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Current Status of Clinical Application of Point-of-Care Testing

Hyung-Doo Park, MD, PhD

• ***Context.***—**The clinical applications of point-of-care testing (POCT) are gradually increasing in many health care systems. Recently, POCT devices using molecular genetic method techniques have been developed. We need to examine clinical pathways to see where POCT can be applied to improve them.**

Objective.—**To introduce up-to-date POCT items and equipment and to provide the content that should be prepared for clinical application of POCT.**

Data Sources.—**Literature review based on PubMed searches containing the terms *point-of-care testing*, *clinical chemistry*, *diagnostic hematology*, and *clinical microbiology*.**

Conclusions.—**If medical resources are limited, POCT can help clinicians make quick medical decisions. As POCT technology improves and menus expand, areas where POCT can be applied will also increase. We need to understand the limitations of POCTs so that they can be optimally used to improve patient management.**

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Point-of-care testing (POCT) is defined as a laboratory test performed outside a central laboratory, usually at or near a clinical treatment site or by a patient. In most circumstances, medical staff perform POCT, but patients perform some POCT at home. Point-of-care testing is usually performed when quick decision-making is required, such as in an emergency room or when urgent treatment is to be determined. The advantages of POCT compared with central laboratory testing include shorter wait times for results and earlier discharge home.[1] The Table shows common POCTs and clinical situations. Current commercial point-of-care (POC) platforms can produce results faster than laboratory-based assays, but this improvement generally results in reduced accuracy.

Many analytes can be qualitatively detected or quantitatively measured using POCT; examples of commonly used POCTs are tests for glucose, blood gases, cardiac markers, urinalysis, creatinine, prothrombin time/international normalized ratio (INR), infectious diseases (human immunodeficiency virus [HIV], respiratory syncytial virus, influenza, etc), and drug screening. The considerable success of POCT is attributed to increasing clinical demand, heavy industry promotion, short turnaround time, economical and practical factors, and advancements in technology, such as lab-on-a-chip systems that use miniaturization, micromachining, microfluidics, nanotechnology, and wireless communication.[2]

This paper aims to describe the different applications of POCT and to review their limitations so that they can be used in the appropriate clinical pathways.

DIAGNOSTIC HEMATOLOGY

In hematology, POCT is generally limited to hemoglobin and hematocrit testing by blood gas devices and point-of-care coagulation monitoring, such as prothrombin time and INR for patients on warfarin.

Some studies have investigated portable instruments using newer technology, such as single-sample cuvettes and image analysis, microfluidic cartridges, and the lab-on-a-chip/micro total analysis system platform, which provides complete blood cell count tests including 3-part differential white blood cells, red blood cells, platelet count, and hemoglobin for rapid diagnosis in resource-poor environments.[3–5] A rapid complete blood cell count and differential blood panel can help clinicians determine whether a patient is suffering from a viral or bacterial infection and whether he or she requires admission and antibiotics.

The use of POC INR testing has become popular for at-home testing and allows patients to easily use a device to monitor their INR and report their results to a clinician (either in person or via telephone), who can then adjust anticoagulant dose, if necessary.[6] The most common symptom of patients with venous thromboembolism is chest pain or dyspnea, but patients may also present with leg problems, arm pain, or chest tightness, or be asymptomatic.[7] In a systematic review and meta-analysis of 11 trials with data for 6417 participants and 12 800 person-years of follow-up, there was a significant reduction in thromboembolic events in the self-monitoring INR group (hazard ratio, 0.51; 95% CI, 0.31–0.85) on oral anticoagulation.[8] Participants younger than 55 years showed a striking reduction in thrombotic events (hazard ratio, 0.33; 95% CI,

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From the Department of Laboratory Medicine and Genetics, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Republic of Korea.

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Corresponding author: Hyung-Doo Park, MD, PhD, Department of Laboratory Medicine and Genetics, Samsung Medical Center, Sungkyunkwan University School of Medicine, 81 Irwon-ro, Gangnam-gu, Seoul 06351, Republic of Korea (email: nayadoo@hanmail.net).

Common Point-of-Care Tests	
Test	**Clinical Setting**
Blood gases	ICU settings, emergency rooms, operating rooms
Cardiac markers	Emergency rooms
Creatinine	Radiology suites prior to contrast administration
Diabetes (glucose, HbA_{1c})	Home monitoring for patients with diabetes, inpatient monitoring for glycemic control
Drug screening	Emergency rooms, outpatient treatment programs, workplace testing
hCG (pregnancy)	Emergency rooms, ICU settings
Infectious diseases (HIV, RSV, influenza, etc)	Outpatient and emergency settings for treatment decisions and cohorting or isolation
PT/INR	Coagulation clinics, cardiology practices, home monitoring
Urinalysis	Physician offices

Abbreviations: HbA_{1c}, hemoglobin A_{1c}; hCG, human chorionic gonadotropin; HIV, human immunodeficiency virus; ICU, intensive care unit; INR, international normalized ratio; PT, prothrombin time; RSV, respiratory syncytial virus.

0.17–0.66), as did participants with mechanical heart valves (hazard ratio, 0.52; 95% CI, 0.35–0.77), so the authors[8] suggested that patients should be offered the option to self-manage their disease with suitable health care support.

In one investigation,[9] negative D-dimer test was valuable in ruling out acute pulmonary embolism in patients with a low pretest probability in hospital outpatient or accident and emergency settings. Combined with pretest probability scores, point-of-care D-dimer tests are a quick and safe way to rule out venous thromboembolism and improve patient experience.[10] In addition, the D-dimer POC device was comparable with the laboratory device and was sufficiently accurate for use as a screening tool in the emergency department (ED) setting.[11] In a prospective observational study[12] of 104 patients who underwent simultaneous D-dimer measurements using the 2 analyzers, the median time for D-dimer results from triage by VIDAS (bioMérieux SA) was 258 minutes (interquartile range, 173–360 minutes) and that by AQT90 FLEX POCT analyzer (Radiometer Medical ApS) was 146 minutes (interquartile range, 55–280.5 minutes). Following implementation of the rapid whole blood D-dimer test in the ED, there was a 13.8% decrease in patients admitted to the hospital, a 7.3% increase in patients discharged from the ED, and a 6.4% increase in patients admitted for observation only.[13] General practitioners can safely exclude pulmonary embolism by using the Wells criteria in combination with either a qualitative POC D-dimer or a quantitative D-dimer test.[14]

CLINICAL CHEMISTRY

Glucose testing is the most commonly used POCT item in the field of clinical chemistry. The most common POC glucose test is glucose testing strips, which comprise 53.7% of the total global POCT market.[15] Blood glucose POCT was first used primarily at home or in nursing homes and was later expanded to inpatient settings, such as intensive care and postoperative inpatient environments, to help achieve strict glycemic control. Intensive glycemic control reduces long-term microvascular complications of diabetes. Previous representative reports include the Diabetes Control and Complication Trial[16] in subjects with type 1 diabetes and the United Kingdom Prospective Diabetes Study[17] in subjects with type 2 diabetes.

Van den Berghe et al[18] followed 1548 patients and reported that intensive blood glucose control to levels of 79–110 mg/dL using insulin decreased mortality from 8% to 4.6% in a small homogenous population of patients in the surgical intensive care unit (ICU). Although POCT glucose meters using whole blood may be ideal in the ICU, risks of POCT include increased variability of results; as such, routine use of capillary blood sampling to monitor glucose level is not recommended in critically ill patients.[19,20] The reliability of POCT glucose measurements depends upon a variety of factors, including underlying disease, patient drug regimens, interfering substances, and instrument analytical performance. Therefore, laboratory blood glucose analysis is recommended if a POCT glucose value is in the critical hypoglycemic or hyperglycemic range.[21] A newer-generation (StatStrip, Nova Biomedical) POC glucose meter met more stringent accuracy criteria because of reduced bias compared with the previous-generation device,[22] and implementation of StatStrip led to better agreement with venous plasma glucose, improved detection of critical low glucose results, and more efficient test utilization.[23,24]

New technologies, such as continuous glucose monitoring (CGM) systems, may help alleviate the risks associated with glucose fluctuations in the ICU.[25–27] Recently, the implantable CGM system (Eversense CGM System, Senseonics) was reported to provide accurate glucose readings through the intended 90-day sensor life with a favorable safety profile in participants with type 1 or type 2 diabetes.[28,29] However, one study[30] indicated that the use of intermittent retrospective CGM did not reduce the risk of macrosomia in 300 randomized pregnant women with type 1, type 2, or gestational diabetes to either CGM (n = 147) or standard treatment (n = 153). Women who were randomized to CGM had a lower hemoglobin A_{1c} (HbA_{1c}) concentration by the end of the pregnancy and smaller babies (reduced median customized birth weight centile and reduced rate of large-for-gestational-age [>90th percentile] infants) compared with women in the usual-care group.[31]

In addition to serum glucose tests, HbA_{1c} measurements are useful for tracking patients with diabetes. Point-of-care testing for HbA_{1c} is increasingly performed in outpatient conditions to monitor glucose control in diabetes mellitus. Laboratory HbA_{1c} is established for both monitoring glycemic control and diagnosing diabetes.[32,33] The American Diabetes Association[32] recommends an HbA_{1c} cutoff of 6.5% (48 mmol/mol) to diagnose diabetes, which is the threshold at which moderate retinopathy is detected. In a case-control study[34] of 607 pregnant women between the 24th and 28th weeks of gestation, screening for gestational diabetes mellitus by measuring HbA_{1c} by G8 (Tosoh Corporation) reduced use of the glucose challenge test. Availability of rapid HbA_{1c} measurements using the DCA 2000 instrument (Bayer) increased the frequency of therapy intensification and lowered HbA_{1c} level in patients with type

2 diabetes in an urban neighborhood health center.[35] The Abbott (formerly Alere) Afinion AS100 HbA_{1c} Dx device is the first and only POC HbA_{1c} method cleared by the US Food and Drug Administration to aid health care professionals in the diagnosis of diabetes.

Several reports[35–40] have cited advantages and disadvantages of the POC HbA_{1c} test in diabetes management, treatment adaptation, and glycemic control. In addition, many studies[38,41–45] have shown advantages of the POC HbA_{1c} test in terms of patient satisfaction and cost-effectiveness. Several studies[46–49] of various POC HbA_{1c} systems identified significant differences in analytical performance, including precision and accuracy. Some HbA_{1c} POC devices had excellent analytical performance, whereas some were not acceptable; continuous performance improvements are needed.[46–49] Imprecision (coefficient of variation) ranged from 1.8% to 4.9% at an HbA_{1c} value of 4.7% to 5.2% for 6 POC instruments (DCA Vantage, Siemens Diagnostics; In2it, Bio-Rad; Afinion, Axis-Shield; Nycocard, Axis-Shield; Clover, Infopia; and InnovaStar, DiaSys).[48] According to data of 6 years of accuracy-based proficiency testing for HbA_{1c}, POCT for HbA_{1c} measurement showed the highest "unacceptable" rate and imprecision.[50] This indicates that the limitations of POCT equipment on precision and accuracy need to be understood and improved. Intensive educational efforts combined with external quality assessment improve the preanalytical phase in general practitioner offices and nursing homes.[51]

Point-of-care testing for creatinine and cardiac markers in the ED is also rapidly changing. Molecularly imprinted polymers have been used as recognition elements in biomimetic sensors contain binding sites complementary in shape and functionality to their target analyte, and molecular imprinting was critically evaluated with respect to detection of cardiac biomarkers indicative of acute coronary syndrome.[52] The most obvious contribution of POCT to cardiovascular disease evaluation is diagnosis of acute coronary syndrome. Currently, diagnosis of acute myocardial infarction is dependent on the change of cardiac troponin (cTn) concentrations, with at least one measurement above the 99th-percentile upper reference limit and evidence of one other listed criterion specified by the European Society of Cardiologists.[53] Despite the importance of the analytical sensitivity of cTn measured by POC devices, there are significant differences in limit of detection among equipment using biosensors and biomimetic sensors for cardiac biomarkers.[52] Although high-sensitivity cTn assays measure relatively low values and document small increases above the 99th percentile upper reference limit, many contemporary and POC cTn assays may not detect small increases within the reference interval or at slightly above the 99th-percentile upper reference limit. This may lead to substantial differences in frequency of events based solely on the cTn assay used.[53] The decision to implement cTn POCT can significantly increase the capacity and efficiency for diagnosing acute myocardial infarction and other related conditions.[54,55]

The analytical sensitivity (limit of detection) of cTnI and cTnT in 12 POC assays varies 20-fold, ranging from 0.008 to 0.15 μg/L.[56] The 99th percentile of cTn values ranges from 0.01 to 0.2 μg/L.[56] In addition, the 99th percentile variability between assays is significant and shows lack of standardization of cTnI and cTnT assays.[56] When a single common population of patients with suspected acute coronary syndrome was used for analysis, the Alere Triage Cardio3 TnI assay (Alere) and the PathFast cTnI-II (Mitsubishi Chemical Medience Corporation) assay had similar diagnostic performance to the central laboratory assay Singulex Erenna TnI (Singulex).[57] The use of point-of-care cTnI measurement allows early rapid diagnosis or exclusion of myocardial infarction. The use of the additional measurement of myoglobin and CK-MB does not provide further diagnostic information.[58] Additional use of ultrasensitive copeptin improves the diagnostic performance of conventional sensitive POCT assays for cTn to overcome lower sensitivities at the cost of decreased clinical specificity.[59]

Point-of-care systems could be used to assess natriuretic peptide, B-type natriuretic peptide, or N-terminal pro–B-type natriuretic peptide levels in the ED and community outpatient settings to monitor the risk of acute heart failure; median time to discharge was reduced with versus without POCT (8.8 hours versus 14.2 hours, $P < .001$).[60] Natriuretic peptides are an important objective tool in diagnosis, prognosis, and management of heart failure, and POCT is a valuable tool for obtaining real-time information, particularly in the emergency room.[61]

Other rapidly developing areas of POCT in the ED are creatinine measurement and pregnancy tests, both of which are used to determine whether patients can be properly referred for radiologic procedures.

Contrast-induced acute kidney injury occurs rarely in patients exposed to iodinated contrast. Screening patients at risk for postcontrast acute kidney injury may be feasible with creatinine POCT technology, as all at-risk patients were identified by several analyzers: i-STAT (Abbott), StatSensor (Nova Biomedical), epoc (Siemens), ABL90 Flex Plus (Radiometer Benelux), ABL800 FLEX (Radiometer Benelux), and STAT Profile Prime+ (Nova Biomedical).[62,63] In another study, i-STAT and epoc were the most well-functioning POC devices but were less user-friendly. StatSensor did not meet any of the error criteria for creatinine or estimated glomerular filtration rate measurements. However, it was more user-friendly than the other POC devices.[64]

Stomach pain, cramps, spasms, and obstetric complications are leading primary causes for women between 15 and 64 years of age to visit the ED.[65] Qualitative urine human chorionic gonadotropin (hCG) POCT is widely used in the ED to assess patient pregnancy status because presenting symptoms may be indicative of an abnormal pregnancy (abdominal pain, vaginal bleeding, pelvic discomfort, and miscarriage), or exclusion of pregnancy is required prior to performing diagnostic or therapeutic interventions that could harm a developing fetus.[55] The claimed lower limit of detection for urine hCG in many POC devices ranges from 6.3 to 50 mIU/mL, with most falling between 20 and 25 mIU/mL.[66] Some reports have shown that qualitative hCG POC devices can result in erroneous negative consequences due to excess hCG variants[67–71] and poor analytical sensitivity.[72–74] Kamer et al[75] reported that 4 commonly used hCG POC devices (Alere hCG Combo Cassette [Alere], ICON 20 hCG [Beckman Coulter, Inc.], OSOM hCG Combo Test [Sekisui Diagnostics, LLC], and Sure-Vue Serum/Urine hCG-STAT [Fisher Scientific]) were susceptible to false-negative results at low concentrations of urine hCG. An evaluation of sensitivity for the hook effect caused by hCG β core fragments showed that susceptibility to inhibition of 11 types of POCT equipment varied greatly; only 2 devices exhibited minimal to no susceptibility to hCG β core fragments.[67] Laboratory physicians and clinicians

should be aware of the limitations of using urine hCG POC devices to rule out early pregnancy.

Drug screening tests are frequently ordered in patients presenting to the ED with acute psychiatric symptoms such as agitation, ataxia, delirium, altered mental status, or psychosis. There are advantages and disadvantages regarding the usefulness of drug of abuse screening in an emergency room. Tenenbein[76] reported that emergency drug screening was unlikely to significantly impact patient management in the ED. Point-of-care testing for drugs of abuse and therapeutic drugs in the ED may be effective, less costly, and more rapid than the laboratory-based screening system.[77–79] However, immunoassays for drugs of abuse have poor specificity (inaccuracy), and there is no correlation between the presence of drugs or metabolites in the urine and toxic effects or clinical impairment.[80] Point-of-care testing is based on immunochromatography, in which a drug in the patient's sample competes with drug and antibody conjugates in the test to allow or block development of a colored line; most POCTs are visually interpreted in a few minutes.[81] An optimal screening test is not an optimal diagnostic test, and urine drug screens are primarily designed as a screening test.[76] Interpretation of negative screening results, whether expected or unexpected, can also be challenging. Several factors must be considered, including assay cutoff, cross-reactivity, time since last dose, low immunoreactivity, and individual metabolism.[80] The nature of the screening test allows false-positive results in some cases, but additional gold standard confirmatory testing, such as chromatography and mass spectrometry, can be carried out for confirmation.

Urine and serum (or plasma) are the most frequently used specimens for clinical toxicologic testing, but oral fluid may also be a rapid and accurate way to screen for psychoactive substances.[82] Overall estimates of reliability in oral fluid with POCT devices showed high variability for detecting amphetamines, benzodiazepines, cannabinoids, cocaine, and opioids.[83] When choosing a POCT device, certain features should be considered, such as forensic utility, reliability of device manufacturer, specimen type, test menu, analytical methodology and performance, result interpretation, and cost.[83,84]

Point-of-care testing blood gas analyzers for electrolytes and basic metabolic panels including β-hydroxybutyrate and lactate measurements facilitate management of several scenarios and may be useful in ED and ICU settings.[55] There is fair evidence that POCT of arterial blood gas results in the ICU and ED leads to improved clinical outcomes when POCT reduces therapeutic turnaround time compared with central laboratory testing.[85] Although arterial blood gas analysis remains the gold standard to assess acid-base, ventilation, and oxygenation status in critically ill patients, venous blood gas analysis has been shown to correlate with arterial blood gas analysis and has been proposed as a safer, less invasive alternative to arterial blood gas analysis for undifferentiated critically ill patients in the ED and ICU.[86,87] Calculated arterial blood gases from venous samples and pulse oximetry are comparable to arterial blood gas values. Point-of-care testing could reduce the logistic burden of arterial sampling, facilitate improved screening and follow-up, and reduce patient pain.[88] A retrospective study and prospective analytical observational studies at multiple health care sites showed sufficient agreement between sodium, potassium, and ionized calcium results obtained from blood gas and central laboratory analyzers to enable prompt clinical decision-making.[89–91] With proper training and education of the ED care team, POCT can be used as an effective tool for managing patient flow in the ED.[92]

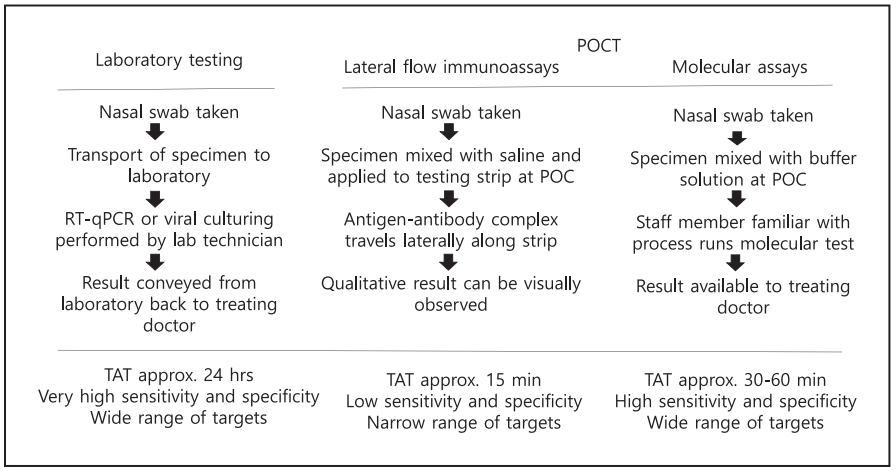
C-reactive protein (CRP) provides diagnostic value for ruling in or ruling out serious bacterial infection in febrile children.[93] Preantiretroviral therapy POC CRP testing may reduce mortality by identifying HIV patients at high risk for poor outcomes.[94] Brouwer and van Pelt[95] compared 2 semiquantitative strips (Actim CRP strips [Medix Biochemica] and Cleartest CRP strips [Servopax]) and 6 quantitative CRP tests (Afinion AS 100 analyzer [Axis Shield], QuikRead go [Orion Diagnostica], Smart analyzer [Eurolyser Diagnostica], iChroma analyzer [Boditech Med Inc.], Microsemi [Horiba Ltd.], and AQT90 FLEX [Radiometer Medical ApS]) to the Synchron CRP method (Synchron analyzer; Beckman Coulter), using the Clinical and Laboratory Standards Institute EP9 protocol. They concluded that the semiquantitative CRP strips could be used to discriminate between normal and increased levels of CRP, and that the Smart and Afinion would be the preferred quantitative analyzers for POCT, taking into account both analytical validation and practical evaluation.[95] Immunochromatographic methods were used in semiquantitative strips, and various methods such as immunoturbidimetric assay, solid-phase immunochemical assay, fluorescence sandwich immunoassay, and solid-phase sandwich immunoassay were used in quantitative CRP analyzers.[95] In addition, immediate POC CRP testing is reliable in forensic settings such as during autopsy and at postmortem inspection.[96]

CLINICAL MICROBIOLOGY

Point-of-care testing immunodiagnostics in routine clinical laboratories commonly depend on antibodies as biorecognition elements in which the biomolecular interaction is monitored by sophisticated equipment provided by the assay manufacturer. Most widely applied recognition elements are monoclonal or polyclonal antibodies.[97] The World Health Organization has called for development of a rapid, biomarker-based, nonsputum test capable of detecting all forms of tuberculosis at the POC to enable immediate treatment initiation. Lipoarabinomannan is the only World Health Organization–endorsed tuberculosis biomarker that can be detected in urine, an easily collected sample.[98]

Lateral flow immunoassay is the most popular diagnostic tool that meets the required standards for colorimetric assays.[99] Lateral flow immunoassay provides sensitive and precise quantitative determination of target analytes because it carries out immunologic recognition at a variety of concentrations with frequently used labels, such as gold nanoparticles, quantum dots, and up-converting phosphorescent labels.[100] However, limitations should be considered according to the characteristics of the lateral flow immunoassay, such as visual interpretation and the possibility of misunderstanding, incorrect timing (read within a specific time), detection sensitivity, and manual input of results.

Quantitative reverse transcription polymerase chain reaction is the reference standard laboratory test for influenza diagnosis. New rapid diagnostic tests for influenza that show sensitivity and specificity comparable to those of real-time polymerase chain reaction assays are available (Figure).[101–104] Diagnosis of patients with influenza by POCT resulted in significantly higher rates of antiviral prescription in a systematic review of the impact of POCT for influenza on outcomes of patients with acute respiratory tract



Generalized steps in methods of diagnostic testing for influenza (adapted from Egilmezer et al[101] with permission). Abbreviations: POC, point of care; POCT, point-of-care test; RT-qPCR, quantitative reverse transcription polymerase chain reaction; TAT, turnaround time.

infection.[101] Although rapid molecular POCT for respiratory viruses (FilmArray Respiratory Panel, BioFire) in adults presenting to a hospital with acute respiratory illness was not associated with reduction in overall duration of antibiotics, more patients in the POCT group than in the control group received single doses or brief courses of antibiotics.[105] Importantly, a negative POCT test does not confirm the absence of influenza, and ED clinicians should use other confirmatory tests to avoid diagnostic delays or to confidently exclude influenza.[106]

Multiplex detectability is necessary for emergency treatment depending on disease stage or interactional infections. Brendish et al[107] reported several molecular platforms with potential for POCT use and evidence for clinical and economic benefits of testing for respiratory viruses in adults: Alere i Influenza A&B (Alere), FilmArray Respiratory Panel (BioFire Diagnostics), and Xpert Flu (Cepheid). Use of the FilmArray Respiratory Panel for detecting influenza A (H1 and H3), influenza B, respiratory syncytial virus, rhinovirus, enterovirus, human metapneumovirus, parainfluenza virus types 1 through 4, coronaviruses (OC43, 229E, HKU1, and NL63), and adenovirus was associated with reduced length of stay, improved influenza detection, and antiviral use, and appeared to be safe.[105] Hagen et al[108] suggested that introduction of a FilmArray meningitis/encephalitis panel into routine clinical procedures is associated with significantly reduced length and days of therapy for empiric antiinfective treatment in children with suspected meningoencephalitis (4.0 versus 3.0, $P = .04$, and 8.0 versus 6.0, $P = .02$, respectively). Patients with exacerbation of airway disease should undergo respiratory virus testing at the POC using a comprehensive syndromic multiplex panel rather than a molecular POCT for influenza alone, which would not detect the majority of viruses associated with early antibiotic discontinuation.[109]

An evaluation of 4 POC HIV tests (Chembio DPP HIV-1/2, Determine HIV-1/2 Ag/Ab Combo, INSTI HIV-1/HIV-2 Rapid Antibody Test, and OraQuick ADVANCE Rapid HIV-1/2 Antibody Test) using unprocessed oral fluid and whole blood specimens showed that sensitivity of whole blood POCTs ranged from 95.53% to 97.21%, and specificity was high for all tests (range, 99.44%–100.00%).[110] Despite relatively high specificity and sensitivity of POC HIV tests, the authors[110] suggested that organizations should have a plan to manage false results that occur because of the limitations of POCTs (eg, lower sensitivity to identify acute HIV infection, effects of antiretroviral therapy and pre-exposure prophylaxis on oral fluid tests, low positive predictive value among pre-exposure prophylaxis populations). In a systematic review and meta-analysis,[111] rapid POC HIV testing was highly accurate compared with conventional tests and offered a clear advantage of timely interventions to reduce mother-to-child transmission of HIV. If POCT results for HIV are indeterminate, the test result should not be considered preliminarily positive or negative, and repeat POC HIV testing or HIV testing at an approved HIV testing laboratory is required.[112] Dual POCT screening for HIV and syphilis (SD BIOLINE HIV/Syphilis Duo Test, Standard Diagnostics; MedMira Multiplo Rapid TP/HIV Antibody Test, MedMira; and Chembio Dual Path Platform HIV/Syphilis Assay, Chembio Diagnostic System) was more cost-effective than single rapid tests and prevented more adverse pregnancy outcomes.[113] The FACSPresto POC $CD4^+$ T-cell test (Becton Dickinson) is useful and does not have significant variability in reliability when performed by nonlaboratory health care workers. Hence, it may be a valuable instrument to increase access and coverage of CD4 estimations for monitoring HIV-infected individuals in developing countries.[114–116] Expansion of molecular POC type *Mycobacterium tuberculosis* testing, including drug resistance testing, is also highly desired and necessary.[2]

The coronavirus disease 2019, which began in December 2019, is a severe acute respiratory syndrome coronavirus 2 infection, and real-time reverse transcription polymerase chain reaction is currently the most reliable diagnostic method for coronavirus disease 2019 around the world.[117] Serologic testing may be helpful for diagnosis of suspected patients with negative reverse transcription polymerase chain reaction results and for identification of individuals with an adaptive immune response to severe acute respiratory syndrome coronavirus 2, indicating recent or prior infection.[118] But the POC immunochromatographic immunoglobulin (Ig) M/IgG antibody assay had low sensitivity during the early phase of severe acute respiratory syndrome coronavirus 2, and immunochromatographic assay alone is not recommended for initial diagnostic testing for coronavirus disease 2019.[119]

CONCLUSIONS

Point-of-care testing is likely to play an increasing role in health care delivery in the future. It will improve access to

health care and increase the efficacy of service provided to patients.[49] Although POCT provides laboratory results faster than the traditional central laboratory, process improvement is needed to optimize the accuracy of laboratory results.[92]

Molecular POCT for common pathogens in select populations, such as in intensive care or other common illness presentations, needs to be evaluated to further improve patient care and effectively manage health care resources.[120] Despite several advantages of POCT, limitations include cost, imprecision and inaccuracy, requirement for an interdisciplinary approach, and human error. Although the use of POCT is expanding in many areas, the limitations must be understood and improvements in analytical performance achieved to properly interpret POCT results.

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