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Patterns of Empiric Treatment of *Chlamydia Trachomatis* Infections in an Underserved Population

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Abstract

BACKGROUND AND OBJECTIVES—Appropriate treatment of *chlamydia trachomatis* (CT) sexually transmitted infections (STIs) is important. Much of this treatment is empiric, and most research on treatment patterns has been conducted in emergency department settings. Few studies have focused on CT treatment in outpatient primary care settings, especially among underserved populations. We aimed to study patterns of empiric CT treatment in an urban safety net clinic.

METHODS—We examined electronic health records from all patients in whom a CT lab test was completed between January 1 and December 31, 2007 (n=1,222). We manually reviewed charts to confirm patient demographics, CT testing, STI symptoms, known exposure, empiric treatment, test results, and follow-up. We then conducted univariate and multivariate analyses to study patterns of and characteristics associated with receiving empiric treatment. We also assessed follow-up for non-treated patients with positive tests.

RESULTS—Among 488 patients who presented with STI symptoms and who were tested, 181 (37.1%) were empirically treated. In multivariate analyses, women with symptoms had significantly lower odds of receiving empiric treatment, as compared with men. Of the 1,222 patients tested, 75 had a positive CT laboratory test; seven (9.3%) of these patients did not receive empiric treatment and had no documented posttest treatment.

CONCLUSIONS—A minority of patients with STI symptoms were empirically treated. Outpatient clinicians should consider whether a patient meets guidelines for empiric STI treatment; this decision should take into account the feasibility of prompt follow-up. This may be especially important in women presenting with STI symptoms.

The US Centers for Disease Control and Prevention (CDC) report an estimated 19 million new sexually transmitted infections (STIs) per year.[1] Infections caused by *chlamydia trachomatis* (CT) are the most commonly reported STIs, with 2009 overall prevalence rates estimated as 409.2 cases per 100,000.[1] Effective and timely treatment of CT and other STIs is important because of the potential for severe disease and complications related to

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undetected and ongoing infections, including pelvic inflammatory disease in women that may lead to infertility and/or tubal pregnancy and urethral strictures or epididymitis in men. In the United States, an estimated $358 million is spent annually on the costs of managing complications from CT infections.[2] The potentially serious complications and the highly contagious nature of the organisms during sexual contact have led many clinicians to use empiric treatment in patients prior to obtaining laboratory confirmation.

The CDC recommends empiric treatment for symptomatic patients who are at high risk for infection (patients with new or multiple sexual partners, under age 25 years, engage in unprotected sex) or are "unlikely to return for a follow-up evaluation."[3] Treatment is also recommended for sexual partners of those with a positive test. Past studies that have focused on the empiric treatment of patients with suspected STIs have found widely variable rates.[4–11] In some studies, up to 65% of patients who were not empirically treated had no documented follow-up.[4,6,9] The majority of this research to date has been conducted in emergency department (ED) settings; less is known about patterns of empiric treatment of CT in outpatient settings, especially among underserved and homeless populations. The study of these patterns in primary care populations is important to better understand which sociodemographic characteristics may be associated with different treatment patterns, including whether a symptomatic patient is not treated or whether a patient with a positive test is lost to follow-up. Yet, few studies have reported on specific factors associated with treatment.

To address these information gaps, we studied patterns of empiric treatment of CT in an underserved urban safety net clinic, which predominantly serves homeless youth and young adults. We aimed to determine characteristics associated with whether individuals reporting symptoms of or exposure to STIs were empirically treated and whether patients not empirically treated, but found to have a positive CT test, were lost to follow-up.

Methods

Study Population and Data Source

This study was performed in an urban primary care safety-net clinic in Portland, OR, which serves a large population of homeless and underserved youth and adults. The clinic uses an electronic medical record, GE Centricity, and stores data in a data warehouse. These data were extracted through a pivot table program in Microsoft Excel. Parameters were set to extract information from all patient encounters in which a test was ordered and performed for CT infection between January 1 and December 31, 2007 (n=1,333 encounters). There were 111 encounters that represented repeat visits from the same patient who had more than one CT test performed in the study year. We used the following algorithm to select one encounter from each unique patient: if the patient reported symptoms at only one visit, that visit was selected; if the patient reported symptoms at more than one visit or in none of the visits, an encounter was randomly selected for that patient. One visit encounter per patient was electronically linked to the patient's demographic variables collected at that visit encounter (age, sex, domicile status, race/ ethnicity, family size, monthly income, and poverty level). The study population included 1,222 discrete patients. The medical records

from all patients were manually reviewed independently by two research team members to obtain and confirm the completeness of the data abstracted.

Variables

The dependent variables of interest included whether the patient presented with STI symptoms, known STI exposures; whether the patient received empiric treatment for suspected STI; the prevalence of positive CT lab tests; and follow-up of positive tests in untreated patients.

A subject was considered to be symptomatic if he or she reported any of the following symptoms: testicular pain, burning on urination, rectal discharge, sensitivity, itching, pharyngitis with history of receptive oral intercourse, pelvic pain, dysuria, dyspareunia, post-coital bleeding, or intermenstrual bleeding or spotting. Known exposures were defined as documented sexual activity with a partner who tested positive for either chlamydia or gonorrhea STI. Subjects were classified as having received empiric treatment or as not treated. Those who received inappropriate treatment were considered not treated. Inappropriate treatment included regimens that did not provide effective coverage for chlamydia and gonorrhea. In addition, the use of quinolones without a documented penicillin allergy was also classified as inappropriate empiric therapy for gonorrhea because the CDC excluded it from its recommendations in early 2007.[12] Subjects given antibiotics with instructions not to take them unless notified that the test was positive were also categorized as not treated.

Laboratory test results were classified as positive or negative for CT. At the time of the study, the clinic used a nucleic acid amplification test (NAAT) for diagnosis of CT on samples obtained from urine, cervical swab (for women), or intraurethral swab (for men). The NAATs have a sensitivity of approximately 85%–90% and a specificity of 95%–99.9%, with urine specimen having a slightly lower sensitivity than cervical or intraurethral swabs.[13] For events with a positive test but no empiric treatment, the follow-up time between diagnosis and treatment was calculated as the number of days between the date on which the clinic received a positive result and the date on which the patient ultimately received notification and treatment (where relevant). Information regarding follow-up was abstracted for 13 months beyond the date a positive lab test was received by the clinic. Patients with no documented follow-up within 13 months of the lab test result were considered lost to follow-up.

Independent variables included age, sex, domicile status, race/ethnicity, family size, monthly income, and poverty level. In regard to domicile status, patients were considered (1) “housed” if they owned or rented a house or apartment, (2) “unstably housed” if they were couch surfing, living with parents or guardians, living in a recovery center, staying with friends/relatives and paying no rent, living in transitional housing, traveling with no fixed home, or unable to pay rent in the last month, (3) “street homeless” if they were camping, living in a park, under a bridge, in a shelter, in a vehicle, or on the streets. These categories are used by our clinic and adhere to guidelines put forth by the US Health Resources and Services Administration for Health Care for the Homeless Programs.[14]

Analysis

We first described the sociodemographic characteristics, the prevalence of symptoms, and known exposure among the study population. We then described the frequency of symptomatic presentation, reports of known STI exposures, empiric treatment, and resulting laboratory tests. We also reported on positive and negative cases that received or did not receive empiric treatment. Finally, we conducted univariate (Pearson's chi-square tests) and multivariate (logistic regression) analyses to assess characteristics associated with different patterns of empiric treatment among individuals presenting with symptoms of or exposure to STIs. We also conducted univariate analyses to examine characteristics associated with being lost to follow-up, among the subgroup of patients with a positive CT test who did not receive treatment. The data were analyzed in SPSS version 17.0. All analyses set alpha levels at $P < .05$. The study protocol and all aspects of the study were reviewed and approved by the Oregon Health and Science University Institutional Review Board (IRB #4578).

Results

During the study year, a total of 1,222 patients had at least one CT test completed, 737 men and 485 women. Most patients were under the age of 41 (mean age was 28; median age was 25), and an estimated one quarter (26.6%) were experiencing street homelessness. Over three quarters (77.0%) of patients had incomes below the federal poverty level (Table 1).

A total of 488 patients reported STI symptoms, 49 reported a known STI exposure, and 22 of the 49 who reported a known STI also reported symptoms. In this study population, 37.1% of patients who presented with STI symptoms, 91.8% of patients with known STI exposures, and 90.9% with both STI symptoms and exposure were empirically treated with appropriate antibiotics (Table 2). There were 75 positive CT laboratory tests, and 46 (61.3%) of these patients were empirically treated prior to confirming infection.

Of the 515 patients with symptoms and/or exposure, 281 were empirically treated. Among the 707 without symptoms or exposure, only 14 were empirically treated (data not shown in tables). As shown in Table 3, patterns of empiric treatment differed among patients presenting with symptoms of or exposure to STIs. In univariate analyses, those less likely to receive empiric treatment were women, street homeless or unstably housed individuals, those earning less than 100% of the federal poverty level, and non-Hispanic individuals. When controlling for all factors believed to be conceptually important, the only statistically significant association was for women who had lower odds of empiric treatment, as compared with men (odds ratio [OR]=0.11, 95% confidence interval [CI]=0.07–0.17). There was almost no difference between the unadjusted and adjusted OR for this variable.

Table 4 shows characteristics associated with a positive CT test among patients presenting with symptoms of or exposure to an STI. Of note, women had statistically lower odds of a positive CT test than men (OR=0.28, 95% CI=0.12–0.65) in the multivariate regression analyses.

Among the 29 patients with a positive CT test who were not empirically treated, the median time to follow-up was 8.1 days, and the majority of cases had documented follow-up in less

than 17 days. Seven individuals had no documented follow-up in the 13 months after test results were obtained. In univariate analyses, race was significantly associated with no documented follow-up among patients with positive CT lab tests and no empiric treatment (Table 5). Six (40%) of the non-white patients were lost to follow-up versus only one (7.1%) of the white patients (P=.039). Although statistically significant associations were not found for any of the other demographic variables, the difference in follow-up associated with housing status were nearly significant (P=.082) with a higher percentage of patients reporting street homelessness lost to follow-up (45.5%), compared with the unstably housed (16.7%) and the housed (0%). There was no significant difference in follow-up between individuals who had presented with symptoms of or exposure to STI and those who did not.

Discussion

Previous studies have examined patterns of empiric treatment for CT in the Emergency Department;[4,6,7,9,15] however, no previous studies to our knowledge have looked specifically at patterns of empiric STI treatment among a predominantly homeless population in a primary care setting. The urban clinic we studied is unique from the Emergency Department setting in both continuity and level of illness acuity, which might explain some of our most interesting findings. For example, we found that only 37.1% of symptomatic individuals were empirically treated with antibiotics. This finding was likely due to the fact that symptoms were broadly defined in our study, including testicular pain, rectal symptoms, pharyngitis, pelvic pain, dyspareunia, post-coital bleeding, or inter-menstrual bleeding or spotting in addition to the symptoms of urethritis and cervicitis in the CDC guidelines. Clinicians may have deviated from national guidelines for certain patients in this primary care setting because they had established continuity with the clinic or a reliable follow-up plan. In addition, only 6.1% of tested individuals in our study had a resulting positive CT test result, which likely reflects that many tests were done for screening as would be common practice in a primary care setting, as compared with the Emergency Department, where studies have shown a GC/CT prevalence of 6.4%–13.6%, with the highest prevalence in populations under 31 years old.[4,6,7,9]

Under-treatment More Common in Women Than Men

Among individuals with STI symptoms or exposure, we found significantly lower rates of empiric treatment in women versus men, which is worth noting especially as the sequelae of untreated chlamydia infections have serious consequences for women, including infertility and potentially life-threatening infections. This difference between women compared to men may be related to the broad range of differential diagnoses among women who present with symptoms of STIs and/or the breadth of symptoms we included. Women in our study were also less likely to have a positive CT laboratory test, so it could be argued that clinicians were justified in prescribing empiric treatment to women less often. However, some women did have resulting positive tests and were lost to follow-up. When faced with the broad differential diagnoses for women, clinicians could be aided by same-day point-of-care testing or clinical decision tools to determine the appropriateness of empiric treatment. For example, Reed et al developed a decision tree using recursive partitioning analysis to help predict which adolescent female patients presenting with symptoms would have a positive

test for cervical infection of chlamydia or gonorrhea.[8] This study developed a rule that was 75% sensitive, 71% specific, with 85% negative predictive value. The best predictors of a positive test for chlamydia or gonorrhea were a male sexual partner with penile discharge, absence of yeast forms on wet prep, >10 WBCs on vaginal gram stain, African American race, and absence of hormonal birth control.[8] This study was performed in an urban pediatric emergency department and may not apply to all other settings but demonstrates the potential usefulness of a clinical decision support tool.

Few Cases With No Documented Follow-up

Our study found a lower rate of individuals with a positive test who were lost to follow-up, as compared to ED-based studies. Studies conducted in Emergency Departments have found follow-up failure rates up to 81%.[6,8,13] Our study found that only seven (24.1%) of the 29 individuals with a positive CT test who did not receive empiric treatment had no documented post-test follow-up treatment. Only one study in the ED setting, described by Kelly et al, had a similarly low rate of cases lost to follow-up, which may have been due to a more intensive follow-up program unique to their ED, funded by the city health department.[11]

We speculate that our primary care clinic setting may have contributed to better follow-up rates, as compared to rates reported in ED-based studies because the primary care environment has a higher level of continuity and reliable follow-up systems in place. Nonetheless, despite the unique aspects of the primary care setting, nearly one quarter of individuals in this study with a positive test who were not empirically treated were lost to follow-up with no documentation of posttest treatment. Non-whites were more likely lost to follow-up than whites. Although not statistically significant, we did observe that a lower percentage of homeless individuals were empirically treated, and a higher percentage were lost to follow-up. This vulnerable population faces a unique set of challenges, including communication and transportation barriers that affect their ability to obtain timely medical care and follow-up.[16–20]

Limitations

This retrospective chart review study had an inevitable element of observer bias on the part of the reviewers. This study was also limited by the way in which symptoms were defined and classified during chart abstraction. The list of symptoms was developed by a representative group of clinicians and researchers on our team. It was broader than the CDC definition and, therefore, may have contributed to the low rates of empiric treatment, especially among women. Further, each of the specific symptoms were not recorded, so we were unable to examine whether certain presenting symptoms (eg, dyspareunia) were less likely than others (eg, discharge) to correlate with a positive CT test or to warrant empiric therapy. This information would be helpful to further describe possible reasons for why empiric treatment was used more often in some cases and to inform decision support mechanisms to aid clinicians in making decisions regarding empiric treatment.

Finally, we may have underestimated the total number of cases who received follow-up treatment for a positive test, as the state laboratory also receives information regarding

positive CT test results and makes attempts to contact all confirmed-positive cases. Therefore, it is possible that patients received treatment outside of this clinic, though this is also true for any clinic or ED study.

Future Studies

This study was an important collaboration between family medicine educators, researchers, and learners aiming to contribute information to a void in the literature regarding empiric treatment of a common primary care treatable condition. Areas for future study by similar teams could include the evaluation of how the availability and systematic use of point of care testing options (eg, wet mounts, gram stains, rapid urine test, etc) or clinical decision support algorithms may help to more appropriately target empiric treatment for persons at highest risk for chlamydia infection. An investigation of how best to adapt and translate decision support tools developed in hospital settings (eg, decision tree created by Reed et al[8]) into primary care settings would also be useful. Another study could examine whether complications of untreated infections (pelvic inflammatory disease, infertility, epididymitis) occur more commonly in certain populations in order to inform empiric treatment practices. Lastly, we noted several subjects who received multiple CT tests in the course of 1 year and some with more than one positive result. Further examination of these subjects, although they seem motivated to be tested and seek care, may help inform the care of high-risk patients.

Conclusions

A minority of patients with STI symptoms in this study were empirically treated for CT infection. Among those not empirically treated, a small subset did have a resulting positive CT laboratory test and were lost to follow-up. Outpatient clinicians should carefully consider whether a patient meets guidelines for empiric STI treatment; this assessment could be aided by point-of-care testing and decision support tools. Further, STI empiric treatment decisions should also take into account the feasibility of prompt follow-up, especially in transient and homeless populations. This may be especially important in women presenting with STI symptoms who had lower odds of receiving empiric treatment in this study.

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Table 1

Demographics of Patients Tested for *Chlamydia Trachomatis* From an Urban Safety Net Clinic From January 1 to December 31, 2007

Characteristics	n (%)
Sex	
Female	485 (39.7)
Male	737 (60.3)
Age	
14–25	623 (51.0)
26–40	472 (38.6)
>40	127 (10.4)
Domicile/housing status *	
Housed	452 (37.0)
Unstably housed	443 (36.3)
Street homeless	325 (26.6)
Unknown	2 (0.2)
% of federal poverty level (FPL)	
≤ 100% FPL	941 (77.0)
101%–150% FPL	119 (9.7)
151%–200% FPL	54 (4.4)
>200% FPL	107 (8.8)
Unknown	1 (0.1)
Race	
Alaska Native/American Indian/Native Hawaiian/Pacific Islander	26 (2.1)
Asian	26 (2.1)
Black/African American	59 (4.8)
White/Caucasian	826 (67.6)
Multi-ethnic	127 (10.4)
Other	150 (12.3)
Unknown	8 (0.6)
Ethnicity	
Non-Hispanic	1,017 (83.2)
Hispanic	205 (16.8)

n=1,222

Data source: Electronic record data from an urban safety net clinic (validated through manual chart review).

* Housed—own or rent a house or apartment. Unstably housed—couch surfing, living with parents or guardians, living in a recovery center, staying with friends/relatives and paying no rent, living in transitional housing, traveling with no fixed home, or unable to pay rent in the last month. Street homeless—camping, living in a park, under a bridge, in a shelter, in a vehicle, or on streets.[14]

Table 2

Empiric Antibiotic Treatment and Chlamydia Laboratory Test Results of Subjects Presenting With Symptoms of or Known Exposure to an STI, From an Urban Safety Net Clinic, January 1–December 31, 2007

	# Presenting With Symptoms* of STI (n=488) n (% out of 488)	**# Reporting Known Exposure to an STI (n=49) n (% out of 49)**	**# Reporting Both Symptoms* of and Known Exposure to an STI (n=22) n (% out of 22)**	**# With Positive Laboratory for Chlamydia STI (n=75) n (% out of 75)**
Positive test result	51 (10.5%)	16 (32.7%)	7 (31.8%)	N/A
Empiric treatment with appropriate** antibiotic regimen for chlamydia and gonorrhea STI	181 (37.1%) (+28 cases treated with inappropriate antibiotics)	45 (91.8%)	20 (90.9%)	46 (61.3%) (+1 case treated with inappropriate antibiotics)

Data source: Electronic record data from an urban safety net clinic population (validated through manual chart review).

STI—sexually transmitted infection

*Symptoms of STI included one or more of the following: testicular pain, burning on urination, rectal discharge, sensitivity, itching, pharyngitis with history of receptive oral intercourse, pelvic pain, dysuria, dyspareunia, post-coital bleeding, or intermenstrual bleeding or spotting.

**Appropriate treatment included regimens that provided effective coverage for chlamydia and gonorrhea.[3]

Table 3

Univariate and Multivariate Associations Between Patient Characteristics and Empiric Treatment Patterns, Among Patients Presenting With Symptoms of STI and/or Known Exposure to STI

	Empirically Treated with Appropriate Antibiotics			
Characteristics	**# (% Within Demographic Subgroup)**	***P* Value**	**Unadjusted OR (95% CI)**	**Adjusted OR (95% CI)**
Sex				
Female	63 (22.6%)	**<.001**	**0.11 (0.07–0.17)** *	**0.11 (0.07–0.17)** *
Male	171 (26.9%)		1.00	1.00
Age				
<25	127 (46.5%)	.600	1.10 (0.78–1.55)	1.53 (1.00–2.33)
>25	107 (44.2%)		1.00	1.00
Housing status **				
Housed	88 (55.7%)		**1.74 (1.11–2.72)**	1.13 (0.63–2.01)
Unstably housed	80 (39.8%)	**.007**	0.92 (0.60–1.40)	0.82 (0.49–1.35)
Street homeless	65 (41.9%)		1.00	1.00
% of federal poverty level (FPL)				
≤ 100% FPL	188 (43.4%)	**.034**	**0.60 (0.37–0.97)**	0.89 (0.49–1.64)
> 100% FPL	46 (56.1%)		1.00	1.00
Race				
White	138 (41.9%)		0.72 (0.50–1.03)	0.66 (0.42–1.06)
Non-White	91 (50.3%)	.070	1.00	1.00
Ethnicity				
Non-Hispanic	180 (43.2%)		**0.62 (0.40–0.96)**	1.05 (0.59–1.88)
Hispanic	54 (55.1%)	**.033**	1.00	1.00

Bold indicates statistically significant at $P<.05$.

Data Source: Electronic record data from an urban safety net clinic (validated through manual chart review).

STI—sexually transmitted infection

* There was only a slight difference between the unadjusted odds ratio 0.111 (95% CI=0.074–0.165) and the adjusted odds ratio 0.108 (95% CI =0.071–0.165) for sex.

** For a description of housing status categories—see footnote for Table 1.

Table 4

Univariate and Multivariate Associations Between Patient Characteristics and Positive Chlamydia Tests, Among Patients Presenting With Symptoms of STI and/or Known Exposure to STI

	Positive Chlamydia Test			
Characteristics	**# (% Within Demographic Subgroup)**	***P* Value**	**Unadjusted OR (95% CI)**	**Adjusted OR (95% CI)**
Sex				
Female	19 (6.8%)	**<.001**	**0.23 (0.10–0.53)** *	**0.28 (0.12–0.65)**
Male	41 (17.4%)		1.00	1.00
Age				
≤25	37 (13.6%)	.254	1.18 (0.54–2.59)	1.45 (0.64–3.30)
≥25	23 (9.5%)		1.00	1.00
Housing status *				
Housed	20 (12.7%)		3.05 (1.00–9.27)	2.11 (0.61–7.28)
Unstably housed	24 (11.9%)	.203	1.16 (0.47–2.90)	1.07 (0.42–2.75)
Street homeless	15 (9.7%)		1.00	1.00
% of federal poverty level (FPL)				
≤ 100% FPL	47 (10.9%)	.208	0.35 (0.11–1.17)	0.53 (0.14–1.98)
> 100% FPL	13 (15.9%)		1.00	1.00
Race				
White	33 (10.0%)		0.50 (0.22–1.13)	0.45 (0.18–1.13)
Non-White	27 (14.9%)	.191	1.00	1.00
Ethnicity				
Non-Hispanic	47 (11.3%)	.540	0.56 (0.19–1.60)	0.96 (0.29–3.15)
Hispanic	13 (13.3%)		1.00	1.00

Bold indicates statistically significant at $P<.05$.

Data Source: Electronic record data from an urban safety net clinic (validated through manual chart review).

STI—sexually transmitted infection

* For a description of housing status categories—see footnote for Table 1.

Table 5

Characteristics and Follow-up Among Patients With Positive Test for CT Infection But Not Empirically Treated

	Positive CT Lab Test With No Empiric Treatment (n=29)		
	Documented Follow-up (total n=22)	No Documented Follow-up (total n=7)	
Characteristics	**n (%)**	**n (%)**	***P* Value**
Sex			.197
Female	13 (68.4%)	6 (31.6%)	
Male	9 (90.0%)	1 (10.0%)	
Age			.947
≤25	16 (76.2%)	5 (23.8%)	
>25	6 (75.0%)	2 (25.0%)	
Housing status *			.082
Housed	6 (100%)	0 (0%)	
Unstably housed	10 (83.3%)	2 (16.7%)	
Street homeless	6 (54.5%)	5 (45.5%)	
% of federal poverty level (FPL)			.121
≤100% FPL	16 (69.6%)	7 (30.4%)	
>100% FPL	6 (100%)	0 (0%)	
Race			**.039**
White	13 (92.9%)	1 (7.1%)	
Non-White	9 (60.0%)	6 (40.0%)	
Ethnicity			.554
Non-Hispanic	18 (78.3%)	5 (21.7%)	
Hispanic	4 (66.7%)	2 (33.3%)	
Reported STI symptoms and/or exposure			.321
Yes	11 (68.8%)	5 (31.3%)	
No	11 (84.6%)	2 (15.4%)	

Bold indicates statistically significant at $P<.05$.

Data source: electronic record data from an urban safety net clinic (validated through manual chart review).

CT—chlamydia trachomatis

STI—sexually transmitted infection

* For a description of housing status categories—see footnote for Table 1.