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**TREATMENT OUTCOMES ASSOCIATED WITH IMPLEMENTATION
OF AN EXPRESS STI TESTING MODEL IN A PREP CLINIC IN
AUSTIN, TEXAS**

DIANE CHAU

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IN AUSTIN, TEXAS

by

DIANE CHAU, BS

APPROVED:



MELISSA B. HARRELL, PHD

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2020

DEDICATION

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OF AN EXPRESS STI TESTING MODEL IN A PREP CLINIC
IN AUSTIN, TEXAS

by

DIANE CHAU
BS, The University of Texas at Austin, 2018

Presented to the Faculty of The University of Texas

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

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TREATMENT OUTCOMES ASSOCIATED WITH IMPLEMENTATION
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IN AUSTIN, TEXAS

Diane Chau, MPH, BS
The University of Texas
School of Public Health, 2020

Thesis Chair: Melissa B. Harrell, PhD

It is unknown whether express STI testing is as effective as comprehensive STI testing. The research aims of this study are: (1) to describe the patients who obtained a STI testing at the Kind Clinic between February 01, 2019 to January 31, 2020; (2) to determine the association between STI testing type and sociodemographic factors, clinically-relevant factors, and treatment outcomes; (3) to visualize time-to-treatment among STI type and testing types for comparison on a diagnosis-level and a patient-level.

Electronic medical records were abstracted for 2,201 patients that received an STI test during February 01, 2019 and January 31, 2020 at the Kind Clinic in Austin, Texas. Patients were categorized into those who (1) only underwent express STI testing, (2) only underwent comprehensive STI testing, or (3) underwent both express and comprehensive testing. Bivariate analyses were performed to examine potential differences in patient demographics, clinically relevant factors, and treatment outcomes by testing category. Histograms were generated to examine time-to-treatment by testing category, too.

A significantly greater proportion of Asian or Pacific Islanders, females (those assigned at birth & those who identify as females), and straight individuals underwent express testing compared to comprehensive testing. Express testing had a larger proportion of unestablished patients compared to other testing modalities, a smaller proportion of individuals with a known HIV diagnosis, and a smaller proportion with an active PrEP prescription. Histograms showed that time-to-treatment outcomes were similar between express and comprehensive testing, and tabulations of treatment completion also showed no significant differences.

Our study shows that express STI testing can be an effective alternative STI testing model for a high-risk population in a PrEP clinic, as per treatment outcome similarities between express STI testing and other testing modalities. Express testing may offer clinics an opportunity to reach a wider audience than traditional comprehensive testing does.

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BACKGROUND

Express STI Testing

Express STI (Sexually Transmitted Infection) testing is an accelerated or “fast-track” STI testing protocol offered to asymptomatic individuals, implemented with the goals of saving clinical resources, improving efficiency of STI testing, and increasing patient volume. While the process of express testing can vary to meet the needs of the clinic, the general flow in express testing is (1) triaging asymptomatic patients to determine eligibility for express STI testing; (2) collecting biological samples for STI testing; and (3) notifying patients of test results and offering resources for treatment, if necessary (Chambers et al., 2018; O’Byrne et al., 2016; Rietmeijer, 2013). At step one, if patients do not qualify for express testing, they are re-routed to a medical provider, for a comprehensive STI exam instead. Patients that undergo a comprehensive exam are patients that do not qualify for express testing or may qualify but opt for a comprehensive exam. It should be noted that leading up to the moment of express testing sample collection, patients have the option to switch over to a comprehensive exam at any time.

The eligibility criteria for express testing may include being an established patient, not having had a known STI exposure, or not having a partner with a recently diagnosed STI. Express testing is different than a comprehensive STI testing exam in that patients do not see a medical practitioner, do not get a physical examination, and only submit biological samples for testing. The express testing model has only been implemented in a restricted number of clinical settings. Few evaluations of express testing have been conducted, since it is a new protocol in this field.

The benefits of the express STI testing model are expected to be felt for both the patients and the clinical site. Express STI testing, due to its accelerated and less-invasive nature, is expected to expand patient volume and offer a less invasive testing method for those with privacy concerns, ultimately reducing patient wait-times and decreasing patient turn-away rates (Chow et al., 2018; Rietmeijer, 2013; Shamos et al., 2008). With an expanded clinical capacity, more individuals have quicker access to testing services, thus decreasing time until disease detection and treatment and reducing the number of individuals potentially exposed from a patient unable to access testing services. For the clinical site, express STI testing also requires less resources than a comprehensive STI testing appointment, allowing the clinic to expand their volume of care without adding an additional burden on resources (Whitlock et al., 2018). Consequently, express STI testing may be a method that can ultimately contribute to the national effort to decrease rates of STI's.

While an express STI testing program may increase the efficiency of STI testing and reduce the clinical burden of executing such tests, concerns have been raised pertaining to the quality of care patients receive (Rietmeijer, 2013). Specifically, express testing eligibility and recommended testing sites are based on what a patient is willing to disclose and consent to. Issues of missed diagnoses are especially a concern for implementing express testing. The resultant infections that may result from an incomplete testing for site-specific STIs could confer more societal harm than the clinical or individual benefit of express testing (O'Byrne et al., 2016; Rietmeijer, 2013).

Variations in Current Models

Currently, there is no established standard of best practices when implementing an express STI testing model. Express testing is used as an umbrella term in published literature that involves any STI testing model that does not include a detailed examination by a practitioner but allows a generalized STI testing panel.

In the United States, the National Association of County and City Health Officials (NACCHO) is being sponsored by the CDC's Division of STI Prevention to perform an evidence-based large-scale assessment of express STI testing programs. This initiative forms a data collaborative with five U.S. national sites offering express services, an endeavor that is currently underway and not expected to be completed until May 2020. Internationally, the growth of express STI testing services continues, with positive results from evaluations of express STI programs that have been implemented in Canada, Australia, and the United Kingdom (Chow et al., 2018; Gamagedara et al., 2014; Gratrix et al., 2018; O'Byrne et al., 2016; Rukh et al., 2014; Shamos et al., 2008; Whitlock et al., 2018).

Overall, studies have reported that the number of occurrences of gonorrhea and chlamydia identified from express STI tests are less than or equal to that obtained from a comprehensive STI test (Shamos et al., 2018; Rukh et al., 2014). Moreover, patients are notified of testing results faster due to improved communication systems aided by advancements in technology (Chow et al., 2018; Whitlock et al., 2018). Clinical costs of implementing an express testing program are less than that of a traditional comprehensive exam (Chow et al., 2018; O'Byrne et al., 2016; Shamos et al., 2008). However, evaluating the percentage of patients that complete treatment after STI detection from express services

compared to a comprehensive service has shown inconsistent results (Rukh et al., 2014; Gratrix et al., 2015).

Public Health Significance

Sexually transmitted infections are bacterial, viral, or parasitic infections that can transmit between people during physical intimacy or sexual contact (Centers for Disease Control and Prevention, 2019). Since the discovery of the first STI treatment at the turn of the twentieth century, researchers and medical professional have undergone a large and concerted national effort to reduce STI rates by advancing therapeutic drug discovery, educating the public on safe sex practices, and expanding STI testing for the general population. Today, after over 100 years of STI reduction efforts, STI rates are still on the rise and represent a large burden on public health in the United States.

On October 09, 2019, the Centers for Disease Control and Prevention (CDC) released new findings revealing that for the fifth consecutive year, STI rates are the highest they have ever been in the United States, citing a total of 2.5 million cases of chlamydia, gonorrhea, and syphilis combined (Centers for Disease Control and Prevention, 2019). This alarming trend continues in recent STI clinic closures across the country and a shrinking public health funding for STI prevention services (Leichliter et al., 2014). Based on the current landscape for STI prevention and treatment, we are currently in need of more efficient and innovative ways to combat the record high rates of STIs, especially in high risk populations.

The study will take place at the Kind Clinic, specifically the central and north Austin locations. The Kind Clinic is a rapidly expanding non-profit sexual health clinic that offers

services to patients free-of-charge. The Kind Clinic specializes in pre-exposure prophylaxis for HIV (PrEP), STI treatment and testing, gender-affirming care, HIV treatment and testing, and non-occupational post-exposure prophylaxis (PEP). According to data from 2018, patients at the Kind Clinic are approximately 62% lesbian/gay/homosexual, 16% bisexual, 14% heterosexual, and 8% other. Oftentimes, the Kind Clinic acts as a safety net sexual health clinic and works closely with other community partners to connect patients to accessible and affordable sexual health and wellness services. Several current implementations of express STI testing exclude men-who-have-sex-with-men (MSM) individuals from receiving express services, due to the higher risk of STIs within the MSM population and due to the missed counseling opportunity for risk reduction. Additionally, the Kind Clinic serves primarily as an STI prevention clinic and is the largest prescriber of PrEP in Texas. This setting is unique as pharmaceutical methods of risk reduction may result in successful implementation of express testing for a population that would have been excluded.

Research Question and Specific Aims

In January 2018, the Kind Clinic, located in Austin, Texas, began implementing an express STI testing model to supplement traditional comprehensive STI exams already being offered. The goal of this study was to evaluate the reach and effectiveness of the express STI testing model by comparing it with the clinic's comprehensive testing model. The research aims of this study were: (1) to describe characteristics of the patients who obtained a STI testing at the Kind Clinic between February 01, 2019 and January 31, 2020, by testing type; (2) to evaluate differences in sociodemographic factors, clinically-relevant factors, and

treatment outcomes, by testing type; and (3) to visualize and test for differences in time-to-treatment by STI and testing type.

METHODS

Study Design and Participants

A cross-sectional study was performed to investigate potential differences among those who exclusively utilized express testing services, comprehensive testing services, or those who utilized both express and comprehensive testing services at the Kind Clinic between February 01, 2019 and January 31, 2020. The study included all patients who obtained and completed at least one STI test during this time period (N = 2,021). Completion of an STI exam was determined by having at least one STI test laboratory result, regardless of result value. Patients with medical records sealed for personal safety reasons were excluded from the study.

Data Collection

Four datasets with information on patient demographics, STI test event(s), laboratory result(s), and treatment outcomes were obtained via electronic health records maintained by Athena Health. A unique patient ID number available in each of these datasets was used to link them prior to de-identification for subsequent data analyses.

Since Athena Health stored each dataset separately, each STI laboratory result was obtained and merged with the proper STI testing type per patient, after matching for testing date and laboratory processing date. Unmatched STI laboratory results were reviewed per

patient and manually matched with the proper testing type for the appointment. After the testing type was matched with laboratory results, an algorithm was applied to match the closest appropriate treatment given for each positive lab result. Because there was no identifying variable that could connect laboratory data and treatment data, a matching algorithm identified the closest appropriate treatment using four criteria: (1) the treatment date occurred after the testing date, (2) the treatment was the appropriate therapy for the STI diagnosed, (3) the treatment was closest to the initial test date rather than a subsequent testing date, if present, and (4) the treatment occurred within thirty days of testing. Testing type, laboratory results, and treatment data were then deidentified.

For data analysis, the dataset was collapsed at (1) the patient-level, in order to compare patients that used express, comprehensive, or both services during the study period and at (2) the appointment-level, to compare time-to-treatment given an express or comprehensive STI test.

Exposure

For patient-level analysis, individuals in this study were categorized into three testing categories depending on the type of services the patient utilized during the study period: express testing, comprehensive testing, or both express and comprehensive testing. Patients that qualified for express STI testing must self-report that they did not: (1) have any STI-related symptoms (discharge, painful or burning urination, genital sores/rashes/itching, testicular pain, lower abdominal pain), (2) have a sexual partner diagnosed with an STI, and (5) wished to speak to a provider for questions or concerns. Patients that answered “yes” to

any of the testing criteria were routed to a comprehensive STI exam and testing with a provider. Otherwise, the express STI testing protocol is employed. The number of testing events per patient is not accounted for within these categories, so long as the patient exclusively used the testing type listed. For appointment-level analysis, the testing event is categorized either as express testing or a comprehensive testing.

STI Diagnosis and Treatment Factors

Chlamydia, gonorrhea, and HIV were the three STI categories considered for this analysis since laboratory tests for each are offered in both express and comprehensive STI testing. Syphilis was not analyzed due to the lack of data distinguishing a reactive antibody test as either a new primary infection or simply evidence of a prior treated infection.

In patient-level analysis, a patient was considered to be positive for the STI category if the patient tested positive at least once via a testing event that occurring during the study period. The total number of patients for each STI type is determined by the number of patients among 2,021 that submitted a laboratory specimen for the STI during a testing event. To be considered treated for the STI category, the patient must have received treatment within thirty days for all positive results of each STI. Failure to obtain treatment for one positive result, even if there may be multiple positive results due to multiple testing visits during the study period, resulted in the patient considered as untreated for the STI category. The number of days between the testing event and the treatment for each positive STI result was calculated and averaged over the number of testing events as the days until treatment by STI category, per patient.

In appointment-level analysis, all positive diagnoses reported by the Kind Clinic during the study period was included. A STI diagnosis was considered to be any positive result for a STI pathogen (i.e., chlamydia, gonorrhea, or HIV). Treatment was completed if the appropriate treatment was administered within 30 days of the testing date.

Clinically Relevant Factors

Clinically relevant factors are individual-level characteristics associated with clinical care and therefore are only considered in patient-level analysis. A patient was categorized as having a positive HIV status at time of testing if the patient completed a HIV positive-care appointment at the Kind Clinic prior to at least one testing event. An active PrEP status indicated the patient had a prescription for PrEP that overlapped with at least one STI testing date, after accounting for quantity per prescription and refill per prescription. Additionally, an unestablished patient was a patient who had the first appointment date at the Kind Clinic match with a STI testing date during the study period. In other words, unestablished patients had no previous contact with the Kind Clinic, prior to this testing date. Established patients did.

Sociodemographic Factors

Sociodemographic factors were abstracted from electronic medical records during data collection. These factors include race and ethnicity (Non-Hispanic White, Hispanic or Latino, Black, Asian or Pacific Islander, and other/multiple races [including Native

American]), sex assigned at birth (male/female), gender identity (male/female/genderqueer or other), sexual orientation (gay or lesbian/straight/bisexual/other), highest level of educational attainment (less than or equal to high school diploma (or equivalent), some college or Associate's degree, Bachelor's degree, or graduate degree or higher) , employment status (full-time/part-time/unemployed), insurance status (insured/uninsured), marital status (single/married/divorced/widowed), and household size. Patient age in years was calculated as the average age at each testing event.

Data Analysis

To describe the population of individuals that obtained an STI testing at the Kind Clinic, prevalence data was reported as tabulations, frequencies, and percentages. Bivariate analyses were employed to ascertain if there were differences in relevant factors between testing categories in patient-level analysis using the Pearson's χ^2 test and Fisher's exact test for categorical variables and ANOVA tests for continuous variables (see **Tables 2A-2B**). Histograms were generated by testing categories and were then stratified by STI type for both appointment-level analysis as well as patient-level analyses (see **Figures 1-4**). STATA statistical software was used to perform data management, analyses, and visualization.

Human Subjects Considerations

The study involved retrospective chart review for program evaluation and no more than minimal risk to subjects was expected. All data management and analysis were performed using an encrypted laptop provided by the Kind Clinic. Institutional review board

exemption was obtained under 45 CFR 46.101(b) through the Committee for Protection of Human Subjects at the University of Texas Health Science Center at Houston (Approval #: HSC-SPH-19-1070).

RESULTS

Patient-level characteristics

Patient-level characteristics were reported as demographic factors in **Table 1A** and STI diagnosis and treatment in **Table 1B**. Between February 01, 2019 to January 31, 2020, a total of 2,021 individuals obtained at least one express or comprehensive STI testing. Of the 2,021 individuals (see **Table 1A**), 77% were male at birth and 73% identified as male presently; half (50%) were gay or lesbian. The average age of patients was 32 years old (± 9.60) and 43% were non-Hispanic White. The majority of individuals (60%) were unestablished patients at the Kind Clinic, so were approaching the Kind Clinic for the first time, for this STI testing.

Among these individuals, 55% of them only utilized comprehensive testing services, 34% only utilized express testing services, and 8% utilized both express and comprehensive services (see **Table 1B**). The STI positivity rate among these individuals overall was 12% for chlamydia, 13% for gonorrhea, and <1% for HIV. Of those that tested positive for chlamydia, the average time to treatment (i.e., time between the testing event and treatment) was 4.53 days (± 4.62) among those who tested positive for gonorrhea, the average time to treatment was 3.48 days (± 5.25). A total of eight individuals tested positive for HIV and four patients established HIV-positive care with the clinic within an average of 3.80 days (± 3.49), while

the other four patients were referred to the Austin Public Health. A small proportion of individuals (7%) had a PrEP prescription that overlapped with at least one of their STI testing dates and 2% of individuals had a prior HIV diagnosis for at least in one of their test dates.

Appointment-level outcomes

There were statistically significant differences in STI positivity, by category of testing services for both chlamydia and gonorrhea (**Tables 2A** and **2B**). Analysis on HIV was not performed due to the limited sample size. The prevalence of a positive STI test was significantly greater among those who underwent both express and comprehensive testing, compared to those who underwent comprehensive testing or express testing only. However, there was no statistically significant difference between the mean number of days from testing until treatment among testing categories for both chlamydia and gonorrhea. Significant differences between testing modalities were also observed for the following variables: having a prior HIV diagnosis at time of testing, having a PrEP prescription at time of testing, patient status at the clinic, race and ethnicity, sex assigned at birth, gender identity, and sexual orientation among different testing categories.

Specifically, the express STI testing category had a lower prevalence of individuals with a prior HIV diagnosis and individuals prescribed PrEP at the time of testing compared to the other two testing categories (**Table 2A**). Additionally, the prevalence of unestablished patients among those that underwent express testing was significantly greater compared to those who underwent comprehensive testing or those that underwent both express and comprehensive testing.

The express testing only category had a higher prevalence of Asian or Pacific Islanders compared to comprehensive testing only or both testing types. The prevalence of those who were assigned male sex at birth and those that identity as male were greater among those that underwent comprehensive testing compared to those that underwent express testing. The prevalence of those that reported a being gay or lesbian was greater among those that underwent comprehensive testing compared to those that underwent express testing.

Data visualization

Histograms exploring time-to-treatment outcomes between testing categories were generated for patient-level (see **Figures 1 & 2**) and appointment-level analyses (see **Figures 3 & 4**). Since the standard STI treatment protocol recommends presumptive treatment at the time of testing for patients experiencing STI symptoms (all of whom would have undergone comprehensive testing), all testing events that resulted in same-day treatments were excluded in all figures to allow for comparison between express and comprehensive testing.

The time-to-treatment histograms depicted in **Figure 1** showed that the average number of days it took per person to return for a STI treatment were similar between those that utilized express testing services only, comprehensive services only, and those that utilized both services. This trend was observed once again after stratifying the time-to-treatment for a specific STI diagnoses (see **Figures 2A** and **2B**), suggesting similar treatment outcomes on a patient-level, irrespective of STI testing type or STI diagnoses.

Both histograms in **Figure 3** depicted similar time-to-treatment curves for pooled chlamydia and gonorrhea diagnoses reported by the Kind Clinic, consistent with patient-level

results reported in **Table 2A**. When stratified by STI type, **Figures 4A** and **4B** showed that this similarity in time-to-treatment was comparable between express and comprehensive testing.

Tables and Figures

Table 1A: Demographics of patients who underwent STI testing(s) at the Kind Clinic between February 01, 2019 to January 31, 2020 (N = 2,021).

	No.	(%) ¹
Race and Ethnicity		
White	868	(42.95%)
Hispanic or Latino	357	(17.66%)
Black	169	(8.36%)
Asian or Pacific Islander	102	(5.05%)
Other/multiple races	290	(14.35%)
Age (years), mean (S.D.)	31.27	(9.60)
Sex Assigned at Birth		
Male	1546	(76.50%)
Female	475	(23.50%)
Gender Identity		
Male	1469	(72.69%)
Female	414	(20.48%)
Genderqueer or Other	73	(3.61%)
Sexual Orientation		
Gay or lesbian	1000	(49.98%)
Straight	449	(22.22%)
Bisexual	372	(18.41%)
Other	88	(4.35%)
Education		
≤ High School diploma (or equivalent)	334	(16.53%)
Some college or Associates degree	578	(28.60%)
Bachelor's Degree	683	(33.80%)
≥ Graduate Degree	319	(15.78%)
Employment Status		
Full time	1211	(59.92%)
Part time	293	(14.50%)
Unemployed	190	(9.40%)
Insurance Status		
Insured	959	(47.45%)
Uninsured	667	(33.00%)
Missing	395	(19.54%)
Marital Status		
Single	1,632	(80.75%)
Married	168	(8.31%)
Divorced	91	(4.50%)
Widowed	5	(0.25%)
Household Sizes		
1	559	(67.19%)
2	122	(14.66%)
3	45	(5.41%)
4 or more	76	(4.21%)
Missing	1219	(60.32%)

¹ Column percentages reported, unless specified otherwise.

⁸ Household size was excluded from further analysis, due to extensive missingness.

S.D. = standard deviation

Table 1B: Clinical characteristics of patients who underwent STI testing(s) at the Kind Clinic between Feb. 01, 2019 to Jan. 31, 2020 (N = 2,021).

	N	(%) ¹
STI Testing Model		
Comprehensive	1,111	(54.97%)
Express	743	(36.76%)
Both comprehensive and express	167	(8.26%)
STI Diagnosis and Treatment		
Chlamydia		
Positive/Total ²	227/1945	(11.67%) [¥]
Treated within 30 days ³	226/227	(99.56%) [¥]
Days until treatment (mean), S.D. ^{4, 5}	4.53	4.62
Gonorrhea		
Positive/Total ²	248/1945	(12.75%) [¥]
Treated within 30 days ³	248/248	(100.00%) [¥]
Days until treatment (mean), S.D. ^{4, 5}	3.48	5.25
HIV		
Positive/Total ²	8/1551	(0.52%) [¥]
Treatment within 30 days ³	4/8	(50.00%) [¥]
Days until treatment (mean), S.D. ^{4, 5}	3.80	3.49
HIV Status at time of testing⁶		
Positive	43	(2.13%)
Negative	1978	(97.87%)
PrEP Status at time of testing⁷		
Active PrEP	133	(6.70%)
No/Not Active PrEP	1853	(93.30%)
Patient Status		
Unestablished	1,214	(60.07%)
Established	807	(39.93%)

¹ Column percentages reported, unless specified otherwise

² (Total number of patients that tested positive for STI, at least once during study period)/(total number of patients that tested for the STI, at least once during study period)

³ Proportion of patients that received treatment for STI within 30 days, among total number of patients that tested positive for STI

⁴ Average number of days until treatment for STI calculated per patient. Mean average number of days calculated for sample.

⁵ S.D. = standard deviation

⁶ HIV Status at time of testing = Patient received at least one STI test with prior HIV-positive diagnosis

⁷ PrEP = pre-exposure prophylaxis for HIV. PrEP Status at time of testing = Patient received at least one STI testing when they had an active PrEP prescription at time of testing

⁹ Syphilis treatment unavailable, due to complexities of treatment regime.

[¥] Row percentage

Table 2A: Differences in demographic characteristic by STI testing type among patients who received an STI testing at the Kind Clinic between Feb. 01, 2019 to Jan. 31, 2020. (N = 2,021).

		Express (n = 743)		Comprehensive (n = 1,111)		Both (n = 167)		X ² / F-statistic	P-value
		N	(%)	N	(%)	N	(%)		
Race and Ethnicity								18.82	0.016*
	White	323	(49.46%)	476	(48.47%)	69	(45.70%)		
	Hispanic or Latino	65	(9.95%)	91	(9.27%)	13	(8.61%)		
	Black	128	(19.60%)	199	(20.26%)	30	(19.87%)		
	Asian or Pacific Islander	50	(7.66%)	49	(4.99%)	3	(1.99%)		
	Other/multiple races	87	(13.32%)	167	(17.01%)	36	(23.84%)		
Age (years), mean (S.D.)		30.89	9.36	31.58	9.79	30.87	9.42	1.31	0.2689
Sex Assigned at Birth								15.03	0.001*
	Male	533	(71.74%)	883	(79.48%)	130	(77.84%)		
	Female	210	(28.26%)	228	(20.52%)	37	(22.16%)		
Gender Identity								18.82	0.001*
	Male	502	(69.92%)	846	(78.48%)	121	(75.63%)		
	Female	188	(26.18%)	195	(18.09%)	31	(19.83%)		
	Genderqueer or Other	28	(3.90%)	37	(3.43%)	8	(5.00%)		
Sexual Orientation								44.56	<0.001*
	Gay or lesbian	303	(43.53%)	595	(56.40%)	102	(64.56%)		
	Straight	210	(30.17%)	218	(20.66%)	21	(13.29%)		
	Bisexual	150	(21.55%)	193	(18.29%)	29	(18.35%)		
	Other	33	(4.74%)	49	(4.64%)	6	(3.80%)		
Education								3.58	0.733
	≤ High School diploma (or equivalent)	128	(18.21%)	183	(17.33%)	23	(14.84%)		
	Some college or Associates degree	199	(28.31%)	325	(30.78%)	54	(34.84%)		
	Bachelor's Degree	253	(35.99%)	375	(35.51%)	55	(35.48%)		
	≥ Graduate Degree	123	(17.50%)	173	(16.38%)	23	(14.84%)		
Employment Status								3.90	0.420
	Full time	455	(72.80%)	653	(69.91%)	103	(76.30%)		
	Part time	107	(17.12%)	166	(17.77%)	20	(14.81%)		
	Unemployed	63	(10.08%)	115	(12.31%)	12	(8.89%)		
Insurance Status								4.75	0.093
	Insured	377	(61.40%)	483	(56.49%)	99	(63.06%)		
	Uninsured	237	(38.60%)	372	(43.51%)	58	(36.94%)		
Marital Status									0.632 [‡]
	Single	585	(85.65%)	902	(85.82%)	145	(89.51%)		
	Married	63	(9.22%)	96	(9.13%)	9	(5.56%)		
	Divorced	33	(4.83%)	51	(4.85%)	7	(4.32%)		
	Widowed	2	(0.29%)	2	(0.19%)	1	(0.62%)		

Column percentages reported, unless specified otherwise

S.D. = standard deviation

[‡] Fisher's Exact test

* Significant P-value at alpha = 0.05

Table 2B: Differences in STI diagnosis and treatment, PrEP status, and demographic characteristic by STI testing type among patients who received an STI testing at the Kind Clinic between Feb. 01, 2019 to Jan. 31, 2020. (N = 2,021).

		Express (n = 743)		Comprehensive (n = 1,111)		Both (n = 167)		X ² /F-statistic	P-value	
		N	(%)	N	(%)	N	(%)			
STI Diagnosis and Treatment										
Chlamydia										
	Positive	48	(6.46%)	143	(12.87%)	36	(21.56%)	37.82	<0.001*	
	Days until treatment (mean), S.D.	7.62	3.22	7.57	4.25	6.27	2.60	1.25	0.289	
Gonorrhea										
	Positive	37	(4.98%)	179	(16.11%)	32	(19.16%)	59.28	<0.001*	
	Days until treatment (mean), S.D.	9.19	3.85	8.46	4.87	8.92	5.87	0.22	0.803	
HIV										
	Positive	3	(0.40%)	5	(0.45%)	0	(0.00%)	--	--	
	Days until treatment (mean), S.D.	6	0	6.5	0.71	--	--	--	--	
HIV Status at time of testing									<0.001* ‡	
	Positive	3	(0.40%)	32	(2.88%)	8	(4.79%)			
	Negative	740	(99.60%)	1,079	(97.12	159	(95.21%)			
PrEP Status at time of testing									52.32	<0.001*
	Active PrEP	15	(2.02%)	92	(8.28%)	26	(15.57%)			
	No/Not Active PrEP	728	(97.98%)	1,019	(91.72%)	141	(84.43%)			
Patient Status										
	Established	169	(22.75%)	550	(49.50%)	88	(52.69%)	145.28	<0.001*	
	Unestablished	574	(77.25%)	561	(50.50%)	79	(47.31%)			

Column percentages reported, unless specified otherwise

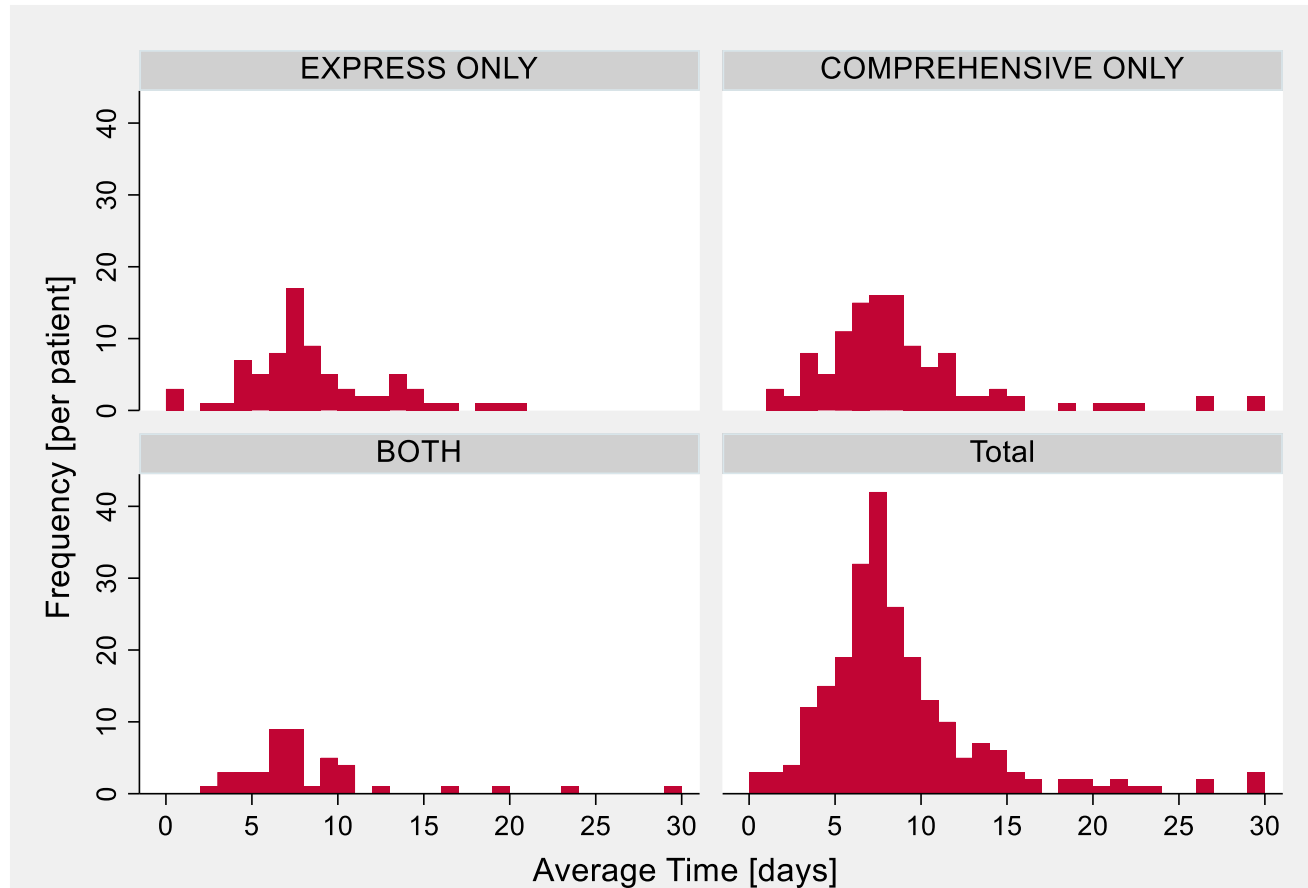
PrEP = pre-exposure prophylaxis for HIV

S.D. = standard deviation

[‡] Fisher's Exact test

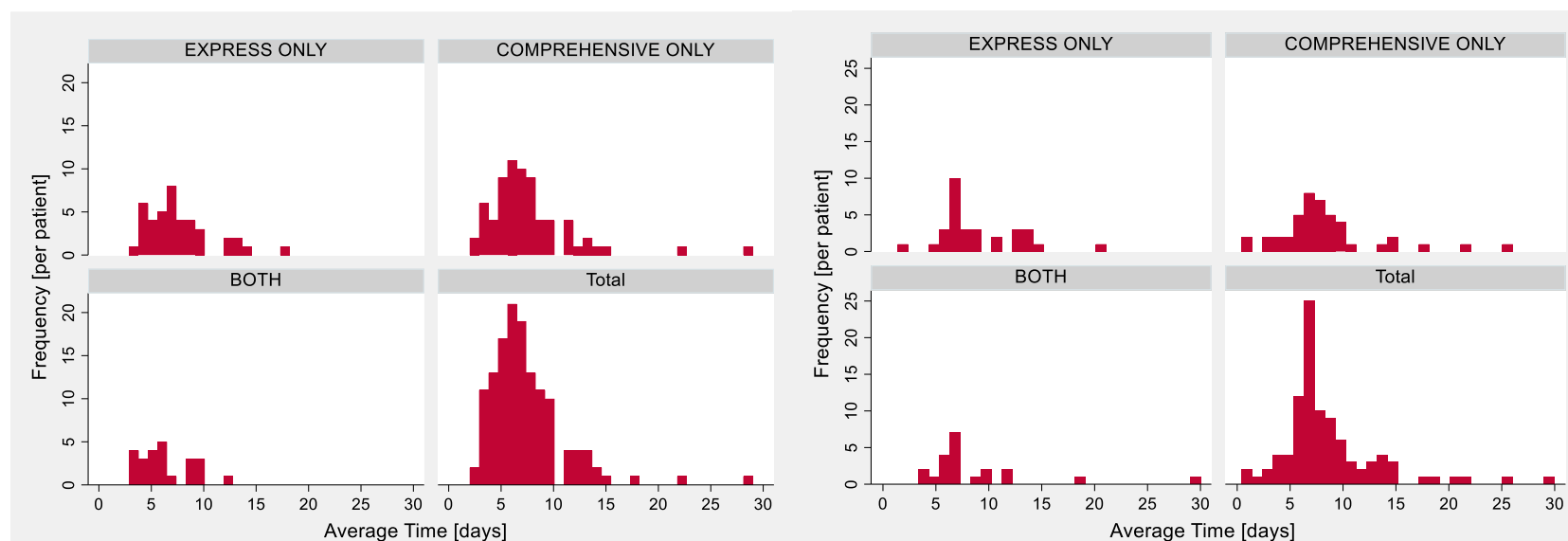
* Significant P-value at alpha = 0.05

Figure 1: Average number of days from testing to treatment date for all positive STI diagnoses per patient, ever diagnosed with a STI at the Kind Clinic between February 1, 2019 to January 31, 2020, stratified by STI testing category. (N = 2,021)



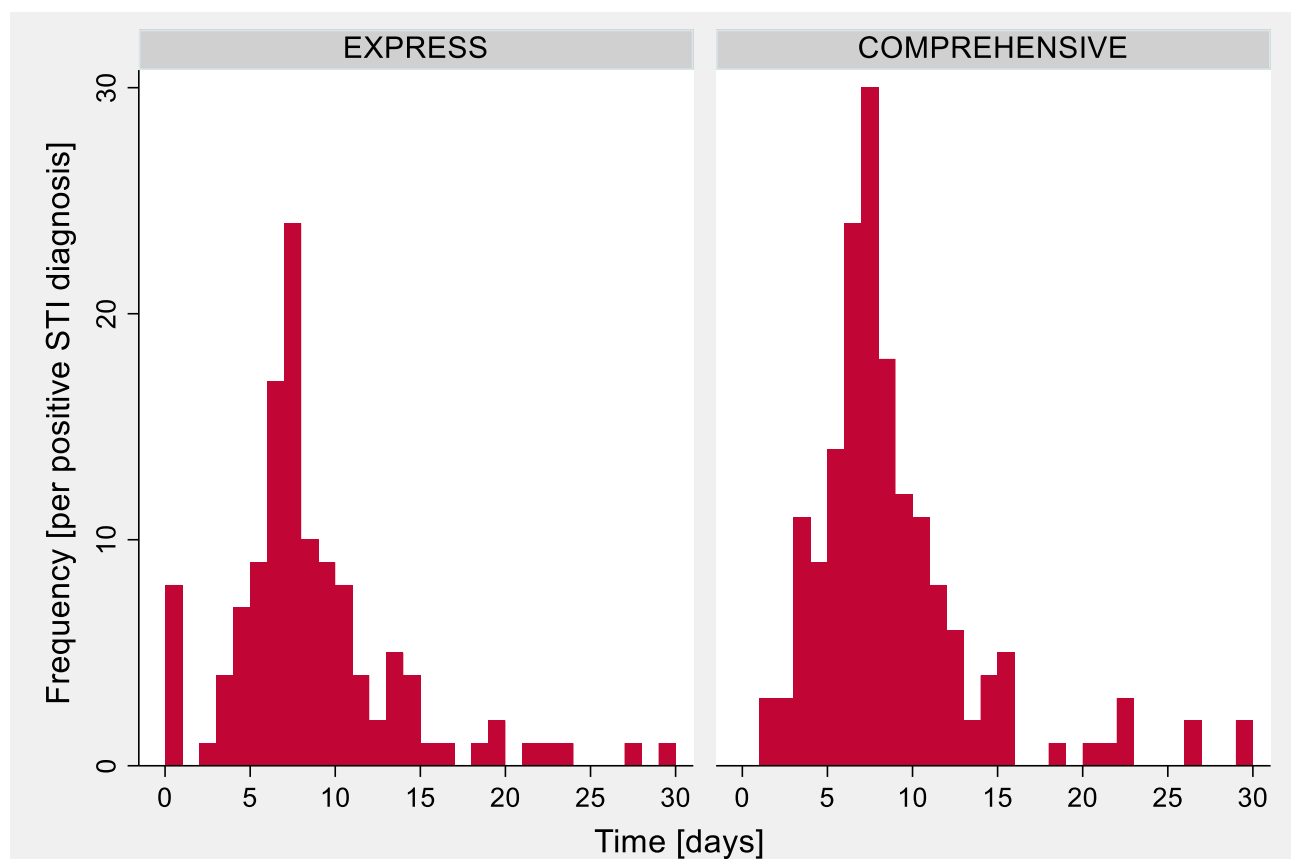
*STI diagnoses with treatment administered on day of testing were excluded to allow for fair comparison between testing categories.

Figure 2: Average number of days from testing to treatment date for all positive STI diagnoses per patient, ever diagnosed with a STI at the Kind Clinic between February 1, 2019 to January 31, 2020, stratified by STI testing category and STI type. **(A)** left: stratified STI testing category for chlamydia diagnoses; **(B)** right: stratified STI testing categories for gonorrhea diagnoses. (N = 2,021)



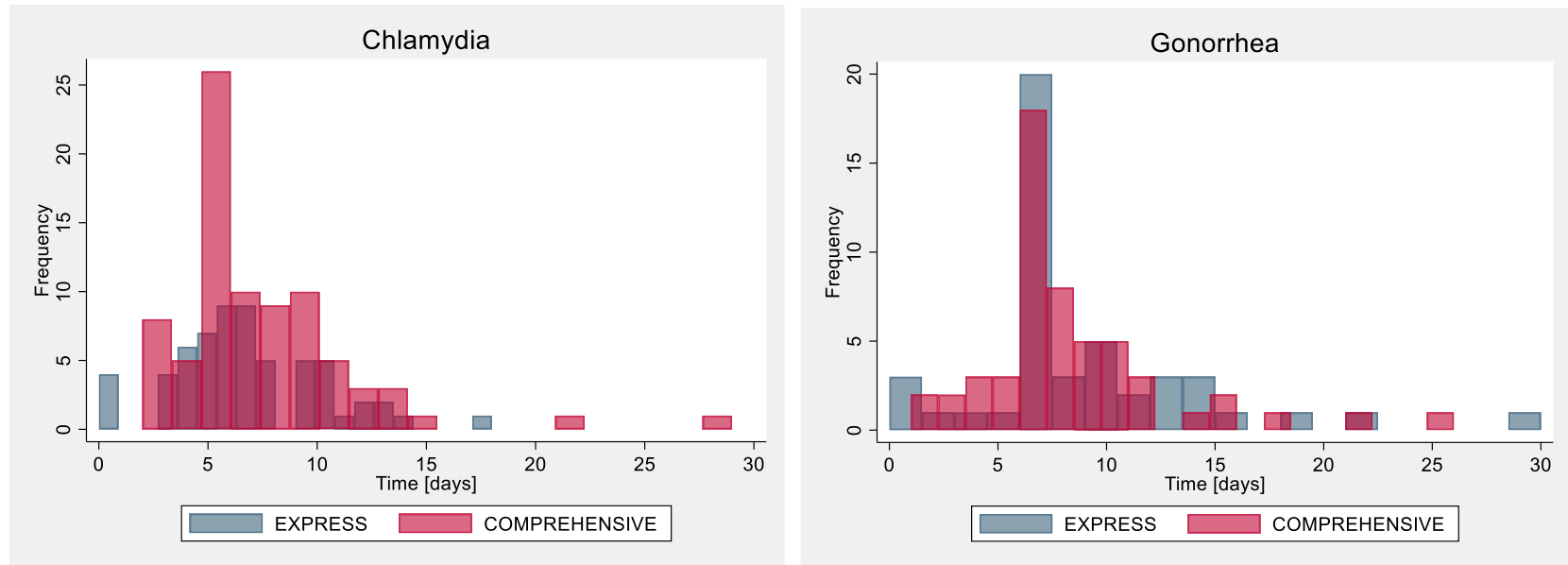
*STI diagnoses with treatment administered on day of testing were excluded.

Figure 3: Number of days between testing date and treatment date for each positive STI diagnosis reported by the Kind Clinic between February 1, 2019 to January 31, 2020, stratified by STI testing type. (N = 292)



*STI diagnoses with treatment administered on day of testing were excluded to allow for fair comparison between express and comprehensive testing types (N = 183).

Figure 4: Number of days between testing date and treatment date for each positive STI diagnosis reported by the Kind Clinic, stratified by STI category with superimposing testing types. **(A)** left: stratified by chlamydia diagnosis; **(B)** right: stratified by gonorrhea diagnosis. (N = 292)



*STI diagnoses with treatment administered on day of testing were excluded (N = 183).

DISCUSSION

The express STI testing is an accelerated or fast-track STI testing model that is gaining traction as an alternate testing model because of its ability to increase STI testing volume in an operationally sustainable manner; however, the effect of this testing model is largely unknown. For example, it is unclear if this testing model reaches a different clinical audience, or if treatment outcomes are more or less effective than comprehensive testing. Understanding the outcomes of an express STI testing model will be essential for not only effective program implementation, but also to inform the potential of express STI testing in the national effort to reduce STI rates in the United States.

This cross-sectional study examined the differences between those who underwent express STI testing, comprehensive STI testing, or both express and comprehensive STI testing using an electronic medical chart abstraction of 2,201 patients that obtained an STI testing at the Kind Clinic from February 01, 2019 to January 31, 2020.

Express STI testing was a well-utilized screening method in the study period: 37% of patients that received an STI test exclusively received express testing(s) and an additional 8% utilized express services along with comprehensive services. There was a greater proportion of new or unestablished patients that utilized exclusively express STI testing, which may indicate that express STI testing can provide a unique opportunity to offer additional STI preventative services, as the Kind Clinic primarily functions as a PrEP clinic, at present. The ability of express STI testing to be a bridge to or magnet for new patients was examined and reported in one other study performed at the Edmonton STI Clinic in Ottawa, Canada (Gratrix et al., 2015). Investigators found that the proportion of new patients for clinical

visits of express STI testing was 47.1%, compared to 37.4% for other STI testing. While these shared findings may suggest that the implementation of an express STI testing model may offer an additional benefit by expanding clinic reach, additional research is required to validate these findings in other clinical sites.

Only three additional studies have published results regarding treatment outcomes, with conflicting findings. While one study found no differences in treatment outcomes between STI testing models (Gratrix et al., 2015), two reported significant differences in either time to treatment (favoring express testing) or the percentage treated (disfavoring express testing) (Rukh et al., 2014; Shamos et al., 2008). While further evidence is required to ascertain treatment outcomes of express STI testing, findings for this study, using both patient-level and appointment-level analysis, suggest that treatment outcomes do not differ among patients that utilized a certain testing type, nor among individual testing events, for chlamydia or gonorrhea diagnoses. Treatment outcomes in this study were defined by time-to-treatment. On average, this was 7.62 and 9.19 days for chlamydia and gonorrhea diagnoses, respectively, among those who utilized express testing, 7.57 and 8.46 days for chlamydia and gonorrhea diagnoses among who utilized comprehensive testing, and 6.72 and 8.92 days for chlamydia and gonorrhea diagnoses those who utilized both testing types. This is the first study to look at treatment outcomes of express STI testing in a high-risk population, and these results support the effectiveness of implementing an express STI testing model for this clinic as it pertains to patient compliance. However, since a large proportion of established patients are current or previous users of PrEP, this may indicate a

more preventative or proactive behavioral difference among this patient population that may not be observed in other patient populations.

Lastly, we do want to highlight the unique opportunity we had with this research being performed with a very unique patient-population, since a large majority of our patients at the Kind Clinic would be categorized as high-risk for having an STI. In several clinical settings that implement an express STI testing model, these demographic high-risk factors (i.e., MSM individuals) would have excluded these patients from receiving express STI testing (Gamagedara et al., 2014; Rietmeijer et al., 2013; Rukh et al., 2014; Shamos et al., 2008). The justifications for doing so are understandable: express STI testing should be reserved for the most low-risk tier of patients for fear of missed diagnoses and express STI testing may be a missed opportunity for STI behavioral risk consultation (O’Byrne et al., 2016; Rietmeijer et al., 2013).

However, several studies have shown that the key to reducing missed STI diagnoses is proper STI pathology testing and testing multiple anatomical sites (Koedijk et al., 2012; van Liere et al., 2014). The caveat with express STI testing, then, is how to promote accurate patient reporting so that patients are properly routed to the appropriate testing type. Furthermore, such measures should be enacted irrespective of patient characteristics (e.g., age, gender identity, sexual orientation, etc.).

Implementation of an express STI testing model, moreover, does not have exclude behavioral risk counseling, since the counseling can be performed by other healthcare professionals. In fact, this is already being done in multiple clinical sites (Gratrix et al., 2015; O’Byrne et al., 2016; Whitlock et al., 2018). For example, the Dean Street Express Clinic in

London, U.K. – a testing clinic that exclusively provides express services – offers sexual health counseling with health advisors at the close of each appointment (Whitlock et al., 2018). The Sexual Health Centre in Ottawa, Canada employs registered nurses to perform the express STI testing, so that express patients have the option to discuss STI concerns and receive counseling from a medical professional (O’Byrne et al., 2016). At the Kind Clinic in Austin, Texas, the medical assistant that performs the express STI testing discusses methods of STI prevention, such as use of condoms and limiting sexual partners, at each testing. As such, express testing can be implemented with behavioral counseling, so that it will not be a missed opportunity for risk reduction counseling overall.

Limitations and Strengths

As with any cross-sectional study, this study is prone to selection bias as the sample obtained may not be representative of the clinic population. Moreover, the study was performed using data from the Kind Clinic and may not be generalizable to other populations.

Another limitation to this study was the inability to analyze syphilis data. As stated previously in the text, the complexity involved in determining if a reactive antibody syphilis test was a new infection made it impossible to interpret the syphilis numbers in a meaningful way. We also limited the STI types of interest to three pathogens and were not able to study other types of STIs such as non-gonococcal urethritis.

An algorithm to identify the treatment for a positive STI laboratory test was also used and poses another limitation for this study. This algorithm was required since the electronic

medical records system did not have a case identifier that referenced the laboratory result which prompted a STI treatment. As a result, it is possible that the testing and treatment pairing may have been misidentified in the process.

Lastly, there was a small sample size of patients that utilized both testing methods compared to those who exclusively used express or comprehensive testing. The small sample size may have led to smaller effect sizes during comparisons.

CONCLUSION

This study has shown that express STI testing is an effective testing model compared to the existing comprehensive STI testing model. Patients that utilized express STI testing returned for treatment with a similar delay compared to those that utilized comprehensive STI testing, indicating that treatment outcomes did not differ between STI testing models. Moreover, express STI testing was able to reach a greater proportion of new patients that required STI testing services compared to comprehensive STI testing. Not only did express testing services expand the existing testing capacity, but also may be able to reach patients that would not have been reached otherwise. Express testing services, therefore, is an effective alternative testing model to increase the testing capacity of the clinic while minimizing additional strain to clinical resources.

APPENDICES

Appendix A: IRB Approval from the Committee for the Protection of Human Subjects by the University of Texas Health Science Center



Committee for the Protection of Human Subjects

6410 Fawcett Street, Suite 1100
Houston, Texas 77030

Dr. Diane Chau
UT-H - SPH - Austin Regional Campus

December 19, 2019

HSC-SPH-19-1070 - Outcomes Associated with an Implementation of an Express Testing Model in a PrEP Clinic in Austin, TX

The above named project is determined to qualify for exempt status according to 45 CFR 46.101(b)

CATEGORY #4 : Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via iRIS to the Committee for the Protection of Human Subjects for review.

INFORMED CONSENT DETERMINATION:

Waiver of Consent Granted

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):

Waiver for Retrospective Chart Review granted:

Information to be accessed: medical records

PHI to be retained: none

STUDY CLOSURES: Upon completion of your project, submission of a study closure report is required. The study closure report should be submitted once all data has been collected and analyzed.

Should you have any questions, please contact the Office of Research Support Committees at 713-500-7943.

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