VALUE AND ACCURACY OF POINT-OF-CARE TESTING

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Point-of-care testing (POCT), or portable blood analyzers, can be a solution to provide reliable results in several circumstances. For the clinician, POCT provides another supportive tool for expedient diagnosis, monitoring and management of their patients' health conditions.

Despite the benefits, however, there are several challenges associated with these methods, since they require clinical staff, rather than laboratory-trained personnel, to perform the testing. Additional challenges include management of analyzers outside of the laboratory and managing the overall accuracy of the instrumentation. An increased risk of result errors may also occur from a lack of understanding of the importance of quality control and quality assurance practices. POCT does require the appropriate Clinical Laboratory Improvement Amendments (CLIA) certificate and medical oversight. The Centers for Disease Control and Prevention has tools to assist with POCT and quality system compliance on its website (*www.cdc.gov/labquality/tools-and-resources.html*).

In a recent study, a hospital with a dedicated POCT management team performed an analysis and found 24 different tests were being performed through POCT, comprising 10.8% of all the hospital's laboratory tests. To maintain compliance with regular site inspections, checklists and mandatory remedial action plans were implemented. Following this, inspection citations were reduced from 3.17 to 0.27 per testing site. The average cost of POCT tests was $1.89 (not including labor or the approximately $0.80 per test to cover the cost of the POCT management team). The researcher suggests that both direct and indirect costs should be included when evaluating POCT[1] and the cost of repeat testing in the laboratory to verify abnormal results should also be incorporated.

Mitigation methods include documentation of POCT orders and results, improved training of personnel and demonstration of sustained competency of individuals performing tests.[2] Errors in results can occur when a clinician uses an incorrect sample source, such as venous or arterial blood, instead of the manufacturer's recommendation of capillary blood for testing.[3] Patient attributes and comorbid conditions may also affect results; therefore, providers should be aware of limitations to restrict basing treatment decisions on potentially inaccurate results. Although POCT may be desirable because of the rapid result turnaround times, its potentially negative factors include the risk of errors that may occur, particularly those depending on the operator's experience in properly

collecting, handling and transferring specimens. A study to evaluate pre-analytical errors leading to machine error found an error rate of 6.8%, in which 2.3% were attributable to operator error.[4]

COST CONCERNS

It is estimated that within the next decade, the cost of treating coagulation-related disorders will reach $800 billion. Ideally, hemostasis assays would be able to simulate results under flow conditions while only utilizing small samples and providing results in a timely fashion.[5] Activated clotting times and viscoelastic testing (VET) are the most utilized coagulation POCT. There is no definitive standard for either test—meaning that interpreting results is dependent upon activators and the device used.[6] Results of a study comparing VET with conventional coagulation tests (CCT) demonstrated that VET holds several advantages, including cost-effectiveness. The potential for larger cost savings exists in using VET, with its rapid turnaround time to avoid complications from hemorrhage and its ability to effectively treat bleeding, which may positively impact care that otherwise would add to hospital costs.[7] However, a trained clinician is needed to ensure proper result interpretation.

A review of 18 invasive and five non-invasive hemoglobin (Hgb) POCT devices found that deficits exist in measurement accuracy for the intended purpose of screening blood donors for suitability and for use in patients—in part due to the sample source of a fingerstick. A mean value for systematic calculation of Hgb was -0.27 g/dL for invasive and -0.17 g/dL for non-invasive devices. Although near a target of 0 g/dL, the 95% confidence intervals (CI, ±1.96 g/dL for invasive and ±2.5 g/dL for non-invasive) are not within a clinically adequate target range. For example, in the operating room, Hgb values between 6 and 10 g/dL require higher levels of accuracy with confidence limits of ±0.5 g/dL. For anemia screening purposes, a confidence limit of ±1.0 g/dL is needed for precise detection of the lower values. Insufficient accuracy leads to uncertainty and erroneous decisions.[8]

Osborn et al. found that sensitivity and specificity were 99.1% (95% CI 94.8-100.0) and 71.0% (95% CI 64.4-76.9), respectively, for invasive POCT Hgb and 81.6% (95% CI 72.5-88.7) and 75.4% (95% CI 68.8-81.1), respectively, for non-invasive POCT Hgb. This indicates that both are clinically useful to screen for anemia.[9] When comparing POCT Hgb to central laboratory testing of venous samples in large volume transfusion, the POCT was not interchangeable with the complete blood count Hgb.[10] The POCT analyzer was less precise once the Hgb fell below 7 g/dL; therefore, the recommendation was that a CBC should be conducted within 30 minutes following the transfusion. This lack of precision does not exclude these POCTs; rather, it demonstrates the importance of their application. The devices may be used to trigger the need for further laboratory testing or measurement trends.

PATIENT BLOOD MANAGEMENT PROGRAMS

In patient blood management (PBM) programs, POCT provides a means of identifying anemia, blood loss and coagulation function while prescribing the right treatment at the right time for the right reason. POCT analyzers generally require smaller amounts of blood, thus contributing to PBM measures to minimize iatrogenic losses. The portability, at either the bedside or in close proximity

to the patient, may be considered advantageous to the health care team. PBM programs may lead implementation efforts of POCT as well as initiatives for utilization and expansion. This may include the use of POCT Hgb measurements as a screening tool for anemia or the expanded use of VET in intensive care or in obstetrical patients. PBM programs have the ability to identify opportunities, assemble multidisciplinary teams, create protocols and algorithms, and measure outcomes.

In conclusion, POCT has become a necessary laboratory service that holds an important role within patient care and PBM programs. Consideration must be given to user training and competency, as well as knowledge of device sensitivity and specificity. Caregivers should be able recognize patient conditions that could potentially impact test results. Growth continues in the types and number of tests that can be done at the POCT providing additional opportunities for PBM programs to support improving patient outcomes.

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