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What is the cost of pelvic inflammatory disease and how much could be prevented by screening for *Chlamydia trachomatis*? Cost analysis of the POPI (prevention of pelvic infection) trial.

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Abstract

Objectives: To describe healthcare settings attended by women with clinical pelvic inflammatory disease (PID), to calculate the cost of a PID episode and to estimate how many cases could be prevented in London annually at current chlamydia screening levels.

Methods: An ethnically diverse sample of 2259 16-24 year old, sexually active, female London students were recruited to a chlamydia screening trial in 2004-6 of whom 94% (2115) were followed up after 12 months for incidence of PID. A cost analysis examined healthcare settings attended by women with PID; the cost of an episode of PID; and the number of cases of PID in London due to untreated chlamydia at baseline which could be prevented per year at 2009 annual screening levels.

Results: Of 35 PID cases 17 (47%) first presented in general practice, 15 (42%) at a genitourinary medicine clinic, two elsewhere and one was admitted to hospital. The average number of consultations for a PID episode was 2.0 (range 1-4) and the average cost was £163 (range £29-£960). Assuming 414,345 sexually active women aged 16-24 in London, 6% chlamydia prevalence at baseline, and a 7.3% difference in PID rates between screened and unscreened chlamydia positives, 391 (95% C.I. - 44 to 882) cases of chlamydia associated PID costing £63,733 could be prevented each year in London at 21.5% 2009 annual screening levels.

Conclusions: Most women with PID were managed in the community. The number and cost of PID cases prevented by a single annual chlamydia screen is low, suggesting that cost-effectiveness may depend mainly on the prevention of long-term sequelae.

Key messages

- About 90% of PID episodes in women aged 16-24 years in the POPI (prevention of pelvic infection) trial were managed in general practice or genitourinary medicine clinics.
- The average cost of an episode of PID was £163.
- At 2009 21.5% annual screening levels and 6% chlamydia positivity, around 400 episodes of PID, associated with £64,000 in healthcare costs, may be prevented per year in London.

BACKGROUND

Many developed countries have set up *Chlamydia trachomatis* screening programmes, but it is uncertain whether these are cost effective.¹ The English national chlamydia screening programme has been criticized for both its cost (over £100 million) and the lack of outcome data, particularly on prevention of pelvic inflammatory disease (PID).^{2;3} There are two crucial reasons why a single chlamydia test is likely to have only a small effect in reducing the incidence of PID over 12 months. First it will only prevent the estimated 30% of PID which is due to chlamydia.⁴ Secondly it will not prevent PID due to incident chlamydial infection occurring during the year.⁵

Economic evaluations demonstrate the cost effectiveness of chlamydia screening to rely mainly on the prevention of PID and potential complications – tubal factor infertility, ectopic pregnancy and chronic pelvic pain.⁶ At present, few data exist on the healthcare seeking behaviour of women with PID and the associated healthcare costs. Historically acute PID was treated mainly in hospital⁷, but recent changes in PID diagnosis and management have led to wide variation in cost estimates.^{6;8-10}

The POPI (prevention of pelvic infection) chlamydia screening trial is unique in prospectively screening and following up 94% of 2529 female London students for 12 months and obtaining medical records of those diagnosed with PID.⁵ Using data from the POPI trial, the aims of this study were to examine the type and number of healthcare settings visited by women with PID, to calculate the cost of an episode of clinical PID, and to estimate how many cases of PID could be prevented per year in London at 2009 screening levels in the English national chlamydia screening programme. We also conducted an exploratory study comparing EQ5-D scores at baseline and after 12 months in women with and without PID.

METHODS

The POPI Trial

The design, recruitment methods and results of the POPI trial have been described elsewhere.^{5;11} Briefly, between 2004-6, an ethnically diverse sample of 2529 16-27 year old sexually active, female students were recruited from 20 London universities and colleges. Participants completed a questionnaire and provided self-taken vaginal swabs and consent for follow up and access to their medical records after 12

months. Samples randomly allocated to the intervention group were tested for chlamydia immediately and women with positive tests were referred for treatment. Samples in the deferred screening group were frozen at -80°C and tested after 12 months. Based on follow up questionnaires backed by a medical record search, three genitourinary medicine physicians blind to group allocation and baseline chlamydia status, used modified Hager's¹² and CDC criteria ¹³ to classify cases into probable, possible or not PID.

Only women aged <25 years are eligible for the English national chlamydia screening programme. For this analysis we therefore excluded 270 women aged 25 or older and restricted it to the 2259 women aged 16 to 24 (mean 20.3 years SD 2.2). Of these women, 28% (623/2243) were from black ethnic minorities, 44% (991/2245) reported two or more sexual partners in the previous year, and 6% (135/2252) were chlamydia positive at baseline. Follow up at 12 months was 94% (2115/2259).

Healthcare seeking behaviour for PID associated symptoms

For each identified PID episode, data on clinical consultations across all healthcare settings were extracted from patient and general practice questionnaires and medical records. We included all cases of PID presenting during 12 months follow up. We defined an episode of PID as all consultations related to symptoms, treatment and follow up of PID within 13 months of baseline screening. Healthcare settings were categorised into general practice, genitourinary medicine clinics, hospital outpatient, hospital inpatient and other (such as walk-in or primary care centres).

PID costing

For each visit we extracted the following information from the records: the staff involved and their time, the drugs, pathology and consumables. Where there were no data on the staff grade or time, assumptions were made by the lead clinicians (PO & PH). We excluded one woman from the cost analysis as she was treated as an outpatient at a hospital in the USA and no medical records were available. The total cost per episode of PID was the sum of the clinical staff cost, drugs, pathology and consumables used, and any inpatient care in a given episode. The clinical cost per minute included the indirect and overhead cost for a clinical member of staff.^{14;15} The drug costs were taken from the published Drug Tariff for September 2008.¹⁶ The costs of pathology were from local data and other estimates.^{15;17}

The costs for first and follow-up visit to an outpatient genitourinary medicine clinic (£139, £82 respectively) were taken from the national tariff.¹⁸ In a sensitivity analysis we also estimated the actual time and consumable costs. The costs of a visit to an accident and emergency department (£75) and outpatient gynaecology clinic visit (£145) and a three day non-elective inpatient episode for a late miscarriage associated with PID (HRG code M09, £786),were also taken from the national tariff.¹⁸ As in previous analyses, the costs of partner notification were not included.⁶ All costs were estimated in £UK2008/9, using published estimates from that time period where available.

Scaling up to the London population

There were approximately 505,299 16-24 year old women in London in 2008/9¹⁹ of whom 82% (414,345) were estimated to be sexually active²⁰. For various chlamydia prevalences^{5;21} and screening rates we estimated the number of PID cases due to chlamydia at baseline and those preventable by a single chlamydia test using the new risk reduction estimate observed in women aged 16-24 in the POPI trial.⁵ We also completed a further analysis using the predicted 2010 39% coverage rate.²² The preventable PID associated cost was estimated by multiplying the number of preventable cases by the newly estimated cost of PID. We made no assumptions about the duration of chlamydia infection or reinfection rates.

Health related quality of life in participants with and without PID

Baseline and follow up questionnaires included questions for the generic health related quality of life measure EQ5-D. This tool has two parts; the EQ5D descriptive system with the five dimensions mobility, self-care, usual activities, pain, and anxiety/depression and the EQ-5D visual analogue scale where the 0 and 100 endpoints are the worst and best possible health state. Weighted UK preference values were linked to the self-reported health state scores for a 0-1 index where 0 is death and 1 is perfect health.²³ Exploratory analyses were performed comparing scores at baseline and follow up in women with and without PID using t-tests.

RESULTS

Incidence of PID

There were 36 cases of PID in the 2115 women who were followed up for 12 months: overall incidence 1.7% (36/2115, 95% C.I. 1.2 to 2.3). The incidence of PID in

women who were chlamydia positive at baseline was 1.5% (1/66) in the screened group and 8.8% (6/68) in the deferred screening controls. The difference in PID rates between screened and unscreened chlamydia positives was 7.3% (95% C.I. -0.82 to 16.5%).

Healthcare settings for PID

A case note review indicated the 35 women diagnosed with PID in the UK made a total of 69 visits to a healthcare setting for related symptoms and management (Table 1). Most women attended a general practice surgery or genitourinary medicine clinic. There was an average of 2.0 (SD 0.9, range 1 to 4) attendances at any healthcare setting per PID episode. One woman was admitted for 3 days of inpatient hospital care.

Cost of clinical care for an episode of PID

The average costs of attendances in each setting and for the first attendance at that setting are given in Table 2 (details in the Appendix). Aside from one case, the first visit in a given setting was more expensive than subsequent visits, due to a longer estimated clinical visit and greater pathology costs. The estimated average cost per attendance across all settings was £83 (£68 if the genitourinary medicine tariff was used). Given an average of 2.0 attendances per woman, this works out to £163 (£29-£960) healthcare costs per case (£135 using the estimated costs in genitourinary medicine clinics rather than the tariff). Doubling the estimated amount of clinician time per visit increased the average PID episode cost to £191 (SD £160).

London-wide rate of PID and annual cost of PID due to chlamydia infection at baseline

Assuming a 7.3% difference in PID rates between screened and unscreened chlamydia positives in the POPI trial, Table 3 shows the estimated number and cost of PID cases in London prevented by a single chlamydia test over 12 months using different prevalences of chlamydia and different rates of screening. Assuming a 6% chlamydia prevalence, 21.5% screening coverage in 2009 and 8.8% progression to PID rate, we would expect an estimated 471 cases of PID due to chlamydia at baseline annually in London of which at least 391 (95% C.I. -44 to 882) cases costing £63,733 (95% C.I -£7,172 to £143,766) could probably be prevented each year (highlighted Table 3). The current cost of a screen in London is £45¹⁷ which scales to a total screening cost of £4,008,788 at 21.5% coverage.

EQ5-D and EQ Visual Analogue Scale scores in women with and without PID

Twenty eight women with PID (78%) and 1641 without PID (79%) completed both baseline and follow up questionnaires including the EQ5-D section. Women who developed PID had significantly lower scores than those who did not at both baseline and follow up (Table 4).

DISCUSSION

Principal findings

Around 90% of women with PID were managed in the community, mainly in general practice or genitourinary medicine clinics, and there was only one hospital admission. The average cost of an episode of PID was £163. At 21.5% 2009 annual screening levels around 400 (95% C.I. -44 to 882) cases of PID due to chlamydia at baseline and costing approximately £64,000 (95% C.I. -£7,000 to £144,000) could probably be prevented each year in London.

Strengths and weaknesses

This is the first study to calculate the cost of PID in London and provides new accurate information on the healthcare seeking behaviour and current management of women with PID. The data are from the largest community based prospective study of PID in sexually active women aged 16-24 to date, providing crucial data on the rate of progression to PID in women with treated and untreated chlamydial infection. The follow up rate was very high and we were able use medical records to estimate the costs of each attendance within an episode of PID. The definition of PID, based on analysis of clinical records and questionnaires by experienced genitourinary medicine physicians is likely to be more robust than diagnoses taken from general practice²⁴ and genitourinary medicine clinic databases²⁵.

The main limitation is that the number of PID cases was small due to the low prevalence in this community-based population and we could not include asymptomatic cases. The results are also likely to underestimate the potential benefits of chlamydia screening. Evaluating the effect of a single chlamydia test for women omits potential savings (and costs) due to repeated screening, sexual health promotion, and screening men which should ultimately reduce the prevalence and incidence of chlamydia.⁶ The effectiveness of chlamydia screening may be underestimated in the POPI trial because nearly half the untreated chlamydia positives in the deferred screening group were tested for chlamydia independently

during the trial.⁵ The cost of an episode of PID may be underestimated due to incomplete data and the lack of patient costs, indirect costs and partner notification costs. Also, our estimates focus on the costs of acute PID, and we did not include the potential long-term costs of PID. Previous studies have shown that potential long-term consequences such as ectopic pregnancy and infertility, can comprise a substantial proportion of the overall costs of PID.⁶

Another weakness is that the diagnosis of PID lacks specificity and sensitivity and the definition of PID has a large impact on reported incidence.²⁶ However, our PID incidence was the same as in the Scholes trial²⁷ and similar to that in general practice²⁴. Secondly, our estimates of the incidence of PID in London and potential cases prevented by screening involve many assumptions and have wide confidence intervals which cross 0, yet may be the best available at present. A single chlamydia test over 12 months will not prevent all cases of PID. This is further reflected in the estimated range of 'cost savings'. The EQ5-D is a blunt instrument for quality of life, and it was not completed by women at the time they had PID. However the finding that women who went on to develop PID had lower quality of life at baseline is novel. Finally, women in the POPI trial may not be representative and did not include women who had never been sexually active. However, the proportion reporting two or more sexual partners in the previous year was similar to London women in the national survey for attitudes and sexual lifestyles 2000 population based study²¹ and chlamydia positivity rates were similar to national chlamydia screening programme London rates.

Comparison with other studies

The £163 cost of a PID episode in our study was slightly greater than the £139 (UK £2008 equivalent) used in the cost effectiveness analysis by Adams and colleagues⁶. This could be because we had clinical data which showed that most women had more than one consultation for a PID episode. However, this is only the cost for acute PID. If the costs include the long-term complications such as tubal infertility, the average life time cost may range from \$1060 - \$3180.²⁸ The cost of screening per quality adjusted life year has previously been estimated for the current NCSP strategy; £27,262 assuming a progression to PID rate of 10%.⁶ As our PID cost estimate is similar to the one used by Adams et al (£163 versus £137(47)), estimates for the screening cost per quality adjusted life year are also likely to be similar if used in the previous model with similar assumptions.

Estimates of the burden of PID in London from the POPI trial and genitourinary medicine clinic (KC60) surveillance data were similar at around 7000 cases per year. Assuming a 1.7% incidence of PID (as in the POPI trial) and 414,345 sexually active women aged 16-24 living in London gives an estimate of 7044 (95% C.I. 4973 to 9530) cases of PID due to any cause in London in 2008/9. For comparison there were 6182 diagnoses of PID in London genitourinary medicine clinics in 2008.²⁵ Since these data are not stratified by age, if we assume that, as with chlamydia diagnoses¹, around 40% of cases were in women aged 25 or more, this suggests there were approximately 3709 cases of PID in women aged 16-24 attending genitourinary medicine clinics. If a similar number were diagnosed in general practices, this suggests, that there were around 7418 episodes of PID in London in 2008 which is in line with the POPI trial estimate.

There is considerable public health burden of PID associated morbidity. However, few studies have attempted to explore the health related quality of life. One study found that women who had had PID reported lower mental and physical health scores than women who had not had PID.²⁹ However our study appears to be the first to assess EQ5-D both before and after an episode of PID. It suggests that some women who go on to develop PID may already have a lower quality of life perhaps associated with a more at risk lifestyle⁵ and clinicians could consider the possibility of additional health or psychosocial problems. We were unable to assess the effect potential long-term sequelae may have on quality of life.

Implications

Most women with PID were managed in general practice or genitourinary medicine clinics. This suggests that some patients with PID may be choosing to be managed in the community, and general practitioners should perhaps be more open towards diagnosing PID. It also implies that using a single source of data such as primary care or hospital may be inadequate for PID surveillance in England. Our results suggest that to prevent one case of PID over 12 months, 13 women with chlamydia need to be treated. The cost of clinical PID was relatively low compared to costs of screening, but all chlamydia screening strategies are likely to improve health and cost money⁶. In 2009 it probably cost around £4 million in chlamydia screening (at £45 per test) to prevent 400 cases of clinical PID in London associated with £64,000 in healthcare costs, but policy makers need to be aware of other potential benefits of regular screening. These include sexual health promotion and reducing STI incidence. Meanwhile these improved estimates of the cost and incidence of PID can

be used to inform further modelling and economic analyses of the impact of chlamydia screening.

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Ethical approval: This study was approved by Wandsworth Research Ethics Committee (reference 03.0012).

Competing interest statement

All authors declare that the answer to the questions on your competing interest form are all No and therefore have nothing to declare.

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Authors' contributions

AA, EJ, KT, and PO designed the study, reviewed the literature and were responsible for writing the manuscript. AA, PH, EJ and PO performed data extraction. IS provided data from the HPA. AA, EJ, KT, SK and PO analysed the data. All authors commented on drafts of the manuscript and approved the final version.

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	General Practice	Genitourinary Medicine Clinic	Hospital outpatient*	Hospital inpatient**	Other***
Where first attended for PID	17	15	1	0	2
Total women attending type of site	21	16	5	1	3
Total attendances at healthcare settings	31	27	6	1	4

Table 1 Healthcare setting attendance for 35 women¹ diagnosed with PID during the study period based on questionnaires and review of medical records.

¹ A further woman was excluded from the detailed cost analysis as she was diagnosed and treated for PID as a hospital outpatient in the USA and no medical records were available

* Including accident and emergency and gynaecology

**Hospital inpatient stay of 3 days for late miscarriage and PID

***Other: Walk-in and primary care centre

	General Practice (SD)		ary Medicine c* (SD)	Hospital outpatient** (SD)	Hospital inpatient*** (SD)	Other**** (SD)
Source of costs	Estimated	Tariff	Estimated	Tariff	Tariff	Estimated
Average cost per first attendance at the setting	41 (15)	139 (n/a)	110 (21)	89 (31)	786 (n/a)	53 (24)
Average cost per all attendances	35 (16)	116 (29)	79 (46)	87 (29)	786 (n/a)	42 (8)

Table 2 Cost per attendance at different healthcare settings (UK£ 2008/9) for 35 women diagnosed with PID during the study period based on questionnaires and review of medical records

*Note: Genitourinary medicine clinic costs are estimated two ways: either using the national tariff (first visit is £139, follow-up £82), or by estimating the time, drugs, consumables and test costs.

**Includes both accident and emergency and outpatient gynaecology estimates which are tariff based

***Inpatient stay of 3 days for late miscarriage and PID

****Other: walk-in and primary care centre.

Table 3 Estimated number and cost of PID cases prevented by a single chlamydia test over 12 months for 414,345 sexually active women aged 16-24 in London with different prevalences of chlamydia and different rates of screening

	Assumed chlamydia prevalence	Number of women aged 16-24 screened	Number of chlamydia positive women	Expected PID cases over 12 months in <u>unscreened</u> women with chlamydia (8,8%)	Assumed screen coverage	Expected PID cases over 12 months in <u>screened</u> women with chlamydia (1.5%)	Preventable PID cases <u>Risk</u> <u>difference</u> (7.3%, 95% C.I0.82 to 16.5)**	Total preventable PID-associated healthcare costs (at £163 per case)*
NATSAL 2000* chlamydial prevalence	3%	414,345	12431	1094	100%	187	908 (-102 to 2,052)	£148,004 (-£16,626 to £334,476)
NCSP 2009 chlamydial prevalence	6 %	414,345	27261	2399	100%	409	1990 (-224 to 4,498)	£324,370 (-£36,512 to £733,174)
NCSP 2009 6% chlamydial prevalence and 21.5% coverage	6%	89,084	5345	471	21.5%	81	391 (-44 to 882)	£63,733 (-£7,172 to £143,766)
NCSP 2010* expected 39% coverage	6%	161,595	9696	853	39%	146	708 (-80 to1,600)	£115,404 (-£13,040 to £260,800)

* Assume population estimate remains the same.

**Risk difference calculated by number of PID cases expected in unscreened women minus cases expected in screened women.

		Baseline		12 months follow up			
	Participants with PID (n=28)	Participants without PID (n=1641)	Difference (95% C.I.)	Participants with PID (n=28)	Participants without PID (n=1641)	Difference (95%C.I.)	
Mean EQ- 5D Score (SD)	0.86 (0.16)	0.94 (0.11)	0.08 (0.04 to 0.12)	0.89 (0.16)	0.94 (0.11)	0.05 (0.01 to 0.09)	
Mean EQ- VAS Score (SD)*	72.5 (14.4)	80.3 (14.8)	7.8 (2.1 to13.4)	71.5 (24.8)	80.5 (16.2)	9.03 (2.8 to 15.2)	

Table 4. Baseline and follow up EQ5-D and EQ Visual Analogue Scale scores in women who did and did not develop PID.

* The number of respondents for EQ-VAS is slightly fewer: PID=27, no PID=1609

Setting	Personnel	Cost/ min*	Mean (range) mins/visit	Comment/ Reference
General Practice	Receptionist	0.47	0.5	Assumed to be the same as for a receptionist in genitourinary medicine clinics
	Nurse	0.57	13 (10-20)	Per minute of client contact, with qualification costs ¹⁴
	Doctor	2.70	10 (5-15)	Per minute of patient contact, with qualification costs, but excluding direct staff costs (i.e. nurse) ¹⁴
Genitourinary Medicine Clinic	Receptionist	0.47	4.8 (0.5-5)	LSHP SH tariff ¹⁵
	Nurse, day ward (Band 5)	0.73	15	Per minute of patient contact, with qualification costs ¹⁴
	Nurse (team leader) & Health Adviser (Band 6)	1.12	17(5-20)	Per minute of patient contact, with qualification costs ¹⁴
	Medical Consultant	2.77	16 (5-20)	Per patient related minute, with qualification costs ¹⁴

APPENDIX: Detailed costing

Item	Unit	Unit cost	Comment/ Reference
Chlamydia & Gonorrhoea laboratory processing	test	10.61	Estimate from St George's
Urine Pot	item	0.22	15
Vaginal swab (for CT/GC)	item	1.50	15
Transport Tube	item	0.25	15
Lab/pathology request form	item	0.25	15
Gloves	pair	0.04	15
Speculum	item	0.79	15
KY	dose	0.29	15
High vaginal swab (for microscopy)	item	0.22	15
Slide (for microscopy)	item	0.10	15
Treatment: blended cost (see below)	treatment	10.97	Average, see calculation below
Notification- phone call	per min	0.15	Assumption
Notification- text message	per text	0.10	Assumption

BASHH - recommended PID (blended cost) ³⁰	treatment	10.97	=(A+B) + average(C, D) + E
A. i.m. ceftriaxone 250mg stat.	1 dose	2.94	Rocephin + 1% lignocaine ¹⁶
B. injection kit	kit	0.28	To administer injection, includes antiseptic wipe, needle, syringe, plaster ¹⁵
C. oral doxycycline	100mg/ 14 days	1.61	100mg caps, in packs of 8 (scale 7/8) for 2 packs ¹⁶
D. oral ofloxacin	400mg/ 14 days	12.63	400mg tabs, pack of 5 & pack of 10^{16}
E. oral metronidazole	400mg/ 14 days	0.63	400mg tabs, pack of 21, scale by 2/3 ¹⁶
Additional costs	Unit	Unit cost	Comment/ Reference
Azithromycin	1g	8.91	4x 250mg capsules, Zithromax ¹⁶
Cefalexin	500mg 14 days	2.19	250mg capsules ¹⁶
Ciprofloxacin	500 mg * 10d	0.87	16
Clotrimazole	500g and cream	5.21	Canesten combi ¹⁶
Coamoxiclav	250mg/125mg; 21 tabs	4.09	16
Codeine	15 mg * 30d	1.39	16
Culture for GC	Sample	7.14	Estimate from St George's
Diclofenac	50mg	0.29	Assume diclofenac potassium 25 tabs x2, 1 dose
Erythromycin	500mg bd 14 days	5.95	Erymax (erythromycin 250mg gastro-resistant capsules), in pac of 28 ¹⁶
Fluconazole	150 mg	0.47	16
HIV and syphilis test	test	8.00	Estimate from St George's
Levonelle	1500mg	5.11	Levonorgestrel 1.5mg tabs ¹⁶
Mefanamic acid	500mg	2.29	Assume 3xday/7 days; (for 28 pill 500mg) ¹⁶
Microscopy (in-house)	Sample	5.00	Assumption (10 min Band 5 & consumables)
Trimethoprim	200g bd 3 days	0.08	Packs of 14 tabs ¹⁶
Urine pregnancy test	test	0.80	Assumption

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