

Utilizing point-of-care testing to optimize patient care

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ARTICLE INFO

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Key words:

point-of-care testing, near-patient testing,
patient outcomes, patient-centered care

ABSTRACT

Background

Point-of-Care Testing (POCT) is clinical laboratory testing conducted close to the site of patient care. POCT provides rapid turnaround of test results with the potential for fast clinical action that can improve patient outcomes compared to laboratory testing.

Methods

Review the advantages of POCT and discuss the factors that are driving the expansion of POCT in modern healthcare

Results

Portability, ease-of-use, and minimal training are some of the advantages of POCT. The ability to obtain a fast test result and the convenience of testing close to the patient are increasing the demand for POCT. Healthcare is finding new opportunities for growth in the community and POCT is facilitating this growth.

Conclusions

This article will review the advantages of POCT and how POCT is complimenting patient care in a variety of settings.



INTRODUCTION

Point-of-Care Testing (POCT) is clinical laboratory testing conducted close to the site of patient care. (1) There are many POCT devices available for a variety of acute and chronic illnesses: glucose meters, hemoglobin A1c and ketones for diabetes; hemoglobin/hematocrit and gastric or fecal occult blood tests for anemia and bleeding; erythrocyte sedimentation rate and C-reactive protein (CRP) for inflammation; urine and whole blood human chorionic gonadotropin (hCG) for pregnancy, luteinizing hormone (LH) for ovulation, follicle stimulating hormone (FSH) for menopause, premature rupture of membranes (PROM) and fern test for delivery, semen counts for male fertility; urine dipsticks, urine and whole blood creatinine, urea, and microalbumin for renal function; cholesterol, HDL, LDL and triglycerides for lipids; troponin and brain natriuretic peptide (BNP) to diagnose myocardial infarction and manage heart failure; prothrombin (PT), international normalized ratio (INR), activated clotting time (ACT) and activated partial thromboplastin time (aPTT) to assess coagulation; urine drugs of abuse testing for addiction and emergency management; blood gas, electrolytes, basic metabolic and comprehensive chemistry panels; rapid streptococcus, mononucleosis, human immunodeficiency virus (HIV), helicobacter pylori; amines and pH for bacterial vaginosis, respiratory syncytial virus (RSV), influenza, and most recently SARS COVID-2 virus tests. The menu of POCT has grown rapidly over the past 10 – 15 years and continues to expand continuously with the introduction of new tests. The global POCT market is expected to exceed

US \$44.6 Billion by 2025 with a compound annual growth rate of 9 %.(2)

POCT are simple devices or visually interpreted dipsticks and kits. POCT is low maintenance and easy to use. A majority of POCT is waived complexity under the US Clinical and Laboratory Improvement Amendments of 1988 (CLIA), which have minimal requirements for testing. (3) CLIA waived POCT requires no performance validation prior to routine patient testing. There is no formal operator training and competency required. Operators must only follow manufacturer instructions for use. So, CLIA waived tests can be performed by non-laboratory staff with only a high school education and minimal test orientation. This allows for rapid implementation when needed. Modern POCT devices have computerized data management that collects the operator and patient ID and can transmit this information with the test result to the electronic medical record. POCT data management and operator/quality control lock-out features enhance regulatory compliance.(4, 5) POCT is portable allowing the test to be transported easily to the patient. POCT utilizes unprocessed urine and whole blood, so capillary fingerstick samples can be utilized. This facilitates testing at locations where phlebotomy isn't available.

POCT SETTINGS

POCT disrupts the current health care model where a physician sees a patient, orders a test, the patient has blood collected, the sample is sent to a lab, later results are reported back to the physician, the physician acknowledges the result and takes clinical action. With the current model turnaround of test results depends on the distance to transport a specimen to a laboratory and the speed of laboratory instrumentation. Delays can occur and results may not be delivered for several hours or days depending on the test and the complexity of laboratory workflow.

POCT brings the laboratory to the patient, simplifies the testing process and shortens the time to clinical action.

The convenience of POCT and the potential for rapid turnaround of test results find applications for POCT in a variety of healthcare settings. Historically, POCT was first implemented on hospital nursing units to allow for rapid management of acute inpatients in the intensive care units, operating rooms, and emergency departments. But outpatient use of POCT in physician offices and clinics soon followed. POCT in the clinic allows physicians to counsel patients and make treatment adjustments while the patient is being seen.

Currently, POCT has expanded beyond the clinics and is being used by school nurses and emergency medical staff at sporting events, concerts, and festivals. POCT is supplied in medical transport vehicles, helicopters, and ambulances. POCT is available on cruise ships, trains, commercial airlines, and is packed on travel tours, expeditions, and POCT (blood gas analyzers) has even been taken to the top of Mount Everest. POCT has been deployed by governments in military field hospitals, disaster relief, and medical aid to remote areas of developing countries. Exposure to extremes of temperature, humidity and other environmental conditions is a challenge in some settings. Storage and testing outside of controlled hospital or clinic conditions is a consideration in managing the quality of test results.

PATIENT-CENTERED CARE

Healthcare is moving toward patient-centered care which empowers the patient to take a role in their care. Recent regulatory changes in the US give patients the right to access their personal health information under the Health Insurance Portability and Accountability Act (HIPAA). Amendments to CLIA in 2014 allow laboratories to give completed test reports to the patient

or their representative. The final HIPAA rules were issued jointly by the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control (CDC), and the Office of Civil Rights (OCR) which is the agency that enforces HIPAA. Kathleen Sebelius, the Department of Health and Human Services (DHHS) Secretary summarized the impact of patient access to laboratory test reports, "Information like laboratory results empower patients to track health progress, make decision with healthcare professionals and adhere to treatment plans." (6)

Patient portals are websites that healthcare institutions have developed as a response to the HIPAA regulatory changes. On the patient portal, patients can see their laboratory results, ask their caregiver questions, request new appointments, view personal medical information, and pay bills. Some institutions are even providing full access to the physician clinical notes in the medical record. Patient portals are a one-stop shop for the patient's healthcare needs. POCT results as well as laboratory results are visible. While physicians have been the traditional client of the laboratory, our test results and comments that accompany those results, need to change so that the comment is understandable and interpretable by the general consumer without a medical background. We need to rethink common abbreviations like QNS (quantity not sufficient) or technical terms like icterus in lieu of common descriptors like "insufficient sample volume to perform test" or "bilirubin interference".

With the recent COVID pandemic more emphasis is being placed on telehealth and remote healthcare. Patient portals are just one means of connecting physicians with patients who may be on quarantine or working from home. POCT plays a role in these changing healthcare models. Home testing devices can download results into the patient's medical record for the physician to review. Patient self-testing devices like PT/INR and glucose meters are available, but

data from monitoring devices like continuous glucose monitors, blood pressure, pulse oximeters and even weight from digital scales can also be downloaded to monitor the patient remotely. Video conferencing can monitor the condition and demeanor of the patient, assess for overall status, and even take size measurements to assess wound recovery. Wearable devices and health applications in smart watches can monitor temperature, pulse, and other parameters to warn of potential fever, or alert to ovulation for fertility cycles. More health information is available to physicians remotely than ever before.

CHANGING HEALTHCARE MODELS

Delivery of healthcare is changing to better meet patient needs. People are busier than ever during the COVID pandemic, working from home, virtual schooling their children, on top of the daily responsibilities of cooking, cleaning, and maintaining the house. Getting a doctor appointment may be challenging with fewer appointments available and the risk of contact with other patients in the waiting rooms. So, doctor-on-call services are becoming more popular. These services allow the patient to rest where they are while a doctor or nurse practitioner comes to them. Originally developed in partnership with hotel concierge to provide service for tourists or visitors who may get sick while traveling and not know where to turn. Now, phone applications are available to place a request (similar to calling an uber or lyft car service) where the health problem is described, and the doctor-on-call responds with an estimated time of arrival. The doctor-on-call goes to the patient's hotel room, home or apartment, takes a medical history, performs a basic physical exam, and offers starter packs of medications until the patient gets home or can have a pharmacy deliver a full prescription. POCT is offered by the doctor-on-call with tests such as rapid strep, influenza, pregnancy, urine

dipsticks. With the recent COVID pandemic, this service can even collect nasal swabs to deliver for laboratory testing while the patient quarantines at home or in their hotel room.

Pharmacies are also taking a greater role in healthcare. People often wake up not feeling well but cannot get an appointment the same day to see their routine doctor. So, many pharmacies are opening clinics where the patient can sign-up for a same day appointment and wait in their car until called in for their appointment. This decreases the contact between patients in a waiting room. These pharmacy clinics provide a variety of services including pre-employment, sports and school physicals, immunizations, allergies, rashes, bites, screening for sexually transmitted infections, travel medicine, diabetes screening, pregnancy, and smoking cessation. Some even have EKG and X-ray machines available on-site to assess for conditions, sprains, and fractured bones. These clinics offer a range of POCT including PT/INR, influenza, glucose and hemoglobin A1c, urinalysis, rapid streptococcus, mononucleosis, pregnancy and even molecular POCT for SARS CoV-2. The pharmacy clinic performs phlebotomy and can collect specimens to send out for other tests not available on-site. Some of these clinics are even being run by larger medical institutions as a means of community outreach and to provide for care of lower acuity conditions as an outpatient rather than an emergency room visit. Some pharmacies and healthcare institutions are even offering drive-thru healthcare services for collection of nasal swabs for SARS CV-2 testing and as flu vaccination centers.

CONCLUSIONS

POCT is an increasingly popular means of providing laboratory testing with rapid turnaround of test results close to the patient. A wide menu of POCT is currently available and new tests are

continuously being introduced on the market. POCT is utilized in a variety of healthcare settings and is taking on new roles with the recent COVID pandemic. Doctors-on-call and pharmacy clinics are just two examples how healthcare is connecting with the community to drive patient-centered care. The patient is in the driving seat, taking charge of their health and demanding healthcare services that meet their needs at their convenience and timeframe. The future of POCT promises new sensors, wearable devices and smart technologies that are less invasive and can better connect the patient with their physician. The convenience and ease-of-use will find new POCT applications and develop novel ways that laboratory diagnostics can improve patient outcomes in the future.

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