Novel interventions to reduce re-infection in women with chlamydia: a randomized controlled trial

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BACKGROUND: The aim of this study was to determine whether postal testing kits (PTKs) or patient-delivered partner therapy (PDPT) for partners of women with Chlamydia trachomatis reduce re-infection rates in women, compared with partner notification by patient referral.

METHODS: Three hundred and thirty women testing positive for chlamydia, at clinics for genitourinary medicine, family planning and termination of pregnancy in Edinburgh, were randomized to one of three partner interventions: patient referral, PTK (partners post urine for testing) or PDPT (1 g azithromycin for partners). Women submitted urine for chlamydia testing every 3 months. The primary outcome was re-infection assessed as time to first positive result by the Cox proportional hazard regression. The proportion of partners tested or treated with each intervention was determined.

RESULTS: Out of 330 women, 215 (65%) were retested over 12 months. There were 32 of 215 women (15%) who retested positive (7, 15 and 10 women from the patient referral, PTK and PDPT groups, respectively). There was no significant difference in re-infection between PDPT versus patient referral (HR 1.32, 95% CI 0.50–3.56), PTK versus patient referral (HR 2.35, 95% CI 0.94–5.88) or PDPT versus PTK (HR 0.55, 95% CI 0.24–1.24). There was no significant difference in the proportion of partners confirmed tested/treated between the patient referral (34%) and PTK (41%, P = 0.32) or PDPT (42%, P = 0.28) groups.

CONCLUSIONS: PTK and PDPT do not reduce re-infection rates in women with chlamydia compared with patient referral. However, PDPT may offer other advantages such as simplicity and cost compared with patient referral.

Key words: Chlamydia trachomatis / patient-delivered partner therapy / partner notification / postal testing kits / re-infection

Introduction

Treatment of Chlamydia trachomatis in women is important to prevent complications such as tubal infertility and ectopic pregnancy. A prospective study in England demonstrated that repeat infection in women occurs in up to 30% of cases (29.9 per 100/person-year) (Scott Lamontagne et al., 2007). It has previously been shown that many cases of re-infection are due to resumption of sexual intercourse with an untreated partner (Blythe et al., 1992; Rietmeijer et al., 2002; Scott Lamontagne et al., 2007). Since re-infection in women is believed to increase likelihood of tubal obstruction, it is imperative that infected partners are successfully treated (Patton et al., 1990; Rank et al., 1995).

Partner notification has been the standard means of managing sexual partners of patients with chlamydia in the UK. This usually involves the index patient notifying sexual contacts of the risk of infection (patient referral) and advising them of the need for testing and treatment. This traditionally involves partner attendance at specialized genitourinary medicine (GUM) clinics, where they may be offered empirical epidemiological treatment for chlamydia at the same time as testing (BASHH guideline, 2006). However, men may be reluctant to attend a clinic for testing and treatment due to the stigma associated with sexually transmitted infections (STIs) and the asymptomatic nature of chlamydia (Darroch et al., 2003; Mulholland and Van Wersch, 2007). Furthermore, there is good evidence that during the
delay in seeking health care, up to 50% of individuals with an STI will continue to have sex (without a condom), thus increasing the risk of re-infecting an already treated partner (Mercer et al., 2007).

Novel partner interventions that have been proposed include ‘postal testing’, whereby index patients provide partners with a home sampling kit, to post a urine sample to a laboratory for chlamydia testing (postal testing kit, PTK) (Andersen et al., 1998). Individuals are then informed of the result and treatment is arranged if necessary. Two randomized controlled trials conducted in Denmark reported higher partner testing rates of the result and treatment is arranged if necessary. Two randomized controlled trials conducted in Denmark reported higher partner testing rates with PTKs (Andersen et al., 1998; Østergaard et al., 2003). However, these studies did not examine re-infection rates in index patients. Expedited treatment of partners via patient-delivered partner therapy (PDPT) is another partner intervention that involves the clinician providing index patients with anti-chlamydial therapy (usually 1 g azithromycin), for them to give to sexual partners (Ramstedt et al., 1991; Schillinger et al., 1991; Schillinger et al., 1995; Golden et al., 2005; Kissinger et al., 2005). This strategy is controversial, since the clinician is providing treatment for individuals that they are unable to evaluate clinically. Nevertheless, it has previously been used in Sweden and is currently permissible in 14 states in the USA for treating sexual partners for chlamydia (Ramstedt et al., 1991; Centers for Disease Control and Prevention, 2008). A systematic review of studies comparing PDPT with patient referral demonstrated that PDPT resulted in a greater proportion of partners ‘reported’ by index patients (with chlamydia) to have been treated (Trelle et al., 2007). Furthermore, lower rates of re-infection were observed in studies using PDPT where index cases had chlamydia and gonorrhoea, or urethritis (Golden et al., 2005; Kissinger et al., 2005). To date, no study has been conducted in the UK to examine the efficacy of either PTK or PDPT for testing/treating partners of women with chlamydia. Furthermore, no study has been conducted in any other country comparing all three partner interventions for chlamydia (patient referral, PTK and PDPT) directly.

The primary aim of this study was to determine whether PTK and PDPT (azithromycin) reduced re-infection rates in women with uncomplicated C. trachomatis infection over 12 months compared with patient referral. In addition, we wished to determine the proportion of partners tested/treated with each intervention (secondary outcome).

Methods

Patient recruitment

Between May 2004 and December 2006, all women aged 16–45 who tested positive for C. trachomatis (uncomplicated chlamydia only) at a city centre family planning clinic (FPC), GUM clinic or a hospital termination of pregnancy (TOP) in Edinburgh were invited to participate in the study. A total of 330 women agreed to participate. In order to be eligible for the study, women had to: have at least one sexual partner who had not been treated and whom they could contact, be planning to remain resident in Lothian (Edinburgh and surrounding area) over the following 12 months and be able to give written informed consent. Furthermore, women with partners who had known or suspected allergies to azithromycin or with significant medical illnesses (to pose concern about safety of administering azithromycin) were not considered for the study.

Women were randomized to one of the three partner intervention strategies: (i) patient referral, (ii) PTK or (iii) PDPT. Randomization was conducted using sealed opaque envelopes containing computer generated randomization numbers in blocks, stratified for each recruitment site (performed by statistician R.E.). Subjects were recruited by either the study research nurse (A.J.) or doctor (L.M.), who had both received extensive training in partner notification. All subjects received written and verbal information about chlamydia and the importance of partner treatment. Demographic data were collected on all subjects including smoking history, deprivation category area of residence (based upon the Carstairs methodology), parity, most recent contraceptive use and sexual history (Carstairs and Morris, 1991). Women agreed to submit a urine sample at three monthly intervals over 12 months for repeat testing for chlamydia using the COBAS Amplicor CT test (Roche Diagnostics, Basel). Since the chlamydia laboratory used for the study is the only chlamydia testing laboratory within the Lothian region, we were able to determine whether subjects or their partners were tested out-with the study (in the region), in order to obtain as accurate data as possible regarding the re-infection rate in women and to validate the numbers of partners who were tested. For the purposes of the study, we have equated the repeat positive test rate in women as re-infection rate.

Ethical approval for the study was obtained from the Lothian Research Ethics Committee (LREC/2003/6/12). In addition, approval for the study was also obtained from both the Research and Development Department and the Chief Pharmacist of the Responsible Health Care Trust. All subjects gave written informed consent.

Patient referral

For subjects randomized to patient referral, details of sexual contacts within the past 6 months were recorded on standard proformas (used by local GUM service). All women agreed to contact partners themselves and were provided with standard contact slips (used by local GUM service) to facilitate partner notification. Women were also provided with an information leaflet about chlamydia with details of GUM clinics that partners could attend. Subjects were contacted by telephone (maximum of three phone calls) by the recruiting study nurse or doctor 4 weeks after study entry to check if women had successfully contacted partners. The number of sexual partners who subsequently attended GUM clinics was determined from the GUM clinic records.

Postal testing kit

For subjects randomized to PTK, details of sexual contacts were recorded in the same way. Women were given a PTK to deliver to each sexual partner for them to produce a sample of urine at home for posting to the laboratory for chlamydia testing.

The PTK consisted of a universal container for the urine sample, absorbent sleeve in which the container fitted, a laboratory form to complete with details of how partner wished to be contacted with the result (phone call, text and email), an instruction leaflet and a postage-paid, pre-addressed envelope into which the sample and form would be placed and sent direct to the laboratory. The PTK also included a leaflet about chlamydia and information about the study with contact details of the study nurse (if further information was required). Information was also provided about GUM clinics that men could attend for testing and treatment if they preferred. Each PTK request form was coded so that the chlamydia laboratory could identify the test as being a study sample. For those men who subsequently tested positive, the study nurse arranged treatment at GUM.

Patient-delivered partner therapy

Subjects randomized to PDPT were supplied with one treatment pack (1 g dose of azithromycin) to give to each sexual partner. The partner treatment pack also contained an information leaflet about the study with contact details of the study nurse, information about chlamydia, a drug safety leaflet (with contra indications to azithromycin) and details of GUM clinics they could attend for testing/treatment if they preferred. The study information leaflet contained a ‘tear-off’ slip that the partner was asked to complete.
and return (in a pre-addressed postage-paid envelope) to confirm that they had taken the medication. There was also an ‘objection’ slip that could be completed and returned, if the partner objected to treatment in this way. Details of sexual contacts were recorded as for other groups.

**Partner testing/treatment rates**

Women in all groups were contacted by the study nurse or doctor by telephone at 6 months to determine the number of partners that they had successfully contacted (delivered a contact slip, PTK or PDPM to partner as appropriate). In order to determine the actual numbers of partners who were known to have been treated or tested (validated partner testing/treatment rates), the laboratory and FPC and GUM clinic databases were checked to determine whether partners with details that matched those provided by the index patient had attended or submitted a sample for testing.

**Women re-testing**

At study entry, all women were given a PTK for themselves and asked to post a urine sample to the laboratory for re-testing for chlamydia at 3 months. Further PTKs were sent to subjects at 6, 9 and 12 months for repeat testing. These PTK samples were labelled with the non-identifying subject study code so that laboratory staff who reported the results were unaware of the randomization group that women belonged to. Subjects were sent a £5 music voucher as an incentive, upon receipt of the urine sample. For those women who subsequently tested positive, the study nurse arranged treatment at GUM. The study nurse contacted all subjects who failed to submit a sample at a given time to remind them that a test sample was overdue (up to a maximum of three phone calls).

**Statistical analysis**

We assumed a re-infection rate of 30% in women in the patient referral group and 10% in women in PTK and PDPT groups (Kissingler et al., 1998; Honey et al., 2002). Power calculations demonstrated that 52 women in each group (total 156 subjects) would give 90% power at 5% level of significance. We planned to recruit 110 women to each arm (total 330 subjects) to ensure that even with a predicted 50% drop-out, the study would remain adequately powered (Blythe et al., 1992).

Comparison of demographic features in women was performed using t-tests, Kruskal–Wallis or \( \chi^2 \) tests. \( \chi^2 \) tests were also used for comparing the proportions of male partners tested/treated. For comparison of rates of re-infection in women, the time to the first positive result was compared between pairs of study groups by the Cox proportional hazards regression, taking into account the different numbers of tests returned by censoring at the last follow-up time. In addition, in order to take account of the number of repeat tests performed in women in each group, comparison of rates of re-infection was also made by \( \chi^2 \) tests with adjustment for numbers of tests, by including the latter as a covariate in multiple logistic regressions.

**Results**

**Recruitment**

Three hundred and thirty women were recruited to the study (Fig. 1) over 18 months (TOP \( n = 134 \), FPC \( n = 60 \) and GUM \( n = 136 \)). Five hundred and five women were approached to take part (65% participation rate). One hundred and forty-five women were ineligible and a further 30 women refused to participate (Fig. 1). The reasons for refusal and ineligibility are shown in Supplementary Table S1. Based upon the limited demographic data that was available for women who did not participate in the study, a comparison of participants and exclusions (Supplementary Table S2) showed that those excluded were less deprived (lower deprivation category of area of residence score) than participants (\( P = 0.017 \)).

**Demographics of subjects**

The demographics of subjects randomized to each partner intervention group are shown in Supplementary Table S3. There was no significant difference between groups in any of the demographic characteristics.

**Re-infection in women over 12 months: primary outcome**

Out of 330 women, 215 returned at least one sample over 12 months (65%). There were 13 women who informed us that they no longer wished to participate in the study (2 at 3 months and 11 at 6 months) (Fig. 1). Submission of a test showed a significant positive correlation with age (more in older women \( P = 0.01 \)), use of dual contraceptive protection (at baseline) \( P < 0.007 \), a negative correlation with previous births \( P = 0.049 \), previous miscarriage \( P = 0.04 \) or previous TOP \( P = 0.047 \). Subjects from TOP clinics were significantly less likely to return a sample for testing than subjects from other sites (51%, 25% and 23% subjects not returning sample from TOP, FPC and GUM, respectively, \( P < 0.001 \)).

Overall, 32 of 215 women (15%) re-tested positive at least once over the 12 months. Significantly more women with repeat positive tests had been recruited from GUM than other sources (21, 6 and 5 women from GUM, TOP and FPC, respectively, \( P = 0.009 \)). Two women tested positive twice during the year (total 34 repeat positive tests). Of the 34 of the positive tests, 21 (62%) were within 6 months of the index infection, with 14 of 34 (41%) positives within the first 3 months. In 24 of the 34 repeat positive tests (71%), women reported that they were with the same sex partner (as at initial infection). In 9 of the 24 same partner cases (38%), the partner was not treated at initial infection for chlamydia.

For those 215 women who returned at least one sample for testing, there was no significant difference in positivity [patient referral 10% (\( n = 7 \)), PTK 22% (\( n = 15 \)), PDPT 13% (\( n = 10 \)) in women from each partner intervention group (\( P = 0.11 \)). Time to the first positive result was compared between pairs of study groups, taking into account the different numbers of tests returned by censoring at the last follow-up time, showed no significant difference in re-infection rates between groups (Table I).

After adjusting for the numbers of tests in a logistic regression, the difference in the re-infection rate between patient referral and PTK was significant (adjusted odds ratio and CI of 2.88, 1.05–7.87) for PTK versus patient referral, respectively, \( P = 0.036 \) (Table II). Women whose partners were assigned to PDPT submitted significantly more repeat tests (\( P = 0.027 \)) (Table III).

**Index patients reported partner contact rates**

At 6 months, 146 women (44% of subjects) responded to telephone contact with the study nurse or doctor. Of the responders, 142 (97%) reported that they had been able to contact all (\( n = 125 \)) or some (\( n = 17 \)) of their partners successfully and had supplied them with the contact slip, PTK or PDPM as appropriate (Table IV). There
Figure 1 Consort flowchart (modified) shows numbers of subjects responding at each three monthly stage of study. Numbers of subjects responding at each stage differ as some subjects responded at some stages and not others.
was no significant difference either in the proportion of women reporting that had successfully contacted all partners or in the number of partners reportedly contacted per woman in patient referral, PTK and PDPT groups, respectively.

### Validated partner testing/treatment rates: secondary outcomes

The 110 women in the patient referral group had 134 partners. Examination of the GUM clinic database confirmed that 26 of these partners (19%) were known to have attended GUM. A further 20 men (15%) were known to have been tested or treated elsewhere (based upon verification of laboratory and FPC clinic databases). Thus, in total, 46 partners (34%) were definitely tested and/or treated. Of these men, 40 were tested for chlamydia and 20 tested positive (50%).

The 110 women in the PTK group had 124 partners. Twenty-nine men returned the PTK (23%). A further 22 men (18%) were known to have been tested or treated elsewhere (based upon verification of laboratory and GUM and FPC clinic databases), giving a total of 51 (41%) partners known to have been tested and/or treated. Of the 49 men tested, 31 were positive for chlamydia (63%).

The 110 women in the PDPT group had 125 partners. Forty-six men returned the ‘confirmation slip’ for PDPT (32%). No ‘objection’ slips were received. Of these men, 16 (35%) also attended FPC or GUM for testing. A further six men who did not return a confirmation slip were known to have been tested elsewhere (total of 22 men; 18% tested). Thus, in total, 52 men (42%) in this group were known to have been tested/ treated. There was no significant difference in validated testing/treatment rates (34% versus 38% versus 42% for patient referral, PTK and PDPT, respectively) between the intervention groups on a simple comparison using all women randomized. The odds ratios (95% CIs) for partner testing/treatment rates in PTK versus patient referral were 1.34 (CI 0.78–2.29) and for PDPT versus patient referral were 1.36 (CI 0.80–2.33). Significantly poorer partner testing/treatment rates were observed among partners of women recruited from TOP (35% versus 59% versus 58% partners tested/treated from TOP, GUM and FPC, respectively; *P* < 0.001).

Examination of GUM databases and FPC clinic records to determine the number of additional (secondary) female contacts of those men in patient referral and PTK groups who attended clinics for treatment revealed that no secondary female contacts were known to have attended.

### Discussion

In this study, PTK and PDPT did not reduce re-infection rates with chlamydia in women compared with patient referral. We had hypothesized that women whose partners received a novel intervention would have lower rates of re-infection, but this was not observed. Clearly, subjects in the study had unrestricted time with the study.

<table>
<thead>
<tr>
<th>Table I</th>
<th>Adjusted hazard ratios (95% CIs) for risk of re-infection in women according to treatment group: patient referral, PDPT and PTK</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDPT versus patient referral</td>
<td>PTK versus patient referral</td>
</tr>
<tr>
<td>Hazard ratio (95% CI)</td>
<td>1.32 (0.54–3.56)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table II</th>
<th>Odds ratios (95% CIs) for positivity in first named groups compared with the second named</th>
</tr>
</thead>
<tbody>
<tr>
<td>All subjects</td>
<td>PDPT versus patient referral</td>
</tr>
<tr>
<td>Unadjusted</td>
<td>1.47 (0.54–4.02)</td>
</tr>
<tr>
<td>One test</td>
<td>Unadjusted</td>
</tr>
<tr>
<td>Adjusted</td>
<td>1.30 (0.45–3.74)</td>
</tr>
</tbody>
</table>

First row shows simple comparison (ignoring number of tests), second row shows those who submitted at least one test and third row adjusts for number of tests.

<table>
<thead>
<tr>
<th>Table III</th>
<th>Repeat tests conducted in women according to treatment group: patient referral, PTK and PDPT</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Patient referral</td>
</tr>
<tr>
<td>Number of tests</td>
<td>39 [36]</td>
</tr>
<tr>
<td>4</td>
<td>32 [29]</td>
</tr>
</tbody>
</table>

Figures shown are number [%] of tests returned over 12 months in each group.

<table>
<thead>
<tr>
<th>Table IV</th>
<th>Index patient reported partner contact rates according to treatment group: patient referral, PTK and PDPT</th>
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<tbody>
<tr>
<td></td>
<td>Patient referral (n = 46)</td>
</tr>
<tr>
<td>Contacted all partners, n (%)</td>
<td>36 (78)</td>
</tr>
<tr>
<td>Contacted some partners, n (%)</td>
<td>8 (17)</td>
</tr>
<tr>
<td>Contacted none of partners, n (%)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Total partners contacted (mean per woman)</td>
<td>51 (1.1)</td>
</tr>
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nurse, supplemented with information and contact slips. Thus, patient referral in this study was of ‘gold’ standard, which may not necessarily reflect the situation in real-life clinical settings or those that do not have access to specialist sexual health advisors or equivalently trained personnel. The results of this study are in keeping with conclusions of a recent systematic review that showed that PDPT was not superior to properly conducted patient referral (enhanced with information and contact slips) for preventing re-infection in index patients with chlamydia (Trelle et al., 2007). Nevertheless, re-infection was no different in the PDPT group, and PDPT may be a simple alternative to patient referral for managing sexual partners of women with uncomplicated chlamydial infection, particularly relevant to general practitioners and other clinicians working in the community, who may lack the specialist skills to assist partner notification and who are dealing with increasing numbers of cases of chlamydia. In Scotland, in 2006, two of three cases of chlamydia in women were diagnosed in non-GUM settings (Health Protection Scotland, 2007). A recent questionnaire study of health professionals who are increasingly involved in the management of chlamydia (general practitioners, gynaecologists, doctors in family planning and practice nurses), towards future alternatives to partner notification, reported that PDPT was highly acceptable to those surveyed (Cameron et al., 2007). The majority of responders were in favour of PDPT either on its own or in combination with PTK (Cameron et al., 2007). Indeed, one in four doctors in this study had already used ‘PDPT’ in the past for this purpose (Cameron et al., 2007). Furthermore, PDPT is an inexpensive strategy since it involves the costs of antibiotic treatment only. Although a disadvantage of PDPT is that it removes the opportunity to trace any other sexual contacts that the partner may have had, this secondary contact tracing seems inefficient, since no additional contacts were traced in our large study of women with chlamydia. Another disadvantage of PDPT is that it removes the opportunity to test partners for other STIs. However, the value of testing for other STIs may depend upon the prevalence within the community. In Lothian, a recent audit of other STIs in 488 partners of women with chlamydia showed that there were no cases of gonorrhoea, syphilis or HIV detected (Manavi et al., 2006). Furthermore, one US study of concurrent STIs in heterosexual sex partners showed a low prevalence of co-existing STIs (Stekler et al., 2005).

In contrast, this study raises concern that PTKs (on their own) should not be introduced as an alternative to patient referral. Following adjustment for the number of tests received from subjects, the use of PTKs was associated with a 2-fold higher odds of re-infection in women. One possible explanation for this observation may relate to the wait between receipt of a positive test result with PTK and treatment, during which time resumption of sex with the index patient and re-infection could occur. This additional ‘delay’ is not applicable to patient referral, since men are usually treated at the same time as testing at GUM clinics (BASHH guideline, 2006). Furthermore, PTK has been reported to be (at least theoretically) an unpopular choice of health professionals in the UK for managing sexual partners in this way (Cameron et al., 2007). Recent guidance from National Institute for Health and Clinical Excellence for England and Wales (NICE) recommended that PTKs should be considered as an alternative to patient referral (NICE guidance no. 3, 2007). Our study findings would contradict this recommendation. In contrast, PTKs could be useful as an adjunct to PDPT allowing a combination of expedited partner treatment and testing if desired. This could be an attractive option, and in the current study, 35% of men who received PDPT chose to attend a clinic in addition to taking PDPT.

A lower rate of re-infection (15%) in women was observed in this study than anticipated (Blythe et al., 1992; Honey et al., 2002; Scott Lamontagne et al., 2007). Given the lower than expected re-infection rate, our study could still remain underpowered to detect significant differences between partner interventions. A multicentre study would be required to recruit sufficient numbers of chlamydia positive women within the same time frame. Although we had a repeat sample from 65% women over 12 months, it is possible that repeat infection was higher among the 35% who did not undergo repeat testing. Furthermore, it is possible that the ‘attention’ of being followed up as part of study participation could be associated with a change in sexual behaviour that confers a lower risk of re-infection. We are certain that our re-infection rates in study subjects are accurate since there is only one chlamydia testing laboratory for Lothian, so all requests for chlamydia testing for subjects conducted out-with the study during the study period would have been performed here. This is the strength of our study compared with other previous studies (Schillinger et al., 2003; Golden et al., 2005).

In concordance with previous findings, most re-infections in women occurred within 6 months and most women were with the same partner, who had not been treated in one-third of cases (Rietmeijer et al., 2002; Scott Lamontagne et al., 2007). This would support the proposal that women with a positive chlamydia test should be re-tested within 6 months (Scott Lamontagne et al., 2007).

A secondary outcome of our study was the proportion of sexual partners known to have been tested/treated with each intervention. Previous studies relied solely upon index patient ‘reported rates’ of partner testing/treatment (Schillinger et al., 2003; Golden et al., 2005). Our study is the only study to provide validated evidence of this. This is important because in those women (44% of total) who responded to telephone contact, high rates of partner testing/treatment rates were reported. However, for the group as a whole, the validated i.e. known proportion of partners tested/treated was lower (34–42%). In contrast to previous studies, we observed no significant difference in partner testing/treatment rates between interventions (Schillinger et al., 2003; Golden et al., 2005; Kissinger et al., 2005). It is still possible that our figures for numbers of men taking PDPT is an underestimation, since men may have taken the medication but not returned a confirmation slip. Even if more partners did take PDPT, we did not observe a significant difference in re-infection rates between women in this group and the patient referral group.

Women from TOP clinics were significantly less likely to be re-tested and partners were less likely to be tested/treated, regardless of the intervention offered, highlighting the particular challenge that women in this group present for developing strategies to tackle repeat infection. It is possible that poorer compliance with repeat testing in women from TOP may be because they want to forget their recent unwanted pregnancy and thus a study that reminds them of this. It is also possible that fewer partners were successfully treated because relationships had ended culminating in an unwanted pregnancy.

This study provides evidence that would support the introduction of PDPT into routine National Health Service practice in the UK as an alternative to patient referral for treating sexual partners of women with uncomplicated chlamydial infection. An evaluation of its effectiveness as...
a partner intervention after introduction into everyday clinical practice would clearly be important. PDPT is inexpensive, so implementation should not prove costly. In the UK however, use of PDPT without the controlled confines of a research study cannot currently be recommended. One major barrier to implementation of PDPT is the ethical difficulty regarding administering azithromycin ‘blindly’ to partners that one has not been able to assess clinically. Fortunately, azithromycin belongs to the macrolide group of antibiotics, which have a low incidence of allergic reactions and relatively few contraindications. Although we were unable to monitor adverse events, we are not aware of any serious adverse events as a result of treatment with azithromycin in this study. Furthermore, we did not receive any ‘objection’ slips from partners, nor negative feedback from index patients. Another major barrier to adopting PDPT for clinical use is legislative difficulty. Legislation will require to be put into place to overcome the statutory and regulatory inhibitions that impede usage of azithromycin in this way (Medical Defence and Dental Union Scotland—personal communication). With the increasing public health problem of chlamydia and the growing body of evidence that PDPT is safe and effective, we believe that the time has come for the necessary legislative change (as effected in certain states of the USA) so that azithromycin can be used for managing sexual partners of women with uncomplicated chlamydia (Centers for Disease Control and Prevention, 2008).

Author’s role

All authors contributed to study design and analysis. L.M. and A.J. recruited subjects. S.T.C. wrote the paper and all other authors’ revised the paper and approved the final paper.

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