The Laboratory-Clinical Interface*

Point-of-Care Testing

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Key words: bedside diagnosis; microchemistry; point-of-care testing; stat laboratory; therapeutic turnaround time

Abbreviations: CAP = College of American Pathologists; CLIA = Clinical Laboratory Improvement Amendments; ED = emergency department; HCFA = Health Care Financing Administration; JCAHO = Joint Commission on Accreditation of Healthcare Organizations; LAP = Laboratory Accreditation Program; LOS = length of stay; NCCLS = National Committee for Clinical Laboratory Standards; OR = operating room; POC = point of care; QA = quality assurance; QC = quality control

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oint-of-care (POC) testing refers to the performance of diagnostic testing at or near the site of patient care rather than in the traditional central laboratory. Bedside diagnostic blood testing has been demonstrated1 to be capable of achieving accuracy, rapidity, and usefulness in blood conservation. POC testing is truly a “work in progress” that is affected by numerous regulatory, managerial, quality, and “turf” issues. Sites for POC testing include areas of the hospital that provide care to patients in the most urgent need of rapid diagnosis and therapy. These sites include the emergency department (ED), the operating room (OR), critical care units, and certain outpatient areas.2 Bedside glucose testing is another common form of POC testing. This article focuses on the use of analyzers for patient care testing. Evaluation of monitors such as blood gas monitors is found elsewhere.3,4

POC testing is a concept that extends functions previously performed in the stat laboratory. Stat laboratories were and continue to be dedicated laboratory space usually adjacent to ORs, critical care units, or the ED. For a long time, the stat laboratory has served the needs of critical care units by facilitating rapid turnaround time with accurate analyte determinations.5 New instruments that are compact and portable now permit stat testing to evolve further to the use of whole-blood analyzers at the bedside. The bedside laboratory offers many advantages.6 It permits immediate real-time analysis rather than waiting minutes to hours for test results to become available. The specimen does not need to be transported, and specimen labeling is limited. Further, it may reduce preanalytic errors and contribute to quality assurance, since the specimen is only handled by one person at the bedside. It clearly improves the clinician-patient interface and decreases the time necessary before therapeutic decisions are made. For example, certain analyte determinations, such as the blood lactate level, may rapidly assist clinicians in establishing a diagnosis of circulatory shock and in contributing to the formulation of an early prognostic opinion.7 Disadvantages of POC testing relate to lack of documentation, quality control issues, a limited test menu, and the potential for increased cost. These issues are discussed in detail later.

HISTORICAL PERSPECTIVE

Historically, diagnostic technology has influenced where testing is performed. Large and complex
laboratory analyzers have allowed testing to be batched efficiently and economically in centralized locations. With the evolution of the central laboratory, methods of quality control matured significantly and produced accurate and precise results. Current technologic advancement is characterized by microchemistry (biosensors and whole-blood analysis), microcomputerization, miniaturization, and noninvasive testing procedures. These advances allow a shift in complex testing to the patient’s bedside. The economically driven need to shorten length of stay (LOS), reduce hospital costs, and manage scarce resources, without compromising patient outcome, has prompted health care systems to implement POC testing. However, implementation of POC testing without proof of efficacy raises important concerns. The issues involved include cost, quality control, personnel limitations, the strengths and weaknesses of the existing laboratory, regulatory matters, and the specific patient population served by the facility. The assessment of efficacy of POC testing will require the cooperative effort of both clinicians and laboratorians. In this article, these concerns are addressed by a multidisciplinary team with experience in POC testing. Our purpose is to identify the salient issues, to assess the role of POC testing in the delivery of hospital-based health care, and to create a template for the laboratory-clinical interface.

**Potential Advantages and Disadvantages**

Determining the benefits vs disadvantages of POC testing does not lend itself easily to the type of rigorous, randomized, placebo-controlled trial that can be used to evaluate the risk-benefit ratio of a particular medication. Despite this problem, numerous studies have analyzed and produced results that suggest certain advantages and disadvantages to POC testing. Clearly, turnaround time is reduced, and this advantage has been documented. An offsetting issue regarding POC testing is that the testing is usually performed by nonlaboratorians who may not have the type of requisite training that ensures appropriate quality control, troubleshooting of analyzers, documentation of test results, and proficiency testing. A second advantage is that clinical decision making may be augmented. This advantage is illustrated by use of bedside or near-patient blood gas testing for more rapid weaning of patients from mechanical ventilatory support.

LOS was not shortened by availability of POC testing, but the study design has been criticized. Some investigators report that LOS in the ED may be decreased by POC testing.

Depending on the format of the analyzer and its operating expenses, there may be significant cost savings associated with the use of bedside testing. Another advantage would be elimination of preanalytic error. This error is a consequence of the length of time a blood sample sits in the sample tube. Most clinicians are aware of preanalytic error in the form of artificial hypoglycemia in a blood specimen that is not processed in a timely manner. Another medical advantage of bedside testing is decreased iatrogenic blood loss leading to blood conservation. The issue of blood conservation is not trivial since transfusion-related diseases continue to be a major clinical problem. Several investigators believe that blood conservation in critical care is especially important since patients in critical care units are often at risk to need multiple transfusions. The use of microchemical analyzers to limit blood loss, coupled with other strategies of blood conservation such as erythropoietin and transfusion algorithms, may help to limit the need for transfusions in acutely ill individuals.

Nurses are the personnel in acute care settings who often perform POC testing. A survey of critical care nurses was conducted in which the nurses who performed POC testing felt that this type of diagnostic approach was helpful to patients; however, they desired that laboratory personnel take responsibility for the testing. Kost has suggested that POC testing will provide the greatest advantage when integrated with performance maps, algorithms, and care paths. The goal of POC testing, if implemented, should be to improve patient outcomes. Certain assays such as whole-blood lactate and myocardial injury markers recently developed for qualitative POC testing for cardiac troponin T and troponin I, appear to have a role in acute care medicine and seem to be useful when performed near the patient. Additionally, a test cluster consisting of quantitative myoglobin, creatine kinase-MB mass, and troponin I is clinically efficient, and current literature supports rapid turnaround time for myocardial injury markers. The role of other assays in POC testing is less clear. For example, the measurement of cytokines such as interleukin-6 may possibly be useful in the assessment of patients with sepsis or ARDS. Advantages and disadvantages of POC testing are summarized in Table 1. We recommend careful assessment of these advantages and disadvantages when implementing POC testing and selecting testing modalities, in order to meet individual institutional goals and objectives.
POC testing means testing at or near the point of patient care.\textsuperscript{22} Testing is performed outside the main hospital laboratory but within the hospital, in clinics, and at various other distributed sites (Table 2). POC technologies have many applications and are particularly useful in settings in which rapid response improves patient care. Hospital sites include critical care areas such as the ED, ICUs, cardiac care units, burn units, and ORs. On-site testing is useful for evaluating patients at the scene of accidents and during transport to medical facilities in helicopters and emergency vehicles. Applications also include use aboard ships, in airplanes, at military field hospitals, and in other portable hospitals. POC instruments also are useful for extending laboratory testing to areas where there is a low volume of testing and a central laboratory would be cost prohibitive, such as nursing homes, outreach clinics, and rural physician offices.

Laboratory medicine has traditionally defined an analyzer as an \textit{in vitro} measurement device that requires the permanent removal of blood, fluid, or tissue from the patient. A monitor is defined as providing patient-dedicated measurements that do not require permanent removal of blood, fluid, or tissue from the patient.\textsuperscript{3,4} Monitoring devices are either noninvasive or invasive. A blood monitor is either \textit{ex vivo} or \textit{in vivo}. Therefore, POC testing devices include \textit{in vitro}, \textit{ex vivo}, and \textit{in vivo} methodologies.\textsuperscript{32,33} Currently, there is a proliferation of small, handheld analyzers and other portable or transportable devices for POC testing. These instruments provide rapid response test results. Therapeutic turnaround time includes two intervals: (1) the time from test ordering to receipt of results and (2) the time from receipt of results to treatment (Fig 1). Fast therapeutic turnaround time is recognized as one of the primary drivers in the shift of testing from the main laboratory to the POC.\textsuperscript{1,36–40}

### Types of POC Testing

POC testing encompasses a large variety of testing options\textsuperscript{32,37} (Table 3). When evaluating POC testing,

### Table 1—Advantages and Disadvantages of Point-of-Care Testing

<table>
<thead>
<tr>
<th>Potential Advantages</th>
<th>Potential Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased therapeutic turnaround time</td>
<td>Lack of adequate documentation</td>
</tr>
<tr>
<td>Rapid data availability</td>
<td>QC and proficiency testing issues</td>
</tr>
<tr>
<td>Augmented clinical decision making</td>
<td>Unauthorized testing</td>
</tr>
<tr>
<td>Increased real-time patient management</td>
<td>Poor analytic performance</td>
</tr>
<tr>
<td>Shortened LOS</td>
<td>Problems of training and competency</td>
</tr>
<tr>
<td>Decreased preanalytic error</td>
<td>Increased preanalytic error</td>
</tr>
<tr>
<td>Decreased patient cost per episode</td>
<td>Data not recorded</td>
</tr>
<tr>
<td>Test clustering</td>
<td>Sample handling error</td>
</tr>
<tr>
<td>Decreased iatrogenic blood loss</td>
<td>Limited test menu</td>
</tr>
<tr>
<td>Increased patient throughput</td>
<td>Decreased entry of results in patient record</td>
</tr>
<tr>
<td>Fewer redundant blood tests</td>
<td>Postanalytic error (e.g., transcription error or communication failure)</td>
</tr>
<tr>
<td>Convenience for the clinician</td>
<td>Need for separate license(s)</td>
</tr>
<tr>
<td>Improved clinician-patient interface</td>
<td>Failure to comply with regulations</td>
</tr>
<tr>
<td>Customized instrumentation</td>
<td>Increased costs</td>
</tr>
<tr>
<td>Convenience when laboratory is inaccessible</td>
<td>Duplication of instruments and methods</td>
</tr>
<tr>
<td>Attractiveness</td>
<td>No critical values notification system and/or documentation</td>
</tr>
<tr>
<td>Rapid response to critical results</td>
<td>Integration with performance maps, algorithms, and care paths</td>
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### Table 2—Sites of POC Testing

<table>
<thead>
<tr>
<th>Location</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>Procedure suites (e.g., cardiac catheterization laboratories)</td>
</tr>
<tr>
<td></td>
<td>Patient-focused care centers</td>
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<tr>
<td></td>
<td>Satellite laboratories</td>
</tr>
<tr>
<td></td>
<td>Near-patient testing locations (permanent, temporary, mobile)</td>
</tr>
<tr>
<td></td>
<td>Critical care workstations in the OR, ED, and ICU</td>
</tr>
<tr>
<td></td>
<td>Bedside (alternate/alternative site, ancillary, decentralized, and waived testing)</td>
</tr>
<tr>
<td></td>
<td>Modular plug-ins for intensive care systems</td>
</tr>
<tr>
<td>Outpatient</td>
<td>Clinics and specialty care centers</td>
</tr>
<tr>
<td></td>
<td>Urgent care centers</td>
</tr>
<tr>
<td></td>
<td>Patient-focused care facilities (e.g., ambulatory surgery, heart center, chronic care)</td>
</tr>
<tr>
<td></td>
<td>Physician offices</td>
</tr>
<tr>
<td></td>
<td>Home (e.g., self-monitoring of blood glucose)</td>
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<tr>
<td></td>
<td>Wellness testing areas (e.g., screening)</td>
</tr>
<tr>
<td>Rescue</td>
<td>Space shuttles and space stations</td>
</tr>
<tr>
<td></td>
<td>Helicopter and other aircraft for patient transport</td>
</tr>
<tr>
<td></td>
<td>Ships, submarines, and other nauticals</td>
</tr>
<tr>
<td></td>
<td>Emergency ground vehicles (e.g., ambulances)</td>
</tr>
<tr>
<td></td>
<td>Points of disaster and emergency rescues</td>
</tr>
<tr>
<td></td>
<td>Settings of military field operations</td>
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</tbody>
</table>
It is important that health-care providers consider the exact modality that is being utilized. One can divide testing into in vivo, ex vivo, and in vitro techniques that are clinician- or patient-directed.

Clinician-directed testing is performed by the physician, physician assistant, nurse, respiratory care practitioner, or other qualified personnel. In patient-directed testing, the patient or a family member performs the test.

In vitro testing can be performed at the patient’s bedside or in a near-patient setting such as a ward, office, or clinic. Available technology frequently dictates the site of testing (Table 2). Handheld and portable devices can be used at the bedside. A major advantage of many handheld devices is that they are relatively maintenance free, sturdy, and ready to use. Transportable devices require a cart for movement. Large transportable instruments can be placed at the bedside but are better suited for near-patient uses. An innovative system utilizes remote review to improve testing efficiency by analyzing specimens in a near-patient setting and transmitting data to the central laboratory. Results are evaluated, approved, and quickly made available to the bedside practitioner using computerized bidirectional communications.

Evolving technologies are providing clinicians and patients with the opportunities to perform in vivo testing. IV, intra-arterial, subcutaneous, and transcutaneous techniques are available or under development for measurement of $P_{O_2}$, pH,

### Table 3—POC Testing Options

<table>
<thead>
<tr>
<th>I. In vivo and ex vivo testing</th>
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<tbody>
<tr>
<td>A. Clinician-directed testing</td>
</tr>
<tr>
<td>1. Invasive sensor (in vivo)</td>
</tr>
<tr>
<td>a. IV</td>
</tr>
<tr>
<td>b. Intra-arterial</td>
</tr>
<tr>
<td>c. Subcutaneous</td>
</tr>
<tr>
<td>2. Noninvasive sensor (ex vivo)</td>
</tr>
<tr>
<td>a. Exhaled air</td>
</tr>
<tr>
<td>b. Urine</td>
</tr>
<tr>
<td>c. Transcutaneous</td>
</tr>
<tr>
<td>d. Gut lumen</td>
</tr>
<tr>
<td>B. Patient-directed testing</td>
</tr>
<tr>
<td>1. Transcutaneous</td>
</tr>
<tr>
<td>2. Exhaled air</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>II. In vitro testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Clinician-directed tests</td>
</tr>
<tr>
<td>1. Transportable, portable, and handheld analyzers</td>
</tr>
<tr>
<td>2. Dipstick technologies and test kits (ie, blood, urine)</td>
</tr>
<tr>
<td>3. Fixed or site-dedicated analyzers</td>
</tr>
<tr>
<td>4. Robotic workstations</td>
</tr>
<tr>
<td>B. Patient-directed tests</td>
</tr>
<tr>
<td>1. Handheld analyzers</td>
</tr>
<tr>
<td>2. Dipstick technologies and test kits (ie, blood, urine)</td>
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</tbody>
</table>
PCO₂, glucose, lactate, and electrolytes. Noninvasive technologies also are being developed for measurement of analytes in exhaled air and via the lumen of the GI tract. Current in vivo analyzers measure analytes directly in the patient (ie, IV, intra-arterial). Ex vivo devices use patient specimens that are withdrawn from the patient and analyzed just outside the body (ie, intra-arterial catheter attached to an analyzer). Some devices allow for return of the specimen (ie, blood) to the patient.

Cost Considerations

Published economic analyses of POC testing have employed such different treatments of costs that great uncertainty clouds the entire subject. We consider this to be a major deficiency in the current status of considerations in the implementation of existing or new POC technologies. The impact on revenue can be substantial and variable, dependent on percentage of capitated patient reimbursement. Each institution is likely to have a unique combination, including Medicare and other payer issues, contractual agreements, and managed care commitments, that needs to be understood.

Within and outside a central laboratory, all elements of cost attributable to additional or replacement testing need to be recognized. These elements include everything from test ordering to result receipt, including all preanalytic activities, transport, transcription, and communication. The equally correct but fundamentally different approaches of full attribution vs incremental costing may both be required. Decisions as basic as the inclusion or exclusion of any labor cost for POC testing personnel or for depreciation of capital purchases have been treated entirely differently in the published literature. Also, the treatment of laboratory or POC testing site overhead and hospital step-down expenses must be done properly. Recognition of the actual costs of personnel training, supervision, consultants, quality control, proficiency testing, licensure, and regulatory compliance cannot be ignored. Potentially misleading accounting practices, such as cost shifting, wastage, and neglect of the impact of errors on other costs, must be avoided.

One also must consider the cost of patient and physician time for medical evaluation. The ability to make a quick diagnosis and institute immediate treatment may decrease ICU time, hospital time, and outpatient time for both patient and physician. For example, the ability to perform POC testing in a physician’s office negates the need for a laboratory visit to have blood drawn and eliminates the need for a follow-up phone call or visit. POC testing also decreases the time required for a nurse or physician to retrieve results and contact the patient. This fast service is usually perceived by the patient and clinician as improved care. The perceived improved care and rapid diagnosis also may aid in obtaining healthcare contracts in the managed care environment.

We recommend a standardized format for economic analyses of POC testing. This format should capture the realities of patient care and testing, as we know it, and also conform to the accounting conventions of financial reporting employed by hospitals and businesses.

Quality Control Issues

The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) established minimum quality standards for all laboratory testing sites in the United States. Conceptually, patients are entitled to quality laboratory results, regardless of who performs the tests and where or when they are performed. No one finds the premise of universal quality in laboratory testing objectionable. The issue is not one of intent, but rather the means to best achieve it.

The Health Care Financing Administration (HCFA) and the Centers for Disease Control and Prevention developed the CLIA 88 implementation regulations built on specific activities designed to assure quality laboratory results. The regulations mandate quality assurance (QA) and quality control (QC) practices based on traditional approaches. QC materials that mimic patient samples monitor the analytical process, the skill of the analyst, and the ruggedness of the testing process in the laboratory environment. The required QA practices, including analyzing at least two (external) controls per day of testing, were reasonable for laboratory-based instrumentation and analysts in that setting.

At the time the CLIA 88 rules were promulgated, POC instrumentation, as we know it today, was in the early stages of invention and innovation. Tests, such as urine dipsticks and glucose meters, were viewed in CLIA 88 as being simple and foolproof and were placed on the waived list—exempt from CLIA QC and QA requirements. The CLIA 88 rules did not foresee a new paradigm in laboratory testing technology, collectively known as POC testing. This technology allows the introduction of sophisticated testing devices that are compact, nearly foolproof, highly portable, and able to generate almost instantaneous results.

The shift of testing to POC settings away from the central laboratory, where skilled analysts and highly automated instrumentation are capable of processing
multiple samples, creates a dilemma in terms of following the CLIA 88 QC and QA requirements. In the POC setting, personnel may not be skilled laboratory analysts, knowledgeable about QC concepts, or able to devote a large amount of time to assessing quality. When reagents are relatively inexpensive, as in the clinical laboratory, traditional QC practices are tolerable. With unit-use devices that incorporate all the necessary components into a single test packet, QC costs become a major consideration.

Manufacturers realize that POC settings entail a multiplicity of factors that influence test quality. The strategy is to attempt to design foolproof devices capable of assessing many elements evaluated by traditional QC and QA practices. Although present POC testing devices vary in their assessment of quality, many include electronic and function checks to guard against common mistakes, such as inadequate sample volume and improper calibration, and against adverse environmental conditions, such as reaction temperature, reagent viability, and compromised optics, all of which can affect test quality. Some devices contain internal QC systems ranging from the simple positive/negative to sophisticated quantitative measurements. Currently, these devices are viewed as having “non-traditional or alternative means of ensuring the test systems are producing the correct result.” Quality assurance issues such as drawing blood from the wrong patient, incorrect sample handling and processing, and using the wrong anticoagulant still need to be addressed.

New concepts in QC technology must complement the changes introduced by POC testing. Concurrently, the regulators must change from enforcing the traditional quality mandates to assessing whether all the components of the testing process adequately meet defined quality goals. According to the Centers for Disease Control and Prevention, the next revisions in CLIA 88 requirements will combine the existing mandates for patient test management, QC, and QA into a new “quality assurance” or “quality monitoring” section. The intent is to allow testing sites “to use alternative methods for evaluating quality in the areas of environmental controls, operator controls, and test system controls.”

Universal quality standards that are understandable, measurable, and translatable into performance specifications are the missing link. Publicizing current manufacturers’ claimed error rates is not the solution, since the information is not uniform or transferable to other systems or manufacturers. Regulators and POC sites working with manufacturers must incorporate product defect information, based on universal quality standards, into a quality system. For example, a POC site may choose to use a product with a 10% defect rate. If the site QC protocol (rules) has an error detection capability of 90%, undetected failures on patient samples theoretically will occur only 1% of the time. This may be an acceptable quality standard. Similarly, if the true product defect rate is 0.1% or 0.01%, there is little benefit from any external QC protocol. In this case, QA practices might emphasize training and patient results correlation. This simplistic example illustrates the potential benefits for clinicians, laboratories, manufacturers, and regulators (that is, the POC community) when quality specifications based on actual data become the foundation for regulatory approaches. We recommend that this principle should be central to the foundation for future standards.

CURRENT REGULATORY REQUIREMENTS

All laboratory testing, including that performed at the POC, falls under CLIA 88. The key to meeting specific POC regulations is knowing which agency will do the inspection.

POC Testing Under the CLIA 88 Certificate of the Central Laboratory

When the central laboratory is responsible for POC testing, the inspection agencies can include HCFA, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Laboratory Accreditation Program (LAP) of the College of American Pathologists (CAP). JCAHO and CAP have received deemed status from HCFA, which means that voluntary standards of each organization meet or exceed those of CLIA 88. While CAP-LAP and JCAHO have many subscribers, other professional organizations have deemed status as well. States also can impose specific requirements on POC testing.

When the central laboratory chooses to be accredited by CAP-LAP and holds the CLIA 88 certificate for all testing, POC testing will be inspected by CAP. If the laboratory subscribes to CAP-LAP and the hospital to JCAHO, POC testing will be inspected by CAP, since JCAHO will accept laboratory accreditation by CAP without further inspection. If the laboratory does not subscribe to CAP-LAP but the hospital is JCAHO-accredited, JCAHO will inspect POC testing. Finally, if neither CAP-LAP nor JCAHO accreditations are sought, HCFA will inspect POC testing for compliance with CLIA 88 requirements.

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POC Testing Under a Separate CLIA 88 Certificate

POC testing under a separate CLIA 88 certificate, based on the specific tests performed, is viewed as an independent laboratory responsible for meeting all of the appropriate regulations. If a POC site chooses CAP-LAP for accreditation, the inspection will be based on the POC Checklist (no. 30), which is limited to equipment that is handheld or transported to the patient; the Limited Services Checklist (no. 25), which is for POC testing sites offering a menu of 10 to 20 analytes; or the Blood Gas Laboratory Checklist (no. 26), which is for sites performing just blood gas measures and related whole-blood analytes. JCAHO will inspect POC sites when CAP-LAP was not chosen and the hospital is JCAHO-accredited, and HCFA will inspect when no voluntary accreditations are sought by the laboratory or hospital.

Complexity of POC Testing

An additional factor that determines specific regulatory requirements is the level of test complexity performed by the POC sites. Tests fall into one of three major categories—waived, moderate, or high complexity—based on performance difficulty. Each level has different requirements in terms of personnel, QC, method performance verification, and external proficiency testing. Current test classification is available from the specific test manufacturers and from the World Wide Web. Most POC sites perform only waived and moderate complexity tests. However, if any test is modified, that is, the user chooses not to follow manufacturer’s directions, the test becomes high complexity and is subject to more stringent requirements.

POC Testing and CLIA 88 Requirements

Waived Testing: This category has no specific requirements other than to follow the manufacturers’ directions. Waived tests are not subject to proficiency testing. The POC testing site will not be inspected by HCFA unless a complaint is filed.

Moderate Complexity Testing—Personnel: For each CLIA 88 certificate that includes moderate complexity testing, individuals with the proper qualifications must be identified for four positions: director, clinical consultant, technical consultant, and testing personnel. When the central laboratory is responsible for POC testing, meeting the personnel requirements is usually only a matter of providing POC testing personnel with appropriate on-the-job training. For POC sites under separate certificates, finding personnel meeting all the requirements may be more difficult.

Quality Assurance: CLIA 88 integrates a total quality management philosophy into the regulations and requires each laboratory to establish a comprehensive QA program and follow written policies and procedures to evaluate the ongoing and overall quality of the testing process. CLIA 88 mandates that tests performed by different instruments and methods for the same analyte under the same certificate be compared to each other at least twice each year. In addition, individuals involved in POC testing must be adequately trained and their competence documented, twice the first year and then once each year thereafter, for all tests performed.

Quality Control: At a minimum, moderately complex POC testing must meet seven QC requirements: (1) follow manufacturers’ directions, (2) have a procedure manual, (3) calibrate or check calibration at least every 6 months, (4) run two levels of QC materials (for most analytes), (5) follow specified QC procedures for some analytes (e.g., blood gases, coagulation), (6) perform and document remedial actions, and (7) keep these records for ≥2 years, depending on the test.

Proficiency Testing: CLIA 88 mandates proficiency testing for certain analytes. When the central laboratory is responsible for POC testing, it participates in a HCFA-approved proficiency testing program. The POC site interfaces with the proficiency testing process through method comparison data that are collected at least semiannually as part of QA. If the POC site holds its own CLIA certificate, the requirement for comparison testing with the central laboratory is removed but the site must participate in a HCFA-approved proficiency testing program for all the regulated analytes offered. Other analytes that are not evaluated by proficiency testing must be assessed for accuracy by some means at least twice each year.

POC Testing and JCAHO Requirements

Waived Testing: JCAHO recognizes waived tests as defined by CLIA 88 but has specific requirements for these tests, including: (1) defining the purpose of the test in diagnosis, treatment, or screening, and determining whether follow-up confirmatory testing is needed; (2) identifying testing personnel and the supervisor of the testing activities; (3) documenting initial personnel training and continued competency; (4) having current written procedures; (5) defining QC to meet the minimum manufacturer’s recommendations; and (6) maintaining appropriate QC and test records. These records...
must include a mechanism to link the analysts, QC records, instrument and instrument problems, and individual patient test results. Note that for each glucose meter used, at least two levels of control are required each day a glucose test is performed.

**Moderate Complexity Testing:** For moderate complexity testing, JCAHO generally follows CLIA 88. The qualifications are identical for each of the four personnel positions, and the same seven QC requirements apply. JCAHO does require evidence that each method produces accurate results on a consistent basis before being placed into use. This means that for new methods, POC sites need to verify accuracy and precision and ensure that the manufacturer’s suggested reference interval range applies to the patient population. For previously established methods, where the same method used in the central laboratory is used at the POC, QC data and test performance history are adequate to confirm test validity.

**Proficiency Testing and Quality Assurance:** JCAHO requirements for proficiency testing are identical to those for moderate complexity testing under CLIA 88. The accuracy of analytes not evaluated by proficiency testing must be verified at least twice each year. JCAHO also requires that all the methods used at the institution for the same analyte be compared and the interrelationship be documented at least twice each year. This requirement includes testing done under different CLIA certificates.

**POC Testing and the CAP-LAP Requirements**

**Personnel:** CAP-LAP63,66 views all testing, including POC testing, as highly complex, regardless of the CLIA complexity category. Five personnel categories—director, clinical consultant, technical supervisor, general supervisor, and testing personnel—are mandated by CLIA 88 for high complexity testing. Because some testing sites may have difficulty finding qualified individuals to fill all of the positions, CAP-LAP allows individuals meeting the CLIA 88 personnel requirements, based on actual CLIA-defined test complexity, to fill the positions. CAP-LAP requires a listing of all testing personnel authorized to perform tests, documentation of their initial training, and proof of continued competence. If visual color discrimination is necessary for test interpretation, an assessment for color acuity is needed. Color-impaired personnel can be employed, but their duties must be assigned accordingly.

**Quality Control:** CAP-LAP has seven QC requirements. POC sites must follow manufacturers’ directions and have a procedure manual that is in substantial compliance with the National Committee for Clinical Laboratory Standards (NCCLS) GP-A3 document67 and that includes documentation of initial and annual reviews by the director (or director’s designee). POC sites must calibrate methods or verify calibration at least every 6 months. Recalibration is unnecessary if the method’s reportable range is limited to the range of calibration verification. The requirement to check linearity every 6 months was dropped in the latest checklist revisions. Two levels of QC materials per day are required for most analytes. Some analytes, such as blood gases and coagulation, have specific control procedures. Electronic controls now can be substituted for traditional liquid controls in the POC setting. Qualitative tests must be evaluated with an external positive and negative control each day of use. Remedial actions for all out-of-control situations must be documented. The records must be kept for $\geq 2$ years, depending on the test. These records must establish an audit trail that links the analytes, QC records, instrument and instrument problems, and individual patient test results. In addition, the POC QC program must show evidence of daily review, documented weekly review by the technical supervisor, and a monthly secondary review by the director or director’s designee.

**Verification of Performance Specifications:** CAP-LAP requires verification of performance for all tests introduced after September 1, 1996. Parameters to assess before implementing a procedure include accuracy, precision, analytical sensitivity and specificity, reportable range (defined either by linearity or calibration verification), and reference interval (reference range). CAP-LAP suggests that performance specifications be documented with reference materials, split patient samples, chart review and/or QA procedures, or other suitable means.

**Proficiency Testing:** This has long been an important component of CAP-LAP. CAP-accredited laboratories must participate in proficiency testing, when available, for every analyte tested under the CLIA 88 certificate. When the POC site is under the central laboratory CLIA 88 certificate, the director can choose which site will provide the proficiency testing data. Usually, the central laboratory will analyze the proficiency testing samples. The semiannual comparison of test results links the POC site with the central laboratory. If the POC site has its own CLIA 88 certificate, it must participate in proficiency testing as an independent laboratory under CAP-LAP. In both situations, the accuracy of analytes not evaluated by proficiency testing must be verified at least twice each year.

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Recommended Strategies for Accreditation

We recommend the following strategies for accreditation. First, each institution must decide whether POC testing will stand alone under a separate CLIA 88 certificate or be under the direction and responsibility of the central laboratory. Because regulations applicable to POC testing emanate primarily from the three regulatory agencies (HCFA, JCAHO, and CAP), it is essential to weigh the pros and cons of different administrative structures before making decisions—there is no one right answer for all institutions. The organizational design adopted will drive other decisions on the scope of testing under each CLIA 88 certificate, the inspection agency(ies), and the number and costs of proficiency testing programs that must be purchased to satisfy regulatory requirements. Second, a broad and integrated perspective that covers the entire health system will help streamline operations, reduce costs, and enhance performance. For example, some institutions are electing to use JCAHO for POC testing and CAP for the central laboratory, a parallel arrangement that synchronizes inspection of distributed sites with the system-wide JCAHO institution inspection and relieves the central laboratory of some of the administrative and financial burdens of an extremely broad CAP inspection. Third, to successfully pass inspections, it is necessary, of course, to know the detailed practical requirements of the agency or agencies with jurisdiction over different POC sites. Finally, state and any special accreditation requirements must be considered.

Clinical Applications—Decision Pathways

To ascertain the role of POC testing in today’s health-care delivery system, we recommend that prospective clinical trials be performed to investigate the potential to establish benefit through some combination of cost savings and improvement in clinical outcome. The ability to provide accurate test results more rapidly is only the first in a series of steps that might lead to patient benefit. Subsequent steps of equal or greater importance include proper interpretation of the significance of the results and initiation of an appropriate management plan based on the results. To give POC testing an appropriate opportunity to demonstrate efficacy, trials should use care paths to guide proper application of POC testing. These care paths should include the selection of appropriate patients to undergo POC testing, integration of the measurements into medical decision making, and quality control of testing. Pertinent outcome data should include LOS (ED, ICU, OR, and/or hospital) as well as important morbidities.

True and accurate cost comparisons are essential. These studies should be randomized and prospective. To minimize population imbalance due to patient heterogeneity, a large multicenter study is ideal.

Trials should focus on integrated strategies that improve outcomes, as demonstrated, for example, by Steffes et al.13 These authors conducted a prospective study to assess the merits of POC testing integrated with an ordering protocol vs the use of conventional clinical laboratory testing without whole-blood analysis. The primary setting was a surgical ICU in a tertiary care, university teaching hospital. In response to cost reduction, the surgical, pediatric, and medical ICUs were integrated by means of a protocol designed to deliver clinical laboratory services to all three sites more promptly and efficiently. Reengineered services included: (1) a new on-site surgical ICU laboratory positioned to serve all three ICUs and eliminate 20 to 30 min of transport time for most specimens; (2) implementation of whole-blood analysis; (3) user-focused, service-specific order forms with very few ordering steps; (4) mandatory daily renewal of test orders; (5) temporal test sequences patterned for different problems (eg, testing every 4 h to monitor glucose for insulin infusion); (6) placement of whole-blood analytes toward the top of the order form; (7) a limited array of additional tests indicated by service; (8) alternating testing schedules for work flow optimization; (9) patient-focused test clusters (eg, adult parenteral nutrition, modular enteral feeding); (10) anticipation of test orders over 24-h intervals and preparation of order entry, labels, and specimen containers in advance, when feasible; (11) preprinted minimum volume of blood required; (12) transcription-free triplicate forms for the bedside care plan, laboratory, and medical record; and (13) continuous interaction between nursing and laboratory staff.

The patient-focused, integrated approach decreased the number of procedural steps by 33%, allowed all routine tests to be performed at scheduled times, reduced the number of records or forms by ≥ 80%, and reduced the chance of mislabeling specimens. In the medical ICU, the number of tests per patient for each 24 h decreased. In the surgical ICU, turnaround time (routine and emergency orders), sample volume, and amount of blood removed all improved significantly. The total amount of blood taken from the patient in 24 h decreased by 63%; this reflected the use of 1-mL syringes and instructions to nurses to match the minimum volumes preprinted on laboratory-generated labels when obtaining blood specimens. Preprinted labels improved efficiency on the units. Whole-blood analysis facilitated small sample volume. ICU personnel often combined separate
blood collections into one. Medical technologists, who performed the testing, could work more efficiently, and physicians felt they saved time. Based on preanalytic, analytic, and postanalytic time saved, Steffes et al\(^1\) attributed substantial financial savings to the integrated strategy. These savings derived primarily from reduced stat and routine blood collections, streamlined order and specimen processing, decreased transport and transfusions, and enhanced personnel efficiency in the clinical laboratory and the ICUs. In another study that focused on the OR setting, Despotis et al\(^2\) demonstrated the efficacy of integrating POC testing and a transfusion algorithm to improve both medical and economic intermediate outcomes.\(^2\)

The need to perform prospective studies within an integrated framework is reinforced by studies that have evaluated technology that may not be firmly implanted within the context of the care plan. For example, a recently published report cited the failure of pulmonary artery catheterization to impact positively on ICU patient outcome.\(^6\) Although this study did raise legitimate concerns about the impact of the PA catheter on outcome in the critically ill patient, valid criticisms of this study include not only the retrospective nature of the analysis, but more importantly, a design issue that is also germane to the evaluation of POC testing: the clinician, when provided with a clinical measurement that was not previously available or that was made available more rapidly, did not necessarily ensure the use of that information to the benefit of the patient, even if that potential existed. This circumstance applies both to the measurement of occlusive pressure with a pulmonary artery catheter and diagnostic testing at the patient’s bedside. Therefore, integrated strategies would be expected to increase the likelihood of benefit from POC testing. As part of these strategies, performance maps, algorithms, and care paths\(^2\) for POC testing should be developed by individuals with expertise, experience, and insight into the impact of laboratory variables on medical decision making and should offer the clinician a template for using these bedside measurements. Care plans should be developed using evidence-based literature assessment, if literature is available, and expert consensus when it is not available. These integrated strategies should be developed with consideration of both clinical outcome and cost.

If prospective trials of POC testing demonstrate cost savings with no change in clinical outcome, or improved clinical outcome, they should be offered for broad implementation. However, administrative challenges may still remain in their implementation. It is important to insure that any proven clinical utility or cost savings is carried over to day-to-day utilization. Integrative strategies for POC testing shown to be effective in clinical trials may not be entirely appropriate for a particular hospital because of interinstitutional differences. This issue should be weighed before implementation. Implementation also will require the unified involvement and support of hospital clinicians and laboratorians. For appropriate coordination, we recommend that clinicians ensure use of POC testing within the care path that has shown proven benefit, and that laboratorians provide quality control, technical education, and minimization of analytic error.

**Education and Training**

Table 4 lists our recommendations for an aggressive education and competency program that encourages a multidisciplinary academic design, integration of learning objectives, and use of a competency plan.\(^2\) These using POC testing must understand how to interpret and act on rapid response test results to manage patients optimally. All operators of POC devices must meet the regulations of CLIA 88 and the standards of the JCAHO or

<table>
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<th>Table 4—Recommendations for Training and Education*</th>
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<td>1. Define educational goals for POC testing, integrate training, and design academic programs to qualify knowledgeable clinical partners, clinical specialists, supervisors, and directors in this area.</td>
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<td>2. Integrate important learning objectives, such as patient outcomes, medical indications for testing, anticipated results, clinical interpretation and significance, critical limits, principles of instrument operation, patient conditions, specimen requirements, biohazard precautions, test performance, limitations of methods, interfering substances, QA, QC, and results documentation; train in the preparation of procedure manuals that include these and other important entries (e.g., algorithms, care paths, formulae, reference intervals, and annual review).</td>
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<td>3. Design a competency plan to certify personnel (laboratorians, nurses, and physicians) to perform POC testing and its pre- and postanalytic tasks, follow licensing and accreditation requirements and maintain permanent records.</td>
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<td>4. Identify trained supervisors and users of POC testing, review access requirements periodically, and allow only personnel authorized for POC testing to perform tests, operate instruments, use robotic laboratories, and perform remote review.</td>
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<td>5. Periodically update knowledge and skills, observe the competency of instrument operators where they perform the testing, and document proficiency with written, oral, or practical examinations.</td>
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<td>6. Provide librarianship to assure that the process steps of the POC testing program are well documented, including QC, calibration procedures, and results review, for example.</td>
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*Reproduced with permission from the author.\(^2\)
CAP. Under CLIA 88, testing sites performing exclusively waived tests do not have to meet any personnel requirements. However, JCAHO training and competency requirements are more stringent. Hospitals that elect the CAP-LAP, which holds deemed status from HCFA, must adhere to the CAP-LAP standards, whereby all testing, including that performed at the point of care, must follow the training and competency requirements defined for the high complexity category under CLIA 88.

Accreditation Objectives for Training and Education

The CAP inspection checklist for POC testing focuses on awareness and enhanced performance. CAP standards require that: (1) “all personnel are knowledgeable about the contents of procedure manuals relevant to the scope of their testing activities” (questions 30:0420, 30:0429); (2) “the person(s) performing the tests have adequate, specific training and orientation to perform the tests offered” (question 30:0670); and (3) there is “a documented program to ensure that each person performing point-of-care testing maintains satisfactory levels of competence” (question 30:0690). Personnel must “detect clerical errors, significant analytical errors, and unusual laboratory results” (question 30:0370) and document “corrective action when control results exceed defined tolerance limits” (question 30:0620). The proficiency testing section emphasizes documentation of proficiency, rotation of personnel, and continuing education (question 30:0325). NCCLS guidelines emphasize important program objectives, such as performance of instrument maintenance and function checks, proper procedures for patient test performance, recording and reporting of patient results, assessment of problem-solving skills, verification of knowledge by examination, and use of operator proficiency in personnel evaluations. Collectively, these accreditation objectives call for a thorough understanding of the principles and practice of POC testing.

Status of Training and Education for POC Testing

Despite published and publicized accreditation requirements and professional guidelines for training and education, there are well-documented deficiencies in POC testing as it relates to bedside glucose testing programs. In 1989, a survey of 1,300 educators in diabetes care showed that of 378 respondents, 80.4% had an initial certification program for blood glucose monitoring, but 38.5% lacked recertification to document continued performance. One group assessed experience in three hospitals and observed that nursing personnel consider bedside glucose testing “a secondary responsibility that is accorded lower priority than other patient-focused nursing responsibilities.” Nursing personnel typically are in charge of training. In 1993, 241 hospital respondents of 6,000 surveyed members in a professional laboratory management association reported that nursing was primarily responsible for decentralized testing equipment training for all sites except surgery, where 47% reported that the central laboratory took responsibility. In a 1996 survey of southeastern US laboratory managers, 21.3% of 150 respondents felt that personnel training requirements were the most important disadvantage of POC testing; only cost was cited more frequently (29.3%). In 1993, a survey of 1,043 US hospital laboratories reported that of 365 respondents, 53% were not responsible for training non-laboratory personnel in POC testing. In 1994, a University Hospital Consortium benchmarking survey of 36 members showed that only about 25% of laboratories supported training and education for POC testing (Fig 2). Figure 2 also shows that >90% of laboratories supported QC and QA procedures and established or reviewed policies and procedures. Programmatic weakness in POC testing can be reduced through training and educating of operators in quality principles. Training programs, at least in part, will be institution-specific. Only recently have the majority (61%) of laboratories reported being involved in training for POC testing.

Leadership

Leadership for training and education should address: (1) multidisciplinary cooperation and teamwork, (2) training appropriate for an emerging technology, (3) continuous education and review of personnel performing POC testing, and (4) assessment of the clinical importance of rapid response test clusters and their interpretation in patient management. We recommend forming a well-focused performance enhancement team that has responsibility and authority for policies and procedures for competency, QA, proficiency testing, biohazard containment, risk management, instruments (including procurement, evaluation, calibration, implementation, backup, and discontinuation), and other aspects of testing. If the hospital laboratory is accredited through CAP-LAP, it is both practical and cost-effective to reduce duplication of accreditation and inspection fees by having the clinical laboratory director provide leadership, identify operators, designate the frequency of training, document certification and recertification, provide industry liaison and
updates, maintain authority, and delegate (as necessary) administrative responsibility for the POC testing program. To avoid preanalytic errors, it is important that sample acquisition and transfer are performed properly. Ideally, QC should be done by each operator and tracked quantitatively. QC might be rotated among operators, provided QC results are well-documented. Key to successful performance is responsibility to qualify personnel, to assure that QC standards are maintained, and to prohibit inappropriate use of POC instruments. If the hospital laboratory or decentralized sites are not accredited by CAP-LAP, we recommend that a single director or consensus team have authority and provide oversight for training and education, as well as for the entire POC testing program.

**Monitoring Performance**

Performance monitoring should match the intended clinical objective, type of system, test complexity, and professional discipline. For glucose monitoring, published evaluation templates can be used to design and conduct oversight functions.\(^7^7\) State professional certification requirements may differ from regulatory requirements. Generally, documented demonstration of competency in POC testing is required twice in the first year and annually thereafter for all tests performed. There should be direct observation of testing personnel and/or tracking of operator performance monitors.\(^7^9\) Skill levels and performance abilities must be documented, particularly for those who perform tests infrequently. For CAP-LAP, personnel are advised to certify annually by signature that policies and procedures have been reviewed for the tests performed. Skills renewal and competency testing should be adjusted in part to remedy problems, such as poor performance with QC or proficiency testing. Use of publications, videos, and a local intranet can facilitate information dissemination and provide a depository for educational media. Virtual media accessible through the Internet provide additional education resources.\(^4^0\) For centers with academic programs, we recommend integrating POC testing concepts into curricula of medical schools, nursing schools, courses for allied health professionals, and continuing medical education sessions. An important focus should be the optimization of the clinical value of rapid response testing and its effect on medical and economic outcomes.\(^2^,^2^2^,^3^5\) Education and training, performance review, and progressive improvement are fundamental to the successful fulfillment of the multidimensional requirements now facing POC testing programs.

**Future Considerations**

Appropriate test clusters, immediate results, accurate analyses, and informed clinical interpretation will continue to be goals for the laboratory-clinical interface.

1. **Test Clusters.** The appropriateness of test clusters depends on objectives for diagnosis, mon-
Monitoring, and therapy, and must take clinical priorities into consideration. The timing of test results is more important with some tests than with others. For example, prostate-specific antigen and glycosylated hemoglobin levels generally do not require rapid response. Creatinine and alanine aminotransferase levels, when used to assess organ status, are urgent tests. The standard of care requires a much faster response for blood gas, electrolyte, lactate, and glucose measurements when using these analytes to assess vital tissue oxygenation, perfusion, and substrate status in critically ill patients. Coagulation indices, myocardial injury markers, and early inflammatory response markers also may merit rapid response testing and therefore may be important in POC settings.

2. Therapeutic Turnaround Time. Rapid therapeutic turnaround time of test results allows an attending clinician to implement therapy immediately for unstable patients. These test results provide objective evidence on which to base medical decisions. In addition, rapid response results at the POC enable clinicians to make therapeutic decisions during the course of rounds, a situational process termed “physician capture.”

3. Accuracy and Precision. Test result accuracy and precision should be sufficient for clinicians to use results reliably at thresholds for medical diagnosis decision making. Physicians should have confidence that changes in analyte values over time represent valid trends on which to base therapy.

4. Interpretation. The wealth of patient information available regarding laboratory test results and the power of the computer enable and facilitate supportive interpretation with statistical probabilities. Integration of testing and interpretation becomes more attractive as the array of POC devices and test clusters increases in complexity.

Certain trends give insight into the future. Noninvasive, continuous, and inexpensive monitoring are goals for POC technology. Continuous in vivo and periodic, automated ex vivo (patient-attached) testing is finding its way into ICUs. In the interim, in vitro whole-blood analysis has made it possible to provide urgently needed information at the patient’s bedside and has created a paradigm shift from central laboratory to POC testing.

Recognition that reimbursement for defined diseases is limited makes it financially attractive to move patients from more expensive to less expensive settings (e.g., ICUs and hospitals to ambulatory and chronic care facilities). Therefore, the trend is for hospitals to accumulate increasingly sicker patients. This trend makes the following prediction, based on the “Top Ten Predictions” for the future, seem likely: hospitals will increasingly focus on POC testing and critical care stat testing, and other tests will be performed in efficient central and/or regionalized laboratories that cover aggregated patient groups in geographically consolidated managed care consortiums.

SUMMARY

POC testing provides an opportunity for clinicians and laboratorians to work together to consider how best to serve the patients within an individual institution. Each health system has unique characteristics relative to patient population, as well as a unique laboratory structure. If physicians, nurses, laboratorians, and pathologists work collaboratively, the best interests of patients will be served. In some institutions that cater to specific patient groups, POC testing may offer clear and distinct advantages. In other institutions with sophisticated transport systems and established rapid response capabilities, the quality resulting from central laboratory testing may outweigh any advantages of bedside testing. Clearly, attention to regulatory issues, QC issues, the importance of proper documentation, proficiency testing, performance enhancement, and cost-effectiveness is requisite. As the technology for diagnostic testing advances through more microcomputerization, microchemistry, and enhanced test menus, the concept of POC testing will need perpetual revisiting. We hope that the information provided here will aid clinicians, laboratorians, and administrators in their quest to best serve their patients.

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