Ensuring the Quality of Point-of-Care Testing in a Large and Decentralized Ambulatory Care Setting

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ABSTRACT

Objectives: In this project, we assessed the breadth, quality, trends, and outcomes of point-of-care (POC) testing and regulatory compliance in 200 University of California, Los Angeles (UCLA) Health system outpatient clinics.

Methods: We retrospectively extracted clinic POC test orders, results, and e-prescription data from the UCLA electronic health record over a 1-year period.

Results: Over 100,000 total tests were performed, encompassing 10 POC tests. Initially, 40% of clinics did not have complete licensure, but after implementation of the POC team, this metric improved to 100% licensure within 6 months. Most clinics used two or fewer POC tests, resulted fewer than 200 tests per year, and performed little to no external quality control measures. Our data analytics approach showed that peak POC testing occurred in January 2015, driven by influenza and urinalysis testing, and that both the testing and resulting clinical decision making do not routinely follow society guidelines.

Conclusions: This decentralization of laboratory testing presents challenges to ensuring quality POC testing. Optimization and analysis of informatics data allow for the identification of POC test utilization trends, areas of improvement for clinical workflows, and increased education on national guidelines.

Point-of-care (POC) testing is defined as a pathology or laboratory test that is performed at the site of clinical interaction, on or on behalf of the treating physician, at the time of patient consultation, therefore allowing the physician to make an immediate decision regarding treatment.[1] Because tests are performed in a nonlaboratory setting, the tests are designed to be as simple as possible. POC tests must undergo US Food and Drug Administration (FDA) waiver approval to be used in Clinical Laboratory Improvement Amendments (CLIA)–waived settings, such as an outpatient clinic. Alternatively, moderately complex POC testing can be performed in certain POC settings by licensed personnel. As technology has rapidly advanced, the number of POC tests performed throughout the University of California, Los Angeles (UCLA) Health system has increased, necessitating a structured approach to ensure quality. Globally, POC testing was estimated to be worth $15 billion in 2011 and represents more than a quarter of worldwide laboratory testing.[2,3]

Early diagnosis and monitoring is a major benefit of POC testing.[4] POC tests for infectious disease (eg, gonorrhea, chlamydia, group A strep [GAS], influenza) provide early diagnosis and treatment in selected groups.[5-7] A retrospective study in pediatric patients found that children with early diagnosis of influenza in the emergency department had shorter hospital stays, an increased chance of effective antiviral prescription, and decreased overall testing.[8] In addition, POC tests have improved the ability of patients and physicians to directly monitor chronic conditions such as diabetes[9,10] and improved clinic workflow by decreasing the number of follow-up calls for laboratory results.[11] With the increasing importance of patient satisfaction metrics, the availability of POC testing has improved patient satisfaction.[11,12]

The major difference between POC testing sites and CLIA-certified clinical laboratories is the rigor of the quality control measures and level of federal regulation that ensures the highest quality of clinical laboratory testing. POC tests are only valid within the manufacturers' protocols and reference ranges, outlined in the package insert. Deviation from protocols and regent expiration can result in errors that put patients at risk. Audits of POC sites with CLIA waivers identified serious issues with quality of testing[13] that include inadequate training, inability to locate procedure protocols, and failure to routinely follow manufacturers' instructions. In addition, physicians and mid-level providers have insufficient knowledge about the limits of POC tests, which can lead to poor patient care.

The rapid increase in POC testing locations and the expansion of the technology make it difficult to ensure quality in POC testing. Many countries and hospital systems, including UCLA, have attempted to provide oversight of POC tests using faculty from affiliated pathology departments,[14,15] who are experts in medicine and quality control for laboratory tests. The role of the UCLA Department of Pathology and Laboratory Medicine POC management team is to provide guidance for test implementation and performance. This article outlines the approach and goals of an interdisciplinary, pathology-led ambulatory outpatient program for POC testing. Through the use of data collected from the electronic health record (EHR), we assess the quantity, quality, and informatics needs of outpatient clinics using POC testing.

Materials and Methods

Data on regulatory compliance quality metrics from ambulatory care clinics were collected between 2014 and present day through direct survey of clinics by pathologist or ambulatory nursing quality managers. Clinical and patient data were extracted from the Clarity Databases, which maintain the UCLA EHR from a 1-year period (October 2014 to September 2015) representing the number, location, clinician, and types of POC tests documented in the EHR. All POC tests used at UCLA are described in ❚Table 1❚. All medical record analysis was performed under UCLA institutional review board approval.

Results

Goals of an Ambulatory Outpatient Program

UCLA Health performs POC testing in CLIA-waved sites across 300 square miles of Southern California. The

❚Table 1❚ Tests Offered by the Ambulatory Point-of-Care Program Between October 2014 and September 2015

Analyte	Reagents and Testing Instrumentation	Company
Chem 8	iSTAT Chem 8+ Cartridge and iSTAT Handheld Analyzer	Abbott (Chicago, IL)
Fecal occult blood	Hemoccult Test Kit	Beckman Coulter (Brea, CA)
Glucose	Hemocue Glucose 201 Microcuvettes and Hemocue Glucose 201 Analyzer	Beckman Coulter
Glucose	Accu-chek Inform II Test Strips and Accu-chek Inform II meter	Roche (Basel, Switzerland)
Group A strep	QuickVue Dipstick Strep A Test Kit	Quidel (San Diego, CA)
Hemoglobin	Hemocue Hb 201 Microcuvettes and Hemocue Hb 201+ analyzer	Beckman Coulter
Mono test	OSOM Mono Test Kit	Sekisui Diagnostics (San Diego, CA)
Pregnancy dipstick	QuickVue One-Step hCG Urine Test Kit	Quidel
PT/INR	Coaguchek XS Test Strip Coaguchek XS Meter and Coaguchek XS Plus Meter	Roche
Urine dipstick	Multistix 10SG Reagent Strips and the Clinitek Status Connect Urine Dipstick Reader	Siemens (Munich, Germany)

INR, international normalized ratio; PT, prothrombin time.

Department of Pathology and Laboratory Medicine outpatient POC management team is a consultative service for POC testing. This service provides guidance in testing modalities, regulatory compliance, POC test protocols, and standardized operator education. The goal is to ensure all diagnostic tests performed within the UCLA Health system are performed with as high a quality as tests within a CLIA-licensed facility. Laboratory testing in the ambulatory and outpatient setting is performed at a significant distance away from laboratory experts, who are adept in testing, standardized protocols, and results interpretation. While the tests performed in an outpatient setting are CLIA waived and considered low complexity, they are not immune from preanalytical, analytical, and postanalytical errors. In the absence of standardized workflows outlining a directed protocol, there may be inaccurate test results, inaccurate interpretation, and an increased risk to patient safety.

The UCLA ambulatory POC group's mission has three major goals to ensure patient safety: standardization of POC test offering, standardized operator education, and regulatory compliance. Focusing on the above

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seeks to apply basic laboratory principles into outpatient POC testing to develop a systemwide approach with minimal burden on the staff. Therefore, patients can be assured that no matter the location of test performance, the quality of testing is equivalent to a test performed under the auspices of the clinical laboratory.

Compliance With State and Federal Licensure

UCLA Health has clinics spread over 300 square miles in Southern California. These span from Orange County to the south to Ventura County to the north. It is not possible to contain all the ambulatory care settings within a single CLIA laboratory license. Each clinic must apply for a CLIA-waived status and a California State license for POC testing. Our ambulatory POC program provides guidance in regulatory compliance. At the onset, 80% of clinics were compliant with federal regulation, and only 20% of clinics were compliant with state regulation. Six months after implementation of the ambulatory POC team, there was 100% compliance with CLIA-waived regulations at the federal and state levels.

Standardization of POC Testing

One of the greatest challenges in POC testing is decentralization of testing. Within a large health system, there are incentives to ensure that testing performed anywhere in the health care system is accurate, is precise, and can be replicated in an independent clinic or laboratory. When standardizing the POC test menu at UCLA Health, we prioritized the use of specific tests and platforms that were well established in the clinical laboratories and have downstream options for automation and EHR integration. This allowed us to limit the number of different platforms and tests for the same analytes, streamline test performance and resulting workflows, and develop uniform training and protocols across multiple sites.

Each outpatient clinic address requires its own medical director, who has complete authority and liability over POC testing in the clinic. At the initial assessment, there were at least four different pregnancy tests used throughout UCLA Health, with some individual clinics stocking two different models of the same test. Performance differences between urinalysis (UA) dipstick assays or urine pregnancy tests (sensitivity and specificity) can be substantial and potential for error increased as each version of the test has slightly different protocols, interpretive criteria, and reagents.

To date, there are many FDA-approved and CLIA-waived versions of glucometers, urine dipsticks, and pregnancy tests. Our solution to standardize reagent orders was to provide access to reagents through the UCLA Materials Management division. This arrangement streamlined inventory of reagents and bulk purchases through UCLA, allowing for greater purchasing power and better pricing than independent purchases by smaller clinic groups.

The clinics performing POC tests ranged from comprehensive primary care clinics and urgent cares to highly subspecialized urology clinics. We opted for testing that was flexible in the degree of automation and EHR integration. For example, for the UA, one can provide a manual interpretation, but there is also a machine that includes automated timer and interpretation. This can be highly beneficial in busy clinics performing high volumes of UA testing. These same readers also have the potential to interface with our EHR (Epic-based CareConnect), which reduces transcription errors.

State of Ambulatory POC Testing at UCLA

Over a 1-year period, we quantified the number of POC tests performed in the ambulatory outpatient setting. During the 1-year period analyzed, we found 100,068 tests that were ordered and resulted from outpatient clinics **Figure 1**. Given the size of our outpatient system, we believe that this number vastly underrepresents the true amount of ambulatory POC testing taking place within UCLA Health. For example, certain tests, such as Monospot, are never ordered and resulted, but inventory through material and management services suggests that they are being used frequently at ambulatory clinics. We estimate, based on inventory from Materials Management, that only half of the POC testing that is occurring is being captured in the EHR. There are several reasons for this. First, the result can more easily be documented within the free text of the clinical note. Second, the system has not been billing for POC testing. Therefore, documentation of POC tests within the EHR was not a high priority in the period we assessed.

In our data, we find that most testing performed are UA tests, which make up 41% of outpatient POC tests (n = 40,979) (Figure 1). A total of 149 clinics performed at least one POC test. Of these, 62 (41%) ordered and resulted only a single POC test, suggesting that test utilization is highly dependent on both clinic culture and specialty. Furthermore, only a single clinic ordered all 10 tests **Figure 2A**. We also demonstrated that most clinics performing these tests order fewer than 200 tests per year **Figure 2B** or the equivalent of a single test per day. When we split up the test orders among different types of tests, such as UA, hemoglobin (Hb), and influenza, we find that the use of testing is much more restricted and specialty specific. As expected, three urology clinics make up 36% of all POC UA tests performed. Outside of urology, we did not find significant utilization of POC UA tests across any other specialty group. We identified clinics that

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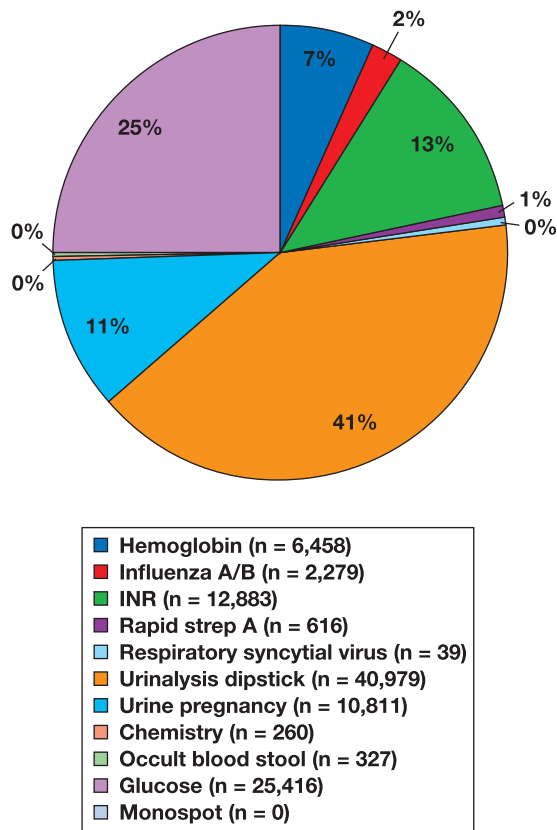
Figure 1 The number of documented laboratory point-of-care tests documented in the electronic health record across the University of California, Los Angeles Health Outpatient Network over a 1-year period, October 2014 to September 2015.

performed high numbers of Hb testing were usually pediatric or family medicine and represented the routine Hb testing as part of the well-child check.[16]

Infectious disease (ID) testing makes up a relatively small proportion of POC tests, with influenza A and B, GAS, and Monospot comprising 3.8% of all POC tests performed (approximately 2,895 tests in a 1-year period). Despite the physical presence of all three tests in multiple clinics, we found no documented evidence that the Monospot was ever ordered and resulted through computerized physician order entry into the EHR. Overall, the use of ID POC tests, such as for influenza A and B, appears to be very clinic specific **Figure 2C**, as only a few clinics perform POC tests for infectious disease. This may represent a difference in clinical workflow and an urgent care service where specific symptoms may trigger the use of ID testing a priori. POC ID tests are critical, as early detection of treatable infection can decrease the length and severity of infection. Other tests, such as lateral flow assays for respiratory syncytial

virus, were only performed at a single urgent care clinic, with a total of 40 tests performed over the course of a single year.

Quality in POC Testing

Physician surveys regarding the implementation and use of POC testing demonstrate strong concerns regarding the reliability of POC testing.[17] Reliability is based on test design (sensitivity and specificity), operator competence, and the routine assessment of quality control. In clinical laboratories, there are external validation tests to ensure accuracy. However, no such metrics exist in the typical POC setting. At the initial assessment of the outpatient POC sites, there was little to no external quality control performed by any of the clinics and no record of lot numbers or expiration dates. Clinics did not have dedicated timers to ensure that staff are timing the tests by the manufacturers' guidelines. The timing of incubation is a critical aspect of testing, as extended incubations can result in higher false-positive rates. An investigation of a recent cluster of GAS diagnoses at a rural outpatient clinic was ultimately attributed to prolonged incubation, leading to increased false positivity,[18] and multiple patients were likely overtreated based on these false-positive results.

Data Analytics to Identify Trends and Outcomes From POC Testing

To explore the role of POC testing over the course of 1 year, we examined the number of tests ordered per month to assess both utilization and clinical practice. Between October 1, 2014, and September 30, 2015, there were 2,280 POC rapid antigen influenza tests electronically ordered and resulted in the UCLA outpatient settings. To identify seasonal trends in POC testing over the course of a 1-year period, we determined if testing changed significantly on a monthly basis. Our study demonstrated that there is a peak in POC testing in January, coinciding with the predicted influenza season in California **Figure 3**. While influenza testing is highest at this time point, a significant number of influenza tests are ordered outside of influenza seasons, when the test has a far lower positive predictive value due to low prevalence of disease. Both the number of tests and the positivity rates were significantly higher in the peak influenza season (November to March), and testing outside of this period was almost 100% negative. We also asked whether physicians trust results from POC influenza testing. For patients receiving negative influenza tests, physicians never sent a specimen for the more sensitive polymerase chain reaction (PCR)–based testing in clinical microbiology. Current recommendations from the Infectious Diseases Society of America (IDSA) and
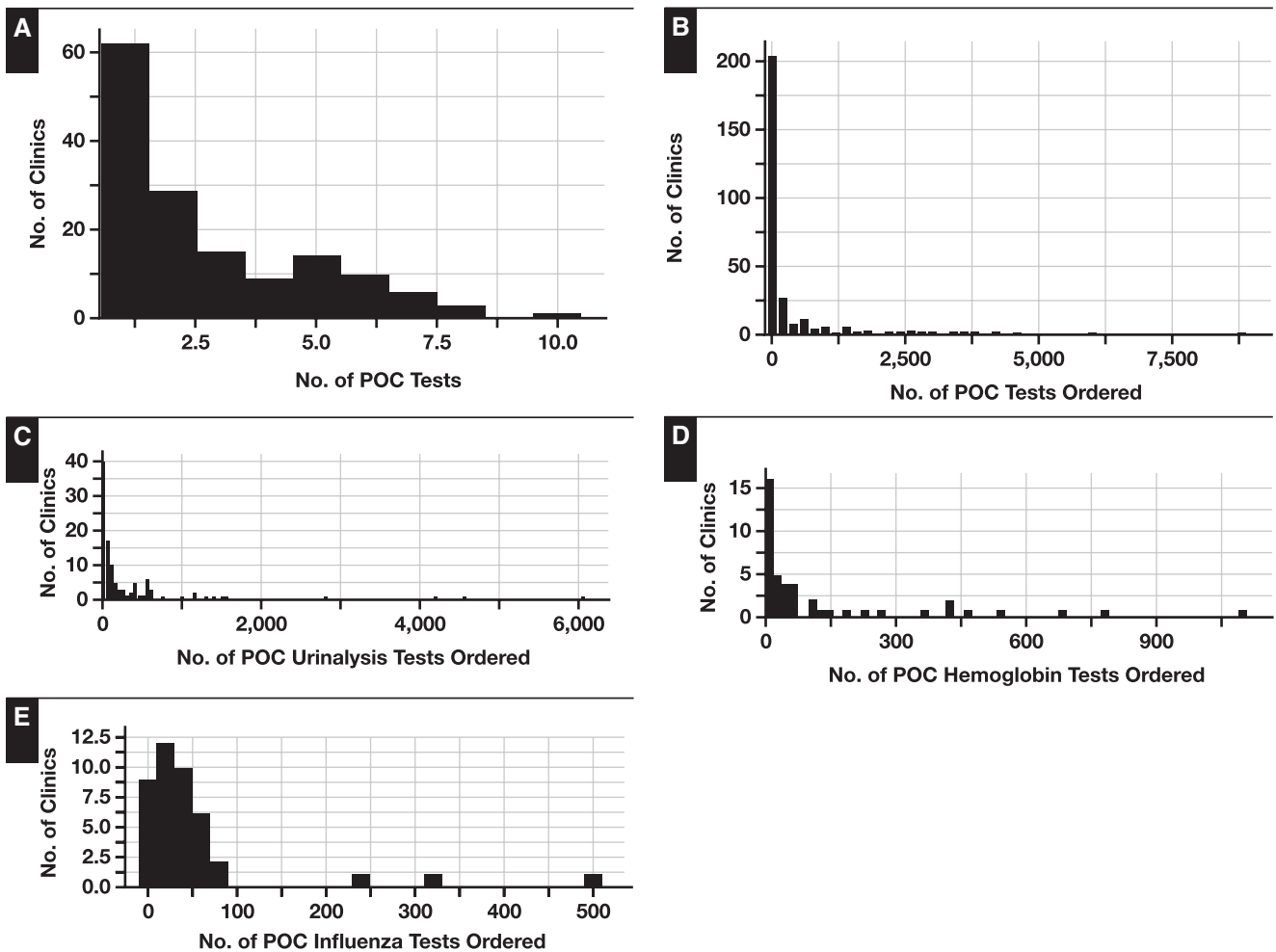
Figure 2 Overview of point-of-care (POC) testing per clinic. **A**, Only a small fraction of clinics performs all the POC tests. Most clinics only perform one to two tests. **B**, Most clinics perform fewer than 200 tests per year. Clinics that perform more than 2,000 are high-throughput subspecialty clinics. **C**, The most highly ordered tests are urinalysis, and most clinics order fewer than 100 per year. Subspecialty urology clinics account for the high-volume POC urinalysis testing. We observe the same effect for POC hemoglobin (**D**) and influenza (**E**) testing, with only a few clinics ordering the majority of tests systemwide.

the Centers for Disease Control and Prevention (CDC) suggest that negative rapid influenza tests should be followed up with a PCR-based testing, particularly during influenza season.[19,20] More sensitive PCR-based testing, performed in the CLIA-certified clinical microbiology laboratory, has a longer turnaround time (~24 hours), and results may not be returned early enough for therapy to be effective. The major utility of POC influenza A and B testing is that if diagnosed and treated early, antivirals can shorten duration of symptoms.[21,22] In pediatric and adult populations, rapid antigen lateral flow tests have poor sensitivity, between 68% and 75%, but greater than 95% specificity.[23-25] The sensitivity of lateral flow tests in influenza is influenced by the age of the patient, viral load at the time of testing, and particular strain that predominates in a given influenza season.

To assess the effect of influenza testing on physician prescribing, we pulled e-prescription data for the 7-day period after POC influenza testing for all patients who received POC influenza tests. Of the 2,280 tests ordered, 523 patients had at least one (influenza A or influenza B) positive result, and only seven (1.3%) were prescribed oseltamivir phosphate. Even in the presence of a positive influenza testing, 28 (5.3%) individuals were prescribed an antibiotic. For those who received a negative result on the POC influenza test, 15 (0.8%) individuals received oseltamivir phosphate while 269 (15%) received an antibiotic. A positive test result only increased the likelihood of oseltamivir phosphate prescription, while a negative test result increased the likelihood of an antibiotic prescription. The prescription of an antibiotic even in the presence of a positive influenza test remains surprising but is consistent with
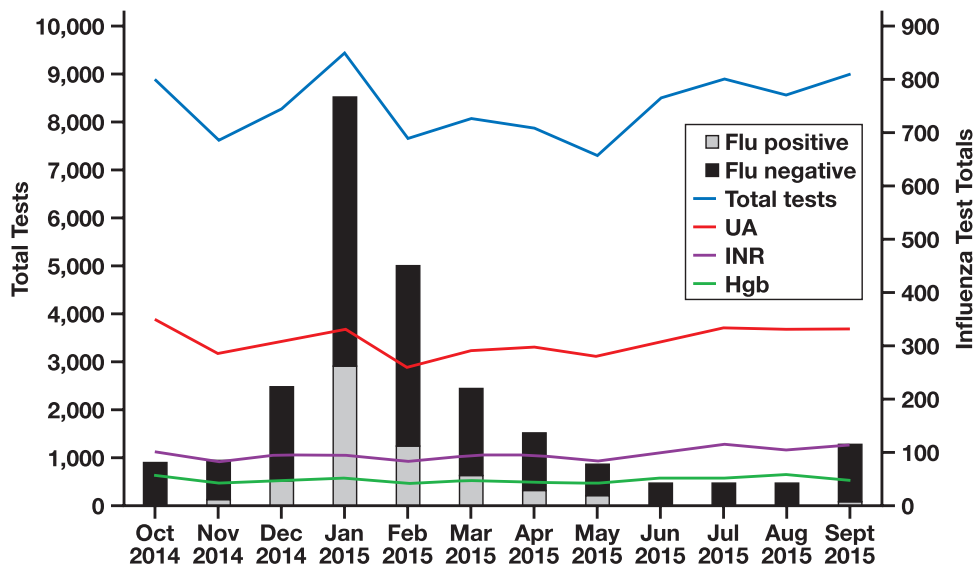
Figure 3 Number of ordered tests fluctuates throughout the year. Total testing peaked in January 2015. This can be attributed partially to the peak of flu season and point-of-care influenza testing. However, there is also a smaller peak in number of urinalysis tests ordered in January.

previous studies showing the persistence of antibiotics in the hospital setting, despite a positive influenza test,[26] where those patients who maintained antibiotics were also more likely to have chronic lung disease.

GAS testing by the POC lateral flow test allows for early detection and treatment with appropriate antibiotic to prevent the later stage manifestations.[27] Primary care physicians can score the pretest probability of GAS infection based on age, symptoms, and physical examination findings to assess the probability of strep infection and the pretest probability for a rapid antigen POC test to yield a true-positive result.[28] Over the course of a 1-year period, there were a total of 616 POC rapid strep A screens, of which 444 were negative. IDSA guidelines provide a strong recommendation that negative rapid GAS tests should be backed up with culture in the child and adolescent population due to the high prevalence of GAS infection in those younger than 18 years.[29] However, none of the individuals younger than 18 years (n = 92) within our data set with a negative rapid GAS had backup culture-based testing.

Informatics as the Key to Understanding POC Testing Within a Large Hospital System

A centralized and streamlined informatics system for both ordering and resulting POC tests is a surprisingly critical piece of POC testing. From the clinical providers' end, an intuitive system for POC testing where one can order, result, and bill for services removes the major barriers in POC testing. Therefore, informatics should be optimized to ensure that all parties are benefiting from POC documentation. For an outpatient POC team, informatics and data analytics is a powerful tool that can identify areas that would benefit from increased automation of EHR integration, identify the future needs for POC testing, and reveal areas of improvement.

Within our EHR, we have a large number of test results for the POC tests ordered in the clinic. Because of early decentralization of the POC test offerings, manual free-text entry was used rather than the preferred standardized result entry. Here we highlight the serious problems with free-text entry results. For tests that have a small number of possible results (eg, 1+, 2+, 3+, 4+), the manual free-text entry amplifies the multitude of unique manually entered results **Figure 4**. For example, for the UA result components, there are some fields with over 500 unique entries. While a small proportion of this represents different kits and reagents, it does not explain the major discrepancies in results. For tests such as influenza A and B, we have identified more than 40 unique entries for a test with three interpretive options: positive, negative, and indeterminate. In contrast to free-text entry, the test for GAS has a restricted number of tests entries, making global interpretation of test results and utilization far easier. The variability in result entry can lead to confusion by the treating clinician and have a negative effect on patient care.
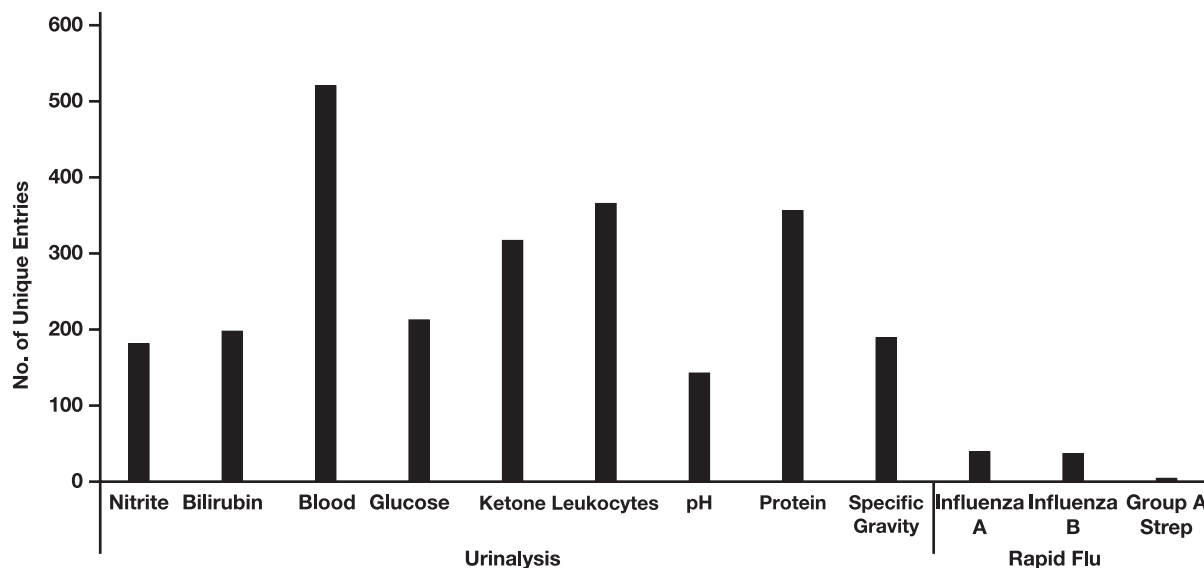
Figure 4 Use of manual free-text entry without categorical options introduces significant errors. Lack of standardization of urinalysis tests used required a manual free-text entry for the test strips. In this scenario, there was significant variability in free-text entry, much of which represented errors in entry. Compared with group A strep testing, in which entry results were limited to three options (positive, negative, indeterminate), the data were far more structured.

Discussion

The future of POC testing is bright and has the potential to improve early diagnostics for a wide range of infectious and other disease states. Across a large health care system, growth of POC testing implemented in a standardized and high-quality fashion can represent a space where clinical diagnostic efficiency and patient satisfaction[11] converge. As the number of POC tests increases, outpatient clinics are pushed to bring on several testing modalities. Unfortunately, these clinics have limited expertise in quality control and regulatory compliance set forth by CLIA and state governments. Our implementation of the outpatient POC testing team successfully increased the number of basic quality control metrics, optimized testing space and workflows, and increased regulatory compliance to 100% within 6 months of implementation of our program.

One of the primary concerns about POC testing among physicians is reliability. Reliability of testing is dependent on the test characteristics, clinical workflows, operator training, and quality control. Although POC tests are constantly improving sensitivity and specificity, the more challenging aspect to POC testing is the variability of workflows between physicians and clinics. By standardizing testing workflows, we can ensure that nurses and medical assistants rotating between facilities demonstrate competency across multiple clinical spaces. We can also reduce prices on POC tests, automation, and EHR interfaces through high-volume purchasing. Most important,

standardization of interpretive capabilities would remove interpretive variability associated with POC testing. POC testing would benefit from a single machine that can be used for timing and interpretation of a variety of test types. Use of a single machine to perform and interpret tests would provide a significant improvement to the heterogeneous methods in use within most outpatient clinics and provide a singular point of interface within the EHR. To date, a single platform that encompasses a majority of CLIA-waived POC tests does not exist.

The limitations of our study are the reliance on tests that are ordered and resulted in the EHR to identify POC tests that are performed. We believe that the snapshot we have generated represents a small fraction of POC testing performed throughout the outpatient UCLA Health system. Any POC tests that are only documented in the clinical note (as opposed to as a laboratory result) are not captured in our analysis. The systematic documentation in the EHR serves three major purposes: (1) improve patient care and continuity, (2) track and predict POC test needs, and (3) identify tests and patients in case of product recalls. Therefore, thinking through the cycle of a POC, from the ordering workflows to resulting and EHR documentation, is critical.

The emerging transition to nucleic acid–based infectious disease testing has the potential to bring high-sensitivity and high-specificity tests directly to the patient bedside. Most POC tests, as currently used, have their primarily utility in ruling in a particular disease or infection

(the tests exhibit a high sensitivity). The tests are poor at ruling out disease (the tests exhibit low specificity). This is especially true for infectious disease testing, where POC testing can provide early diagnosis and treatment, preventing more serious complications. As the number of POC options continually increases, we should be cognizant of the burden associated with multiple forms of testing that begins to add increased complexity to a non-laboratory setting. For example, the rapid antigen detection tests for influenza A and B have a poor sensitivity compared with laboratory-based PCR methods. These poor sensitivities, in influenza and for other infectious diseases, will result in missed opportunities to administer appropriate therapy that can modulate disease severity and prevent late sequelae, such as rheumatic fever. Recent advancements in POC technology, which feature the use of nucleic acid amplification testing, may alleviate the concerns surrounding sensitivity as they are far more sensitive than the direct antigen detection methods, with similar specificities[30] and turnaround times.

Within our large and expanding outpatient facilities, UCLA Health has placed a priority on capturing the breadth of POC tests performed, so that we can continually improve test offerings and interpretive capabilities in a clinic-specific fashion. Understanding how clinics are using this testing requires a hands-on approach, interfacing directly with clinics and the persons who perform the tests. Through our interdisciplinary outpatient POC team, we can assess the specific needs of a clinic and provide insight into best practices to ensure quality of testing. In addition to immediate diagnostic capabilities of POC tests, understanding the impact of these tests on patient care in the various clinical settings can prevent potential patient safety issues. For example, the CDC investigated a suspected outbreak of GAS in Wyoming that was ultimately attributed to overtesting in the pediatric population with GAS carriage rather than more stringent criteria based on clinical symptomatology.[18] Our data show that both testing and resulting clinical decision making do not routinely follow society guidelines, as negative GAS tests were not followed up with culture-based testing in patients 18 years and younger. Furthermore, data demonstrating the impact of POC tests on clinical decision making and outcomes can be used to develop appropriate clinical decision support guidelines or identify areas that would benefit from optimizing efficiency for incorporation of POC tests into clinical workflow.

Compared with a national survey of family physicians, UCLA outpatient practices use POC testing far less than physicians in other settings[17] who report the use of more than 15 different kinds of POCs weekly. While our study likely is not fully representative of the breadth of POC testing through the UCLA Health system, we capture some of the major barriers surrounding widespread and standardized use of POC testing in a large outpatient network. Our initial work has demonstrated that a top-down approach guiding POC test selection, creation of optimal workflows, and expertise in quality control and regulatory compliance can be of enormous benefit to outpatient clinics. The laboratory expertise in conjunction with nursing supervisors allows clinics to optimize testing and decrease prices through bulk purchases. A POC team allows clinics to focus their expertise in patient care with guidance on areas of clinical laboratory expertise: high-quality testing. Integration with the EHR[31] will be central to improving patient care and clinic workflows, as well as identifying potential safety issues in POC testing.

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