Point-of-Care Testing: The Great Boom Ahead

Today's Healthcare Requires POCT with Comprehensive Data Management & Integration Solutions

The value-focused environment of today's healthcare is increasing demand for POCT. And not just POCT, but rapid, accurate, and integrated POCT results. Improvements in patient outcomes and satisfaction can be realized when laboratory results are made available in real-time at the patients' point of care. Yet, POCT tends to be siloed and often is not managed by the lab. To meet the evolving needs of healthcare, laboratories need to actively manage POCT. To do so effectively, lab managers who oversee POCT can benefit from a data management and connectivity solution that integrates POCT results into the patient's chart and eases the challenges of POCT management.

Kim Futrell September 2016



Table of Contents

hift in Healthcare Renews Focus on Integrated POCT	
OCT Management Challenges	
POCT Integration from Decentralized Testing Locations	
Management Challenge: Operator Certifications	
Device Tracking, QC, & Calibration Verification	
Billing Challenges	
History of POCT Connectivity	
POCT: From Bedside Glucose to Interfaces	
POCT Connectivity Standards5	
OCT Case Study: Healthcare Organization in Nebraska 6	
Time Wasted Manually Typing in Glucose Results	
Verification of Manual Results Wastes More Time	
Nearly \$40,000 Saved in Staff Time	
OCT Case Study: 365-bed Hospital in Ohio	
Time Wasted Manually Typing in UA Results	
Over 3,300 Hours/Year Wasted Typing in Manual Results	
Scanned "Blobs" Mean No Data Mining	
mportance of a Quality Management Program for POCT 9	
OCT Must be Integrated to Reach Full Potential 9	
Orchard Software's POCT Management & Connectivity Solution—Orchard® Trellis™	
Notes	

Shift in Healthcare Renews Focus on Integrated POCT

The U.S. healthcare system is undergoing tremendous change, focusing on improved population health, better patient outcomes, more patient engagement, all at affordable and reasonable costs. With this new focus, point-of-care testing (POCT) is becoming the great boom because of its tremendous potential in value-based care, specifically in situations where a rapid turnaround time (TAT) can have a profound impact on downstream costs and outcomes. The biggest advantage to POCT is that providing faster access to test results can expedite speed of diagnosis and subsequent treatment. For example, POCT in the right situations (such as an urgent care location or ED) can reduce unnecessary hospital admissions or imaging.

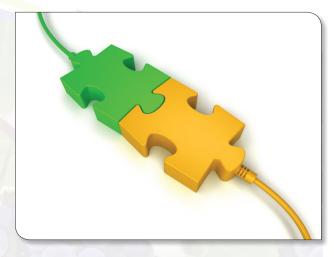
With patient engagement becoming more important in healthcare, the fact that POCT is often associated with increased patient satisfaction is another factor driving growth in the POCT market. POCT typically requires a much smaller sample volume and this can be significant for certain patient populations like neonatal or ICU patients to avoid iatrogenic anemias. The technology behind the devices and the ability to electronically integrate the results is becoming more reliable and more affordable, which is also driving adoption.

POCT Management Challenges

In order to achieve the real-time benefits associated with POCT, not only does the test have to be performed at the point of care, but the results have to be electronically integrated into the patients' charts and immediately available to the care team. When this is the case, POCT can improve the efficiency of providers and potentially improve patient outcomes. However, management of POCT dispersed throughout a healthcare organization presents many challenges. For one, POCT often takes place in silos within a larger healthcare delivery network and may not be under the laboratory's management.

POCT Integration from Decentralized Testing Locations

Because POCT sites can be widely scattered across a healthcare campus, it is important to have a robust POCT management system capture important testing information and manage regulatory compliance.² Ideally, the POCT program can be efficiently and effectively monitored from a remote location. In reality, few healthcare organizations have been able to successfully integrate their POCT into their EHR. POCT decentralization is one of the factors that contributes to the fact that only 10% of POCT are electronically integrated.³ The full value of POCT is only seen when those results are immediately accessible in the patients' EHR.



Management Challenge: Operator Certifications

Not only do healthcare organizations performing POCT need those results integrated to expedite TAT, but in a large facility with hundreds of devices and thousands of operators, POCT operator certification can be quite a challenge. Tracking a large number of operator training and certification dates can be better managed with

assistance from a POCT management system. Regulatory requirements directly associated with POCT are increasingly making it virtually impossible to manually monitor a comprehensive POCT program.⁴

Often POCT operators are not trained as laboratorians, so they may not readily see the reason behind certain seemingly tedious tasks (QC, QA, maintenance, etc.). When POCT falls in with other lab testing so that it is viewed as a laboratory extension, it is more readily accepted that POCT results should be included in any overall interface decisions related to lab testing.⁴

POCT oversight by the laboratory improves4:

- CLIA regulatory compliance
- Training (and its documentation) for all operators
- Review of calibrations, QC, & QA
- Verification of results before release
- Systems for ordering, reporting, and storage of results
- Automatic capture of billing information
- Monitoring of electronic integration

Device Tracking, QC, & Calibration Verification

Along with keeping up with a multitude of operator certifications, large POCT operations have a large number of POCT devices that must be tracked. QC and calibration verification must be monitored for each device to assure quality testing and meet regulatory requirements. Having a POCT management system that allows the Point-of-Care Coordinator (POCC) to remotely track devices, review QC, and document calibration verification can be a life saver in large POCT operations.

Billing Challenges

In addition, often the processes in place for POCT billing capture are either poorly organized in a manual system or just not billed for at all. The fact that most POCT is not electronically captured is the cause of substantial loss of revenue that if properly collected could offset the cost of the POCT.⁴

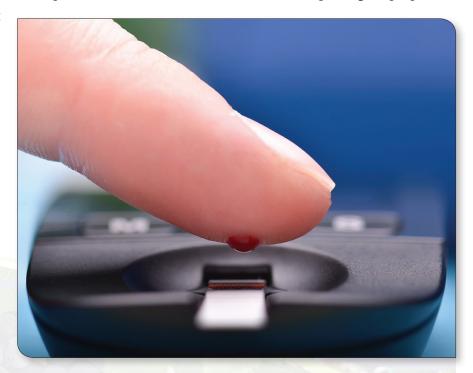
History of POCT Connectivity

Two decades ago, there was essentially no electronic data management for POCT. Test results and related information were manually recorded in the patients' paper charts or on log sheets located near the testing area. To manage POCT, the POCC would have to physically visit each testing location to review documentation.² Technology to enable real-time remote management of POCT data was unavailable. Additionally, there were no standards that required POCT devices be designed for connectivity.² Furthermore, historically, LISs had not been developed to include management of POCT data.

POCT: From Bedside Glucose to Interfaces

Bedside glucose testing is by far the most widespread and largest volume in the POCT market. These were the first devices developed for the POCT market. In many hospitals, this involves hundreds of devices and thousands of operators. First generation POCT devices developed in the 1990s involved the POCC transporting a laptop

into each POCT location and downloading patient results each month. Later, devices were developed that were kept in the patient testing locations cradled in their own docking stations. Results from the devices were downloaded each time the device was docked. This potentially involved a bi-directional interface that allowed for reagent lot numbers and QC data to be downloaded to the devices, and it could be interfaced to the billing system or LIS.2 Next came the ability to interface devices from different manufacturers, followed by real-time wireless connectivity with bi-directional communication to wireless-enabled devices.2



POCT Connectivity Standards

In 2000, the Connectivity Industry Consortium was formed with the goal of developing POCT connectivity standards. These standards evolved into the Clinical and Laboratory Standards Institute POCT1-A.² The connectivity standard greatly improved the quality of POCT. The intent of the standard was to work toward a plug and play environment for POCT connectivity, where devices are easily interfaced to LIS, EHR, and HIS.

The standards also opened the door for the development of POCT management systems capable of connecting multiple devices from various manufacturers, eliminating the need for a computer for each POCT device. CLSI now has a consensus committee that oversees the development of ongoing POCT standards.³

Today there are many devices capable of reducing or eliminating operator and analytical errors, and there are POCT management systems available that enable automatic electronic flow of data from the POCT devices to the LIS and EHR, as well as providing remote access to QC and operator certification data. While many POCT devices can be directly interfaced to the LIS, most are connected to the LIS through proprietary data management systems (DMSs).²

In years past, manufacturers of POCT devices focused on improving analytical performance. Laboratories would integrate POCT solutions without concern over how the results would be integrated. Now, these manufacturers must also provide up-to-date connectivity and informatics solutions inherent to the devices in order for the POCT devices to be relevant. Savvy laboratories are looking for POCT solutions capable of data integration and IT solutions that encompass all aspects of laboratory information management.⁴

Problems associated with POCT connectivity

- Cost of interfaces
- Device and connectivity solution limitations
- Differences between POCT vs. core lab testing
- Database requirements for POCT
- Multitude of variant remote POCT devices

POCT Case Study: Healthcare Organization in Nebraska

In discussing the transition to using a POCT connectivity solution, the Laboratory and Pathology Operations Manager at a large multi-specialty healthcare organization in Nebraska feels that one of the biggest challenges involved in the oversight of POCT is the fact that testing is commonly performed by a multitude of non-laboratory-trained personnel. And while these may be top employees, it can be difficult to train them about the importance of proper QC, documentation, and other laboratory-focused regulatory requirements. The ability to remotely manage certifications and QC can be of great value to a busy manager who has the added task of POCT oversight.

Time Wasted Manually Typing in Glucose Results

Their facility uses several different POCT devices and testing is performed by hundreds of end users from lab, nursing, and radiology. They now have fully integrated glucose POCT. Before they had this functionality, they were manually entering thousands of glucose results, taking a significant amount of time to manually type in results.

"Implementation of wireless integration and automatic downloading of results has been huge for us because we were spending a great deal of time entering results that can now be spent on other tasks," says the lab manager. In only looking at POCT for glucose, their phlebotomists were manually typing in about 50 glucose results from approximately 20 glucose devices every day, plus several more from periodic intervals throughout the day. If you add together time spent documenting these results at the bedside and traveling down to the lab to type the results into the computer, the total time spent significantly increases. Once in the lab,

[POCT] Connectivity saves us

up to two hours per day

that we can now use to be

more productive, not to mention

the errors we have eliminated.

- Laboratory & Pathology Operations Manager

the technical staff spent time manually entering results into the LIS. After their connectivity solution was in place, inefficiency due to manual entry of results was eliminated. "Connectivity saves us up to two hours per day that we can now use to be more productive, not to mention the errors we have eliminated," adds the lab manager.

Verification of Manual Results Wastes More Time

Additionally, as per regulations, they have a procedure for the verification of any manually entered result that must be performed prior to release of results. The procedure requires that a second technical personnel member review any manually typed in result for accuracy, and this double-check is documented in the LIS. So, additional time-savings has been realized by reducing the manual entry and associated double-checking.

Nearly \$40,000 Saved in Staff Time

If you take this example and extrapolate the potential savings, within a large healthcare facility this can add up to a substantial amount. For instance, in a large teaching hospital, annual bedside glucose testing volumes approach 70,000/year.⁵ If each glucose takes one minute to be manually entered, this is equivalent to 1,167 hours of staff time; multiplied by an average Medical Assistant (MA) salary of \$12/hour, this equates to about

\$14,000 per year spent in labor costs associated with the manual entry of bedside glucose testing. If you calculate this using the average Medical Technologist (MT) hourly wage of \$31/hour, it equates to \$36,177 per year spent typing in glucose results.

Healthcare organization in Nebraska reports: more than \$36,177/ year spent on manually typing glucose results.

POCT Case Study: 365-bed Hospital in Ohio

The Business Manager of Ancillary Services at a large 365-bed hospital, where approximately 500 staff members perform POCT, shared some of their challenges for handling POCT prior to implementation of a connectivity solution. The POCT operators were either manually typing results into the EHR or, worse (from a structured data standpoint), scanning in instrument printouts or worksheets.

Time Wasted Manually Typing in UA Results

The team did a time study to track the savings associated with having their POCT Urinalysis (UA) results electronically integrated. For consistency, timing started after users were in the patient chart, and UA order choices include drop-down options for result choices. Because a UA contains ten or more components that need to be entered (specific gravity, pH, protein, glucose, etc.) and each of these has multiple possible answers, on average employees had to scroll through dozens of results choices to complete one UA. On average, this takes a staff member 2.5 minutes per UA. So, for example, for every 24 UAs, in addition to the time it takes to perform the testing, manually entering results would add an hour of tech time.

Over 3,300 Hours/Year Wasted Typing in Manual Results

To put this in perspective, they perform about 80,000 urinalyses each year. If you multiply that volume by 2.5 minutes, that adds up to 200,000 minutes or 3,333 hours spent manually entering results just for that one lab test. If we estimate the average MA salary for entering results as \$12/hour, this means that their laboratory has \$40,000/year of staff time allocated to this task alone.

365-bed hospital in Ohio reports: \$40,000 / year spent on manually typing UA results.

Scanned "Blobs" Mean No Data Mining

Furthermore, to avoid the labor-intensive method of manually ordering and entering UA results, some of their testing locations actually scan the UA printouts from the analyzer or handwrite results on old manual logs and scan these into the EHR because it is easier and faster. The business manager is quick to point out, "In these cases, there is no data mining for POCT, because scanning does not provide discrete data."

The lab team is excited about eliminating this tedious, error-prone task and gaining the efficiencies brought on by a comprehensive POCT management and connectivity solution. The new POCT connectivity solutions is expected to reduce errors associated with the manual entry of results as well as organize tracking of operator competency assessments. "In a healthcare organization of our size and diversity, it is nearly impossible to accurately track

certification without software support. We are looking forward to having a powerful POCT connectivity solution to help us monitor this as we go forward," says the business manager.

Importance of a Quality Management Program for POCT

No matter the combination of POCT devices, operators, or data management/connectivity, it remains important to develop a strong POCT management program to ensure quality and timely access to POCT results.² POCT management can

In a healthcare organization of our size and diversity, it is nearly impossible to accurately track certification without software support.

 Business Manager of Ancillary Services at a large 365-bed hospital

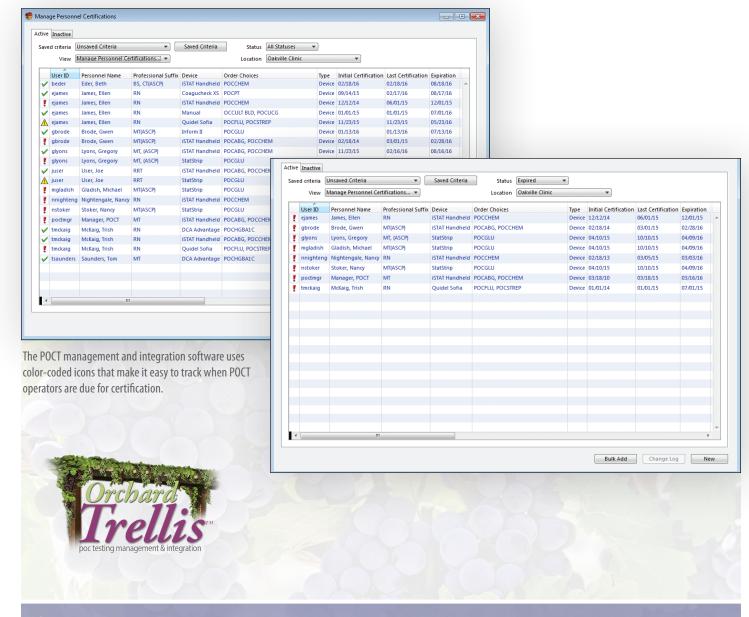
be complex because of the diversity of device types and their software, and because testing locations may be spread across a large healthcare organization's network. Large facilities may have a POCT management team that is jointly responsible for POCT decisions and oversight. The challenges inherent to POCT make it imperative that managers have a comprehensive POCT management system and connectivity solution as a tool to organize and track testing data, as well as manage regulatory requirements such as operator certifications and QC. Often managers in charge of POCT have many other responsibilities. Having a software solution that enables POCT management (QC, certifications, emails to end users, push down messages to POC devices, etc.) remotely from one location can be extremely beneficial.

POCT Must be Integrated to Reach Full Potential

Having a strong POCT management system and connectivity solution can dramatically reduce the amount of time spent manually typing in results, eliminate errors inherent to manually entered results, and facilitate real-time access to the results so that providers can make timely care decisions. In the advancing arena of healthcare data analytics to support patient-centered care and population health management, it is no longer a luxury to have POCT electronically integrated—it is a necessity. POCT must be immediately available in the patients' charts so that the benefits associated with rapid TAT are fully realized and the POCT data is included in the overall data snapshot of the healthcare organization to facilitate analytics-driven business decisions.

Orchard Software's POCT Management & Connectivity Solution—Orchard® Trellis™

At Orchard Software, we believe POCT plays 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 electronically integrated and available in the EHR. To address the connectivity challenge, Orchard offers several deployment options depending on your facility's specific needs. In addition to providing connectivity, Orchard's solutions can track certification management, allow for remote monitoring of QC, and enable rules-based decision support questions at the POC. The flexibility of Orchard's suite of products offers a variety of ways to meet your POCT management and connectivity needs. If you would like to learn more about Orchard's POCT management and connectivity solutions, please call (800) 856-1948, visit www.orchardsoft.com/orchard-trellis/, or contact us at sales@orchardsoft.com.





A "Must Read" for Laboratorians & Healthcare Leaders

If you are interested in learning about the laboratory's role in the changing healthcare environment, download Orchard's informative white papers at www.orchardsoft.com/whitepapers.

- The Value of the Lab in the New Healthcare Model
- The Value of Data in the New Healthcare Model
- Structured Data: Essential in Healthcare Analytics & Interoperability
- Effective Test Utilization: A Laboratory's First Step in Contributing to the New Healthcare Model
- Laboratory Informatics: Supporting the Future Needs of Healthcare
- Laboratory Point-of-Care Testing: A Future Outlook
- Laboratory Data Integration Driving Meaningful Medical Analytics
- Tulare County Public Health Lab's Lean Journey
- Molecular Informatics: Shaping Change in the Lab
- Extending the Laboratory's Reach to Meet Healthcare's New Paradigm

Notes

- 1. Park, K. S., Heo, H., & Choi, Y. K. (2013). Design and realization of integrated management system for data interoperability between point-of-care testing equipment and hospital information system. *Healthcare Informatics Research*, 19(3), 222–228. Retrieved from http://doi.org.proxy.cc.uic.edu/10.4258/hir.2013.19.3.222
- Lewandrowski, K., Gregory, K., & Macmillan, D. (2011). Assuring quality in point-of-care testing: Evolution of technologies, informatics, and program management. Archives of Pathology & Laboratory Medicine, 135(11), 1405-1414. Retrieved from http://dx.doi.org/10.5858/arpa.2011-0157-RA
- 3. Blick, K. E. (2001). The essential role of information management in point-of-care/critical care testing. *Clinica Chimica Acta*, 307(1-2), 159-168. Retrieved from http://dx.doi.org10.1016/S0009-8981(01)00460-0
- 4. Nichols, J. H. (2015). Point-of-care testing: Past experience and future challenges. *Point of Care:*The Journal of Near-Patient Testing & Technology, 14(4), 103-105. Retrieved from http://dx.doi.org10.1097/POC.000000000000000099
- Lee-Lewandrowski, E., Laposata, M., Eschenbach, K., Camooso, C., Nathan, D, M., Godine, J. E., ... Lewandrowski, K. (1994).
 Utilization and cost analysis of bedside capillary glucose testing in a large teaching hospital: Implications for managing point of care testing. *Journal of Medicine*, 97(3), 222 230. Retrieved from http://dx.doi.org/10.1016/0002-9343(94)90004-3

OrchardSoftware



701 Congressional Blvd., Suite 360 Carmel, Indiana 46032

www.orchardsoft.com (800) 856-1948

Write the author at kfutrell@orchardsoft.com

