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Original Contribution

Point-of-care influenza testing does not significantly shorten time to disposition among patients with an influenza-like illness☆

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ABSTRACT

Introduction: Availability of anti-viral agents and need to isolate infected patients increases the need to confirm the diagnosis of influenza before determining patient disposition.
Objectives: We sought to determine if time-to-disposition (TTD) was shorter among patients tested for influenza using an Emergency Department (ED) Point-of-care (POC) test compared to core laboratory (lab) test and to determine difference in antibiotic use between groups.
Methods: We prospectively enrolled a convenience sample of ED patients for whom influenza testing was ordered during influenza season 2017. Participants were randomized to POC or lab. Data collected included demographics, chief complaint, influenza test results, turnaround time (TAT), whether antibiotics were given, and TTD. Descriptive statistics were calculated and group comparisons conducted using chi squared and Wilcoxon Rank Sum tests.
Results: Study population included 100 in the POC group and 97 in the lab group. Demographics were similar between POC and lab participants. More flu positive results were reported in the POC group compared to the lab group (51.0% vs. 33.0% $p = 0.01$). The median TTD was 146.5 min (IQR 98.5) for POC group and 165.5 min (IQR 127) for lab group ($p = 0.26$). The median TAT was 30.5 min (IQR 7.5) for POC group and 106.0 min (IQR 55) for core lab group ($p = 0.001$). Antibiotics were given to 14.0% of POC participants and 14.4% of lab participants ($p = 0.93$).
Conclusions: Although use of a POC influenza test provided more rapid TAT than use of a core lab test, there was no significant difference in TTD or antibiotic use between groups.

1. Introduction

Symptoms attributable to influenza-like illness are common complaints presenting in the Emergency Department (ED) during the winter months of each year's "influenza season." The availability of anti-viral agents (e.g. neuraminidase inhibitors) and the need to cohort patients with infectious diseases has increased the need to confirm or negate the diagnosis of influenza prior to determining a disposition for patients [1,2].

Diagnosing influenza clinically is challenging, as the signs/symptoms of illness are non-specific, and features of other infections often overlap with influenza. At many institutions diagnostic testing for influenza is processed in an off-site core laboratory. Typical processing run-times can range from 20 to 75 min. In addition, turnaround time (TAT) from specimen collection to result reporting is increased by specimen transport time from collection site to the core laboratory, lab staffing, and workflow variables such as batch versus on-demand testing, assay-specific sample preparation, and electronic versus manual result reporting.

The cobas® Liat Influenza A/B assay (Roche Molecular Systems, Indianapolis, IN) is a CLIA-waived rapid automated Polymerase Chain Reaction (PCR) test that may be performed using nasopharyngeal swabs (NPS) at the point-of-care (POC) by operators who do not require extensive or formal laboratory training. With a clinical sensitivity >99% and specificity >94% [3], this POC test is superior to legacy rapid antigen tests and overall, is competitive in sensitivity and specificity to core laboratory influenza PCR tests (see below). The processing run-time of the assay is only 20 min. POC testing optimizes time to diagnosis because it is performed on demand and eliminates transport time to a core lab or other location.

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ED overcrowding is a recognized problem and epidemics of influenza are associated with increased burden on EDs [4]. The use of the cobas® Liat Flu A/B assay in the ED has the potential to significantly decrease both time to diagnosis and time to disposition (TTD) of patients with possible influenza. This increased operational efficiency can minimize ED throughput time which has far-reaching effects on ED overcrowding and consequently, ED safety. The availability of a test for an accurate and rapid diagnosis of influenza in a timely manner might also decrease the use of other treatment modalities, including the unnecessary use of antibiotics.

The goal of this study was to compare the ED visits of patients presenting with influenza-like illness randomized to receiving either the cobas® Liat Influenza A/B POC assay performed in the ED, or having influenza A/B testing performed in the hospital's core microbiology laboratory. The primary aim was to compare the TTD between the two groups. A secondary aim was to compare the administration or prescription of antibiotics between the groups.

2. Methods

2.1. Study design

This was a prospective, randomized 2-arm study that enrolled a convenience sample of ED patients for whom influenza testing was physician-ordered per usual ED clinical protocols or at a physician's discretion. The study took place over a 6-week period during influenza season (2/7/17 to 3/17/17). The study was approved by the Boston Medical Center Institutional Review Board. Additionally, the study was registered with ClinicalTrials.gov with identifier NCT02979730, and adhered to the Consolidated Standards of Reporting Trials statement.

2.2. Study setting and population

The study site was an urban, academic ED and level 1 trauma center that receives approximately 130,000 patient visits per year. The ED is nationally recognized as the primary “safety net” provider of care for the underserved population in the city; 72% of patients are on government-payor insurance, over 70% of the patients are racial or ethnic minorities, and approximately 32% do not speak English as a primary language.

2.3. Study protocol

2.3.1. POC test verification and core lab testing

The cobas® Liat assay was used for the ED POC group; vendor-claimed analytical sensitivity 100% (influenza A and B), specificity 96.8% and 94.1% for influenza A and B, respectively [5]. In order for the Liat device to be used for clinical care at our institution, verification and validation of the device was completed by the core microbiology lab and POC staff, prior to any patient enrollment. ED Research Assistants (RAs) were then trained on use of the cobas® Liat device and how to enter results into the Electronic Medical Record (EMR).

Core laboratory testing at the study site for influenza A/B (or “core lab” testing arm) was previously verified and already in place for patient care and included the PCR-based Xpert Flu assay (Cepheid, Sunnyvale, CA, NPS Sensitivity/flu A/B 100%/100%, Specificity 100%/100%) [6] and antigen detection by instrumented fluorescent immunoassay, the Sofia Influenza A + B FIA (Quidel, San Diego, CA, NPS Sensitivity/flu A/B 69%/87%, NPS Specificity 98.4%; overall sensitivity 78%/86% compared to PCR-based methods) [7]. Both assays enable differential detection of influenza A and B virus. The Xpert Flu and Sofia A + B FIA have assay run times of 75 min and 15 min to a negative result, respectively. Sample transport time to the study site's core lab from the ED (via courier or pneumatic tube) ranged from 30 to 60 min on average. Upon receipt in the core lab an average of 15 min transpired for hand-off to the microbiology lab, sample accession, and sample preparation time before performing each assay. Manual result entry for the Sofia assay added an extra few minutes to TAT; Xpert assay results were essentially instantaneously uploaded from the instrument to the LIS and EMR via electronic interface. Samples were collected and tests performed according to the respective manufacturer instructions.

Test results from both study arms were used clinically for patient care.

2.3.2. Selection of participants

Participants were enrolled from the Adult ED, the Pediatric ED, and the fast-track area during the study period. Screening and enrollment took place Monday through Friday, 8 am to 11 pm, when the RAs were available to approach patients, obtain written informed consent, collect nasopharyngeal swab (NPS) samples, and either perform the POC testing or send specimens to the core lab for testing. All English speaking patients who had symptoms consistent with influenza-like illness and who the clinician determined should have had a NPS collected for influenza A/B testing during this time period were considered eligible for inclusion in the study. Potential participants were excluded if they had been previously enrolled in the study, if the clinician ordered a comprehensive multiplex PCR respiratory pathogen assay instead of an influenza A/B-only test, or if the influenza test result was already available by the time the participant was approached by the RA.

RAs screened the EMR and/or were paged by ED clinicians for eligible participants. Once written informed consent was obtained, study participants were randomized in a 1:1 ratio to either the “ED POC” arm or the “core lab” arm. Block randomization with block sizes of 2, 4 and 6 participants was completed by a biostatistician in an independent study location prior to the start of the study. The Principal Investigators were blinded to the arm that each participant was randomized to. All participants provided written informed consent, or in the case of minors, a parent or legal guardian provided written informed consent.

2.3.3. Interventions

RAs collected all NPS samples from participants and either completed the POC test on the cobas® Liat Influenza A/B device in the ED or sent them to the core microbiology laboratory for testing. For those samples being sent to the core lab, the ED clinician could order either Sofia Influenza A + B (antigen testing) or Cepheid Xpert Flu assay (PCR) at their discretion.

For the POC group, as soon as the results from the cobas® Liat assay were available, the RAs notified the treating clinician of the result (negative or positive for influenza A or B; or an invalid result). These results were then directly entered into the patient's EMR by the RA who performed the test. For participants whose POC test had an invalid result, a second test was run on the cobas® Liat device. If the repeat POC text was invalid, the NPS swab was sent to the core laboratory for processing.

For patients assigned to the core lab group, per laboratory protocol, results were entered into the EMR and only positive influenza test results were called to the ordering ED clinician.

2.4. Key outcome measures

The primary outcome measured was the TTD defined as the time from when a patient was placed in the ED treatment room until the disposition (either admit, observe, or discharge) was ordered in the medical record. The secondary outcome measured was antibiotic use, either administered in the ED or the writing of a prescription upon discharge from the ED. The intermediate outcome of TAT was calculated for each group as well, defined as the time from when the influenza test was ordered in the EMR until the time the result of the influenza test was manually entered into or electronically posted to the EMR. Demographic data for study participants were also collected.

2.5. Data analysis

2.5.1. Sample size determination

Based on retrospective data generated by the hospital's clinical data warehouse, the average TAT for an influenza assay ordered from the ED and processed by the core laboratory was 168 min, with a standard deviation of 96 min. The estimated TAT for an ED POC test was approximately 30 min [3]. ED POC and core lab group sample sizes of 84 and 84 respectively were chosen to achieve 80% power to detect a minimum difference of 42.0 min (25% reduction) between the mean TTD levels of the two groups, with estimated group standard deviations of 96 min and with a significance level (alpha) of 0.05 using a two-sided two-sample *t*-test. This assumed similar standard deviations for both groups' TTD as the SD for the POC group was unknown. In order to account for withdrawals, invalid assays, errors and indeterminate results, we enrolled 100 participants in each group.

2.5.2. Analysis procedures

Study data were collected and managed using REDCap (Research Electronic Data Capture), a secure, web-based data capture application. Independent two sample *t*-tests were used to compare continuous variables and chi-squared test for categorical outcomes. For continuous variables that were non-normally distributed, non-parametric Wilcoxon Rank Sum tests were used to compare the outcomes between groups. Descriptive summary statistics were reported using means and standard deviations for continuous measures and percentages for categorical variables. p-Values ≤ 0.05 were considered significant. Data were analyzed using SAS v9.3 (Cary, NC).

We also stratified data by disposition (admitted/discharged) and report those results. Further sensitivity analyses were performed on subgroups that, based on prior literature, were expected to have different TTD outcomes from the rest of the study sample. These included (a) influenza positive participants, (b) participants with test results completed prior to disposition (thus excluding patients who had disposition before their test results were received), (c) participants in the core lab group who underwent influenza testing via the PCR assay in the core lab rather than the antigen assay, and (d) participants under age 2 years.

3. Results

3.1. Characteristics of study participants

Two hundred fifty-seven eligible patients were approached for enrollment (see Fig. 1). Of these, 6 refused, and 51 were excluded (21 had comprehensive respiratory panels performed rather than exclusive influenza tests, 21 non-English speaking, 9 for other reasons). Two hundred participants were enrolled, and 3 were dropped from the core lab group due to incorrect test orders.

The final study population included 100 in POC group and 97 in the core lab group, however one participant from the core lab group could not be included in analysis because the EMR did not list a disposition time. There were 6 cases where the POC instrument showed an invalid test result and the participant subsequently had the test performed in the core lab. Their data were analyzed in an intention-to-treat manner, as part of the POC group. In the core lab group, 63 (64.9%) participants' test results were analyzed using the PCR assay, while the remaining 34 (35.1%) participants in the Core lab group had their test results analyzed using the antigen assay.

Demographic characteristics between the POC participants and core lab participants were similar with respect to mean age, gender, and race (see Table 1). Age of enrolled participants ranged from 4 months to

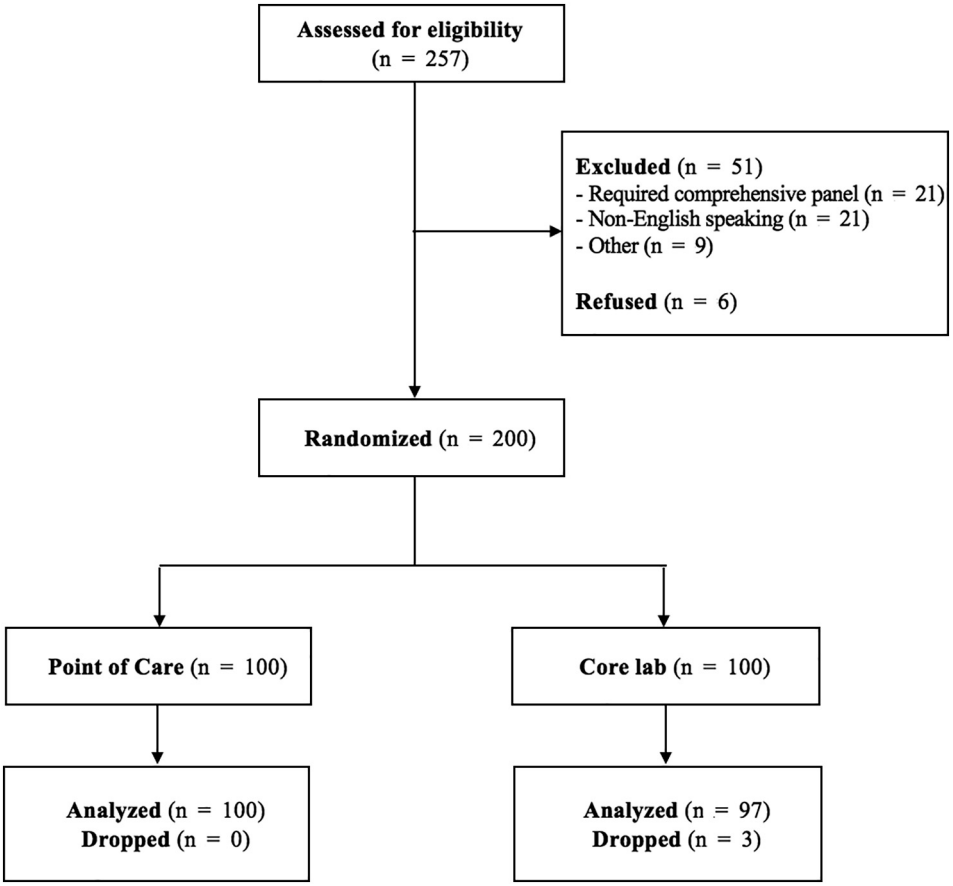

Fig. 1. Enrollment flow chart.

Table 1
Characteristics of study participants (n = 197).*

Characteristic	Core lab (n = 97)	Point of care (n = 100)
Age – mean years (SD)	33.9 (20.2)	37.4 (21.6)
Male sex (%)	38 (39.2)	52 (52.0)
Race (%)		
White	14 (14.4)	19 (19.0)
Black	63 (65.0)	63 (63.0)
Asian	3 (3.1)	3 (3.0)
Not documented	17 (17.5)	15 (15.0)
Hispanic/Latino (%)	21 (21.7)	21 (21.0)
Positive influenza test (%)	32 (33.0)	51 (51.0)
Influenza type A (% of positive tests)	27 (84.4)	44 (86.3)
Discharged from ED (%)	81 (83.5)	78 (78.0)
Number of Patients <2y (%)	8 (8.2)	4 (4.0)

* No significant differences between the groups except for % of positive influenza test results (p = 0.01).

82 years. There were more flu positive results observed in the POC group compared to the core lab group (51.0% vs. 33.0%, p = 0.01) but a similar percentage of influenza type A (86.3% vs. 84.4%), and discharged participants (78.0% vs. 83.5%).

3.2. Main results

Outcomes TTD and TAT were not normally distributed in the two study arms' results so the Wilcoxon Rank Sum test was used to compare these continuous outcomes between the POC group and core lab group. The median TTD was 146.5 min (IQR 98.5) for POC group and 165.5 min (IQR 127.0) for the core lab group (p = 0.26) as shown in Table 2. The POC group median TAT was 30.5 min (IQR 7.5) versus the core lab median TAT of 106.0 min (IQR 55.0) (p < 0.001). For antibiotic usage, no significant difference in the proportion of antibiotics prescribed between the two groups was observed with 14.0% in the POC group and 14.4% in the core lab group (p = 0.93). In Table 3, we show primary outcomes stratified by disposition status. We found that comparisons of outcomes between the POC and core arm groups were similar regardless of disposition status.

For additional sensitivity analyses shown in Table 4, there was no significant difference in the median TTD among influenza positive participants with 131.0 min (IQR 66.0) in POC group and 143.5 min (IQR 101.1) in core lab group (p = 0.81). When looking at the subgroup of participants whose influenza assay result was obtained before being given a disposition (i.e. excluding those who had a disposition in place prior to results of influenza testing), there is a statistically significant difference in median TTD with 147.5 (IQR 105.0) in the POC group compared to 193.0 min (IQR 104.0) in core lab group (p < 0.001). Finally, among the core lab group of study participants, the TATs were significantly different between those who underwent PCR testing (TAT of 113.0 min, IQR 40.5) and those who underwent antigen testing (TAT of 58.0, IQR 35, p < 0.001). Compared to the ED POC group, the core lab subgroup who underwent PCR testing (and not antigen testing), had a statistically significant different TTD, with 146.5 min in POC group (IQR 98.5) compared to 178.0 min in the core lab group (IQR 115.0 to, p = 0.01).

A sensitivity analysis was planned for participants under 2 years old, however there were insufficient participants in this subgroup to perform a meaningful comparison.

4. Discussion

Our study found no significant difference in either our primary outcome of TTD, nor in our secondary outcome, of antibiotic administration/prescription, regardless of whether participants had their influenza testing done by the POC test or the core lab test. Although

Table 2
Primary and secondary outcomes

	Core lab (n = 97)		Point of care (n = 100)		Wilcoxon rank sum p-value
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Time to disposition, in minutes[a]	185.9 (110.0)	165.5 (127.0)	168.9 (91.7)	146.5 (98.5)	0.26
Turnaround time, in minutes	108.1 (45.7)[b]	106.0 (55.0)	35.2 (19.9)	30.5 (7.5)	<0.001
Antibiotics prescribed	14 (14.4%)		14 (14.0%)		0.93[c]

[a] For core lab, n = 96 due to 1 patient missing disposition time
[b] One outlier had a TAT of 3209 min (over 2 days) that was excluded from this calculation. If included, the mean TAT was 140.1 min (318.1).
[c] Chi-squared test.

Table 3
Primary outcomes for discharged and admitted patients

Discharged patients (n = 159)					
	Core lab (n = 81)		Point of care (n = 78)		Wilcoxon rank sum p-value
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Time to disposition (mins)[a]	181.5 (113.4)	155.5 (113.5)	153.1 (80.5)	133.0 (59.0)	0.09
Turnaround time (mins)	142.2 (348.2)	106.0 (55.0)	33.4 (12.5)	30.5 (7.5)	<0.001
Antibiotics prescribed	7 (8.6%)		4 (5.1%)		0.53[b]
Admitted patients (n = 38)[c]					
	Core lab (n = 16)		Point of care (n = 22)		Wilcoxon rank sum p-value
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	
Time to disposition (mins)	208.0 (91.4)	197.0 (129.0)	225.0 (108.0)	227.0 (136.0)	0.66
Turnaround time (mins)	129.0 (31.3)	129.0 (44.5)	41.6 (35.3)	30.5 (8.0)	<0.001
Antibiotics prescribed	7 (43.8%)		10 (45.5%)		0.92[d]

[a] For core lab, n = 80 due to 1 patient missing disposition time.
[b] Fisher's exact test.
[c] Admitted patients included 4 ICU patients.
[d] Chi-squared test.

Table 4
Sensitivity analysis

Time to disposition subgroup category	Core lab (n = 97)			Point of care (n = 100)			Wilcoxon rank sum p-value
	n	Mean (SD)	Median (IQR)	n	Mean (SD)	Median (IQR)	
Influenza positive	32	147.2 (67.2)	143.5 (101.0)	51	146.0 (71.7)	131.0 (66.0)	0.81
Received test result before disposition	62	223.9 (115.0)	193.0 (104.0)	90	173.7 (93.8)	147.5 (105.0)	<0.001
Core lab, PCR assay only[a]	63	207.1 (116.3)	178.0 (115.0)	100	168.9 (150.7)	146.5 (98.5)	0.01

[a] Study participants in Study Arm 2 (Core Lab arm) whose test was analyzed using the PCR assay rather than the antigen assay.

there was a 17 min (11%) difference in the median TTD between the two groups, this was not statistically significant as the variability in TTD between participants, as measured by the IQR, was quite large in both randomized groups. These results were observed despite the statistically significant difference in TAT between the two groups.

It is helpful to frame our findings within this evolving context of ED POC influenza testing literature. However, extrapolation from prior literature is confounded by study heterogeneity, advancing management guidelines, improved technology and expanding POC test options which continue to change the landscape of provider practices and outcome studies. All prior studies have important differences from our study that are worth noting, in an attempt to place the results of this study in an appropriate context.

Early studies of ED POC influenza from 2002 to 2006 primarily took place in pediatric EDs and showed mixed results, with some finding significant differences in outcomes when patients have POC influenza testing, and some not. Two found that knowledge of results of influenza attesting influenced diagnostic decision making, including fewer studies ordered and fewer antibiotics given [8,9]; however, another study in the same time frame found no difference in physician management [10]. However, it is important to note that our study had insufficient data to analyze pediatric patients separately, and patients in the control arm in all these aforementioned studies were not informed of the outcome of the influenza test at all, or had no influenza test performed, rather than finding out these results in a delayed fashion.

In 2011, the Center for Disease Control and Prevention expanded their recommendation for the use of antiviral agents in the management of patients with confirmed or suspected influenza who have severe illness or are at risk of complications [11]. Studies performed since then have addressed this by using a standard care arm. Two studies performed in this manner found that use of a rapid test resulted in decreased LOS compared to standard diagnostic testing [12,13], though one did note that a false negative POC test delayed influenza diagnosis [13].

Our study is different from many prior studies in that our POC arm used the cobas® Liat Influenza/AB assay, the first real-time PCR-based molecular assay to be FDA-cleared and CLIA-waived for POC use in the U.S. Prior to the availability of these new molecular diagnostic tools, EDs wishing to improve TATs for influenza testing had to rely on the previously available rapid antigen detection tests (RADTs) which have sensitivities as low as 50–70% [14]. Although RADTs have specificities of 98%, their poor sensitivity suggests that a negative RADT does not rule out the diagnosis of influenza. Negative RADT in this setting would require the clinician to send an NPS sample for direct fluorescent antibody (DFA) or for PCR-based testing in the core laboratory, or for viral culture with a TAT sub-optimal for clinical triage and disposition in the ED. These limitations form the basis for some of the unsatisfactory findings in prior POCT studies.

In recent years an alternative to legacy RADT emerged. Instrumented influenza antigen detection assays with improved fluorescent-based chemistries offered more cost-effective antigen-based assays with improved analytical performance, although not quite as good as PCR. In our protocol, for participants randomized to the core lab group, clinicians were given the option of ordering PCR-based or instrumented antigen-based influenza testing, as was usual practice at our institution prior to the study. Although the sensitivity of instrumented antigen-based testing is known to be lower than PCR-based testing, the TAT was, as expected significantly shorter. When we eliminated those participants who underwent the antigen testing and included only those who underwent PCR testing (which has comparable accuracy to the POC test), we did find a statistically significant difference in TTD between the core-lab group and the POC group.

The sensitivity analyses we performed were guided by prior literature. Patients receiving a positive influenza diagnosis have been found to have decreased workup and decreased TTD, however our study did not find this to be the case. Febrile patients who are under 2 years old are more likely to have extensive ED workup, and prior studies have indicated that among this group of patients POC influenza testing does influence outcomes [10,15]. However, our study had too few participants in this age group to perform meaningful analysis.

Many participants in our study, particularly in the core lab group where the TAT is generally longer, were discharged before the final influenza diagnosis was obtained. When those participants were excluded from the analysis, there was a significant difference in the primary outcome of TTD. It is unknown why an influenza test was ordered and performed in these cases, but its result was unnecessary for disposition in these cases. Possible explanations are that other etiologies of patient's symptoms were identified, or the clinical status of the patient improved or declined to such an extent that disposition decisions were able to be confidently made without necessitating additional results.

The results of our study and our sensitivity analysis, in conjunction with prior studies, support the idea that disposition decision is multifactorial. Individual laboratory test results are taken in conjunction with other data points in determining disposition decision. Additionally, multiple factors influence patient flow in EDs. In academic EDs in particular, multiple providers including medical students, resident physicians, and attending physicians frequently evaluate patients prior to disposition. Each of these steps takes time. Because the TAT of the core laboratory influenza test was rapid compared to prior studies, and also compared to institutions where batched laboratory tests are performed, it is likely that there were instances in which the results of the core laboratory test were available prior to any decision making, negating the expected advantage for POC TAT and its impact on TTD.

4.1. Limitations

This was a convenience sample from a single institution and thus may be subject to sampling bias and also may not be generalizable to other EDs. However, this institution serves a diverse population of patients. Additionally, the POC arm testing was performed, in our study, by a dedicated RA who was not working clinically. The lack of other patient care responsibilities may have resulted in more rapid TAT for the POC arm that would not be seen in a real-world situation. However, because the cobas® Liat Influenza CLIA waived test is quick to perform and can be done by non-clinicians, we feel the performance times we achieved are realistic to expect outside of the study setting. This study was not powered for subset analyses related to lab and ED staffing across shifts, or for differences in patient clinical acuity and their respective potential impact on TAT and TTD.

5. Conclusions

In conclusion, as we found no differences in TTD or administration of antibiotics, it is likely that in our ED the result of influenza testing was not the rate-limiting step for either of these outcomes. The benefits of newer POC influenza assays with regard to improved diagnostic accuracy and quicker TAT are clear, however systems and workflow need to be appropriate in order to realize the full benefits of this new technology.

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