Point of Care Testing

White Paper

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Executive Summary

Clinical diagnostic laboratory tests detect disease, confirm diagnoses, monitor chronic conditions and assess overall patient health. To maximize the impact of these tests on patient management and health outcomes, test results must be timely and accurate. Delivering rapid and accurate diagnostic information to treating healthcare professionals improves individual patient care (at potentially lower cost) and may improve public health more broadly, particularly in underserved populations.

"Send-out" testing performed in reference laboratories can take days or weeks to return results. This delay may impede appropriate patient management and increase the likelihood that patients will not receive clinically indicated treatment or follow-up in a timely manner. Inadequate follow-up after testing is a significant challenge globally—the World Health Organization World Alliance for Patient Safety identifies it as a priority and has issued guidelines and landscape analyses supporting the use of point of care (POC) infectious disease tests, including sexually transmitted disease testing and rapid tuberculosis tests, among others.[1,2,3] Lengthy turnaround times for test results also can have serious negative impacts on quality of care, a patient's treatment plan and patient outcomes.

In contrast to traditional send-out testing, point of care testing (POCT) is performed where healthcare is provided, close to or near a patient.[4] In many cases, POCT returns results to the treating clinician within minutes, while the patient is still present at the healthcare encounter. Currently available POCT tests can diagnose, monitor or assess the status of a wide range of conditions. Providing faster access to reliable results enables providers to expedite diagnosis and treatment decision-making, which in turn improves patient care.[5] POCT also can reduce unnecessary hospital admissions and expensive follow-up tests by identifying or ruling out other illnesses.[6]

POCT is appropriate to meet the needs of a wide variety of patients. POCT is available for a variety of infectious and chronic diseases and can be used in both hospitals and primary healthcare settings.[7][8] Ongoing technical improvements and increasing

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[1] The Research Priority Setting Working Group of the World Alliance for Patient Safety. *Summary of the evidence on patient safety: implications for research*. Geneva, Switzerland: World Health Organization, 2008. https://apps.who.int/iris/handle/10665/43874.
[2] *WHO Standard: Universal Access to Rapid Tuberculosis Diagnostics* (World Health Organization, 2023).
[3] *Point-of-care tests for sexually transmitted infections: Target product profiles* (World Health Organization, 2023).
[4] Kost GJ. *Principles and practice of point-of-care testing.* Philadelphia: Lippincott, Williams and Wilkins; 2002.
[5] Uys PW, Warren R, van Helden PD, *et al*. Potential of rapid diagnosis for controlling drug-susceptible and drug-resistant tuberculosis in communities where Mycobacterium tuberculosis infections are highly prevalent. *J Clin Micro.* 2009;47:1484–90.
[6] St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev. 2014 Aug;35(3):155-67. PMID: 25336761; PMCID: PMC4204237.
[7] Florkowski C, Don-Wauchope A, Gimenez N, Rodriguez-Capote K, Wils J, Zemlin A. Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM) – does it leverage any advantage in clinical decision making? *Crit Rev Clin Lab Sci*. 2017; 54:471–494. doi: 10.1080/10408363.2017.1399336.
[8] Chen H, Liu K, Li Z, Wang P. Point of care testing for infectious diseases. Clin Chim Acta. 2019 Jun;493:138–147. doi: 10.1016/j.cca.2019.03.008. Epub 2019 Mar 8. PMID: 30853460; PMCID: PMC6462423.

acceptance will only increase POCT's positive impact on patient outcomes, laboratory workloads and healthcare-associated costs.[9]

Background

Clinical utilization of POCT is primarily intended to improve patient outcomes by expediting the delivery of accurate and timely results to inform patient care plans, allowing such plans to be both evidence based and cost effective.[10] POCT may be performed in a variety of settings, including physician offices, outpatient clinics, pharmacies, intensive care units, emergency rooms and skilled nursing facilities.[11] POCT is performed on easily obtained specimen types, such as blood, urine, saliva or swabs from mucosal surfaces. Clinicians use POCT devices to test for and monitor both noncommunicable diseases that require continuous oversight (*e.g.*, diabetes mellitus, congestive heart failure and long-term anticoagulation) and acute infections that require timely delivery of targeted treatment to prevent the spread or progression of the illness (*e.g.*, strep throat, urinary tract infections, methicillin-resistant Staphylococcus aureus and respiratory viruses).

POCT analytical systems accurately and quickly detect many diverse analytes, often with easy-to-use analyzers that do not require substantial operator training. Unlike traditional laboratory testing, which may require time to produce actionable results (*e.g.*, to allow for transportation of a specimen to an offsite laboratory), POCT often produces results within minutes to help guide patient management, including therapeutic decision-making, patient counseling and follow-up care plans during the patient's visit.[3]

Clinicians offer POCT in a variety of locations. Many POCT services are "waived" complexity under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which indicates that those tests are simple to run and unlikely to produce an erroneous result. As a result, there are no minimum education requirements for personnel performing waived tests. Operators can use these tests in any setting with a federal (and/or state, where required) clinical laboratory license, provided the test is performed consistent with its US Food and Drug Administration (FDA) approved directions for use.[12]

POCT devices come in many forms but can generally be split into two categories: handheld tests and benchtop devices. Handheld tests include visually read lateral flow immunoassay tests and qualitative test strips. An example of a handheld test is a blood glucose reading provided by a handheld blood glucose testing device, which uses a test strip that captures a blood sample and is inserted into and read by the machine. POCT benchtop devices allow for more complex built-in fluidics similar to those found in high-complexity reference laboratories, but generally have a smaller footprint and require less technician interaction to produce patient results. For example, tests that use polymerase

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[9] Nichols JH. Utilizing Point-of-Care Testing to Optimize Patient Care. EJIFCC. 2021 Jun 29;32(2):140-144. PMID: 34421482; PMCID: PMC8343046.

[10] Quinn AD, Dixon D, Meenan BJ. Barriers to hospital-based clinical adoption of point-of-care testing (POCT): a systematic narrative review, *Crit. Rev. Clin. Lab Sci.* 53 (2016) 1–12.

[11] Clinical and Laboratory Standards Institute: Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline. *CLSI document POCT08-A*, Vol. 30 No.23, 2010.

[12] CMS. *Title 42 CFR 493 Medicare, Medicaid and CLIA Programs; Regulations implementing the Clinical Laboratory Improvement Amendments of 1988 Standards and Certification: Laboratory Requirements*. Washington, DC: Federal Register; 1992. p. 7001–7288.

chain reaction (PCR) technology to test for COVID-19 using a nasal swab combined with reagents may be read by a tabletop analyzer. POCT devices also use amplified probe methodologies for other types of infectious disease testing.[13] Indeed, the COVID-19 pandemic has spurred and driven the development of miniaturized, high-throughput and automated PCR systems.[14] While the quantitative variant-polymerase chain reaction (qRT-PCR) is the gold standard for diagnosis of viral infections, POC antigen tests also proved to be helpful during the COVID-19 pandemic.

POCT impacts care across myriad disciplines within medicine. A pre-pandemic study showed that the top 10 conditions for which US family physicians reported using POCT were diabetes mellitus, urinary tract infections, strep throat, influenza, pregnancy, anemia, infectious mononucleosis, anticoagulation, acute cardiac conditions and lipid disorders.[15]

POCT Case Examples

Diabetes Mellitus

Diabetes mellitus is a chronic metabolic disease characterized by elevated levels of blood glucose that over time lead to serious damage to critical organs.[16] Blood glucose POCT is important for managing diabetes in several settings, including acutely when patients are hospitalized. Hyperglycemia and hypoglycemia are associated with increased morbidity, mortality and length of hospital stays.[17,18] Monitoring blood glucose levels in hospitalized patients is important for determining the appropriate types and quantities of medications and food they should receive.[19] The expedient turnaround of glucose POCT results leads to faster treatment decisions in response to glycemic fluctuations.

POCT is also used to monitor hemoglobin A1c (HbA_{1c}) in diabetic patients. POCT devices for HbA_{1c} use a drop of capillary whole blood, collected via the finger-prick procedure. Experts recommend that people with diabetes and stable glycemia have an HbA_{1c} test at least twice per year, and those with unstable glycemia as often as every three months.[20] The availability of POCT for HbA_{1c} is helpful in monitoring treatment response and management. Several studies have found that POCT for HbA_{1c} has the potential to improve diabetes management by changing both physician and patient

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[13] St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev. 2014 Aug;35(3):155–67. PMID: 25336761; PMCID: PMC4204237.
[14] Gupta N, Augustine S, Narayan T, O'Riordan A, Das A, Kumar D, Luong JHT, Malhotra BD. Point-of-Care PCR Assays for COVID-19 Detection. Biosensors (Basel). 2021 May 1;11(5):141. doi: 10.3390/bios11050141. PMID: 34062874; PMCID: PMC8147281.
[15] Augustine J. Sohn, John M. Hickner, Fasika Alem. Use of Point-of-Care Tests (POCTs) by US Primary Care Physicians. The Journal of the American Board of Family Medicine May 2016, 29 (3) 371–376; DOI: 10.3122/jabfm.2016.03.150249.
[16] WHO. Diabetes. Accessed May 17, 2023. https://www.who.int/health-topics/diabetes#tab=tab_1.
[17] Baker ST, Chiang CY, Zajac JD, Bach LA, Jerums G, MacIsaac RJ. Outcomes for general medical inpatients with diabetes mellitus and new hyperglycaemia. *Med J Australia*. 2008;188(6):340–343.
[18] Umpierrez GE, Isaacs SD, Bazargan N, You X, Thaler LM, Kitabchi AE. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab*. 2002;87(3):978–982.
[19] Klonoff DC. Point-of-Care Blood Glucose Meter Accuracy in the Hospital Setting. Diabetes Spectr. 2014 Aug;27(3):174–9. doi: 10.2337/diaspect.27.3.174. PMID: 26246776; PMCID: PMC4523734.
[20] American Diabetes Association. 6. Glycemic targets: standards of medical care in diabetes—2018. *Diabetes Care*. 2018;41(suppl 1):S55–S64.

behavior, as actionable results are available to make recommendations and have discussions with patients in real time.[21,22] A randomized controlled trial of type 1 and insulin treated type 2 diabetic patients found that patients who received HbA_{1c} POCT had significantly decreased levels at six and 12 months compared to those who did not receive POCT.[23] Another prospective controlled trial found that HbA_{1c} POCT in patients with type 2 diabetes increased the frequency of hypoglycemic agent dosage adjustment, indicating more personally tailored treatment, while also lowering HbA_{1c} levels compared to patients who did not receive same-day test results.[24]

In recognition of the utility of HbA_{1c} tests, USPSTF and specialty societies identify the HbA_{1c} test as clinically appropriate screening, and Medicare recently agreed to expand coverage of diabetes screening tests to include HbA1c.[25]

Urinalysis

Clinicians commonly use point-of-care urine assays (*e.g.*, dipsticks) to assess glucose, leukocytes, ketones, nitrite proteins, pH, urobilinogen, bilirubin and other analytes in urine samples.[26] Dipsticks can be used to quickly evaluate patients for urinary tract infections, kidney disease and diabetes. Early intervention for these conditions may reduce morbidities that can arise from delayed treatment. A meta-analysis found evidence that dipstick tests are especially useful in excluding the presence of infection for urinary tract infections if the results of both nitrites and leukocyte-esterase are negative, thus reducing unnecessary prescription of antibiotics.[27] Automated technologies, such as automated test strips and microscopy- and flow cytometric-based instruments, have also been able to reduce the labor intensity of urinalysis.[28]

Group A Streptococcal Pharyngitis

Several rapid antigen tests are currently available to identify sore throat caused by Group A Streptococcal pharyngitis. Doctors may use these tests during primary care visits to evaluate children or adults presenting with sore throat. While many patients with sore throat have a viral etiology for their symptoms, strep throat is a bacterial infection

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[21] UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet*. 1998;352(9131):837–853.
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[24] Miller CD, Barnes CS, Phillips LS, *et al*. Rapid A1c availability improves clinical decision-making in an urban primary care clinic. *Diabetes Care*. 2003;26(4):1158–1163. doi:10.2337/diacare.26.4.1158.
[25] Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program. Centers for Medicare and Medicaid Services, 2023.
[26] Lepowsky E, Ghaderinezhad F, Knowlton S, *et al*. Paper-based assays for urine analysis. *Biomicrofluidics* [Internet]. 2017.
[27] Devillé WL, Yzermans JC, van Duijn NP, Bezemer PD, van der Windt DA, Bouter LM. The urine dipstick test useful to rule out infections. A meta-analysis of the accuracy. BMC Urol. 2004 Jun 2;4:4. doi: 10.1186/1471-2490-4-4. PMID: 15175113; PMCID: PMC434513.
[28] Oyaert M, Delanghe J. Progress in Automated Urinalysis. Ann Lab Med. 2019 Jan;39(1):15–22. doi: 10.3343/alm.2019.39.1.15. PMID: 30215225; PMCID: PMC6143458.

that must be treated with antibiotics. If not treated in a timely manner, complications can arise that may result in heart and kidney damage.

In addition to rapid antigen POCT, nucleic acid amplification POCT has become available that can provide results within 15–24 minutes. A retrospective study found that implementation of PCR POCT as standard of care in outpatients with acute pharyngitis symptoms reduced inappropriate antibiotic prescriptions by 44.1% for patients with a negative PCR POCT result.[29]

Sexually Transmitted Infections

The COVID-19 pandemic disrupted access to diagnostic and preventive services for sexually transmitted infections (STIs). One study found that from 2019 to 2020, new HIV diagnoses reported to the Centers for Disease Control and Prevention decreased by 17%. A substantial decline in HIV testing during this period also was observed, however.[30]

Reports of other STIs in the United States have increased in recent years, with yearly increases in cases of gonorrhea, chlamydia and syphilis.[31] Traditional laboratory testing leads to delays in treatment and often loss to follow-up when patients who require treatment are unreachable. POCT represents an opportunity to timely address STIs by allowing clinicians to provide immediate test results and prescribe appropriate treatment, thus reducing risk of morbidity and spread of infection.[32] A decision analysis found that compared to laboratory tests, POCT for chlamydia allowed clinicians to treat more cases of infection by reducing loss to follow-up.[33] A randomized controlled trial found that compared to traditional laboratory testing, rapid POCT for chlamydia and gonorrhea in the emergency department led to a significant reduction in overtreatment for women without infections and significantly improved the delivery of appropriate treatment for patients with infections.[34] Another study in the same setting also found a significant increase in treatment appropriateness in the POCT group, and reduced time to diagnosis. Researchers projected that POCT would save the urban emergency

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[29] May L, Sickler J, Robbins EM, Tang S, Chugh K, Tran N. The Impact of Point-of-Care Polymerase Chain Reaction Testing on Prescribing Practices in Primary Care for Management of Strep A: A Retrospective Before-After Study. Open Forum Infect Dis. 2022 Mar 24;9(5):ofac147. doi: 10.1093/ofid/ofac147. PMID: 35531385; PMCID: PMC9070329.

[30] DiNenno EA, Delaney KP, Pitasi MA, *et al*. HIV Testing Before and During the COVID-19 Pandemic—United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:820–824. DOI: http://dx.doi.org/10.15585/mmwr.mm7125a2.

[31] Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance*. Atlanta, GA: US Department of Health and Human Services, 2018:2019.

[32] Widdice LE Hsieh Y-H Silver B, et al. Performance of the Atlas rapid test for Chlamydia trachomatis and women's attitudes toward point-of-care testing. Sex Transm Dis 2018; 45:723–727.

[33] Gift TL, Pate MS, Hook EW 3rd, Kassler WJ. The rapid test paradox: when fewer cases detected lead to more cases treated: a decision analysis of tests for Chlamydia trachomatis. *Sex Transm Dis*. 1999;26(4):232–240. doi:10.1097/00007435-199904000-00010.

[34] Gaydos CA, Ako M-C, Lewis M, Hsieh Y, Rothman RE, Dugas AF. Use of a rapid diagnostic for chlamydia trachomatis and Neisseria gonorrhea for women in the emergency department can improve clinical management: report of a randomized controlled trial. Am Emerg Med 2019;74(1):36–44. Doi:10.1016/j.annemergmed.2018.09.012.

department approximately $37,000 annually because of differences in cost per test, appropriate use of antibiotics and decreased need for readmission.[35]

POCT for several STIs, including HIV, may be used in settings such as physician offices, community-based clinics, urgent care facilities and outpatient healthcare facilities. The approved tests typically provide actionable results within 10–40 minutes.[36]

COVID-19

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel coronavirus whose spread across the world in 2020 led the World Health Organization to declare a pandemic. As of November 2023, there had been more than 770 million confirmed cases of COVID-19, including almost seven million deaths globally.[37] The US Department of Health and Human Services Secretary announced a public health emergency (PHE) in early 2020, which was soon followed by legislation giving the federal government additional flexibilities for the duration of the PHE. The FDA authorized the first COVID-19 test for use in "waived" settings in 2020 and has since authorized or approved dozens of tests for use. Several types of COVID-19 POCT are available:

- **Nucleic acid amplification tests (NAATs)** for SARS-CoV-2 specifically identify the ribonucleic acid (RNA) sequences that comprise the genetic material of the virus. These tests have been authorized for use in a variety of settings, including point of care. Since the beginning of the COVID-19 pandemic, the FDA has authorized more than 50 NAATs for emergency use, with the first NAAT receiving full FDA authorization in 2023.

- **Antigen tests** use immunoassay technology to detect the presence of specific viral proteins, otherwise known as antigens. These tests have a high specificity but are less sensitive (*i.e.*, less able to accurately detect all positive cases) than NAATs. Antigen tests are widely available for use at the point of care.

- **Antibody tests** received emergency use authorization from the FDA and are used to determine if a person has COVID-19 antibodies, which may be indicative of recent past infection or response to vaccination.

Throughout the COVID-19 pandemic, NAATs and antigen tests were the most widely used primary diagnostic tools for COVID-19 detection. The rapid and reliable detection of the COVID-19 virus facilitated by these tests allowed healthcare providers to prescribe and users to obtain proper treatment, and allowed patients to isolate to avoid infecting others.[38,39]

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[35] Rivard KR, Dumkow LE, Draper HM, Brandt KL, Whalen DW, Egwuatu NE. Impact of rapid diagnostic testing for chlamydia and gonorrhea on appropriate antimicrobial utilization in the emergency department. Diagn Microbiol Infect Dis. 2017;87(2):175–179. doi:10.1016/j.diagmicrobio.2016.10.019.
[36] Centers for Disease Control and Prevention. Types of HIV Tests. Accessed from https://www.cdc.gov/hiv/basics/hiv-testing/test-types.html.
[37] WHO COVID-19 Dashboard. Geneva: World Health Organization, 2020. Available online: https://covid19.who.int/ (last cited: [November 11, 2023]).
[38] US National Institutes of Health. NIBIB RADx® Tech Timeline. 2020. Accessed from: https://www.nibib.nih.gov/covid-19/radx-tech-program/radx-tech-timeline.
[39] Centers for Disease Control and Prevention. Overview of Testing for SARS-CoV-2, the virus that causes COVID-19. 2023. Accessed from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html.

Cost Profile

Equipment/Technology/Process

POCT is often conducted using either handheld or benchtop devices whose technology can be characterized as miniaturization and/or parallel analyses. Many disciplines are represented in POCT, including molecular biology, optical and electrical engineering, and microfluidic and software algorithms.[40] A review of recent trends in POCT found that advances can be attributed to continuous developments in biosensors, microfluidics, bioanalytical platforms, assay formats, lab-on-a-chip technologies and complementary technologies.[41]

In contrast to automated laboratory instruments that analyze many samples, POCT typically analyzes one sample at a time. However, multiplexed POCT has become more prevalent in the past decade.[42] This technology allows POCT to screen various analytes simultaneously through spatial separation of detection sites, regional separation of channel networks/electrode arrays and use of various labels.[43] Many handheld POCT devices are based on immunosensors that utilize electrochemical or optical transductors.[44] These devices often use quantitative and qualitative strips that rely on fingerstick capillary samples, which are then applied directly to the device, eliminating the need for labelling and transporting samples to instruments used in a lab. Alternatively, dipsticks with reagent and reflectance technology may be used to estimate how much of an analyte is present in a urine or whole blood sample.[45] Immunostrips are biosensing devices that use colorimetric, fluorometric and electrochemical approaches to analyze a variety of sample types.[46]

Tabletop or benchtop instruments act as miniaturized forms of laboratory instruments. They can be found in a variety of settings, including physician office laboratories, pain management clinics and urgent care centers (among others). Benchtop POCT analyzers are typically more complex than unit-use machines. They use a variety of analytical principles such as spectrophotometric substrate and enzyme-activity measurement, hematological particle counting and sensor-based blood-gas analysis.[47] These systems can have built-in fluidics and typically utilize unit use reagents. They can be performed by a broad range of clinical personnel who are not laboratory trained. A common type of

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[40] PCR Technologies for Point of Care Testing: Progress and Perspectives. Salvatore Petralia and Sabrina Conoci. *ACS Sensors* 2017 *2* (7), 876–891. DOI: 10.1021/acssensors.7b00299.
[41] Vashist SK. Point-of-Care Diagnostics: Recent Advances and Trends. Biosensors (Basel). 2017 Dec 18;7(4):62. doi: 10.3390/bios7040062. PMID: 29258285; PMCID: PMC5746785.
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[43] Araz M.K. Microfluidic multiplexing in bioanalyses. *J. Lab. Autom.* 2013;**18**:350–366.
[44] St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev. 2014 Aug;35(3):155–67. PMID: 25336761; PMCID: PMC4204237.
[45] Walter B, Greenquist AC, Howard WE., 3rd Solid-phase reagent strips for detection of therapeutic drugs in serum by substrate-labeled fluorescent immunoassay. Anal Chem. 1983;55:873–8.
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[47] Luppa PB, Müller C, Schlichtiger A, Schlebusch H. Point-of-care testing (POCT): Current techniques and future perspectives. Trends Analyt Chem. 2011 Jun;30(6):887–898. doi: 10.1016/j.trac.2011.01.019. Epub 2011 Mar 21. PMID: 32287536; PMCID: PMC7125710.

benchtop POCT is a blood gas analyzer. This device can analyze blood for hemoglobin derivatives, urea, glucose and other indicators by using multi-spectral absorbance. Blood gas analyzers are often configured with a CO-oximetry unit. In comparison to laboratory equipment, POCT devices are low weight, compact and lower in power consumption.[48]

Volume/Efficiency

In a hospital- or clinic-based setting, POCT's main advantage is a faster turnaround time than testing performed in the central laboratory. There is also no need to batch samples. Central laboratory testing involves multiple steps, including collecting samples from the patient, transporting them to the laboratory, running each sample through its respective test and reporting the results back to the treating clinician.[49]

The benefits from reduced turnaround time have been studied extensively in the emergency room, with evidence emerging in other settings. Studies have found that POCT provides results significantly faster than in-laboratory testing during high-volume situations. Once implemented in a hospital's practice workflow, POCT can streamline and accelerate processes, reducing the need for time-intensive preparation and transportation of samples to laboratories and administrative follow-up scheduling.[50,51] A systematic review of studies reporting the application of POCT in emergency departments with outcomes of the time to intervention or disposition found that all included studies associated POCT with more rapid decision-making, which resulted in decreased time to appropriate interventions and increased time to negative interventions in the last lines of critical care.[52] Another study found that after implementation of HbA_{1c} POCT, participating practices experienced an 80% reduction in the number of required visits scheduled and a 75% reduction in the number of venous blood collections.[53] POCT has also been shown to reduce the length of stay for patients in the emergency department, creating more room for new patients in need.[54]

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[48] St John A, Price CP. Existing and Emerging Technologies for Point-of-Care Testing. Clin Biochem Rev. 2014 Aug;35(3):155–67. PMID: 25336761; PMCID: PMC4204237.
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[50] Patzer KH, Ardjomand P, Göhring K, Klempt G, Patzelt A, Redzich M, Zebrowski M, Emmerich S, Schnell O. Implementation of HbA1c Point of Care Testing in 3 German Medical Practices: Impact on Workflow and Physician, Staff, and Patient Satisfaction. J Diabetes Sci Technol. 2018 May;12(3):687–694. doi: 10.1177/1932296818759690.
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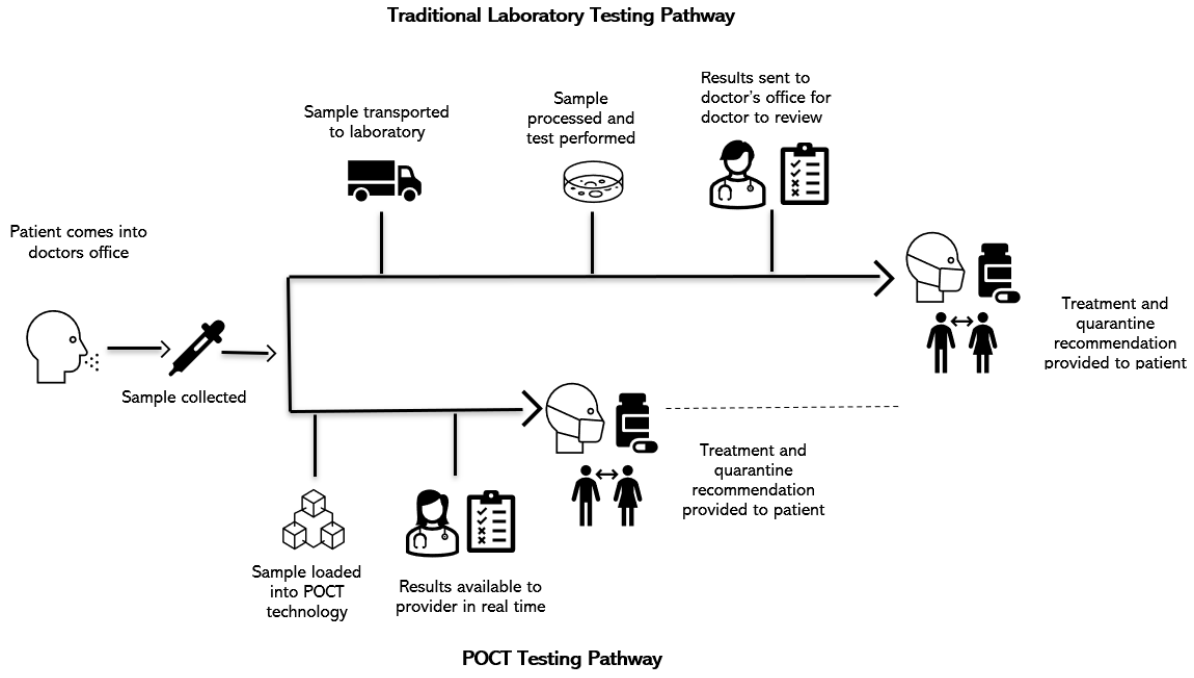
[52] Rahsepar S, Sanie Jahromi MS, Abiri S, Akhavan R, Akhavan H, Abbasi B, Maleki F, Ahmadnezhad S, Rezvani Kakhki B, Kalani N, Adibi P. Point-of-Care Tests' Role in Time Metrics of Urgent Interventions in Emergency Department; a Systematic Review of Literature. Arch Acad Emerg Med. 2022 Oct 10;10(1):e82. doi: 10.22037/aaem.v10i1.1817.
[53] Patzer KH, Ardjomand P, Göhring K, Klempt G, Patzelt A, Redzich M, Zebrowski M, Emmerich S, Schnell O. Implementation of HbA1c Point of Care Testing in 3 German Medical Practices: Impact on Workflow and Physician, Staff, and Patient Satisfaction. J Diabetes Sci Technol. 2018 May;12(3):687–694. doi: 10.1177/1932296818759690.
[54] Lee-Lewandrowski, E., Corboy, D., Lewandrowski, K., Sinclair, J., McDermot, S. and Benzer, T.I. (2003) Implementation of a Point-of-Care Satellite Laboratory in the Emergency Department of an Academic Medical Center: Impact on Test Turnaround Time and Patient Emergency Department Length of Stay. Archives of Pathology & Laboratory Medicine, 127, 456–460.

Figure 1: Comparison of POCT and Traditional Laboratory Testing Pathways



Overall Cost

Overall, it is difficult to compare POCT cost to laboratory-based testing cost because of the variability in tests available and clinical situations. POCT may be more expensive than traditional laboratory-based testing on a per-unit basis because the technology involved is advanced and, in many cases, novel. However, POCT requires smaller sample volume than tests performed in central laboratories, can often be performed by non-laboratory staff[55] and can aid in more targeted treatments, fewer hospital admissions and reduced lengths of stay.[56,57] POCT also saves time by reducing the number of follow-up phone calls, letters and revisits necessary in primary care practices.[58] A study assessing the cost-effectiveness of POC creatinine testing to assess kidney function prior to contrast-enhanced computed tomography imaging found that the cost-effectiveness of POCT appeared to be driven by reduced delays within the patient care pathway.[59] In another study, cost of illness was found to be 26% lower when POCT

[55] CLIA does not require personnel performing CLIA "waived" testing to meet any minimum experience or educational requirements (beyond training on the system and following the package insert). In contrast, moderate and high complexity laboratory personnel are subject to certain incremental educational/experience requirements. *See* 42 CFR 493.1423 (outlining requirements for moderate complexity testing personnel) and 493.1489 (outlining requirements for high complexity testing personnel).

[56] Gunnarsson RK, Orda U, Elliott B, *et al*. Improving antibiotics targeting using PCR point-of-care testing for group A streptococci in patients with uncomplicated acute sore throat. *Aust J Gen Pract*. 2021;50(1-2):76–83. doi:10.31128/AJGP-07-20-5518.

[57] Melhuish A, Vargas-Palacios A, Yaziji N, *et al*. Cost evaluation of point-of-care testing for community-acquired influenza in adults presenting to the emergency department. *J Clin Virol*. 2020;129:104533. doi:10.1016/j.jcv.2020.104533.

[58] Crocker JB, Lee-Lewandrowski E, Lewandrowski N, Baron J, Gregory K, Lewandrowski K. Implementation of point-of-care testing in an ambulatory practice of an academic medical center. *Am J Clin Pathol*. 2014;142(5):640–646. doi:10.1309/AJCPYK1KV2KBCDDL.

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was used to diagnose influenza compared to clinical judgment alone. Authors attributed their findings to fewer follow-up general practice visits, fewer additional diagnostics and a reduction in hospitalizations.[60]

POCT allows for increased early control of diseases and infections, which can consequently reduce the costs of disease- and infection-related outcomes. A study researching the cost effectiveness of POC HbA_{1c} testing in primary care settings found that even though the POC HbA_{1c} device was more expensive than the laboratory method, these expenditures were offset by savings from decreased hospitalizations, heart attacks, strokes, amputations, ophthalmic procedures, blindness, dialysis and other disease-related complications.[61] Similarly, an analysis of hepatitis C virus (HCV) POC assay for HCV screening found that HCV POC assay generated a cost reduction of $21.15 compared with the standard-of-care screening. The study concluded that early detection and treatment of undiagnosed individuals can prolong people's life span and save healthcare costs associated with HCV-related complications.[62]

Several studies have found that using POCT to detect influenza in patients in emergency departments reduces transmission and improves workflow. Transmission is reduced by using results to implement social distancing practices, and workflow is improved by lowering rates of nosocomial infections that contribute to more severe complications and increase morbidity among emergency department patients.[63,64]

Regulatory Overview

POCT devices are medical devices under the Federal Food, Drug, and Cosmetic Act and therefore are subject to FDA regulation. The FDA classifies all medical devices, including POCT, into one of three risk-based classifications based on the level of control necessary to ensure that the device is safe and effective.[65] Low risk (Class I) devices are generally exempt from FDA premarket review. Moderate risk (Class II) devices are generally subject to the premarket notification (510(k)) requirement, under which manufacturers must establish that their product is substantially equivalent to a legally marketed predicate device. High risk (Class III) devices are subject to premarket approval, which requires manufacturers to provide valid scientific evidence (often in the

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computed tomography imaging. Eur J Radiol. 2021 Sep;142:109872. doi: 10.1016/j.ejrad.2021.109872. Epub 2021 Jul 27. PMID: 34339953.

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[64] Pedersen CJ, Rogan DT, Yang S, Quinn JV. Using a novel rapid viral test to improve triage of emergency department patients with acute respiratory illness during flu season. J Clin Virol. 2018 Nov;108:72–76. doi: 10.1016/j.jcv.2018.09.008. Epub 2018 Sep 15. PMID: 30261422; PMCID: PMC7106347.

[65] Food and Drug Administration. Classify Your Medical Device. Accessed from https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

form of clinical trials) establishing that the device is safe and effective for its intended use. POCT may be classified into any of these categories depending on the intended use.

The FDA also establishes the complexity of POCT under CLIA. The FDA assigns POCT to one of three CLIA categories: waived, moderate or high complexity.[66] Many POCT sites operate under a CLIA Certificate of Waiver. This waiver exempts them from most CLIA requirements, but allows them to offer only "waived" complexity tests and requires them to follow the manufacturer's directions for use for the test. "Waived" tests are tests that the FDA has determined are simple laboratory examinations that have an insignificant risk of producing an erroneous result, or that have been approved for home use. If a POCT laboratory wishes to perform "moderate" or "high" complexity tests, it must obtain a CLIA Certificate of Compliance or Certificate of Accreditation, which requires the laboratory to meet minimum requirements for personnel, facilities, quality systems and proficiency testing. If using an FDA-approved or FDA-cleared test kit, a moderate or high complexity laboratory must verify, through clinical validation studies, that the test performs in a manner comparable to the specifications established by the test's manufacturer before reporting results using the system to clinicians and/or patients.

Laboratories performing POCT may also be subject to licensure by the state in which they are physically located. Some states require professional licensure for individuals performing POCT.

Third-Party Payer Reimbursement

Third-party payers may pay for POCT in various ways, depending on the payer and the patient's location at the time the specimen is collected. Under Medicare rules, for example, POCT furnished to beneficiaries in a physician office setting would be paid at 100% of the allowable Clinical Laboratory Fee Schedule (CLFS) rate for the test, if the test is reasonable and necessary for treatment of the patient's condition. Reimbursement for POCT furnished in a hospital outpatient setting, however, is often bundled into Medicare's payment for other substantive services furnished during the same admission, with certain limited exceptions.

Private payers cover POCT testing to varying degrees. Increasingly, payer positions are memorialized in written coverage policies, which may vary with respect to a number of variables, including tests addressed, site of service and patient eligibility criteria.

Clinical Equivalence

Accurate test results are critical to inform immediate patient management decisions and to avoid patient harm. The clinical equivalence of POCT has been assessed by many studies across a variety of test types. Several POCT types, such as blood gas analysis,[67]

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[66] Food and Drug Administration. Administrative Procedures for CLIA Categorization. Accessed from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/administrative-procedures-clia-categorization.

[67] Kankaanpää, M., Holma-Eriksson, M., Kapanen, S. *et al.* Comparison of the use of comprehensive point-of-care test panel to conventional laboratory process in emergency department. *BMC Emerg Med* **18**, 43 (2018). https://doi.org/10.1186/s12873-018-0198-x.

glucose measurement[68] and blood count,[69] have been found to have similar accuracy to corresponding core lab tests. POC PCR influenza assays have been developed with greater than 95% sensitivity and specificity compared to centralized PCR assays.[70,71,72] A prospective open-lab study also found that PCR POC strep tests had high sensitivity, high specificity and rapid turnaround times compared to a laboratory-based two-step rapid antigen detection test.[73]

Value Proposition

The value of POCT lies in its ability to provide immediate, accurate diagnostic information and improve access to clinically appropriate care. As discussed above, POCT streamlines the diagnostic process by improving workflow efficiency, thus decreasing overall costs of healthcare. Further, POCT allows physicians to focus on patient care, enhances healthcare delivery and enables effective treatment plans. Providers and patients alike see the value in POCT, with one survey finding that patients felt POCT would encourage adherence to their treatment regimen for comanaging their diseases with their doctors.[74] An interview of clinicians who had used POCT found that benefits included planning onward care trajectories and facilitating communication, both between professionals and with patients and their families.[75]

POCT enhances access to healthcare for disadvantaged patients. Many poor and/or rural populations in low- and middle-income areas lack access to laboratory services. As a result, infections may go undetected until disease progression has occurred and more serious symptoms arise. A study conducted in rural North Carolina found that implementing HbA_{1c} POCT improved glycemic control and decreased clinical inertia among participants. When compared to the previous standard laboratory testing for HbA_{1c} with delayed feedback of results and delayed medication intensification, participants had a significant decrease in HbA_{1c} and an increased rate of medication

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[68] Roth-Kleiner M, Stadelmann Diaw C, Urfer J, Ruffieux C, Werner D. Evaluation of different POCT devices for glucose measurement in a clinical neonatal setting. *Eur J Pediatr*. 2010;169(11):1387-1395. doi:10.1007/s00431-010-1243-2.

[69] Ivaska L, Niemelä J, Leino P, Mertsola J, Peltola V. Accuracy and feasibility of point-of-care white blood cell count and C-reactive protein measurements at the pediatric emergency department. PLoS One. 2015 Jun 2;10(6):e0129920. doi: 10.1371/journal.pone.0129920.

[70] Nolte FS, Gauld L, Barrett SB. 2016. Direct comparison of Alere I and COBAS Liat influenza A and B tests for rapid detection of influenza virus infection. J Clin Microbiol 54:2763–2766. doi: 10.1128/JCM.01586-16.

[71] Chen L, Tian Y, Chen S, Liesenfeld O. 2015. Performance of the Cobas® Influenza A/B assay for rapid PCR-based detection of influenza compared to Prodesse ProFlu+ and viral culture. Eur J Microbiol Immunol **5**:236–245. doi: 10.1556/1886.2015.00046.

[72] Binnicker MJ, Espy MJ, Irish CL, Vetter EA. 2015. Direct detection of influenza A and B viruses in less than 20 minutes using a commercially available rapid PCR assay. J Clin Microbiol **53**:2353–2354. doi: 10.1128/JCM.00791-15.

[73] Rao A, Berg B, Quezada T, Fader R, Walker K, Tang S, Cowen U, Duncan D, Sickler J. Diagnosis and antibiotic treatment of group a streptococcal pharyngitis in children in a primary care setting: impact of point-of-care polymerase chain reaction. BMC Pediatr. 2019 Jan 16;19(1):24. doi: 10.1186/s12887-019-1393-y.

[74] Lilly CM, Ensom E, Teebagy S, DiMezza D, Dunlap D, Hafer N, Buchholz B, McManus D. Patient Preferences for Point-of-Care Testing: Survey Validation and Results. Point Care. 2020 Dec;19(4):112–115. doi: 10.1097/poc.0000000000000214.

[75] Dixon, S., Glogowska, M., Garland, S. *et al.* Clinician perspectives on having point of care tests made available to them during out of hours home visiting. *BMC Fam Pract* **22**, 246 (2021). https://doi.org/10.1186/s12875-021-01571-0

intensification after implementation of HbA_{1c} POCT.[76] Another study, which introduced POCT to screen for syphilis in pregnant women living in low- and middle-income areas, found that the introduction of POCT resulted in large numbers of women being tested and treated for syphilis, averting many stillbirths and reducing neonatal mortality. The outcomes from this study resulted in policy change in all of the project areas, who decided to incorporate POCT into national guidelines.[77]

Future Outlook/Technological Considerations

POCT has the potential to revolutionize healthcare delivery. The COVID-19 pandemic transformed how healthcare providers used POCT and highlighted the benefits of having quick and reliable results available at the time of treatment.[78]

POCT devices have continued to see growth in connectivity to health information systems. These advancements allow for real-time sharing of test results, which can facilitate even faster clinical decision-making and improve capabilities for monitoring health conditions.[79] Artificial intelligence (AI) is also being used to enhance POCT capabilities through predictive analytics. AI-powered algorithms have the potential to improve speed of analysis and interpretation of test results.[80] POC molecular testing is being used to assess biomarker data and deliver precision cancer care. This approach offers considerable advantages to clinical cancer care by reducing delays in test results, as biomarker results are often the rate-limiting step in initiating systemic therapy.[81]

The future of POCT will likely be characterized by increased accessibility and portability. As technology continues to advance, we likely will see more connectivity, including real-time data, and integration with technology.

Advancements in technology such as microfluidics and sensor technologies have contributed to miniaturization of POCT devices. Smaller devices are more portable,

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[76] Mary Nicole John, Kathryn E. Kreider, Julie A. Thompson, Katherine Pereira; Implementation of A1C Point-of-Care Testing: Serving Under-Resourced Adults With Type 2 Diabetes in a Public Health Department. *Clin Diabetes* 1 July 2019; 37 (3): 242–249. https://doi.org/10.2337/cd18-0082.

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[81] Sheffield BS, Beharry A, Diep J, Perdrizet K, Iafolla MAJ, Raskin W, Dudani S, Brett MA, Starova B, Olsen B, Cheema PK. Point of Care Molecular Testing: Community-Based Rapid Next-Generation Sequencing to Support Cancer Care. Curr Oncol. 2022 Feb 23;29(3):1326–1334. doi: 10.3390/curroncol29030113.

which provides greater accessibility in remote or resource-limited settings.[82,83] Other technological advancements include improved capabilities in analyte testing.[84] Many tests are evolving to include multiplexed assays, which can be used to detect multiple markers in a single test.[85,86] Simultaneous detection of multiple markers can help provide healthcare providers with a more complete picture of their patients' health and enable them to create more personalized and comprehensive treatment plans.

FAQ

1. Is POCT as accurate and reliable as send-out lab testing?

Yes, POCT is as accurate and reliable as send-out testing for many tests. When used properly by trained personnel, POCT has been shown to have similar sensitivity and specificity as corresponding send-out lab testing.[87,88,89,90]

2. Does POCT result in improved patient outcomes?

POCT produces actionable test results quicker than send-out lab testing. The timeliness of treatment may improve patient outcomes by reducing delays in clinically indicated treatment and avoiding downstream complications. It also reduces the risk of loss to follow-up in patients by allowing practitioners to establish a treatment plan on the spot.

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[82] Zarei M. Advances in point-of-care technologies for molecular diagnostics. *Biosens Bioelectron*. 2017;98:494–506. doi:10.1016/j.bios.2017.07.024.

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[89] Binnicker MJ, Espy MJ, Irish CL, Vetter EA. 2015. Direct detection of influenza A and B viruses in less than 20 minutes using a commercially available rapid PCR assay. J Clin Microbiol **53**:2353–2354. doi: 10.1128/JCM.00791-15.

[90] Chen L, Tian Y, Chen S, Liesenfeld O. 2015. Performance of the Cobas® Influenza A/B assay for rapid PCR-based detection of influenza compared to Prodesse ProFlu+ and viral culture. Eur J Microbiol Immunol **5**:236–245. doi: 10.1556/1886.2015.00046.

3. How does the cost of POCT compare to that of lab testing?

On a unit-cost basis, POCT is generally considered to be more expensive than send-out lab tests. However, POCT has been shown to reduce spending in healthcare settings by improving workflow and practice efficiency.[91,92,93]

4. Is implementing POCT difficult? Won't it disrupt my office workflow?

POCT has been shown to improve workflow by streamlining and accelerating processes, reducing the need for time-intensive preparation and transportation of samples to laboratories, and eliminating the need for follow-up scheduling.[94,95]

5. Is POCT testing suitable for all populations/patients? What populations benefit the most?

A variety of POCT tests are available to meet the needs of a diverse range of patients and populations. All patients can benefit from POCT, but it may have a particularly meaningful impact on rural and/or disadvantaged communities where access to laboratory testing and access to care is otherwise limited.

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[94] Patzer KH, Ardjomand P, Göhring K, Klempt G, Patzelt A, Redzich M, Zebrowski M, Emmerich S, Schnell O. Implementation of HbA1c Point of Care Testing in 3 German Medical Practices: Impact on Workflow and Physician, Staff, and Patient Satisfaction. J Diabetes Sci Technol. 2018 May;12(3):687–694. doi: 10.1177/1932296818759690.

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Appendix

Top 20 HCPCS Codes by Medicare Fee-for-Service Payments by Spending in Office Settings – 2022

Rank	HCPCS Code	Long Descriptor
1	80053	Blood test, comprehensive group of blood chemicals
2	85025	Complete blood cell count (red cells, white blood cell, platelets), automated
3	80307	Testing for presence of drug, by chemistry analyzers
4	87798	Detection test by nucleic acid for organism, amplified probe technique
5	80061	Blood test, lipids (cholesterol and triglycerides)
6	84443	Blood test, thyroid stimulating hormone (TSH)
7	G0482	Drug test(s), definitive, utilizing (1) drug identification methods able to
8	83036	Hemoglobin A1C level
9	G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to
10	87426	Detection test by immunoassay technique for severe acute respiratory syndrome
11	82306	Vitamin D-3 level
12	G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to
13	87635	Amplified DNA or RNA probe detection of severe acute respiratory syndrome
14	G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to
15	U0003	Infectious agent detection by nucleic acid (dna or rna); severe acute
16	84153	PSA (prostate specific antigen) measurement, total
17	83970	Parathormone (parathyroid hormone) level
18	87801	Detection test by nucleic acid for multiple organisms, amplified probe(s)
19	87804	Detection test by immunoassay with direct visual observation for influenza virus
20	82607	Cyanocobalamin (vitamin B-12) level

Source: McDermott+Consulting analysis of 100% Physician/Supplier Procedure Summary limited data set and 100% outpatient limited data set standard analytic file for 2022, and CMS 2022 CLFS files. Outpatient claims were defined as paid through the CLFS if the claim contained a billtype for 14X and included a paid HCPCS that is paid through the CLFS.