### **Evaluation of Outcomes of a Newly Implemented Sexually Transmitted Infection Rapid Testing System**

A Thesis submitted to The University of Arizona College of Medicine-Phoenix in partial fulfillment of the requirements for the Degree of Doctor of Medicine

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This work is dedicated to my family for their endless love and support.

To Jeff, for always listening and reminding me of what is important in life. And to my classmates, the best group that I could ever wish for to accompany me on this amazing ride.

I would like to acknowledge the physicians and staff at the Maricopa County Health Department for their tireless commitment to the people of Maricopa County and the pursuit of excellence in public health.

Additionally, I would like to acknowledge Dr. Renuka Khurana for being an amazing mentor for this project, Tom Mickey for his help and technical support, Dr. Melanie Taylor for her mentorship and revisions, and Dr. Campos-Outcalt for his direction and guidance.

#### **Abstract:**

Objectives: To evaluate the outcomes of a newly implemented express testing system for sexually transmitted infections at the Maricopa County Public Health Department.

Methods: This study reviewed data that was collected by the Maricopa County Public Health Department. There are two avenues for sexually transmitted infection (STI) testing at the department. Individuals are given a questionnaire at the time of check-in to assess their possible exposure to others who might have sexually transmitted infections and their symptoms at the time of presentation. Those who are asymptomatic and deemed to be at low risk for infection are sent to the express testing system, while individuals who are determined to be at higher risk for infection or are actively symptomatic, are seen by a provider for a comprehensive visit. Testing that is offered to patients, regardless of visit type is; urine nucleic acid amplification for Chlamydia trachomatis (CT) and Neisseria gonorrhea (GC), and blood tests for syphilis and HIV. Results were evaluated from September 2008 to March 2010. Data were evaluated for difference in positivity of the express testing patients as opposed to those who saw a provider, as

well as the demographic differences between the two groups. Also evaluated, was the treatment obtained by individuals in the express testing group, and the time to return for treatment.

Results: Between September 01, 2008 and March 31, 2010, there were 33294 visits made to the clinic for STI testing. Of these, 4232 (12.7%) were express testing visits. During this time, a total of 3268 cases of CT and 1030 cases of GC were diagnosed. Express testing had a lower incidence of CT and GC, with 204 and 24 cases respectively. Compared the provider visits, the incidence of CT and GC were lower in express testing with CT being 4.8% (vs 10.5% in provider visits), and GC 0.6% (vs 6.5% in provider visits). Of the express testing CT cases, 90.2% returned for treatment, with an average return time of 16.9 days, as compared to 92.6% treatment with an average return time of 13.8 days in the provider visit group (66% were treated the same day). Of the express testing GC cases, 87.5% returned for treatment, with an average return time of 9.8 days, as compared to 88.5% return for treatment and average return time of 13.7 days in the provider visit group (70.2% were treated the same day).

Conclusions: The express testing option provides an efficient way to increase clinic productivity, while providing STI testing to patients who are asymptomatic at the time of presentation, and offering diagnosis and treatment for those who were initially asymptomatic.

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#### **Introduction:**

Testing and treatment of sexually transmitted infections is paramount as public health measures, to prevent the spread of these infections and to decrease morbidity and ongoing community transmission. Many individuals with infections may be asymptomatic and it is important to recognize and treat these individuals to prevent complication of untreated disease<sup>(2,5)</sup>. Testing for STIs has improved over the years, and testing has become more sensitive, specific, and cost-effective. Nucleic acid amplification testing (NAAT) of urethral or endocervical specimens for Gonorrhea and Chlamydia are quick and convenient way to test individuals, with highly sensitive and specific results<sup>(1,2)</sup>. In addition, DNA amplification may be performed on urine specimens which has been shown preferable for many patients as compared to physician obtained endocervical or urethral swab, with similar results to NAAT <sup>(1,6)</sup>.

Previously, testing at the Maricopa County Public Health Clinic has involved all patients, symptomatic or asymptomatic, being evaluated by a medical provider for evaluation. This algorithm limited the number of patients that could be seen in the clinic by putting the burden of testing all patients on the clinic providers. Since September

of 2008, a new testing algorithm has been implemented. Patients who present to the STI clinic are asked to fill out a questionnaire to determine their STI risk level and symptoms. Through the questionnaire, patients are triaged to either provider visits, or express testing during which urine and blood samples are taken without patients seeing a medical provider.

Since the inception of the new system, cursory evaluation of clinic attendance has been thought to show an increase in productivity and public access to STI testing. Preliminary reports indicate that many of the individuals who use the rapid testing system are new to the clinic, which leads us to believe that the system is increasing the capacity of the clinic, as well as increasing public use of the clinic. Similar systems have been implemented at other sites and have been shown to increase clinic productivity and client base<sup>(4,7)</sup>.

This study is aimed at further evaluating the clinical outcomes of this new system. We will address the possible difference in positivity of the patients who are sent to express testing as compared to the patients who see a medical provider. At the same time, we will assess the treatment obtained by individuals in the express testing system, and the time to return for treatment.

#### **Methods:**

Sample: The Maricopa County Public Health Department services the greater Phoenix metropolitan area, and offers testing, treatment, and counseling for the estimated 4 million individuals in the area. The sample for this study will consist of individuals who reported to the county health department for STI testing between September 1, 2008 and March 31, 2010.

Clinic System: Patients who present to the STI clinic are asked to fill out a questionnaire to determine their STI risk level and symptoms. If the patients are deemed to be at high risk (STI-related symptoms, a man who has sex with men (MSM), recent contact to a partner with an STI, pregnancy, injection drug use, exchange of sex for money or drugs, or other high-risk sexual behaviors) they are automatically triaged to see the medical provider. If patients are at low risk for having an infection (have none of the aforementioned situations) and are asymptomatic, they are triaged to express testing. Express testing involves the collection of urine and blood specimens, which are used for testing. In either case, the patient can then leave the clinic, and will be contacted with their test results. If results are

positive, the patient is instructed to return to the clinic to be seen by a medical provider and receive treatment.

Measures: We evaluated the following aspects of the express and comprehensive testing systems; (a) number of express visits during the study period, (b) demographics of the patients in express and comprehensive testing, (c) STI prevalence, and (d) the time to return for treatment in the express testing patients.

Simple chi square statistical tests were used to assess significance. Statistical analysis was performed using Microsoft Excel 2007.

#### **Results:**

During the study period, there were 33294 visits made to the clinic for STI testing. Of these, 4232 (12.7%) were express testing visits.

Demographics: Overall, the express and comprehensive visits had a similar distribution by gender with a lower percent of women (33.8%) in express testing (41.6% in provider visits). There was a higher percentage of Whites (35%) and Hispanics (31%) in express testing, than individuals who identified themselves as Other

Caucasian (15.6%), Black (13.9%), Asian (2.5%) or Non-Hispanic Black and Native Americans (1% each). This distribution was similar to that seen in the provider visits. The age distribution between the two testing options was fairly similar with a majority of the visits taking place between ages 15 and 25 years (40.6% in ET, 35.9% in provider visits), and 26 and 35 years (34% in ET, 34.8% in provider visits), and less visits taking place between 36 and 45 years (13.4% in ET), and >45 years (12% in ET), versus 16.9% between the ages of 36 and 45 years, and 11.4% above 45 years of age in the provider visit group (Table 1).

STI Diagnosis: During the study period, 3268 cases of CT and 1030 cases of GC were diagnosed. Express testing had a lower incidence of CT and GC, with 204 and 24 cases respectively. Compared the provider visits, the incidence of CT and GC were lower in express testing with CT being 4.8% (vs 10.5% in provider visits), and GC 0.6% (vs 6.5% in provider visits) (Table 2).

Follow up: Of the 204 CT cases in express testing, 185 patients returned to the clinic for follow up (90.2%), with an average return time of 16.9 days. Out of the 24 express testing GC cases, 21 patients (87.5%) returned for treatment, with an average return time of 9.8

days. There were a total of 3064 positive CT cases diagnosed at provider visits. Of these, a total of 2838 were treated, 2034 (66%) were treated the same day, and 805 returned to the clinic for treatment, with an average return time of 13.8 days. Additionally, there were 1006 GC cases diagnosed in the provider visits in the time period studied. Of these, a total of 890 (88.5%) received treatment, with 707 (70.2%) being treated the same day. The remaining individuals who tested positive (183 patients), had an average return to clinic time of 13.7 days (Table 3).

#### Discussion:

As the need for faster and more cost-effective methods of testing becomes greater, providers and clinics constantly strive for more efficient ways of testing and treating patients. It is imperative that testing options are convenient for patients, while at the same time being reliable and economical. Also, with health care costs on the rise, it is important to make every attempt to budget the time of the health care provider in order to serve a greater population while keeping the cost of care low. STI clinics are a perfect example of how a triage

system can be used to manage a busy clinic and utilize health care resources in a conservative manner.

In order to effectively care for a large population, it is important that many diseases are screened for, and treated before they are spread to the population at large, with sexually transmitted infections being a perfect example of this. In order to prevent the spread of infection and reduce overall morbidity, it is important to detect and treat infection before many individuals are exposed. Many of these infections are asymptomatic, or have an asymptomatic period, and it is imperative to be able to identify and treat these diseases as soon as the affected individual presents for care. STI testing has become more sensitive, specific, and cost-effective. The implementation of express testing has also opened avenues for individuals who are asymptomatic and would probably rather not see a medical provider, to be tested without seeing a provider until the time of treatment.

The Maricopa County Public Health Department services the Phoenix metro area, with an estimated population of over 4 million people. In September 2008, the express testing option was implemented into the clinic workflow for individuals who were deemed at low risk for infection and who were asymptomatic. From the

inception of this system to March 31, 2010, there have been 4232 visits in the express testing system. Proportionately more females were triaged to comprehensive visits than were triaged to express testing. The ethnic distribution between the two testing options was fairly similar and most likely represents the general ethnic distribution of the greater Phoenix area. There was an overall positivity rate of 5.4% in the express testing option, as compared to 14% in the comprehensive visits. This speaks to the fact that many patients who have STIs are asymptomatic at the time of diagnosis and shows that the format of the express testing system is useful in screening for disease in these asymptomatic individuals.

There are several limitations to this study. First, access to treatment records from other clinics was not available. It is possible that individuals whom were contacted regarding positive results, went elsewhere for treatment and were recorded as "untreated" in this study. Second, it is possible that individuals who presented for express testing were initially treated at provider visits and were presenting for test of cure. If this situation had occurred, we were unable to differentiate between these individuals and those who were presenting for initial testing. Finally, testing and treatment for syphilis infections

was not evaluated due to data collection techniques. In the data sets used, we did not evaluate for new syphilis infections versus individuals who had already been treated, or were in the process of being treated, and the RPR titer was not included in the analysis. Due to this, we were not able to speak to the positivity and treatment rates for syphilis infection.

#### **Future Directions:**

Further study will be needed to determine if those who tested positive for STIs and did not receive treatment, were treated elsewhere or were lost to follow up. This would help determine if changes are needed in the follow up and call-back process of the clinic. Additional analysis could also be performed to assess if the rapid testing system was attracting a different clientele to the clinic than when only provider based testing was offered. Further analysis of the triage system should also be performed to determine if patients have been adequately triaged to the appropriate testing system. We will also need to determine if patients who are triaged to express testing are truly asymptomatic, or if they are somehow symptomatic and are misinterpreting the triage questionnaire, purposefully misrepresenting

their symptoms on the questionnaire, or are unsure of the process as a whole. Finally, an evaluation of the clinic wait times should be undertaken to determine if the option of express testing reduces patient wait times and improves patient satisfaction.

#### **Conclusions:**

The express testing system offers a fast and convenient way for asymptomatic individuals to be tested for sexually transmitted infections. Since many individuals with sexually transmitted infections are asymptomatic at the time of presentation, the express testing system is an effective way to test individuals who may not have originally sought medical attention. The express STI testing system provides an effective way to increase patient testing, prioritize symptomatic patients for a clinician evaluation and streamline the flow of a busy STI clinic.

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Table 1: Demographics by visit type

		Express N(%)	Clinic N(%)	P value
Total		4232	29062	
Gender				< 0.0001
	Male	2784 (66.1%)	6988 (58.4%)	
	Female	1425 (33.9%)	4979 (41.6%)	
Race/Ethnicity				< 0.0001
	American			
	Indian	37 (1%)	150 (1.4%)	
	Asian	103 (2.5%)	182 (1.6%)	
	Black	562 (13.9%)	1892 (17.4%)	
	Black, Non-			
	Hispanic	38 (1%)	99 (1%)	
	Caucasian	631 (15.6%)	597 (5.5%)	
	Hispanic	1252 (31%)	5520 (50.8%)	
	White	1414 (35%)	2432 (22.3%)	
Age				< 0.0001
	15-25	1693 (40.6%)	4312 (35.9%)	
	26-35	1418 (34%)	4176 (34.8%)	
	36-45	556 (13.4%)	2026 (16.9%)	
	>45	501 (12%)	1368 (11.4%)	
	<15	1 (0%)	123 (1%)	

<sup>\*</sup>Please note, if demographic information was missing for a particular category, that visit was not counted in the computation for that particular category.

Table 2. Positive CT and GC

	Express	Clinic	
	N(%)	N(%)	P value
Positive for		3064	
CT	204 (4.8%)	(10.5%)	< 0.0001
Positive for		1006	
GC	24 (0.6%)	(3.5%)	< 0.0001

Table 3: Follow up and Treatment

	ET	Clinic
CT		
% Positive	4.8% (204)	10.5% (3064)
	90.6%	
%(N) Receiving Treatment	(185)	92.6% (2838)
%(N) Treated same day	N/A	66% (2034)
Average time to return for		
treatment (N)	16.9 days	13.8 days (805)
% (N) not receiving treatment	9.3% (19)	7.3% (225)
GC		
% Positive	0.6% (24)	3.5% (1006)
%(N) Receiving Treatment	87.5% (21)	88.5% (890)
%(N) Treated same day	N/A	70.2% (707)
Average time to return for		
treatment (N)	9.8 days	13.7 days (183)
% (N) not receiving treatment	12.5% (3)	11.5% (116)



# Evaluation of Outcomes of a Newly Implemented Sexually Vicki Sein MSIV¹, Renuka Khurana MD, MPH², Tom Mickey MPH² **Transmitted Infection Rapid Testing System**

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## Introduction

Testing and treatment of sexually transmitted infections are peramount as public health measures in order to prevent the spread of these infections, and to decrease morbidity and ongoing community transmission. Many individuals with infections may be asymptomatic and it is important to ornopication of untreated diseasel<sup>2,3</sup>. Testing for sexually transmitted infections has improved over the years, and testing has become more sensitive, sexually associated and complete the specific and cost-effective.

Perviously, sesting at the Maricopa County Public Heath Clinic involved all patients being evaluated by a medical provider at the time of their visit. This algorithm limited the number of patients that could be seen in the clinic by putting the burden of testing all patients on the clinic providers. Since September of 2008, a new testing algorithm has been implemented, in which patients are screened for risk of infection and triaged to either a visit with a provider, or the express festing system.

The purpose of this research was to evaluate the outcomes of a newly implemented express testing system for sexually transmitted infections at the Maricopa County Public Health Department.



Figure 1: Maricopa County Health Department

# This study reviewed data that was collected by the Marricopa County Public Health Department. The sample for this study consisted of individuals who reported to the county health department for sexually transmitted infection resting between September 1, 2008 and March 31, 2010. Data was collected for all individuals who visited the clinic during this time period and extracted from the cities deather the micro statabase for analysis.

	Express	Clinic
Chlamydia		
% Positive	4.8% (204)	4.8% (204) 10.5% (3064)
	%9.06	
%(N) Receiving Treatment	(185)	92.6% (2838)
%(N) Treated same day	N/A	66% (2034)
Average time to return for		
treatment (N)	16.9 days	13.8 days (805)
% (N) not receiving treatment	9.3% (19)	7.3% (225)
Gonorrhea		
% Positive	0.6% (24)	3.5% (1006)
%(N) Receiving Treatment	87.5% (21)	88.5% (890)
%(N) Treated same day	N/A	70.2% (707)
Average time to return for		
treatment (N)	9.8 days	13.7 days (183)
% (N) not receiving treatment	12.5% (3)	11.5% (116)

Figure 2: Follow up and Treatment

# Methods, continued

There are two avenues for sexually transmitted infection resting at the department. Individuals are given a questionnaire at the firm of check-in to assess their likelihood of having sexually transmitted infection. Those who are asymptometic and deemed to be at low risk for infection are traged to the express testing system, while individuals who are determined to be at higher risk for infection are seen by a provider for a comprehensive visit.

Testing that is offered to patients, regardless of visit type is; urine testing for Chlamydia trachomatis and Neisseria gonorrhea, and blood tests for syphilis and HIV.

Data were evaluated for difference in positivity of the express tetaing patients as opposed of those who saw a provider, demographic differences between the two groups, and the time to return for treatment. Analysis was performed using Microsoft Excel 1997, satistical analysis was performed using Chi squared tests.

### Results

During the study period, there were 33294 visits made to the clinic for sexually transmitted infection lesting. Of these, 4232 (12.7%) were express resting visits.

Demographics: Overall, the express and comprehensive visits hand a slightly different distribution by gender, race, and age. There was a lower percent of women in express lesting as compared to clinic visits, as well as a higher percentage of men seen in express testing.

# Results, continued

There were more individuals who identified themselves as White or Caucasian seen in express themselves as White or Caucasian seen in express identified themselves as Hispanic triaged to clinic visits. Age distribution was slightly similar, though there were more individuals in the 15-25 age range seen in express testing. Please see Figure 3.

STI Diagnosis. During the study period, 3288 cases of Chlamydia and 1030 cases of Gonorithea were diagnosed. Express testing had a lower frequency of both infections as compared to provider visits.

		N(%)	Clinic N(%)	Ь
Total		4232	29062	
Gender				<0.0001
	Male	2784 (66.1%)	6988 (58.4%)	
	Female	1425 (33.9%)	4979 (41.6%)	
Race/Ethnicity				<0.0001
	American Indian	37 (1%)	150 (1.4%)	
	Asian	103 (2.5%)	182 (1.6%)	
	Black	562 (13.9%)	1892 (17.4%)	
	Black, Non-	200000000000000000000000000000000000000		
	Hispanic	38 (1%)	99 (1%)	
	Caucasian	631 (15.6%)	597 (5.5%)	
	Hispanic	1252 (81%)	5520 (50.8%)	
	White	1414 (85%)	2432 (22.3%)	
Age				<0.0001
		1693		
	15.25	(40.6%)	4312 (35.9%)	
	26-35	1418 (34%)	4176 (84.8%)	
	36-45	556 (13.4%)	2026 (16.9%)	
	>45	501 (12%)	1368 (11.4%)	
	10	1 100/1	100 /10/	

Figure 3: Demographics

As the need for faster and more cost-effective methods of religing becomes greater, providers and clinics constantly strive for more efficient ways of testing and treating patients. It is imperative that testing options are convenient for patients, while at the same time being reliable and economical. Also, with health care costs on the rise, it is important to make every attempt to budget the time of the health care provider in order to serve a greater population while keeping the cost of care low. Public health clinics are a prefect example of how a triage system can be used to manage a busy clinic and utilize health care resources in a conservative manner.

The Maricopa County Public Health Department services the Phoenix metro area, with an estimated population of over 4 million people. In September 2008, the express testing option was implemented into the clinic workflow for individuals who were deemed at low risk for infection and who were saymptomatic. From the inception of this system to March 31, 2010, there have been 4222 visits in the express testing system.

The ethnic distribution between the two testing options was slightly different, but likely represents the options was slightly different, but likely represents the general ethnic distribution of the greater Phoenix area overall. There was an total positivity rate of 5.4% in the express testing option, as compared to 1.4% in the comprehensive visits. This speaks to the fact that many patients who have sexually transmitted infections are asymptomatic at the time of diagnosis and shows that the format of the express testing system is useful in screening for disease in these asymptomatic individuals.

## Conclusions

The express testing system offers a fast and convenient way for asymptomatic individuals to be tested for sexually transmitted infections. Since many individuals with sexually transmitted infections are asymptomatic at the transmitted infections are asymptomatic at the time of presentation, the express testing system is an effective way to test individuals with many or burdens exually transmitted infection testing system provides an effective way to increase applient testing, prioritize symptomatic patients for a clinician evaluation and streamline the flow of a busy public health