Blood Sample Processing: Clinical Perspectives on Recent Developments in Technology and Laboratory Operations

Marcia Armstrong, MS, CLS
(2010-2011 President, American Society for Clinical Laboratory Science, Washington, DC
Professor Emeritus, University of Hawaii, Kapiolani College, Honolulu, HI)

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n recent years, as technology has increased in availability and complexity, medical laboratorians have been presented with a range of both opportunities and challenges. Automated processing enables technologists to perform a greater variety of tests on smaller sample quantities with greater accuracy of outcomes. It also allows highly skilled medical laboratory scientists to avoid repetitive logistical tasks in favor of higher-level analytic activities. Because automated processing requires fewer skilled personnel to run, it also helps laboratories to reduce operating costs and eliminates the necessity of hiring additional staff in times of labor shortages. Given these advantages, an increasing number of laboratories are connecting hematology and chemistry analyzers to automated platforms.

Yet while automated process technologies have enhanced workflow efficiency and outcomes in many laboratories, many others have encountered compatibility concerns between analyzers and the tubes used to contain the samples. In addition, some tubes used for an automated process have been designed to function in manual processing. Process stoppages caused by incompatible equipment can have significant negative impacts on workflow efficiency, laboratory maintenance costs, and time to disease diagnosis and treatment. Participants agree that there must be an industry-wide movement to establish and document greater compatibility between collection devices and analyzers.

Laborators have also needed to learn how to get more out of less as industry pressures to increase blood conservation have intensified. Unnecessarily large blood samples can pose significant health risks for anemic and other vulnerable patients. In recognition of these risks, in early 2010 the Joint Commission announced the pilot implementation of a series of blood management initiatives at hospitals across the United States. Blood conservation is a core priority area of this program. Following analysis of the pilot test results, a technical advisory panel will review the data and make a recommendation to the National Quality Forum for endorsement. The likely outcome of this program will be a continued emphasis on increasing conservation, thereby decreasing the need for some transfusions and also reducing operating costs associated with biological waste disposal.

The No. 1 2010 National Patient Safety Goal of the Joint Commission is improving the accuracy of patient identification (ID). Reducing the number of ID-dependent procedures decreases the risk of misidentification. In addition, given the potential risks to patients of blood sample misidentification, eliminating ID labeling errors has also become a cornerstone of medical laboratory scientist and technician training. However, as blood sample sizes have decreased, microtubes accommodating smaller sample quantities have come into routine use. These smaller tubes have imposed additional challenges for laboratorians as they require the use of special miniaturized labels that do not include complete information or larger labels wrapped around the tube that must be removed in the lab.

Sample Sizes

Participants agree that the health care industry’s push toward smaller blood sample sizes has created a range of special challenges for laboratory staff. All participants agree that the previous quantity of 10 mL was excessive, and 3 mL is adequate for most routine patients. Blood collection staff, including phlebotomists and nurses, may not collect even that reduced amount from neonatal or medically fragile patients. Some participants maintain that this fairly routine occurrence, referred to as Quantity Not Sufficient (QNS), is more accurately described as an “improper draw” because of the altered blood-to-tube additive ratio (ie, anticoagulant or clot activator). There are also industry pressures for medical staff to use microtubes in blood collection in order to minimize sample volumes, especially in intensive care units (ICUs). However, while laboratorians understand and sympathize with the desire of medical staff to minimize blood draw—particularly among very sick or frail patients in the ICU, where the amount of blood taken from a single patient can exceed 1 liter over the course of 1 inpatient stay—they also need to emphasize the importance of having an adequate amount of sample of sufficient quality and an automated process-compatible collection device

Abbreviations

ID, identification; QNS, Quantity Not Sufficient; ICU, intensive care unit; POC, point-of-care; ASCP, American Society for Clinical Pathology; IRB, institutional review board; NICU, neonatal intensive care unit

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Note: This article is based on a roundtable discussion held November 11, 2010, in New York, NY.
to perform multiple thorough and accurate tests. Participants agree that not having sufficient volumes for analysis can raise operating costs and place significant stress and demands for additional vigilance on laboratory staff, who in some cases must ask blood collection staff to obtain repeat draws from neonatal or medically fragile patients.

Another driver of decisions to resample is sample degradation. There was consensus among participants that generally samples older than 12 hours should not be relied on for accurate analyses. For example, 1 important area of concern in the analysis is blood glucose levels, because glucose levels decrease in whole blood within a few hours following sample collection. Participants agree that the need to redraw based on sample degradation is particularly difficult to justify to blood collection staff.

Consistent problems with point-of-care (POC) testing, which is performed by non-laboratory staff, seem to have yielded some sympathy among collection staff for the challenges involved in medical laboratory testing, including pressures to perform multiple tests on low-volume samples. There was general consensus among participants that most errors occur in the pre-analytical and post-analytical phases, either in sampling or in the interpretation of results.

**Automated Processing**

Automated processing further reduces errors but also imposes special challenges for testing low-volume samples. One participant used the analogy of upsetting a retail shopping queue by proffering cash instead of a credit card. Introducing a microtube into an automated process often has the same outcome: it impairs workflow efficiency by introducing a manual procedure into an automated process. This problem is especially pronounced for participants from larger facilities relying on automated processing to save time in the course of hundreds or thousands of sample processing cycles each day. Another participant maintained that he needed to place microtubes within larger tubes to accommodate a full-size (non-miniaturized) label. Participants agreed that a microtube designed for automated processing and capable of accommodating a full standard-size patient ID label would be a valuable innovation and would “absolutely reduce errors.”

Although participants agree that using microtubes does not increase the likelihood of an error, they also note the percentage of processing problems is higher with microtubes due to the manual processing and labeling required. One issue of particular concern is increased handling time. Laboratories are constantly under pressure to improve turnaround time for samples. It is standard procedure for clinical laboratorians to limit the frequency of directly handling or combining samples because each additional manual step increases handling time as well as the likelihood of an accidental exposure to bloodborne pathogens. Participants agreed that minimizing the handling of tubes should remain a top priority for clinical laboratories and in staff training.

The most valuable benefit of automation, particularly for larger facilities, is the standardization of processing time. Participants agree that increasing the predictability of the analysis cycle can have a significant positive impact for overall workflow efficiency. This added efficiency is especially important for facilities using smaller sample sizes. In addition, there are moderate operating cost savings associated with automation, estimated as approximately 5%-10% annually for larger institutions following a 3- to 4-year payback period. These cost savings can be even more substantial for institutions currently relying on manual handling of microtubes, which increases the per-test cost because the current microtube offerings are not automation compatible. Though the initial capital outlay for the necessary equipment proves difficult for many small- to mid-sized institutions to manage, automation is a desirable goal for most facilities.

**Training and Laboratory Management**

Participants also offered perspectives on a range of key industry trends, clinical laboratory management issues, and potential areas of process improvement.

**An Aging Workforce**

Given the increasing importance of technological know-how among clinical staff, it is interesting to note the nationwide average age of a clinical laboratory scientist is between 47-49, and many are approaching retirement age. At 1 participant’s facility, the average age is 57. In 2004 the American Society for Clinical Pathology (ASCP) issued *The Medical Laboratory Personnel Shortage*, a seminal report on this alarming trend. Since then, the organization has established scholarships and academic partnerships to combat the growing shortage of qualified new clinical laboratory staff. Nevertheless, as of 2010 the U.S. Bureau of Labor Statistics maintains that, among medical laboratory scientists and technic平ns, “the number of job openings is expected to continue to exceed the number of jobseekers.” Participants agree that an infusion of young, well-educated, and technologically savvy laboratorians is critically important for the industry as automation process technologies become more common.
Introducing New Technologies and Products

Participants agree that medical laboratory professionals are generally able to teach each other when a new or unfamiliar product or technology is introduced. However, there were significant differences in the latitude granted to participants by their institutions in terms of product choice. In some facilities, product choice is dictated by vendor contracts with little clinical input, while other institutions allow staff to purchase virtually any products they wish so long as they demonstrate the economic value of products and stay within “old-fashioned capital budgets.”

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There are also significant differences in the product approval process by institution. In some cases, institutional review board (IRB) approval and exhaustive parallel studies are required. One participant added that these studies can be difficult or impossible to perform when they involve non-consenting populations such as neonates. Yet in general, medical laboratory scientists and technicians and even some laboratory directors have little say in materials management decisions, “In reality,” 1 participant argued, “hospital administrators” make these decisions, and the decision-making process can result in “some pretty tough battles.” While some participants reported relatively effective coordination between their institution’s administration and laboratory staff, for most medical laboratory professionals, the value proposition for a new product must be substantial to justify the stress associated with the approval process.

Though participants understand the necessity of a rigorous review process, they also strongly believe that most institutional review processes can be streamlined. In addition, clinical laboratory personnel should have more influence in the proposal and approval of new products within their professional purview. Undertaking these 2 steps will yield multiple significant benefits for workflow efficiency and overall analytical outcomes.

Pre-analytical Variability and Personnel Training

One specific area of achievable improvement in the blood sample collection and analysis process lies in the pre-analytical phase with phlebotomists6 and other medical staff who collect laboratory specimens. Participants agree and studies show that the pre-analytical phase is where most of the errors in the diagnostic process occur. Though estimates in the clinical literature vary significantly, from 56%7 to 93%,8 pre-analytical variability accounts for a clear majority of diagnostic errors.

Participants agree the most likely reason for pre-analytical variability is lack of professional training related to sample collection. While rigorous national certification standards exist, it is common for someone to be hired as a phlebotomist with no certification at all. Moreover, there is too much reliance on on-the-job training and informal peer instruction, and there are very limited continuing education opportunities. Compounding these problems is a growing trend toward staff downsizing and elimination of dedicated phlebotomy teams, thereby involving phlebotomists in blood sample collection only in cases of a difficult draw.

A less direct but still substantial factor is the “pay and prestige gap” that often exists between phlebotomists and other clinicians. Participants indicated that phlebotomists are often “low on the totem pole” in hospital and laboratory settings. Professional disregard for the phlebotomy profession was noted to be especially inappropriate given the pivotal function of these professionals in patient care and in obtaining and handling specimens.

Conclusions

Clinical laboratory scientists involved in diagnostic or clinical analysis confirm there is increasing pressure from health care policymakers and hospital management to reduce blood volume in sampling. They also note that blood collection or medical staff, especially phlebotomists and nurses who work in ICUs and neonatal ICUs (NICUs), widely support this goal. While recognizing the benefits in terms of reduced waste and improved patient comfort and safety, laboratory scientists report continuing challenges in efforts to analyze samples where volumes are insufficient or where the amount of anticoagulant is not appropriate for the volume of blood, potentially compromising the sample. There are also operational difficulties associated with the incompatibility of most currently available microtubes with automated processing technologies. Factors such as redraws caused by insufficient blood sample volumes, questionable sample quality, labeling errors, and manual handling of microtubes that cannot be processed using automated technologies continue to have a negative impact on analytical accuracy and laboratory efficiency.