Understanding the potential of this evolving capability

Prehospital systems have been performing point-of-care lab testing since the introduction of whole blood glucose testing via glucometers.

Point-of-care testing (POCT) allows the provider to gain objective information at a patient’s bedside rather than waiting for blood to be sent to a hospital’s lab for results.

Presently, laboratory data impacts more than 70% of medical decisions, and with an annual growth in volume of more than 10%, POCT is one of the fastest-growing areas of clinical lab testing. Now, with the expansion of evidence-based medicine in prehospital care, community paramedicine and critical care transport, the proper use of well-defined prehospital POCT has the potential to improve patient care and reduce overall healthcare costs.

The seriousness of prehospital POCT cannot be overstated, as use of lab results requires not only the actual result but proper training to understand its significance in the context of the patient’s condition. Prehospital systems considering adding point-of-care technology need to consider how the results can impact their patient care. If a lab result won’t impact prehospital care or transport decisions, blood need not be drawn during prehospital care. Labs that can impact patient care deserve strong consideration for implementation. Implementing a point-of-care testing program requires a thorough understanding of lab testing regulations, available devices and the tests that are available.

This article explores the vast potential of prehospital point-of-care lab testing. Because POCT is very device-specific, the authors want to emphasize that the inclusion or exclusion of any POCT device should not be construed as an endorsement or discredit against any system.
Clinical Laboratory Improvement Amendments

Performing laboratory testing without proper authorization is illegal and places patients at risk. All patient body fluid testing for data that may impact patient care is controlled and regulated by the Centers for Medicare & Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA). Congress established the CLIA in 1988 to ensure standardized quality control, accuracy and safety. Under its definitions a laboratory is any "facility that does laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health." Two states, New York and Washington, have developed their own regulations and guidelines. Both utilize their own accreditation process and have been granted CLIA exemptions.

CMS regulates both the manufacturers and users of laboratory testing devices. Any time a manufacturer develops a new lab device to be used for medical testing, it must be submitted to the Food and Drug Administration (FDA) for categorization. Devices not intended to assist in the diagnosis, prevention or treatment of a disease do not need FDA approval and may not be used by a medical professional during the assessment and treatment of patients. For example, many of the devices used by athletic trainers during sporting events, such as lactate meters, are not regulated for medical care.

While all devices must be approved, the FDA understands that not all tests need equal regulation. In 2003 the FDA was given the authority to establish lab test complexity levels. Three categories of lab tests have been established based upon seven criteria established through the CLIA regulations. These categories are high complexity, moderate complexity and waived testing. Establishing these levels allows each lab to obtain a certificate and accreditation appropriate for the type of testing it performs.

Every testing system is evaluated using the categorization criteria. Systems receiving scores of 12 or less are categorized as moderate-complexity; systems with scores of more than 12 are considered high-complexity (see Table 1). For a device to be waived from CLIA accreditation, it must only perform a simple test with minimal risk for an incorrect result that could alter patient care. Manufacturers may apply for a CLIA waiver for their device when the system can be used by patients of their own homes.

Once devices receive their classification, they may be sold to medical professionals for laboratory use. Every laboratory must receive a certification and accreditation appropriate to the devices it uses. While most hospital labs are accredited as highly complex, physicians’ offices, pharmacies and EMS services may only use a few devices and can be accredited as moderate-complexity clinical labs. Accreditation may be achieved directly from CLIA, the Joint Commission (appllicable to hospital programs only) or the College of American Pathologists.

Prehospital accreditation is possible. In North Carolina, New Hanover Regional Medical Center’s AirLink/VitaLink Critical Care Transport recently became the first prehospital transport program accredited as a clinical lab by the College of American Pathologists. When healthcare providers use only waived devices for their lab testing, accreditation is not required; however, such a program is required to obtain a CLIA-waived certificate. Obtaining this certificate is federal law; it allows CMS to know where patient testing is being performed, and it requires the lab to acknowledge it will follow the device manufacturer’s recommendations for training and use.

While all accredited laboratories are inspected, CMS also inspects 2% of the more than 150,000 CLIA-waived laboratories to ensure proper education is provided to those performing tests, proper competencies (annual at a minimum) are completed and proper procedures are being followed. The goal of these surveys is to educate waived laboratories about the importance of proper education, record keeping and technical practice. There are approximately 80 waived point-

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>SCORE OF 1</th>
<th>SCORE OF 3</th>
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<tbody>
<tr>
<td>Knowledge</td>
<td>Minimal scientific and technical knowledge required; may be taught on the job</td>
<td>Specialized scientific knowledge required to perform preanalytic, analytic or postanalytic testing</td>
</tr>
<tr>
<td>Training and experience</td>
<td>Minimal training or limited experience required to perform test</td>
<td>Specialized training is essential or substantial experience necessary for test performance</td>
</tr>
<tr>
<td>Reagents and materials</td>
<td>Reagents and materials are stable and reliable; they are prepackaged or premeasured with no special handling required</td>
<td>Reagents and materials may be labile and require special handling. Preparation may include manual steps such as volumetric measurements</td>
</tr>
<tr>
<td>Characteristics of operational steps</td>
<td>Operational steps are either automatically executed or easily controlled</td>
<td>Steps require close monitoring or control; may require special preparation, precise temperature control or procedural steps</td>
</tr>
<tr>
<td>Calibration, quality control (QC) and proficiency testing</td>
<td>Calibration and QC materials are stable and readily available</td>
<td>Calibration, QC and proficiency materials may be labile</td>
</tr>
<tr>
<td>Test system troubleshooting and equipment maintenance</td>
<td>Troubleshooting is automatic or self-correcting or requires minimal judgment. Maintenance is seldom required and can be easily performed</td>
<td>Troubleshooting requires decision making and direct intervention to solve most problems. Maintenance requires special knowledge and skills</td>
</tr>
<tr>
<td>Interpretation and judgment</td>
<td>Test processes require minimal judgment or interpretation</td>
<td>Testing processes require extensive judgment, resolution of problems requires extensive interpretation</td>
</tr>
</tbody>
</table>
of-core tests available, several of which are identified in Table 2, although many of these are not pertinent to prehospital care. Table 3 identifies tests that are considered moderately complex.

All laboratories, including accredited EMS agencies, must meet CLIA regulations for provider training, baseline education, ongoing competency, medical record keeping and quality control. The greater the laboratory’s accreditation, the greater their requirements become. Every prehospital provider who uses a glucometer has had to perform a daily high and low liquid quality control (QC) test. This test is part of the CLIA requirements for patient safety.

Every day before patient care, waived devices must be tested to ensure they are working properly against a known sample (the liquid test solution). Each provider must have an education file that contains proof of education and that initial and annual competencies have been completed and passed for each device used. Additionally, daily QC logs must be maintained. Further, physician orders (protocols) are required for each specific test performed. For example, check a patient’s blood glucose could be included in an altered mental status protocol. As more advanced devices are employed, such as the epoc blood analyzer or the i-STAT, each result is considered a test and requires an order. Thus, the protocol must be comprehensive to cover all tests for which you can get results.

For example, the epoc blood analyzer will provide you an arterial blood gas, lactate, hematocrit and hemoglobin, and basic chemistry, all with the same test. If your protocol only reads check a lactate, you cannot report and record the other results. It’s important to understand this when selecting a device to ensure that written protocols allow prehospital providers to take full advantage of the test results that can be provided.

Interestingly, there are no regulations regarding one’s ability to interpret the lab results. While prehospital providers must understand how to both run and inter-

### Table 2: Examples of Tests Granted CLIA-Waived Status

<table>
<thead>
<tr>
<th>Test</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dipstick urinalysis</td>
<td>i-STAT crea cartridge (creatinine)</td>
</tr>
<tr>
<td>Urinary pregnancy test</td>
<td>Accu-Stat drugs of abuse home tests</td>
</tr>
<tr>
<td>Fecal occult blood</td>
<td>Cholestech LDX (cholesterol)</td>
</tr>
<tr>
<td>Whole blood glucose</td>
<td>Scarlet fever rapid test</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Partial thromboplastin time (PTT)</td>
</tr>
<tr>
<td>Ovulation tests</td>
<td>i-STAT CHEMB+ cartridge</td>
</tr>
<tr>
<td>i-STAT 6+ cartridge</td>
<td></td>
</tr>
</tbody>
</table>

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pret the results, most laboratories provide results to physicians to interpret. This is an interesting gap, and for prehospital systems it means you must work closely with a medical director to determine how to use the lab results to manage patients. To help manage all of these regulations, it is beneficial to have a point-of-care coordinator to oversee implementation and management of the lab program. This coordinator must understand the training, quality control and proficiency testing regulations.

It’s best practice to have a point-of-care coordinator in CLIA-waived programs as well because even though waived tests have limited risk, they are not without risk. For example, waived glucometers have a nationally accepted variable of ±20% when hematocrit and hemoglobin levels are normal, and when anemia is present a glucometer’s variation can exceed 30%.4 One of the greatest reasons for error in obtaining results is the failure to follow proper procedures. A point-of-care coordinator can help by ensuring proper technique during initial training and practice. One of the biggest gaps CMS has found in CLIA-waived programs has been in documentation of personnel qualifications and training.1

Point-of-Care Testing

Traditional laboratory testing involves taking samples (blood) from the patient to an established laboratory. Point-of-care testing is lab testing completed at or near the patient’s bedside and outside of a traditional lab environment. The goal of POCT is to increase the speed of lab results, leading to faster diagnoses and more immediate clinical care decisions.5

All lab testing performed by prehospital systems is considered point-of-care. When a prehospital provider draws blood into tubes and delivers it to a receiving facility for analysis, POCT is not being performed, and the results are not being used in EMS decision-making. A blood draw for later use by the hospital is regulated by CLIA; however, responsibility for the blood handling is pushed onto the receiving hospital (this is why many hospitals do not accept blood drawn in the prehospital environment).

There are real and measurable benefits to point-of-care lab data, including rapid critical decision making and early disease recognition. Examples include identification of hyperkalemia (high potassium) as the cause of EKG changes that could preclude a cardiac arrest, recognizing a non-ST segment elevation myocardial infarction (NSTEMI) by an elevated troponin and identifica-

<table>
<thead>
<tr>
<th>Lactate</th>
<th>Troponin I</th>
<th>Hemoglobin A1c</th>
<th>INR</th>
<th>ABG</th>
</tr>
</thead>
</table>

Table 3: Point-of-Care Tests Considered Moderate-Complexity

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tion of septic shock by an elevated lactate level in the presence of a known infection. Utilization of point-of-care testing requires providers not only be able to read lab results, but also understand their context and significance.

It’s reasonable for all prehospital systems to consider implementing a point-of-care testing system beyond a glucometer, as point-of-care testing has been shown to alter prehospital care in up to 30% of its uses. Prehospital providers can use data to change the IV fluids administered, adjust ventilator settings and treat life-threatening electrolyte imbalances, and in community paramedicine the data can be used to provide important feedback to primary care providers about their patients.

There are many devices to consider, and while prehospital programs have typically limited themselves to CLIA-waived devices, this is no longer necessary.

Depending on the needs of your program, there are many devices on the market that can perform a range of tests. Several years ago the Lactate Pro meter was granted CLIA-waived status for serum lactate levels; unfortunately the manufacturer discontinued this device, and it is no longer available for purchase. The Lactate Plus (Nova) may soon be available for medical professionals.

There are two devices that offer comprehensive blood analysis, the i-STAT (Abbot Point of Care) and the epoc Blood Analysis System (Alere). The i-STAT is a mixed device with some CLIA-waived tests and some moderate-complexity tests. Their most comprehensive CLIA-waived test is the CHEM8+ cartridge which results electrolytes (Na, K, Cl, ionized Ca), CO₂, anion gap, glucose, creatinine, urea nitrogen, and hematocrit and hemoglobin. Several other CLIA-waived i-STAT cartridges offer a limited selection of these tests. All i-STAT cartridges capable of an arterial blood
Gas, troponin or lactate levels are moderate-complexity tests.

A downside to i-STAT cartridges is that they must be kept refrigerated and then warmed to room temperature prior to use. Alternatively, the epoc blood analyzer has one single test card which offers arterial blood gas, electrolytes (same as i-STAT), glucose, hematocrit and hemoglobin, and a lactate level. This card requires no refrigeration but is considered moderate-complex testing as well. Before picking a device, consider what tests you need and can use to manage your patient care.

**Lactate**—The use of lactate levels is quickly becoming the standard of care. Lactic acid production indicates anaerobic metabolism, so any condition that results in anaerobic metabolism leads to increased lactic acid levels. A normal lactate level is less than 2 mmol/L, and levels greater than 4 mmol/L are generally considered significant for underlying illness.

Use caution, though, when considering use of a lactic acid level. Without proper correlation to the patient’s condition, it is meaningless. Elevated lactate levels are not normal, but they don’t always mean a crisis. Following a long run, athletes are expected to have an elevated lactate, as their muscles were stressed during exercise. Understanding the significance of an elevated lactate requires knowledge of when to look for it as well. For example, an elevated lactic acid level in the presence of an infection could confirm the presence of severe sepsis; however, following a traumatic emergency it can mean hypovolemia and early stages of shock. Elevated lactate following major trauma is a predictor of ICU admission and major injury. Grand mal seizures are another common cause of elevated lactate levels.

Several years ago, several point-of-care lactic acid meters were released with the goal of helping make it easier to recognize critical illness. In 2007 some of these meters (the i-STAT and Nova’s Lactate Plus) were compared to two hospital methodologies. Investigators found the i-STAT had a bias for lower-than-expected results when analyzing known critically high lactate levels, and the Lactate Plus had a bias for higher-than-expected lactate levels. The original use of the Lactate Plus meter was to evaluate athletes, so no CLIA status was required (athletes are not considered patients in this context, so the device cannot be used for clinical decision making). In 2013, a new study demonstrated that the Lactate Plus meter can produce reliable results without bias. While the Lactate Plus has not yet gained a CLIA status for patient use, approval is expected soon. Thus, any program wishing to begin lactate testing will need to become accredited as a moderate-complexity clinical lab.

**Electrolytes**—Presently, no single point-of-care testing system can test every electrolyte. While this should eventually be corrected by device manufacturers, prehospital systems can obtain results for the electrolytes they are most likely to manage during prehospital care: potassium (K), sodium (Na) and calcium (Ca).

Normal potassium levels are 3.5–5 mEq/L. It is necessary to maintain potassium in this range to ensure proper cardiac cell function. Both hypokalemia and hyperkalemia are life-threatening emergencies that may be experienced by any patient. Patients on diuretics, potassium supplements and with end-stage renal disease are at particular risk for potassium-related emergencies.

A weekly potassium check for a heart failure patient who takes diuretics could prove lifesaving. Community paramedics can use POCT data to trend a patient’s potassium week to week and identify upward or downward trends in potassium and other electrolyte levels.

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tion can be utilized to call the patient’s physician to have medications altered, all from the patient’s home, saving the healthcare system the costs of physician visits as well as the potential cost of the in-hospital management of a hyperkalemic or hypokalemic emergency.

Sodium is the most common electrolyte in our body and has a normal range of 135–145 mEq/L. By obtaining sodium levels, prehospital providers can assess a patient’s hydration status and better evaluate which fluids to administer (or withhold) and when other drugs may be safe. Early recognition can allow earlier intervention before a true emergency develops, as both hyponatremia and hypernatremia can cause altered mental status, and hyponatremia can lead to seizures.

Hematocrit and hemoglobin—There is true value in determining a patient’s hematocrit and hemoglobin, which have baseline values of 35%–45% and 14–18 g/dL, respectively. A patient’s hemoglobin measures their actual hemoglobin level (the oxygen-carrying protein on red blood cells), while hematocrit is the percentage of the blood’s volume in red blood cells. Community paramedics can use these to monitor a chronic condition such as anemia, as well as more acute conditions such as GI bleeding. Field responders and critical care teams can establish baseline hematocrit and hemoglobin levels for later trending in the emergency department and during the patient’s hospital admission. While in acute blood loss these levels will not immediately decrease, a decline can be seen as fluid is administered (as little as 1–2 liters) and within about an hour of the body compensating for the blood loss.

Troponin I—Some prehospital systems have been drawing and determining troponin levels for several years. When managing suspected cardiac patients, the standard of care is a 12-lead EKG to look for STEMI. However, not all patients experiencing an acute coronary event have ST segment elevation on their 12-lead. The rationale of allowing paramedics to determine troponin levels has been to activate the cardiac catheterization lab for patients experiencing a non-ST segment elevation myocardial infarction.
(NSTEMI), evidenced by ongoing chest pain as well as an elevated troponin I. However, recent evidence suggests that emergent catheterization is not necessary during an NSTEMI; catheterization within 24 hours is indicated instead. Delayed catheterization should not stop a provider from obtaining a prehospital troponin level, as early recognition remains important.

This past year authors led by Joseph Venturini, MD, studied sample blood from chest pain patients and ran their blood in a controlled manner in moving ambulances. They found that mobile point-of-care testing devices can evaluate a troponin I in a moving ambulance and produce reliable results compared to the same device used in an emergency department. This study validated that these tests can be performed accurately during the prehospital phase of care. Only the i-STAT currently offers point-of-care troponin I testing in a device suitable for ambulance use. However, the test is classified as moderate-complexity, and thus the laboratory using the cartridge must obtain the proper accreditation.

Arterial blood gas—There are no CLIA-waived arterial blood gas (ABG) tests. Any lab wishing to perform an ABG must be accredited as moderate-complexity. That said, there is a real benefit to being able to perform an ABG during prehospital care. An ABG measures a patient’s pH, pCO₂, pO₂, SaO₂, and bicarbonate (NaHCO₃); for normal ranges see Table 4. All arms of prehospital care, from 9-1-1 systems to community paramedics and critical care teams, can benefit from an ABG. Response systems can use the ABG to distinguish respiratory distress from respiratory failure.

It is important that prehospital systems integrate their patient care into a patient’s hospital medical record. Integrating information can help reduce repetitive testing and streamline care. Many healthcare systems have created a process to upload prehospital 12-lead EKGs so that all healthcare providers can look at a single first 12-lead; this is especially important when managing a STEMI patient. Unfortunately, this is more challenging for laboratory data. Before a physician can use prehospital results in trending and comparison of laboratory data, two important logistical barriers must be overcome. First, the tests reported by prehospital providers must follow the same methodology as tests performed in the hospital. This is seen every day when prehospital providers identify a critically high glucose level on a CLIA-waived meter and the emergency department sends blood to the lab prior to administering insulin.

This is a particular problem for a point-of-care troponin I. While POCT can say the level was positive, the hospital cannot look at the actual number and monitor its change over time, as the hospital lab’s methodology is typically quite different from the i-STAT’s. Don’t interpret this as a reason to forego the test, but realize there are limitations. If you identify that a hospital has a different methodology than your point-of-care device, CLIA regulations mandate that its lab does not put your point-of-care results in the same system as its lab results. When testing devices use different methodologies, they are ultimately calibrated differently, which makes a comparison between devices extremely difficult.

Additionally, when selecting point-of-care devices, work with your receiving hospitals to determine what, if any, devices can be uploaded into their hospital systems. This works well when prehospital systems transport to only one or two receiving hospitals, but can be problematic among multiple healthcare systems. Some point-of-care systems have wireless technology to automatically upload at a hospital into the patient’s electronic record. When this isn’t possible, plan ahead to have the ability to print your results to leave with a receiving physician.

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and may be able to determine who should receive CPAP or intubation. Critical care teams should use an ABG on every ventilated patient to ensure ventilator settings are appropriate. Community paramedics who treat patients with chronic breathing disorders may be able to catch worsening conditions earlier and allow physician intervention before more intensive care is necessary.

Summary

Point-of-care testing is a rapidly evolving yet complex field. As your POCT program grows, take the time to understand the regulations, as they are important to ensuring patient safety. The regulations established by CLIA are designed to ensure consistent and reliable laboratory results that can accurately impact patient care. When beginning your look into POCT, first identify what labs can directly impact your patient care, then look for a device that meets your needs.

REFERENCES


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