

The Future Outlook for Laboratory POCT

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Changes in the U.S. health care delivery system are underway, driven by the need to reduce escalating costs and improve patient care outcomes. Additionally, advances in both lab testing technology and health information technology (HIT) are pushing toward a more patient-centered, proactive health care system. Bringing lab testing to the patient's side in situations where this type of testing can improve care or reduce costs fits well in this new model. Ultimately, the increase in point-of-care (POC) diagnostics is a positive one. Point-of-care testing (POCT) provides immediate results in non-laboratory settings to support a more patient-centered approach

to health care delivery, allowing for rapid treatment of the patient, and in many cases eliminating unnecessary downstream costs.

POCT Demand Increasing

Many elements are converging to drive the demand for POCT. We are experiencing an increase in infectious diseases in developing countries, a growing elderly population, and a steady rise in chronic diseases (see Figure 1). Also driving the demand for POCT is patient preference and the renewed emphasis on patient satisfaction and patient engagement. Correspondingly, POCT home usage is at an all-time high and expected to continue to rise.

Figure 1: Factors Driving POCT Market

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

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LABORATORY POCT, CONTINUED

In addition, POCT manufacturers are making continuous progress in research and development, creating products with newer, more advanced technologies. The technology involved in POCT has evolved in many cases to be comparable to the centralized laboratory in quality and meeting clinical needs. Advancements have been made that make testing simple enough that it can be accurately performed by moderately trained staff. Many tests that previously required a laboratory for testing can now be tested at the point of care. Even more complex molecular diagnostic products are being developed directly for the POC market. This is one of the most prominent areas of POCT growth.

POCT Benefits

The full potential of POCT is best realized in situations or disease states where having the result immediately available is imperative to treatment, reducing downstream costs associated with unnecessary imaging or longer hospital stays. Also, in situations 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. Properly implemented POCT empowers providers to make decisions at the patient's side, and the faster results allow for immediate clinical care decisions.

Notably, POCT in the right scenario can reduce downstream costs that are much greater than the cost of

the POCT (see Figure 2). While many laboratorians think of POCT as expensive, it is important to think of the ensuing results of a faster turnaround time (TAT). For example, rapid POCT has the potential to:

- Reduce post-op care time
- Reduce ED time
- Reduce hospital admissions
- Reduce hospital length-of-stay
- Optimize drug treatments
- Decrease inappropriate use of drugs¹

The majority of POCT is CLIA-waived, and it is steadily becoming easier for POCT to qualify as waived because manufacturers are making tests easier to use. This is of note because waived testing has less stringent regulatory rules than non-waived. The number of CLIA-waived tests increased from about eight tests in 1992 to more than 100 as of 2014, representing thousands of test systems and devices. The number of laboratories issued a certificate of waiver has grown exponentially, from 20% to 71% of the more than 250,000 CLIA-enrolled laboratories.²

POCT Challenges

POCT, in some ways, is a conundrum in that it is intended to be performed by non-laboratorians yet, in order for testing quality to equal that of the core laboratory, oversight needs to be by those who understand the importance of quality lab testing. This has led to contradictory opinions about POCT

Figure 2: Potential Benefits of POCT

Right POCT in the Right Situations Can Improve

- Consistency
- Accuracy
- Provider satisfaction
- Patient satisfaction
- Patient engagement
- Downstream costs
- And ultimately patient outcomes

oversight. POCT management can be quite a challenge, particularly in a large facility where testing can include dozens of sites, hundreds of POCT devices/kits, and thousands of operators. The good news is that there are now advanced POCT software solutions (e.g., Alere, Orchard Software, Telcor) available that can track certification.

The fact that POCT is often performed by non-lab trained personnel can be a challenge as well. Testing may be performed by clinical personnel with minimal laboratory knowledge, such as nurses, medical assistants, respiratory therapists, etc. These staff members are typically focused on direct patient care and may not understand why lab testing has been added to their already-full plates. They may be unfamiliar with routine laboratory procedures, such as the importance of proper patient preparation, sample collection, calibration, instrument maintenance, and quality control.

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LABORATORY POCT, CONTINUED

Also, the simplicity of waived testing can be deceptive. There are myriad ways that staff can unintentionally produce an incorrect result, and interpretation is often subjective or visually/lighting dependent. Historically, laboratorians have been concerned over the accuracy of POCT due to the risk of analytical errors. Yet, for certain tests, while the POCT results may not directly correlate with the same test run in the core lab, the benefit of the rapid TAT outweighs the analytical variance. This has to be carefully weighted to determine where POCT can provide the most benefit.

POCT Connectivity Adds Value

In a discussion about what lies in store for POCT, the importance of POCT connectivity must be included. Having POCT electronically integrated reduces manual entry errors and provides real-time access to results. In addition, in today's health care environment where we are leveraging HIT tools to measure outcomes that drive reimbursements and better outcomes, the true value of POCT results requires integrating those results into the EHR and/or HIE. Only when this is in place can the true value of POCT be realized. Having results immediately available in the EHR makes results accessible to all members of the health care team, allowing for quicker diagnosis and treatment and the inclusion of POC results in healthcare analytics.

What Does the Future Hold?

POCT is already making great strides in reducing hospital-acquired infections such as Methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile*, generating millions of dollars in savings and improved patient care. These advancing developments in POCT for infectious disease biomarkers are expected to continue. POCT can be of particular benefit in diseases that typically depend on the traditional 24-48 hour TAT in microbiology, allowing providers to initiate care immediately.

The new focus on engaging patients in their health plan and the availability of various health care apps is also expected to increase dramatically in the future. We already have headsets that measure brain waves, clothing that measures vital signs, insoles to track elderly patients' movement patterns—all capable of sending data wirelessly to providers. Personal health monitoring is expected to continue to produce groundbreaking innovations and be a large part of the reform of our health care system.

The emphasis of care is shifting from reactive medicine toward disease prevention and early detection, as well as management of multiple chronic conditions. With the development of smaller devices and wireless communication, how providers care for patients is changing dramatically and patients are beginning to take a much-needed, more active role in their own health care.

Lab's Responsibility in POCT

With a united goal of improving patient care, laboratorians have a responsibility to be involved in finding patient care situations where POCT can support demands for rapid diagnosis and treatment, and reduce downstream costs. In the changing health care landscape, the role of the laboratory is expanding. Laboratorians have more opportunities to affect patient care and to increase the lab's clinical effectiveness beyond the walls of the lab. POCT offers this opportunity.

Whether lab testing takes place within the laboratory or at the patient's side, lab professionals who understand the intricacies of testing and the importance of proper laboratory processes have an obligation to be involved in the oversight and growth of POCT.

They can influence decisions that will encourage appropriate POCT usage where it is most beneficial to improve patient care. POCT integration offers another opportunity for laboratorians to be an integral part of the future of diagnostics.

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The POL/Office Team: Improved Patient Safety

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Introduction

While the doctor-patient relationship has always been considered the center of medical care, this relationship does not exist in a vacuum. Today, it is supported by interrelated systems of individuals, procedures, technologies, regulations, and organizational structures associated with the care provided. Laboratories are an integral part of this larger construct, and the improvement in patient safety achieved is shared by all systems involved.¹

Through effective organizational teamwork where competent individuals work together (through all phases of the testing process) to ensure that the most accurate test results are provided in a timely manner to the requesting physician, patient safety is maximized.

The POL Testing Process²

Most errors that occur in the testing process occur in the pre and post-analytical phases of testing. When the testing process is further defined into distinct activity steps commonly experienced in a physician office setting (see below), the location of potential errors is also identified:

Ordering: A physician makes a decision to obtain a test and communicates that decision to the appropriate personnel.

Implementation: The order is transmitted to those performing the test and/or obtaining the specimen(s); the patient is prepared for the test and/or the specimen(s) are obtained.

Tracking: The test order is monitored internally (within the primary care practice) until the results are returned.

Return of results: The results are sent back to the office (and to the physician) from testing facilities or locations.

Response: The physician makes a decision as to the meaning of the results and creates an action plan.

Documentation: Physician and/or staff note in the medical record that the result has been reviewed; that

the physician has responded to the result; and that the patient has been notified.

Notification: The patient is informed of his/her test result and the physician's recommendations for action.

Follow up: The process whereby abnormal results and/or results requiring action are monitored until such action is taken or the patient refuses the action.

In a field as complex as medicine, there are multiple potential sources of ambiguity (e.g., patients with similar names) and small mistakes (e.g., incorrect filing of a test result) that can cascade into consequences disproportionate to their sources (e.g., allowing a critical condition to go untreated). Testing represents a common arena for these types of errors. According to data from the National Ambulatory Medical Care Survey, the average family physician sees approximately 100 outpatients per week and orders diagnostic tests on 39% of them.

A Culture of Safety and Teamwork

An organization has a "culture of safety" when it understands the need for an organizational approach to address these risks, and is willing to commit the necessary resources. These organizations take advantage of new opportunities (e.g., information technology) to improve quality. Safety and adaptability are not static properties of an organization but reflect a dynamic struggle to create safety.

Quality care is dependent upon effective teamwork, where competent individuals work together (through all phases of the testing process) to ensure that the most accurate test results are provided in a timely manner to the requesting physician. Teamwork can be categorized as internal, i.e., within the laboratory; and external or ancillary, as relating to other departments or systems within the greater organization.

Improved quality patient care and enhanced patient safety requires an understanding of how the testing process involves interaction with organizational systems

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beyond the laboratory. It can be described as a multi-phase process, wherein multiple people, tasks, technologies, and environmental and organizational factors interact to determine the outcome.

Teamwork is a two-way process, where open communication between laboratory professionals and those in other departments meet regularly to discuss issues of mutual concern. When carried out with mutual respect, careful planning, open and honest assessments of common needs, and issues to be addressed, the result is enhanced quality of patient care.

Support Institutional Teamwork³

1. **Encourage communication** between management and staff, and between the laboratory and the rest of the office. Be open to new ideas, feedback, and suggestions.
2. **Reporting of issues, problems, events, and errors is encouraged and supported.**
3. **Learning culture:** issues, problems, events, and errors are handled as learning opportunities, with

corrective actions for the lab team; not used to denigrate employees.

4. **Ensure that all new employees are mentored into the team culture of the medical practice,** as well as properly trained and vetted for competency.
5. **Recognize achievement.** Celebrate successes due to combined efforts of staff; thank people for doing a job well; publicly recognize hard work; praise staff commitment during difficult times.
6. **Help all employees succeed.** Provide employees with the resources and support to do their work, and as they show signs of readiness, be willing to entrust them with new tasks and greater responsibility.

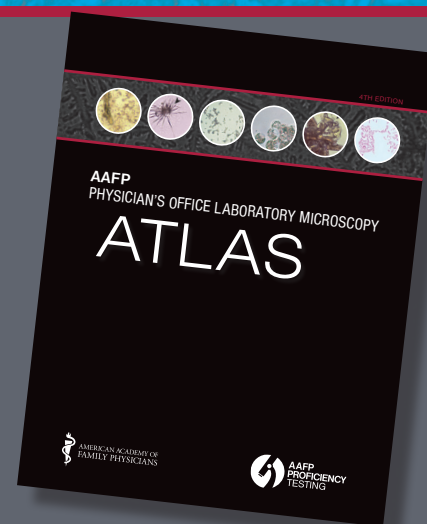
Support Process Improvements:⁴

- **Implement a formal test-tracking system.** A tracking system assures that all tests ordered are returned, ideally to the physician but at least to the practice. Such a system requires that all physicians in a practice agree to standardize how they order tests and how returned results will be handled. Although a formal tracking

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system can be incorporated within an EHR, this is not a requirement for having a working system. A system needs to be simple, have some built-in redundancies (to account for human error in entering data), and be accessible and accountable to multiple people.

- **Make a policy of notifying every patient of every result.** “No news is good news” should be a policy relegated to history. Practices should decide on a standardized system for notifying patients of both normal and abnormal results.
- **Empower patients to serve as safety double-checks.** Patients should be educated as to what tests are being ordered, their purpose, and when (and how) results will be relayed. If patients do not receive their results within a specified time, they should not assume that means “everything is OK.” Rather, they should be instructed to contact the office for the results.
- **Only file signed reports, letters, dictations, and results.** Whereas many offices have a policy that nothing enters a chart (electronic or paper) without being signed first, too often, unsigned or inappropriately signed reports get filed. The response to the report (normal, abnormal) also needs to be noted by the physician, and empowering all who find such a breach to take steps to fix it can help ensure the system succeeds.

Ensure Office Staff are Adequately Trained and Competent

One area of special importance is ensuring the proper training and competency of all non-laboratory staff that are involved in the pre-analytic and post-analytic phases of testing. It is easy to think of front office personnel, including those who may also perform phlebotomy, or order lab supplies, as “other than” laboratory people; however, they play significant roles in the operation and success of the lab. This is especially true for the pre-analytic phase of patient testing, as office staff are often involved in getting important patient information, ensuring that specimens are sent to the requested reference labs, and performing data entry on the office computer system. This multi-tasking may also extend to post-analytic activities such as receiving specimens

collected off site as well as the receiving and filing of reference lab reports. This includes front office personnel, including receptionists, medical assistants, secretaries, phlebotomists, couriers, and even the office manager, are properly trained for anything they do that affects any aspect of the laboratory operation. This training should be documented. This need extends beyond training to competency assessment. One possibility is to consider incorporation of competency assessments of laboratory-related activity into staff evaluations. It is also important to remember that this is often the staff that interacts directly with patients providing pre-test preparation information.

Ensure Participation in Multi-disciplinary Committees

Laboratory management also should ensure that there is appropriate representation on all institutional committees handling issues of mutual concern. These committees could include:

- Medical Executive
- Pharmacy and Therapeutics
- Transfusion Services
- Infection Control
- Safety and Employee Health
- Waste Management

Conclusion

There are many more ways in which teamwork for the mutual goal of improving patient safety can be achieved, but the key here is to see the laboratory as part of the entire institutional team, not as a separate insular department striving for quality care on its own.

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Deadline for credit is September 30, 2017. Only employees of laboratories currently enrolled in AAFP-PT are eligible to participate in this CME activity.

The material necessary to review and answer the following questions may be found in this issue of *P.O.L. Insight*. Answers may be submitted at www.aafp.org/pt/cme. The Accreditation information is located on the page 13 of this issue.

1. Under CLIA regulations, a laboratory is never allowed to modify an FDA-approved test method.
 - a. True
 - b. False
2. You do not have to notify CLIA or your accreditation organization after modifying a waived test procedure.
 - a. True
 - b. False
3. If you use an instrument to test an analyte not on the manufacturer's test menu, it's not a modification as long as the manufacturer's reagents are used.
 - a. True
 - b. False
4. Which of the following is NOT a modification of a test system?
 - a. Changing the incubation time for blood cultures from 48 to 24 hours before a weekend because you read that positives will almost always be evident within a day, so the result will be just as valid.
 - b. You are able to purchase reagents for your hematology instrument from a different manufacturer at half the cost, and after QC was run, you felt the quality was assured.
 - c. The manufacturer states that agar plates must be at room temperature before plating, but you always seem to receive specimens for plating at the end of the day, after the unused plates have been returned to the refrigerator, you use these anyway.
 - d. You change the sequence of your quality control runs from the beginning of your run, to the middle of the run.
5. Modifying an FDA-approved method automatically defaults the test to the High Complexity category.
 - a. True
 - b. False
6. Performing a Strep Screen (swab) on an open wound when the directions specify use as a throat culture is a modification of the test Strep procedure.
 - a. True
 - b. False
7. Once lab developed tests (LDTs) have been validated, they are no longer considered modified test procedures.
 - a. True
 - b. False
8. Personnel considerations for labs that are now high complexity due to adoption of modified test procedures are mainly about the testing personnel.
 - a. True
 - b. False
9. A moderate-complexity laboratory which adds a lab developed test (LDT) must obtain additional accreditation/compliance certifications.
 - a. True
 - b. False
10. If the lab is already a high-complexity laboratory, then modifying a test procedure can be handled as if it was just another added test, with minimal added expense.
 - a. True
 - b. False
11. Test system modifications can include _____ .
 - a. Using tests for purposes other than those approved by the FDA
 - b. Switching from one CLIA-waived method to another
 - c. Apply results in a way not prescribed in the package insert
 - d. A and C only
12. High sensitivity tests are used to _____ .
 - a. Rule out a specific condition
 - b. Confirm results of prior testing
 - c. Confirm a specific condition
 - d. None of the above
13. In which of the following situations does POCT provide the most benefit?
 - a. When POCT is performed by laboratory-trained staff in the core lab
 - b. When having the result immediately available is imperative to treatment
 - c. When the patient can receive real-time counseling based on the test results
 - d. When results can reduce downstream costs associated with unnecessary imaging or longer hospital stays
 - e. B, C, and D

14. Which of the following statements are applicable to POCT?
- Properly implemented POCT empowers providers to make decisions at the patient's side.
 - Faster results allow for immediate clinical care decisions.
 - Rapid POCT has the potential to reduce post-op care time and ED time.
 - A and B
 - All of the above.
15. The majority of POCT is CLIA non-waived.
- True
 - False
16. Which of the following is considered a challenge to POCT?
- Keeping up with training and competency assessments for POC devices and operators
 - Testing is far away
 - Often performed by non-lab trained personnel
 - POCT are expensive
 - A and C
17. POCT provides a more patient-centered approach to health care delivery by providing immediate results and allowing for rapid treatment.
- True
 - False
18. The increase in POCT can be attributed to:
- An increase in infectious diseases
 - Growing elderly population
 - A rise in chronic conditions
 - All the above
19. The higher costs of POCT may be offset by a downstream cost savings.
- True
 - False
20. The true value of POCT can only be realized by integrating with an EHR or HIE.
- True
 - False
21. POCT has the potential to significantly reduce turnaround time for microbiology testing.
- True
 - False
22. Office staff training and competency in the laboratory testing process is only necessary when it involves direct patient contact work.
- True
 - False
23. Most errors in the testing process occur in the pre- and post-analytical phases.
- True
 - False
24. The laboratory staff is in control of the entire testing process, and therefore needs most of the training and competency assessments.
- True
 - False
25. One way to encourage teamwork is to encourage "bottom up" communication from staff to management.
- True
 - False
26. Representation on multidisciplinary committees is an effective way to get organizational feedback on laboratory issues.
- True
 - False
27. Providing "normal" test results to patients wastes their time; it is only important to inform them of "abnormal" test results.
- True
 - False
28. Which of the following is NOT part of the POL testing process?
- Patients are provided with pre-test instructions as needed by either the lab or office personnel.
 - Test orders are carried out by the lab once the specimen is acquired.
 - Test results are held by the lab until the physician requests these for the follow-up visit by the patient.
 - Physicians or their staff document the test results in the patient's chart once the decision has been reviewed.
 - Follow-up action for abnormal test results are carried out and documented.
29. In addition to staff directly performing laboratory testing, laboratory competency assessment testing should also include the following personnel:
- Front desk staff
 - Phlebotomists
 - Office manager
 - All of the above
30. Front desk staff may have a role in which of the following laboratory functions:
- The pre-analytic phase of patient testing involving handling patient information, patient preparation, and specimen handling
 - The post-analytic phase of patient testing, including receiving and filing reports
 - The analytic phase of patient testing
 - A and B only

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2016-C CME Answers

1. B	11. D	21. A
2. B	12. C	22. B
3. B	13. E	23. A
4. D	14. E	24. B
5. A	15. B	25. A
6. A	16. E	26. A
7. B	17. A	27. B
8. B	18. D	28. C
9. B	19. A	29. D
10. A	20. A	30. D

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