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Improving Management of Suspected Chlamydia and Gonorrhea in Adolescents with a Rapid Diagnostic Test

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ABSTRACT

Introduction. We aimed to determined the impact of an intervention using rapid chlamydia (CT)/gonorrhea (GC) testing on reducing unnecessary antibiotic use, undertreatment of CT and/or GC, and length of stay (LOS) in an urban safety-net pediatric emergency department. **Methods.** Before 2020, we tested for CT/GC using a batched nucleic acid amplification test, with results available the following day. Starting in January 2020, we implemented rapid nucleic acid amplification test. Our primary outcome variables were undertreatment and overtreatment. We defined undertreatment as GC and/or CT-positive patients who did not receive appropriate treatment. We defined overtreatment as GC or CT-negative patients who received antibiotics. The balancing measure was the LOS. **Results.** There were 758 patients evaluated in the preimplementation period (2019), 612 in the implementation period (2020), and 626 in the postimplementation period (2021). Postimplementation, overtreatment decreased from 18.4% to 8.1%. Undertreatment did not differ by period but was less common among those tested with rapid versus standard testing (12.7% versus 9.9%, $P = 0.05$). Median LOS increased from 166 minutes (preimplementation) to 187 minutes (implementation) and 202 minutes (postimplementation; $P < 0.001$). **Conclusions.** Rapid CT/GC testing reduced unnecessary antibiotic use but increased LOS due to patients waiting for the test results before being discharged. Given the rapid increases in CT/GC rates and antimicrobial resistance, health systems should consider implementing rapid testing to appropriately direct antimicrobials to patients most likely to benefit. *(Pediatr Qual Saf 2023;8:e634; doi: 10.1097/pq9.0000000000000634; Published online February 13, 2023.)*

INTRODUCTION

The prevalence of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) infection has markedly increased over the past 2 decades.[1] Over half of GC isolates are resistant to antibiotics, and untreatable GC is now one of the greatest threats to public health globally.[2] In 2017, treatment of reproductive tract infections, primarily CT and GC, became the most common reason we prescribe antibiotics in our outpatient clinics and the fourth most common reason in our emergency department and urgent care centers.[3]

Adolescents are disproportionately affected by CT and GC and account for 50% of annual cases, even though they comprise only 15% of the United States population.[4] This poses significant challenges to care because adolescents frequently utilize emergency departments as their only source of care[5] and are at greater risk for failure to follow-up. We previously reported that within our urban safety-net health system, 13% of patients with CT and/or GC did not return for treatment, and younger patients were less likely to be treated than older patients.[6] Untreated infections can cause serious morbidity, including pelvic inflammatory disease, infertility, and disseminated infection.[7] Conversely, treatment with antibiotics when not needed results in increased resistance[8] and adverse drug events.[9,10] Thus, a timely, accurate diagnosis of infection is needed to ensure that patients receive treatment while minimizing unnecessary antibiotic use.

Standard testing is typically completed in batches using nucleic acid amplification test (NAAT) with a turn-around

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time of 24–74 hours. Rapid diagnostic testing (RDT) using NAAT is similarly accurate to standard testing with a 90-minute turn-around time.[11,12] In adult cohorts, rapid testing reduced undertreatment and overtreatment of CT and GC.[13,14] In this pragmatic quality improvement project, we aimed to determine the impact of a CT/GC RDT on unnecessary antibiotic use, undertreatment of CT and/or GC, and length of stay (LOS) in an urban safety-net pediatric emergency department (PED).

METHODS

This project was a pragmatic, quasi-experimental evaluation of a quality improvement intervention to improve the management of CT and GC infections. The intervention took place in the PED at Denver Health and Hospital Authority (DHHA) in Denver, CO. DHHA is a large, urban, academically affiliated, integrated health system. The system is the region's primary safety-net health system, and 75% of patients served are at or below 150% of the federal poverty level.[15] DHHA also serves a diverse population. For example, in 2018, 58% of patients identified as White, 26% as Black, and 15% as other/unknown race; 47% of patients identified as Hispanic.[16] The PED is a 19-room separate pediatric department for patients 0–19 years of age with an annual patient volume of 26,000.

Intervention

We convened a multidisciplinary team that included (1) a pediatrician from the antimicrobial stewardship team, (2) a PED medical director, (3) a laboratory director of service, and (4) clinical microbiology laboratory staff. The team collaboratively conducted a casual analysis of prescribing practices and mapped processes of suspected CT/GC management in the PED. (**See Figure, Supplemental File 1, *http://links.lww.com/PQ9/A450***). Based on these analyses, we created a key driver diagram, Specific, Measurable, Achievable, Relevant, and Time-Bound Aim, and identified change concepts (Fig. 1). We found that overtreatment and undertreatment were largely driven by not having test results before patient discharge from the PED. We completed a feasibility assessment of each change concept to identify potential intervention options. We found that some change concepts (eg, financial assistance) were not feasible, and other change concepts had been previously trialed without success (eg, having patients call to receive results). Therefore, we decided to focus on implementing an RDT to improve care.

Before 2020, we tested for CT/GC using a batched NAAT [Aptima Combo 2 Assay (Panther System), Hologic, Inc., Marlborough, Mass.] with results available the following day. In January 2020, we switched testing for CT/GC to RDT NAAT [Xpert CT/NG Assay (GeneXpert System), Cepheid Inc., Sunnyvale, Calif.]. Our laboratory clinically validated the RDT for use in the PED. We created a new order in the electronic health record (EHR; EPIC, Verona, Wis.) that was easily accessible to clinicians and educated clinicians via email and at a staff meeting. Residents from 5 training programs rotate through the PED in 1–2-week rotation blocks. We included education regarding the implementation and use of the RDT in the welcome email sent from the medical director to all trainees rotating through the PED at the beginning of the month. We could not use the RDT during some periods in 2020 as it competed with one of our severe acute respiratory syndrome coronavirus 2 tests for supplies and instrument time. When the RDT was not available, clinicians used standard batch testing. In 2021, RDT supplies stabilized, and the test was consistently available. Patients were not required to wait for test results before discharge; the provider assigned to manage results for the day would contact the patients via phone and arrange management when results were available. We implemented clinical care guidelines for managing CT/GC and electronic decision support in the EHR, including medication orders and follow-up test guidance, in 2018 (before this intervention). Because the optimal strategy for discharge from the PED depends on the individual patient and the volume of patients in the PED, clinicians determine the optimal discharge time and presumptive treatment (if prescribed) at their discretion rather than using an algorithm. Using the Model for Improvement, we evaluated real-time RDT use and management to assess the need for additional Plan-Do-Study-Act cycles. Given the effectiveness of the initial iteration, nearly all subsequent Plan-Do-Study-Act cycles focused on adaptations needed for pandemic-associated supply shortages.

Measures

The primary outcome measures were overtreatment and undertreatment of CT or GC. We defined undertreatment as CT and/or GC-positive patients who did not have appropriate antibiotic treatment ordered in the PED. We defined overtreatment as CT or GC-negative patients with antibiotic treatment ordered in the PED. We defined appropriate antibiotic treatment using DHHA institutional clinical care guidelines, which reflect the Centers for Disease Control and Prevention guidelines.[17] Guidelines are available to DHHA clinicians on a website and an antimicrobial stewardship app[18] and were updated during the intervention period to reflect changes in national guidelines. We defined appropriate treatment for CT as either doxycycline or azithromycin and appropriate treatment for GC as either ceftriaxone or cefixime. We considered patients not treated if they did not have appropriate antibiotics ordered for a positive CT and/or GC test within 7 days of their PED encounter. Process measures were the time to result defined as when clinicians placed the order until the time the test resulted and the percentage of patients tested with the RDT. The balancing measure was LOS, defined as the time from PED arrival to PED departure.

Analysis

We included patients 12 and 19 years of age (inclusive) who underwent CT/GC testing in the PED. We excluded

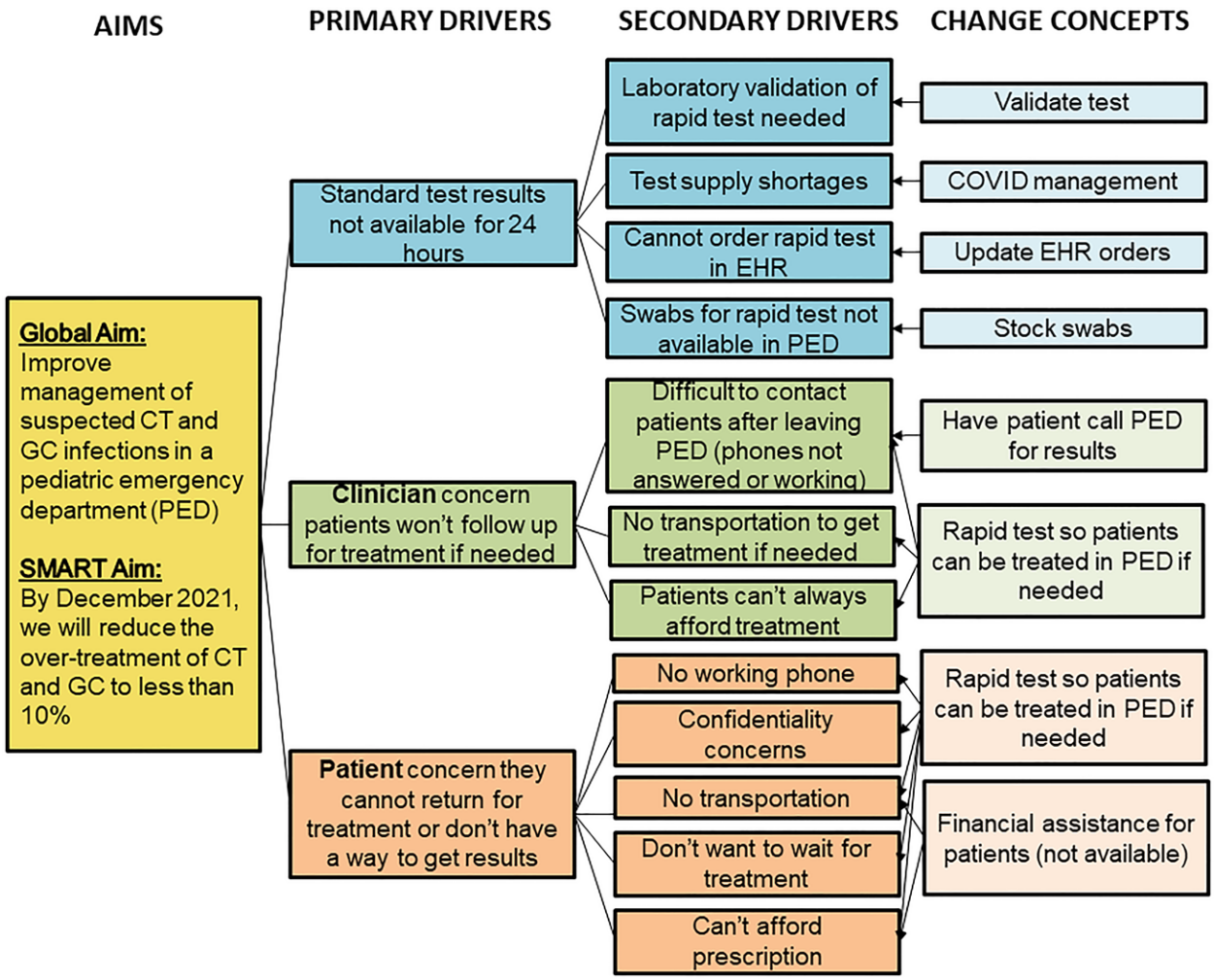

Fig. 1. Key driver diagram of overtreatment and undertreatment of suspected chlamydia and gonorrhea in the PED.

patients with a diagnosis of pelvic inflammatory disease, defined by an *International Classification of Diseases* version 10.0 group (**text, Supplemental File 2, *http://links.lww.com/PQ9/A451***), since they should be prescribed antibiotic treatment regardless of test results.

We retrospectively extracted data from the EHR on patients tested for CT/GC from January 1, 2019, to December 31, 2021. Data were extracted into SAS (Cary, N.C.) from the EPIC data warehouse using standard data tables in the Clarity reporting database. Data included demographic variables, language preference, medical home, CT/GC test type performed (standard versus RDT), CT/GC test results, antibiotics (ceftriaxone, cefixime, azithromycin, and doxycycline) received in the PED, antibiotics (ceftriaxone, cefixime, azithromycin, and doxycycline) received within 7 days of the PED encounter, time to result, and LOS.

We defined study periods as preimplementation (baseline; 2019), implementation (2020), and postimplementation (2021). The implementation period included a staged rollout of the intervention components and intermittent test supply shortages resulting from the COVID-19 pandemic. We calculated summary statistics for patient demographic characteristics by time. We plotted the percentage of patients per month who were overtreated, undertreated, received no treatment, and were evaluated with the RDT on statistical process control (SPC) p-charts. We used 3 sigma limits to set the upper and lower control limits. We created SPC p-charts using QI Charts Version 2.0.22 (Scoville Associates, Tex.). We used standard SPC charting rules for determining special cause (eg, 8 or more consecutive points above or below the centerline) as evidence of improvement.[19]

Continuous variables, including time to result and LOS, are presented as means with standard deviations or medians with ranges depending on their distribution. They were compared using analysis of variance or Wilcoxon rank sum test. Finally, we directly compared overtreatment, undertreatment, no treatment, time to result, and LOS between adolescents tested with the RDT versus standard test (regardless of time). We compared continuous variables using analysis of variance or Wilcoxon rank sum test and categorical variables using the chi-squared test or Fisher exact tests (cell count <5). We performed

statistical analyses with SAS Enterprise Guide 7.1 (Cary, N.C.) and defined significance as alpha = 0.05 using 2-tailed tests.

The Quality Improvement Committee of DH, which the Colorado multiple institutional review board authorizes at the University of Colorado, Denver, and the DHHA Ethics Committee reviewed the project and determined it was not human subjects' research.

RESULTS

There were 758 patients evaluated for CT/GC in the preimplementation period (2019), 612 in the implementation period (2020), and 626 in the postimplementation period (2021) who met the inclusion criteria. Age, gender, race, ethnicity, language preference, insurance, and identified medical home were similar across the 3 periods. In total, 18%–21% of patients tested over the entire study period had GC and/or CT. CT infection was more common (16%–18% of patients tested) than GC infection (5%–8% of patients tested; **Table, Supplemental File 3, *http://links.lww.com/PQ9/A452***).

After the introduction of the RDT, the monthly percentage of patients who were overtreated decreased from 18.4% in the preimplementation and implementation periods to 8.1% (an absolute difference of 10.3%; Fig. 2) in the postimplementation period when testing supplies had stabilized. We detected special cause beginning in January 2021 and plotted updated mean and control limits in the SPC chart. We did not detect special cause in the SPC charts for undertreatment (mean percentage 11.5%) or no treatment (mean percentage 7.1%; Fig. 3; **Figure, Supplemental File 4, *http://links.lww.com/PQ9/A453***). Table 1 shows overtreatment, undertreatment, and no treatment by period and stratified by CT and GC infections.

Figure, Supplemental File 5, http://links.lww.com/PQ9/A454 shows the monthly percentage use of the RDT, which increased from 54.8% during the implementation period (2020), when there were supply shortages, to 73.3% in the postimplementation period (2021) that began in July 2020. We detected special cause beginning in January 2021 and plotted updated mean and control limits in the SPC chart. The median time for the RDT result was 119 minutes in the implementation period and 120 minutes in the postimplementation period. Median LOS in minutes increased from 166 minutes in the preimplementation period to 187 minutes in the implementation period to 202 minutes in the postimplementation period ($P < 0.001$; Table 1).

We analyzed overtreatment and undertreatment by the type of test utilized (Table 2). Overtreatment for CT and/or GC infection was 18.9% with standard testing and 10.7% with RDT ($P < 0.001$). There were also significant differences in overtreatment between the standard testing and RDT in the analysis for CT and GC infections analyzed independently ($P < 0.001$ for both comparisons). Undertreatment for CT and/or GC infection was 12.7% with standard testing and 9.9% with RDT ($P = 0.05$). This difference remained significant when analyzing CT infections (11.5% to 8.6%; $P = 0.03$) but was not different when analyzing GC infections ($P = 0.82$). Presumptive treatment in the PED for those patients discharged before the results were available did not change across the 3 study periods. (**See Table, Supplemental**

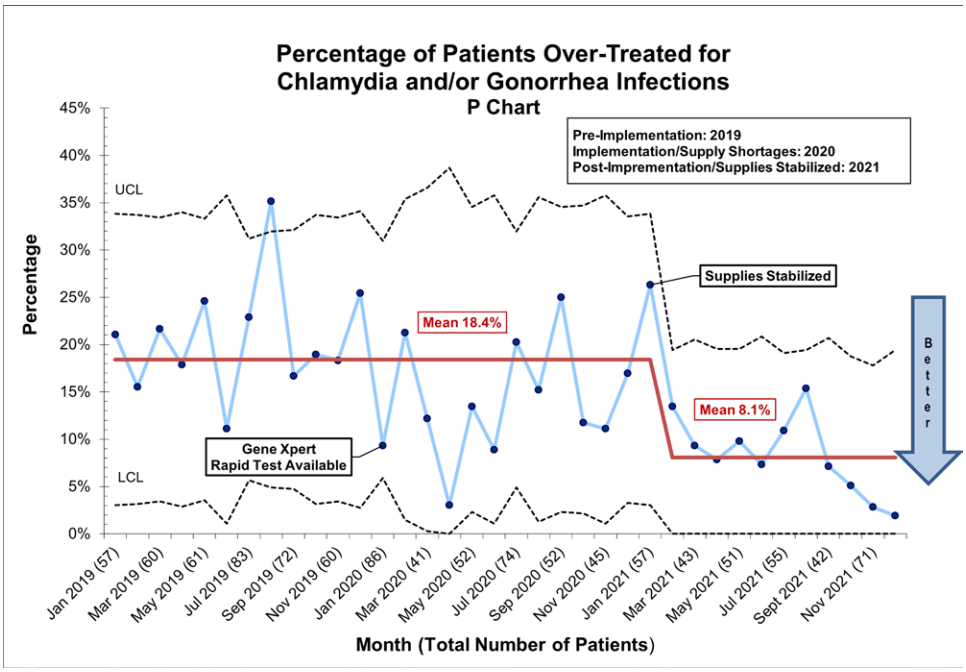

Fig. 2. Percentage of patients overtreated for chlamydia and gonorrhea infections in the PED by period.

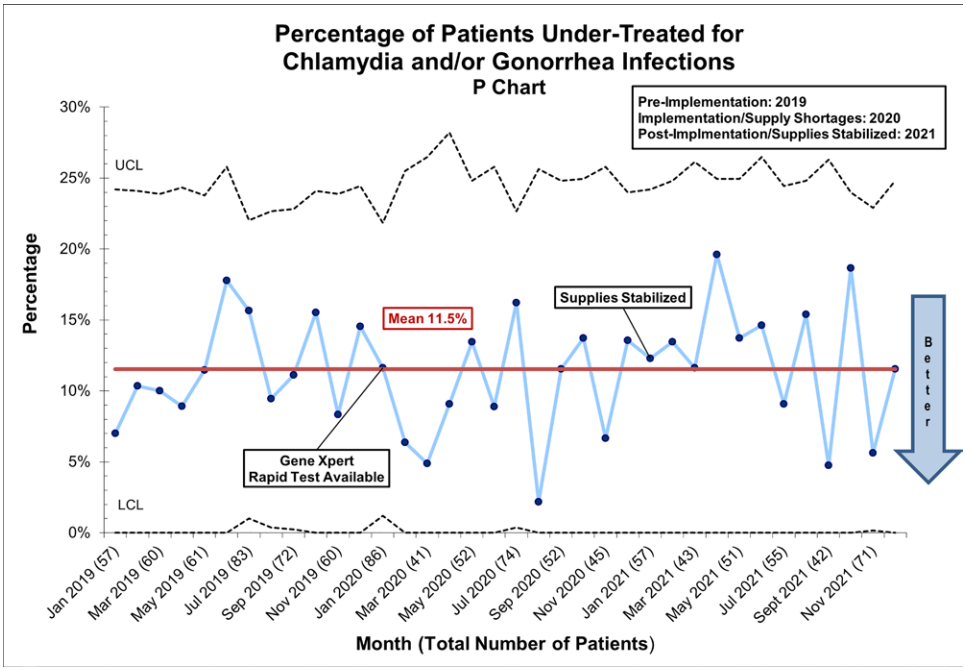

Fig. 3. Percentage of patients undertreated for chlamydia and gonorrhea infections in the PED by period.

Table 1. Outcome Measure by Time Period

Measure	Preimplementation (January–December 2019) N (%) N = 758	Implementation (January–December 2020) N (%) N = 612	Postimplementation (January–December 2021) N (%) N = 626
Primary			
Overtreatment*—any	158 (20.8)	90 (14.7)	61 (9.7)
Chlamydia	105 (13.9)	46 (7.5)	25 (4.0)
Gonorrhea	141 (18.6)	67 (11.0)	50 (8.0)
Undertreatment†—any	89 (11.7)	63 (10.3)	78 (12.5)
Chlamydia	82 (10.8)	58 (9.5)	65 (10.4)
Gonorrhea	15 (2.0)	17 (2.8)	18 (2.9)
No treatment‡—any	43 (5.7)	41 (6.7)	53 (8.5)
Chlamydia	36 (4.8)	38 (6.2)	43 (6.9)
Gonorrhea	9 (1.2)	10 (1.6)	14 (2.2)
Process measures			
Rapid test used§	0 (0)	370 (60.5)	459 (73.3)
Time to result [median (IQR), min]	954 (419–1270)	154 (114–515)	137 (112–289)
Rapid diagnostic test§	0	119 (106–141)	120 (108–146)
Standard test¶	954 (419–1270)	679 (413–1183)	515 (326–1289)
Balance measure			
LOS [median (IQR), min]	166 (113–235)	187 (134–254)	202 (142–279)

*Antibiotic for chlamydia and/or gonorrhea ordered when test was negative.
†Antibiotic for chlamydia and/or gonorrhea not ordered while the patient was in the PED and test was positive for chlamydia and/or gonorrhea.
‡No antibiotic ordered within 7 days of a positive test for chlamydia and/or gonorrhea.
§Xpert CT/NG Assay (GeneXpert System), Cepheid Inc., Sunnyvale, CA.
¶Aptima Combo 2 Assay (Panther System), Hologic, Inc., Marlborough, MA.

File 6 *http://links.lww.com/PQ9/A455*.) We analyzed overtreatment and undertreatment for the subgroup of patients who had the RDT completed during the implementation and postimplementation periods, stratified by whether the RDT result was available at the time of discharge. (**See Table, Supplemental File 7, *http://links.lww.com/PQ9/A456***.) Of the patients who had the RDT completed, those who had the RDT results available before discharge were significantly less likely to be undertreated compared to those who did not have the RDT results available before discharge (7%–15.4%; $P < 0.001$). There were also significant differences for CT infections (5.2%–14.7%; $P < 0.001$) but not GC infections. Overtreatment of chlamydia was greater when the

Table 2. Differences in Outcome Measures between Standard and Rapid Testing

Measure	Standard* N (%) N = 1167	Rapid† N (%) N = 829	*P*‡
Overtreatment§—any	220 (18.9)	89 (10.7)	<0.001
Chlamydia	132 (11.3)	44 (5.3)	<0.001
Gonorrhea	190 (16.3)	68 (8.2)	<0.001
Undertreatment¶—any	148 (12.7)	82 (9.9)	0.05
Chlamydia	134 (11.5)	71 (8.6)	0.03
Gonorrhea	30 (2.6)	20 (2.4)	0.82
No treatment‖—any	74 (6.3)	63 (7.9)	0.27
Chlamydia	63 (5.4)	27 (6.5)	0.30
Gonorrhea	19 (1.6)	14 (1.7)	0.92
Time to result [median (IQR), min]	861 (393–1249)	119 (107–144)	<0.001
LOS [median (IQR), min]	165 (111–235)	206 (155–279)	<0.001

*Aptima Combo 2 Assay (Panther System), Hologic, Inc., Marlborough, MA.
†Xpert CT/NG Assay (GeneXpert System), Cepheid Inc., Sunnyvale, CA.
‡Pearson's chi-squared tests for categorical variables and Wilcoxin rank sum tests for continuous variables.
§Antibiotic for chlamydia and/or gonorrhea ordered when test was negative.
¶Antibiotic for chlamydia and/or gonorrhea not ordered while the patient was in the PED and test was positive for chlamydia and/or gonorrhea.
‖No antibiotic ordered within 7 days of a positive test for chlamydia and/or gonorrhea.

RDT results were available before discharge (6.7% compared to 2.7%; $P = 0.02$).

DISCUSSION

We found high RDT uptake by clinicians and a substantial reduction in unnecessary antibiotic use utilizing an RDT for CT and GC testing in a PED. Though there was not an overall reduction in undertreatment when measured longitudinally (Table 1), undertreatment was less common in patients tested with the RDT than with the standard test (Table 2). In addition, we found a modest increase in LOS after RDT implementation, which a test with a faster turn-around time could mitigate.

Overtreatment occurred for 21% of patients at baseline and occurred even when results were available before discharge. This finding may have been from the misclassification of pelvic inflammatory disease since we relied on electronic data. In addition, when the PED was busy, providers may have ordered the test and antibiotics simultaneously for throughput time as sexually transmitted infection treatment is stocked for ease of administration. Also, providers may have treated for high-risk partner exposure even if the test was negative, given the high community prevalence of CT. Diagnostic uncertainty and fear of loss to follow-up are key drivers of overprescribing, particularly for high-risk populations.[20] These challenges are difficult to address with clinician-level interventions and likely result in inequitable treatment rates. Assuring results are available before discharge circumvents these challenges and promotes the delivery of more equitable care. Implementing an RDT reduced unnecessary antibiotic use by 10% (absolute percentage) and required minimal training or infrastructure changes. The results have been sustained for over a year postimplementation with no additional resource utilization. Because our organization already had GeneXpert System instruments, only small health record changes to facilitate orders were necessary. In our experience, as an Antimicrobial Stewardship Center of Excellence, this implementation was easier than previous interventions.

Although we did not realize a reduction in undertreatment over time, patients managed with RDT versus standard testing were significantly more likely to be treated. Thus, more uptake of the RDT may reduce undertreatment. Significant reductions in undertreatment have been documented in large studies of adult cohorts.[13,14] Undertreatment occurred even when the results were available before discharge. We believe that this is related to the turnover of residents and the intermittent availability of the test during the implementation period. Residents and some attendings also rotate through the adult emergency department where only the standard test is available. Therefore, they may not have realized the result would be available within 2 hours and discharged the patient before checking the results. During implementation, we saw periodic reductions in the use of the RDT secondary to pandemic-associated test supply shortages. It is unclear why 23% of tests ordered in the postimplementation period used standard rather than RDT testing. Potentially, trainees or float staff may not have been aware of test availability.

Additionally, pandemic-associated challenges necessitated stocking swabs for both standard testing and the RDT, which may have inadvertently resulted in clinicians choosing the standard test. Studies with adult cohorts have found reductions in undertreatment with RDTs.[13,14] Before this intervention, we utilized active recall to ensure appropriate treatment, which has demonstrated efficacy in other settings,[21,22] However, we found it to be fraught with challenges, including obtaining confidential or working phone numbers, time trying to contact patients, lack of transportation to return for treatment, and lack of financial resources to fill prescriptions. Given the unique challenges of follow-up for adolescents, we expect RDTs to be more beneficial than in adult settings. More rapid turn-around times would ensure that test results are

available before discharge and would likely reduce the modestly elevated LOS we observed. Currently, clinicians are evaluating a more rapid test with a 20–30-minute turn-around time.

Although we did not complete a formal cost analysis, a future analysis would be helpful to systems considering implementation. The costs of implementing were low. They included analyst time to make EHR changes for ordering (estimated 4 hours) and time to draft education emails and present at meetings (estimated 2 hours). However, the RDT test is more expensive than the standard test (about double). Also, additional laboratory personnel costs are associated with RDT testing since the tests cannot be run in large batches. For systems without GeneXpert systems, capital costs of equipment and training of laboratory personnel require consideration. In contrast, using the RDT likely reduces costs by reducing staff time required to recontact patients with positive results for management and arrange treatment. Additionally, using the RDT likely reduces costs associated with overtreatment (medications, adverse drug events, and antimicrobial resistance) and undertreatment (follow-up care, medical complications such as pelvic inflammatory disease and infertility, and transmission).

Given the success of this intervention, we piloted the use of the RDT in outpatient family medicine clinics (unpublished data). Because patients do not stay in primary care for 90 minutes, clinicians call patients with results within 2 hours of the test. Therefore, we hypothesized that it would be easier to contact patients within 90 minutes rather than 1–2-day turn-around time. Unfortunately, the 90-minute turn around resulted in poor uptake by clinicians because patients could not reasonably wait in clinics for results. We encountered similar challenges with active outreach for patients tested by RDT versus standard testing. Thus, the RDT did not improve overtreatment or undertreatment, and we have discontinued its use in primary care settings. Based on our experience in ambulatory care settings, we believe that an RDT with a turn-around time of <30 minutes would improve care for patients with suspected CT and/or GC. In addition, the widespread implementation of PCR systems during the COVID-19 pandemic could facilitate implementation with minimal system infrastructure requirements.

Strengths of this intervention include the simplicity of intervention, which improves scalability and sustainability. We were able to evaluate a large sample size over 3 years. Electronic data extraction, instead of manual chart review, permitted a robust, nonlaborious evaluation. Other systems could use this methodology, including those with limited resources. This evaluation also had several limitations. We could not distinguish screening in asymptomatic patients versus symptomatic testing. Electronic health data may have resulted in misclassification for some patients. Some antibiotics might have been appropriate even if the test was negative (eg, pelvic inflammatory disease). We cannot prove that the outcome measure results were due to the intervention or may reflect natural changes over time. We also could not capture treatment data for patients treated outside of DHHA. Because this was a single-center project, the results may not be generalizable, although the DHHA population is similar to other urban systems.[16] Finally, the episodic use of the RDT during the implementation period may have influenced results; the best comparison is between the preimplementation and postimplementation phases.

In conclusion, an RDT for CT/GC effectively reduced antibiotic overprescribing and was easy to implement and sustain. A more rapid test will likely reduce undertreatment, LOS, and translatability to nonemergency department settings. Given the rapidly increasing rates of CT and GC, growing antimicrobial resistance, and challenges with positive result management, our approach to these infections must evolve. RDTs could be a pragmatic approach to improving sexually transmitted infection care and reducing unnecessary antibiotic use.

DISCLOSURE

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