Patient-Delivered Therapy for Chlamydia: Putting Research Into Practice

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Background: **In 2001 California State lawmakers authorized patient-delivered therapy for sex partners of patients with chlamydial infection. Several studies have suggested that patient-delivered therapy is effective in the treatment of infected partners.**

Goal: **The goal was to inform clinicians of the effectiveness and feasibility of patient-delivered therapy for the management of partners of sexually transmitted disease cases.**

Study Design: **A review of studies regarding patient-delivered therapy was performed. A descriptive cross-sectional analysis of clinic data was also done. The proportion of patients with chlamydia receiving therapy for partners and stratification by year and selected characteristics were evaluated with statistical analysis software (SAS).**

Results: **Studies suggested patient-delivered therapy decreased the incidence of chlamydia infection and the risk of reinfection from an untreated partner. The annual proportion of cases in which patient-delivered therapy occurred at the San Francisco STD Clinic was approximately 23%.**

Conclusions: **Patient-delivered therapy is a beneficial and feasible addition to partner notification in the management of chlamydia. Expansion of patient-delivered therapy should be considered seriously in public health policy and clinical care.**

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ON SEPTEMBER 29, 2000, Governor Gray Davis of California signed into law Senate Bill 648, which authorizes physicians and nurse practitioners to prescribe, dispense, furnish, or deliver additional antimicrobial therapy to patients with diagnosed genital chlamydia for their sex partners. This law became effective January 1, 2001.

Genital chlamydial infection, like other sexually transmitted diseases, is an infection affecting a partnership.[1] Several studies have documented infection rates among partners to be between 30% and 70%.[2] Current recommendations for effective management of patients with genital chlamydia require evaluation and treatment of all sex partners within the past 60 days.[3] Partner notification can be by patient referral, in which the patient notifies and refers the partner for treatment, or by provider referral, in which the provider (such as a staff member of the clinic or health department) notifies and encourages the partner to obtain treatment. Partner notification, however, has its limitations: it is costly to organizations and has only limited effectiveness.[4]

While partner notification may have a role in the control of small outbreaks, partner notification has never been adequately funded to be a viable control strategy. For hyperendemic infections such as chlamydia in California, there may be more than 600,000 new infections a year. Therefore, given the extent of the chlamydia epidemic in California and the lack of additional resources, new control strategies were needed. This set the stage for adoption of Senate Bill 648, authorizing medical care providers to offer patient-delivered therapy to case-patients with chlamydia.

The risk for reinfection among patients with untreated sex partners may be as high as 14% at 4 months to 25% at 1-year.[5, 6] The principal danger of reinfection is the increased risk among women for pelvic inflammatory disease (PID), with each repeated infection increasing the risk for PID severalfold.[2] Pelvic inflammatory disease is costly in terms of both healthcare dollars and morbidity. The estimated cost of PID in the United States may be between $2 billion and $4 billion annually.[7] The medical consequences of the disease may include hospitalization and subsequent infertility, chronic pelvic pain, and tubal pregnancy. The important role that chlamydial infection plays in the development of PID was demonstrated by Scholes and others,[8] who showed that regular screening for and treatment of chlamydial infection substantially reduced the incidence of PID.

Recognizing the role that prompt treatment of sex partners may have in preventing repeated infections and their sequelae, some physicians routinely prescribe patients additional therapy for their sex partners.[9] This practice is called patient-delivered therapy. Several studies have associated patient-delivered therapy with lower rates of recurrent or persistent infection. An observational study of patients at a New Orleans clinic showed that patient-delivered therapy was associated with a 50% reduced incidence of chlamydial infection at 1 year of follow-up.[10] Another observational study also showed that patient-delivered therapy was associated with reduced incidence of chlamydial reinfection.[11]

More recently, the Centers for Disease Control and Prevention completed a randomized, multisite study comparing patient-delivered therapy versus routine counseling and referral among women with diagnosed chlamydial infection. Although the findings did not

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TABLE 1. San Francisco City Clinic Guidelines for Patient-Delivered Therapy, 2001

1. Patient is diagnosed with chlamydial, gonococcal infection, nongonococcal urethritis or trichomoniasis.
2. Patient understands the importance of partner medical evaluation and treatment.
3. Patient knows the name and location of recent (within 60 days) sexual partners.
4. Patient understands the risks of prescribed medications including allergic reactions and drug-drug interactions.
5. Patient agrees to notify and deliver patient-delivered therapy packet to partner(s).

achieve statistical significance at the $P < 0.05$ level for a two-tailed test, at follow-up there was a strong trend showing a 20% reduction in the rate of reinfection in the patient-delivered therapy group, with a greater reduction among patients who reported their partners most likely received therapy.[12]

Not only is there increasing evidence from epidemiologic studies that patient-delivered therapy is efficacious, but also preliminary data suggest that among those who accept patient-delivered therapy it results in a high proportion of partners receiving treatment. In an evaluation of partner management at our clinic in San Francisco, 73% of patients who received therapy to deliver to their partners reported that their partners were treated.[13] Another study, in Seattle, in which participants with untreated partners were offered extra medication to deliver to a partner, showed that 76% agreed to obtain extra medication for a partner; among those, 84% did pick up the extra medication at a pharmacy.[14]

Current recommended treatments for chlamydial infection include a regimen of doxycycline (100 mg by mouth twice a day for 7 days) or azithromycin (1 g by mouth once). Both drugs are safe and well-tolerated, have few adverse effects, and have few frequent adverse interactions with other drugs. Azithromycin is believed to be safe in pregnancy and is approved for administration to children. Studies show that the two drugs have comparable efficacy and are associated with an approximately 95% rate of treatment success.[2]

The potential risks of patient-delivered therapy are primarily to female partners, who may be undertreated for more serious or complicated infections such as PID. The frequency of asymptomatic PID among female partners of men with chlamydial infection is unknown but likely is low. These women who would have been diagnosed with PID by clinical examination will receive treatment only for uncomplicated chlamydial infection. The sequelae of undertreating PID as an uncomplicated infection are unknown but could include tubal scarring and infertility. Additional risks include missed opportunities for education, counseling, and screening for other sexually transmitted diseases, including HIV. It is also possible that the increased antimicrobial use in the short-term may lead to increased community-level antimicrobial resistance, but the frequency of prescriptions is no greater than if sex partners had presented for evaluation and received recommended epidemiologic treatment.[15] Last, if the strategy is effective in reducing the transmission of chlamydia, the decreased burden of disease in the population would decrease use of antimicrobials for treatment and reduce the selective pressure that fosters resistance.

Since December 1998 at San Francisco City Clinic, the only municipal STD clinic in San Francisco, patient-delivered therapy has been a clinical management tool available to all clinicians (Table 1). Once a patient is identified as infected with chlamydia, clinicians discuss the importance of partner treatment with their patients. Clinicians then assess the ability of patients to notify relevant sex partners of their exposure and their need for treatment. The likelihood that notified sex partners will return for evaluation

TABLE 2. Number and Percent of Chlamydia Patients Receiving Therapy for Partners, by Selected Characteristics and Year, San Francisco City Clinic, 2000–2002*

	Number Per Year		
Variable	2000	2001	2002
Total no. of chlamydia cases	902	1022	550
Percentage of patients receiving partner therapy	22%	23%	23%
Behavioral risk groups: % (n/N)			
FSM/F	23 (55/238)	24 (56/235)	29 (36/125)
MSF	21 (87/409)	24 (98/414)	28 (40/142)
MSM	20 (50/249)	22 (79/361)	18 (48/274)
Age group: % (n/N)			
<25 y	18 (59/326)	22 (75/334)	27 (43/161)
25–34 y	25 (88/354)	25 (98/400)	21 (47/225)
≥35 y	21 (47/222)	23 (65/288)	21 (35/164)
Race/ethnicity: % (n/N)			
Asian	21 (22/107)	21 (28/133)	29 (24/84)
Black	25 (70/278)	27 (80/299)	32 (42/131)
Hispanic	17 (35/201)	23 (44/191)	16 (16/98)
Native American	33 (1/3)	33 (1/3)	50 (1/2)
Pacific Islander	29 (4/14)	38 (5/13)	30 (3/10)
White	21 (61/292)	21 (80/381)	17 (39/224)
Gender: % (n/N)			
Female	23 (55/238)	24 (56/235)	29 (36/125)
Male	21 (139/664)	23 (181/786)	21 (88/422)
Transgender	0 (0/0)	100 (1/1)	100 (1/1)

*Data through 5/25/02.
FSM/F = females who report sex with males; MSF = males who report sex with females; MSM = males who report sex with males; n = number of chlamydia cases receiving PDT in subgroup; N = number of chlamydia cases per year per subgroup.

and the comfort level that patients have in bringing medications to their partners are also evaluated by the clinician. If both the clinician and patient agree that it is unlikely that the sex partner will seek medical evaluation and treatment and the patient can notify the partner and deliver medications, the patient is offered extra medications to deliver to their partner(s).

Patients receive a therapy packet consisting of an information sheet on the infection and the antimicrobial that they deliver to their relevant sex partners. Recipients of patient-delivered therapy are strongly advised to visit their doctor for medical evaluation and treatment, with a particular emphasis on the need to be evaluated for other STDs. They are also advised to speak to their doctor or a clinician at San Francisco City Clinic before taking the medication if they have allergies to medications; have chronic liver, kidney, or heart disease; or are currently taking other medications. In addition, partners are informed about the possible side effects of the medication and asked to report any potentially serious reactions.

Since patient-delivered therapy was made available at City Clinic, about 23% of patients with chlamydia have received it (Table 2). Among those receiving extra therapy, the median number of doses given was one (range, 1–6). Patients not receiving patient-delivered therapy packets believed either that their partners were more likely to seek evaluation and treatment on their own or that they were unable to deliver the medications. Reasons for being unable to deliver medications included not knowing the name or whereabouts of a recent partner and not feeling comfortable disclosing the information to the partner. Last, clinicians could refrain from offering patient-delivered therapy if, in their judgment, the patient had inadequate understanding of the risks of the medications.

The legalization of patient-delivered therapy in California raises some larger questions. The most obvious question to the public health practitioner is whether it will increase the number of sex partners receiving chlamydia treatment and ultimately reduce the transmission of chlamydia and the community-level burden of disease. Perhaps it will, but only time will tell. To the clinician, the important question is whether patient-delivered therapy is safe medical practice. Many clinicians, along with the Medical Board of California, the California Medical Association, and the California Department of Health Services, fully support the benefits over the potential risks of patient-delivered therapy. Finally, health policy–makers will question whether this practice will erode the sanctity of the physician–patient interaction and lower the barrier to increased telephonic or Internet-based diagnosis and clinical management. It is doubtful that this would occur, but if it did, perhaps there are clinical situations that can best be managed by expediency and empowerment of the physician and patient to do what is practical and common sense.

As the practice of public health and medicine continues to evolve with safer and newer technology for disease management, researchers and clinicians need to remain at the forefront of health policy and public health practice. Policy needs to remain evidence-based and to balance individual risk with public health benefit. Patient-delivered therapy is an excellent example of how, in times when new disease control strategies are urgently needed, epidemiologic research can inform public health policy to create safe medical practice and sound public health.

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