinel laboratory in the pandemic influenza context.

Related Work
OIG is conducting a study of laboratory preparedness for bioterrorism and other public health emergencies. We expect to issue a final report on those findings in early 2008.

METHODOLOGY

Scope
We surveyed officials in all 50 States and the District of Columbia (hereafter referred to as States) about the extent to which they conducted the eight critical tasks for public health laboratory testing as required by the Guidance. Four of these critical tasks require coordination with clinical laboratories. We also asked the officials about public health and sentinel laboratory capability to subtype H5 influenza, as well as the type of preparedness exercises conducted by State public health laboratories (i.e., tabletop or full-scale).

Data Collection
We contacted the Cooperative Agreement coordinators in all States to inform them about our survey and to request the names of the most appropriate respondents. In most cases, we were referred to the State laboratory director or the bioterrorism coordinator. We sent an electronic mail survey to these public health laboratory officials identified by the Cooperative Agreement coordinator in each State and had a 100-percent response rate.

Data Analysis
We transferred State responses to our survey into an electronic database. Using the database, we determined the total number of States that reported performing each of the eight critical tasks. Where appropriate, we determined whether the State conducted an activity for both State public health and clinical laboratories.

Limitations
We asked State public health laboratory officials the extent to which they conducted the eight critical tasks for public health laboratory testing as required by the Guidance. However, responsibility for some of these tasks may fall under another State or non-State entity (e.g., the Office of Emergency Preparedness and Response or the College of American Pathologists, respectively). In addition, we did not collect supporting documentation to verify State responses to our survey, and we did not ask States about the performance measures associated with the eight critical tasks. Finally, our survey determined the extent to which State public health laboratories met Guidance requirements to include clinical laboratories in their preparedness planning. We did not directly survey clinical laboratory officials to determine whether they had performed pandemic influenza preparedness activities independent of the State public health laboratories.

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

RESULTS

***Critical task 1*: All States reported that they conduct year-round influenza testing**

Year-round influenza testing can detect the emergence of influenza viruses outside the normal influenza season. This early detection may lead to a faster public health response to a potential pandemic influenza outbreak. All 51 States reported that their public health laboratories conduct year-round influenza testing.

***Critical task 2*: All States reported the capability to perform PCR to detect and subtype influenza, but sentinel laboratory capability to subtype H5 influenza is limited or unknown**

The H5 strain of influenza infects birds but does not typically infect humans. However, it has caused human deaths and has the potential to evolve into a human pandemic strain.

Although not specifically required by the Guidance, all 51 States reported public health laboratory capability to use PCR to subtype the H5 influenza strain. The H5 subtyping test is currently only available to public health laboratories. Consistent with this, 44 of 51 States reported that they have no sentinel laboratories with the capability to perform H5 influenza subtyping, and 4 States reported that they did not know whether sentinel laboratories in their State had H5 influenza subtyping capability. However, this capability may be necessary to meet increased testing needs during an H5 influenza pandemic.

***Critical task 3*: States reported that they electronically exchange influenza data with CDC and public health laboratories to a greater extent than with clinical laboratories**

Public health officials often rely on patient-level data from clinical laboratories to determine an appropriate response to a public health event. Similarly, clinical laboratories often rely on State and national data from public health laboratories and CDC to determine appropriate laboratory testing.

Almost 90 percent of States (45 of 51) reported exchanging electronic influenza data with CDC. Similarly, almost 90 percent of States (45 of 51) reported either that they exchanged electronic influenza data within the State public health laboratory system (24 of the 45 States) or that this requirement was not applicable (21 of the 45 States). For example, this requirement is not applicable in a State with only one public health laboratory.

However, only 35 percent of States (18 of 51) reported electronic influenza data exchange between public health laboratories and clinical laboratories.

Table 1 shows the number of States reporting that the State public health laboratories exchanged electronic influenza data.

Table 1

Number of States Reporting That Public Health Laboratories Electronically Exchanged Influenza Data		
Entities With Which the Public Health Laboratories Electronically Exchanged Influenza Data	**Yes**	**Not Applicable**
CDC	45	0
Other State Public Health Laboratories	24	21
Clinical Laboratories	18	0

***Critical task 4*: Over half of all States reported that they instituted surveillance for influenza-like illness among laboratory personnel at risk for atypical influenza**
Laboratory personnel who conduct influenza testing are at risk of developing illness from seasonal influenza, as well as atypical influenza present during a pandemic. The earlier illness is detected, the earlier the State may take action and attempt to contain its spread. Sixty-two percent of States (32 of 51) reported that they conduct surveillance for influenza-like illnesses among laboratory personnel at risk of developing atypical influenza.

***Critical task 5*: States reported that they conduct pandemic influenza preparedness exercises in public health laboratories to a greater extent than in clinical laboratories**
Preparedness exercises present public health personnel hands-on practice of emergency plans and procedures. Exercises may also identify potential response weaknesses in advance of an actual event.

Eighty-two percent of States (42 of 51) reported developing operational plans to augment public health laboratory capacity during an influenza pandemic. Forty-three percent of States (22 of 51) reported conducting tabletop exercises of their operational plans, and 20 percent of States (10 of 51) reported conducting full-scale exercises.[15]

In contrast, 55 percent of States (28 of 51) reported developing operational plans for clinical laboratory capacity. Thirty-one percent of States (16 of 51) reported conducting tabletop exercises of plans to meet the increased need for clinical laboratory testing capacity during an

[15] In a tabletop exercise, participants respond to a simulated emergency without time constraints from an office environment. Tabletop exercises are intended to evaluate plans and answer questions about coordination and assignments of responsibility. In a full-scale exercise, participants respond to a simulated emergency under time constraints conditions just as they would in a real-world event. Full-scale exercises are intended to identify problems that may arise in executing a plan.

influenza pandemic, and less than 10 percent of States (5 of 51) reported conducting full-scale exercises.

Table 2 shows the number of States reporting that they have developed operational plans to augment laboratory capacity in an influenza pandemic and have tested those plans through tabletop or full-scale exercises.

Table 2

Number of States Reporting That They Have Developed and Tested Plans To Augment Laboratory Capacity		
Pandemic Influenza Preparedness Activity	**Public Health Laboratory Capacity**	**Clinical Laboratory Capacity**
Developed operational plan	42	28
Exercised operational plan – tabletop	22	16
Exercised operational plan – full-scale	10	5

***Critical task 6*: States reported that they conduct annual assessments of influenza-related practices in public health laboratories to a greater extent than in clinical laboratories**
Annual assessments of laboratory practices help to ensure that laboratory personnel are using the most current practices in responding to an influenza outbreak.

Depending on the laboratory practice, 65 percent to 82 percent of States (33 to 42 States) reported that the State public health laboratories conduct annual assessments of influenza-related activities in public health laboratories. However, only 12 percent to 20 percent of States (6 to 10 States) reported that the State public health laboratories conduct the same annual assessments in clinical laboratories.

Table 3 shows specific influenza-related practices and the corresponding number of States that reported conducting at least annual assessments in public health and clinical laboratories.

Table 3

Number of States Reporting That the Public Health Laboratories Annually Assess Influenza-Related Practices		
Areas State Public Health Laboratories Assess Annually	**Public Health Laboratory Assessments**	**Clinical Laboratory Assessments**
Influenza diagnostic testing proficiency	42	10
Adherence to influenza biosafety containment	42	7
Adherence to influenza biomonitoring protocols	33	6

Twenty-one States reported that they do not assess clinical laboratories on the activities specified in the Guidance because this function is performed by other organizations (e.g., the College of American Pathologists or the Centers for Medicare & Medicaid Services in its oversight of the Clinical Laboratory Improvement Act).

***Critical task 7*: States reported that they conduct tests on pandemic influenza preparedness activities for frontline laboratory personnel to a greater extent than for frontline clinicians**
Frontline clinicians and laboratory personnel who perform diagnostic tests play a significant role in public health emergency response. They may be the first to identify and trigger a State's response to illness in communities.

Depending on the laboratory practice, 53 percent to 73 percent of States (27 to 37 States) reported that their public health laboratories test frontline laboratory personnel on pandemic influenza preparedness activities (e.g., protocols for safe specimen collection and testing and referring potential cases of novel influenza).

Less than 25 percent of States (11 of 51) reported that their public health laboratories test clinicians on how to submit suspected influenza specimens to a testing laboratory. Even fewer States (7 of 51) reported that their public health laboratories test clinicians on the person they should contact when referring a potential case of novel influenza or on protocols for safe specimen collection or testing.

Table 4 lists specific pandemic influenza preparedness activities, along with the number of States reporting that their public health laboratories test each activity for frontline laboratory personnel and clinicians.

Table 4

Number of States Reporting That the Public Health Laboratories Test Influenza Preparedness Activities for Laboratory Personnel and Clinicians

Preparedness Activity Tested	Laboratory Personnel Testing	Clinician Testing
Protocols for safe specimen collection	28	7
Protocols for safe specimen testing	32	7
How to refer a potential case of novel influenza	27	8
Person to contact when referring a potential case of novel influenza	29	7
How to submit specimens to a referral laboratory	37	11

Two States reported that they do not test frontline laboratory personnel or clinicians because they receive pandemic influenza preparedness testing or training through a third party (e.g., the Health Resources and Services Administration or the State Office of Epidemiology). In addition, one State reported that because public health laboratory personnel are not responsible for collecting specimens or referring potential cases of novel influenza, they are not tested on these tasks.

***Critical task 8*: Twenty-five percent of States reported that they determine how hospitals and health care systems would use pandemic influenza communication tools**

Accurate communication during a health event enables public health officials to determine the optimal course of action in responding to an event. States should formalize communication procedures in advance to avoid confusion and miscommunication during an actual event.

Twenty-five percent of States (13 of 51) reported that their State public health laboratories have determined how hospitals and health care systems would use pandemic influenza communication tools to report information to public health and response partners during an event. Of these 13 States, 6 further reported that their public health laboratories have determined how communication tools would be used for regional hospital coordination.

Twenty-seven percent of States (14 of 51) reported that they have not determined how hospitals and health care systems would use communication tools because this function is carried out by other State entities (e.g., the Office of Public Health Emergency Preparedness or the Bureau of Epidemiology).

CONCLUSION

Pandemic influenza preparedness projects supported by Phase II Guidance funding should be completed in 3 years, ending in 2009. Most State public health laboratories reported that they have already performed some of the requirements specified by the Guidance. For example, all States reported that their public health laboratories performed the requirement for year-round influenza testing. In addition, over half of States reported instituting surveillance for influenza-like illness among laboratory personnel. Although not specifically required by the Guidance, all States also reported public health laboratory capability to subtype H5 influenza, but sentinel laboratory capability to subtype H5 influenza is limited or unknown. However, this capability may be necessary to meet increased testing needs during an H5 influenza pandemic.

Our survey results demonstrate that opportunities exist to improve public health laboratory coordination with clinical laboratories. For the critical tasks involving both public health and clinical laboratories, States reported performing the required activities for public health laboratories to a greater extent than for clinical laboratories.

Clinical laboratories will likely be among the first to detect an influenza outbreak because they perform diagnostic testing ordered by clinicians. Therefore, coordination between State public

health and clinical laboratory officials is critical to decrease the time needed to detect and report a pandemic influenza outbreak.

If you have any questions about this memorandum report, please do not hesitate to contact me or one of your staff may contact Claire Barnard, Director of External Affairs, at (202) 205-9523 or through e-mail [Claire.Barnard@oig.hhs.gov]. To facilitate identification, please refer to memorandum report number OEI-04-07-00670 in all correspondence.

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