

## Guest Editor



LAB NOTES is very pleased to have Dr. Kathleen Becan-McBride as our first Guest Editor. Dr. Becan-McBride is the University of Texas, Houston Health Science Center, Texas-Mexico Border Coordinator for Health Services; Professor in the Department of Clinical Laboratory Sciences; and Professor in the Department of Pathology and Laboratory Medicine. She received her BS, MEd, and EdD from the University of Houston and has board certification as an MT (ASCP). She completed a three-year term as Chair of the statewide HETCAT Council and also a two-year term as Chair of the University of Texas System Texas-Mexico Border Health Advisory Panel. She has published 11 books, an ASCP-published computer-based instructional module on blood collection, and over 50 journal articles. She has been invited to numerous countries as a guest speaker, and has been cited in a number of *Who's Who* books. In addition, Dr. Becan-McBride serves as an Advisory Panel Member for the *Vacutainer*<sup>SM</sup> Safety Institute, and is the founder of the VSI Blood Collection Education Program.

## Feature

### The Risks Associated with Phlebotomy Decentralization

By Mary Ellen Cortizas, PBT (ASCP), Manager of Laboratory Medicine, Children's Hospital, Boston

Phlebotomy is a risky business because of its potential for exposing its practitioners to virulent bloodborne pathogens. Blood-filled, hollow-bore needles--such as those used for venipuncture--are responsible for the highest rates of seroconversion from bloodborne pathogen exposure.<sup>1</sup>

Despite the high level of risk, there remains a tendency to view phlebotomy as an easy-to-learn, entry-level skill that anyone can perform. However, the reality is that phlebotomy is a technical skill that requires a high degree of manual dexterity and the ability to deal with many details at once. Becoming a good and safe phlebotomist requires constant practice and close supervision by seasoned phlebotomists.

Misconceptions of what phlebotomy truly entails have caused phlebotomy to become an easy pick for inclusion into new models of care. In many facilities, phlebotomy duties are assumed by nonphlebotomy staff, such as multiskilled clinical assistants or phlebotomists who are transferred from the clinical laboratory department and assigned to individual patient-care areas under the supervision of the nursing department. In a survey the Becton Dickinson VACUTAINER® Safety Institute<sup>SM</sup> mailed to a variety of healthcare workers, respondents were asked if they feel there is a trend at their institutions for nonphlebotomy personnel to collect and transport specimens. About six out of 10 hospital-based participants answered affirmatively. Conversely, less than one-third of nonhospital respondents (27%) indicated the same.<sup>2</sup>

There are often valid and pressing reasons for decentralization. Increased efficiency of patient care with respect to turnaround times for blood collections is one common reason. In addition, a significant amount of money can be saved by consolidating positions. Although healthcare providers cringe at using cost savings to justify changing procedures, they can no longer overlook opportunities to save large sums of money.

Debates about decentralization often focus on the potential for decline in specimen quality and patient satisfaction. Respondents to the survey from the VACUTAINER® Safety Institute<sup>SM</sup> substantiated a decline in specimen quality.<sup>2</sup> For example, one respondent commented that, "Additional nonlab personnel drawing blood has contributed to greater specimen-reject rates due to hemolyzed samples, clotted samples, improperly labeled samples, and misidentified patient samples."

#### Increased Risk

There seems to have been little consideration of the potential for increased blood and body fluid (BBF) exposure as a result of these changes. Whether or not decentralization of phlebotomy will result in more people suffering exposure to blood and body fluids is an important question that should be considered now, rather than in hindsight. Organizations that are contemplating such changes in phlebotomy services need to be aware of how this risk may increase if they implement the changes, and what steps to take to avoid compounding the hazards.

Since decentralization is a relatively new process, actual increases in BBF exposures have yet to be documented. This does not mean that increased risk cannot be foreseen, given what is known about the current process. Consider the following hypothetical decentralized phlebotomy program.

At ABC Hospital, both the decentralization of phlebotomy and the inclusion of phlebotomy responsibilities in other jobs mean that more people are performing phlebotomy than in the past. Without a doubt, these staff are given less training, practice, and skilled supervision than the traditional phlebotomist, because more people are performing the same amount of work, but often in isolation from each other. Because blood-collection tasks are spread among many more healthcare workers, each one performs a few

phlebotomies--compared to the past, when the phlebotomist's main responsibility was to collect blood from numerous patients. The phlebotomist's skills used to be kept "sharp" and efficient by repetition. In the past, the phlebotomists at ABC also had one main departmental location where they could compare strategies in technique and equipment to become more efficient, safe, competent and error-free. However, the isolation of decentralized phlebotomy limits the amount of feedback staff receive, and unsafe techniques may not be identified. For example, discussion of newly available safety blood-collection equipment is less prevalent, because healthcare workers are isolated from the department that receive information and vendor notification on the latest safety products. Likewise, with the larger workforce, turnover is higher, and thus the opportunity to develop "expert" phlebotomists is decreased. As a result, the overall skill level of phlebotomy at ABC may decrease. With a decline in blood-collection skill level in the institution, the likelihood of errors and resultant BBF exposure becomes even more acute.

This scenario hypothesizes a risk created by decentralization of phlebotomy services. If proper attention is paid to the potential problems of decentralized phlebotomy, training and continuing-education programs can be created that minimize safety risks.

As shown in the survey results from the VACUTAINER® Safety Institute<sup>SM</sup>, respondents who believe there is a trend toward nonphlebotomy personnel collecting and transporting specimens were asked to consider whether the shift has resulted in an increase in accidental needlesticks and/or tube breakage. Over four out of 10 hospital-based respondents and more than one-fourth of nonhospital respondents (27%) believe that there have been more needlestick injuries because of this trend. Between 23% and 27% of respondents have seen a rise in tube breakage.<sup>2</sup> The personal trauma for a BBF exposure to the healthcare worker and the costs to the healthcare institution are considerations that must be addressed with foresight rather than hindsight. It has been estimated that the cost of a needlestick injury ranges from \$200 to \$2,000 for laboratory tests and follow-up.<sup>3</sup> These figures do not include the costs of occupationally acquired HIV, hepatitis B or other infections. Neither do they include the personal suffering of the healthcare worker and his/her family.

## **Solutions**

The overall key to a successful decentralized phlebotomy program is joint collaboration between the clinical laboratory department and the nursing/patient-care department where phlebotomy will reside.

The first decision to be made is where a new model of phlebotomy service will be successful. For instance, areas with difficult phlebotomy populations--such as pediatrics and geriatrics--require the most expert phlebotomists. Patient population and volume of blood work should be considered, to determine whether decentralization is feasible or whether central phlebotomy should remain responsible. Areas with high volumes of mostly routine venipunctures are more suitable for the new decentralized models.

After a decision has been made to decentralize, it is important for the supervisors and administrators from the clinical laboratory and nursing departments to jointly develop a strategic plan for transferring blood-collection responsibilities to the nursing/patient care department. This strategic planning should incorporate a new decentralized workflow analysis for specimen collection, transportation, and processing, in order to ensure the efficiency and cost-effectiveness of this tactic. As the clinical laboratory and nursing departments collaboratively develop the new blood-collection process, they should continue to discuss and resolve issues during the training period of the personnel who will be collecting the blood specimens. A structured training program should be developed, implemented, and controlled by the central phlebotomy staff in the clinical laboratory. In addition to actual venipuncture techniques, orientation to the clinical laboratory and its process is essential to overall phlebotomy quality. Safety procedures are a key component to the training. If training is centralized, all persons performing phlebotomy will be taught the same procedure; also, a central resource will exist to evaluate competence and provide corrective feedback.

Objective criteria for successful completion of the program should be included. These criteria could include successful completion of a specified number of venipunctures and a required number of hours in the laboratory, along with passing a written and/or practical exam.

After initial training is complete, continuing education and yearly competency assessment in good phlebotomy and safety practice must be required for staff. Responsibility for maintaining and evaluating skills should be retained by the central phlebotomy section within the clinical laboratory, with an expert and objective evaluator assigned to the entire program.

Performance criteria specific to the appropriate blood collection techniques--such as venipuncture, skin puncture, and bleeding time--should be developed and used by the central phlebotomy supervisor as tools for the decentralized phlebotomy team. In addition to evaluating the actual blood-collection procedures, it is imperative to evaluate the blood collector's ability to transport the blood specimens in a timely, safe, and appropriate manner to the specimen processing point. These performance criteria should be made known to the nursing staff, since they will be evaluating the decentralized phlebotomy team on other performance criteria, such as preparation of the patient for various procedures, motivation in their responsibilities, etc. The central phlebotomy supervisor should have opportunities to review the overall performance of the healthcare workers performing phlebotomy, because other responsibilities can sometimes affect blood-collection performance. Knowing about difficulties employees are having with their responsibilities can assist the supervisor to redirect the healthcare worker toward better work performance in all areas. The central phlebotomy staff should also evaluate and select appropriate safety devices and provide training to all persons who will use the equipment.

Ongoing supervision of phlebotomy staff should be shared by the nursing/patient-care management and the central phlebotomy management. Keeping both groups accountable avoids the problem of one party thinking that the other is responsible, and vice versa. It works well to use the evaluative performance criteria developed by the central phlebotomy supervisor as the accountability criteria for blood collection. Thus, the nursing supervisor knows from the other performance criteria what he/she is accountable for in terms of supervision.

Finally, throughout the program, continuous improvement monitors for phlebotomy skills and safety should be tracked. This will identify potential problems and risks as soon as possible, so that corrective action can be taken. As an example, two continuous improvement monitors might be: (1) number of specimen collection errors traced to improper patient identification and (2) number of specimens collected with improper timing. These two examples monitor high-risk and problematic activities, as suggested by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).<sup>4</sup>

The central phlebotomy staff should gather data on how well the decentralized phlebotomy team performs on the improvement monitors and compare these data to thresholds previously determined by the clinical laboratory administration. From these findings, a plan for corrective action and follow-up monitoring and reporting should be developed. Corrective action may range from short-term retraining all the way to deciding that decentralization in a given area was not feasible in the first place. Follow-up monitoring can determine whether the actions taken helped reduce the number of specimen-collection errors and the different types of errors. Also, the cost of these errors can be estimated by assessing the labor and supplies used when the error was made.

In sum, decentralized phlebotomy should not have to entail an increased safety risk for staff. Program evaluation, consistent training programs, and ongoing assessment are the minimum features necessary to implement a successful decentralized phlebotomy program that minimizes safety risks.

#### References:

1. Jagger J, Balon M and Tereskerz PM. Recordkeeping and the OSHA Bloodborne Pathogens Standard: what hospitals record vs what is required. *Advances in Exposure Prevention*. 1995; 1(4): 1, 6-7.
2. Data on file. Becton Dickinson and Company, Franklin Lakes, New Jersey.
3. U.S. Department of Veterans Affairs. *Needle Stick Prevention in the Department of Veterans Affairs: Monographs I, II and III*. Milwaukee, WI: National Center for Cost Containment, 1995.
4. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). *1995 Comprehensive Accreditation Manual for Hospitals*. Oakbrook Terrace, Illinois: JCAHO, 1995.

## Editorial Commentary

By Kathleen Becan-McBride, EdD, MT (ASCP)

Considering that a needlestick injury is the single occupational exposure most likely to transmit HIV, hepatitis B, and/or hepatitis C, it is ironic that some healthcare institutions assume there is minimal risk in transferring phlebotomy responsibilities to healthcare providers having little blood-collection training and experience. As Ms. Cortizas has indicated, a mindset exists that phlebotomy is an easy-to-learn, entry level skill that anyone can perform.

It has been researched and documented that hollow-bore needles used for blood withdrawal have greater potential for transmitting HIV to healthcare providers than do other types of needles (e.g., those used for immunizations).<sup>1</sup>

The high level of risk associated with blood collection is probably not overlooked, but rather not known by decision makers at healthcare facilities. In this era of rapid, cost-cutting changes in the healthcare delivery system, healthcare institutions are attempting to increase efficiency of patient care by decentralizing phlebotomy. This approach to the blood-collection responsibility follows the Pew Health Professions Commission recommendations to integrate healthcare services at the clinical level.<sup>2</sup> However, the integration of the blood-collection responsibility needs to occur with an emphasis on the importance of structured training in phlebotomy.

Through my experience in healthcare delivery, I have found that many healthcare providers who have had blood collection added to their already long list of responsibilities resent this additional responsibility. Thus, the commitment to blood collection training or retraining is sometimes ignored. When blood collection responsibilities are decentralized and integrated into other assigned responsibilities, a clear proactive message must be communicated to the healthcare providers that blood collection responsibilities *require* safety training beyond what any other responsibilities require. Knowledge is the key to ensure that blood-collection safety protocols and engineering controls are utilized in this era of decentralization.

In addition to the necessary blood-collection training in the decentralization process, the healthcare facility in transition should maintain a central phlebotomy department. As Ms. Cortizas has pointed out, a central phlebotomy department is necessary, in order for a healthcare facility to: 1) provide consistency in training for *all* healthcare providers having blood-collection responsibilities; 2) select appropriate blood collection safety devices for the entire facility; and 3) provide inservice training on the proper use of the blood-collection safety equipment. In some institutions an oxymoronic outcome of phlebotomy decentralization has been the implementation of a safety initiative to use blood collection safety equipment, but it is purchased from different vendors for different areas of the institution. This lack of a centralized educational and ordering process for blood-collection safety equipment has led to hazardous collecting conditions, since mismatching of vendor equipment (e.g., safety adapters, self-sheathing needles, plastic tubes, etc.) has sometimes resulted in blood leakage and further risk of exposure. Having a centralized phlebotomy department can help ensure effective training in the use of safety equipment for the decentralized team, as well as increase cost-effectiveness through single-source bulk purchasing of blood-collection safety supplies and equipment.

As the "bullet train" of managed healthcare speeds down the track, it seems futile to fight decentralization. However, it is important to continue to fight to achieve and maintain a safe work environment. From the standpoint of blood collection, a significant reduction in bloodborne pathogen exposures and transmissions to healthcare providers will only be achieved through proper blood-collection training and implementation of safety equipment.

**References:**

1. Chiarello LA. Evaluation of needlestick prevention technology: a perspective from the New York State Pilot Study Experience. *Advances in Exposure Prevention*. 1995;1(5):3-5.
2. Pew Health Professions Commission. *Health Professions Education and Managed Care: Challenges and Necessary Responses*. San Francisco: UCSF Center for the Health Professions, Aug. 1995.

## In Control

*Special Section: Practical Information Concerning Efforts to Understand and Control Infectious Disease*

### Problems in Laboratory Testing in Primary Care

By Paul A. Nutting, MD, MSPH; Deborah S. Main, PhD; Paul M. Fischer, MD, et al.

The quality of clinical laboratory testing is important because of the key role laboratory testing plays in promoting and maintaining the public's health. In the fall of 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in response to concern that laboratory problems were an important public health concern that required federal oversight. It was noted in the CLIA debate that little scientific evidence was available to document the frequency of laboratory problems or their impact on patient care.<sup>1</sup> Provisions of CLIA, therefore, directed the U.S. Department of Health and Human Services to complete studies to document the extent of such problems. As an initial effort, the Centers for Disease Control and Prevention (CDC) published a review of the scientific literature that relates to CLIA.<sup>2</sup> This review found few published studies on problem rates in testing patient samples and only one that examined the impact of laboratory problems on patient care.<sup>3</sup> In this 1991 study at a single hospital, 363 laboratory "incidents" were studied. Ninety-three percent of all problems occurred in either the preanalytic or postanalytic phase, while 7% occurred during the laboratory procedure itself. When the medical records were reviewed to examine the impact of these problems on patient care, no effect was found in 70% of patients, while 24% of patients were subjected to additional blood drawing and 6%, although not harmed, were subjected to what was judged to be additional risk of improper or inappropriate care.

Evidence suggests that most laboratory problems occur during the preanalytic and postanalytic phases of the total testing process.<sup>3-5</sup>

The most common laboratory problem is probably not related to testing per se, but rather to the keyboard entry of laboratory data. Errors in keyboard entry have been reported to occur at a rate of 3% to 5%.<sup>6</sup> Hownitz recently reported results from the Quality Assurance Program of the College of American Pathologists suggesting that analytic problems are insignificant in comparison to preanalytic and postanalytic problems.<sup>5</sup> Analytic problems are likely to become even less common due to ongoing improvements in and automation of laboratory procedures.

Previous studies have viewed testing problems from the laboratory perspective, often expressing problems solely in terms of deviation from a reference value. This perspective provides little information on the impact of problems on patient care. To completely understand the importance of laboratory problems, it is necessary to look at the broader context of clinical care, including the role of laboratory tests in clinical decisions. Since clinical decisions are usually based on information from multiple sources, it has been argued that clinicians may serve as a filter for laboratory problems, and thus limit their potential negative impact on patient care.<sup>5,7</sup>

## METHODS

### *Study Setting*

The Ambulatory Sentinel Practice Network (ASPN) is collaborating with the CDC in a series of studies to develop methods to better understand the role of laboratory testing in primary care, the frequency and nature of laboratory problems, and their impact on care and outcomes. This report describes a study to identify the characteristics and frequency of laboratory problems in primary care and to assess their impact on patient care from the perspective of the clinician. The ultimate goal is to improve patient care by identifying sources of problems in laboratory testing and reducing or eliminating the common sources of such problems, regardless of the location at which the laboratory service is rendered.

### *Data Collection*

A total of 124 primary care clinicians in 49 ASPN practices reported and described all laboratory problems detected during a six-month period from April 18 to October 17, 1993. To increase the number and variety of problems described, the practices were instructed to report any irregularity which the practice considered to be important in the full spectrum of the laboratory testing process. After approximately 2 and 4 months of data collection, feedback was given to the practices on the problems being reported in an effort to increase completeness of reporting.

### Analysis

The problems reported were coded into one of five problem categories (Table 1) consistent with standard categorization of phase of testing.<sup>3,5</sup> The categories included two preanalytic steps (test initiation and specimen collection and handling), the analytic phase, the postanalytic phase, and a category of "inconsistent results," in which the clinician indicated that the test result was not consistent with the patient's clinical picture. The inconsistent result could not be assigned to a specific step in the testing process, however.

**Table 1. Coding Categories for Laboratory Problems Reported by Phase of Testing**

Phase of Testing	Problem Description	Examples Given
Preanalytic Test Initiation	Failure of communication regarding test wanted	None given
Specimen Collection or Handling	Inappropriate specimen obtained or specimen integrity compromised in handling or transport	Delay in specimen collection; specimen lost or insufficient; specimen clotted or hemolyzed; specimen pickup or delivery delayed; processing delay or error; inappropriate specimen collected; specimen sent to wrong laboratory; problem with collection instrument; wrong patient sampled or sample mislabeled; mismatched specimen
Analytic	Problem occurring during the conduct of the testing procedure	None given
Postanalytic	Problem in handling or communication of a test result	Incomplete, missing, or erroneous report; delayed turnaround time; misplaced or misfiled result; report unclear
Inconsistent Result	Test result inconsistent with the patient's clinical picture	None given

For 24 of the 49 problems judged to have an impact on patient care, the practices provided adequate detail to allow researchers to assess the magnitude of the impact. Problems were considered to have significant impact if it appeared that the diagnosis or treatment was affected. Otherwise the impact was considered minor.

## RESULTS

A total of 180 laboratory problems were detected and reported by the practices during the six-month study. Of the problems reported, 45% were reported by primary care clinicians, 28% by in-office laboratory personnel, and 26% by office nursing staff.

During the study time frame, the participating practices completed a total of 160,714 patient visits for a crude frequency of 1.1 laboratory problems per 1000 patient visits.

Table 2 shows the distribution of the reported problems by phase of testing. Overall, problems detected in the preanalytic phase were most common (55.6%).

**Table 2. Distribution of the Reported Problems by Phase of Testing**

	<b>Phase of Testing</b>	<b>Total No. (%)</b>	<b>Physician Office Laboratory, No. (%)</b>	<b>Referral Laboratory, No. (%)</b>
Preanalytic	Test Initiation	39 (21.7)	8 (17.8)	31 (23.0)
	Specimen collection and handling	61 (33.9)	11 (24.4)	50 (37.0)
<b>Total</b>		100 (55.6)	19 (42.2)	81 (60.0)
Analytic		24 (13.3)	18 (40.0)	6 (4.4)
Postanalytic		50 (27.8)	8 (17.8)	42 (31.1)
Inconsistent result		6 (3.3)	0	6 (4.4)
<b>Total</b>		180 (100)	45 (100)	135 (100)

Forty-nine (26.9%) of the reported problems had an effect on patient care. These distribute across the phase of testing in a pattern similar to the total as shown in Table 3. For 24 of the 49 problems reported to have an effect on patient care, the problem description included information about the impact of the problem. Of this subset of problems with known patient impact, the impact was judged clinically significant in less than half (45.4%), with the remainder usually requiring a repeat of the specimen collection.

Researchers identified 10 problems with a known impact that were judged to have a significant effect on patient care. These problems, shown in Table 4, include three problems with Papanicolaou tests, two with prothrombin times, and one with each of the following: a false-negative human immunodeficiency virus (HIV) antibody test, a false-positive pregnancy test, a delayed report on a potassium test that required prompt results, a false-negative urine culture, and a delayed report of stool culture.

**Table 3. Distribution of Problems Judged to Have an Effect on Patient Care by Phase of Testing**

	<b>Phase of Testing</b>	<b>Total Reported Problems, No. (%)</b>	<b>Problems With An Effect on Patient Care, No. (%)</b>
Preatalytic	Test Initiation	39 (21.7)	4 (8.2)
	Specimen collection and handling	61 (33.9)	17 (34.7)
<b>Total</b>		100 (55.6)	21 (42.9)
Analytic		24 (13.3)	8 (16.3)
Postanalytic		50 (27.8)	16 (32.6)
Inconsistent result		6 (3.3)	4 (8.2)
<b>Total</b>		180 (100)	49 (100)

**Table 4. Problems Judged to Have a Significant Impact on Patient Care\***

<b>Test</b>	<b>Problem</b>	<b>Nature and Source of Problem</b>	<b>Impact on Patient Care</b>
HIV antibody	False negative	Referral laboratory; analytic error	Diagnosis delayed
Urine pregnancy test	False positive	Referral laboratory; inconsistent result (exact source of problem not know n)	Uterine ultrasound examination performed
Pap test	Specimen lost	Referral laboratory; specimen collection and handling problem (specimen lost between practice and referral laboratory)	Test repeated
	Endocervical cells reported in a posthysterectomy patient	Referral laboratory; inconsistent result (exact source of problem not know n)	Test repeated
	Specimen lost	Referral laboratory; specimen collection and handling problem (specimen lost between practice and referral laboratory)	Test repeated
Potassium	Delayed report on a test requiring prompt results	Referral laboratory; postanalytic error	Patient hospitalized for hypokalemia

Urine culture	False negative	Physician office laboratory; postanalytic error (result misreported by practice nurse)	Treatment delayed
Stool culture	Delayed reporting of <i>Campylobacter</i> infection	Hospital laboratory; postanalytic error (delayed report by hospital laboratory)	Treatment delayed and hospital stay prolonged
Prothrombin time	Therapeutic range misstated by laboratory	Referral laboratory; analytic error	Development of hematoma
	Delayed report	Referral laboratory; postanalytic error	Delay in adjustment of warfarin dosage

\*"HIV indicates human immunodeficiency virus; "Pap" indicates Papanicolaou

A comparison of the frequencies with which patients of the ASPN and those of a national sample of family physicians received selected laboratory tests is shown in Table 5. Similarity in the frequencies of test ordering is apparent for most tests. The ASPN differed from the national sample by more than 15% in four of 22 categories; ASPN patients of both sexes received more HIV serologic tests and ASPN female patients received more Papanicolaou tests and fewer tests for streptococcal infection.

**Table 5.** Comparison of Frequency of Test Ordering by U.S. Family Physicians in the Ambulatory Sentinel Practice Network (ASPN) and in the 1991 National Ambulatory Medical Care Survey (NAMCS)\*

Test	ASPN Physicians		NAMCS Physicians	
	(n=83) Male Patients	(n=229) Female Patients	Male Patients	Female Patients
Cholesterol level	5.6	4.2	4.9	4.2
HIV serology	0.51	0.43	0.35	0.25
Test for streptococcal infection	3.0	2.4	3.5	3.1
Pap test	0	7.0	0	5.9
Urinalysis	8.8	13.9	7.9	13.7
Other laboratory test	16.4	21.0	16.5	18.3

\*The values given are percentages of patient visits. HIV indicates human immunodeficiency virus; "Pap" indicates Papanicolaou. Frequencies are age-adjusted within gender. Adjustment was also made for pregnancy status, since a larger proportion of visits by female patients to ASPN clinicians was for prenatal care. Adjustments were made using the pooled population from both samples.

## COMMENT

According to the 1992 National Ambulatory Medical Care Survey (NAMCS), Americans made more than 750 million visits to office-based physicians in 1992. During which physicians ordered more than 100 million urinalyses, 16 million tests for "strep throat," and nearly 24 million measures of serum cholesterol

concentration.<sup>8</sup> Little is known about why physicians order laboratory tests, how the information contributes to clinical decisions, the frequency of laboratory problems, and their effect on patient care.

This is the first study of laboratory problems in primary care and the first that identifies problems from the practice perspective. Using voluntary reporting from clinicians and other office personnel, the study estimates the frequency of laboratory problems to be approximately 1.1 per 1,000 patient visits. The frequency of problems with laboratory testing among ASPN practices is 3.4 per 1,000 patient visits that include one or more laboratory tests. A study is currently under development that will refine this estimate based on the number of laboratory tests ordered.

Thus, this study suggests that problems with laboratory testing that are apparent to the practice are relatively infrequent, but patient care is affected in about 27% of occurrences. Of the problems reported, a minority were attributed to the analytic phase, while most problems were related to communication and specimen management, especially with those tests sent to referral laboratories for analysis. Analytic problems associated with referral laboratories may be underreported with the methods used in this study, however, since the clinician would be unaware of problems detected and solved at the referral laboratory.

This study has four limitations. First, the possibility exists that ASPN clinicians, by the nature of their voluntary participation in research, may not reflect typical primary care physician practice in terms of laboratory test ordering practices, selection of referral laboratories, and management of their office laboratories.

Second, the study was designed to examine laboratory problems from the practice perspective and thus might underreport problems not apparent to the practice. Its strength, however, lies in assessing the impact of the problem on clinical decision making and ultimately the impact on the patient. Third, the study might be weakened by the possibility that the participating practices had an incentive to underreport laboratory problems to avoid self-inculpation.

Finally, the total number of laboratory tests ordered by site of testing was not recorded. It is not clear whether proportionately more problems were associated with testing sent to referral laboratories than with office laboratory testing.

The results of this study will be confirmed and clarified by further study under a cooperative agreement between the ASPN and the CDC. A more detailed examination of the nature and frequency of laboratory problems is under design and will denominate problems by specific test and site of testing. Future studies will assess the impact of laboratory problems in health and economic terms.

Subsequent studies will also determine whether certain problems occur systematically and whether they are amenable to preventive interventions. Further work under this cooperative agreement will examine patterns of laboratory use, the clinical utility of laboratory tests, and patient perceptions and satisfaction with laboratory testing in primary care.

#### References:

1. Senate Committee on Labor and Human Resources. *Report 5.2477*. Washington, DC: U.S. Government Printing Office; 1988.
2. Boone DJ. Literature review of research related to the Clinical Laboratory Improvement Amendments of 1988. *Arch Pathol Lab Med*. 1992;116: 681-693.
3. Ross JW, Boone DJ. Assessing the effect of mistakes in the total testing process on the quality of patient care. In: *1989 Institute on Critical Issues in Health Laboratory Practice: Improving the Quality of Health Management Through Clinician and Laboratorian Teamwork*. Institute on Critical Issues in Health Laboratory Practice; 1991. Abstract.
4. Finn AF, Valenstein PN, Burke MD. Alteration of physicians' orders by nonphysicians. *JAMA*. 1988; 259: 2549-2552.
5. Howanitz PJ. From start to finish, how accurate are lab tests? *CAP Today*. July 1994: 41.
6. Tuckerman JF, Henderson AR. The clinical biochemistry laboratory computer system and result entry: validation of analytical results. *Comput Methods Programs Biomed*. 1985; 20: 103-116.

7. Fischer PM. A clinician's perspective on testing quality. In: Martin ML, Addison BV, Wagner WM, Essien JDK, eds. *Proceedings of the 1989 CDC Institute on Critical Issues in Health Laboratory Practice*. Atlanta, Ga: Centers for Disease Control and Prevention; 1991; 1126-1129.
8. Schappert SM. *National Ambulatory Medical Care Survey; 1992 Summary*. Hyattsville, Md: National Center for Health Statistics; 1994. Advance Data From Vital and Health Statistics, No. 253. This article was excerpted from *JAMA*. 1996; 275: 635-639. The authors' work was funded by the ASPN and the CDC.

## Medical Lore

### The History of Becton Dickinson – Part 1 In The Beginning

It was the bright South west sun and a gesture of kindness that brought Becton and Dickinson together. Fairleigh Dickinson, a young man in his early 30s, was seated in a railroad station dining room in Texarkana, Texas, awaiting his breakfast. The morning sun blazed through an opening in the window shade. A younger man in his late '20s, seated nearby, walked to the window and adjusted the shade. In a gesture of appreciation, Dickinson invited Maxwell Becton to join him for breakfast.

Over coffee, the two found they had a great deal in common. Both were descendants of pre-Revolutionary British families. They had grown up just 40 miles apart in the eastern part of North Carolina. Becton was a partner in a small medical-supply firm based in Boston. Dickinson was a traveling salesman for the Baker Paper Company of Saugerties, New York. Both were on extended sales trips across the country.

The two men decided to travel together through Texas to San Francisco, each selling his own line. In the late 1800s, most towns had more physicians, hospitals and pharmacies than stationers. Dickinson usually finished his sales stops before Becton, and he soon noticed that Becton was able to carry his complete line of fever thermometers in a tidy satchel, while his stationery had to be lugged about in heavy cases. As the two continued on sales calls together, Dickinson came to believe that Becton's line was not only easier to carry, but also had a more promising future. Dickinson offered to invest in Randall, Becton and Company, on the condition that the firm move to New York, but Becton's partner Randall was not interested. In later years, Randall was heard to say it was the biggest mistake he ever made.

Shortly thereafter, Maxwell Becton walked into the New York office of Baker Papers and said to Dickinson, "When are we going to start business?" "Does your partner want to sell out?" asked a surprised Dickinson. "No," replied Becton, "but I have sold out." Dickinson matched Becton's investment of \$4,000 to form a partnership. Becton, Dickinson and Company opened for business in September 1897, scarcely a year after that first chance meeting in Texas.

## Order Of Draw

Over the past one to two years, there has been much discussion in the healthcare industry about the correct order of drawing evacuated blood collection tubes. The most order-of-draw questions Becton Dickinson VACUTAINER® Systems receives relate to the VACUTAINER® Brand SST® Tube. The SST® Tube contains silica particles, which act as a clot activator, and are considered to be an additive in the tube. This is also true of VACUTAINER® PLUS serum (red top) tubes, which have the same silica clot activator to initiate the clotting process in the plastic serum tube. Therefore, Becton Dickinson VACUTAINER Systems does consider these tubes to be part of the additive tubes in the order of draw (see BDVS order-of-draw sidebar, below). Historically, however, most customers have considered the SST® Tube to be a plain serum tube and have placed it near the beginning of the draw.

The current National Committee for Clinical Laboratory Standards (NCCLS) guideline, "Procedure for the Collection of Diagnostic Blood Specimens by Venipuncture--Third Edition," (Document H3-A3, Vol. II, No. 10, July 1991), does not specifically address the placement of the SST® Tube, or any tube containing clot activators such as thrombin, in the order of the draw (see sidebar, below). However, this guideline, which is currently under revision, may change the order of the draw to reflect the BDVS-recommended order of draw. *LAB NOTES* will publish the new NCCLS information in an upcoming issue when it is available.

### **Becton Dickinson VACUTAINER® Systems' Recommended Order of Draw:**

- Serum (Glass Tube)
- Citrate
- Heparin
- PST™ Gel Separator Tube with Heparin
- EDTA
- Then, other additives
- SST®
- Serum (Plastic)

**NOTE: Always follow your facility's protocol for order of draw**

### **National Committee for Clinical Laboratory Standards (NCCLS) Recommended Order of Draw:**

The recommended "order of draw" when drawing several specimens during a single venipuncture is as follows:

1. Blood culture tube
2. Nonadditive tube (e.g., red stopper)
3. Coagulation tube (e.g., blue stopper)
4. Additive tube (e.g., green stopper)

The recommended "order of draw" for additive-containing tubes is:

1. Citrate-containing tube (blue stopper)
2. Heparin-containing tube (green stopper)
3. EDTA-K<sub>3</sub>-containing tube (lavender stopper)
4. Oxalate/fluoride-containing tube (gray stopper)

## **Becton Dickinson VACUTAINER® Systems New Product News**

### **VACUTAINER® Brand UNIQUET® Single-Use Tourniquet**

It is estimated that 6% to 12% of the population has some degree of latex sensitivity, with latex allergic reactions ranging from very mild to severe. In the healthcare industry, this latex sensitivity is a newly recognized, potentially life-threatening problem facing both healthcare workers and their patients.

To help address the latex risk in health care, Becton Dickinson VACUTAINER® Systems has recently introduced a latex-free tourniquet. The VACUTAINER® Brand UNIQUET® tourniquet is made of a unique, synthetic, latex-free material that eliminates the potential for allergic reactions, while performing similarly to a latex tourniquet for adequate vein occlusion. The UNIQUET® is packaged in a small box of 50 tourniquets, and each tourniquet is designed for single use. The additional advantage of this single-use product is that it eliminates transfer of organisms from one patient to another.

For more information about the VACUTAINER® Brand UNIQUET® tourniquet, contact your Becton Dickinson VACUTAINER® Systems sales representative.