# Packaging and Shipping Capabilities of New York State Hospital Laboratories: A 3-year Drill Assessment

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**ABSTRACT:** In a previous publication, we discussed the results of the 2006-2007 New York State (NYS) Hospital Laboratory Drill Series which emphasized the need for ongoing testing and evaluation of laboratory preparedness capabilities, particularly those required to support hospital functions during a public health emergency. In this paper, we will discuss how a follow-up drill series in 2007-2008 was implemented in an effort to re-assess the ability of NYS acute care hospital facilities to recognize and respond to a suspected bioterrorism, chemical terrorism or pandemic flu emergency specimen submission event. We will explain how the results of the follow-up drill series, when compared to those of the original exercise, warranted a statewide hospital laboratory preparedness drill held in 2009, focused solely on addressing the overarching deficiency of chemical terrorism (CT) specimen submission capabilities. Although drill results conclude that NYS acute care hospital facilities are much better prepared than 3 years ago to support hospital functions during a CT public health emergency event, they also highlight the continued need to improve competency.

**INDEX TERM:** Laboratories, Hospital; Emergency Preparedness; Laboratory Techniques and Procedures.

**ABBREVIATIONS:** AAR = after action report; BT = bioterrorism; CDC = Centers for Disease Control and Prevention; COC = chain-of-custody; CT = chemical terrorism; DOH = Department of Health; HEPP = Health Emergency Preparedness Program; HPN = Heath Provider Network; HSEEP = Homeland Security Exercise Evaluation Program; IATA = International Air Transport Authority; 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; US DOT = United States Department of Transportation; WC = Wadsworth Center

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## INTRODUCTION

In our previous publication, we presented the design, implementation and evaluation of a hospital laboratory preparedness drill series that took place in New York State (NYS) during 2006-2007.[1] The goal of the drill series was to test the notification, referral and packaging and shipping (P&S) preparedness capabilities of all hospital laboratories in NYS following a suspected bioterrorism (BT), chemical terrorism (CT), and/or pandemic influenza (Pan Flu) event. The drill population consisted of every acute care hospital facility

in NYS, located outside the 5 boroughs of New York City (NYC), that would be required to submit clinical specimens to the NYS Department of Health (DOH) Wadsworth Center (WC) laboratory for confirmatory testing during a public health emergency.

It is well recognized that the clinical laboratory assumes the role of a first responder during times of public health emergency and, as such, laboratory staff must be competent to collect patient specimens and, either provide rapid analysis for diagnosis, or properly package, ship and refer the specimen to a state or federal facility capable of performing confirmatory testing. [1-3] Clinical laboratories situated within acute care hospital facilities will particularly be tasked with supporting hospital response to large scale public health emergency events since, in their aftermath, large numbers of affected persons will flood the hospital emergency department in seek of immediate medical attention.[1-2]

Since 1999, NYS DOH has collaborated with federal, state and local agencies to provide training and evaluate the competencies of state and local preparedness partners. In addition, the 2006-2007 NYS Hospital Laboratory Drill Series was the first exercise in the nation to go beyond the use of paper-based surveys to functionally assess hospital laboratory preparedness capabilities across an entire state.[1]

Results of the 2006-2007 NYS Hospital Laboratory Drill Series concluded that NYS acute care hospital facilities were far more competent to refer and submit clinical specimens during a BT public health emergency than during a Pan Flu or CT emergency event.[1] Most hospital facilities had the ability to directly access the NYS DOH secure alert notification system to retrieve drill guidance and properly refer their drill specimen to the NYS DOH WC laboratory (92%). However, upon evaluation of specimen submissions received by the laboratory, while the majority of BT packages had no P&S deficiencies (68%), only 27% of Pan Flu packages and 20% of CT packages had no P&S deficiencies. Realization of this hospital preparedness shortfall prompted the decision to conduct a follow-up drill series in 2007-2008, in an effort to improve hospital laboratory preparedness capabilities within NYS. Ultimately, results from both the original and follow-up drill series' warranted the implementation of a statewide drill in 2009, specifically targeted to evaluate hospital laboratory preparedness capabilities following a CT public health emergency event.

## METHODS

*Follow-up drill series (Year 2)*

The follow-up 2007-2008 NYS Hospital Laboratory Drill Series (Year 2) was a continuation of the original drill series in 2006-2007 (Year 1).[1] As such, there were no differences in drill design, objectives or execution between Year 1 and Year 2 (Table 1). To summarize, the NYS DOH Laboratory Response Network (LRN), in collaboration with the DOH Hospital Emergency Preparedness Program and the Office of Science, planned, designed, and administered a series of seven hospital laboratory drills over an 8-month timeframe, that incorporated every acute care hospital facility in NYS (excluding NYC) that could potentially submit BT, CT and/or Pan Flu clinical specimens to the NYS DOH WC laboratory during a public health emergency. In total, the follow-up drill series (Year 2) targeted 144 hospitals serving 57 counties within NYS. Each drill involved up to thirty hospital laboratory facilities, under the leadership of their associated Regional Resource Center (RRC), and at least one NYS DOH WC reference laboratory: Clinical Bacteriology, Chemical Terrorism or Clinical Virology. The objective of the drill series was to evaluate the capability of NYS hospital laboratories to access and implement proper notification, referral, packaging, shipping and chain-of-custody procedures during a BT, CT or Pan Flu public health event. Drill events were projected through a defined scenario, with simulated specimen submissions to drive and evaluate response activity.

Like the original drill series, all communication during the follow-up drill series occurred through the NYS DOH secure internet-based commerce system known as the Health Provider Network (HPN) and included the following: introduction/closing conference call notifications, drill activation/termination notices, and post-drill survey dissemination. At the time of drill activation, each hospital facility received notification of a scenario event requiring action (BT, CT or Pan Flu), and given 72 hours to complete specimen referral to the appropriate NYS DOH WC laboratory. In the follow-

up drill series (Year 2), hospital facilities were assigned a different scenario from the year prior in an effort to exercise a different P&S capability (i.e., if a hospital was drilled with a BT scenario in Year 1, then it was drilled with either a CT or Pan Flu scenario in Year 2). Upon receipt of drill specimens by the laboratory, each package was evaluated (using the same evaluation criteria used in Year 1) in accordance with United States Department of Transportation (US DOT) and International Air Transport Authority (IATA) regulations for the P&S of diagnostic specimens and infectious materials (Table 1).

**Table 1.** A comparison of drill methods for NYS hospital laboratory preparedness drills, from Year 1 through Year 3. The goal of each year's drills was to evaluate the notification, referral and packaging and shipping (P&S) capabilities of all NYS acute care hospital facilities following a suspected Bioterrorism (BT), Chemical Terrorism (CT), or Pandemic Flu (Pan Flu) event

| Method | Year 1 | Year 2 | Year 3 |
|---|---|---|---|
| Drill informational letter sent to all acute care hospital facilities and Regional Resource Centers (RRC) in NYS | √ | √ | √ |
| Hospitals receive notifications via the Health Provider Network (HPN) to participate in pre/post drill calls | √ | √ | |
| Hospitals sorted according to RRC, and each group drilled separately over an 8-month time period (7 drills total) | √ | √ | |
| All hospitals drilled simultaneously | | | √ |
| Hospitals receive drill activation notification via the HPN | √ | √ | √ |
| Hospitals eligible to receive a BT scenario event | √ | √ | |
| Hospitals eligible to receive a CT scenario event | √ | √ | √ |
| Hospitals eligible to receive a Pan Flu scenario event | √ | √ | |
| Hospitals given 72 hours to respond to event (i.e., refer submission to the appropriate NYS DOH laboratory) | √ | √ | √ |
| Hospitals receive drill termination notification via the HPN | √ | √ | √ |
| Drill submissions evaluated per federal regulations for the P&S of diagnostic specimens and infectious materials | √ | √ | √ |
| Hospitals receive a post-drill survey via the HPN and return completed form back to NYS DOH | √ | √ | √ |

Because drill packages were labeled as "Biological Substance, Category B", but did not actually contain an infectious agent, a special US DOT permit, issued to the NYS DOH Wadsworth Center, was obtained so as to clearly identify packages as pertaining to a drill, and not the referral of a true clinical specimen.[4] As such, adherence to the regulations of the US DOT special permit was a required P&S component of the drill series.

Readers seeking further explanation of follow-up drill series methods – including drill population and drill design (communication/connectivity, referral, and evaluation of specimen submission) – beyond the summary provided above, are advised to reference our previous work from the original drill series.[1]

*Targeted CT drill (Year 3)*

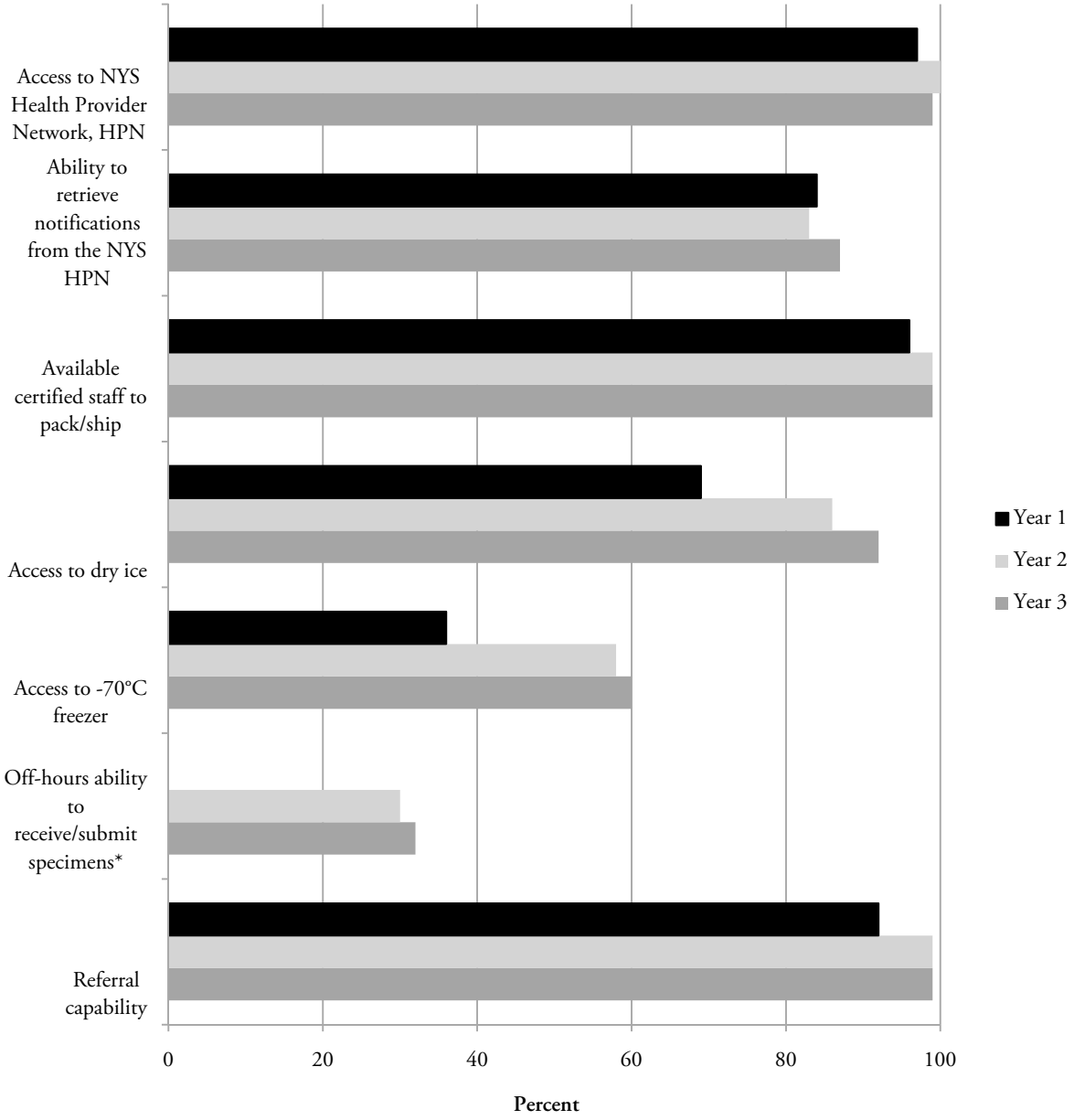
Due to the overarching deficiencies in CT P&S capability (as concluded by Year 1 and Year 2 drill results), a statewide hospital laboratory preparedness drill to specifically evaluate hospital laboratory response capabilities during a CT public health emergency event was implemented in May 2009. The drill population included all 146 acute care hospital facilities in NYS, serving 57 counties. Except for the following details, there were no differences in drill design, objectives or execution between the previous drill series' (Year 1 and Year 2) and the targeted CT preparedness drill (Year 3). First, introduction and closing conference calls among hospital facilities and the NYS DOH were eliminated. Instead, each hospital facility received a single informational letter in January 2009 via the HPN providing notice that a statewide P&S drill would occur in the coming year, and require their participation. Second, the exercise was activated statewide without prior announcement. Lastly, all hospitals were activated simultaneously, and with the same scenario of a public health emergency involving a suspected CT exposure event (Table 1).

## RESULTS

An objective of both the original (Year 1) and follow-up drill series (Year 2), as well as, the targeted CT drill (Year 3) was to reinforce established NYS DOH notification and specimen processing protocols to all acute care hospital facilities in NYS. To ensure that hospital laboratories are able to retrieve facility-specific information during an emergency, the need for up-to-date and redundant contact information on the secure HPN Communications Directory was emphasized.

Throughout all drills, survey results regarding hospital laboratory HPN connectivity capabilities were similar and indicated good competency to receive and respond to an emergency notification (Table 2). On average, the majority of hospital facilities did not encounter difficulties directly accessing the secure HPN (99%) or retrieving laboratory-specific notifications and guidance providing instructions for specimen referral and submission (85%).

**Table 2.** A comparison of critical resources for responding to emergency specimen submission events at all NYS acute care hospital facilities (excluding New York City), as part of statewide hospital laboratory preparedness drills, from Year 1 through Year 3




* *Only qualitative data collected in Year 1*

Another objective of each drill was to measure the adequacy and availability of hospital laboratory P&S trained staff, supplies and resources. Drill events emphasized the need for P&S trained staff (hospital and laboratory) for back-up and surge capacity. Again, survey results from all drills were similar and indicated that, on average, the vast majority of hospital facilities (98%) had staff trained in accordance with IATA/US DOT regulations for the P&S of diagnostic specimens and infectious materials (Table 2). Drill activities also emphasized the need for an adequate supply of P&S materials and access to P&S resources. Subsequent to the original drill series, improvements were noted in the ability of NYS hospital laboratories to have access to critical resources for responding to emergency specimen submission events (Table 2). Survey results from the follow-up drill series (Year 2) revealed that 86% of hospital facilities had access to dry ice in the laboratory, either on-site or purchased from a vendor, and 58% had access to a –70 C freezer that could be committed for the storage of clinical specimens during an emergency. During the original drill series (Year 1), access to these resources was 69% and 36%, respectively. Results from the targeted CT drill (Year 3) showed further improvement and indicated that the majority of participating hospital facilities have access to dry ice in the laboratory (92%), as well as, access to a –70 C freezer during an emergency (60%).

An important gap to note, however, is that approximately 40% of hospital facilities lack laboratory access to a –70 C freezer. Use of this resource is required for specimen storage following a suspected chemical exposure event. As outlined by federally-mandated Centers for Disease Control and Prevention (CDC) guidance, during a chemical event response, urine specimens collected from persons potentially exposed to a CT agent must be frozen immediately at –70 C and shipped with dry ice.[5] It is vital to the integrity of the urine specimen that the specimen remain frozen during transport, in order to be properly analyzed for CT metabolites and provide useful data for patient diagnosis and treatment.[2]

Another significant gap in hospital laboratory preparedness was noted regarding off-hour P&S capabilities. Throughout all drills, competency in this area was poor (Table 2). According to survey results from both the follow-up drill series (Year 2) and the targeted CT drill (Year 3), had the exercise been designed to evaluate hospital laboratory preparedness efforts during night/weekend/holiday shifts, approximately 69% of hospital facilities would have encountered difficulties regarding the availability of courier pick-up, availability of P&S trained staff, and access to critical P&S resources, such as dry ice.

A final objective of both the original (Year 1) and follow-up drill series (Year 2), as well as the targeted CT drill (Year 3), was to evaluate hospital laboratory referral, packaging, and shipping procedures. Across all drills, good competency was demonstrated regarding specimen referral (Table 2). During the follow-up drill series (Year 2), 99% of hospital facilities demonstrated the ability to properly refer a suspect BT, CT or Pan Flu clinical specimen for shipment to the appropriate NYS DOH WC laboratory within 72 hours of drill activation, which was improved from 92% in Year 1. Year 2 drill results additionally concluded that hospital facilities were better prepared to package and ship clinical specimens during a BT or Pan Flu submission event than during a CT submission event (Table 3).

**Table 3.** A comparison of packaging and shipping (P&S) capabilities during a public health event (BT=Bioterrorism, CT=Chemical Terrorism, Pan Flu=Pandemic Flu) at all NYS acute care hospital facilities (excluding New York City), as part of statewide hospital laboratory preparedness drills, from Year 1 through Year 3

| | Packaging & Shipping Capability (Packages with no P&S deficiencies, %) | | |
|---|---|---|---|
| | **BT** | **CT** | **Pan Flu** |
| Year 1 | 68 (27/40) | 20 (9/44) | 27 (13/48) |
| Year 2 | 64 (30/47) | 29 (14/48) | 53 (27/51) |
| Year 3 | _ | 41 (59/144) | _ |

Upon evaluation, the majority of BT and Pan Flu packages arrived to the laboratory with no P&S deficiencies (64% and 53%, respectively), while only 29% of CT packages arrived to the laboratory with no P&S deficiencies. In comparison, during the original drill series (Year 1), 68% of BT submissions, 27% of

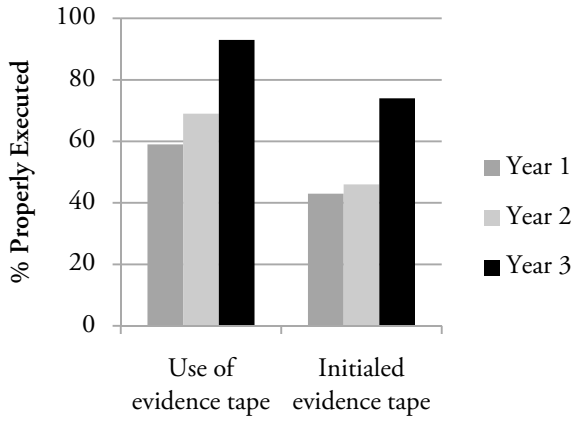
Pan Flu submissions and 20% of CT submissions arrived to the laboratory with no P&S deficiencies. Thus, while hospital laboratory competency regarding P&S capabilities remained in good standing for BT submissions from Year 1 to Year 2, and improved for Pan Flu submissions, competency continued to remain poor for CT specimen submission capabilities.

During the targeted CT drill (Year 3), 99% of hospital facilities demonstrated the ability to refer a suspect CT clinical specimen to the NYS DOH CT laboratory within 72 hours of drill activation (Table 2). Upon evaluation, 41% of CT packages arrived to the laboratory with no P&S deficiencies. Although the latter finding indicates a continued hospital laboratory preparedness gap regarding CT P&S preparedness capabilities, it also shows that overall competency has improved since Year 1 and Year 2, when only 21% and 29% of packages arrived to the laboratory without any P&S deficiencies, respectively (Table 3). The most frequent P&S deficiencies cited for CT drill packages were the inability to maintain proper chain-of-custody (COC) of specimens and the lack of adequate refrigeration.

Results of the CT targeted drill concluded that many hospital facilities do not follow proper COC procedures regarding the use of evidence tape, as required for CT specimen submission. In accordance with federally-mandated CDC guidance, all layers of secondary packaging must have their closure secured with a single strip of evidence tape, initialed half on the packaging and half on the evidence tape by the person making the seal.[5] It is critical that specimens collected following a CT exposure event be preserved with evidence tape should the specimen become potential evidence, as part of a criminal investigation in the future.[3] During both the original and follow-up drill series', the majority of CT specimen submission errors resulted from the inability to adhere to proper COC procedures regarding the use of evidence tape. Of all CT submissions in the original drill series (Year 1), 41% lacked evidence tape, and 57% lacked properly initialed evidence tape. In the follow-up drill series (Year 2), 31% of all CT submissions lacked evidence tape, and 54% lacked properly initialed evidence tape. Much improved during the targeted CT drill (Year 3), only 7% of all CT submissions lacked evidence tape securing their closure. In addition, only 26% of all CT submissions lacked evidence tape, initialed half on the packaging and half on tape by the person making the seal (Table 4). Interesting to note, only 6% of CT submissions lacked initials on the tape completely, while 20% of the packages had evidence tape that was initialed, but the initials were improperly confined entirely within the borders of the tape.

Results of the targeted CT drill also found that many hospital facilities did not package their CT submission with an adequate amount of refrigerant material, as outlined by federally-mandated CDC guidance. Results concluded that 20% of all submissions lacked the inclusion of dry ice. Following a chemical exposure event, however, it is critical that collected urine specimens are frozen immediately, and shipped on dry ice to ensure that they remain frozen or freeze during transport, so that proper analysis of chemical metabolites can be performed.[2,5] While federal guidance does not dictate the amount of dry ice to be used, it is essential that the package contain an amount sufficient to keep the specimens frozen upon arrival at the LRN CT laboratory. However, during the course of package evaluation, it was observed that the evidence tape on the packaging had a tendency to become non-adhesive and

**Table 4.** A comparison of chain-of-custody procedures regarding the use of evidence tape required for CT specimen submissions, at all NYS acute care hospital facilities (excluding New York City), as part of statewide hospital laboratory preparedness drills, from Year 1 through Year 3



shatter when an adequate amount of dry ice was used to refrigerate a drill specimen. This is of particular concern in that had the package contained an actual specimen for submission, such evidence tape issues would have severely compromised the legal intention of chain of custody (Figure 1).

**Figure 1.** Examples of compromised evidence tape. When an adequate amount of dry ice was used to refrigerate a drill specimen, the evidence tape on the packaging had a tendency to become non-adhesive and shatter.

## CONCLUSION

Despite conducting 3 years of statewide hospital laboratory preparedness drills, there remains a gap in P&S proficiency among acute care hospital facilities in NYS. Results of both the original drill series (Year1) and the follow-up drill series (Year 2) concluded that hospital facilities were better prepared to respond to a BT or Pan Flu specimen submission event than a CT specimen submission event. Identification of this preparedness gap warranted the need for a statewide drill specifically targeted to evaluate hospital laboratory response capabilities following a CT public health emergency event. During the targeted CT drill (Year 3), 41% of hospital-based laboratories were successful in their effort to properly package a suspect CT specimen for shipment, and adhere to COC procedures. In comparison, only 21% and 29% of CT packages arrived to the laboratory without any P&S deficiencies during Year 1 and Year 2, respectively. While results of the targeted CT drill show that the ability of NYS hospital laboratories to support hospital functions during a CT public health emergency event has improved since the implementation of NYS drill exercises, they also highlight the continued need for increased competency.

In a recent survey, conducted by CDC to assess terrorism preparedness at hospitals nationwide, 76% of responding hospitals reported to have staff trained on terrorism-related chemical exposures; however, the extent or content of such outreach was not defined.[6] Most current literature agrees with our drill results, and strongly supports the need for continued hospital laboratory training regarding CT P&S techniques and COC procedures.[1,2,7] While many laboratories have become familiar with the LRN in regards to responding to recent biological events (i.e. potential biothreat agents and pandemic influenza virus), they are less accustomed to the infrastructure and chemical capabilities of the LRN in response to mass chemical exposure events, including specimen collection and P&S procedures. Following an emergency CT event, hospital laboratories will be tasked with collecting blood and/or urine specimens from all exposed persons. Analysis of blood and urine specimens will determine exposure to a variety of chemicals including, cyanide, metals and volatile organic compounds and will, subsequently, guide patient treatment efforts. Although studies suggest that the majority of hospitals have access to CT clinical response guidelines, currently, most laboratories do not have the instrumentation, methods or skills necessary to complete confirmation analysis.[1,2,8] As such, it is critical that hospital laboratory staff be competent to properly package, ship and refer CT specimens to a reference laboratory for confirmatory testing.

In an effort to aid NYS hospital facilities in improving their current preparedness capabilities, as well as to lend State support for such enhancements, each year following drill completion, after-action reports (AAR) were distributed to each hospital participant, as well as, to the DOH Hospital Emergency Preparedness Program (HEPP). Every hospital facility received a unique AAR, detailing facility-specific P&S deficiencies, as well as aggregate regional information. In turn, HEPP was provided with a copy of all AARs, as well as, a Homeland Security Exercise Evaluation Program (HSEEP) AAR/Improvement Plan. We encourage all public health partners to utilize our NYS hospital laboratory preparedness drills as a template, to identify emergency response gaps found at other hospital facilities across the nation.

Looking ahead to the future, the continuation of hospital laboratory preparedness outreach activities in NYS may take a different approach. Based on a recent needs assessment survey conducted among emergency department staff in upstate New York, additional training regarding chemical preparedness was an indicated priority.[9] Optimal methods of outreach were reported to include in-person trainings, drills, training videos and computer-based trainings. Consideration of these findings, and in an effort to optimize convenience and limit obstacles such as staff and resource shortages, future statewide trainings may be designed and implemented using on-line or computer-based courses. Nevertheless, the need to maintain and strengthen hospital preparedness capabilities across NYS is a constant and critical issue, and independent of the modality of training, meaningful outreach activities will continue to take place.

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**ERRATA:** The Fall 2010 Volume 23 of Clinical Laboratory Science was published with a page error in the FOCUS section. Page 228 was inadvertently replaced with a duplicate copy of page 223 during production. The online version of the Fall 2010 issue is correct and may be accessed on the ASCLS web site. ASCLS and Clinical Laboratory Science regret this production error of the journal. It is our intent to provide the most professional journal possible for the profession and we apologize to the authors and readership.