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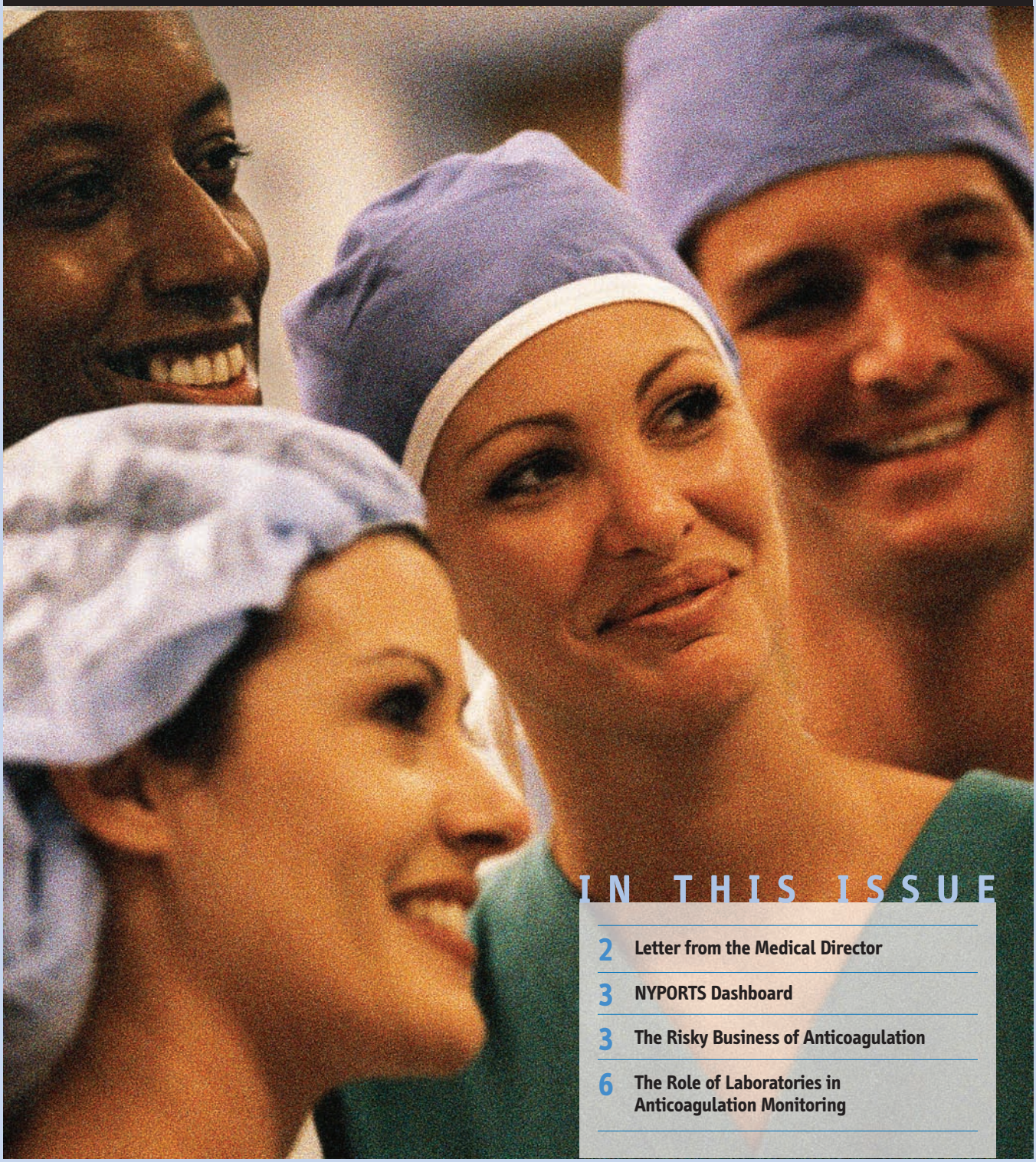

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Letter from the Medical Director

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

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Executive Deputy Commissioner

With this issue, the Department of Health is taking a different approach to presenting the New York Patient Occurrence Reporting and Tracking System (NYPORTS) findings. On page one, you will now find a Dashboard of key NYPORTS indicators to give a brief overview of reporting trends and types of occurrences. For more information about NYPORTS and patient safety, visit **nyhealth.gov/nysdoh/healthinfo/patientsafety.htm.**

More importantly, it is our goal in this and future editions to provide an in-depth analysis of one or two key patient care issues. For example, in the enclosed newsletter, there are articles dedicated to anticoagulation medications and the role of laboratories in monitoring the use of these medications.

We welcome your ideas for future articles by contacting the Patient Safety Center at 518-408-1219. Please also contact us if you are interested in working with us on an article based on your hospital's experience with an adverse event and how that was used as an opportunity to improve patient care.

Thank you for your continued efforts in the area of patient safety.

Sincerely,

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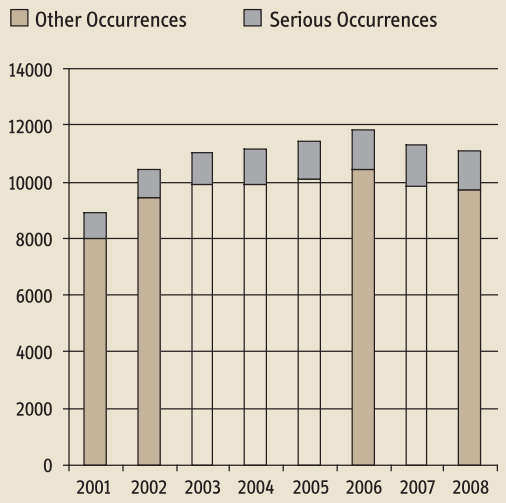
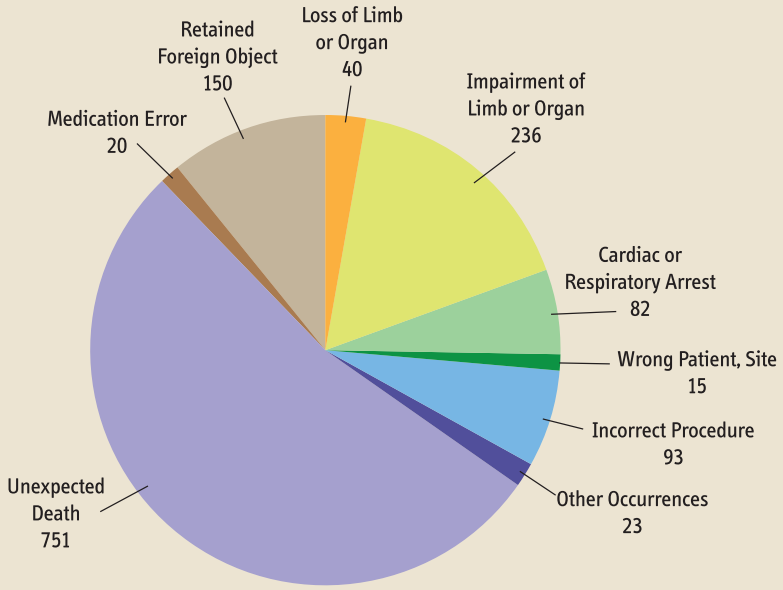
NYPORTS Dashboard

Hospital Occurrences Reports per Year



Serious Hospital Occurrences Reported in 2008



Graphs include only hospital occurrences from reporting categories that have been reportable to NYPORTS for 2001 through 2008. Serious occurrences are those which required a root cause analysis.

The Risky Business of Anticoagulation

The New York State Department of Health receives five or six reports per year of deaths related to medication errors resulting in over anticoagulation. Thirty percent of medication errors related deaths reported to NYPORTS from 2003 to 2008 involved over anticoagulation.

Many patients who experienced adverse events related to over-anticoagulation were on long term anticoagulation therapy prior to admission. Almost 80% who experienced adverse events had a history of heart disease, stroke, or other cardiovascular disease. Nine patients were being treated for documented or suspected thrombolic events (deep vein thrombosis or pulmonary embolism), with seven deaths. The majority of patients with anticoagulant-related medication errors experienced bleeding; twelve (29%) had intracranial hemorrhage, twelve (29%) had bleeding at a surgical or puncture site, eight (20%) had abdominal or peritoneal bleeding, and five (12%) had bleeding at other sites.

Anticoagulant related medication errors reported to NYPORTS, 2003-2008

Type of anticoagulant	Number of occurrences	Number of deaths
Heparin	21	9
Low molecular weight heparin (LMWH)	17	14
Warfarin	8	6
Direct thrombin inhibitor	4	3
Multiple anticoagulants	2	2

Overdoses: Dosing errors were the most common type of medication error involving anticoagulants. There were a wide variety of factors contributing to the overdoses. Nine events involved misplaced decimals when programming the infusion pump: seven of which involved heparin and two involved a direct thrombin inhibitor. Five patients died, with two deaths directly attributable to the infusion error. Based on review of the root cause analysis (RCA) reported to NYPORTS for these events, the difference in outcomes can at least in part be attributed to the effectiveness of communication. Among the patients who survived, the fact that there was an infusion error was immediately communicated to the physician, who could then order lab tests and reversal agents. Among the patients who died, poor communication played a

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role in both the recognition of the error and failure to notify the physician of the error once identified. It is clear that the RCA team felt the delay in rescuing the patient was as much at fault as the original programming error.

Another common error associated with anticoagulant overdosing is related to prescribing. Low molecular weight heparin (LMWH) in particular is subject to prescribing errors because the dose must be adjusted for patients with renal dysfunction or morbid obesity. Seven deaths were reported among patients with renal dysfunction who had bleeding complications when on LMWH (six deaths) or a direct thrombin inhibitor (one death). LMWH dosing for anticoagulation is also dependent upon patient weight, and two adverse events reported were due to an inaccurate patient weight being recorded on their electronic medical record. In one case the patient's weight in pounds was entered into the "weight in kilograms" field, an error that has also been reported frequently with other medication overdoses. The hospital's electronic medical record allowed staff to toggle between lbs. and kgs. when entering data, increasing the risk of incorrect data entry.

Could this happen in your hospital? After this unfortunate death, the hospital changed the system to only allow kgs. In the other event, the patient's self-reported weight was used to determine the dose of LMWH because there was not an appropriate scale in the emergency department. The dose was not adjusted after she was admitted. The hospital ordered new scales for the emergency department that could accommodate patients who were unable to stand. They also revised their pharmacy policy to require actual weight in kgs. when dispensing medications after the initial stat dose.

There has been recent media attention on the vulnerability of newborns to heparin overdose and the issue of "look-alike" vials whereby adult dosing vials were used for newborns.

A similar error occurred in a New York facility when a pharmacist requested a "yellow-top" vial from a technician and accidentally used 100unit/ml vial instead of 10unit/ml vial, both of which had yellow tops. Fortunately, no harm resulted from this error. As described below, a second overdose event occurred because the wrong concentration of heparin was selected when preparing the medication at the point of administration. **How does your institution address the risk of this all too common error?**

A case of wrong vial overdose

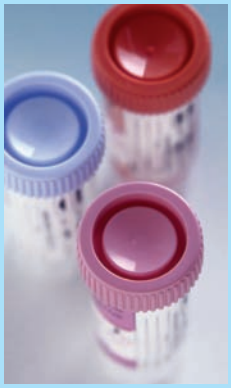
Events: The emergency department physician ordered a 4500 unit heparin bolus for a patient with a suspected pulmonary embolism. The electronic display on the automated medication storage cabinet listed the concentration as 10000 units/ml, but ED nurse misread the concentration as 1000 units/ml and used four and a half 1 ml vials to prepare the dose. Because the overdose was not recognized immediately, protamine was not administered until over 12 hours after the overdose was administered. The patient experienced an intracranial hemorrhage and died the next day.

Root causes: Although several aspects of patient care contributed to the delay in reversing the overdose, the root cause analysis team felt that the display on the medication dispensing cabinet may have contributed to the error, since the 10000 units/ml concentration did not allow for display of the comma (10,000), making it more difficult to read. They contacted the manufacturer of the cabinet to make the suggestion that the display allow commas. Human factors likely also contributed to the apparent mistaken understanding of the concentration. Needing to use multiple vials to obtain the prescribed dose should have triggered a recheck of the concentration on the vial and of the dose prescribed. **(Patient Safety rule: Think twice if you need to use more than 1 vial of anything.)** The hospital standardized the concentration of heparin available in all medication dispensing units throughout the hospital and implemented smart pump technology to trigger alerts regarding possible inappropriate dose settings. In a follow-up conversation, the Director of Pharmacy reported that the more they dug, the more opportunities for standardization they found. For example, after finding that several

(continued) The Risky Business of Anticoagulation

different heparin concentrations were being used by different services using interventional radiology methods to treat patients, they held a meeting to discuss the dosing needs within each service, creating the opportunity for all involved services to reach an agreement regarding standardization of heparin dosing.

Patient monitoring errors: The identification of inadequate monitoring as a type of medication error is relatively new. Monitoring errors can occur at every phase of the medication process, prescribing, dispensing, preparation, and administration. Thirty percent of adverse events involving anticoagulants reported to NYPORTS were directly attributable to monitoring errors, but improvements in monitoring and communication of critical values may also have improved outcomes for patients who experienced other errors. For example, the death following the heparin overdose described above may have been preventable with more timely recognition of the patient's over-anticoagulation and reversal with protamine. Although monitoring errors accounted for fewer reported events compared to overdoses, there were approximately the same numbers of deaths associated with monitoring errors as there were with overdoses.



In addition to monitoring errors associated with delayed communication of critical values, adverse events have been reported when a blood specimen is inadequate for laboratory testing; when laboratory values are not checked prior to prescribing or administering the anticoagulant; and, when bleeding/bruising is not recognized clinically as a sign of over-anticoagulation.

Failure to communicate

Events: An elderly patient was admitted for suspected stroke and was started on warfarin with a target International Normalized Ratio (INR) value between 2 and 3. A few days after admission a prescribed INR was not drawn. This missed lab test was overlooked by the care team. Several days later, the patient was found lethargic and unresponsive. A CAT scan indicated intracranial bleeding. The INR was over 6, a critical value. The lab technician had called the floor to communicate the critical value to the nurse, but was placed on hold. After several attempts to contact both the nurse and the doctor, the technician returned to work – never telling anyone about the critical value. The patient continued to deteriorate, and the care team did not become aware of the abnormal INR until over 10 hours after the initial lab test and CT scan. The patient died before treatment could be administered.

Root causes: The hospital's procedure for communicating critical values failed to work. The procedure indicated that the nurse was to be contacted when the critical value could not be communicated to the doctor. The policy did not address what was to be done when the nurse was also not available. The hospital enhanced their communication policy so that critical values would be communicated up the chain of command when needed. This communication failure compounded the inadequate monitoring of INR values during the patient's admission. The hospital's anticoagulation policy was not specific enough – indicating only that monitoring should be "ongoing." Policy was revised to include daily INR monitoring, as recommended. The INR ordered midway though her hospital stay that was apparently never drawn fell into the "QUALITY CHASM". An improved process for monitoring and communication could have helped to prevent the adverse outcome.

Other errors: The third most common type of error was administering anticoagulants when it was not clinically appropriate as determined by the facility during the Root Cause Analysis (RCA). Reported events include administering anticoagulation therapy just prior to surgery or too soon after surgery and not discontinuing anticoagulation therapy when suspected thromboembolic events are ruled out. Administration after the order was discontinued and "duplication of class" errors occurred when there was failure to reconcile changes in form or dose of anticoagulants at admission, change of level or care, or at discharge:

Double dose hand-off

Events: Patient was admitted from the emergency room following a fall. The patient developed a deep vein thrombosis, which was treated with both heparin and low molecular weight heparin, with a plan to place the patient on warfarin therapy for a few months after discharge. The physician wrote an order for "Coumadin 10mg PO tonight." This dose was given in the Intensive Care Unit at 5:00 pm. The patient was transferred to the floor at 8:00 pm, with the warfarin order on the transfer sheet. An additional 10mg dose was given on the floor at midnight. The following night (24 hours later), the nurse checked the INR recorded on the patient's chart, and found it to be in the therapeutic range, but this INR value was from the night before, prior to the extra dose of warfarin. The patient was then given 7.5mg warfarin at 1:00 am. At 7:00 am, the patient's INR was 8.1.This critical value was communicated to the doctor, who requested a repeat specimen. The patient's condition declined throughout the day, and she died the following morning.

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Root causes: The root cause analysis team determined that there were a number of issues contributing to this patient's outcome. The extra dose of warfarin was related to an unclear written order ("tonight" instead of a specific time), unclear hand-off communication from the Intensive Care Unit (ICU) to the floor and incomplete transfer medication reconciliation. Suggested preventive measures included standardizing time for INR levels to be drawn and for coumadin to be given. The team also determined that the patient was over-anticoagulated with the combination of LMWH, heparin and warfarin. The extra dose of warfarin was not recognized until the information gathering for the root cause analysis following her unexpected death.

Finally, the critical value INR was not treated as aggressively as it could have been, and the patient did not receive fresh frozen plasma until almost 24 hours after the first critical value was reported. This critical value was communicated to a first year resident on his first day of rotation. Lack of knowledge and inadequate orientation was also identified as a possible contributing factor. This is not as rare an event as one might want to think but it is a good example of HUMAN ERRORS. **Do you have a process or system you think reduces the chances of an error such as duplication of medication administration when patients are transferred from one unit to another?** ***Share your story and it may appear in the next issue of this newsletter.***

Conclusions: In 2008, almost 8,000 newly acquired deep vein thrombosis or pulmonary embolisms were reported to NYPORTS. Prevention of these events requires balancing not only the risks of bleeding, but also the burden to the patient and the costs to the health care system. We can optimize the risk/benefit ratio by systematically lowering the risks associated with use of anticoagulants. Technology can contribute through advances such as smart pump technology, electronic medical record with medication reconciliation, enhanced pharmacy systems, more effective communication and computer physician order entry. **But as the technology advances, we cannot lose sight of the vital role of communication in all aspects of patient care.**

The Role of Laboratories in Anticoagulation Monitoring

For warfarin and heparin, laboratory monitoring is needed to guide clinicians in adjusting the dose of the drugs. For warfarin therapy, the clotting ability of the patient's blood is reported in terms of the INR. For unfractionated heparin, the clotting time is measured with the Activated Partial Thromboplastin Test (aPTT or APTT). The performance of these tests for anticoagulant therapy monitoring is a particular challenge for the laboratory and the accuracy of these tests is dependent upon many factors. This continuum of laboratory testing is commonly broken down into three phases: preanalytic, analytic, and postanalytic:

- The **preanalytic phase** includes specimen collection and storage prior to testing. The collection must be done with the proper type of specimen tube for the test using correct phlebotomy technique. Other considerations include the volume of blood drawn into the tube, the order of the draw when multiple tubes are used for different tests, and how difficult the specimen was to collect. Also important is the amount of time that passes between specimen collection and testing. Laboratories have established rejection criteria to weed out samples that, if accepted, would result in inaccurate results.
- The **analytic phase** involves the conduct of the test itself, including proper set-up of instrument, running controls to verify instrument operation, and establishing the correct reference range. Considerations need to be given to the selection of test system, standardized procedures, training and ongoing competency of analysts, and use of correct International Sensitivity Index (ISI) to report the INR.

Testing for Coumadin® or warfarin therapy poses a unique challenge due to the varying sensitivity of the instruments and reagents used by different laboratories. In an effort to create a standardized reference range across many different test systems, the International Normalized Ratio (INR) system was created by the world health organization WHO in 1983. Each lot of reagent is assigned an International Sensitivity Index (ISI) by the manufacturer. ISI is a factor that defines the test s relationship to manual coagulation tests, which are the most sensitive. Laboratories must make sure they change the ISI when a reagent or test system is changed or patients INR will be inaccurate. Even when this is done correctly, INR will vary across different laboratories, and clinicians should be aware of the limitations of the INR when monitoring their patients, as a change in laboratories can cause a clinically significant change in the INR.

(continued) The Role of Laboratories in Anticoagulation Monitoring

- The **postanalytic phase** includes reporting of normal and critical values back to the clinician. A protocol for communication should include using correct reference range, providing accurate interpretive information, and identifying critical or inconsistent values. Interpretation may also include a delta check, which is comparing the results to previous results from the same patient to identify clinically inconsistent values.

Clinical Laboratory Evaluation Program (CLEP): The Wadsworth Center's CLEP works to ensure the accuracy and reliability of laboratory test results. The program performs on-site inspections, proficiency testing, and evaluation of the qualifications of personnel of clinical laboratories that test specimens for New York residents. CLEP also receives and investigates complaints related to laboratory testing practices. Complaints related to the performance of anticoagulant monitoring are relatively rare, accounting for only 2% of the complaints received by the program. They included concerns about test validity and about delays in reporting results. Overall, effective communication of laboratory results represents 10% of the complaints investigated by CLEP. Laboratories are routinely audited to ensure that they have protocols for reporting critical values, but laboratories and health care providers must partner to ensure the effectiveness of critical value reporting.

CLEP followed up a complaint of a laboratory as not tracking time of specimen collection and thus not being able to demonstrate that specimens for anticoagulant monitoring were being tested within generally accepts timeframe for specimen stability. The laboratory provided feedback that laboratories are under pressure from health care providers to perform anticoagulant monitoring tests regardless of the time elapsed between testing and collection. Both PT and aPTT results can be affected if samples are aged, due to the labile nature of the clotting factors. In patients who are not on anticoagulant therapy, abnormal values can result in unnecessary follow-up testing. For patients on anticoagulant therapy, a test result that is artificially prolonged due to improper handling of the specimen might result in adjustments to dosing that are not clinically supported.

Specimen handling is critical to accurate anticoagulant monitoring testing. Based on this feedback, a survey was sent to 318 laboratories performing anticoagulant testing for the *Activated Partial Thromboplastin Test (APTT)*. This test was chosen for the study because it is particularly sensitive to delays in testing. Professional consensus standards[1] recommend that specimens for patients on heparin therapy are tested within four hours of collection to ensure an accurate result. The time between collection and testing can be extended if the laboratory separates and freezes the plasma or establishes, through formal studies, an alternate timeframe for specimen stability. More than 80% of the laboratories surveyed self-reported that they were complying with this four hour requirement. The remaining 20% reporting they exceeded the recommended four hour timeframe will be assessed to determine on what basis they allow testing beyond this threshold.

CLEP field staff also conducted audits of laboratory practices for handling specimens for anticoagulant monitoring over an eight month period, from August 2008 to March 2009. Over 40 facilities were audited for specimen testing and reporting practices. Preliminary analysis of these data show laboratories are largely compliant with industry standards for anticoagulant monitoring tests [1,2] Given the critical nature of the tests, CLEP, along with the New York State Health Department's Wadsworth Center and industry subject matter experts, will continue to refine standards and educate laboratories and health care providers about the importance of proper specimen handling and analytic performance for tests used to monitor anticoagulant therapy.

1. H21-A4, Collection, Transport and Processing of Blood Specimens for Testing Plasma; Clinical Laboratory Standards Institute, Approved Guideline, Fourth Edition

2. H47-A, One Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Clinical Laboratory Standards Institute, Approved Guideline

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