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Trends in Point of Care Testing



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Key Points

- Point-of-care testing, with the advances in technology and connectivity in the last 20 years, has become a prominent laboratory service.
- Point-of-care testing can significantly improve laboratory turn-around times by shortening pre- and post analytical times.
- Point-of-care testing can offer easier access for patients at remote locations and other off-site areas.
- Point-of-care testing requires an inter-disciplinary effort to ensure that quality results are obtained.
- Cost-effectiveness of point-of-care testing can be realised under controlled conditions.

Point-of-care testing (POCT), also known as near-patient testing, alternate-site testing, decentralised testing, or bedside testing, is defined as the ability to provide patient testing outside of the central laboratory. POCT is not only performed at a patient's hospital bedside, but in the operating theatre, critical care unit, maternity unit, emergency department, prisons, nursing homes, physician's office, on emergency vehicles (ambulances), at health fairs, or at home. More recently, local pharmacies have adopted the technology to provide a one-stop service.

The overall intent of POCT is to make critical laboratory tests available to the care and management of patients in a timely and accessible manner. This patientcentred focus moves healthcare toward the early detection, prevention, and better management of the patient. From the early descriptions of point-of-care testing in 1984 (Hruszczyk 1998), its implementation has grown exponentially and is recognised as an independent section of the clinical laboratory. The worldwide growth of POCT has been estimated to be about 12% to 15% a year compared to the 6% to 7% growth rate of central laboratories (Wagar 2008). Other estimates put the POCT worldwide diagnostic market's worth at around \$27.5 billion (€21.6 billion) by the year 2018 (ABC12 2014).

Common Point-Of-Care Testing Analytes

Acetaminophen	Haematocrit
ACT (Activated Clotting Time)	Haemoglobin
Alcohol (Ethanol)	Lactate
ALT	Leukocyte esterase
Albumin	Nitrite
Bilirubin	Occult blood (Fecal & gastric)
Blood gases	Potassium
BNP	Protein
BUN	Prothrombin/INR
CKMb	RSV
Chloride	Sodium
Cholesterol	Specific gravity
Creatinine	Strep A
Glucose	Tuberculosis
Haemoglobin	Troponin
Haemoglobin A1c	Uric acid
HCG	Urinalysis
HIV	Urobilinogen
Hepatitis C	
H. pylori	
Influenza	
Ketones	

Table 1.

How it Works

There are three types of laboratory POCT instruments currently in use: (Price 2008).

(1). Single-use devices incorporate qualitative strips or cartridges such as dipsticks, complex strips, and immunostrips. An example would be the single-use glucose urine dipstick. Complex strips contain several layers for each pad on the stick, of which the top layer is semi-permeable keeping red blood cells from the reaction sites. Examples would be the common 10-parameter dipstick strip used for urinalysis and a strip that measures haemoglobin and glucose. Immunostrips utilise an antibody that recognises a specific analyte. Detection can be visual with the use of an immunosensor device.

(2). Single-use quantitative strip or cartridge utilises a charge-coupled device (CCD) camera that provides a quantitative value. The most frequently measured analyte is glucose. Some other analytes that have been adapted to this kind of technology are cardiac markers, electrolytes, coagulation tests, fertility tests, allergy tests, drugs of abuse, and blood gases.

(3). Multi-use cartridges are similar to the single-use device differing in its capacity to analyse more than one sample that uses a single cartridge that contains adequate amounts of reagents and calibrators for a fixed number of patient analyses.

These devices are based on technology developed in the 1950's. Using a technique borrowed from the newspaper industry that promoted quick drying of ink, a reagent-impregnated paper pad was laminated to a plastic strip that was used in testing urine (College of American Pathologists Point of Care Testing Committee 2013). Over the following several decades, a number of additional reagents were developed. Technological advances in microfluidics, optical readers, and miniature computerisation have led to the development of compact, efficient, and affordable POCT devices. Wireless connectivity to a Laboratory Information System (LIS) provides a smooth and prompt transmission of test results to a healthcare provider and the patient's medical record. It is anticipated that these portable devices will eventually incorporate the same technologies used in smartphones (SHE'D - 'shrink, hide, eliminate, and define') making POCT an even more powerful testing modality, especially as the test menu for POCT grows (College of American Pathologists 2013). Table 1 lists some of the more common analytes used in point-of-care testing.

Benefits

The main benefits of POCT are its portability and rapid turnaround time (TAT) for results. In one study (Kendall 1998), haematology, chemistry, and blood gas testing TATs were reduced by 74 minutes, 86 minutes, and 21 minutes, respectively. Based on quicker TATs, decision making was significantly altered in only 7% of patients in the cohort, yet these changes in management were critical to patient care. In addition, use of whole blood samples saves time by not having to wait for clotting and centrifuging; samples do not have to be transported to the central laboratory; and no loss of specimen integrity due to processing delays. POCT requires smaller blood samples (generally a fingerstick), thus a benefit in testing neonatal patients and difficult-draw or elderly patients. Subsequently, smaller reagent volumes are used. With improved TATs, monitoring of certain patient conditions may also be improved leading to greater patient satisfaction (Crocker 2013; Modern Humanities Research Association 2013). In non-hospital settings, follow-up office/clinic visits and phone calls may not be necessary when laboratory results are readily available (Lewandrowski 2013). This is particularly helpful with young patients and the elderly who otherwise might have to have a return office visit. When clinicians receive timely results, the length-of-stay (LOS) for patients in the emergency department may also be reduced (Hortin 2014). This can avoid unnecessary treatment or additional testing, saving time and costs (Kendall 1998). Many devices are linked wirelessly to the LIS, thus avoiding transcription errors, quicker availability of results, and appropriate documentation for billing purposes.

Disadvantages

POCT has had its share of detractors over the years, mostly regarding the reliability of results when compared to a central laboratory. Though technology has significantly improved POCT quality, there are still many opportunities for errors to occur. The Ontario Laboratory Accreditation body declared that POCT errors were a major source of error compared to other laboratory errors, generally in the analytic phase of testing, accounting for 65% of errors (Kendall 1998). While some POCT manufacturers claim that quality control practices similar to those found in a central laboratory are not necessary, it is clear that a quality systems management protocol for POCT needs to be in place (Kee 2014). A particular concern with ensuring quality practices with POCT is training. Often times, POCT is performed by non-laboratorians who may have received only a cursory introduction as to how a particular device is to be used. Even for those that have been trained, the infrequency of performing POCT can lead to procedural errors. Use of POCT in some developing countries has faced their own difficulties due to inconsistent electrical power, lighting, refrigeration, and high staff turnover (Hortin 2014). Improper care of the devices, including infection control, can result in serious problems. The Centers for Disease Control and Prevention (CDC) issued a warning when a shared glucose meter was improperly decontaminated resulting in an outbreak of viral hepatitis (Centers for Disease Control and Prevention 2012). Deploying multiple types/makes/models of devices to various hospital departments, clinics, and physician offices compounds this situation. With different devices, different procedures are needed of each type. Initial training and recurring competency assessments are critical to maintaining a quality systems POCT program (Ford 2010; Kee et al. 2014; Wagar 2008).

Conclusion

One cannot avoid talking about POCT without addressing the cost benefit of such a program. The initial outlay for equipment purchases is greater for a central laboratory compared to POCT, however, the cost per test is generally higher for POCT due to a lower economy of scale (Hruszczyk 1998). Yet, looking at expenses at a macro-level, other savings may be appreciated by shortening patient LOS. In other studies, savings (in equipment, reagents, and labour) were seen when several satellite stat laboratories were closed once POCT was implemented (Pearlman 2007). Patients that can be discharged sooner open time slots for other patients, thus increasing workload, improving patient workflow, and limiting additional expenses seen with longer patient stays.

POCT has come a long way in the past 20 years. With improved technology the test result accuracy for most POCT devices is comparable to those from a central laboratory under the proper user conditions. Quicker TATs allow clinicians to make faster medical decisions and perhaps limit

unnecessary treatments and/or other procedures (Kendall 1998; Nichols 2000). It should be noted that POCT does not necessarily mean better patient outcomes, only that results are available sooner. Also, POCT currently has limited test menus, thus clinicians may have to wait for other, more complex laboratory tests that can be performed only in a central laboratory before further patient action can be taken.

Point-of-care testing can be a tremendous asset to many types of healthcare providers and healthcare settings. Critical to having a successful POCT program is to ensure quality practices are in place and are faithfully followed. Poor training, improper care of equipment, and lack of quality control is detrimental to the program. The best programs are based on inter-disciplinary team work with the laboratory taking a lead role in managing the program. Each site that provides patient care must carefully evaluate the need for POCT, the equipment to be used, and the personnel performing the tests to ensure accurate and useful data are generated.

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