

Perspectives On Blood-Based Point-Of-Care Diagnostics

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Karalee Quig¹
Elizabeth G Wheatley²
Matthew O'Hara²

¹POC Testing Consultant, Aurora, CO, USA; ²Boston Strategic Partners, Inc., Boston, MA, USA

Background: Point of Care (POC) diagnostics are an essential component of modern medicine and are employed in a variety of clinical disciplines to improve patient outcomes and provider efficiency. Despite these benefits, there are aspects of POC testing which may still hold room for improvement. In the present study, a group of healthcare professionals familiar with different facets of blood-based POC testing provided their perspectives on the benefits and challenges of POC testing within their respective fields.

Materials and methods: The study was conducted from April to June 2019, in Colorado, United States of America. Five healthcare professionals, each working in a distinct field (anesthesiology, nursing, emergency medicine, trauma surgery, and POC management) were interviewed. Results from each of the interviews were transcribed as qualitative perspectives on POC diagnostics.

Discussion: The general consensus among participants in this study is that POC testing is tremendously beneficial, providing rapid test results, increased access to diagnostics, and improvements in hospital efficiency. However, significant challenges remain in blood-based POC diagnostics, particularly in maintaining sample quality, due to the fact that devices used for sample acquisition and handling are not designed for POC. This raises the possibility for interferences like hemolysis to occur, which may alter diagnostic results. Errors in POC diagnostics, whether due to sample, operator, or instrument error, may cause providers to lose confidence in the test. This lack of confidence can lead to duplicate testing and delayed patient diagnoses.

Conclusion: The perspectives presented in this study suggest there is a significant need for improvement in the pre-analytical phase of POC testing, and that current practice employs specimen collection technology not designed for POC. Therefore, one hypothesis is that the introduction of a collection device designed specifically for POC could reduce pre-analytical errors, standardize sample quality, improve efficiency, and further benefit patient care.

Keywords: patient diagnostics, point-of-care, blood, hemolysis, pre-analytical phase, emergency medicine, trauma

Introduction

POC testing has become widely adopted in many different healthcare settings and its use has steadily grown over the past four decades.¹ POC testing has evolved in recent years to include the use of portable and benchtop analyzers, test strips, cartridges and kits, a wide variety of analytes, and numerous specimen types including blood.^{1,2} Perhaps the most well-known advantage of POC diagnostics is the rapid turnaround time for test results – particularly essential within disciplines for which rapid or sequential test results are necessary to support patient care, such as in the emergency department (ED),³ critical care unit,⁴ or during procedures like cardiac or trauma surgery.⁵ The portability and accessibility of POC devices allow

Correspondence: Matthew O'Hara
Boston Strategic Partners, Inc., 4
Wellington Street Suite 3, Boston, MA
02118, USA
Tel +1 617-901-1654
Email matt.ohara@bostonsp.com

testing to be performed by a range of professionals interacting with the patient, including nurses, physicians, and technicians.^{1,6} Since its adoption, POC has significantly improved patient morbidity and mortality and is considered to be an essential component of a number of clinical disciplines.^{7–9}

Despite these advantages, there are still challenges that exist within POC, and in particular, with POC diagnostics utilizing patient blood. In the present study, a group of five healthcare professionals intimately familiar with POC testing within their respective fields were interviewed to describe the challenges they encounter and the methods by which they attempt to mitigate these challenges. The goal of this study is to identify areas in which POC testing may warrant improvement or further attention in future studies, which would ultimately advance clinical efficiency, healthcare provider satisfaction, and most importantly, patient care and outcomes.

Materials And Methods

Study Setting And Participants

The study was conducted from April 2019 to June 2019, in Colorado, United States of America. Participants who were interviewed for their perspectives in POC testing were male and female medical professionals who either previously worked or were actively working at several of the largest hospitals in the greater Denver area. Participants had either a medical or nursing degree, or had worked in a supervising position in POC diagnostics.

Participant Interviews

Healthcare professionals who participated in the study engaged in the interviews willingly. The interviews were conducted by professional consultants, in private settings, using a standardized interview guide. The guide contained structured questions to ensure baseline topics in POC were assessed across each profession, as well as open-ended questions for obtaining the individual perspectives of each professional. Interviews took approximately one hour, during which time responses were transcribed in real-time with the consent of the participant. Identifying information for participating medical professionals has been excluded, and no patient identifying information of any kind was obtained during the interview. The results from each interview were transcribed in a qualitative manner to portray the perspective of the participant, and all participants were given a copy of the manuscript for

review. This study was exempt from IRB approval based on section 46.104(2) of e-CFR data in effect on July 19, 2018, at ecfr.gov.

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Anesthesiology

Challenges In Continuous And Reliable Patient Monitoring

The challenging aspect of caring for patients under anesthesia, is that there is a need for continuous and reliable patient monitoring throughout the entire surgical procedure. A component of this continuous monitoring involves repeated blood draws through an established arterial line, which according to this anesthesiologist, is surprisingly tedious to execute. Repeated flushing of the line and returning of flushed cells can increase the risk for sample hemolysis (the rupturing of red blood cells and release of hemoglobin and other cellular contents), which can in turn lead to inaccurate diagnostic results such as spuriously elevated potassium levels. In this clinician's experience, the complexity of the line tubing contributes to bubble formation in roughly 10–12% of the blood samples, which can alter diagnostic results as well. Continuous patient monitoring requires that any change in patient status be detected as quickly as possible – a standard that is difficult for anesthesiologists to meet when relying solely on the turnaround time of the central lab.

Reliability of test results is also a concern in patient monitoring. Challenges in reliability have been described with both portable POC devices and the central lab. From the perspective of this anesthesiologist, it is often difficult to load a blood specimen into the POC testing cartridge without the formation of bubbles, which may alter test results for parameters such as blood gasses, and POC devices cannot detect sample quality interferents like hemolysis, leading to uncertainty when abnormally high or low results are obtained.^{10–12} Although central labs are known to be more analytically reliable, this clinician has observed that when sending samples to the central lab from the operating room, pre-analytical error rates can reach up to 40%, likely due to transportation issues or mislabeling of the specimen itself.

Impact On Monitoring And Patient Care

The need for continuous patient monitoring has led anesthesiologists to rely heavily on the use of POC testing devices, given these devices have a turnaround time on the

order of minutes for diagnostic results. When certain critical situations like the need for a blood transfusion arise, treatment decisions can be made rapidly thanks to the use of POC testing and other diagnostic tools, which from the perspective of this clinician, markedly improve the quality of urgent care. Relying on a high volume of POC tests, however, also means a significant component of the quality of patient care is dependent on the accuracy of sample collection and cartridge loading. For example, the occurrence of hemolysis or bubbles during these steps may lead to abnormal test results, causing patient monitoring to become delayed while blood draws are repeated, and specimens are re-tested.

Workarounds And Areas For Improvement

According to this anesthesiologist, there is currently no standardized device or specific protocol designed for both collection and deposition of samples into POC testing cartridges, that will aid in controlling hemolysis, bubbles, and sample volume. As a result, there are several techniques which are regularly practiced among operators to minimize these issues. One such method involves the use of a syringe with a blunt tip needle to fill the POC testing cartridge. Another example of deviation of technique between operators is placing the Luer lock tip of the syringe right into the well and loading the cartridge, versus the recommended technique of dropping the sample from the syringe into the well to allow capillary action to move the sample into the chamber. Although placing the Luer lock against the well may form a seal that improves sample loading, the pressure of placing the Luer lock into the well may raise the risk for hemolysis. Despite the fact that these techniques are each executed as consistently as possible, this clinician has found that roughly 10% of the time there is still a complication with the POC diagnostic result – suggesting that pre-analytical sample acquisition and handling errors have approached their lower limit without a specialized device to streamline this process.

Nursing Efficiency Challenges

Nursing is an inherently challenging job – requiring the ability to balance care across multiple patients simultaneously. On top of the high volume of patients which nurses often care for, the perspective of this nurse is that there are additional challenges associated with treatment efficiency, especially when patient care or discharge becomes stalled while waiting for diagnostic results. This rate limiting step often stems from the longer turnaround

time observed in hospital central labs, and can become particularly frustrating when efficiency is essential for managing the continuous stream of patient intake, treatment, and discharge.

The Impact Of POC On Nursing Efficiency

The rapid and accessible diagnostic testing provided by POC is hugely beneficial for nursing efficiency. With a turnaround time of ten minutes for important blood tests such as lactate, troponin, and arterial blood gasses, it is the perspective of this nurse that the use of POC testing significantly accelerates patient care and has the potential to decrease patient length of stay in the ED. Rather than having to wait for test results from the central lab, the ability to test the patient first-hand using POC also increases nurse involvement in patient treatment and diagnostics. In addition to facilitating the highest level of patient care and improving efficiency, this nurse expressed the sentiment that the use of POC diagnostic testing significantly increases job satisfaction for nurses overall.

Areas For Improvement

This healthcare provider has observed firsthand that certain POC blood tests, like lactate or the prothrombin time and internal normalized ratio test (PT/INR), are particularly sensitive to sample integrity, resulting in a greater risk for artifactual readings. This observation has led to the adoption of the convention that the sample be out of the patient and into the testing cartridge within 30 seconds in order to avoid false positives or other diagnostic errors. This convention, while seemingly effective, leaves little room for error in executing the pre-analytical steps involved in POC sample preparation. In support of this, although standardized training protocols are implemented to minimize error rates and maximize sample integrity, there are still occasional errors that are observed by this nurse, which lead to re-tests – negatively impacting efficiency. This perspective suggests currently available techniques may therefore not be fully optimized, indicating there is room for more improvement in POC sample collection efficiency.

Emergency Medicine

Meeting The Urgent Demands Of The ED

One of the most challenging aspects of working as a doctor in the ED is meeting the degree of urgency that accompanies ED patient care. The urgent nature of emergency medicine makes the speed of diagnostic results a

particularly critical factor in providing quality patient care. The ability to satisfy time constraints in the ED is also essential for meeting certain hospital accreditations, such as the Chest Pain Center Accreditation or Primary Stroke Center Certification.^{13,14} From the perspective of this physician, these certifications are important and beneficial qualifications for a hospital to have.

There is also a general perception among physicians that POC tests are not as analytically sensitive as the central lab. This means despite the urgency for care, abnormal or elevated results in POC are often interpreted cautiously in emergency medicine. This situation can prove to be particularly challenging for emergency practitioners such as this one, who are balancing risk mitigation with the urgency for treatment.

POC In Guiding Emergency Care

Patient admissions in the ED range in type and severity, but one of the more common reasons for admission stem from cardiac-related events.¹⁵ When there is suspicion of a cardiac event such as a myocardial infarction, a blood draw and test for circulating troponin is standard for guiding patient care. To meet certain accreditation criteria the initial troponin test result needs to be completed in 45 minutes or less, which in this physician's experience, cannot always be guaranteed when using a central lab. Therefore, the assessment of analytes like troponin for myocardial infarction or lactate for sepsis, rely heavily on POC diagnostics to assist in meeting this turnaround time requirement. POC troponin is also useful for monitoring patient progression over the course of several hours, and sequential negative results can also be utilized to justify patient discharge. This emergency medicine doctor feels the use of POC for patient diagnostics and discharge helps to decrease the length of stay for patients and increases the efficiency of the ED overall.

Areas For Improvement

Due to the urgency and risks associated with ED patient care, POC tests for troponin are often performed simultaneously with the central lab, to ease the uncertainty or lack of confidence in the POC test. In addition, POC tests are readily re-drawn and repeated even if the result might be correct, as a "better safe than sorry" type approach. This convention is not ideal because excessive repeated testing is wasteful, substantially drives up the cost for the hospital, and unnecessary blood draws contribute to patient discomfort. Ideally, improvements in sample quality will

lead to more reliable POC diagnostic results which would increase confidence for ED physicians and reduce the number of unnecessary re-tests, saving time in urgent care settings.

Trauma Surgery

Challenges In Monitoring Trauma Patients

The nature of trauma patients compared to more stable patients, is that their status is extremely fragile and can drastically change from one moment to the next. Consequently, trauma patients require more extensive and frequent diagnostic monitoring, in order to continually re-orient their treatment plan. Although blood specimens used for diagnostics are a vital component of trauma patient monitoring, this surgeon finds it can be challenging to successfully draw blood from severe trauma patients. This is likely due to several physiological factors, including decreased blood volume from blood loss. The protocol during a trauma activation also requires numerous medical professionals to aid in patient care rapidly and simultaneously. This physician emphasizes that in the event of a disorganized trauma activation, a crowded and chaotic environment can contribute to challenges associated with proper sample acquisition, handling, and processing.

Trauma Care Relies On POC Diagnostic Testing

From the perspective of this surgeon, POC testing is an absolutely essential component of trauma patient care. As part of a trauma code, there is a standardized procedure that is initiated immediately, and includes obtaining a baseline panel of blood tests as quickly as possible, making POC diagnostics a very valuable asset. Some of the most important POC blood tests for guiding treatment in trauma surgery are arterial blood gasses, hematocrit, and coagulation parameters.^{16,17} Many trauma centers are also integrating POC thromboelastography and rotational thromboelastometry into their protocols for directing blood products resuscitation. In the case of elevated POC potassium, if the patient's clinical presentation is consistent with the test results the physician will generally begin cardioprotective management immediately, while a central lab test is run to confirm the result is not due to sample hemolysis.

Areas For Improvement

During instances in which the patient presentation does not match the POC test result, a new blood draw is obtained and re-tested using the central lab. This can delay patient

care considerably. In the experience of this physician, blood samples collected for POC testing will often turn out to be hemolyzed, clotted, or un-usable in some way, resulting in a re-draw. Studies have revealed hemolysis rates in blood samples taken from trauma patients in particular can reach up to 25%.¹⁸ In the opinion of this trauma surgeon, the main area of the pre-analytical phase of POC testing in which improvements could be made, is in sample acquisition. This would significantly advance the speed and quality of trauma patient care and increase confidence in POC diagnostic results.

POC Manager

Challenges In Maintaining POC Standardization

Although POC testing is essential for patient care in many areas across the hospital, its use requires a standardized training regimen for safe and optimal execution. Despite the adoption of rigorous training protocols for POC testing, this POC manager feels there are several aspects in the pre-analytical phase that introduce unavoidable degrees of variability into the sample quality.

Differences In Blood Collection Techniques For POC

Blood for POC diagnostics may be collected using medical equipment which is most comfortable and convenient for both the clinician and patient. One such example is that when collecting a sample for POC testing, rather than sticking the patient again with another needle, the sample is often drawn from an existing peripheral venous catheter (PVC). PVCs are meant for infusions rather than draws, and are more likely to collapse during a blood draw and hemolyze the sample. In addition, this POC manager has observed the requirements for preparing samples in POC are variable and sometimes include transfer to a secondary tube before loading into a POC testing cartridge. With each additional transfer step during which the blood may pass through a narrow needle, the risk for hemolysis, bubbles, and compromised sample quality, as well as the potential for needlesticks and blood exposure, may increase. The methods for blood collection encountered by this healthcare professional tend to be inconsistent, and therefore the quality of the blood draw is inherently subject to large variability.

For the most part, POC coordinators have confidence in the instruments they utilize, and the instrument operators who have been trained to perform the testing correctly. This POC manager feels that questionable test results generally raise suspicion of the sample quality itself, i.e.

“garbage in equals garbage out,” rather than raising concerns regarding the performance of the instrument.

Conclusion

POC testing has become a vital component of patient care, particularly in time sensitive disciplines like emergency medicine, critical care, and surgery. The stakeholders who participated in this study indicate that the rapid turnaround time for POC diagnostics reduces time to clinician decision making, has the potential to reduce patient length of stay, and improves patient care. Additionally, POC diagnostics are an essential component of the constant monitoring necessary for trauma patients and during certain surgical procedures.

Despite these benefits, however, the clinician perspectives gathered in this study suggest that pre-analytical phase errors contribute to a substantial degree of challenges that are currently impacting the efficiency and accuracy of blood-based POC diagnostics. Interferents like clotting, air contamination, and hemolysis often occur during the pre-analytical phase, which involves sample acquisition and handling, and can lead to diagnostic inaccuracies. These sources of errors are well-recognized, and as a result, clinicians have designed workarounds to address these issues. Such workarounds may include placing time limits between acquisition and cartridge loading to preserve sample quality, repeated POC testing as a “better safe than sorry” type approach, or specific techniques which utilize existing equipment. These workarounds tend to differ across care settings, applications, and individual users. Workarounds may also involve extra handling steps, such as transferring the sample to a secondary container, which may further compound the likelihood of errors.

These perspectives suggest that central to the challenges that exist within POC diagnostics, is the fact that many sample acquisition devices in use today are not specifically designed for POC testing, making errors in the pre-analytical phase difficult to control for. This suggests the pre-analytical phase of blood-based POC testing could benefit from a device that is designed to help standardize this process, by minimizing the number of transfer steps, controlling sample volume, and reducing the introduction of interferents like hemolysis, air bubbles, or other errors that could potentially impact sample quality.

Since its adoption, POC diagnostic technology as a whole has continued to advance over time. Emerging technologies such as microfluidics and Lab-on-a-Chip

tools show potential for future applications in blood-based POC testing by increasing accessibility, expanding the scope of analytical targets, and improving analytical-phase sensitivity.¹⁹ Collectively, this literature and our study indicate there is a need for improved technology in blood-based POC diagnostics. Such advancements would ideally serve to standardize the collection and handling process, improve sample consistency and quality, and ultimately enhance the confidence that is placed in POC test results. By addressing these challenges, POC diagnostics would advance the scope of diagnostic testing, further improve clinical efficiency, and extend the standard of patient care.

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Disclosure

Ms Karalee Quig reports personal fees from Becton Dickinson, during the conduct of the study. Dr Elizabeth G Wheatley reports personal fees from Becton Dickinson, during the conduct of the study and outside the submitted work. Mr Matthew O'Hara reports personal fees from Becton Dickinson, during the conduct of the study and outside the submitted work. The authors report no other conflicts of interest in this work.

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