The Effectiveness of Patient-Delivered Partner Therapy and Chlamydial and Gonococcal Reinfection in San Francisco

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Background: Patient-delivered partner therapy (PDPT) has been evaluated in randomized trials. No analysis has examined the impact of PDPT once implemented programmatically.

Methods: We examined the association between receiving PDPT and *Chlamydia trachomatis* and *Neisseria gonorrhoeae* reinfection within 1 year in patients diagnosed at San Francisco City Clinic between October 31, 2005 and March 31, 2008. Propensity score modeling was used to control for the difference between persons who did and did not receive PDPT.

Results: There was no significant difference between patients who received PDPT and those that did not in the crude cumulative risk for repeat infection with *C. trachomatis* or *N. gonorrhoeae*. Using propensity score analysis, the adjusted relative risk was 0.99 (0.86–1.14) for chlamydial reinfection and 0.90 (0.72–1.11) for gonococcal reinfection. Further analysis looking at men who have sex with men, men who have sex with women, and females showed no significant reductions in relative risk of reinfection for *C. trachomatis* or *N. gonorrhoeae* in these sub populations.

Conclusions: Continued evaluation of PDPT on reinfection rates in real world settings as well as cost-effectiveness analyses of PDPT are needed to assess this alternative method of partner treatment.

The timely treatment of exposed sex partners is essential to the effective control of bacterial sexually transmitted diseases (STDs). Partner notification and patient referral are 2 methods used to achieve that goal. Partner notification is the process in which health care workers or disease intervention specialists (DIS) inform known sex partners of an infected index patient about potential exposure to an STD, and offer testing and treatment if necessary.[1,2] In patient referral, or self-referral, on the other hand, the patient notifies and refers partners for testing and treatment.[2] Because of the higher cost of partner notification, patient referral is the more common practice in chlamydia and gonorrhea control.[3]

As a means to expand patient referral, expedited partner therapy evolved. Expedited partner therapy is the process of treating partners of patients diagnosed with an STD without a clinical assessment of the partner. Patient delivered partner therapy (PDPT) is one form of expedited partner therapy where an index patient diagnosed with an STD is given medications to give to their sex partners. Nationally, the Centers for Disease Control and Prevention have endorsed expedited partner therapy but have also recognized limitations in its implementation including the potential for missed comorbidity, such as undiagnosed pelvic inflammatory disease, trichomoniasis, and HIV infection, in the treated partners who do not undergo a clinical evaluation.[2,4] Additionally, because the evidence that demonstrates the efficacy of PDPT is limited to heterosexuals, national recommendations only support the use of expedited partner therapy in heterosexuals.[2]

Because PDPT requires the provision of medication to a person (the index patient's sex partner) who is not evaluated by a clinician, the practice has uncertain legal status in many health jurisdictions. Currently, PDPT is permissible in 21 states.[5] In San Francisco, the health department began programmatic distribution of PDPT for chlamydia and gonorrhea in 1998.[6] California guidelines permit the use of expedited partner therapy in men who have sex with men (MSM) but does not advise for or against routinely using expedited partner therapy in this population.[7] In San Francisco, it is the policy of the STD control program to offer PDPT to the partners of patients diagnosed with chlamydia, gonorrhea, nongonococcal urethritis, and trichomoniasis, regardless of sexual orientation or gender of sex partners, if the sexual contact occurred within the prior 60 days.[8]

PDPT has been shown to increase the proportion of partners who receive treatment. However, it has been harder to prove effectiveness. Some[9,10] but not all[11,12] randomized trials using reinfection rates as an outcome have found PDPT to be efficacious. The higher partner treatment rates demonstrated with PDPT have led to its legalization in many states and resulted in the expansion of PDPT provision. Because of the high cost of efficacy trials and the fact that PDPT has become standard of practice, it is unclear whether additional effectiveness trials will be conducted. Therefore we evaluated the effectiveness of PDPT for chlamydia, nongonococcal urethritis (NGU), and gonorrhea using a "real-world" setting—a municipal STD clinic. Because we anticipated that patients receiving PDPT would be different than those who did not receive it, we adjusted for baseline differences in the groups using propensity score modeling.

MATERIALS AND METHODS

All patients seen at the San Francisco City Clinic, the municipal STD clinic, during October 31, 2005 and March 31, 2008 and diagnosed and treated for gonorrhea, chlamydia, and NGU were considered eligible and included in this analysis. If patients had multiple eligible visits during that time frame, only

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the first visit was included. As part of the standard visit at the STD clinic, clinicians collect sexual risk behavior history.

In this analysis, we examined whether receipt of PDPT for chlamydia and/or gonorrhea was associated with reinfection within 1 year. Reinfections were determined by matching cases of chlamydia and gonorrhea with the San Francisco STD registry (which includes all reported chlamydia and gonorrhea morbidity for San Francisco residents). Reinfection of *Chlamydia trachomatis* was defined as a diagnosis of chlamydia or nongonococcal urethritis, at least 30 days after and within 365 days of the original diagnosis. Cases of NGU were included because those case-patients are often presumptively treated for chlamydia and given PDPT before lab results are returned. NGU was a reportable condition in California until 2006. Reinfection of *Neisseria gonorrhoea*e was defined as a diagnosis of gonorrhea at least 30 days after and within 365 days of the original diagnosis. Reinfection events were not limited to those diagnosed at the STD clinic; reported morbidity from any provider was considered a reinfection.

All patients diagnosed with chlamydia and/or gonorrhea at San Francisco City Clinic are encouraged to notify their sex partners of exposure and to refer partners for testing. Additionally, clinicians offered PDPT to patients who reported that they were able to locate sex partners and were willing to provide them with medications. Patients who accept PDPT are given "Partner Packs" which contain safer sex materials, condoms, instructions for taking the medication, and medications for partner treatment. Partner Packs for female partners of chlamydia patients contain 1 g Azithromycin and Partner Packs for male partners of chlamydia patients contain 100 mg twice daily $\times$ 7 of Doxycycline or 1 g Azithromycin. Both male and female partners of gonorrhea patients receive 400 mg Cefpodoxime. If a patient was diagnosed with gonococcal infection by a stat Gram stain, he or she was given a partner pack that contained both 400 mg Cefpodoxime and 1 g Azithromycin because chlamydial coinfection could not be ruled out at the time of diagnosis/treatment. However, if a patient had a positive nucleic acid amplification test (NAAT) for gonorrhea and a negative NAAT for chlamydia, he or she was only given 400 mg Cefpodoxime as PDPT. Although there is no limit to the number of Partner Packs offered per patient, clinicians encourage patients only to take Packs for partners they feel confident they can locate. Clinicians document the number of Partner Packs that are distributed in the patient's medical record. Patients who do not receive PDPT are encouraged to notify their sex partners of an STD exposure and urge them to be treated for STDs.

Sociodemographic and behavioral characteristics reported at diagnosis were compared between patients who did and did not receive PDPT using Pearson χ^2 and Fisher exact test statistics. To adjust for baseline differences between patients receiving and not receiving PDPT, we used a propensity score approach, a methodology useful in comparing nonrandomized groups.[13] Propensity score analysis involves calculating the probability that each patient would receive PDPT based on those factors associated with receiving PDPT and then utilizing these probabilities (or propensity scores) to adjust for differences between the PDPT and non-PDPT groups.

First, we used logistic regression with backwards elimination to estimate individual probabilities (propensities) of receiving PDPT. The estimated probability of receiving or not receiving PDPT was based on the following characteristics: patient's age, race/ethnicity, sexual orientation, HIV-infection status, whether the patient had multiple partners (2 or more in either the last 2 or 3 months depending on the year of visit), a history of injection drug use, anonymous partners in the prior 3 months, Internet partners in the prior 3 months, history of STD in the previous 3 months, whether the patient was symptomatic at the visit, diagnosing clinician (clinicians with at least 100 visits were categorized independently), and homelessness. Homelessness was not used in the propensity score model for gonorrhea, as there were no known homeless patients in this subpopulation. To assess model fit, c-statistic and overlap of box plots were examined. We then constructed 2 log-binomial regression models to estimate the effect of PDPT on reinfection of *N. gonorrhoeae* and reinfection of *C. trachomatis* separately.[14] These models estimated relative risks (RR) of reinfection, and their corresponding 95% confidence limits, adjusted for propensity score.

To examine the effect of PDPT among subpopulations the same method described above was employed in 3 groups of STD clinic patients: MSM, men who have sex with women (MSW), and females. In generating propensity scores for the MSW gonorrhea analysis, "Other" race was not included because only one patient fit this category. Additionally, HIV status was dropped from the model in this subpopulation because of unstable estimates because of low numbers. Although in the main analysis, clinicians with at least 100 visits received their own category, for the subpopulation analyses, the clinician variable was categorized so that less than 30% of diagnosing clinicians were included in the "other" category. Additionally, the "Other" race category was not included in the female gonorrhea model because of only one patient falling into this category.

For the analysis of the total populations, as well as for each subpopulation, we also looked at reinfection at 3 months, 6 months and 9 months. Additionally, as another subanalysis, we also limited the analysis to patients with only one reported partner at the time of diagnosis. Finally, in another subanalysis, we excluded patients diagnosed with NGU.

All analyses were done using SAS 9.1 (SAS Institute, Cary, NC). As these were deidentified records undergoing retrospective analyses for public health evaluation, this study was considered exempt from human subjects considerations by the San Francisco Department of Public Health in accordance with the Code of Federal Regulations, Title 45.

RESULTS

Between October 31, 2005 and March 31, 2008, chlamydia was diagnosed at 4418 visits and gonorrhea was diagnosed at 2115 visits at the San Francisco STD Clinic. Among the chlamydia diagnoses, 1911 (43.3%) of the patients were given PDPT. Of the chlamydia PDPT recipients, 7% of MSW received Doxycycline partner packs and 16% of females received Doxycycline partner packs; 63% of MSM received Doxycycline partner packs rather than Azithromycin because Doxycycline might treat incubating syphilis. Among the gonorrhea diagnoses, 921 (43.6%) of the patients were given PDPT. Patient characteristics are shown in Tables 1 and 2. For patients diagnosed with chlamydia, the PDPT and non-PDPT groups differed significantly with respect to race/ethnicity, HIV-infection status, multiple partners in the prior 3 months, anonymous partners in the prior 3 months, history of injection drug use, and whether the patient was symptomatic at the visit (Table 1). Among the gonorrhea diagnoses, the PDPT and non-PDPT groups differed among race/ethnicity and whether the patient was symptomatic at the visit (Table 2).

The crude relative risks (RRs) of reinfection with *C. trachomatis* and *N. gonorrhoeae* by PDPT status are shown in

TABLE 1. Baseline Characteristics of the Patients With Chlamydia, San Francisco, 2005–2008

	Received PDPT n (%)	No PDPT n (%)	*P*
Total	1908 (43.21)	2508 (56.79)	
Sex			0.1107
M	1749 (91.67)	2264 (90.27)	
F	159 (8.33)	244 (9.73)	
Sexual orientation			0.0797
F	159 (8.33)	244 (9.73)	
MSM	1033 (54.14)	1393 (55.54)	
MSW	716 (37.53)	871 (34.73)	
Age, yr			0.0558
<20	65 (3.41)	101 (4.03)	
20–24	283 (14.83)	405 (16.15)	
25–29	398 (20.86)	482 (19.22)	
30–34	309 (16.19)	369 (14.71)	
35–39	303 (15.88)	369 (14.71)	
40–44	257 (13.47)	322 (12.84)	
45+	293 (15.36)	460 (18.34)	
Race/ethnicity			<0.0001
Asian/Pacific Islander	189 (9.92)	297 (11.85)	
Black	528 (27.72)	522 (20.83)	
Hispanic	339 (17.80)	463 (18.48)	
White	823 (43.20)	1206 (48.12)	
Other	26 (1.36)	18 (0.72)	
HIV status			0.0004
Negative	1463 (76.68)	1821 (72.61)	
Positive	266 (13.94)	358 (14.27)	
Unknown	179 (9.38)	329 (13.12)	
Multiple partners in prior 3 mo			<0.0001
Y	1324 (69.39)	1574 (62.76)	
N	460 (24.11)	668 (26.63)	
Unknown	124 (6.50)	266 (10.61)	
Met partners on the internet in prior 3 mo			0.0631
Y	230 (12.05)	277 (11.04)	
N	886 (46.44)	1102 (43.94)	
Unknown	792 (41.51)	1129 (45.02)	
Anonymous partners in the prior 3 mo			<0.0001
Y	255 (13.36)	413 (16.47)	
N	849 (44.50)	960 (38.28)	
Unknown	804 (42.14)	1135 (45.26)	
History of injection drug use			0.0023
Y	117 (6.13)	139 (5.54)	
N	1,145(60.01)	1392 (55.50)	
Unknown	646 (33.86)	977 (38.96)	
STD in prior 3 mo			0.3264
Y	107 (5.61)	124 (4.94)	
N	1801 (94.39)	2384 (95.06)	
Symptomatic at Chlamydia diagnosis			<0.0001
Y	1379 (72.27)	1570 (62.60)	
N	529 (27.73)	938 (37.40)	
Homeless at diagnosis			0.4559
Y	5 (0.26)	4 (0.16)	
N	1903 (99.74)	2504 (99.84)	

TABLE 2. Baseline Characteristics of the Patients With Gonorrhea, San Francisco, 2005–2008

	Received PDPT n (%)	No PDPT n (%)	*P*
Total	921 (43.53)	1195 (56.47)	
Sex			0.2680
M	868 (94.25)	1112 (93.05)	
F	53 (5.75)	83 (6.95)	
Sexual orientation			0.1190
F	53 (5.75)	83 (6.95)	
MSM	725 (78.72)	960 (80.33)	
MSW	143 (15.53)	152 (12.72)	
Age, yr			0.5311
<20	34 (3.69)	35 (2.93)	
20–24	131 (14.22)	166 (13.89)	
25–29	180 (19.54)	219 (18.33)	
30–34	154 (16.72)	193 (16.15)	
35–39	164 (17.81)	199 (16.65)	
40–44	126 (13.68)	177 (14.81)	
45+	132 (14.33)	206 (17.24)	
Race/ethnicity			0.0382
Asian/Pacific Islander	87 (9.45)	123 (10.29)	
Black	226 (54.54)	236 (19.75)	
Hispanic	163 (17.70)	213 (17.82)	
White	433 (47.01)	615 (51.46)	
Other	12 (1.30)	8 (0.67)	
HIV status			0.1904
Negative	657 (71.34)	813 (68.03)	
Positive	226 (24.54)	318 (26.61)	
Unknown	38 (4.13)	64 (5.36)	
Multiple partners in prior 3 mo			0.1492
Y	693 (75.24)	857 (71.72)	
N	155 (16.83)	220 (18.41)	
Unknown	73 (7.93)	118 (9.87)	
Met partners on the internet in the prior 3 mo			0.4259
Y	166 (18.02)	210 (17.57)	
N	359 (38.98)	438 (36.65)	
Unknown	396 (43.00)	547 (45.77)	
Anonymous partners in the prior 3 mo			0.1724
Y	165 (17.92)	245 (20.50)	
N	343 (37.24)	405 (33.89)	
Unknown	413 (44.84)	545 (45.61)	
History of injection drug use			0.1283
Y	79 (8.58)	113 (9.46)	
N	524 (56.89)	627 (52.47)	
Unknown	318 (34.53)	455 (38.08)	
STD in last 3 mo			0.0919
Y	63 (6.84)	61 (5.10)	
N	858 (93.16)	1134 (94.90)	
Symptomatic at gonorrhea diagnosis			<0.0001
Y	622 (67.54)	356 (54.90)	
N	299 (32.46)	539 (45.10)	

Tables 3 and 4, respectively. PDPT was not associated with a reduced risk of reinfection for *C. trachomatis* (RR = 1.04; 95% CI: 0.91–1.19) or for *N. gonorrhoeae* (RR = 0.89; 95% CI: 0.72–1.10). When stratified by subpopulation (MSM, MSW, and females) there were no statistically significant reductions in risk of either chlamydial or gonococcal reinfection with receipt of PDPT in the crude analysis.

Examination of box-plots of propensity scores showed large overlaps, suggesting good balance between PDPT and non-PDPT groups (data not shown). Additionally, the c-statistic for each of the models was ≥0.6. After adjustment for propensity scores, PDPT was not associated with a reduced risk

TABLE 3. One-Year Cumulative Risk of Chlamydial Reinfection by Patient Delivered Partner Therapy, San Francisco City Clinic, October 31, 2005 and March 31, 2008

	Exposed	Reinfection	Crude RR	95% CI
All patients				
PDPT	1911	317 (16.3%)	1.04	0.91–1.19
No PDPT	2507	399 (15.9%)	1.0	—
MSM				
PDPT	1034	192 (18.57%)	0.98	0.83–1.16
No PDPT	1393	264 (18.95%)	1.0	—
MSW				
PDPT	717	106 (14.78%)	1.19	0.93–1.53
No PDPT	871	108 (12.40%)	1.0	—
Females				
PDPT	160	19 (11.88%)	1.07	0.62–1.86
No PDPT	243	27 (11.11%)	1.0	—

of reinfection for either *C. trachomatis* or *N. gonorrhoeae*, overall or within subpopulation (Table 5).

When the study population was restricted to patients reporting only 1 partner at the time of diagnosis, the overall and subpopulation estimates were largely similar to the full study population and there were no statistically significant differences among patients who received PDPT and those that did not (data not shown). Additionally, the results of our analysis did not differ when we examined reinfection at 3, 6, or 9 months (data not shown). Analyses that excluded NGU did not differ from results of the full study population (data not shown).

DISCUSSION

Whereas randomized controlled trials are the gold standard to assess the efficacy of treatment, observational studies can estimate the effectiveness of an intervention once implemented in a real world setting. In this analysis, we utilized propensity scores, which calculate the probability of each patient receiving the treatment, to account for differences in the characteristics of PDPT versus non-PDPT groups. Twelve variables were used in the calculation of propensity scores. These variables included demographics and other covariates that may have influenced whether the patient was offered and accepted

TABLE 4. One-Year Cumulative Risk of Gonococcal Reinfection by Patient Delivered Partner Therapy, San Francisco City Clinic, October 31, 2005 and March 31, 2008

	Exposed	Reinfection	Crude RR	95% CI
All patients				
PDPT	921	123 (13.4%)	0.89	0.72–1.10
No PDPT	1194	180 (15.1%)	1.0	—
MSM				
PDPT	724	114 (15.75%)	0.89	0.72–1.11
No PDPT	959	169 (17.62%)	1.0	—
MSW				
PDPT	144	6 (4.17%)	0.71	0.26–1.93
No PDPT	152	9 (5.92%)	1.0	—
Females				
PDPT	52	3 (5.77%)	2.39	0.41–13.85
No PDPT	83	2 (2.41%)	1.0	—

TABLE 5. Propensity Score Adjusted One-Year Cumulative Risk of Chlamydial and Gonococcal Reinfection by Patient Delivered Partner Therapy, San Francisco City Clinic, October 31, 2005 and March 31, 2008

	Chlamydia Adjusted RR (95% CI)	Gonorrhea Adjusted RR (95% CI)
Overall	0.99 (0.86–1.14)	0.90 (0.72–1.11)
MSM	0.99 (0.83–1.17)	0.90 (0.72–1.13)
MSW	1.07 (0.83–1.39)	0.69 (0.23–2.11)
Women	0.97 (0.54–1.72)	2.57 (0.36–18.19)

PDPT. The propensity scores reduce the bias of treatment selection to estimate the treatment effect on the outcome.[15]

In this analysis, there was no reduced risk of reinfection in patients who received PDPT. When we examined subpopulations of females, MSM, and MSW, the risk of reinfection was not statistically different among those that received PDPT and those that did not for either *N. gonorrhoeae* or *C. trachomatis*. Our observational data are consistent with findings from other randomized trials. In a trial of the efficacy of PDPT on repeat chlamydial infections, Schillinger et al found a 20% risk reduction among patients who had received PDPT. However, this was not a statistically significant difference (12% vs. 15%, $P = 0.102$).[11] Likewise in a trial in King County, WA, PDPT did not statistically reduce the effect of reinfection among patients with a chlamydial infection though a trend in this direction was seen (11% vs. 13%, RR: 0.82, 95% CI: 0.62–1.07); however, PDPT did significantly reduce the risk of reinfection among patients with a gonococcal infection (3% vs. 11%, RR = 0.32 (95% CI: 0.13–0.77).[9] The efficacy of PDPT among women infected with *Trichomonas vaginalis* has also been evaluated; in this study, Kissinger et al found there was no significant difference in number of partners treated per index patient or in reinfection rates among women randomized to receive PDPT compared to standard patient referral though PDPT was more cost-effective.[12]

In our study, reinfection was dependent on patients being retested within a year following the original diagnosis. In a passive retrospective cohort, this may have biased the estimate of reinfection. Patients' likelihood to return to the STD clinic may not have been independent from their risk of infection. Because higher risk patients may have been more likely to return to get tested,[16] this may have resulted in a bias of these estimates; how this bias may have impacted the observed effectiveness of PDPT is unknown.

The randomized, clinical trials measuring the efficacy of PDPT showed modest differences in the rates of reinfection among patients who received PDPT and those that did not.[9–12] Given that the effect sizes in those trials were small, it may be more difficult to see a true difference in an observational study. A challenge in evaluating PDPT is the identification of an appropriate outcome. Although PDPT should reduce reinfection of the index patient if he or she is continually exposed to the PDPT treated partner, if the index patient has new partners during the follow-up period, the impact of PDPT may be minimal. As a result, the randomized trials may have seen a dilution in effect size because some proportion of persons getting PDPT would be reinfected by a new sex partner. Reinfection by the same partner is difficult to measure without the ability to type strains or perform follow-up testing on all infected patients. While all patients were not retested within

one year, all positive cases are reported to the health department regardless of whether they were tested at a STD clinic. PDPT may also increase the percentage of partners treated,[17] which could lead to a decrease in the population's burden of these organisms. However, we were unable to assess that outcome in this study.

Additionally, propensity scores help adjust for confounding with respect to higher risk patients getting PDPT; however, there is still likely some residual confounding. Propensity scores do not adjust for unobserved covariates.[13] Therefore, because our study is not a randomized trial, the unobserved covariates may not be equally distributed among the groups who received PDPT and those that did not.

There were several limitations to this study. First, we assumed that patients who were given Partner Packs gave them to their sex partners and their sex partners took the medications provided. This may have introduced some misclassification into the analysis resulting in an underestimate of the effect of PDPT on reinfection, because patients who received PDPT but whose partners did not take the medication, would receive no benefit from partner treatment. Yet, our study was designed to examine the effect of PDPT when implemented programmatically, and we believe our results better represent how PDPT would be operationalized in a real-world setting. Another limitation is that the timeframe of reinfection used was 1 year. However, we examined shorter time periods and came to similar inferences when compared to the one-year outcome. Additionally, we were not able to determine whether reinfections were the result of sex with the original partner(s) as the index infection or as the result of new exposure from a new partner. The efficacy of PDPT in preventing reinfection is contingent on patient's providing medicines to the partners that initially infected them. If the patient acquires a new partner after the index infection, PDPT would not be expected to reduce the risk of reinfection. However, the molecular or serologic typing data that could help make this determination were not available. Also, unknown covariates that were not included may have also affected a patient's likelihood to get PDPT. Furthermore, given the modest effect PDPT was found to have on reinfection with both chlamydia and gonorrhea, our analysis was underpowered to detect small differences. Finally, the patient population at San Francisco City Clinic may not be generalizable to other areas.

PDPT represents an innovative public health intervention designed to increase partner treatment and ultimately reduce local disease prevalence and transmission. Our analysis of data from the San Francisco STD clinic could not measure any statistically significant effect of PDPT on the risk for reinfection. These findings are consistent with the modest efficacy measured in several randomized trials.[9–12] However, the impact of PDPT on the community burden of chlamydia and gonorrhea is largely unknown. Examinations of how PDPT may influence population levels of disease, as well as reinfection rates, may help inform public health practice in reducing chlamydia and gonorrhea morbidity.

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