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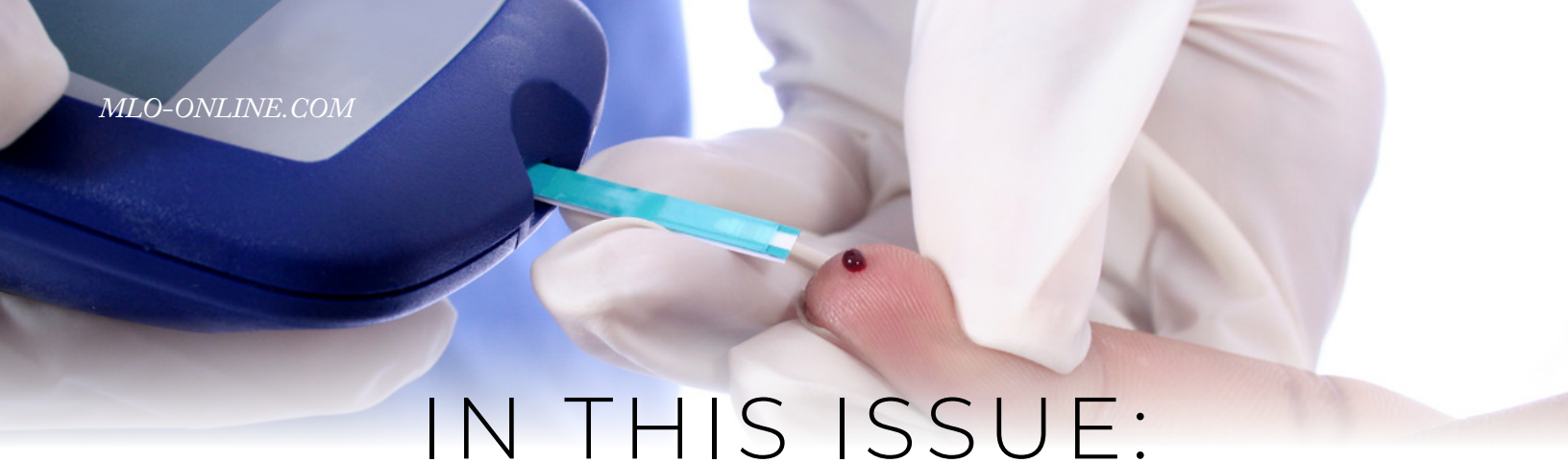

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Point-of-care testing — Managing change when you are not in charge

By Robert F Moran, PhD, FCCM, FIUPAC

LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Describe the organizational use and benefits of POCT testing in healthcare systems.
2. List personnel characteristics that should be employed when positively adapting to change.
3. Discuss tools that can be utilized when assessing the analytical performance of whole blood.
4. Describe the information and symbols that can be included in a lab report to add value and substance to the results.

Managing change is never an easy task — even less so when you are not in charge — which is where most of us find ourselves in point-of-care environments. Point-of-care testing (POCT) defines itself: Clinical laboratory testing conducted close to where patient care is provided. It is focused on real turn-around-time (TAT), from specimen collection, to measurement, and then in the hands of the caregiver. Great for the treating caregiver but it comes at a cost — a technology investment if measurement devices are dedicated to a sufficiently small group of patients and a support infrastructure such as data management systems that must work seamlessly together. Those capital costs and the related system's complexity leads us to a need to understand how it all fits together.

Whatever the regulatory and healthcare environments are, each professional associated with POCT should have a basic understanding of their entire system and their individual responsibilities. Understanding how those responsibilities relate to the 'big picture' will demonstrate how critical everyone's contribution is to overall success. Each caregiver or POCT laboratorian undoubtedly looks at this as appropriate for their own duties, training, and experience. However, the caregiver's or laboratorian's own view should be governed by their organization's circumstances and needs. Key elements of the big picture always depend on combinations of the following:

- **Healthcare environment:**
  - Primary care–standalone (e.g., community urgent care clinics, group practices) or one institutionally linked (e.g., urgent care clinics on or off campus to the sponsoring or proprietary organization)
  - Secondary or tertiary care institutions where the central laboratory (CL) controls the entire POCT operation versus one where a unit/department other than the CL controls all or part of POCT operations.

- **Regulatory environment:**
  - CLIA'88 and state regulations set the standard.
  - Standards and professional organizations Clinical and Laboratory Standards Institute (CLSI)[1] and Association for Diagnostics and Laboratory Medicine (ADLM)[2]
  - Outside the United States, other country or regional authority regulations often incorporate existing standards from standards-setting organizations such as the International Organization for Standardization (ISO).

Each team member's application of their personal knowledge, skills, and attitude is important. Simply being a great laboratorian (or therapist or registered nurse) and applying technical knowledge and skills is not enough. In POCT, laboratorians work alongside direct care givers, sometimes in incredibly stressful and patient–critical circumstances. POCT may well not be the comfort zone.[3] That is why change and its management is crucial. Note that this is not management by the 'suits' but by each active POCT professional. While this continuing education article is directed primarily to clinical laboratory professionals and related staff, many aspects can easily apply to other members of the POCT team.

POCT can bring much more realistic TAT for test results that are directly and immediately applied to patient care. Additionally, POCT can bring clinically better information to the bedside. The improved information may be in 1) the nature of the numeric value itself or 2) the ability to make better-informed clinical decisions because of the timeliness.

The technological advances in measurement and information management have supported many of the changes and have enabled the extension of the laboratory function to locations seen and required for both life-threatening situations or for operational efficiency (e.g., No second visit necessary for diagnosis or treatment). Clearly, this can bring about better immediate care, leading to improved clinical outcomes compared to central laboratory testing (CLT), and at the same time ensure that no patients are 'lost' between visit and testing and follow-up visit.[4]

Rather than focusing on the entire range of technical and managerial issues, this article will focus on three things: 1) Change and leading it when you are not in charge; 2) special quality control/assessment tools for POCT and their significance; and 3) specimen characteristics that affect result meaning, including how they can be readily communicated. Each of these is intertwined with the major aspects of POCT operation and management as defined by the AACC (now ADLM) Academy of Clinical Biochemistry Guideline (Academy Guideline), as well as being embodied in the CLSI Guideline mentioned above, both of which should be readily available to any professional involved in POCT.

PART I: CHANGE MANAGEMENT

Change is constant, or at least constantly occurring. What you thought you knew last week is different today. This requires awareness on the part of each professional in POCT. Not every change requires a new protocol or standard operating procedure (SOP), but it does require knowledge.

The management of POCT (i.e., the big picture) is outlined in the AACC (renamed ADLM) Guideline[2] and encompass all major aspects that can apply in POCT. They are: 1) Interdisciplinary Committee, 2) Education,[5] 3) Staff and staffing, 4) PT/EQA programs, 5) Data management, 6) Selecting POCT, 7) Processes and outcomes.

'The real picture' reflects the AACC Guideline, but it is different. It is what each professional in POCT faces each shift. There are several aspects to one's personal management of change, but we will focus on one and lead into two examples. The most successful change management depends on you and how you interact with other team members.

Where are you in the POCT plan?

The basic expectation for each person comes from the traditional job description. It should go beyond that. An ideal job/position description that I have seen starts with the traditional job description, but adds the following in a clear, simple set of expectations: 1) Core knowledge required, 2) requisite technical skills, 3) attitude (KSA). This last item, attitude, possibly the most important, can encompass many things from internal team interactions to adhering to changing conditions cheerfully. A satisfactory attitude means that one conducts their use of knowledge

and skills efficiently, pleasantly, and in accord with the reasonable expectations of the environment. Understanding these three aspects of you and the position is key to both personal and professional success. Depending on one's own expertise or interest, discerning which of the Academy's areas of focus is personally significant may have an impact on how you assess your own areas of activity outside the basic functions of the position.

Engage with others within the POCT Team and consider the make-up of your institution's POCT interdisciplinary group. Considering what communities each represents may serve you well in understanding and conducting your role of managing when you are not in charge. Also see what informal systems exist to make things operate. When seeing something different than you expect, best to say, "Hey that's a bit (or a lot) different than at my last place. Can you explain it, so I understand it better," rather than, "I was taught" or "We did it this way at XX." Recheck the SOP, then bring it up during coffee break.

Engage with others outside the POCT Team, especially those who POCT interacts with. Engaging with others may be a challenge for some laboratorians. This is where the Attitude from KSA comes into play. To be most effective, it is important to know something of the demands placed on each area with whom one interacts. Those accustomed to direct patient care may have different sorts of demands and perspectives. They may not, for example, understand that not all heparin is ok for use in blood collection — you are just being fussy. When you see what a registered nurse or pulmonary function technician must do, you will be much better able to understand how their 'attitude' affects their perspective of the 'Lab Tech.' Engaging with 'others' is likely to make you realize they are not much different than the folks in the lab — your common point is resolving issues to improve the care of the patient. And that is the key to managing change when you are not in charge.

Recent experiences with SARS-CoV-2 should be a reminder that while some change is always happening, occasionally the change is so abrupt and significant that it affects not just us but most of humanity. Being prepared suggests that having the basic technical knowledge and skills for the job isn't enough.[5] Looking outside the box and anticipating inevitable change is a requirement for survival not just success! Using the concepts described above may well be applicable to each of the topics that follow.

PART II: ASSESSING REAL SYSTEM ANALYTICAL PERFORMANCE – WHOLE BLOOD

The actual specimen type measured by many POCT systems is whole blood. Why then, are QC/EQA/PT materials used for validating performance made from other materials? Shouldn't we know how well the system works on blood? An obvious example where a difference is for oxygen partial pressure (pO_2). Most, if not all artificial control media cannot completely mimic whole blood for the measurement of pO_2. Less obvious are the electrolytes of whole blood, especially sodium and to a lesser extent chloride.[6-9]

Of course, the sellers of QC materials will all say that their materials work 'like' blood, and they are not misleading you — all are capable of validating calibration and basic functionality. The fact is that we are accustomed to QC/EQA materials used by the central lab that are just like the actual test specimen (i.e., serum or plasma). But even whole blood–based QC materials are different than our patient test specimen. After all, they need to be stabilized to make them last for several weeks, among other modifications. One solution to this technical dilemma is duplicate analysis of the same specimen. 'Duplicates' were really the method of choice before the onset of commercially available materials — and it is common to use it informally.

A laboratory may choose to assess quality control by using one instrument or even two or more instruments for near-simultaneous analysis of a specimen. The utility of this approach has been thoroughly studied.[10-13] An excellent guide and reference for statistical methods is published by the National Institute for Standards and Technology.[14]

One should expect the same measuring system to be able to repeat its performance on the same specimen. The question is how closely?

Duplicate measurement of multiple specimens will give a good estimate of how closely the system routinely performs. The average difference can be calculated, as well as the random variation of the average. Once this guidance set of statistics (average of duplicates and standard deviation [SD] of duplicates) for each instrument and measurand is set, a simple monitoring plan can be established.

Similarly, two or more instruments (within or between department POCT) are assumed unlikely to have the same measurement error at the same time. Within-instrument comparison using whole blood specimen duplicates is a key to understanding system performance and evaluating complaints of performance. Both inter-instrument bias (average difference) and variance/SD can be assessed and used as an operating guideline. The duplicate measurement approach should not be used as the only method of QC. However, when used as a supplement to and in conjunction with commercial controls, it is a very useful technique for detecting errors on a particular sample (e.g., an air bubble) and for troubleshooting.

Duplicate measurements of whole blood specimens at various times during an interval of known conditions and sample stability can be used as secondary controls for detecting analyzer changes. This can reduce the need for expensive/complicated assessments using a full range of commercial controls. For duplicate values on any whole blood system:

- Check legal/institutional policy regarding use of patient blood. (If there are legal or other concerns for the use of patient blood, consider staff volunteers.)
- Set up (with statistician assistance) a protocol for duplicate testing.
- Include each measurand/analyte
- Include within and between instruments/POCT site as appropriate
- Establish performance then write a policy/practice for routine use.

The duplicate analysis of whole blood on POCT systems that measure whole blood patient specimens is essential practice and helps meet quality management guidelines, especially where it goes beyond the basic QC materials used. It can aid both within and between system assessment of performance, the latter being more significant with the common existence of multi-site measurement in the same healthcare system and the linkage of specimen reports and displays within that system.

This could be an opportunity to apply your KSA to make it happen.

PART III: SIMPLE SPECIMEN SYMBOLS

Most laboratory information is consolidated in a laboratory information system (LIS) that links all systems and data together. However, are 'all systems' designed to link patient registration, wristband-scanner, the collection device itself, and the analyzers on which measurement occurs? The answers vary depending on your institution. Planning for these linkages requires awareness in the initial stages of system development, in which case the issues are relatively simple. Upfront awareness is crucial for long-term planning.

A recently proposed plan for identifying fundamental specimen characteristics can facilitate result interpretation to improve both clinical and quality management. This plan is a simple extension of a recommendation by the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC). IFCC recommendations place specimen information in parenthesis following the measurand (analyte) name and identifies the anatomic source and type of specimen. The proposal simply adds symbols for unique measurement conditions that are available using modern technology (e.g., measuring sodium in the plasma of whole blood).[15,16]

The current system uses, for example, (aB) for arterial blood so the report would have pCO_2(aB). A few additional symbols aids information system specialists since symbol sequence and position is systematic. The additional information makes it obvious if the specimen result is from a venous blood specimen pCO_2(vB). If the specimen is from an arterialized capillary bed, a collection technique subject to certain unique errors, the symbol set would be for oxygen $pO_2(c_aB)$.

Each is linked to the specific specimen and patient, and there is no question regarding the source and its meaning for the laboratorian, caregiver, or information technology (IT) programmers who can link all

from patient to collection device to the final report. An extension of this is what the sensors of the analytical systems do. Both bicarbonate and sodium are measured in a whole blood specimen but measured in the plasma. Bicarbonate could be displayed as HCO_3(aBp). A similar pattern (primary anatomic source then a qualifying subscript followed by specimen type) can be used for other anatomic sources as shown in **Table 1**.

Measurement conditions, such as measurement in plasma (p) or plasma-water (p_w) would follow the type (of specimen) symbol. Example of these currently would be blood gas systems reporting sodium, which uses ion selective electrode (ISE) technology, harmonized to agree with central laboratory systems if plasma protein/lipids levels are normal.[7] Harmonized blood gas systems would/should display Sodium or Na(aBp_h). Most sodium values from the analyzers will agree with the central lab results. But if significantly different (remember those duplicate statistics), there may be a physiological/clinical condition, not an analytical error.

An example of the pattern/sequence for (s_qTYc_q) is as follows:

1) anatomic source followed by the 2) specific qualifier, (subscripted), and the 3) type of specimen then the 4) measurement condition, and its 5) qualifier (subscripted).

pO_2(aB)	The partial pressure of O_2 in arterial blood plasma in equilibrium with whole blood .
pO_2(c_aB)	The pO_2 of arterialized capillary blood. The process of collection requires a specific symbol.
pO_2(a_uB)	The pO_2 of umbilical artery blood. (If artery or vein is not specified, insert the lower case 'u' unsubscripted, as the source.)
cNa(aBp_h)	Concentration of sodium in arterial blood plasma, measured directly (without dilution) with calibration/measurement harmonized with the NIST SRM956.
cO_2(v_{pa}Bt), cO_2(v_mBt)	Concentration of oxygen in mixed venous blood, total of all forms of O_2, (Hemoglobin bound + dissolved), collected from a pulmonary artery.

Table 1. Example charted/displayed symbols and their description.

Note: Measurand names/symbols shown are examples. Local custom is acceptable or even preferable. Our focus is on the specimen characteristics only.

If you see the advantages of this approach, (i.e. Analyte Name (s_qTYc_q)), it is certainly something that will need some discussion, persuasion, and change management to make it work in your institution. But, given the current state of linkages between LIS/HIS and "all-in-one" data management systems, now is an optimal time.

CONCLUSION

Professional laboratory work in a point-of-care environment is significantly different than typical laboratory operations. By working in POCT areas, the laboratorian not only uses the technical knowledge and skills developed by education, training, and experience, but interacts with professionals who have diverse types of views of both laboratory results and of laboratorians. Coupling that with the critical care environment, which may have extremely intense and personal involvement of caregiver and patient at unpredictable times, even an experienced laboratory professional can be challenged.

When given or choosing a POCT assignment, a laboratorian should not think of it as a simple schedule or location change. It can and likely will be far more than that.

- First, you are likely to be interacting directly with the patient. Certainly, in the collection of a specimen but more than that — under acute

conditions found in the emergency department/trauma, critical care units, or the operating theater.

- Second, in addition to those aspects of direct care, reflect on and prepare yourself by considering the points of part one (managing change).
- Last, if you see either or both aspects as challenges you really want, jump into it with both feet. You will not be disappointed. It will be a genuinely exciting place — a place where one can see the application of all your laboratory education, training, and experience put into effect in situations where you see what is happening to real patients, and with care given by or to people you know.

It will never be a routine day again! (Contact the author for some war stories!!)

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Molecular point-of-care testing offers hope to quell the STI epidemic

By Allison McMullen, PhD D (ABMM)

When expressing the breadth of the risk of sexually transmitted infections (STIs), a colleague of mine often shares the stark perspective, "If you're having sex, you're at risk." And she's right. While sex is rarely discussed in an open and candid fashion, it is important to remember that sexual health is *health*, and encompasses all aspects of human sexuality. Sexual health and satisfaction are key components of health and well-being.[1]

We are accustomed to thinking about sexual health as the presence or absence of disease — namely sexually transmitted infections. But the WHO defines sexual health as "a state of physical, emotional, mental, and social well-being," which includes aspects such as reproductive health, access to education and care, and sexual experience free of coercion, discrimination, and violence, among others.[2] This emerging, broader conversation around sexual health is rooted in changes in communication — the more we talk about it, the more informed we are. The more informed we are, the more we can reduce the stigma associated with sexually transmitted infections and improve the uptake of testing.

A SILENT EPIDEMIC, BUT THE CALLS FOR HELP GROW LOUDER

Sexually transmitted infections are inclusive of viruses, bacteria, protozoa, and parasites people can contract through sexual contact. And many STIs have no symptoms, resulting in asymptomatic infections.[3] The burden of STIs in the United States is astounding. One in five people in the U.S. have an STI, equating to 68 million infections[4] and $16 billion in direct medical costs per year.[5] While it's true if you are having sex you are at risk, some populations are disproportionately affected by STIs, including young people aged 15–24, gay and bisexual men, pregnant people, and racial and ethnic minority groups.[6]

The CDC has recommended that STIs be a top public health priority as rates of many STIs continue to increase[7] despite available treatment options. Left undiagnosed or untreated, STIs can lead to harmful and lasting consequences, such as infertility, ectopic or adverse pregnancy outcomes, congenital infection, chronic pelvic pain, increased risk of HIV infection, and psychological harm through stigmatization.[5] These consequences are unacceptable in a world where many STIs are treatable.

In 2021, the U.S. Department of Health and Human Services (HHS) launched a first-of-its-kind national strategic plan aimed at reversing "the recent dramatic rise of STIs in the United States."[8] Focused on chlamydia, gonorrhea, syphilis, and human

papillomavirus (HPV), the plan serves as a roadmap to help federal and non-federal stakeholders at all levels and in all sectors achieve the vision of making the United States "a place where sexually transmitted infections are prevented and where every person has high-quality STI prevention, care and treatment while living free from discrimination."

This plan's vision and goals cannot be achieved without the important role of the diagnostics industry — supporting increased screening volumes, developing medically relevant assays and claim extensions, and advancing new technologies to support point-of-care testing, self-collection, and rapid antibiotic susceptibility testing.

STI DIAGNOSTICS FACE CHALLENGES

Diagnosing STIs is important — because if we test, we can cure or treat, therefore reducing transmission. But challenges remain. Testing underutilization can lead to overtreatment or undertreatment of the infection, and this is if patients even have access to fast and accurate diagnostic solutions. Additionally, similar to respiratory infections, overlapping symptoms among STIs make empirical diagnosis challenging, therefore requiring appropriate diagnostic testing performed in clinical settings.

In a real-world study analyzing more than 23 million instances of patients presenting with symptoms of a urogenital condition, 89% of patients who received antibiotics received their treatment within the first three days of their initial appointment, likely before results from CT (*Chlamydia trachomatis*)/NG (*Neisseria gonorrhea*) testing would be available. This data points to presumptive therapies for diseases that should be tested for and treated accordingly, contributing to suboptimal antimicrobial and diagnostic stewardship. Due to the overlapping symptoms and varying treatment pathways across common STIs including CT, NG, MG (*Mycoplasma genitalium*), and TV (*Trichomonas vaginalis*), definitive diagnosis is critical to making treatment decisions.[9] The study, which analyzed STI testing and treatment patterns in the United States, also showed that fewer than 2 in 10 individuals received CT/NG testing, despite showing symptoms,[9] further demonstrating the underutilization of STI testing.

Rapid and accurate STI testing is needed to inform appropriate treatment recommendations and prevent further transmission. And this is where point-of-care testing can emerge to fight this epidemic, providing broader access, faster testing, and a definitive diagnosis in less than 30 minutes.[10]

HOW PATIENTS CAN BENEFIT FROM STI TESTING AT THE POINT OF CARE

The COVID-19 pandemic accelerated the use of molecular diagnostics at the point of care, allowing the technology to meet evolving customer needs for quick and accurate results, improve the patient diagnostic experience, and increase operational efficiency for providers.

Currently, a majority of STI testing is done in a central lab, with CDC guidelines recommending screening for asymptomatic individuals based on a variety of different risk factors. Given these tests are standard and routine, high-throughput testing is more economical, with up to 96 samples tested at once instead of one every half hour. However, for symptomatic patients in certain settings, STI testing at the point of care allows for a seamless connection of gold-standard molecular diagnostics and treatment. In less than 30 minutes,[10] a patient can learn what they may have contracted and how to treat it.

With the closure of STI clinics,[11] in addition to changes in how people access healthcare, more patients are using point-of-care settings, such as urgent care, emergency departments, women's health clinics, primary care physician offices, and public or student health clinics for diagnosis and treatment. In addition to its high specificity and sensitivity across a variety of diseases, molecular point-of-care testing is evolving to meet customer needs, providing rapid results directly at the site of care, and oftentimes, for multiple disease targets in one assay.

Patients can also benefit from the opportunity to receive treatment during the same visit. Using PCR (polymerase chain reaction) technology, previously only used in the lab, molecular point-of-care testing provides the same high level of accuracy as the lab in a CLIA-waived setting,[12] offering clinicians a high degree of confidence in

diagnosis. This test-to-treat approach can help combat potentially high loss to follow-up rates making treatment more likely and contribute to thoughtful antibiotic and diagnostic stewardship efforts.

Additionally, point-of-care testing has the potential to address barriers in access to care and treatment. By meeting patients where they are, through easily accessed sites of care or organized community outreach, providers have the potential to reach a variety of populations at-risk for STIs, including underserved populations who may have difficulty accessing care or those who face a variety of stigmas and discrimination.

WHAT THE FUTURE OF MOLECULAR POINT-OF-CARE TESTING MEANS FOR SEXUAL HEALTH

Laboratorians, clinicians and leaders in healthcare settings can also find value in molecular point-of-care testing beyond STI diagnosis. With already FDA-approved, CLIA-waived assays for a range of respiratory infections, an investment in decentralized, molecular point-of-care testing has the potential to meet the same-visit diagnosis demand from patients and alleviate staffing strains due to the simplicity of the tests, freeing up laboratorians to address more complex tasks requiring highly-trained professionals.

To date, there are only two FDA-approved tests to diagnose STIs at the point-of-care, including a CT/NG/TV assay and a CT/NG assay – both of which have limited indications compared to the epidemic the U.S., and the world, are facing. However, innovation in this space is well underway, and I expect one day there is the potential for molecular point-of-care testing to cover the whole spectrum of STIs, including expansion to genital lesions, mpox, causes of vaginosis or even HIV.

By making STI testing more accessible, and therefore immediately treatable, there is an opportunity to stop this epidemic in its tracks. And no matter our role in implementing molecular STI testing at the point of care, let's continue to speak up and advocate for sexual health for all.

For more information on Roche's commitment to sexual health, visit https://diagnostics.roche.com/us/en/products/product-category/sexual-health.html.

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Point-of-care testing is the next step for respiratory infections

By Dhaval Waghela

After years of centralization in the clinical testing realm, the field is in the midst of a shift toward decentralization. This trend supports the goals of diagnostic stewardship and getting the right test to the right patient at the right time.

While point-of-care testing has been an option for some clinical situations for many years—rapid flu or rapid strep tests performed at primary care offices are good examples—the need for the full spectrum of testing options was starkly revealed during the COVID-19 pandemic. There was an obvious need for high-quality molecular tests that could be run in hospital laboratories and in reference laboratories. But with all of these clinical laboratories overwhelmed with testing demand, there was an equally clear need for point-of-care options, particularly at-home testing that made it possible for people to get a fairly accurate reading of whether they were contagious so they could take appropriate isolation measures to keep others safe.

For some healthcare situations, this is the model that will serve the entire clinical laboratory community best going forward: a hub-and-spoke approach that allows for all the benefits of centralized testing as well as the advantages made possible through decentralized testing.

While clinical lab testing is well established, it's in point-of-care testing where innovation is needed most. Decentralized testing options must have accuracy approaching that of standard clinical lab tests, but they will also require the speed and ease of use that patients and healthcare professionals have come to expect from the era of rapid antigen tests.

POINT-OF-CARE TESTING IN THE PAST

To understand where point-of-care testing needs to evolve, it is worth looking at how it has been implemented in the past. Based on prior examples, it is understandable that many members of the clinical laboratory community may be skeptical that decentralized testing could ever produce truly reliable and useful results.

Perhaps the best-known examples of point-of-care testing involve the rapid antigen tests that have been used for influenza and group A streptococci. These lateral flow tests became popular among primary care physicians and urgent care clinics for their speed, often delivering results in 10 to 15 minutes. But within the clinical lab community, these tests became known for their lack of sensitivity, with a high rate of false negatives that sent many contagious patients home believing they didn't need to worry about spreading infection. In several meta-analyses of these tests, sensitivity for rapid influenza A and B testing was 67.5% at best and 51% at worst.[1] Sensitivity was lower for influenza B than influenza A, and lower for adults than children.

Due to sensitivity issues, many physicians regularly sent negative test samples to clinical laboratories for confirmatory molecular testing, as recommended by the U.S. Centers for Disease Control and Prevention.[1] But even that was deemed inadvisable by the Infectious Diseases Society of America (IDSA), which in 2019 published new guidelines for flu testing in which they recommended against the use of rapid antigen tests.[2] Instead, the IDSA now recommends the use of rapid molecular tests, which can generate results in an hour or less—still providing same-day answers for patients and physicians but with extremely high accuracy.

RESPIRATORY TESTING SHOULD BE FIRST

While decentralized testing will be useful for a broad range of healthcare needs, it is likely that the first area where it will make a major impact is in respiratory infections. For a number of reasons, this will be the perfect test case to evaluate the utility of this model.

Respiratory testing capacity has always been unpredictable due to its seasonal nature. In summertime, testing ebbs for flu and respiratory syncytial virus (RSV). But in the winter, hospital labs can be overwhelmed by demand for these tests, leaving little bandwidth to manage all of the other clinical tests that have to be run. A reliable point-of-care test for the most common causes of respiratory infections would make it possible to offload much of the peak respiratory testing demand to pharmacies or urgent care clinics, freeing up the hospital laboratory staff to focus on testing for seriously ill patients. When flu, COVID-19, or RSV are at unusually high levels, hospitals might even set up tents or screening stations outside where patients could be given a point-of-care test, allowing those who are not sick enough to be admitted to get the answers they need while avoiding a testing burden on the central lab.

A decentralized model would also help in this space because respiratory infections are highly transmissible. If patients could get accurate results at home, at an urgent care facility, at a primary care office, or at a pharmacy, they could take appropriate measures to avoid infecting others. Each patient who stays safely at home could represent the end of a transmission chain, rather than the continuation of it. Point-of-care testing could reduce community spread and keep more people healthier.

Finally, respiratory testing has been primed for a decentralized approach thanks to advances from the COVID-19 pandemic. Substantial technology development for rapid molecular platforms—including molecular tests that could be performed by patients in their own homes—has paved the way for increased familiarity with point-of-care tests.

HOW DECENTRALIZED TESTING FITS

For optimal results, point-of-care platforms should be integrated into the testing strategy established by a clinical laboratory. Clinical lab teams know best where and how decentralized modes of testing could complement hospital and reference lab testing in their communities, with specific attention paid to the needs of their patient population. For labs serving a large elderly population, for example, perhaps setting up a point-of-care test platform in the local senior center or pharmacy would be most convenient and effective. Clinical labs have tracking data on which customers are submitting requests for testing, and this knowledge will be essential for ensuring that point-of-care testing is rolled out in the best way for the population they serve.

A combination approach could work for healthcare systems such as integrated delivery networks. Hospital labs would continue to run respiratory tests for admitted patients, while point-of-care tests could be used in urgent care and outpatient facilities to expand testing venues

without increasing capacity in existing labs. In this case, using the same point-of-care platform in all of these sites would ensure consistency of results no matter where testing is performed.

In addition, point-of-care testing could be deployed for rural communities and remote facilities associated with integrated delivery networks to provide a better standard of care.

WHAT'S NEXT

It is clear that the testing market is shifting, and that decentralized testing options will be important for managing patient health going forward. With that said, though, point-of-care tests have much to accomplish before they can be broadly adopted. Technology development will be important to ensure accuracy on par with traditional molecular assays, ease of use so even lay people can operate the tests, minimal hands-on time to avoid creating a new testing burden outside the lab, and rapid results for optimal utility. Just as importantly, these developers will also have to collect data about how these platforms are used and what errors might arise to continually hone these new tests for mainstream use.

While that innovation happens—and it is happening, driven in large part by what the laboratory community learned from the COVID-19 pandemic—it will be important for clinical laboratories to begin thinking about how they could implement the best point-of-care options for respiratory testing in their own healthcare facilities. Any concerns about reducing revenues within the clinical lab can start to be addressed in the planning phase as leaders find ways to attribute point-of-care testing revenues to the clinical lab overseeing these platforms. Early adopters who figure out the best way to combine centralized and decentralized testing options for their patient populations will help establish efficient and effective models that can eventually be implemented in healthcare systems around the world.

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Applying laboratory quality principles to real world point-of-care testing systems

By Kathleen David, MT (ASCP) & Jeanne Mumford, MLS (ASCP)

LEARNING OBJECTIVES

Upon completion of this article, the reader will be able to:

1. Discuss the need for a quality management system (QMS) in point-of-care testing (POCT).
2. List the quality system essentials that are recommended for a laboratory QMS.
3. Describe how each quality system essential can be applied to a POCT program.
4. Differentiate between quality assurance (QA) and quality control (QC).

In the Continuing Education article in the April 2023 issue of MLO, laboratory quality management systems were discussed and details provided on each component.[1] When it comes to maintaining quality in point-of-care testing (POCT), we are often presented with very different sets of challenges than our laboratory counterparts. While POCT is subject to the same CLIA regulations, minimal guidance is offered on how to meet those needs in POCT systems. One challenge is that testing personnel who perform POCT are non-laboratorians, meaning that some of the guidance available may not be written in language that non-laboratorian staff can easily understand. Another is that POCT is performed in a variety of settings that can include hospital units, ambulatory sites such as doctors' offices, and a variety of other settings. A final challenge is understanding local, state, and/or federal laboratory regulations. Laboratory staff will have a basic understanding of regulations through schooling and on-the-job training, however, clinical staff whose background and training is strictly focused on patient care, may not have the same knowledge of these requirements.

When setting quality standards in POCT, no national standards exist for quality improvement management. The most common metrics measured for improvement across POCT systems include patient identification (ID) errors, ID limit errors, specimen collection errors, and manual test result entry errors. As stated in the July 2020 "AACC Guidance Document on Management of Point-of-Care Testing" published in JALM, "A quality assurance program is vital to managing errors and the reliability of POCT results."[2] The purpose of this article is to directly compare the contents of

the April 2023 MLO article on laboratory QMS in order to help the reader relate the Quality System Essentials that can be utilized in a POCT system. We will specifically discuss how the key components of a laboratory QMS can be developed to addresses the many challenges in POCT.[3]

QUALITY SYSTEM ESSENTIALS

In the following paragraphs, we will breakdown the components, or essentials, of a laboratory QMS. Then, we'll add practical examples of how these can be applied to support and improve a POCT program. These essentials may be applied to any size POCT program to include a large health system or a small doctor's office practice.

ORGANIZATION AND SUPERVISION

Because POCT is usually performed by staff who do not report to the laboratory, it is essential that lines of communication are clear and defined. The person designated to manage and oversee the point-of-care program should have the necessary credentials, and the CLIA medical director responsible for POCT has clear authority over all testing under the laboratory's CLIA license. Medical laboratory scientists with more than three years of laboratory experience are ideal staff to oversee point-of-care testing. We refer to this person as a point-of-care coordinator, POCC for short. This person is best served with experience in laboratory quality assurance projects.4 In addition to the CLIA laboratory medical director, the point-of-care coordinator, and representation from other disciplines within your health care system should be invited to form a committee to oversee the quality of your POCT program.[2,5]

PERSONNEL

In most cases, testing is performed by non-laboratorians, who are not under the laboratory's supervision. They are nurses, nurse techs, perfusionists, medical aids (MA), certified nursing assistants (CNA), emergency medical technicians (EMT), and other hospital staff. They do not have a background in laboratory medicine yet must understand basic laboratory principles to be successful in testing patients. They need adequate training not only for the testing they perform, but also for laboratory practices like quality control performance. Competency assessment as required by regulations is important to ensure that testing is performed correctly, and results are accurate.

Evidence-based medicine shows that an effective POCT program begins and ends with robust training and competency assessment of operators and testing personnel.[5] Taking the time to invest in training of your POCT operators can be optimized by focusing on unit trainers or superusers. Trainers or superusers are a core group of testing personnel who obtain and utilize additional skills and knowledge of the POCT systems and who will train new personnel and troubleshoot as needed.

EQUIPMENT

Unlike equipment purchased in the laboratory, most point-of-care devices are purchased by the units and clinics that use them. The devices must still be validated for use, especially nonwaived devices. Regulatory requirements state what must be validated/verified before patient testing can begin for both waived and nonwaived devices. Laboratory staff overseeing point-of-care testing must ensure that device maintenance is performed and documented. Laboratory staff should understand how to troubleshoot issues with the devices and kits and know when to contact the point-of-care staff.

PURCHASING AND INVENTORY

Point-of-care devices and supplies are not usually ordered and managed by the laboratory. However, depending on the organization, supplies may be held in the laboratory. If supplies are kept outside of the laboratory, then the point-of-care coordinator must ensure that they are being kept at the appropriate temperature and humidity.

DOCUMENTS AND RECORDS

Procedures covering testing that is performed outside of the laboratory must be available to those performing the testing. If the laboratory document control system only allows access to laboratory personnel, there must be a process to make the documents available for testing personnel. Logs must be developed and managed for quality control and temperature/humidity monitoring and be made available to operators.

PROCESS CONTROL

To monitor quality in the analytical phase of testing, quality control (QC) is essential. This involves materials that have known concentrations of the analyte in question, which must be performed at intervals specified by regulations. This is true in POCT as well. POCT is performed by personnel who have not had laboratory training, and who

therefore do not have a good understanding of what quality control is, and how important it is to accurate results. There is a feeling that any result obtained is acceptable. Many nonwaived POCT devices have internal controls and are eligible for Individual Quality Control Plans (IQCP). Studies are done to determine if QC can be done less often than the CLIA-required two levels of QC per day. A risk assessment is performed, and non-laboratory personnel must be part of the risk assessment. Using an IQCP saves money and time from doing daily QC, while ensuring that the accuracy of results is maintained.[4]

While quality control materials are used to initially verify the lab values obtained on the POCT are accurate and that the tests are performing according to the manufacturer's specifications, quality assessment is a process that should be consistent and utilized to monitor the QC performed on your tests.[4] Quality assessments should be written in a policy and reviewed annually by the CLIA laboratory medical director.

INFORMATION MANAGEMENT

For any laboratory, managing information is essential. This includes both incoming information such as patient demographics, test requests, and specimen type; and outgoing information such as results, units of measure, test comments, and performing laboratory. Many POCT programs utilize a middleware product that serves as device manager as well as a mechanism to get results from the POCT devices to the laboratory information system and then to the hospital information system. The current middleware products on the market can enhance the useability of instruments and allow for QA measures such as operator management, QC lockout, and QC review. These products also allow for the ability to pull data on patient results that can help with improving or eliminating challenges with patient identification errors.

OCCURRENCE MANAGEMENT

Because testing is performed by non-laboratorians, it can be more difficult to manage occurrences. Occurrences are defined as variants to the testing procedure. Two of the strategies developed to mitigate this are operator lockout and QC lockout. The first ensures that only those trained and checked off to use a device have access to use it for patient testing. The second ensures that patient testing is not performed until after QC has been performed as scheduled and is acceptable. Some devices designed for point of care use have both features and some can be managed through the middleware products available. However, there are still point-of-care tests that are either manual or performed on legacy devices that don't have the ability to do lockouts. These tests may require ingenuity to monitor for occurrences.

ASSESSMENT

Point-of-care testing is, by definition, performed outside of the laboratory. Most programs are spread over an entire hospital, and possibly other sites such as clinics, urgent care, and physician offices. This means that assessments will need to be done at all of the relevant sites. Most POCT programs perform routine audits of the testing sites by assessing quality control performance, reagent labeling, temperature/humidity monitoring, maintenance records for devices, and test performance by on-site operators. Having devices interfaced and using middleware to monitor processes are extremely helpful. The POCT team can monitor operator competency compliance and QC performance. In addition, many programs perform internal quality assessments, having the organization's quality team perform audits.

External assessment objectively assesses the performance of testing. Proficiency testing involves unknown specimens sent from an external agency and will assess several aspects of test performance: proper testing protocol, specimen identification, documentation, environmental issues, etc. Investigating proficiency testing failures can bring to light issues that should be addressed in training for operators. If the POCT program is under the same regulatory agency, then non-waived tests must be compared to the laboratory instruments doing the same tests, which is another method for ensuring the quality of POCT results. In addition, POCT programs are subject to inspection by regulatory and accreditation agencies, which will identify any issues with test performance and quality processes.

CUSTOMER SERVICE

Customers for POCT are generally considered to be clinicians who order/use the tests and nursing personnel who perform the testing. A test request process should be in place to assess the requests. Many POCT programs have a committee comprised of POCT personnel, POCT laboratory medical directors, unit managers/directors, educators, hospital administration, and other departments

such as purchasing, quality, infection control and others that have a stake in implementing testing. Standardizing the devices and kits used for POCT is advised. Point-of-care tests are often seen as less accurate than lab tests, and disseminating information on the comparison testing between lab and point-of-care devices can help clinicians feel confidence in POCT results.

PROCESS IMPROVEMENT

Quality indicators, including assessing manual testing quality control errors, compliance with cleaning devices used at the patient bedside, and proficiency testing performance, can be used to improve processes. Internal audits of processes can bring to light issues that must be addressed and resolved to improve the program. In addition, customer service surveys can be done for testing personnel, as well as unit managers/directors and educators, to ensure that the training and competency programs are meeting the needs of quality patient testing.

FACILITIES AND SAFETY

By definition, point-of-care testing is performed outside of the laboratory, and some requirements will be different. Noncompliance with laboratory safety requirements must be explained to the POCT users, as they will not all be familiar with these. It is essential to work with hospital safety, infection prevention, and facilities to ensure that issues relevant to performing laboratory testing are followed. For instance, performing molecular infection disease testing might require a safety shield and testing for contamination. Temperature and humidity monitoring could also be required and needs to be reviewed by POCT staff.

CULTURE OF QUALITY

It is important that point-of-care testing be conducted in the same way and with the same care as testing performed in a laboratory. Test results used for treatment, monitoring, or diagnosis of patients must be consistent no matter where it is performed.[6,7] Quality management of a POCT program needs to be as rigorous and comprehensive as that of a laboratory program. There are differences between the two modalities, but in the final analysis, the patient deserves results that are accurate no matter where they are performed. A POCT quality management program will assure that the test results are high quality and accurate for those clinicians and nursing personnel that rely on them for patient care.

Quality assurance is a key component to a successful POCT program and should be considered in all stages of testing. Quality improvement by way of monitoring data to improve patient safety is also key to ensuring success in POCT.

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Preparing point-of-care testing for the long journey

By Harvey W. Kaufman, MD

Driving a motor vehicle involves real-time inputs of road conditions and hazards. The same is true in healthcare: medical professionals need real-time inputs to guide decisions affecting patient outcomes. Point-of-care tests (POCT) are an option when providing this real-time insight, helping the clinician navigate the care pathway. Like driving, POCT requires skill and attention to avoid both "potholes and accidents" and losing time on the journey.

WHAT IS POINT-OF-CARE TESTING (POCT)?

POCT refers to testing technologies and methods that provide test results at the place, or point, where care is delivered to the patient, versus in a separate laboratory. POCT is typically valued for providing timely test results for conditions requiring rapid treatment. As an example, in surgical pathology, frozen tissue sections are analyzed while patients are being operated on, to provide surgeons with crucial information about the type and extent of disease and to identify if surgical margins are free of disease. Other examples include arterial blood gases in the intensive care unit, providing near real-time critical information about respiratory and metabolic disorders and determining adequate hemoglobin levels in blood donors just prior to their donation. Many are familiar with home POCT applications, including urinary human chorionic gonadotropin (hCG) as the first laboratory confirmation of pregnancy, glucose testing for people with diabetes, and rapid antigen testing for SARS-CoV-2 to diagnose COVID-19.

POCT CAN ADD VALUE WHEN UTILIZED PROPERLY

A recent situation highlights the value of POCT. In response to the outbreak of Ebola virus disease in Uganda, some hospitals in the United States prepared

intensive unit beds to accept incoming high-risk patients, especially those arriving at airports from international cities. This involved creating an extensive test menu using POCT that could be performed by either laboratory or intensive unit personnel in an area adjacent to the patient's hospital room. This approach sought to limit the transfer of potentially infectious specimens to others on the healthcare team.

POCT options continue to expand, driven largely by the value of quick results allowing for timely medical decision making. POCT can also eliminate specimen transportation and storage issues, although confirmatory testing (of the same specimen) may often be warranted. Having near real-time POCT results allow the clinician and patient to discuss diagnoses or next steps in the moment. This capability can be critical in ensuring patients receive results and are adequately directed into care.

For instance, in the case of HIV testing, some patients offered anonymous testing never retrieved test results when testing was sent to a core or reference laboratory, including patients who had positive test results. This suggests that POCT would have provided immediately actionable results. Likewise, testing for sexually transmitted infections (e.g., chlamydia and gonorrhea) following treatment offerings may be more effective when results are nearly immediately available. Thus, POCT can provide timely test results while patients are engaged in their own health.

POCT – SCREENING VERSUS CONFIRMATION

Most POCT tests are designed to screen for potential health risks. Sophisticated laboratory methods may follow to confirm a result. For instance, POCT urine tests may help screen for the presence of controlled drugs as part of a clinical drug monitoring program. But unlike confirmatory lab methods, these POCT devices have certain limitations that can affect clinical decision making. For instance, POCT devices may be unable to differentiate a prescribed opioid from non-prescribed fentanyl. COVID-19 is also a case in point. While rapid POCT antigen tests should be taken serially to confirm a result; molecular laboratory techniques are preferred to confirm a specimen as positive for SARS-COV-2. Laboratory professionals should understand the strengths and limitations of POCT and more sophisticated laboratory methods to ensure they complement, rather than duplicate, each other.

Qualifications:	
1.	Meets the minimum qualifications of testing personnel in a highly complex laboratory, as defined in 493.1489 of CLIA '88.
2.	Understands applicable Clinical Laboratory Standards Institute (CLSI) documents pertaining to POCT.
3.	Ability to communicate effectively and diplomatically within a multi-functional team.
4.	Strong organizational skills.
Functions:	
1.Personnel	
a) Follow the testing personnel responsibility standard as defined in 493.1495 of CLIA '88.	
2.Training and Performance:	
a) Ensure that all hospital staff using POCT devices are adequately trained and competent for test performance, troubleshooting, maintenance, and documentation.	
b) Review policies and procedures and adherence at least once annually.	
c) Perform and record all required instrument maintenance and calibration activities.	
d) Follow the established POCT procedures whenever test systems are not within the POCT established acceptable levels of performance.	
3. Quality:	
a) Collaborates with other departments to develop methods and/or systems for improving quality and controlling costs associated with POCT.	
b) Collects and evaluates quality assurance and quality control data from POCT sites and reports data collected to clinical service and laboratory directors.	
c) Resolves technical problems and ensures that remedial actions are taken whenever test systems deviate from established performance specifications.	
d) Be capable of identifying problems that may adversely affect test performance or reporting of test results.	
e) Documents all actions taken to correct problem(s).	
f) Enrolls in proficiency testing program for all required POCT systems. Maintains records that demonstrate that proficiency testing specimens are tested in the same manner as patient specimens. Follow-up to identify root causes of unacceptable proficiency testing results and implement appropriate corrective and preventative measures.	

Table 1. Sample coordinator job description.

POCT VERSUS IN-LABORATORY TESTING: CHALLENGES AND OPPORTUNITIES

POCT differs from in-laboratory testing through interferences, precision, sensitivity, specificity and different targets (especially immunoassays). Most POCT is less precise than laboratory testing, which is typically performed on more expensive and sophisticated analyzers. As an example, hemolysis may affect a laboratory-based test but not a whole blood-based POCT. However, the greater imprecision and inaccuracy of POCT methods may be acceptable for select clinical applications that benefit from rapid results, such as those outlined above.

POCT assays are classified based on complexity. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) defined waived testing as a simple test with low risk of patient harm resulting from incorrect results (presuming the test is used as described in the FDA labeling including robust quality system). That definition would hardly apply to the plethora of currently performed waived tests, which some POCT fall under. Some POCT results can have huge consequences on diagnoses and treatments especially if performed improperly. Laboratorians face continued challenges and opportunities in providing guidance on the value and limitations of POCT and support for its proper performance and oversight.

Those performing waived testing must follow manufacturers' instructions. Moderately and highly complex tests are considered nonwaived tests and are subject to laboratory inspection and must comply with CLIA quality system standards including proficiency testing, semi-annual calibration/verification, quality control, personnel requirements, and documentation. Whereas hospital core laboratorians have largely mastered CLIA '88 requirements, POCT remains more challenging to manage because it is performed in diverse settings outside of the clinical laboratory.

POCT'S AREAS OF IMPROVEMENT

Many clinicians have outlined four main areas where POCT programs could seek to improve. These include:

- Coordination
- Connectivity
- Control
- Costs

COORDINATION (SEE TABLE 1 FOR A SAMPLE COORDINATOR JOB DESCRIPTION.)

Successful hospital-based POCT programs typically have strong coordinators. Individuals assigned to this role must be qualified, have sufficient time to dedicate to the role, and have the authority to lead and control all aspects of testing. Many hospitals come up short when POCT coordinators lack the complete competency for this role.[1]

The POCT coordinator must also be part of a governance structure that includes nursing, the emergency department, the clinical laboratory, and other stakeholders of the institution to foster clear communication and an alignment of interests. As technology changes, the governance structure should provide a basis to decide which tests to perform, when to replace equipment, and how to address chronic issues.

CONTROL

The ideal way to assure quality performance is to begin before the quality control materials are utilized; that is through training, analyzer maintenance, and documentation.[2,3,4]

POCT procedures should generally follow those in the core clinical laboratory. These procedures include storing all supplies at the right temperature — specifically, refrigerators and freezers must be monitored daily even when POCT is not performed. New lots of reagents or test strips must be evaluated prior to their use. A common approach is to check reagents and test strips upon delivery and run quality control samples at least monthly to check storage conditions and operator performance. Electronic instrument checks may be inadequate in establishing if the whole system functions properly. In POCT, some of the moderately complex testing may have both internal and external controls.

Recording only "in control" quality control results would be like a sports team recording only its wins. This is an unacceptable practice, hiding true assay performance. My observations are that many non-laboratorians do not understand quality control principles and procedures.

Staff education on quality control principles and procedures must be key elements of training prior to initiating new and ongoing POCT analyzers.

Additionally, quality assurance plans are often lacking, even though such plans are vital to addressing ongoing method validation; monitoring operator and document management; and identifying and addressing issues like excessive test failures, expired supplies, or user errors. Shifts and drifts in patient test results are nearly impossible for individual users to identify, but aggregate data analysis can spotlight test faults.

POCT has the option to comply with Individualized Quality Control Plan (IQCP) (see CLIA'88 42 CFR 493.1256(d)), the alternative CLIA quality control option that provides for equivalent quality testing for 42 CFR 493.1250. IQCP has been incorporated in Appendix C of the State Operations Manual.[5] IQCP is an all-inclusive approach to assuring quality. It includes many practices that a laboratory already uses to ensure quality testing beyond requiring that a certain number of quality control materials be tested at a designated frequency. IQCP applies to all nonwaived testing performed, including existing and new test systems.

CONNECTIVITY

Every test result must be appropriately documented to monitor quality control, proficiency testing, and patient care management.

Most POCT, even when appropriately enabled, is not connected to a hospital's electronic health record (EHR) system. This makes each of the pre-analytical, analytical, and post-analytical POCT steps prone to human error, from scanning patient wristbands for correct identification to reporting of the right results to the right patient. Although the POCT result may be written in the patient chart, without the appropriate additional documentation, the test may not be billed properly, and therefore, the true costs of patient care cannot be understood.

COSTS

The true costs of POCT includes instruments, reagents, quality control, proficiency testing, personnel (training, performance, troubleshooting, maintenance, documentation), and oversight.

Whereas some POCT cannot be replaced by standard clinical laboratory testing, some can, and comparisons can be made between the total cost of testing in each setting. The costs of staff for POCT are generally grossly underestimated, in part because of the distributed nature of POCT.

As we begin 2023, one of the most pressing challenges for many health systems is staffing, both within the laboratory and among nursing and other staff who perform POCT. Adequate training and support can be difficult with high staff turnover, staffing on late shifts, and temporary contract staff filling vacant positions. Maintaining technical assessments on all POCT assays for each staff member is an additional and often overlooked major undertaking.

Furthermore, quality control testing must be performed at least once daily on days when testing occurs. This can be costly for hospitals that use some tests infrequently. Lack of adherence not only jeopardizes the quality of testing but also potentially the laboratory license and certification if not reliant on a separate CLIA certificate.

Each test must undergo a full verification procedure at least once every six months and with reagent/strip lot changes. Some hospitals purchase small supply volumes to control inventory costs but do not recognize the added costs associated with frequent reagent/strip lot changes.

As hard as it may be, expired reagents must be discarded or returned, if allowed. Given some tests are performed infrequently in some locations, rotating reagents before expiration can avoid reagent/strip wastage. The POCT coordinator must develop procedures to audit reagent inventories to reduce reagent waste due to expiration.

CONCLUSION

To prepare POCT for the long journey, many EMR systems now include software that facilitates the documentation and control of users who are current with training and technical assessments. These management systems reduce, but do not eliminate, the need to dedicate the necessary resources to perform POCT correctly.

By careful planning, including identifying and developing a strong POCT coordinator, maintaining effective quality control procedures, enhancing electronic connectivity with the EHR system, and strictly tracking costs, hospital laboratories can provide a highly valuable and reliable service that improves medical diagnoses and healthcare management for patients.

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Dr. Harvey Kaufman, senior medical director, **Quest Diagnostics**, established a point-of-care testing program 35 years ago and previously served as medical director, point of care testing at Quest Diagnostics, where he has worked for 30 years.