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ORIGINAL ARTICLE

Infectious Disease

A multicenter randomized control trial: Point-of-care syndromic assessment versus standard testing in urgent care center patients with acute respiratory illness

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Abstract

Objective: Syndromic assessment with multiplex polymerase chain reaction (mPCR) testing in patients with acute respiratory illness (ARI) allows for simultaneous identification of multiple possible infectious etiologies. Point-of-care (POC) syndromic assessment can be conducted in a clinical setting, such as an urgent care center (UCC), without requiring certified laboratories. The primary objective of this study was to determine whether POC syndromic assessment improved patient satisfaction for patients seen at an UCC with ARI; secondary objectives included whether syndromic assessment reduced self-isolation time, increased diagnostic confidence, and reduced overall antibiotic utilization.

Methods: We conducted an unblinded multicenter randomized controlled trial on UCC patients with an ARI. Patients were randomized to either SC (defined as standard UCC testing for ARI) or syndromic assessment with POC mPCR. Patients were surveyed for patient satisfaction, self-isolation plans, diagnostic confidence, and overall antibiotic utilization.

Results: Among the 360 patients enrolled, those in the syndromic assessment group were more satisfied with the time required to communicate the results (98.4% vs. 42.4%, $p < 0.001$) on day of treatment, more likely to resume normal activities sooner (83.3% vs. 69.4%, $p = 0.039$), and more confident in their illness cause (60.7% vs. 29.6%, $p < 0.001$); however, the rate of antibiotic utilization did not differ (33.5% vs. 26%, $p = 1.0$).

Conclusion: In conclusion, our study provides evidence supporting the use of syndromic assessment in UCCs for ARI diagnosis, including patient-centered outcomes

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such as greater confidence in diagnosis and more efficient isolation strategies. This study did not show a difference in more clinically oriented outcomes, such as a change in antibiotic utilization. Future studies should identify clinical care pathways to improve antibiotic stewardship for likely viral syndromes and whether the increased initial cost of syndromic assessment is offset by the clinical benefits and subsequent cost savings.

KEYWORDS
acute respiratory illness, point-of-care test, syndromic assessment, urgent care

1 | INTRODUCTION

Syndromic assessment allows for simultaneous identification of multiple possible infectious etiologies. Point-of-care (POC) syndromic assessment can be conducted during a single evaluation in the clinical setting and may affect patient-reported outcomes. This prospective study of patients with acute respiratory illness (ARI) in an urgent care center enrolled 360 patients and randomized them to standard care versus POC syndromic assessment. The syndromic assessment group was more satisfied with the time required to communicate the results, more likely to resume normal activities sooner, and more confident in their illness cause; however, the rate of antibiotic utilization did not differ.

1.1 | Background

ARI is the most common complaint among patients seeking care in an urgent care center (UCC), accounting for approximately one-third of all visits.[1,2] Most ARI cases are of viral etiology; however, their specific etiology is rarely identified.

1.2 | Importance

Rapid identification of the causative agent of ARIs in UCCs could be beneficial in targeting improved care plans, such as the use of antibiotic and antiviral medication, and providing recommendations regarding self-isolation and when to return to work and school.[2–4] Syndromic assessment with multiplex polymerase chain reaction (mPCR) allows the identification of a variety of bacterial and viral pathogens in a single sample with a greater than 98% accuracy on nasopharyngeal aspirate.[5,6] POC versions of syndromic assessment testing platforms can be used outside traditional laboratory settings by the clinical staff at an UCC, with results available during the same visit.[7] In this multicenter study of UCC patients with ARI, we compared a POC mPCR syndromic assessment test with standard care (SC) testing. In this study, SC testing relied on antigen tests for either SARS-CoV-2, group A streptococci, or influenza A/B, combined with confirmation testing and additional studies in an offsite laboratory. In general, SC testing is limited by the fact that antigen tests have relatively poor diagnostic sensitivity compared with mPCR, and the addition of confirmatory send-out tests typically required 48 h.[8] The use of syndromic assessment with mPCRs is limited by lack of data on patient-reported outcomes and concerns about cost. The use of syndromic assessment in UCC's to improve patient-reported outcomes is unknown.

1.3 | Goals of this investigation

Therefore, the primary objective of this study was to determine whether syndromic assessment improved patient satisfaction. Secondary objectives were to determine whether syndromic assessment reduced patient self-isolation time, increased practitioner diagnostic confidence, and reduced antibiotic utilization in UCC patients with ARI.

2 | METHODS

2.1 | Screening and eligibility

UCC patients were screened based on their chief complaint at presentation for symptoms consistent with ARI. A research assistant approached prospective participants to assess their eligibility and obtain informed consent. Patients aged ≥7 years and clinically stable with at least one symptom of respiratory illness, such as cough, sneezing, runny nose, sore throat, headache, muscle ache, trouble breathing, or fever, were included. Patients were excluded if they were unable to provide informed consent, presented with chronic symptoms (>14 days), were clinically unstable, or were non-English speakers.

2.2 | Study design and setting

We conducted an unblinded, multicenter, randomized controlled trial at two urban free-standing UCCs associated with an academic Emergency Department (ED). Research assistants enrolled eligible participants between May 4, 2022 and November 30, 2022, mostly on

weekdays during daytime hours (8 am to 6 pm) as part of a convenience sample. On average each UCC saw 42 patients per day, approximately 3.5 patients per hour during weekdays, or an estimated 280 patients per week. UCCs were open 12 h per day during weekdays and 8 h on weekends. There was an approximately 0.7% ED referral rate. Staffing at the UCCs was typically by a Nurse Practitioner or Physician Assistant with supplemental staffing by physicians. Neither patients nor practitioners were blinded to the study allocation.

2.3 | Randomization and intervention

Enrolled patients were randomized to either the SC or syndromic assessment group using a randomization module built into the RedCap survey instrument. Patients who were randomized to the syndromic assessment group were tested using the Biofire RP-EZ 2.1 device, an FDA-approved POC mPCR device. Patients in the SC group did not undergo mPCR testing but could get any test routinely available at the UCC or a lab "send-out." Of note, the mPCR testing and respective specimen collection was performed in the clinical setting by research staff who received training on using the machine during a single 1-h session with a representative from the manufacturer; these individuals were not certified laboratory technicians. Patients and practitioners were given results on the day of enrollment. Test results took approximately 1 h and patients who left the clinic before receiving their test results were contacted later the same day. No participants were charged for the study tests. The protocol was approved by The George Washington University Institutional Review Board (NCR213901). The study can be found on clinicaltrials.gov (NCT05467007).

2.4 | Measurement and outcomes

We assessed standard demographic information, vaccination status, insurance status, and quality-of-life measures. After the research team communicated the results either in person or over the phone, all participants were asked to assess their (1) satisfaction with timing of results, (2) intention to self-isolate and resume normal activities, (3) confidence in the cause of their illness, (4) plan for additional diagnostic tests, and (5) plan for work absence. Participants were contacted via telephone after 7 days and a chart review was performed 30 days after the initial visit to assess their clinic course and return visits to the initial UCC, another clinic, or an ED for worsening or persistent respiratory symptoms to the index visit via a review of the electronic health record from facilities in the region.

Practitioner-centered results were collected by research staff using a standardized data collection form after the patient care was completed. After the clinical assessment and following the communication of the results, practitioners were asked about the following outcomes: (1) confidence in diagnosis, (2) recommendations regarding isolation, (3) ability to address patient needs/questions, (4) recommendations regarding the disease course, (5) other follow-up recommendations, and (6) the use of prescription antibiotics. Please see Supporting Information for practitioner and patient questionnaires.

The Bottom Line

Syndromic assessment allows for simultaneous identification of multiple possible infectious etiologies. Point-of-care (POC) syndromic assessment can be conducted during a single evaluation in the clinical setting and may affect patient reported outcomes. This prospective study of patients with acute respiratory illness in an urgent care center enrolled 360 patients and randomized them to standard care versus POC syndromic assessment. The syndromic assessment group was more satisfied with the time required to communicate the results, more likely to resume normal activities sooner, and more confident in their illness cause; however, the rate of antibiotic utilization did not differ.

2.5 | Statistical analysis

Categorical variables are expressed as absolute frequencies and percentages. Continuous variables are presented as the mean and standard deviation or as the median and interquartile range when not normally distributed. Categorical variables were compared using the chi-squared test or Fisher's exact test. Continuous variables were compared using the Student's *t*-test or Mann–Whitney *U*-test, according to the Kolmogorov–Smirnov test of normality. All results were considered statistically significant at $p < 0.05$. The secondary objectives included whether syndromic assessment reduced self-isolation time, increased diagnostic confidence, and reduced overall antibiotic utilization. Regarding the secondary objectives, there are six main questions: (1) Are you confident that you know what is causing your illness? (2) Plan to isolate from friends and family? (3) Plan to seek care from another doctor or healthcare facility? (4) Did the time to receive test results affect you and prevent you from doing activities you normally would do? (5) Were antibiotics prescribed as part of the UCC visit for respiratory illness? (6) Plan to miss work? In the analysis of secondary objectives, we adjusted the *p*-values by applying the Bonferroni procedure for multiple comparisons. This conservative Bonferroni correction method involves multiplying the raw *p*-values by the number of tests (the number of survey questions related to the secondary objectives: 6).

All analyses were performed using R (version 4.1.1, Comprehensive R Archive Network). The sample size was based on the expected high satisfaction for time to result in 90% of patients in the syndromic assessment group versus 60% of those in the SC group with a power of 0.8 and a significance value of 0.05. The study was consistent with the Consort Checklist.

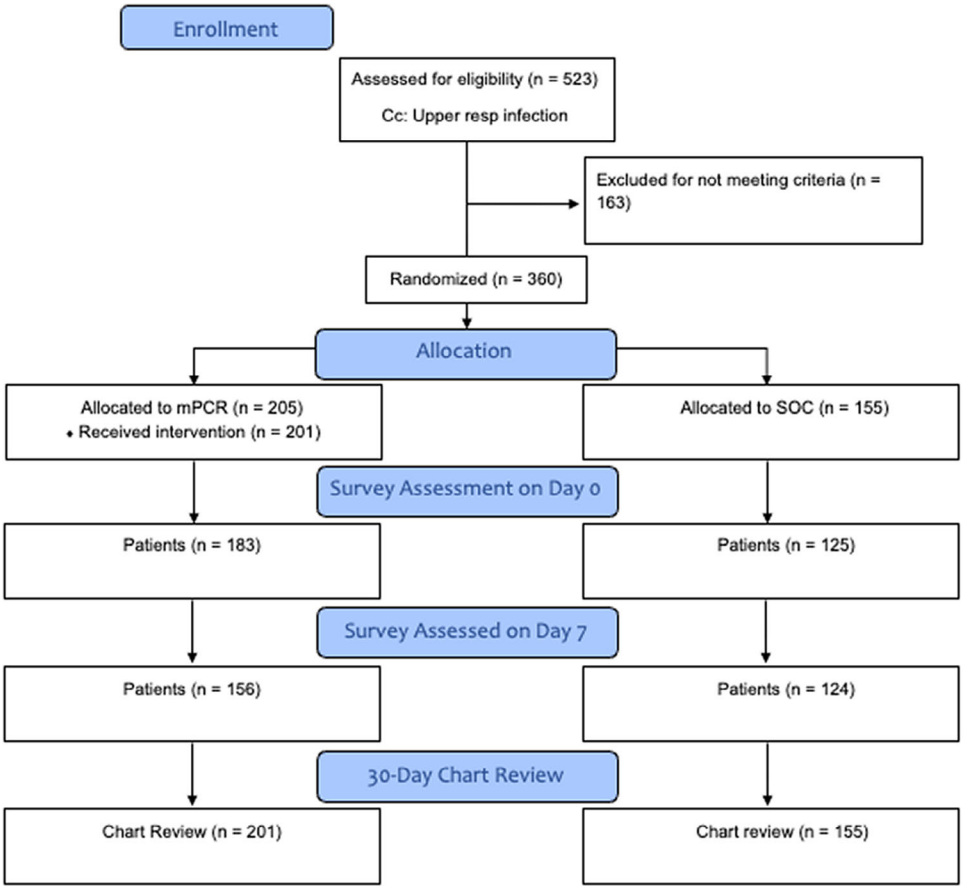

FIGURE 1 Consort diagram for urgent care center. Breakdown of participant flow through the course of the study, specifically the number screened, enrolled, allocated to each group, assessed during respective 7- and 30-day follow-ups, and incorporated in the final analysis.

3 | RESULTS

3.1 | Characteristics of study subjects

Among all visiting UCC patients, 523 were screened for eligibility. After excluding 163 participants who did not meet the eligibility criteria (Figure 1), 360 patients who provided informed consent were included in the study and randomized to the two experimental groups. The study population had a mean age of 34 years, with 64% being women; 50.8 were White, 38.6% were Black, and 8.1% self-identified as Latino patients. No significant differences were observed between groups (Table 1). More than 30% of patients had been vaccinated against influenza in the past year, and more than 90% had received at least one vaccine against SARS-CoV-2. More than 60% of the population described their overall health as "excellent" or "very good," whereas less than 10% described their health as "fair" or "poor."

3.2 | Main results

Following the receipt of the results available on the day of presentation, patients were asked about their satisfaction, plans to isolate, and confidence in the cause of illness (Tables 2 and 3). Significant differences were observed with 98.4% satisfaction in the assessment group versus 42.4% in the SC group. For secondary objectives, after adjusting the *p*-values, the results showed significant differences between the syndromic assessment and SC groups regarding confidence in diagnosis (60.7% vs. 29.6%) and plans NOT to isolate from friends and family (53.6% vs. 36.0%) (Tables 2 and 3).

Both groups reported that it was "important" or "very important" to obtain the results on the same day (95.1% vs. 95.2%). On day 7, in the syndromic assessment group, the number of patients that reported that the time to receive the test results prevented them from performing activities they normally would do was less compared with that of patients in the SC group (16.7% vs. 30.6%, $p = 0.039$). In addition, compared with the SC group, a greater number of patients in the syndromic assessment group agreed with the statement that they were "satisfied with the time it took to receive results" (92.9% vs. 58.9%, $p < 0.001$). We did not observe any overall difference in antibiotic prescriptions between the two groups (33.5% vs. 26.0%) (Table 4). Microbiological laboratory testing of samples from patients in the syndromic assessment group showed that SARS-CoV-2 was the most common virus, followed by rhinovirus (Table 5). Whereas group A streptococci were detected in 16 patients in the SC group and 12 patients in the syndromic assessment group at the UCC using the rapid strep test.

TABLE 1 Baseline information.

	mPCR ($N = 205$), n (%)	SC ($N = 155$), n (%)
Age (years), median age (IQR)	34 (24–49)	34 (26.5–46.5)
Women	138 (67)	94 (61)
Race		
White	100 (48.8)	83 (53.5)
Black	81 (39.5)	58 (37.4)
Asian	13 (6.3)	7 (4.5)
Pacific Islander/other	11 (5.4)	5 (3.2)
Unknown	0	2 (1.3)
Ethnicity		
Hispanic/Latino	19 (9.3)	10 (6.5)
Vaccinated against influenza	68 (33.2)	61 (39.4)
Vaccinated against SARS-CoV-2sa	192 (93.7)	146 (94.2)
Medical history		
Asthma	53 (25.9)	39 (25.2)
Chronic sinusitis	19 (9.3)	10 (6.5)
Diabetes	15 (7.3)	10 (6.5)
COPD/emphysema	14 (6.8)	11 (7.1)
Immunosuppression	14 (6.8)	6 (3.9)
Heart disease	8 (3.9)	8 (5.1)
Cancer	6 (2.9)	7 (4.5)
None of the above	106 (51.7)	90 (58.1)
In general, would you say your health is		
Excellent/very good	124 (60.5)	98 (63.3)
Good	60 (29.3)	46 (29.7)
Fair/poor	21 (10.2)	11 (7.1)

Abbreviations: COPD, chronic obstructive pulmonary disease; IQR, interquartile range; mPCR, multiplex polymerase chain reaction; SC, standard care.

4 | LIMITATIONS

The strengths of this UCC-based study include the large sample size on consecutive patients during enrollment times to limit selection bias. UCCs present a challenging environment for conducting clinical research owing to the lack of research-based infrastructure and emphasis on rapid patient throughput. We overcame this limitation by stationing our research staff that typically works at the academic hospital ED at the UCC to enroll patients. In addition, the randomized design and high rate of ascertainment of primary outcome minimized the risk of bias.

Nonetheless, this study had certain limitations. These include the nonblinded nature of the study design, as both practitioners and patients were aware of the group assignment after randomization. Another limitation was that although all practitioners and patients were informed of the mPCR test results on the same day, some practitioners treated patients and formulated a therapeutic plan without

TABLE 2 Patient-reported results on day 0.

	mPCR ($N = 183$), n (%)	SC ($N = 125$), n (%)	p-value
Are you satisfied by the time to receive the test results? (yes)	180 (98.4)	53 (42.4)	<0.001
Are you confident that you know what is causing your illness?			<0.001
Yes	111 (60.7)	37 (29.6)	
No	43 (23.5)	57 (45.6)	
Unsure	29 (15.8)	30 (24.0)	
Missing	0	1	
Patient received results of tests?			<0.001
Yes	176 (96.2)	26 (20.8)	
No	6 (3.3)	92 (73.6)	
Not tested	1 (0.5)	6 (4.8)	
Missing	0	1	
Plan to miss work?			0.291
Yes	62 (33.9)	60 (48.0)	
No	78 (42.6)	42 (33.6)	
Not applicable	43 (23.5)	23 (18.4)	
Plan to isolate from friends and family?			<0.001
Yes	74 (40.4)	50 (40.0)	
No	98 (53.6)	45 (36.0)	
Unsure	9 (4.9)	27 (21.6)	
Not applicable	2 (1.1)	3 (2.4)	
Plan to seek care from another doctor or healthcare facility?			0.108
Yes	30 (16.4)	17 (13.6)	
No	134 (73.2)	80 (64)	
Unsure	19 (10.4)	28 (22.4)	

Abbreviations: mPCR, multiplex polymerase chain reaction; SC, standard care.

TABLE 3 Patient-reported results on day 7.

	mPCR ($N = 156$), n (%)	SC ($N = 124$), n (%)	p-value
Did the time to receive test results affect you and prevent you from doing activities you normally would do?			0.039
Yes	26 (16.7)	38 (30.6)	
No	130 (83.3)	86 (69.4)	
I am satisfied with the time it took to receive the test results.			<0.001
Strongly agree/agree	145 (92.9)	73 (58.9)	
Neither agree or disagree	7 (4.5)	16 (12.9)	
Strongly disagree/disagree	4 (2.5)	33 (26.6)	

Abbreviations: mPCR, multiplex polymerase chain reaction; SC, standard care.

TABLE 4 Practitioner-centered results.

	mPCR ($N = 155$), n (%)	SC ($N = 104$), n (%)	p-value
Were antibiotics prescribed as part of the IPC visit for respiratory illness?	52 (33.5)	27 (26)	1.301
How confident are you that you know what is causing your patient's illness?			<0.001
Less confident	10 (6.5)	15 (14.4)	
No effect	20 (12.9)	41 (39.4)	
More confident	125 (80.6)	48 (46.2)	
How satisfied are you by the time it has taken to communicate the results to your patient?			<0.001
Less satisfied	5 (3.2)	15 (14.4)	
No effect	11 (7.1)	46 (44.2)	
More satisfied	139 (89.7)	43 (41.3)	
For this patient, how important is it for you to receive test results on the same day?			0.003
Not important/slightly important	7 (4.5)	16 (15.4)	
Moderately important	17 (11)	12 (11.5)	
Very important/important	131 (84.5)	76 (73.1)	

Abbreviations: mPCR, multiplex polymerase chain reaction; SC, standard care.

TABLE 5 Multiplex polymerase chain reaction (mPCR) microbiology results.

Nasopharyngeal sample collected	mPCR ($N = 205$), n (%)
SARS-CoV-2	30 (14.9)
Human rhinovirus/enterovirus	25 (12.4)
Parainfluenza virus	7 (3.5)
Influenza A/H3	5 (2.5)
Respiratory syncytial virus	5 (2.5)
Coronavirus Hku1	2 (1)
Human metapneumovirus	2 (1)
Coronavirus 229e	1 (0.5)
Coronavirus NI63	1 (0.5)
Influenza A	1 (0.5)
Bordetella parapertussis	1 (0.5)
All positives (subtotal)	80 (39 %)

waiting for the test results. It is also possible that patients always prefer more testing and the type of the test is secondary than the fact they received additional testing. Satisfaction was primarily assessed regarding the time taken to communicate results but may not reflect satisfaction with entire healthcare experience. In addition, owing to an unidentified programming error in the automated randomization scheme, we completed the study with an unbalanced number of patients in the study groups. However, the baseline characteristics of the two groups were not significantly different. Finally, some patients presented with strep pharyngitis, a pathogen that was not detected by the current syndromic panel. Future panels of syndromic assessment for ARI's will also target group A strep in addition to the current panel.

5 | DISCUSSION

Traditional PCR is a highly accurate test that tests for one organism at a time and must be performed by certified laboratory personnel. In this study, we tested a POC mPCR in a UCC clinical setting to perform syndromic assessment. Syndromic assessment uses multiplex molecular assays to assess simultaneously for multiple microbial causes of a syndrome. Syndromic assessment is a diagnostic approach that has the potential to improve patient outcomes through improved clinical decision making, optimized laboratory workflow, and enhanced antimicrobial stewardship.[9] Here, we showed that rapid mPCR testing conducted in the UCC affected the confidence in diagnosis and subsequent isolation strategies of patients. The results of this study suggested that the POC mPCR testing is preferred by both patients with ARI and UCC practitioners as a diagnostic method over SC testing methods in terms of satisfaction, diagnostic confidence, and time to results. Individual providers and health systems will need to decide if the benefits are worth the increased cost of syndromic assessment which can cost several hundred dollars (https://www.umms.org/patients-visitors/price-transparency/price-estimate).

Identifying the actual causes of ARI may be important for several reasons. First, due to the availability of antiviral medications specific for SARS-CoV-2, influenza, and RSV and antibiotics for bacterial causes of ARI such as *Bordetella pertussis*, *Chlamydia pneumoniae*, or *Mycoplasma pneumoniae*, correct identification of a specific pathogen can potentially affect treatment. Second, as we showed in this study, patients and practitioners prefer to be told at the point of care the cause of this infection which contributes to high satisfaction and diagnostic confidence. Since the COVID-19 pandemic has killed 7 million people worldwide, patients are less comfortable hearing that their symptoms are due to "just a virus."[10,11] Third, the identification of a specific pathogen may affect how people perceive the need for isolation during this season and their likelihood to undergo vaccination during future seasons.[12,13] Fourth, there is an opportunity to interface directly with public health efforts to track outbreaks that spike throughout the year and have similar symptoms but potentially different outcomes.[12] Finally, there is growing evidence that knowing about co-infections of multiple pathogens affects clinical outcomes and gives clinicians a more complete picture of the syndrome.[13,14]

In our study, we did not see an overall reduction in antibiotic use among patients who underwent mPCR testing. We believe that several factors might explain this lack of reduction. First, creating decision change in practitioners and incorporating new tests into decision process takes time.[15] This lack of change in antibiotic prescribing may illustrate the challenges of behavioral modification of physicians and the lag time to incorporate new technology into established practice

patterns. Second, even with relatively rapid 1-h time to results, most patients had left the clinic or had already discussed the need for antibiotics with practitioner prior to receiving the results. The research team observed that practitioners were unlikely to cancel prescriptions after they had already written them. Anecdotally, the research team did notice that, as the study progressed and practitioners became more comfortable with seeing the results, practitioners were more likely to wait for test results before finalizing medical decision making. A future study conducted by this group will include a 15-min POC mPCR test, which was not available when this study was conducted, and a more structured method of decision support to encourage practitioner to consider the mPCR before medical decision making on treatment plans. In this study, we did not introduce a new pathway for UCC practitioners to withhold antibiotics for ARI with positive viral studies nor did we provide in-servicing to practitioners recommending how to use these results; instead, the test results were provided without decision support. A more structured clinical pathway to incorporate syndromic assessment on ARI patients might have a bigger effect on practice patterns, attitudes, and follow-up strategies. Future studies will utilize an implementation design that uses syndromic assessment as part of structured decision process for ARI.

Decreasing the overuse of antibiotics remains a major goal of our research as it addresses an established public health problem. Approximately 40% of the prescriptions at UCCs are for antibiotics, and accurate and rapid diagnostic testing has the potential of improving antimicrobial stewardship.[2,16] Prior studies have shown a mixed effect of the employment of rapid mPCR testing on antibiotic utilization and antiviral utilization.[17–20] Some studies showed a decrease in overall antibiotic utilization while others showed no change. A recent meta-analysis of respiratory viral testing in the ED showed no association with antibiotic use but an association with higher use of influenza antivirals and lower use of chest radiography and blood tests.[21] We hypothesize that these inconsistent results may reflect differences in timing of the test in relation to physician decision making and the different clinical support that accompanies the new information.

In summary, our study demonstrated that syndromic assessment with a POC mPCR testing for patients with ARI in UCCs is feasible and provides definitive benefits relative to standard testing regarding isolation decisions, confidence in diagnosis, and satisfaction. The ability of POC mPCR to detect respiratory pathogens could result in the earlier administration of appropriate treatment and targeted isolation, potentially reducing the spread of infectious diseases and decreasing the duration of illness. The rapid results and higher sensitivity of mPCR testing have the potential to decrease downstream costs of additional testing. Future studies will evaluate the cost-effectiveness of syndromic assessment in clinical settings outside of UCCs and the role of syndromic assessment and related guidelines to optimize antibiotic stewardship.

AUTHOR CONTRIBUTIONS

Andrew C. Meltzer and Yan Ma contributed to the study conception and design. Aditya Loganathan, Soroush Shahamatdar, Luis W. Dominguez, and Joel Willis were tasked with participant enrollment and data collection. Yan Ma and Wei Zhang formulated the statistical analysis plan and performed the analyses. Andrew C. Meltzer, Aditya Loganathan, Seamus Moran, Soroush Shahamatdar, Wei Zhang, and Yan Ma participated in drafting the manuscript. All authors read and approved the submitted version.

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CONFLICT OF INTEREST STATEMENT

A.C.M. has previously received research grant support and acted as a paid speaker for BioMérieux but declares no non-financial competing interests. All other authors declare no financial or non-financial competing interests.

DATA AVAILABILITY STATEMENT

Data supporting the findings of this study are available from the corresponding author upon request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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