

# Patient-Delivered Partner Treatment for Male Urethritis: A Randomized, Controlled Trial

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(See the editorial commentary by Golden on pages 630–3)

**Background.** Traditional partner referral for sexually transmitted diseases (STDs) is ineffective at assuring that partners are treated. Alternative methods are needed. We sought to determine whether patient-delivered partner treatment (PDPT) is better than 2 different methods of partner referral in providing antibiotic treatment to sex partners of men with urethritis and in reducing recurrence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

**Methods.** Men who received a diagnosis of urethritis at a public STD clinic in New Orleans, Louisiana, during the period of December 2001 through March 2004 were randomly assigned according to the month of treatment for either standard partner referral (PR), booklet-enhanced partner referral (BEPR), or PDPT. At baseline and after 1 month, men were asked to provide information about each partner and were tested for *C. trachomatis* and *N. gonorrhoeae*.

**Results.** Most enrolled index men ( $n = 977$ ) were >24 years of age (51.6%) and African American (95%) and had  $\geq 2$  partners (68.3%). They reported information on 1991 partners, and 78.8% were reinterviewed 4–8 weeks later. Men in the PDPT arm were more likely than men in the BEPR and PR arms to report having seen their partners, having talked to their partners about the infection, having given the intervention to their partners, and having been told by their partners that the antibiotic treatment had been taken (55.8%, 45.6%, and 35.0%, respectively;  $P < .001$ ). Of men who were reinterviewed, 37.5% agreed to follow-up testing for *N. gonorrhoeae* and *C. trachomatis* infection. Those tested were similar to those not tested with regard to the study variables measured. Among those tested, men in the PDPT and BEPR arms were less likely than those in the PR arm to test positive for *C. trachomatis* and/or *N. gonorrhoeae* (23.0%, 14.3%, and 42.7%, respectively;  $P < .001$ ).

**Conclusion.** Among heterosexual men with urethritis, PDPT was better than standard partner referral for treatment of partners and prevention of recurrence of *C. trachomatis* or *N. gonorrhoeae* infection.

The preferred medical management for sex partners of persons with sexually transmitted diseases (STDs) is for all partners to visit a health care clinic for diagnostic testing, treatment, and counseling [1]. For many index patients, notifying partners and persuading them to go to a clinic can be difficult. Partner referral by the index patients is the method most often used by health care

professionals to prompt the partners to seek care [2, 3]. With this method, index patients are asked to inform their partner(s) that they have been exposed to an STD and to encourage them to go to a clinic for testing and treatment. Unfortunately, with partner referral, many partners do not get treated. Studies of chlamydial infection among women demonstrate that only 25%–40% of named male partners actually sought care at a clinic and were treated [3, 4].

Another method of partner management is partner notification by a health care professional. For syphilis and HIV infection, public health professionals elicit partners' names and identifying information from patients and then contact those partners. However, there are not enough resources to provide this assistance for

Received 15 February 2005; accepted 12 April 2005; electronically published 19 July 2005.

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**Clinical Infectious Diseases** 2005;41:623–9

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1058-4838/2005/4105-0008\$15.00

highly prevalent agents of STDs, such as *Neisseria gonorrhoeae* and *Chlamydia trachomatis* (the most common etiologic agents associated with urethritis) [5].

Patient-delivered partner treatment (PDPT) is the process in which antibiotic treatment for partners is provided to an index patient, who is then instructed to deliver the medicine to these partners along with standard instructions to seek evaluation as one would for partner referral alone. The efficacy of PDPT has been examined in both retrospective studies [6, 7] and randomized, controlled trials [8–10] and has shown that partners are more likely to get treated and that index patients are less likely to be reinfected after PDPT, compared with partner referral. PDPT is gaining more acceptance, and although it is not yet explicitly legal in many states, it is widely—albeit sporadically—practiced [2, 11, 12]. PDPT has not been well studied in high-risk heterosexual minority men who present with urethritis. Better partner treatment in this group has the potential to impact morbidity greatly.

Most of the serious urethritis-related morbidities (including pelvic inflammatory disease and infertility) and costs are a result of recurrent infections with *C. trachomatis* or *N. gonorrhoeae* among women [13, 14]. The public health goal of PDPT is different for men than for women. For women, PDPT is used to prevent recurrent infection in index women by eliminating the potential source of reinfection. For men, the primary goal of PDPT is to assure that all of their female partners get treated; reduction of recurrence in men is a secondary goal.

To develop additional options for partner treatment, we also included a second comparison group, the booklet-enhanced partner referral (BEPR) group. Pilot work in a public health clinic in rural Louisiana suggested that the numbers of partners who came in for services increased substantially when the index patients were given a booklet with information referral tear-out cards for their partner(s) (Office of Public Health, personal communication). The purpose of our study was to compare PDPT with BEPR and partner referral to determine the proportion of partners who received antibiotic treatment and, secondarily, to determine the rate of recurrence of infection among index men.

## METHODS

Men who attended a public STD Clinic in New Orleans, Louisiana, during the period of December 2001 through March 2004 were offered enrollment in the study if they had received a diagnosis of urethritis, had a test positive for *C. trachomatis* or *N. gonorrhoeae*, were 16–44 years old, and had at least 1 female sex partner who did not accompany them to the clinic. Of the 977 men enrolled, 86.3% came to the clinic because they had symptoms of an STD, and 13.7% came because they were either a contact of a known *C. trachomatis*– or *N. gonorrhoeae*–positive partner or suspected that they had been.

The diagnosis of urethritis was made by microscopic examination of a urethral smear stained with a mixture of gentian violet (20%) and methylene blue (80%). Men received a diagnosis of nongonococcal urethritis if  $\geq 5$  WBCs/high-power field were present, and they received a diagnosis of gonococcal urethritis if intracellular diplococci were noted on a urethral smear. A urethral swab was obtained and tested for *C. trachomatis* and *N. gonorrhoeae* using the Gen-Probe Pace 2 test (Gen-Probe). All men were treated at this initial visit on the basis of results of the urethral smear. All index men who received a diagnosis of nongonococcal urethritis were treated with azithromycin (1 g). Index men who received a diagnosis of gonorrhea were treated with cefixime (400 mg; prior to removal from the market) or ciprofloxacin (500 mg; after removal of cefixime from the market) and azithromycin (1 g). Consumption of medication by the index men was directly observed by clinic nurses.

For partner treatment, index men were randomized by month in which they attended the clinic to 1 of 3 study arms: the partner referral arm, the BEPR arm, or the PDPT arm. In the standard partner referral arm, men were instructed to tell their partners that they needed to go to either the public STD clinic or the clinic of their choice for STD evaluation and treatment. In the BEPR arm, men were given a wallet-sized booklet that contained 4 tear-out cards with information for the partner and treatment guidelines for the professionals who would see the partners. The partners could then present this card at the clinic of their choice to help the clinician better treat them. If men had  $>4$  partners, they were given additional booklets. In the PDPT arm, men were given packages containing azithromycin (1 g) and cefixime (400 mg) for up to 4 identified sex partners. These packages also contained written instructions about how to take the medication, warnings about adverse effects, and a 24-h nurse's pager number to call if there were any questions or if the partner encountered any problems. In August 2003, when cefixime was taken off the market, this drug was replaced with ciprofloxacin (500 mg). At that time, a warning to not take the medicine if pregnant was added to the medication instruction sheet. All medications were distributed in containers with childproof caps, and the names of the partners (as given by the index man) were written on the bottle. The State Pharmacy Board of Louisiana required that the name be written on the containers to dispense the medication.

Index men were allocated to study arms on the basis of the month of treatment, and the months were randomly allocated among the 3 study arms. Randomization of months was conducted using a blocked scheme of 3 or 6 units (i.e., months) using Microsoft Excel software. Information about each partner was elicited from the index men at baseline and 1 month later using a computer-assisted self interview (CASI). Questions were modeled after the Infertility Prevention Program multicentered

trial [10] and were adapted and pilot-tested before use. Questions on the CASI included information about sexual behavior, condom use, and treatment for each partner identified.

Patients were asked to return 4 weeks after the initial clinic visit (with a window of 2–8 weeks) for a follow-up interview and to provide a urine sample or urethral swab for STD testing. If men refused to give a urine specimen, they were still interviewed, but they were given a smaller incentive. Patients received a small monetary reimbursement for their time (\$10–\$40), depending on their level of participation (i.e., whether they provided an interview, urine specimen, or both). Men were given the option of being interviewed by study staff or undergoing CASI. Men were asked outcome questions for each partner identified on the baseline survey and were also asked questions about any new partners acquired in the follow-up period. The outcome of interest was the response to this question “Did [baseline partner’s name] tell you that he or she took the medicine?” Testing of urine specimens for *C. trachomatis* and *N. gonorrhoeae* was conducted with the strand-displacement amplification method (ProbeTec). Institutional review board approval was obtained from all participating institutions.

## RESULTS

**Baseline characteristics of index patients.** Of 1148 eligible men with urethritis approached, 85.1% agreed to participate in the study. Of the 977 men who participated, most were African American (95.7%), were  $\geq 24$  years of age (51.6%), and had graduated from high school (49.3%) or had some college education (22.6%). Most men reported that they had  $\geq 2$  sex

partners at baseline (68.3%) and reported having only female partners (95.3%). Although the rate of self-reported of binge drinking in the previous 30 days was high (42.5%), the rate of self-reported substance use (cocaine, crack, or heroin) in the previous 30 days was low (5.5%). Participants were evenly distributed between the 3 arms (partner referral arm, 29.2% of subjects; BEPR arm, 35.5%; and PDPT arm, 35.3%), and participants in the treatment arms were similar with respect to variables measured (table 1).

**Baseline partner characteristics.** The 977 men reported information on 1991 partners at baseline. These partners were mostly women (97.6%), and most were described as casual rather than main partners (65.8%). In the majority (87.6%) of partnerships, the index men reported that they could contact the partner(s) if they wanted to do so. For a few of the partnerships, the couples were married (2.2%) or cohabitating (12.6%). Index men reported giving money or drugs to that partner for sex (2.7%) or reported that the partner had physically abused them (7.0%).

**Baseline STD information.** Of 931 men who had results of baseline tests of urethral swabs for *C. trachomatis* and *N. gonorrhoeae*, 54.5% tested positive for *N. gonorrhoeae* only, 15.0% tested positive for *C. trachomatis* only, and 5.9% tested positive for both *C. trachomatis* and *N. gonorrhoeae*. The majority of the men who enrolled had symptoms (86.3%), which were dysuria in 58.6% and discharge in 80.8%.

**Follow-up behavioral information.** Of 977 men enrolled, 78.8% completed a follow-up interview. Those who completed a follow-up interview were similar to those who did not with

**Table 1. Baseline characteristics of 977 subjects in a study of patient-delivered partner treatment (PDPT) for male urethritis, by intervention arm.**

Characteristic	Intervention arm, % of subjects			P
	PR (n = 285)	BEPR (n = 348)	PDPT (n = 344)	
Baseline characteristic				
African American race	96.1	96.8	94.2	.21
High school education	76.1	78.4	77.6	.79
Age of $<24$ years	47.4	45.8	51.7	.28
Symptom				
Burning sensation during urination	54.0	59.2	61.9	.13
Discharge	82.1	76.7	84.0	.04
Any	84.9	83.9	89.8	.06
Partner asked that they come to clinic	14.4	15.2	12.5	.57
$\geq 2$ Sex partners	68.1	65.2	71.6	.20
Crack use	3.5	6.6	6.1	.20
Binge drinking	40.8	42.7	43.8	.75
<i>Chlamydia trachomatis</i> infection	19.5	22.0	21.6	.73
<i>Neisseria gonorrhoeae</i> infection	59.9	60.7	60.9	.97
Completion of follow-up interview	83.5	80.2	77.0	.13

**NOTE.** BEPR, booklet-enhanced partner referral; PR, partner referral.

**Table 2. Behavioral and sexual outcomes for subjects in a study of patient-delivered partner treatment (PDPT) for male urethritis, by intervention arm.**

Outcome	Intervention arm, % of subjects				<i>P</i>	
	PDPT ( <i>n</i> = 705)	BEPR ( <i>n</i> = 707)	PR ( <i>n</i> = 579)	Total ( <i>n</i> = 1520)	PDPT arm vs. BEPR arm	PDPT vs. PR arm
Behavioral outcome						
Subject saw partner	65.1	53.7	54.4	57.8	.002	.005
Subject talked to partner about infection	70.6	52.8	49.1	57.8	.001	.001
Subject checked to see whether partner was treated	63.7	46.8	43.0	51.5	.001	.001
Partner reported to index patient that the medication was taken	55.8	45.6	35.0	46.0	.007	.001
Subject saw partner taking the medication	48.2	32.6	27.1	36.4	.001	.001
Subject gave intervention to partner	69.7	58.3	49.0	59.4	.005	.001
Sexual outcome						
Subject had unprotected sex before partner took medication	8.4	10.2	12.7	10.3	.36	.04
Subject reinitiated sex with baseline partner	34.6	35.3	36.9	35.5	.83	.50
Subject had unprotected sex with any partner <sup>a</sup>	26.5	31.7	34.6	30.8	.19	.05

**NOTE.** *P* values are from unadjusted (bivariate) generalized estimating equations. BEPR, booklet-enhanced partner referral; PR, partner referral.

<sup>a</sup> Analysis conducted by index patient rather than by partnership (*n* = 779).

regard to the following baseline characteristics: arm of the study, race, education level, age, symptoms, whether they were a known contact with a person with *C. trachomatis* or *N. gonorrhoeae* infection, substance use, and binge drinking status. Those who did not complete a follow-up interview were more likely than those who did complete a visit to have  $\geq 2$  sex partners at baseline (74.1% vs. 66.7%;  $P < .05$ ). Because men had the option of being interviewed in the clinic or in the field,

various methods of interviewing were used at follow-up. The mode of interviewing was face-to-face for 40.2% of subjects, telephone for 35.4%, and CASI for 24.3%. There was no difference by arm for the mode of interviewing.

Of 1520 partnerships reported at follow-up interview, index men reported that, during follow-up, 57.6% saw the partner, 35.8% had sex with the partner, 51.0% used a condom every time with that partner, 27.7% had unprotected sex with the

**Table 3. Multivariable model of factors associated with a subject reporting that his partner took the provided medicine at follow-up (*n* = 1520).**

Variable	Partner took medication		OR (95% CI)		
	Percentage of subjects	<i>P</i> <sup>a</sup>	Unadjusted	Adjusted	<i>P</i> <sup>b</sup>
Type of partner					
Main	57.9	.001	1.00	1.00	
Casual	39.5		0.48 (0.39–0.59)	0.64 (0.50–0.80)	.001
Reinitiated sex with partner					
Yes	68.9	.001	4.50 (3.55–5.69)	4.26 (3.31–5.47)	.001
No	33.0		1.00	1.00	
Intervention arm					
PDPT	55.8	.001 <sup>c</sup>	2.25 (1.67–3.04)	2.88 (2.05–4.04)	.001 <sup>c</sup>
BEPR	45.6	.001 <sup>d</sup>	1.56 (1.16–2.10)	1.66 (1.22–2.27)	.001 <sup>d</sup>
PR	35.0		1.00	1.00	

**NOTE.** BEPR, booklet-enhanced partner referral; PDPT, patient-delivered partner treatment; PR, partner referral.

<sup>a</sup> *P* values were obtained from bivariate generalized estimating equations.

<sup>b</sup> *P* values were obtained from multivariable generalized estimating equations. All variables were considered for the model, and the adjusted ORs represent those that were found to be statistically significant in multivariable modeling ( $P < .05$ ).

<sup>c</sup> For PDPT arm vs. PR arm.

<sup>d</sup> For BEPR arm vs. PR arm.

**Table 4. Multivariable model of factors associated with positive results of a follow-up test for sexually transmitted diseases.**

Characteristic	Percentage of subjects positive for <i>Neisseria gonorrhoeae</i> or <i>Chlamydia trachomatis</i> (n = 289)	OR (95% CI)	
		Unadjusted	Adjusted
Age, years			
<24	31.5	1.84 (1.07–3.18) <sup>a</sup>	2.00 (1.12–3.57) <sup>a</sup>
≥24	20.0	1.00	1.00
Intervention arm <sup>b</sup>			
BEPR	14.3	0.22 (0.11–0.45) <sup>c</sup>	0.22 (0.11–0.44) <sup>c</sup>
PDPT	23.0	0.40 (0.21–0.78) <sup>a</sup>	0.38 (0.19–0.74) <sup>c</sup>
PR	42.7	1.00	1.00

**NOTE.** BEPR, booklet-enhanced partner referral; PDPT, patient-delivered partner treatment; PR, partner referral.

<sup>a</sup>  $P < .05$ .

<sup>b</sup> If all men are considered in the denominator (and if patients who did not provide a follow-up urine specimen were considered to have negative test results), the percentages of men are as follows: BEPR arm, 4.6%; PDPT arm, 5.8%; and PR arm, 12.3% ( $P < .01$ ).

<sup>c</sup>  $P < .001$ .

partner before the partner took the medicine, 38.6% reported that the partner had either dysuria or discharge, and 57.7% talked to the partner about the infection. Overall, 59.1% reported that they had an intervention with the partner (i.e., the index man told the partner to get tested, gave the partner the booklet, or gave the partner the medication), 51.3% checked to see if the partner was treated, 44.7% reported that the partner took the medication, and 32.2% of all subjects saw the partner taking the medication.

Men in the PDPT arm were more likely than those in the partner referral arm to report having given the medicine to their partner (compared with telling the partner to get treated; 69.7% vs. 49.0%;  $P < .001$ ), having seen the partner (65.1% vs. 54.4%;  $P < .005$ ), having talked to the partner about the infection (70.6% vs. 49.1%;  $P < .001$ ), having checked to see whether the partner received treatment (63.7% vs. 43.0%;  $P < .001$ ), seeing the partner take the medicine (48.2% vs. 27.1%;  $P < .001$ ), and that the partner told him that the antibiotics were taken (55.8% vs. 35.0%;  $P < .001$ ) (table 2). Men in the BEPR arm reported follow-up and treatment rates that were between those of men in the other 2 arms.

Of the 1520 partnerships reported on during follow-up, 35.8% reinitiated sex during the follow-up period. Men in the PDPT arm were less likely than those in the partner referral arm to have unprotected sex before the partner took the medicine (8.4% vs. 12.7%;  $P < .05$ ) and to have unprotected sex with any partner during the follow-up period than were men in the partner referral arm (26.5% vs. 34.6%;  $P < .05$ ).

#### **Characteristics by report of partner taking medication.**

Subjects who reported that their partners took the medication were similar to those who did not with respect to race, edu-

cation level, age, baseline symptoms, and the fact that they had come to the clinic because they were a contact of a person with *C. trachomatis* or *N. gonorrhoeae* infection. These men also reported fewer partners and were more likely to report that their partners were “main” than “casual” partners, were more likely to be living with that partner, were more likely to have seen that partner, and were more likely to have talked to that partner about the infection. There were no differences in condom use by reported partner treatment status. In adjusted analyses, being a main partner, reinitiating sex, and use of BEPR and PDPT methods were associated with a greater likelihood that the index subject would report that the partner told him that she took the medicine (table 3).

**Follow-up STD information.** Of 770 men who completed a follow-up interview, 37.5% provided a follow-up urine or urethral swab sample. Subjects who provided a urine specimen were similar to those who did not with regard to the baseline characteristics shown above and were also similar with regard to whether they acquired new partners during the follow-up period (14.1% vs. 13.1%;  $P < .75$ ). Men in the partner referral arm were the least likely to provide a specimen, compared with those in the BEPR and PDPT arms (24.2%, 35.5%, and 32.4%, respectively;  $P < .02$ ).

Of the 289 men tested, 242 were tested by the urine strand-displacement amplification assay, and 47 were tested by the swab Gen-Probe Pace 2 test. Of those who tested positive for *C. trachomatis* infection at baseline, 32.9% tested positive for *C. trachomatis* infection at follow-up, and of those who tested positive for *N. gonorrhoeae* infection at baseline, 14.8% tested positive for *N. gonorrhoeae* infection at follow-up. Of the 289 men who had positive test results, 25.3% tested positive for *C.*

*trachomatis* or *N. gonorrhoeae*, 11.7% tested positive for *N. gonorrhoeae* only, 17.5% tested positive for *C. trachomatis* only, 3.9% tested positive for both *C. trachomatis* and *N. gonorrhoeae*, and 43 (15.4%) tested positive for the same organism as at baseline. Men in the partner referral arm were more likely than those in BEPR and PDPT arms to test positive again for the same organism as at baseline (23.5%, 10.7%, and 13.8%, respectively;  $P < .05$ ). The majority (67.4%) of subjects (16 subjects with *N. gonorrhoeae* infection and 21 with *C. trachomatis* infection) who retested positive for the baseline organism denied having reexposure.

Men who tested positive for *C. trachomatis* or *N. gonorrhoeae* infection at the 1-month follow-up visit were similar to those who tested negative with respect to education level, race, baseline drug and alcohol use, number of sex partners, and acquisition of new sex partners. Men in the PDPT and BEPR arms were less likely to have positive test results during follow-up than were those in the partner referral arm (23.0% and 14.3% vs. 42.7%;  $P < .001$ ). If we assume that subjects who did not provide a follow-up urine sample for testing would have had negative test results, the overall rates of positive results of follow-up tests would have been 5.8% in the PDPT arm and 4.6% in the BEPR arm versus 12.3% in the partner referral arm ( $P < .01$ ). Age and study arm were associated with positive test results in follow-up in both crude unadjusted and adjusted analysis (table 4). The adjusted OR for reinfection among those who accepted tested was 0.22 in the PDPT arm, compared with the partner referral arm. Men who reported having unprotected sex with at least 1 untreated partner ( $n = 34$ ) were no more likely to test positive for *C. trachomatis* or *N. gonorrhoeae* infection than were men who did not report this behavior ( $n = 236$ ; 26.5% vs. 24.6%;  $P < .08$ ).

## DISCUSSION

This study demonstrates that men with urethritis who are provided with PDPT are significantly more likely than men managed with standard partner referral to report that their partners were treated with antibiotics and were less likely to become reinfected with *C. trachomatis* or *N. gonorrhoeae*. There are several strengths to this study, including adequate randomization and sample size. The population studied (i.e., mostly heterosexual, African American attendees of an STD clinic) represents the population with the highest rate of STDs in the United States. There was consistency between the behavioral and biological measures. No important adverse incidents were reported, and men in the PDPT arm were less likely to engage in unprotected sex both before their partners took their medicine and throughout the follow-up period, suggesting that this approach did not result in an increase in high-risk sexual behavior.

There are some limitations to the study. Because there was no "test of cure" conducted, and because men were tested 1 month after the initial visits, it is impossible to determine whether the follow-up infections were reinfections with strains from original partners, new infections with strains from newly acquired partners, or persistence of the original infection. However, there is little evidence of *C. trachomatis* resistance to azithromycin [15–17], and data from the Gonococcal Isolates Surveillance Project, a surveillance system to monitor antibiotic-resistant gonorrhea, indicates that in New Orleans, *N. gonorrhoeae* is still susceptible to both cefixime and ciprofloxacin [18]. One important limitation of the study was the low rate of follow-up testing. Although 78.8% of subjects completed interviews, only 37.5% provided a urine specimen. Many men were interviewed by phone and did not want to provide a specimen in the field or to visit the clinic for testing (35.5%). Qualitative interviews of 15 men who did not provide urine samples for testing found that the reasons cited were that the men did not think repeated testing was necessary, were unable to produce a specimen at that time, were afraid that the specimens would be used for other purposes (i.e., drug testing and DNA testing for the legal system or to determine paternity), and were embarrassed about giving a specimen in the field. There is no reason to believe that these concerns depended on the intervention arm. If all men who were not retested were considered to have had negative test results, because symptomatic and reinfected patients may have been more motivated to get tested, the PDPT arm still had the lowest rate of positive test results at follow-up.

The data suggest that the effect of the intervention was large (i.e., men who were in the PDPT arm were 2.88 times more likely to report that their partners told them that they took the medicine and were 0.38 times less likely to have a recurrent infection). BEPR was also found to be efficacious for many of the same findings as PDPT and could serve as a good alternative for places where PDPT is opposed or logistically infeasible. Consideration should be given to instituting these approaches among heterosexual men with urethritis.

## Acknowledgments

We wish to thank the following health care providers for their invaluable assistance with this study: the Delgado STD/HIV Clinic, especially Gloria Williams; Barbara Smith and Cathy Cammarata from Louisiana State University Health Sciences Center (New Orleans); George Oswell and Margaret McKeown from the Office of Public Health; Norine Schmidt, Bruce Hurley, Mandy Roberts, Gina Jenkins, and Angela Powell from Tulane University Health Sciences Center (New Orleans, LA); and Matthew Hogben from the Centers for Disease Control and Prevention (Atlanta, GA).

**Financial support.** Centers for Disease Control and Prevention (co-operative agreement R30/CCR619146 "Optimizing Partner Treatment Strategies").

**Potential conflicts of interest.** All authors: no conflicts.

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