Quality laboratory testing is an essential part of modern medicine. Historically, such testing has been performed in a central location by highly trained medical technologists. Rapid advances in analytical and computer technology, however, have shifted a significant amount of it to the patient bedside or other non-laboratory sites. While point-of-care testing (POCT) offers some key advantages in patient management, it is also giving rise to notable safety concerns related to infection transmission, patient identification and specimen integrity.

Hospital-Acquired Infections

Healthcare-associated infections (HAIs) are a major safety concern due to their adverse effects on patients, their families and the health system. Estimates suggest that approximately 1.7 million HAIs occur annually in the United States alone.1 Multiple studies indicate that hospital surfaces, including POCT devices, may act as vehicles for the transmission of pathological agents such as methicillin-resistant Staphylococcus aureus and HIV.2-3 In August 2010 the FDA and CDC issued a joint recommendation that point-of-care blood testing devices should not be shared and that, if this is not possible, they should be cleaned and disinfected after every use.

The College of American Pathologists has also acknowledged the rising importance of this issue by including a new requirement in its 2012 POCT checklist regarding an infection control policy for portable or handheld testing devices. However, a number of practical difficulties are associated with the institution-wide implementation of such a policy.

Manufacturers vary in their recommendations for the disinfection of POCT devices; moreover, recent studies suggest that...
pathogenic organisms also differ in their susceptibility to any particular disinfectant. Hence, coming up with a simple and effective disinfection protocol that is universally applicable to all devices may be difficult.

An additional and ongoing challenge is ensuring adherence to the policy. For one, POCT users are under significant time constraints, with testing being only one of their many patient care responsibilities. As well, disinfection slows down testing since the surface of the device needs to dry completely before it can be used again. As a result of these factors, users may not take the amount of time and attention needed to properly disinfect a device. Our POCT coordinators repeatedly note this problem during their rounds, as evidenced by the presence of QC material on the devices.

A third issue that remains to be addressed is the disinfection of POCT accessories. Even though QC reagents, test strip vials and meter totes also travel from one patient to another, disinfection policies for such accessories are generally lacking. Some companies have begun to act on this issue by, for example, making individually wrapped test strips or test cuvettes.

**Patient ID**

Patient misidentification in POCT is another ongoing safety concern. Correct identification — and subsequent transmission of results to the appropriate medical chart — is critical for longitudinal patient monitoring and appropriate billing of testing services. ID errors due to incorrect account numbers, multiple patient wristbands and manual information entry have been well documented. Recent studies have also identified errors associated with standard barcode technology. Misreads of the linear bar codes routinely used in healthcare institutions may occur as a result of:

- printing defects,
- lack of adequate error detection in barcode symbology algorithms,
- failure to control for scanner resolution specifications,
- barcode orientation and
- barcode width.

Errors may be of the rejection type — where an incorrect identifier is rejected by the system — or of the substitution type, where the incorrect identifier is accepted by the system. While both are highly undesirable, the latter is perhaps more serious in that the result gets reported to the wrong patient and may lead to unnecessary and harmful treatment.

The use of 2-dimensional bar codes or radiofrequency identification (RFID) technology has been suggested as a potential solution for patient identification issues. A solution that’s already being offered by some vendors is the direct interfacing of POCT devices with admission, discharge and transfer (ADT) data from the hospital information system.
system. This interface enables a setup where the POCT user is required to confirm at least two patient identifiers, such as name and birthdate, before being allowed to proceed with testing. Until this approach becomes more widespread, however, other solutions need to be put in place. These may include reeducation of POCT users on the limitations of current barcode technology and the implementation of a program to verify the integrity of barcode labels.

Specimen Integrity

Specimen integrity has a key role in producing quality POCT results. One particular area of concern is the effect of hemolysis on potassium measurements. This electrolyte is tightly regulated by the body and small physiologic changes can lead to life-threatening complications. All instances of elevated potassium results that cannot be explained clinically require additional workup and may result in patient care delays. Serum index measurements that aid in the detection of hemolysis are routinely performed in the central lab, but such safety checks are not available for POCT analyzers. The only solution is to increase education and awareness of POCT users, including clinicians, on this issue.

Dr. Füzéry is a post-doctoral fellow, and Dr. Clarke is associate professor of Pathology; director, Clinical Toxicology; and director, CPOCT, Johns Hopkins University School of Medicine.

References