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Decreasing Chlamydial Reinfections in a Female Urban Population

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Background: Chlamydia is the most reported bacterial sexually transmitted infection (STI). The rates of chlamydia rose by 19% between 2011 and 2018. The STI National Strategic Plan (2021–2025), encourages coordinated solutions to address STIs and reduce disparities in disadvantaged populations. **Methods:** We implemented institutional policy changes, clinical decision support, including a Best Practice Advisory, and defaulted SmartSet with provider and patient education for women's health clinics at a large county health system. The advisory prompted providers to follow best practices when treating *Chlamydia trachomatis* infections. New *C. trachomatis* diagnosis cohorts were compared preintervention and postintervention for 6-month reinfection rates and patient and expedited partner treatment (EPT) practices.

Results: Five hundred and nineteen women were included in the final analysis. Six-month chlamydia reinfection was lower in the postintervention cohort after adjusting for age (12.3% [26/211] vs 6.5% [20/308], P = 0.02). There was an increase in directly observed therapy of primary patients (17.5% [37/211] vs 77.3% [238/308], P < 0.001), an increase in EPT prescriptions written (4.3% [9/211] vs 79.5% [245/308], P < 0.0001), and a decrease of partners referred out for treatment (61.6% [130/211] vs 5.2% [16/308], P < 0.001) when compared with the control group. The majority of EPT was patient-delivered partner therapy postintervention (3.3% [7/211] vs 69.2% [213/308], P < 0.001).

Conclusions: A multifaceted, streamlined approach was effective in changing provider practices in the treatment of *C. trachomatis*. Increased rates of directly observed therapy for primary patient treatment and increased

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Copyright © 2021 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the American Sexually Transmitted Diseases Association. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. rates of patient-delivered partner therapy were observed postimplementation in addition to lower 6-month reinfection rates in a public women's health clinic setting.

S ome of the challenges targeted by the US Department of Health and Human Samily C. Health and Human Services Sexually Transmitted Infection (STI) National Strategic Plan include preventing new STIs, reducing adverse outcomes of STIs, contributing to research and innovation, reducing disparities and health inequities, and achieving integrated efforts that address the STI epidemic. Suggested strategies from the STI National Strategic Plan to achieve these goals include using technology to improve the efficacy of partner services, advancing the development and use of point-of-care and self-collected diagnostic tests, and supporting the development of STI vaccines.¹ In addition, the strategic plan acknowledges that STI-related health disparities and health inequalities play a role in the rate of reinfection.¹ Although women are at risk for complications from untreated chlamydia, such as pelvic inflammatory disease and tubal factor infertility, challenges to successful patient and partner treatment remain.2

Multiple interventions are needed to result in a reduction of chlamydial reinfections. Patient and partner education, screening, provider alerts, and expedited partner treatment (EPT), including patient-delivered partner therapy (PDPT), have all been studied.^{3–6} Although patient education may be one of the most important strategies to reduce chlamydial reinfection, evidence suggests that a multifaceted approach is best.³

A call to action for a more purposeful approach to EPT among health care professionals that provide care for women has been sounded, although knowledge and practice barriers exist.⁷ Providers have cited limited knowledge of institutional policies regarding EPT, as well as fear of liability, confusion about legality, and availability of partners for counseling as barriers to incorporating this best practice.⁸ Furthermore, the legality of EPT in the United States depends on the state in which the provider is prescribing. In addition, Mmeje et al⁹ found that fewer than half of pharmacists indicated any prior knowledge about EPT when surveyed.

In this quality initiative, we evaluated the effectiveness of a multifaceted, electronically driven best practice intervention in improving provider prescribing, patient and partner treatment, and reducing patient chlamydial reinfection.

MATERIALS AND METHODS

Parkland Health & Hospital participates in the 340B Drug Pricing Program that allows the institution to use its limited resources to serve the community. The program requires that drug manufacturers provide outpatient drugs at a significantly reduced cost. This quality improvement project was approved through Parkland Health and Hospital System's Quality and Safety Department and Office of Research Administration. We implemented

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interventions that fostered immediate patient and PDPT for *Chlamydia trachomatis*. The interventions implemented included in-person provider education, institutional policy changes for providing EPT in a 340b institution, electronic documentation of directly observed therapy (DOT), clinical decision support (Best Practice Advisory [BPA] and SmartSet with built-in provider frequently asked questions), and patient education with partner notification wallet cards and handouts. Best Practice Advisories are alerts built within electronic medical records that aid clinicians to follow best practices and SmartSets provide a grouping of medication and laboratory orders, patient instructions, and billing codes that make treating specific diseases more efficient for clinicians. Extant guidelines for treatment of *C. trachomatis* at the time of this initiative were followed.¹⁰

Patient Population

Female patients 15 years or older with a positive molecular test for chlamydia from any specimen source and written prescription or DOT within 30 days of positive test were included. The women's health clinics (WHCs) are part of a county health system that serves an urban population. Women's health clinics provide family planning, perinatal and other women's health services such as gynecologic and menopausal care. Patients with a diagnosis of HIV were excluded. The preintervention time frame was August 2018 to February 2019, and the postintervention time frame was August 2019 to February 2020, with a 5-month transition period (February 2019 to August 2019) excluded. Patients were followed up for 6 months after the index positive chlamydial test.

Institutional Policy Changes

Clinic Pharmacy (Class D)

The State Board of Pharmacy (Texas Pharmacy Rule §921.91) allows a clinic pharmacy to store, administer, provide, or dispense limited types of prescription medications. Following a policy change, Class D pharmacies in WHCs were able to provide PDPT. Records for treatment provided were stored at each respective clinic, and manual record logs from Class D pharmacies were included in data collection. This policy was housed in the pharmacy department and vetted by pharmacy leadership who disseminated the policy to pharmacy staff. Leadership and education from pharmacy supervisors encouraged the PDPT approach to EPT and proactively addressed pharmacist knowledge regarding EPT.

Utilization of Medication Administration Record

As part of the program implementation, all DOT documentation was standardized and encouraged at the respective clinics to be given in clinic and recorded on the ambulatory medication administration record instead of provided from the Class D pharmacy for the primary patient to take at home.

Provider Education

Communication to increase awareness of the availability of PDPT and electronic clinical decision support was conducted during systemwide staff meetings, targeted optional trainings for individual clinic sites, and supplemented with a frequently asked questions link, which served as a just-in-time refresher within the electronic medical record SmartSet. Although training was not mandatory, the support from departmental leadership ensured that all staff were aware of the initiative. This was accomplished by sending a memo describing the initiative with high priority to all Women's Health Center staff.

Clinical Decision Support

An electronic health record BPA was generated following the result of a positive chlamydia test if no treatment was prescribed at the index visit. The BPA message prompted the provider to prescribe patient and partner treatment with the ability to discretely document reasons for not offering partner treatment. A SmartSet link was embedded in the BPA along with a preview of the SmartSet (Fig. 1). The SmartSet was used to bundle medication and laboratory orders, document clinical findings, place referrals, and provide patient and provider education. The SmartSet that opened depended on specific patient characteristics with four possible SmartSet variations: nonpregnant with or without azithromycin allergy, or pregnant with or without azithromycin allergy. In addition, the SmartSet defaulted to the appropriate patient and partner treatment modalities for the specific clinic. If the clinic had direct access to medication for administration in clinic, then patient DOT was selected. If the clinic housed a class D pharmacy, the partner treatment option was defaulted to provide from the class D pharmacy, and the patient would leave with the "treatment in hand." The SmartSet provided resources for the prescriber and allowed them to select documentation (progress note), select the patient education fact sheet provided (English or Spanish), and order laboratories for other sexually transmitted infections (Syphilis Diagnostic Treponemal CIA, and HIV 1 and 2 Ag/Ab combination screen). Neisseria gonorrhea testing was typically included with C. trachomatis testing, and thus was not reordered. If there was no class D pharmacy available for partner treatment or if the patient was not available to receive DOT, then electronic prescribing with a link to a preferred pharmacy was available. The treatment options in the SmartSet were based on extant CDC recommendations at the time of this initiative: azithromycin 1,000 mg by mouth once, doxycycline 100 mg by mouth twice daily for 7 days, or amoxicillin 500 mg by mouth three times daily for 7 days (reserved for pregnant patients with an azithromycin allergy).

Patient and Partner Education

Patient Education

The bilingual (English/Spanish) patient education provided information about treatment for chlamydia, symptoms associated with an infection, high likelihood of an asymptomatic infection, azithromycin medication information, details for the Dallas County Sexual Health Clinic, and information on free or low-cost sexually transmitted infection services in their area. All materials were reviewed by a health literacy clinical team and approved by the communications department.

Partner Wallet Card

Providers had the option to provide the partner with a wallet card available in English and Spanish. This card included information on the WHC clinic location and contact number as well as the contact number for the Dallas County Sexual Health Clinic. The card also included information on disease transmission, risks of untreated infection, prescribed treatment, safe sex practices, and 3-month retesting recommendations.

Outcomes Measured

The primary outcome measured was 6-month chlamydial reinfection rates, compared in the preintervention and postintervention cohorts. Secondary outcomes included patient index infection treatment modality (electronic prescription, DOT, paper prescription, class D provision—"treatment in hand"), partner treatment modality documentation (none—patient refused, none

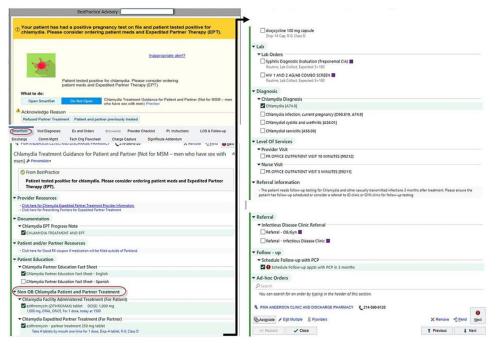


Figure 1. Clinical Decision Support interventions, including a best practice advisory and partner treatment guidance for providers.

—referred to county health department, electronic prescription, DOT, paper prescription, class D provision—"treatment in hand," not documented), and days until repeat test.

Statistical Analysis

Using a random sampling of chlamydia-positive tests, a Cox proportional hazards model was created to evaluate reinfection rates in the postintervention versus the preintervention (historical control) group, with reinfections evaluated in 30-day epochs for up to 180 days after the initial positive test. Kaplan-Meier curves were created to compare the treatment and control groups. The Akaike information criterion was used for the Cox regression model selection, and nominal demographic features were made binary as applicable. Univariate analysis used Pearson χ^2 test for categorical data and Student *t* test for continuous data. A *P* value less than 0.05 was considered statistically significant. All statistical analyses were performed with Python 3.7 (Python Software Foundation). No power analysis was conducted for this quality initiative.

RESULTS

During the preintervention control group (August 2018 to February 2019), 252 women were identified with chlamydia, and 41 were excluded for not meeting criteria for treatment within 30 days of a positive test. In the postintervention epoch (August 2019 to February 2020), 350 women were identified and 42 were excluded, leaving 519 included in the final analysis. Patients were slightly older in the control group ($26.7 \pm 10.1 \text{ vs } 23.9 \pm 6.1$) years, P < 0.001) and the predominant ethnicity and race in both groups was Hispanic-White and non-Hispanic Black. There were no differences in relationship status between the preintervention and postintervention groups (Table 1).

A statistically significant decrease in 6-month *C*. *trachomatis* reinfection rates was observed after the intervention implementation (12.3% [26/211] vs 6.5% [20/308], P = 0.02) (Table 2). Kaplan-Meier analysis paired with the Cox regression

analysis demonstrated separation in infection rates at the 90-day mark, with a significant difference in 6-month reinfection rates after adjustment for age (Fig. 2).

The most common treatment modality for preintervention patients was an electronically provided prescription, whereas DOT was most used in the postintervention epoch. Patients were more likely to have received EPT (4.3% [9/211] vs 79.5% [245/308], P < 0.001) and the most common modality of EPT was PDPT from a Class D pharmacy in the postintervention group [3.3% (7/211) vs 69.2% (213/308), P < 0.001]. The rate of partner referral to the Dallas County Sexual Health Clinic for treatment was statistically lower postintervention (61.6% [130/211] vs 5.2% [16/308], P < 0.001) (Table 2).

The postintervention group had a higher percentage of repeat *C. trachomatis* tests conducted (65.8% [139/211] vs 86.7% [267/308], P < 0.001). Most patients in the preintervention and postintervention groups had a repeat test conducted between 31 and 60 days followed by 61 to 90 days (Table 2).

DISCUSSION

This multifaceted quality initiative aimed to reduce the burden of chlamydia in a women's health clinic population and resulted in a decreased 6-month reinfection rate, increased DOT among patients, increased chlamydia retesting, and increased partner therapy using EPT. Creating streamlined and easy-to-use processes aided clinicians in following best practices when treating both patients and partners for *C. trachomatis*.

Geisler¹¹ demonstrated that DOT administered in youth correctional facilities with 100% adherence to azithromycin and 77% adherence to doxycycline had a 97% and 100% efficacy rate respectively when repeat testing was completed at 28 days. Doxycycline may result in high therapeutic success rates despite decreased adherence¹² and may be preferred for rectal chlamydial infections even in non-DOT settings.^{13,14} However, azithromycin administered in a DOT setting is an important alternative option over doxycycline for several reasons, including transportation or

	Preintervention Group n = 211	Postintervention Group n = 308	Р
Age	26.7 ± 10.1	23.9 ± 6.1	< 0.001
Ethnicity/race			0.177
Hispanic White	134 (63.5)	226 (73.4)	
Non-Hispanic		× /	
White	10 (4.7)	12 (3.9)	
Black	63 (29.9)	66 (21.4)	
Other	4 (1.9)	4 (1.3)	
Relationship status			
Married/common law	34 (16.1)	64 (20.8)	0.223
Single	173 (82.0)	230 (74.7)	0.063
Unable to confirm	4 (1.9)	14 (4.5)	0.169

financial barriers to prescription pick-up, gastrointestinal or photosensitivity side effects, and contraindication in pregnancy.

The CDC recommends retesting for chlamydia in all treated individuals 3 months after treatment, with an additional test of cure 3 to 4 weeks after initial treatment in pregnancy.¹⁰ Our retesting rates were like or higher than those in randomized studies.^{15,16} Retesting in our population primarily occurred between 31 and 60 days instead of the recommended 3 months. Improvement in care processes using clinical decision support guidance has been described; however, the magnitude of the effect varies among different clinical settings and interventions.¹⁷ We believe that including prechecked 3-month follow-up within the SmartSet was the primary driver for repeat testing even though follow-up was not at the recommended interval.

Our overall patient acceptance rate of EPT was similar or higher than that in other studies.^{3,18-20} The addition of literacy level-appropriate bilingual patient education, provider education, and pharmacy policy updates addressed issues previously identified as potential barriers to EPT uptake.^{7,21} The increase in EPT refusals from patients in the postintervention group was 8% (25/308) and could be because of an increased offering of EPT prompted by clinical decision support and institutional policy changes versus referring patients to an outside provider. Reasons for EPT refusal, such as "partner previously treated" or "no longer in contact with partner" are more common than "fear of intimate partner violence" or "not being comfortable discussing the topic with partners."3,19 Further evaluation is warranted to uncover potential unsafe relationships or poor sexual health in women that may contribute to EPT refusal. Fear of intimate partner violence was shown to affect women 2.43 times more than men and may be an important barrier to PDPT in this population.²² Other potential barriers to obtaining PDPT could include race. The STI National Strategic Plan encourages solutions to reduce disparities in disadvantaged populations and Parkland is positioned to help close these gaps. Over 90% of the preintervention and postintervention groups were either Hispanic (White) or Black, who are disproportionately affected by sexually transmitted infections when compared with other races.²³

The multifaceted intervention we implemented resulted in a significant decrease in chlamydial reinfections when the index patient's infection is treated within 30 days. Similarly, in a study by Golden et al.¹⁵ Expedited partner treatment was shown to be beneficial in decreasing persistent or recurrent infections, however, in a secondary analysis this benefit was primarily seen in female patients with gonorrhea infections. There are some key differences between our cohorts of patients that may have led to the success of the EPT initiative in our population. Our cohort included only women treated in a community clinic setting, and this could have led to gender differences in the cohorts because their study cited men as less likely to get retested compared with

women. In addition, only 12% of patients were treated in a similar family planning or community clinic setting, which may have influenced uptake of PDPT. Finally, index patients were given PDPT on the day they were treated for their index infection versus a lag of 6.1 days (±9.2 days), which may have resulted in a faster resolution of infection for their sexual partners in our quality initiative.¹⁵

Accelerated partner therapy programs are currently being investigated that will not only use partner notification but also provide health care professional consultation for partners and kits including the following: antibiotics, educational materials, condoms, and self-sampling tests for HIV, syphilis, gonorrhea and chlamydia.²⁴ Approaches such as these build upon current best practices and will provide further evidence to incorporate multifaceted approaches to sexual health maintenance.

Our study had limitations. The historical cohort was retrospective, and thus data on partner treatment and referral were limited to what was documented in the medical record. Medication receipt could only be confirmed for those receiving DOT or provision from the clinic class D or dispensing from campus retail pharmacy; outside prescriptions were assumed as completed therapy. We were

TABLE 2. Intervention Related Outcomes for Patients Preintervention and Postintervention

	Preintervention Group n = 211	Postintervention Group n = 308	Р
6-mo Reinfection	26 (12.3)	20 (6.5)	0.02
rate			
STI patient RX type	< 0.001		
DOT	37 (17.5)	238 (77.3)	
Class D dispense	62 (29.4)	33 (10.7)	
Outside pharmacy	112 (53.1)	37 (12.0)	
Prescription EPT given	9 (4.3)	245 (79.5)	< 0.001
STI partner RX type			< 0.001
Class D	7 (3.3)	213 (69.2)	-0.001
Outside	2 (0.95)	29 (9.4)	
pharmacy	2 (0.55)	25 (5.1)	
DOT	0 (0.0)	3 (0.97)	
EPT refused	4 (1.9)	25 (8.1)	< 0.001
EPT referred out	130 (61.6)	16 (5.2)	< 0.001
Repeat test	139 (65.8)	267 (86.7)	< 0.001
conducted	157 (05.0)	207 (00.7)	-0.001
Days until repeat			< 0.001
test, d			-0.001
0–30	19 (9)	29 (9.4)	
31-60	61 (28.9)	166 (53.9)	
61–90	28 (13.3)	47 (15.3)	
91–120	28 (13.5) 23 (10.9)	15 (4.9)	
121-150	3 (1.4)	5 (1.6)	
121-130			
101-100	5 (2.3)	5 (1.6)	

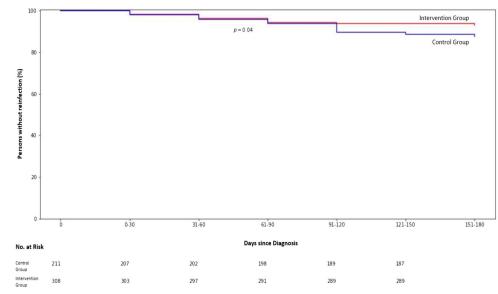


Figure 2. Persons with no reinfection preintervention and postintervention.^a ^a Adjusted for age.

unable to differentiate the weighted impact that each intervention had on provider behaviors related to treatment practices, although the impact of the overall program was positive. Test of cure results were not required for analysis nor did we perform genotyping on chlamydial strains for those with repeat positivity for comparison to index infection. Because of the observational nature of this quality improvement, initiative minimal restrictions for exclusion criteria were implemented in the final analysis. Therefore, there were variances in the pregroup and postgroup that were unanticipated. Of those who followed up, most patients in the postintervention group did so in less than 60 days; however, 42% of those in the preintervention group waited greater than 60 days after their index infection for follow up. The longer duration of time between tests in the preintervention group could have increased their exposure time played a role in the observed reinfection rates.

Chlamydial infections continue to be a serious public health problem. With 80% of infections diagnosed by health care providers rather than STI clinics, interventions that are seamlessly integrated into clinical workflows in real-world health care settings are needed to address the crisis. A multifaceted streamlined approach, including institutional policy changes, clinical decision support, and educational materials, was effective in changing provider practices and reducing 6-month reinfections in an urban nonprofit women's health clinic setting. A replication of these interventions in similar clinic settings that provide various women's health services may yield a similar decrease in chlamydial reinfection rate.

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