Laboratory Point-of-Care Testing: A Future Outlook

POCT Progression & the Importance of Connectivity

Point-of-care technologies are quickly becoming part of the transformation of the healthcare landscape. In the right situations, when implemented properly and thoughtfully, Point-of-Care-Testing (POCT) can have a positive impact on operational efficiency and patient care. Additionally, having POCT test results captured in the EHR will allow for quicker diagnosis and treatment, automated billing, and inclusion of POCT data in valuable medical analytics.

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Notes
Bringing Laboratory Results to the Point of Care

With emerging technological innovations in healthcare, including smartphone apps, biosensors, lab-on-a-chip, and wearable devices—all of which offer a closer connection to the patient—point-of-care (POC) technologies are quickly becoming part of the transformation of the healthcare landscape. The driving concept in support of point-of-care testing (POCT) is to bring testing closer to the patient and results conveniently and quickly to the provider to expedite diagnosis and subsequent treatment. POCT allows for faster clinical decisions in hospitals, physicians’ offices, ambulances, patient homes, and in the field.

The College of American Pathologists (CAP) defines POCT as “testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient.” Because of its convenience, timeliness, and potential to improve patient outcomes, POCT’s popularity has risen in recent years. Empowering providers to make decisions at the patient’s side has the potential to significantly impact healthcare delivery and to help address challenges of health disparities. Moving the test to the patient increases the likelihood that the patient, physician, and care team will receive the results faster, allowing for immediate clinical management decisions. Furthermore, development, implementation, and connectivity of portable diagnostic and monitoring devices for POCT will be part of a successful shift from curative medicine to predictive, personalized, and preemptive medicine.

Explosion of POC Technology

A number of factors, such as the increasing prevalence of infectious diseases in developing countries, the rising incidences of lifestyle diseases such as cardiac diseases and diabetes, the rising usage of home-based POC devices, and technological advancements with regard to development of advanced, faster, and easy-to-use devices are stimulating the demand for POCT (see Figure 1). While POCT is one of the most active segments within the diagnostic industry, the technological capabilities far outnumber the rate of POCT adoption.

| Healthcare reform and patient-centered care |
| Technological advancements (faster, easier-to-use devices) |
| Laboratory staff shortages |
| Increasing older population and more chronic disease |
| Rising incidence of lifestyle diseases (e.g., cardiac, diabetes) |
| Increase in home-based POC usage |
| Increasing trend toward healthcare decentralization |
| Long-term savings |
| Rural locations with limited lab services |
| Prevalence of diseases in developing countries |

Figure 1: Factors Stimulating POCT Demand
In light of the many factors increasing the demand for POCT, manufacturing companies are pushing the envelope to make POCT devices faster, easier, and more reliable. The global POC diagnostics market is forecasted to grow at a compound annual growth rate (CAGR) of 9.3% from 2013 to 2018, and to reach $27.5 billion by 2018. The market accounts for both professional and patient self-monitoring tests and includes testing kits for:

- Blood gases/electrolytes
- Cardiac markers
- Cholesterol/lipids
- Coagulation monitoring
- Drugs of abuse testing (DAT)
- Fecal occult blood
- Food pathogens
- Glucose monitoring
- Hematology
- Infectious diseases
- Pregnancy and fertility
- Tumor/cancer markers
- Urinalysis testing

### Factors Driving the POCT Market

POCT can be an effective means of improving efficiency and outcomes and responding to essential healthcare needs among large populations and in rural areas. POCT is most advantageous when patient treatment can be improved by rapid results. The full potential of POCT is best realized in situations or disease states where having the result immediately available is imperative to treatment, thereby reducing downstream costs. Also, in a situation where the patient can receive real-time counseling based on the test results (e.g., Hgb A1c testing for diabetic status or PT/INR testing to monitor coagulation therapy), POCT becomes highly beneficial.

### Healthcare Reform ➔ Patient-centered Care

Healthcare reform, currently being pursued in the U.S., is encouraging provision of better and more convenient access to healthcare for all patients, particularly those with chronic diseases. The potential for POCT to be part of patient-centric healthcare is apparent because faster results facilitate quicker clinical decisions. As the healthcare landscape shifts (e.g., hospitals consolidate into regional networks with highly specialized medical care performed in core facilities), more services can be offered at the point of patient contact.
Diagnostic laboratory testing is undergoing a similar transformation. Complex, non-urgent tests are performed in core laboratories or in reference sites; routine, acute diagnostic tests are performed in core laboratories or in satellite hospital facilities; and POCT is performed in outpatient clinics, physician office laboratories, retail clinics, and in patient homes. Patients are seeking treatment at local physician offices and retail clinics at a higher rate than ever before. With the focus on providing cost-effective, timely medical care for ambulatory patients, POC laboratory testing has become one of the fastest areas of growth in the medical field, with the number of tests increasing at an estimated 10% to 12% annually.

The creation of the patient-centered medical home (PCMH) placed a renewed emphasis on primary care and made a commitment to patient-centered care. POCT can support PCMHs in their efforts to:

- Improve access to care
- Improve patient experiences
- Improve care quality
- Enhance disease understanding and awareness by the patient

An important aspect of POCT is that typically patients are more satisfied because testing is more convenient for them, contributing to the patient-centered principle. Adding to this, having higher patient satisfaction may influence attainment of Meaningful Use (MU) goals, because one of the main focuses of MU involves increased patient engagement.

**Increase in Older Population & Chronic Disease**

Rising demand for home healthcare and the increasing need to take care of a larger population of elderly patients with multiple chronic conditions is expected to drive POC diagnostics market demand in coming years. This fact, together with government initiatives to shorten hospital length of stay (LOS) by establishing out-patient care models, is collectively forecasted to influence the POC diagnostics market.

**Advances in Technology**

The POCT market is driven by technological advancements as well as by patient preference. Manufacturers are making continuous progress in terms of research and development to create products with newer, advanced technologies. The technology involved in POCT has evolved in many cases to be comparable to the centralized laboratory in terms of quality and meeting clinical needs. Advancements have also been made that make testing simple enough to be correctly performed by moderately trained staff. Many tests that previously required a laboratory for testing can now be accurately tested at the point of care. Even more complex molecular diagnostic products are being developed directly for the POC market.
Laboratory Staff Shortages

Laboratory staff shortages are another factor pushing the development of POC technology. Having less trained staff available has led to an increased level of automation and self-contained systems that require minimal user interaction. Skilled-staff shortages, especially in the field of diagnostics, are expected to accelerate the market penetration rates of POC diagnostic products.

Decentralized Laboratory Testing

There are three key drivers of decentralized lab testing: the increasing virulence of infectious diseases, the growth of companion diagnostics, and the need for better drug monitoring for diseases such as cancer. Additionally, in an effort to reduce costs and LOS, molecular testing for hospital-acquired infections has risen over the last several years. Currently, most molecular diagnostic tests are run in either large reference labs or in CLIA-accredited labs, but as more molecular diagnostic tests become available (particularly for conditions that benefit from a quick result), decentralized labs and near-patient settings are viewed as a viable and growing market. As personalized medicine continues to advance, bringing molecular diagnostic testing to the point of care in the physician's office will continue to be in demand.

On one hand, the push toward decentralized testing can subsequently drive demand for POC technology. On the other hand, even with healthcare reform's focus on cost control through preventive medicine in support of POC decentralized testing, higher direct costs for the performance of individual POC tests could deter some potential users. This is particularly applicable in cases where the reimbursements are not sufficient to justify the costs, and centralized testing resources are available.

Current POCT Market Status

Hundreds of tests once considered too complex for POC are now routinely performed outside the laboratory. Sensor technologies enable the rapid analysis of blood samples for many critical care assays, including chemistries, electrolytes, blood gases, and hematology. Biosensors are used for toxicology and drug screens, measurement of blood cells, coagulation, detection of cardiac markers, and glucose self-testing.

Glucose: Largest Market Segment

The hospital glucose testing market is the largest POCT market segment because of the high prevalence of diabetes and the need for constant monitoring of blood glucose levels. According to statistics published by the International Diabetes Federation, the global prevalence of diabetes is expected to increase from 382 million in 2013 to 592 million in 2035. Moreover, increasing demand for home healthcare to address the rising incidence of diabetes is another market driver. The blood glucose monitoring device market is a very lucrative business with vast future potential—valued at more than $2 billion in 2012.
Cardiac: Fastest-growing Segment
While glucose testing is the largest market segment in POCT, cardiac POCT is considered the fastest-growing segment. Currently, two POC devices dominate the cardiac marker POCT market: the Abbott i-STAT System and the Alere Triage System. Since development, the Triage has seen a 70% increase in volume for cardiac tests, and i-STAT’s volumes have tripled.3

CLIA Waived Status for POCT
While CLIA does not have a category for POCT, the majority of POCT is categorized as CLIA-waived. Waived testing, by CLIA’s definition, involves simple lab procedures cleared by the U.S. Food and Drug Administration (FDA) for home use that are so easy to perform, the probability of erroneous results is minimal. Even if the test is performed incorrectly, there is likely no significant harm to the patient.14

Increasingly, POC tests are able to qualify for CLIA-waived status, making the devices easy to use and decreasing the responsibility of regulatory requirements—another significant driving factor in the POCT market.9 Since 1992, tests categorized as CLIA-waived have increased from eight to roughly 100, representing thousands of test systems. As of November 2014, the number of laboratories that have been issued a certificate of waiver has grown exponentially, from 20% to 71% of the more than 250,000 CLIA-enrolled laboratories.14

Previously only approved for use in non-waived laboratories, the Alere Influenza A & B Test was recently granted the first waiver for a nucleic acid-based test by the FDA. The CLIA-waived status will allow this test to be distributed to a larger variety of non-traditional laboratory sites, including physicians’ offices, emergency rooms, health department clinics, and other healthcare facilities.15

POCT Benefits
While the most obvious benefit of rapid POCT is its potential to expedite medical decision-making, there are a plethora of other probable benefits (see Figure 2). For specific needs, POCT can be a much more efficient method for diagnosis and rapid treatment. For example, if a patient has influenza or another severe respiratory infection, meningitis, or a hospital-acquired infection, the importance of receiving test results without delay and quickly administering treatment can make a huge difference in positive patient outcomes. When properly integrated, POCT allows healthcare workers to capture clinical data quickly and accurately, and streamline workflow and efficiency. POCT, for the right tests in the right situations, can improve consistency, accuracy, patient engagement, patient satisfaction, and ultimately patient outcomes.
### Efficiency Advantages

Because on-site POCT typically requires fewer steps than the transporting, processing, and aliquoting processes that take place in a core laboratory, it is inherently a leaner process. Additionally, because the provider can examine the patient in conjunction with the POCT results, in many cases medical care is more promptly implemented, eliminating the need for physicians to remember a case after test results come back from the main laboratory.

Additional improvements to patient outcomes or workflow happen because POCT results can be linked to patient management immediately in order to move patients through the system faster or handle more patients at a time. Moreover, the rapid availability of POCT results allows for face-to-face instructions that can improve patient understanding of treatment plans.

#### Figure 2: Benefits of POCT

<table>
<thead>
<tr>
<th>Benefits of POCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faster test results lead to more timely triage or treatment</td>
</tr>
<tr>
<td>Less sample volume (neonatal, pediatric, ICU benefit)</td>
</tr>
<tr>
<td>Tests at a variety of remote locations meet a diversity of medical needs</td>
</tr>
<tr>
<td>Decrease pre-analytical concerns related to processing of specimen (e.g., clotting, centrifugation, etc.)</td>
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<tr>
<td>A Lean process</td>
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<tr>
<td>Increase provider and patient satisfaction</td>
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<tr>
<td>Reduce length of hospital stay</td>
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<tr>
<td>Reduce hospital admissions</td>
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<tr>
<td>Optimize drug treatments</td>
</tr>
<tr>
<td>Decrease inappropriate use of drugs</td>
</tr>
<tr>
<td>Reduce postoperative care time</td>
</tr>
<tr>
<td>Reduce ED time</td>
</tr>
<tr>
<td>Optimize clinical efficiency and use of staff time</td>
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</tbody>
</table>

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Gary M. Reisfield, M.D., of the Department of Psychiatry at the University of Florida College of Medicine, likens POCT to the “…Mustang GT of drug tests—fast, cheap, and reliable enough.” He points out that POCT has improved dramatically since the 1990s and early 2000s, and that rapid real-time POC drug testing allows real-time discussions with patients about what their test results mean today. For drug testing, face time with the patient ensures that the past few days of drug use are fresh in the patient’s mind. Rather than contacting patients by phone with a result three or four days later, immediate POC results allow evaluation of results in conjunction with the current physical and emotional presentation of the patient. “There’s absolutely no substitute for having immediate results of a drug test and looking a patient in the eye,” says Dr. Reisfield.16

**Benefits Attributed to Specimen Type**

Additional POCT benefits occur because less sample is typically required for testing. The smaller sample volume is more convenient for patients, particularly for pediatric or neonatal patients, and causes less blood loss and anemia for patients who require frequent testing, such as intensive care patients. Moreover, whole blood POCT requires less hands-on time for processing and reduces the potential for sample deterioration. Testing normally occurs immediately after sample collection, thereby reducing the changes that occur due to continued cellular metabolism, cooling, analyte instability, exposure to the environment, etc.17

**Size & Portability of Device Advantage**

POCT offers more flexibility to meet a diverse range of medical needs because small, portable POCT devices make testing possible in a variety of remote locations, such as underserved populations, rural areas, and locations with limited infrastructure or personnel (e.g., disaster, accident, or military sites).17

**Challenges**

Although POCT provides rapid results and the opportunity for faster medical decisions, the risk of errors with POCT often raises concern over the reliability of test results. In contrast to the core lab, where errors occur most frequently in the pre- and post-analytic phases, POCT errors occur primarily in the analytic phase of testing. This can be related to a lack of understanding or training of non-laboratory staff who are typically involved in POCT or as a result of test limitations and misuse of POCT in extreme environmental conditions.18 While the laboratory offers a structured, controlled testing environment, testing conditions for POCT can vary tremendously. Additionally, the connectivity needed to get POCT results into the EHR fast enough to effect a change in patient care is challenging.
**Management/Oversight**
- Infrastructure
- Lab must be involved

**Testing Performed by Non-laboratory Personnel**
- Need knowledge of specimen handling, QC, QA, PT, etc.

**Analytical Quality**
- Reliability of results
- Variations in test results from multiple testing platforms

**Regulatory**
- Waived vs. non-waived

**Training & Competency Assessments**
- Need to track for all operators
- Differing requirements between regulatory agencies and for waived vs. non-waived

**Data Management & Connectivity**
- Need to capture results electronically (to reduce errors, incorporate data)
- Varying connectivity capabilities of POC devices
- EHR connectivity

**Costs & Billing**
- POCT and lab tests with the same name/CPT code can cause confusion
- POCT devices with multiple tests in one cartridge may not be reimbursed properly

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Figure 3: POCT Challenges
Management/Oversight

Thorough management of POCT can be challenging. Testing may include dozens of sites, hundreds of POCT devices/kits, and thousands of operators that have to be managed in order to assure quality. Larger facilities with numerous devices and locations often employ dedicated point-of-care coordinators (POCC) to ensure proper usage of POC equipment. Often, interdisciplinary POC management teams that include the laboratory, physicians, and nurses are collaboratively responsible for:

- Determining the test menu
- Selecting methodologies
- Establishing policies and procedures
- Confirming certification management (proper training)
- Overseeing regulatory compliance
- Documenting corrective action where necessary
- Providing advisory assistance to the end users of POC technologies

However, regulatory standards hold the laboratory director responsible for managing and supervising POCT quality. In a clinic setting, the laboratory director may be a physician, but in a hospital or health system, the chief of pathology and head of the central laboratory may be responsible. POCT can therefore be at odds with both the staff performing the test as well as the laboratory staff responsible for supervising the test, and this conflict can cause discord.

Testing Performed by Non-laboratory Personnel

Clinical personnel with minimal laboratory knowledge, such as nurses or medical assistants, often perform the majority of POCT. These operators are focused on patient care, are subject to the pressures of a fast-paced work environment, and do not necessarily understand why they must handle POCT—viewed as a laboratory role, not a job for other clinical staff. They are often unfamiliar with routine laboratory procedures regarding the importance of proper patient preparation, sample collection, calibration, instrument maintenance, and quality control.

One of the concerns of laboratory professionals is that POCT equipment will not be used and maintained properly, or will not include appropriate quality control and quality assessment procedures. Non-compliance with standard operating procedures can be a contributory factor in POCT errors. With the diversity of education and experience levels and high turnover rate of staff who perform the tests, quality issues can occur.

Analytical Quality

Also of concern is the variability of results from different analyzers and testing devices. In some instances, POCT results are not necessarily comparable to central laboratory results. Standard methods may not be used in POCT so it may not be possible to compare variant methodologies. Differences in specimen types (e.g., serum, plasma, or
whole blood) can also affect comparative results between POCT and core lab methods. Furthermore, POCT kits and devices may not be FDA approved for all uses that a similar test in the central laboratory is approved for.\(^5\)

Greater variability in results compared to central laboratory testing is common. Just because a test is classified as waived does not guarantee its proper usage and reliability. The simplicity of waived testing can be deceptive, and there are many ways that staff can unintentionally produce an incorrect result when performing waived testing. For example, test interpretation is often subjective and may be visually and/or lighting dependent.

**Regulatory**

Even though POCT is performed by non-laboratory personnel, the laboratory should take primary responsibility in support and oversight of POCT. Proper processes and procedures regarding specimen acquisition and labeling, documentation, QC, proficiency testing, infection control, etc., are vital to best-test performance and proper regulatory
compliance. Figure 4 lists the top three CLIA deficiencies for certificate-of-waiver labs.\textsuperscript{14}

CAP has more than 55 standards that directly apply to POCT, another 75 in the common checklist, and more than 300 in the lab general checklist, all relating to POCT. CAP has POCT standards for each of the following categories:

- Quality management
- Results reporting
- Instruments and equipment
- Personnel
- QC
- Calibration
- Safety
- Provider performed testing\textsuperscript{19}

Citing concern that the lack of oversight and requirements for personnel qualifications and training in an increasingly large number of waived laboratories could contribute to errors and patient harm, COLA Resources, Inc. (CRI) has added 10 criteria specifically for waived testing. CRI’s January 2015 accreditation manual has updated the requirements to include competency testing for staff performing testing at all levels of complexity, and proficiency testing for waived tests.\textsuperscript{20, 21}

Recently, the use of blood glucose meters has brought the issue of “off-label” testing to the forefront. Use of a test outside the FDA’s approved, intended parameters, and outside of what is indicated by the manufacturer, is considered “off-label” testing and immediately becomes subject to non-waived CLIA guidelines. Controversially, new proposed guidance from the FDA on hospital use of glucose meters drastically changes current standards by classifying all glucose meters coming onto the market as CLIA non-waived, whereas previously these tests were waived. This will require an increased education level for operators to perform the tests, plus additional requirements in proficiency testing, training, quality assurance, and other areas.\textsuperscript{13}

**Training & Competency Assessments**

Both CLIA and CAP report confusion between training requirements and ongoing competency assessments. Interestingly, 20\% of CAP deficiencies involving POCT are related to competency testing.\textsuperscript{17} For CLIA and accrediting agencies (CAP and CRI), initial training is required prior to POC device operation, followed by documented competency assessments at specific intervals. Details of specific requirements vary between agencies and between waived and non-waived testing. For waived testing, CAP and CRI require annual competency testing for all operators, whereas CLIA only requires annual competency assessments for personnel performing non-waived testing.\textsuperscript{19, 14, 21}
Data Management & EHR Connectivity

Another concern with POCT is that often the results are not captured electronically and therefore are less accessible and not included in data analytics or automated billing processes. It is imperative that POCT results are properly recorded and electronically linked in the EHR. Often, POCT data is available at the place of testing, but once the patient is no longer at the testing location, POCT results are unavailable unless the devices are connected with the LIS and/or EHR.

While the benefits of having POCT results in the EHR outweigh the concerns, incorporating POCT results in the EHR can add another level of complexity. Connecting POCT devices to an EHR may require a computer interface or middleware and ongoing maintenance that can add costs. Some POCT devices must pass results through a proprietary data manager into the LIS and then into the EHR. Applicable to any lab test, correct display of results in the EHR has to be verified. IT staff may not understand POCT and therefore try to consolidate all methods into one general test display (e.g., glucose). Keeping results separated based on methodology is important for tests in which analyzers may give different results for the same sample and involve different reference ranges.

Costs & Billing

In all areas of healthcare, there is an increasing demand to demonstrate the economic benefits and enhanced patient outcomes that come from the introduction of any new product. Most often, POC tests are associated with higher costs per test due to their faster turnaround time (TAT) and consumable costs. Determining the effectiveness and cost savings of POCT is more involved than your normal cost analysis because savings may not be seen in testing costs alone. Looking at downstream savings such as decreased LOS, readmission rates, and other improvements in patient outcomes makes savings far harder to measure. It can be difficult to quantify the dollar value of a faster TAT and increased patient satisfaction.

Having more than one methodology and CPT code for the same test name can lead to confusion about proper coding for billing, potentially contributing to billing errors. For POCT devices that test several tests on one cartridge or cassette, each test may not be reimbursed. While this type of POCT is beneficial in primary care environments, reimbursements do not reflect this benefit. Currently, manufacturers of these types of POC devices are trying to influence changes in how these multi-analyte POC tests are reimbursed.

In the right situation, costs for POCT can be offset against the greater savings in other areas. Moving to value-based healthcare reimbursement is forcing a change in the way budgets are viewed, specifically in regards to departmental silos. This renewed look at finances may cause reconsideration of where testing is most effective, either in a laboratory or close to the patient.
The Who, What, When, Where, & Why of POCT

It is well acknowledged that for certain health conditions, a delay in receiving a diagnostic test result from a central laboratory is not ideal for the patient. POCT, when implemented properly and thoughtfully, can have a positive impact on operational efficiency and patient care. The secret sauce to successful POCT is determining when and where implementation offers the most benefit. Before making a decision to put POCT in a particular location, you need to know your POC assay and be aware of its limitations. The laboratory must be able to understand the analytic characteristics of the POC assays, how they differ from the same test in the main lab, and educate users about the pros and cons of the specific POCT. In the right circumstance, POCT alternatives can be instrumental in providing patients with the most convenient quality care possible.

With POC’s many challenges, implementation must be carefully planned for and applied in the places where rapid TAT or immediate results for a face-to-face discussion with the patient can have a profound impact. For example, rapid TAT has been shown to be crucial in critical care settings. POCT is a tool that can be used along with the central laboratory and the reference laboratory. However, POCT is often put in place without changing associated processes, which can be an important factor in realizing improved outcomes. Part of the implementation process involves changing the patient workflow or other procedures surrounding testing to gain the most benefit.

Historically, patients have not been very involved in their own healthcare plans, but have instead dealt with a system that often delivers service in a way and at a time that may be inconvenient or inconsiderate of their needs. The renewed patient-centered stance will encourage may healthcare providers to update the way they practice. Laboratory medicine should be in the vanguard of that change given the key role that laboratory data plays in clinical decisions, and that raises the possibility of whether more testing will need to move closer to the healthcare consumer of the future.

Importance of Connectivity

Incorporating POCT to ensure that all staff on the care team throughout a healthcare network have access to results to make timely, optimal care decisions is very beneficial. Having POC test results captured in the EHR allows for quicker diagnosis and treatment, automated billing, and inclusion of POCT data in analytics needed for risk stratification and population health statistics. An important question to consider is how to best integrate your POC test data.

POCT has seen steady progression in the area of connectivity options (see Figure 5), and many of the newer generations of POCT instruments have interfacing capabilities. The original record-keeping method for POCT, unfortunately still in use in many healthcare facilities, is manual documentation of results, QC, competency assessments, etc., on paper logs with no electronic connectivity. Results may then be manually transcribed into the LIS or EHR, introducing opportunity for error. This record-keeping method is typically used for low-volume, instrument-based tests when interfacing is too expensive or too difficult to network. Although rarely used today, an earlier method used to connect POC glucose meters involved physically synching the device with a laptop, primarily to archive historical data.
Newer POC devices involve a central desktop computer networked to instrument docking stations. Initially, this process was modem-based with some systems capable of interfacing to the LIS and/or EHR. Often, POC glucose test results are manually entered directly into the EHR. Operators type POCT results into an EHR flow sheet and can enter other relevant observations or data (e.g., insulin dosage, other medications, patient presentation, etc.), but still have opportunity for transcription errors.21

Today, the preferred connectivity solution to manage POCT results involves middleware that allows multiple devices to interface with the LIS or EHR. Some of the more advanced POCT software solutions can also track certification management for all operators. However, this connectivity can be dependent on the capabilities of the POC devices themselves.21 Some POC connectivity solutions on the market today allow bar code scanning of operator badge, patient armband, and test reagent prior to testing. Test results are matched to a patient medical record number and wirelessly transmitted into the LIS or EHR.

Major benefits are obtained when the output of a POCT device is made available immediately within an EHR. Results can be shared instantaneously with all members of the healthcare team, dramatically improving TAT. A reduction in morbidity and mortality has been associated with goal-directed therapy techniques when used alongside POCT and the EHR.6
Future Outlook for POCT & Advancing Developments

The emphasis of care is shifting toward prevention and early detection of disease, as well as management of multiple chronic conditions. With the development of smaller devices and wireless communication, the way in which providers care for patients is changing dramatically and patients are beginning to take a bigger role in their own healthcare. Healthcare will become more personalized through tailoring of interventions to individual patients. The next decade will bring a new realm of precision and efficiency to the way information is transmitted and interpreted, and thus the way medicine is practiced. Diseases that currently require complex testing in a hospital setting will be handled through bedside monitoring.8

An influential market driver for the in vitro diagnostics (IVD) sector is the emphasis on personalized medicine, particularly in regards to selection of drugs that work best for an individual patient based on genetics. Diagnostics are at the center of achieving this goal, with direct and immediate patient contact being the preferred route rather than working through a centralized laboratory. In personalized medicine, the economic arguments for volume testing within a central laboratory are outweighed in favor of POCT.15

A number of tests are being developed in POC, from new infectious disease biomarkers to polymerase chain reaction (PCR) and molecular testing at the bedside. Wearable biosensors and lab tests on a chip are no longer science fiction, but are actually in development. In addition to new technologies, research findings, new regulatory scrutiny, and economic and business obligations are pushing POCT to carve out a new niche within the healthcare system. Government and industry initiatives are combining with research and clinical practice to steer POCT into its next era.13 Look to see a continued increase in the use of POCT in home settings, on smart phones that can monitor certain key parameters, and in primary care settings.
POCT in Cancer

Current developments in POCT are attempting to address the challenges of diagnosis and treatment of cancer. Early detection of cancer may be possible through capture and analysis of circulating tumor cells (CTCs). CTCs that metastasize from a primary malignant tumor to other organs can cause up to 90% of cancer-related deaths. Being able to capture and analyze CTCs in peripheral blood may be used in the development of tailored treatment plans and monitoring. Researchers have developed a microfluidic device that separates CTCs from whole blood. This technology has broad implications for advancing cancer research and for the clinical management of cancer.8

POCT & Antibiotic Therapies

Going forward, POCT may have a greater impact on antibiotic stewardship. Testing that could occur at the POC to identify a bacterium and its susceptibility patterns could help reduce the use of inappropriate antibiotics and drug-resistant super-bugs. Although this POCT application is not yet available, we are moving in that direction. Now available in the core lab is MALDI-TOF mass spectrometry, which in just a few hours can provide results that in the past would have taken up to 36 hours.13

Molecular POCT

Molecular POCT methodologies are making strides, particularly for microbiology, because traditional methods have such an extended TAT. Hospitals are using rapid PCR testing to test for MRSA and C. difficile to reduce hospital-acquired infections, and clinics are testing to monitor viral load for patients with HIV or HCV to modify treatments. The rapidity of POC molecular microbiology can have a significant downstream positive financial impact by reducing hospital LOS.
The Lab’s Responsibility in POCT
Ultimately, the shift toward POC diagnostics is a positive one. **POCT gives immediate results in non-laboratory settings to support more patient-centered approaches to healthcare delivery, allowing for more rapid treatment of the patient.** In the goal to improve patient care, continued development of POCT can help support the future demands for rapid diagnosis and treatment. Furthermore, making sure POCT is electronically incorporated in a real-time manner can optimize POCT benefits and allow for inclusion of POCT results in valuable health analytics.

The laboratory is often the starting point in the diagnostics chain, and ultimately responsible for ensuring that lab results are accurate and beneficial to the provider and to the patient. **Whether lab testing takes place within the laboratory or at the patient’s side, laboratory professionals who understand the intricacies of testing and the importance of proper laboratory processes to ensure quality have an obligation to be involved in the oversight and growth of POCT.** When the patient situation derives more improvement from a POC test intervention than from lab results performed in the core lab, this actuality takes precedence over other concerns. **Laboratory professionals have the skillset and obligation to influence decisions that will encourage appropriate POCT usage where it is most beneficial to improve patient care, and this offers another opportunity for them to be an integral part of the future of diagnostics.**

Orchard Software’s POCT Connectivity Solution: Orchard Trellis
At Orchard Software, we believe POCT will play an important role as healthcare continues to make changes focused on improving patient care, and we are aware of the many challenges surrounding POCT. Because of the direction healthcare is headed, we also think it is important to have POCT results available in the EHR, and not entered manually but electronically. To address the connectivity challenge, we created Orchard® Trellis™ to bridge the gap. Orchard Trellis is an orders and results management software that uses web services and standard HL7 2.5.1 messaging to serve as a simple “review, click, and go” cost-effective bridge to electronically pass orders and results between remote, low-volume POC devices and your EHR. If you would like to learn more about Trellis, please call 800-856-1948 or contact us at sales@orchardsoft.com.
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