Quality Error Rates in Point-of-Care Testing

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Point-of-care testing (POCT)² represents one of the fastest growing segments of the diagnostics market. Although major advances have been made in the instrumentation and methods used for POCT, further development and enhancements appear to be necessary to meet the challenges presented by the difficult testing environments in which these devices are used. In addition, the varied experience and training of users and their use of samples that may not be optimal for testing continue to present challenges in the implementation of POCT (1).

One of the major advantages of POCT is that it provides much faster access to test results, allowing for more rapid clinical decision making and more-appropriate treatments and interventions. In addition, POCT can help minimize time-dependent changes in labile analytes such as lactate and glucose, which can be caused by delays in sample transport to the clinical laboratory. Finally, many POCT methods require much smaller sample volumes than those needed for testing in the central clinical laboratory.

Preventing medical errors has become a major focus of quality improvement in healthcare. Most errors that occur in the clinical laboratory setting take place during the pre- and postanalytical phases of the testing process, and several studies have documented the types and frequencies of the errors that can occur (2). In addition to the benefits mentioned above, the use of POCT may help reduce the frequencies of some of these errors, such as the preanalytical errors associated with inappropriate sampling, inappropriate preparation or packaging of samples, and misidentification of patients (3). In addition, the decrease in the number of steps necessary to produce a test result associated with POCT should help reduce the potential for errors to occur. Moreover, the fact that POCT is often performed by the individual providing care to the patient may help decrease postanalytical errors due to incorrect transmission of test results; however, implementation of clinical-management decisions immediately on receipt of POCT results can increase the risk to the patient if any of the results are in error, because error-detection schemes such as automatic delta checking are typically not used in these settings.

Although POCT may lead, in theory, to decreases in certain types of errors, little information exists concerning the error rates associated with POCT itself. The study performed by O’Kane et al. and reported in the current issue of the Journal is noteworthy for the large number of different POC tests that were evaluated and the relatively long time period over which the study was performed (4). These investigators evaluated a variety of POC tests over a 14-month period, including blood gases and electrolytes, urine human chorionic gonadotropin, hemoglobin A1c, blood glucose, blood ketones, drugs of abuse, and urine dipstick analysis. The study was performed in 2 acute care hospitals and 1 non–acute care hospital. Errors were classified by cause and graded according to the actual harm caused to the patient because of the error, as well as the potentially worst harm that the error could have caused. A culture of openness that focused on improving the POCT system rather than apportioning individual blame was promoted as the mechanism for assuring the identification of weaknesses in processes and procedures in the POC setting.

Although the actual impact of POCT errors was considered minimal, with 51.8% of errors considered to have no impact on patient care and 48.2% considered to have minimal impact on patient care, a review revealed that the potential impact of these errors was much higher, with 14.7% and 3.6% of the errors considered to have the potential to produce moderately or substantially adverse patient outcomes, respectively. In contrast to errors seen in the clinical laboratory setting, where the vast majority of errors occur in the preanalytical and postanalytical phases of testing, the study of O’Kane et al. shows, interestingly, that two thirds of the errors occurred in the analytical phase of the testing process. The authors indicate that such preanalytical factors as altered sample integrity (e.g., hemolysis, lipemia, icterus, and so on) that would be identified and considered as causes of preanalytical error in the laboratory setting where serum or plasma samples are tested, often go unrecognized in POCT systems that use a whole-blood sample or do not have a defined mechanism for assessing sample integrity. Thus, the actual error rates reported in this study for POCT could...
have been much higher if sample-integrity errors had been identified and taken into consideration.

Of note is that many types of errors reported by O’Kane et al. are not likely to be encountered in the clinical laboratory. For example, 70.8% of the errors associated with glucometer testing were due to delays in testing, because the individuals performing the testing did not have their personal bar codes to allow use of the glucometer. Although such a lockout feature is important for preventing instrument use by nontrained users, this type of error is not likely to be encountered in the clinical laboratory setting. Similarly, the most common error associated with blood gas analysis was due to the requirement for a minor instrument procedure that the operator was unwilling or unable to perform—also a type of error unlikely to be encountered in the clinical laboratory setting.

The most common errors associated with urine human chorionic gonadotropin testing and hemoglobin A1c testing were caused by failure to perform testing of external quality assessment (EQA) samples or failure to submit the results of measurements of EQA samples in a timely manner. Such errors, again, are unlikely to be encountered in the clinical laboratory because trained laboratorians appreciate the need to perform EQA testing and understand the potentially adverse consequences when this testing is not performed in a timely manner. Finally, 5.8% of the errors were due to failure to stock reagents or supplies necessary to perform testing—also unlikely to be an important cause of errors in the traditional laboratory setting.

When considering the errors identified by these authors as important in POCT, it is easy to speculate that such errors may be symptomatic of a lack of accountability of the individuals performing POCT. Given that POCT is often carried out by individuals not previously accustomed to POCT, the need for performing instrument maintenance, instrument calibration, or EQA testing may often be viewed by these individuals as being the responsibility of someone else. Indeed, the major sources of error associated with POCT have previously been categorized by Meier and Jones (5) as most commonly due to operator incompetence, nonadherence to test procedures, and the use of uncontrolled reagents and testing equipment. Thus, although errors associated with POCT likely occur at a higher rate than when testing is performed in the clinical laboratory setting, it is important to recognize that the causes of the errors seen in the POC setting are much different from those observed in the laboratory setting. Further studies are needed to elucidate the types and frequencies of errors observed with POCT.

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