Preface

Kent Lewandrowski, MD
Guest Editor

Point-of-care testing (POCT), also called bedside or near-patient testing, is an emerging specialty in laboratory medicine. Attracting considerable interest in the medical literature, POCT is one of the fastest growing areas in laboratory medicine. In this issue, we present a number of articles on the current state of POCT, circa 2009. It has been 8 years since publication of the first issue of *Clinics in Laboratory Medicine: Point-of-Care Testing*. Over this interval, a number of developments have occurred in the applications and practice of POCT. Major trends in the evolution of POCT include:

- Expansion of the test menu
- Development of more consolidated platforms capable of performing a menu of tests
- Emergence of improved analytical technologies that, in some cases, match the performance of central laboratory instruments
- Appearance of improved data management systems, including vendor-neutral enterprise connectivity solutions
- Progress in making devices easier to use
- Advances in enabling patient self-testing in the home
- Published demonstrations of improved outcomes (especially those related to operational efficiency) with some types of POCT

As described in the previous issue, the history of POCT has been problematic. In the early 1990s, bedside testing began to make significant inroads in hospitals. Handheld glucose meters originally designed for home patient self-monitoring began to appear in hospital inpatient units for the routine management of diabetic patients during their hospital stay. These devices enabled clinicians to obtain glucose values using a finger-stick capillary blood sample and to make immediate adjustments to insulin dosing without delaying clinical decisions while waiting for test results to return from the clinical laboratory. This capability afforded a level of convenience and timeliness that could not be matched by the central laboratory. Other forms of POCT at the time included fecal occult blood testing, dipstick urinalysis, and urine pregnancy testing. Meanwhile, sundry bedside devices, such as refractometers and urimeters, came into use. At this time, POCT was largely unregulated and few hospitals had an organized structure in place to ensure quality testing. Predictably a number of

Clin Lab Med 29 (2009) xiii–xv
doi:10.1016/j.cll.2009.07.015 **labmed.theclinics.com**
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problems began to occur, including those related to quality control, analytical errors, performance of testing by untrained personnel, and lack of proper documentation of patient test results. As a result, hospital and laboratory accreditation agencies began placing increased scrutiny on POCT with more vigorous enforcement of regulatory guidelines mandated by the federal Clinical Laboratory Improvement Amendment (CLIA-88). As POCT became more widespread, it became clear that these technologies were rapidly becoming unmanageable. A number of hospitals experienced embarrassing debacles arising from POCT during routine inspections to renew their laboratory accreditation status. The solution to this problem was to implement formal POCT management teams typically composed of representatives from the laboratory, nursing, and clinical staffs, and from hospital administration.

Initially, laboratory professionals did not embrace POCT. Some of this resistance arose from a genuine concern about the quality of the test results, but a significant part of the issue was concern that POCT would siphon testing out of the clinical laboratory. In the worst-case fear, POCT devices would eventually take over all routine turnaround time–dependant tests and the remainder of the test menu would be sent out to a reference laboratory. This scenario, of course, never materialized. The conventional wisdom a decade ago was that POCT was too expensive, that test results were unreliable, and that POCT was impossible to manage across a hospital campus. Some aspects of these perceptions were true.

From a technology perspective, efforts to improve quality and automate regulatory compliance were spearheaded by the manufacturers of bedside glucose-testing devices, which were, and continue to be, the dominant POCT technology. Several generations of improved devices and software solutions for data management were introduced to solve many of the problems associated with analytical errors and management of testing data. Other vendors developed vendor-neutral open-architecture enterprise-level POCT data management solutions capable of interfacing to multiple devices from different manufacturers. Collectively, these data management solutions significantly improved our ability to manage POCT across the hospital campus and at remote affiliated sites. However, POCT data management and connectivity remains a work in progress particularly for visually read manually performed POCT tests, for which there is currently no satisfactory solution.

Manufacturers have continued to develop new devices and tests designed for applications at the point of care. The fundamental concept underlying POCT is turnaround time. POCT offers the ability to obtain test results at the moment medical decisions must be made. To the extent that timely laboratory test results are essential to many clinical decisions, rapid turnaround time has great conceptual appeal. Yet few published studies have documented improved medical outcomes following implementation of POCT. However, the literature abounds with documentation of the ability of POCT to improve efficiency and to benefit hospital operations. Ironically, although POCT was originally conceived as a mechanism to improve medical outcomes, most of the documented benefits relate to promoting the efficiency of clinical care.

As technologies have improved and more evidence has accumulated that POCT can benefit clinical operations, acceptance of POCT by the laboratory profession has increased. Most laboratory professionals now view POCT as one tool in their arsenal to provide laboratory services to their health care system. The other tools include sending specimens out to reference laboratories and performing testing in a centralized clinical laboratory. Each of these options is appropriate in certain situations but not in others. For example, bedside capillary glucose testing is used almost universally in American hospitals for routine management of diabetic inpatients. Few laboratory professionals would consider eliminating this technology because without

it clinical care would be impaired and the laboratory would be regularly flooded with stat glucose requests several times a day. On the other hand, routine testing for thyroid disease at the point of care would be expensive and inappropriate. This testing is most logically performed in a central laboratory. Finally, esoteric low-volume tests not highly dependent on turnaround time (eg, fractionated urine catecholamines) are most efficiently performed in a reference laboratory. The current typical laboratory test menu is large and expanding rapidly. It is the task of laboratory professionals to determine the most clinically and financially appropriate solutions to provide comprehensive laboratory services. POCT represents one possible solution.

The future of POCT is difficult to predict but will be influenced by many of the factors affecting laboratory medicine more generally, such as regulatory issues, pressure for cost containment, evolving clinical needs, improvements in technology, and shortages of trained laboratory technologists. As the population of the United States continues to grow and to age, demographics will likely create more demand for laboratory services. The most likely future scenario will be steady and continued growth of POCT as new technologies are developed and as more tests become available in point-of-care formats. The ability of POCT to improve workflow on clinical services will likely be a major factor as pressure for cost containment will promote health care models that emphasize smooth, efficient operations.

I wish to thank the various authors who have contributed articles to this issue. Without their contributions and expertise, this issue would not have been possible. I also want to thank the publisher, Elsevier, for sponsoring the *Clinics in Laboratory Medicine* series and their commitment to continuing medical education.

Finally, a dedication: to Nicole Lewandrowski, for giving me encouragement when I need it most.

Kent Lewandrowski, MD
Massachusetts General Hospital
Harvard Medical School
55 Fruit Street, Gray 5 Chemistry
Boston, MA 02114, USA

E-mail address:
klewandrowski@partners.org (K. Lewandrowski)