Coagulation Laboratory Testing Practices in a 2001 Survey of 800 Randomly Selected U.S. Hospitals

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Introduction

Hospital clinical laboratories play an important role in healthcare; and as documented in this survey, virtually all hospital laboratories perform coagulation tests. Such tests are vital to diagnosis, treatment and management of bleeding and hypercoagulability disorders that affect millions of patients in the U.S. The majority of coagulation laboratory tests are performed as screening tests or to monitor therapeutic anticoagulant therapy. These assays are also used in conjunction with other tests to increase overall diagnostic accuracy. Although variation in coagulation testing practices within individual laboratories has been documented, little is known about the extent or nature of variation between hospital laboratories. Variability in some testing processes can affect test result accuracy and interpretation, potentially impacting patient outcomes. We conducted this 2001 survey of U.S. hospital coagulation laboratories to discover sources of variation in coagulation laboratory practices by assessing various pre-analytical, analytical and post-analytical issues and by examining use of selected laboratory practices subject to variation and critical to diagnostic and therapeutic use of tests.

This paper focuses on laboratory practices involving tests for prothrombin time (PT), activated partial thromboplastin time (aPTT), and low molecular weight heparin (LMWH). It also presents selected quality assurance (QA), test ordering and result reporting practices.

Methods

Sampling. From a sampling frame of institutions listed in the 1999 directory of the American Hospital Association (AHA), we randomly selected 800 hospitals (sampling rate, 14%), and assessed practices in their coagulation laboratories. This sampling frame is not limited to the AHA members and it includes 95% of all hospitals in the U.S. as verified against the Online Survey, Certification and Reporting database of CLIA-registered hospitals.

Survey development. A group of coagulation experts and survey methodologists assisted the CDC in the design of this survey, and they further evaluated the content and format of the survey before pilot testing.

Results

Response rate. We received returned surveys from 632 institutions, resulting in a response rate of 79%.

Performance of coagulation tests
97% of respondents reported performing coagulation testing.

Anticoagulant concentration
- 73% reported using 109 mmol/L (3.2%) sodium citrate.*
- 25% reported using 129 mmol/L (3.8%) sodium citrate.
- 1% reported using both concentrations.

*Based on the recommendation of the World Health Organization (WHO) and NCCLS, 109 mmol/L (3.2%) citrate is the anticoagulant of choice (Arch Pathol Lab Med. 1998;122:768–781). Under-filling of specimen tubes containing 3.8% sodium citrate has been reported to prolong PT and especially aPTT results compared to 3.2% sodium citrate (Am J Clin Pathol. 1998;109:754-757)—thus affecting anticoagulant therapy with its consequent implications for patient outcome.

Prothrombin Time Testing Practices

Reporting of results
- 99.8% reported PT as international normalized ratio (INR).
- 97% reported PT in seconds.*
- 16% reported PT as a therapeutic PT ratio.*
- 3% reported PT as INR only.

*Reporting PT results in seconds only may lead clinicians to inappropriately compare results between institutions (Am J Clin Pathol. 1998;109:589–594) and reliance on PT therapeutic ratio has been documented to cause errors in anticoagulant therapy (Arch Intern Med. 1992;152:278–282).

Sensitivity of PT assay to heparin
- 17% reported determining sensitivity of their PT assays to heparin.
- 50% reported selecting a PT-thromboplastin reagent that was insensitive to heparin in the heparin therapeutic range.

According to the College of American Pathologists (CAP), laboratories should determine the sensitivity of their PT assays to heparin (Arch Pathol Lab Med. 1998;122:782–798) and, where possible, select a thromboplastin that is insensitive to heparin in the therapeutic range (Arch Pathol Lab Med. 1998;122:768–781).

Activated Partial Thromboplastin Time (aPTT) Testing Practices

Heparin therapeutic range
64% reported having an aPTT therapeutic range for heparin.
While 64% of those having an aPTT therapeutic range for heparin reported this range when monitoring heparin therapy, 9% included the corresponding heparin concentration with aPTT results.

According to the CAP, adjusted dose and therapeutic heparin require anticoagulant monitoring using a method with a defined therapeutic range (Arch Pathol Lab Med. 1998;122:782–798).

Pre-analytical specimen management
- 96% reported assaying specimens within 4 hours after phlebotomy.*
- 88% reported centrifuging specimens within 1 hour of collection.*
- 82% reported keeping specimens at room temperature.
- 22% reported keeping specimens at 4 °C.

*According to NCCLS, samples can be assayed up to 4 hours after phlebotomy if centrifuged within 1 hour of collection (NCCLS approved guideline–3rd edition. Document H21-A3. Vol 18; No. 20).

Low Molecular Weight Heparin (LMWH) Monitoring Practices

Monitoring of LMWH therapy. 14% reported monitoring LMWH therapy.

Assays used
- 72% reported using an aPTT assay.
- 53% reported using an anti-factor Xa assay.*

*The CAP recommends a chromogenic anti–factor Xa method for monitoring LMWH (Arch Pathol Lab Med. 1998;122:799–807).

Timing of anti-factor Xa assay after administration of LMWH
32% reported performing anti-factor Xa testing 4 hours after injection* while 46% reported not recommending a time for anti-factor Xa testing.

*The CAP recommends that, when LMWH is monitored, the sample be obtained 4 hours after subcutaneous injection of LMWH (Arch Pathol Lab Med. 1998;122:799–807).

Quality Assurance Practices

Responses to accepted quality assurance (QA) practices adhered to by < 90% of the respondents were as follows:

Rejection of specimens
- 32% reported rejecting specimens collected via indwelling catheter.
- 45% reported rejecting specimens if a label did not have a medical record number.
- 85% reported rejecting specimens stored at an inappropriate temperature.
- 86% reported rejecting specimens if they were hemolyzed.

Repeating a test*
- 16% reported usually repeating a coagulation test when results were outside of the reference interval.
- 73% reported usually repeating a coagulation test when a result did not agree with previous results.

Management of test results
- 76% reported reviewing patient's previous results.
- 82% noted that they compared the instrument printout to the reported value.

Other QA check
- 23% reported checking plasma for platelet count after centrifugation.

*The noted practices are not universally accepted.

Test Ordering and Result Reporting Practices

Test requisition. As recommended, respondents reported including the following therapies on test requisition forms: coumadin (53%), unfractionated heparin (39%), heparinoid (33%), LMWH (23%), and salicylate (16%).

Result information for PT, aPTT, von Willebrand factor (vWF) antigen and protein C assays
As recommended,
- 90–98% reported providing measurement units.
- 76–87% reported providing needed specimen comments.
- 93–97% reported providing reference intervals.

The proportions providing therapeutic ranges were as follows: PT (54%), aPTT (38%), vWF antigen (5%), and protein C (5%).
The proportions providing written interpretations were as follows: aPTT (4%), PT (6%), vWF antigen (21%), and protein C (22%).

Reporting of critical values. As recommended, 99% reported critical values. These respondents reported adhering to the following practices:
- critical values telephoned to clinician and call documented (99%);*
- critical values repeated and documented as confirmed (91%);*
- critical values telephoned to clinician and call not always documented (6%);
- critical values indicated on report but no further action taken (5%).

*Recommended practice

Concluding Remarks

Limitations
Various laboratory practices noted in this survey are those the respondents reported; and like any other surveys, they may not reflect actual practices. Surveys are subject to framing biases which can be reduced (e.g., by pilot testing) but not totally avoided.

Generalizability
Due to the high response (79%) and sampling (14%) rates, results of this survey appear to be generalizable.

In conclusion, we found substantial variability in certain coagulation laboratory practices. Some of these practices were not consistent with current guidelines, and they may result in adverse events. Further studies are necessary to determine to what extent the variability we have found contributes to a change in patient outcomes. There appears to be a need for laboratorians and clinicians to work together to understand the reasons behind these variabilities and to develop concerted efforts to better assure compliance with accepted standards of practice.