Functional Assessment of Hospital Laboratory Packaging and Shipping Preparedness in New York State

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The 2006-2007 New York State (NYS) Hospital Laboratory Drill Series was implemented in order to test notification, referral and packaging and shipping (P&S) procedures at acute care hospital facilities (statewide, excluding New York City) that submit suspect bioterrorism (BT), chemical terrorism (CT), and/or pandemic influenza (Pan Flu) clinical specimens to the NYS Department of Health (DOH) Wadsworth Center for confirmatory testing. Results showed that 97% and 84% of hospital facilities had the ability to directly access the notification network and retrieve drill guidance, respectively. Most hospital laboratories (92%) demonstrated the ability to refer specimens to the Wadsworth Center laboratory. Evaluation of specimen submissions found that 68% of BT packages, 27% of Pan Flu packages, and 20% of CT packages arrived to the laboratory with no P&S deficiencies. It can be concluded that acute care hospital facilities in NYS are more prepared to refer and submit clinical specimens during a BT public health emergency than during a Pan Flu or CT emergency event.

ABBREVIATIONS: AAR = after action report; ASCP = American Society for Clinical Pathology; BT = bioterrorism; CDC = Centers for Disease Control and Prevention; CT = chemical terrorism; DOH = Department of Health; DOT = Department of Transportation; HAN = Health Alert Network; HEPP = Health Emergency Preparedness Program; HHS = Health and Human Services; HPN = Heath Provider Network; IATA = International Air Transport Authority; JCAHO = Joint Commission on Accreditation of Healthcare Organization; LRN = Laboratory Response Network; NYC = New York City; NYS = New York State; P&S = packaging and shipping; Pan Flu = pandemic influenza; RRC = Regional Resource Center.

INDEX TERMS: emergency preparedness; laboratories, hospital; laboratory techniques and procedures.

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During times of public health emergency, the clinical laboratory has often been regarded as a first responder.[1-3] As a sentinel facility, the clinical laboratory must be prepared to provide rapid analysis of specimens for patient diagnosis. If a laboratory is unable to perform testing, then it must have both appropriately trained personnel and access to protocols for the collection, packaging, shipping, and referral of specimens, in accordance with submission guidelines, to a state or federal facility that can perform the confirmatory testing.[3-5] Ensuring that protocols are in place and continuously updated will be critical during large-scale public health emergencies, when testing activities must be rapidly completed, as well as coordinated with the actions of state and local health departments.

Clinical laboratories located within acute care hospital facilities have the additional burden of supporting the hospital's response to a large-scale event. While not every hospital is equipped with an on-site clinical laboratory with capability for the full identification of infectious agents, hospital-based laboratories, due to their location, may be confronted with preparedness concerns that differ from those of non-hospital-based clinical laboratories. For example, during a suspected large-scale emergency (e.g., chemical exposure or pandemic influenza outbreak), many affected persons requiring immediate medical attention and/or life sustaining efforts will seek care at the nearest hospital emergency department. Therefore, hospital-based laboratories must have the capability to perform testing and/or to properly collect, refer, package, and ship clinical specimens to a state or federal facility that can perform confirmatory testing during a public health emergency.[3-5]

In 1999, the Centers for Disease Control and Prevention (CDC) was charged by the Department of Health and Human Services (HHS) with ensuring that the healthcare system of the United States was prepared for a public health emergency.[4-5] Since that time, through CDC and HHS-funded cooperative agreements, each state has been tasked with the development and implementation of preparedness plans related to various aspects of health emergency preparedness; in addition to providing state and local health partners with training and guidance, collaborative response planning with all appropriate local, state, and federal agencies was also required. As part of this effort, the New York State Department of Health (NYS DOH) Wadsworth Center, in collaboration with the NYS DOH Health Emergency Preparedness Program (HEPP) and Office of Science, has conducted numerous outreach and training events on the proper assessment, collection, referral, and packaging and shipping (P&S) of clinical specimens and environmental samples to the appropriate state or federal laboratory for confirmatory testing. The targeted audiences have included NYS clinical and environmental laboratory personnel, hospital staff, local/regional health department staff, and first responders. All training materials, including videos, posters, benchcards, and guidance documents, have been directly distributed to outreach participants, and have in addition been archived on the NYS secure Health Alert Network (HAN). The HAN is situated on the NYS DOH Internet-based commerce system, the Heath Provider Network (HPN).

Several studies identifying the capabilities of clinical laboratories to support hospital preparedness have been published.[6-9] Because those studies primarily utilized paper-based surveys to collect information, there was a recognized need for the functional assessment of hospital laboratory preparedness capabilities. Drills, unlike paper-based surveys, would provide a true test of such capabilities. As a result, in 2006-2007 the NYS DOH Laboratory Response Network (LRN), in collaboration with HEPP and the Office of Science, planned, designed, and administered a statewide preparedness exercise, the New York State Hospital Laboratory Drill Series, in order to test hospital laboratory P&S preparedness capabilities. This preparedness drill consisted of a series of seven regional hospital laboratory drills and incorporated every acute care hospital facility in NYS located outside of the five boroughs of New York City (NYC) that would be required to submit clinical specimens to the Wadsworth Center for confirmatory testing in the event of a suspected bioterrorism (BT), chemical terrorism (CT), and/or pandemic influenza (Pan Flu) event or public health emergency.

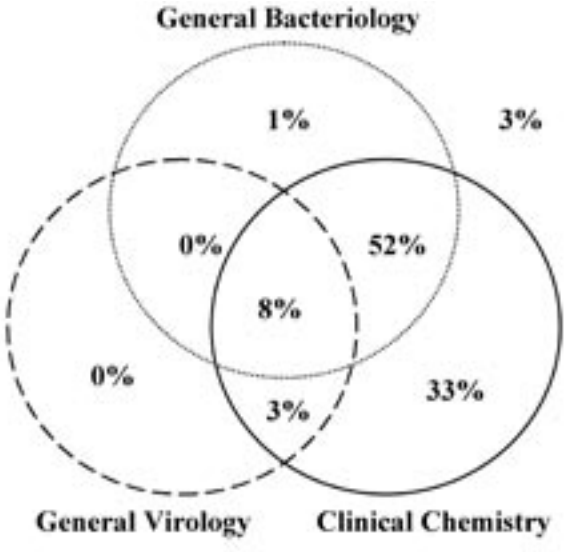
METHODS

Drill population

The New York State Hospital Laboratory Drill Series targeted 144 acute care hospital facilities serving 57 counties within NYS (excluding NYC). As defined through the Health and Human Services Hospital Preparedness Program, any hospital with an emergency department was considered to be an acute care hospital facility. However, the level of patient services and the number of beds varied widely, from very

small community facilities to very large hospital associations. Within the facilities, the testing capabilities of the on-site clinical laboratory also varied significantly. Some laboratories within the hospitals are considered full-service laboratories; they provide a wide range of clinical testing, including comprehensive bacteriological and virological infectious-disease detection, in addition to extensive clinical chemistry analysis. However, some acute care hospital facilities are equipped with laboratories not considered full-service; such laboratories perform basic emergency testing and analysis to facilitate patient stabilization, but they forward any more comprehensive microbiological testing requests to a larger (often off-site) reference laboratory. A comparison of the drill-related clinical laboratory services (General Bacteriology, General Virology, and/or Clinical Chemistry) provided by the hospital facilities included in our drill is illustrated in Figure 1. The majority of participating hospital facilities (52%) perform both General Bacteriology and Clinical Chemistry testing. Eight percent of the acute care hospital facilities have the capability to provide testing for all three services, while three percent are unable to perform any of the services. Despite these significant variations in testing capability, all hospital-based clinical laboratories must be prepared to support hospital response during a health emergency event. Accordingly, all NYS acute care hospital facilities were included in this drill series.

Figure 1. Comparison of the drill-related clinical laboratory services provided by the hospital facilities included in the NYS Hospital Laboratory Drill Series



Drill design

Each drill of the New York State Hospital Laboratory Drill Series included up to 30 acute care hospital facilities, under the leadership of their associated Regional Resource Center (RRC), and at least one reference laboratory within the NYS DOH Wadsworth Center including the Clinical Bacteriology Laboratory, Chemical Terrorism Laboratory, and Clinical Virology Laboratory. Drill activities were designed to evaluate the ability of hospital-based laboratories to recognize and appropriately respond to specimens suspected of containing a biological or chemical agent, or a novel influenza virus strain, as well as to test the laboratories' procedures for activating and implementing proper notification, P&S, and chain-of-custody protocols for specimen referral to the Wadsworth Center. Drill events were staged and projected through a defined scenario—a BT, CT, or Pan Flu rule-out/refer event—with simulated specimen submissions to drive response activity. The objectives of each laboratory drill event included: 1) implementation of established NYS DOH notification and specimen submission protocols; 2) assessment of the adequacy and availability of hospital laboratory P&S trained staff, supplies, and resources; and 3) evaluation of hospital laboratory referral, P&S, and chain-of-custody procedures. Drill events comprised three types of activity: communication/connectivity; referral; and evaluation of specimen submissions.

Communication/connectivity. Drill activities were staged to promote communication and connectivity between acute care hospital facilities and the NYS DOH LRN, as well as between each hospital and its affiliated laboratory. All drill-related communications occurred through the HPN, the NYS DOH secure Internet-based commerce system. Utilizing bulk e-mail and fax information maintained on the HPN, drill notifications were sent to hospital and laboratory personnel in targeted roles. Approximately two weeks before the start of each drill, an introduction conference call was conducted by the NYS DOH LRN with the participating hospital/laboratory facilities and their RRC coordinator to field questions related to preparation activities. On the day of drill activation, each hospital/laboratory and RRC received a notification of the scenario event requiring action. After 72 hours, each facility was sent a stop notification alerting staff to "terminate all drill actions at this time." Subsequently, each hospital facility was sent a follow-up survey, to be completed and returned by fax within two days. Approximately one to two weeks after the close of each drill, the NYS DOH LRN conducted a closing conference call with all participating hospital/laboratory facilities and their RRC to discuss suc-

cesses achieved, and challenges and concerns encountered. In total, these drill activities sought to re-familiarize hospital laboratory staff with established NYS DOH notification/communication policies, and to reiterate the need for accurate and redundant emergency contact information housed within the HPN, so as to ensure that every acute care hospital facility in NYS has the capability to receive facility-specific information during a public health emergency.

Referral. At the time of drill activation, each participating hospital facility received notification of a scenario event requiring action. Each facility was randomly assigned to a BT, CT, or Pan Flu rule-out/refer event, and given 72 hours to complete its response and to refer the suspected clinical specimen to the appropriate Wadsworth Center laboratory for BT, CT, or Pan Flu analysis. Because the Clinical Bacteriology Laboratory (BT analysis), Chemical Terrorism Laboratory (CT analysis), and Clinical Virology Laboratory (Pan Flu analysis) are located at three separate locations, it is critical that specimens be shipped to the appropriate reference laboratory at the correct location; referral errors will delay testing and availability of results. Successful referral of a specimen was dependent upon the hospital laboratory's capability to access and implement the BT, CT, or Pan Flu specimen submission guidance posted on the HPN, and to identify the appropriate Wadsworth Center laboratory for specimen referral.

Evaluation of specimen submissions. Upon receipt of drill specimens at the designated Wadsworth Center referral laboratory, each package was evaluated by the NYS DOH LRN according to United States Department of Transportation (DOT) and International Air Transport Authority (IATA) regulations for the packaging and shipping of Diagnostic Specimens and Infectious Materials, using a checklist designed by the NYS DOH LRN (Table 1). Evaluations were based on the implementation of proper P&S protocols and maintenance of chain-of-custody procedures. Following evaluation, results of the P&S assessment for each participating hospital laboratory were compiled and drafted into an after-action report (AAR). Subsequently, selected drill participants at each acute care hospital facility received an AAR containing their facility-specific evaluation, citing any P&S deficiencies. Participants were made aware that P&S deficiencies could result in rejection of the package for delivery by the courier service, thus delaying specimen receipt/analysis, compromising the integrity of the specimen, and, ultimately, hindering the public health response. After the drill, participating hospital facilities received a follow-up survey requesting input about the drill design and any challenges encountered by the laboratory. Subsequently, information about communication, staff training, and laboratory resources was summarized and distributed, along with the AAR, to selected drill participants.

RESULTS

Communication capabilities

Post-drill survey results of the NYS Hospital Laboratory Drill Series indicated that the majority of participating hospital laboratories did not encounter difficulties in directly accessing the HPN (97%), or in retrieving and responding to laboratory-specific guidance maintained on the network (84%). Because all communication will rely on the HPN system during an actual public health emergency in NYS, this drill series was a practical test of the applicability and efficacy of the network. In recent years, personnel at hospital facilities across the nation have received training on how to access their state's HAN for emergency communication purposes. Results from our drill series support the findings from a previous nationwide survey that indicated that the majority of surveyed medical-surge hospitals were successfully able to utilize electronic notification systems.[6]

Table 1. Checklist for evaluation of specimen submissions during the NYS Hospital Laboratory Drill Series

- Leakproof primary receptacle
- Leakproof, 95kPa pressure resistant secondary packaging
- Evidence tape on secondary packaging*
- Evidence tape initialed ½ on container and ½ on tape*
- Cold packs†
- Absorbent materials
- Documentation
- Rigid outer packaging
- Name and address of shipper
- Name and address of consignee
- Name and phone number of person responsible
- UN 3373 label
- Proper shipping name: Biological substance, category B

*Applies to CT only, †Applies to CT and Pan Flu only

Staff training and laboratory resources

Results of post-drill surveys collected from our exercise revealed that 96% of the acute care hospital facilities had staff trained in accordance with IATA/DOT regulations for the packaging and shipping of Diagnostic Specimens and Infectious Materials. This finding supports those found in previous survey-based studies. Two separate surveys, one among hospital facilities in Kentucky (located within the Metropolitan Medical Response System) and one conducted by the American Society for Clinical Pathology (ASCP) among clinical chemical laboratories (both within and outside the United States), found that the majority of surveyed hospital laboratory staff and surveyed laboratory personnel, respectively, were IATA/DOT certified for the P&S of infectious substances.[7,8] Although our study found that the majority of the acute care hospital facilities have IATA/DOT trained staff, the capability of drill participants to properly package, ship, and maintain chain-of-custody of suspect clinical specimens varied greatly among the three scenario types, as shown in Table 2.

Post-drill survey results identified several issues related to staff training and laboratory resources. Results indicated that if drill activation had occurred during night/weekend/holiday shifts, most participating hospital facilities would have encountered difficulties regarding availability of courier pick-up and P&S trained/certified staff. However, round-the-clock availability of back-up and surge-capacity P&S staff and specimen transport systems is an essential component of an effective public health response. Additionally, although most hospital facilities noted the ability to access dry ice in the laboratory (on-site or purchased from a vendor), a significant proportion of hospital laboratories (31%) lacked such access. Furthermore, 64% of hospital facilities reported that their laboratory did not have access to a -70°C freezer. Access to both of these resources is critical for specimen storage and submission following a suspected chemical exposure event. The above findings support ASCP survey results; the ASCP survey found that fewer than 40% of the surveyed clinical chemistry laboratories had procedures established for courier transport of specimens to local, state and/or federal health agencies, or were equipped with safe and secure storage facilities for clinical CT specimens awaiting shipment to a reference laboratory for analysis.[7]

Table 2. Referral, packaging and shipping capabilities of hospital facilities included in the NYS Hospital Laboratory Drill Series

	Referral capability (Packages received at Wadsworth Center, %)	P&S capability (Packages with no P&S deficiencies, %)
BT	**85** (40/47)	**68** (27/40)
CT	**92** (44/48)	**20** (9/44)
Pan Flu	**98** (48/49)	**27** (13/48)
Average	***92***	***37***

Referral capabilities

Results of the drill series showed that the great majority of hospital laboratories (92%) were able to refer a suspected BT, CT, or Pan Flu clinical specimen within 72 hours for confirmatory testing; 85%, 92%, and 98% of the respective BT, CT, and Pan Flu specimens arrived at the appropriate Wadsworth Center laboratory (Table 2). Our results support the findings from previous survey-based studies. A nationwide survey conducted by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) to assess BT preparedness and response capabilities, found that a significant proportion of the surveyed hospital facilities had contact information for their nearest reference laboratory.[9] Another survey, conducted by the ASCP, reported that the majority of surveyed clinical chemical laboratories had contact information for their state public health reference laboratory with which to discuss specimen submission procedures following a CT event.[7]

P&S capabilities

Our functional assessment of specimen submission techniques revealed that, on average, only a minority of packages (37%) arrived to the Wadsworth Center laboratory with no P&S deficiencies (Table 2). Hospital facilities assigned the BT scenario were most capable in P&S efforts, with 68% of BT packages arriving at the laboratory with no deficiencies. Hospital facilities assigned the Pan Flu scenario showed poorer P&S capability, with 27% of Pan Flu packages arriving at the laboratory with no deficiencies. For maintenance of specimen integrity for analysis, Pan

Flu specimens must be shipped with a refrigerant; however, cold packs were lacking in 51% of specimen submissions. Hospital facilities assigned the CT scenario showed the poorest P&S capability, with 20% of CT packages arriving to the laboratory with no deficiencies. Inability to maintain proper chain-of-custody of specimens was found to be the predominant deficiency; for 74% of specimen submissions, evidence tape was lacking on the secondary packaging, or else the evidence tape was not initialed half on container and half on the tape by the person making the seal.

The inadequacy of CT preparedness capability at laboratory facilities has previously been reported.[7] ASCP survey results showed that 65% of the surveyed clinical chemical laboratories did not have a written protocol for the collection of specimens following a suspected CT event. Furthermore, among those laboratories having a written protocol, fewer than 25% had procedures in place to ensure chain-of-custody, or provided yearly training to staff regarding CT collection and P&S guidelines. Combined, the results from our drill series and from the earlier ASCP survey indicate that there is a critical need among hospital laboratory P&S certified personnel to stay current with training on specimen submission procedures following a suspected chemical exposure event; routine testing and evaluation of preparedness capabilities through functional drills are essential.

CONCLUSION

Results from the 2006-2007 NYS Hospital Laboratory Drill Series emphasize the need for ongoing testing and evaluation of laboratory preparedness capabilities, particularly those required to support hospital facilities during a public health emergency. Training alone is insufficient. Despite three years of free P&S training provided by NYS DOH at eight statewide venues that targeted more than 600 clinical laboratory, hospital, and local/regional health department staff, significant shortfalls in P&S preparedness capability remain among NYS acute care hospital facilities. As a follow-up to the 2006-2007 New York State Hospital Laboratory Drill Series, NYS DOH will implement a second round of drills in 2007-2008. The drill series will re-evaluate the ability of NYS acute care hospital facilities to recognize and respond to a suspected BT, CT, or Pan Flu specimen submission event. Results of the 2007-2008 drill series will be compared to those of the 2006-2007 drill series, to assess improvement regarding hospital laboratory P&S preparedness capabilities.

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