Screening for *Chlamydia trachomatis* at the time of routine Pap smear in general practice: a cluster randomised controlled trial

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ABSTRACT

Objective: To determine whether asking general practitioners to offer chlamydia screening at the same time as Pap screening increases chlamydia screening rates.

Design: A pragmatic cluster randomised controlled trial.

Participants and setting: Doctors from 31 general practices in the Australian Capital Territory performing more than 15 Pap smear screens per year, and all women aged 16–39 years attending those practitioners between 1 November 2004 and 31 October 2005.

Intervention: Doctors in the intervention practices were asked to routinely offer combined chlamydia and Pap screening to eligible women; doctors in the control practices were asked to implement screening guidelines based on a risk assessment of the individual patient (ie, usual practice).

Main outcome measure: Chlamydia screening rate per visit.

Results: There were 26 876 visits by eligible women during the study period: 16 082 to intervention practices and 10 794 to control practices. Chlamydia screening occurred during 6.9% (95% CI, 6.5%–7.3%) of visits to intervention practices and 4.5% (95% CI, 4.1%–4.9%) of visits to control practices. After controlling for clustering and potential confounders, there were twofold greater odds of chlamydia screening occurring during a visit by an eligible woman to an intervention practice than to a control practice (adjusted odds ratio, 2.1 [95% CI, 1.3–3.4]).

Conclusion: Combining chlamydia and Pap screening increases the rate of chlamydia screening in general practice. Implementing this approach would require little additional infrastructure support in settings where a cervical screening program already exists.

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Chlamydia screening, undertaken as part of routine health care for young women, can reduce the incidence of pelvic inflammatory disease and ectopic pregnancy.[1] Despite this knowledge, rates of genital chlamydial infection have increased 20%–500% in the past decade in most parts of the developed world.[2-4] Chlamydia prevalence is estimated to be at least 1.5%–3.2% in the general population,[5,6] and the reported median prevalence in general practice is 4.6% in the United Kingdom,[7] 1.0%–5.6% in the United States[8] and 1.5% in Australia.[5]

Although there are guidelines for screening in primary care and trials of primary care screening have occurred,[9] translating guidelines into practice has been difficult. Barriers to opportunistic chlamydia screening include time pressures, lack of understanding of the benefits of testing and worries about discussing sexual health.[10]

We have previously proposed that a large proportion of women could be screened for chlamydia if chlamydia testing (CT) occurred in conjunction with the Pap smear[11] — a test already firmly established in primary care. Although combining the two tests has been considered in the past,[12] and some specialist providers have implemented combined testing (CT/Pap testing) as part of routine care,[13] the ability of this approach to increase chlamydia screening has not been formally investigated in general practice. In a preliminary study in general practice, we demonstrated that this method was feasible and acceptable and added only a few minutes to the consultation.[11]

We present the results of a cluster randomised controlled trial designed to test the hypothesis that general practitioners asked to routinely combine chlamydia screening with Pap testing in women aged 16–39 years would have a higher chlamydia screening rate than GPs asked to implement targeted screening guidelines.

METHODS

Setting

Our study was conducted between 1 November 2004 and 31 October 2005 in the Australian Capital Territory, which has a population of approximately 325 100.[14]

Participants

Eligibility

General practices were eligible to participate if at least one doctor in the practice collected 15 or more Pap smears annually. All women aged 16–39 years were eligible to participate. The sample frame comprised 99 eligible general practices, 338 GPs and about 50 900 eligible women. The general practice was the primary sampling unit, and the primary unit of interference was the patient visit (ie, the visit at which the women received a Pap and/or chlamydia test).

Recruitment and data collection

The principals of eligible general practices were sent a letter and telephoned to invite their participation. Interested practices were visited by the research nurse, and doctors willing to participate were enrolled. Each doctor consented to the investigators collecting pathology data relating to chlamydia and Pap tests performed by them during the study period. To determine the number of visits made by eligible women to the practices during the study period, consent was also obtained from the doctors to collect deidentified data from Medicare Australia regarding all consultations provided by them to women aged 16–39 years during the study period.

Randomisation of general practices

As part of the randomisation process, and before consent was obtained from the doctors, eligible general practices were stratified by size (small [1–2 doctors], medium [3–5 doctors] or large [>5 doctors]) and balanced by an independent statistician to ensure equal numbers between study arms within a stratum. The statistician generated a concealed randomisation schedule for each stratum using a random permuted block design with four practices per block[15] and provided the nurse enrolling the practices with three folders (one for each stratum) containing sequentially numbered sealed opaque envelopes. Once at least one doctor in an eligible practice had consented to participate in the study, the nurse opened the envelope and revealed the randomisation status of that general practice.

1 Targeted chlamydia screening guidelines[7,16-18]

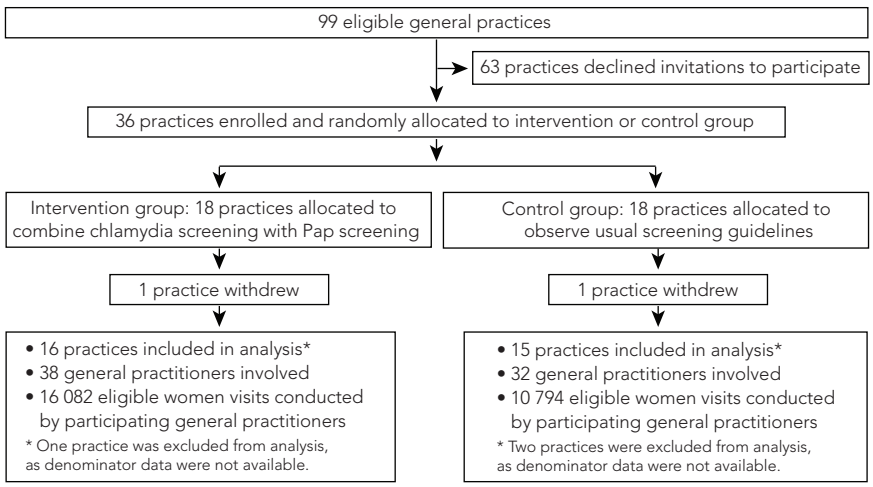
Offer chlamydia testing to women aged 16–39 years experiencing:

- abnormal vaginal discharge;
- postcoital or intermenstrual bleeding;
- lower abdominal pain;
- dyspareunia; or
- dysuria

. . . and/or who:

- are sexually active and < 25 years of age, or ⩾ 25 years of age with a new sexual partner;
- have had two or more partners in the past 12 months;
- have sexual partner(s) with a sexually transmitted disease;
- are seeking uterine instrumentation (eg, termination of pregnancy, intrauterine device insertion; or
- are pregnant. ◆

2 Flow of participants through the trial



Blinding

Interested doctors were informed at the initial practice meeting that the study was designed to investigate two different approaches to chlamydia screening and that their practice would be randomly allocated to one of the two different methods, but were not informed as to which method was the "test" method. The research nurse was also blinded to the randomisation status of each general practice until consent had been obtained. Other members of the research team were blinded to the randomisation status of the practices until the end of the recruitment phase. No formal assessment of the GPs' knowledge of their randomisation status was undertaken.

Intervention and control

Practices in the intervention group were asked to offer screening for chlamydia to all eligible women at the same time as performing a Pap smear. Doctors were provided with study packs containing pathology forms and all the equipment needed to collect specimens for Pap and chlamydia testing. They did not receive any other instructions. Control practices were provided with laminated copies of guidelines for chlamydia screening derived from national and international sources[7,16-18] (Box 1) and were asked to implement these guidelines in the course of their usual clinical practice.

To maximise participation and provide results directly relevant to normal clinical practice, we used a pragmatic trial design. Data about the number and characteristics of women who were approached but declined to participate were not collected, nor were reminders to recruit women to the study issued to either intervention or control group practitioners.

Laboratory aspects

All specimens for chlamydia testing were sent to one of three study laboratories in the ACT that conduct polymerase chain reaction (PCR) testing. All three laboratories used the Roche COBAS Amplicor automated PCR assay to detect *Chlamydia trachomatis* (Roche Diagnostics Systems, Brachberg, NJ, USA).

Outcome measures

The primary outcome measure was the chlamydia screening rate per general practice visit for women aged 16–39 years during the study period. As some doctors perform tests of cure, pathology results from any woman with a positive result having a second chlamydia test within 3 months of the initial test were excluded from the analysis. Chlamydia screening rates among women having a Pap screen were calculated, as well as the age-specific rate of detection of chlamydia for both arms.

Sample size

All 99 eligible general practices in the ACT were invited to participate. For the purpose of power calculations we assumed that a third (33) of the general practices would participate in the study. The estimated increase in chlamydia screening rates was based on chlamydia data from local laboratories and a pilot study conducted in the same geographical area.[11] There was considerable uncertainty in these estimates because of a lack of information about the number of women attending ACT GPs who would be eligible for our study. We determined that, assuming an intracluster correlation of 0.025,[19] 33 clusters (general practices) with at least 100 eligible women visits per practice would enable the detection of a quadrupling of effect from 10% to 40% (optimistic outcome) as well as a doubling of effect from 5% to 10% (realistic outcome) with 80% power and a two-sided significance level of 0.05.

Statistical analysis

The chlamydia screening rate per eligible woman visit was calculated for each practice and averaged across practices. As data for individual women were not available, data were grouped by general practice, and logistic regression models, with adjustment for clustering within general practices, were fitted. The effect on chlamydia screening rates of potential confounders (number of female doctors per practice and number of doctors enrolled per practice) was also tested in the models. Results are reported as odds ratios or adjusted odds ratios with 95% confidence intervals. An intention-to-treat approach was adopted during analysis. Stata statistical software, release 8 (StataCorp, College Station, Tex, USA) was used for all statistical analyses.

Ethical approval

Ethics approval was obtained from the human research ethics committees of ACT Health and the Australian National University.

RESULTS

Of the 99 eligible general practices approached, 36 (36.4%) were enrolled in the study (18 in each arm). One practice in each

3 Characteristics of participating general practices

	Intervention practices ($n = 16$)	Control practices ($n = 15$)	Total
Size of practice			
Small (1–2 doctors)	5	4	9
Medium (3–5 doctors)	5	6	11
Large (> 5 doctors)	6	5	11
Sex of participating GPs			
Male	20	7*	27
Female	18	25	43
Total participating GPs with complete data	38	32	70
Number of practices with at least one female doctor participating	14	13	27
Eligible patient visits†	16 082	10 794	26 876

GP = general practitioner. * There were significantly more female than male GPs enrolled in the control arm ($P = 0.001$). † Eligible patient visits were those made by women aged 16–39 years to the participating GPs during the study period. ◆

4 Number of chlamydia and Pap screens performed during the study

Test	Intervention practices	Control practices	Total
CT/Pap	608	252	860
CT alone	499	231	730
Pap smear alone	1439	1145	2584
Total CT	1107	483	1590
Total Pap smears	2047	1397	3444

CT = chlamydia testing. CT/Pap = combined chlamydia and Pap testing. ◆

arm withdrew during the study period, and denominator data were unobtainable from Medicare Australia for a further three practices (two in the control arm and one in the intervention arm) (Box 2). Characteristics of participating general practices are shown in Box 3.

There were 1590 chlamydia screens performed during the study period (Box 4). Eligible women made 26 876 visits to the participating general practices during the study period — 16 082 visits to intervention practices and 10 794 visits to control practices. Over the 12-month period, chlamydia screening occurred during 6.9% of visits to intervention practices and 4.5% of visits to control practices (Box 5). The chlamydia screening rate per Pap smear among eligible women was 54.1% in intervention practices and 34.8% in control practices (Box 5).

More than half (252/483; 52.2% [95% CI, 47.6%–56.7%]) of chlamydia screening performed in control group practices was combined CT/Pap screening, even though this was not recommended in the screening guidelines for this group. Combined testing represented 54.9% (608/1107; 95% CI, 51.9%–57.9%) of total chlamydia testing in the intervention group.

There were no significant differences between the intervention and control arms in the overall rate of positive chlamydia screens or age-specific rates of positive screens per woman screened (Box 6). Neither were there any significant differences in the rate of chlamydia detected by CT/Pap testing (3.5%) or CT alone (4.9%) (Box 6).

After controlling for clustering and potential confounders, there were twofold greater odds of chlamydia screening occurring during a visit by an eligible woman to an intervention practice than to a control practice (adjusted odds ratio, 2.1) (Box 7).

Pap screening (including combined CT/Pap testing) occurred during 12.7% of visits to intervention practices and in 12.9% of visits to control practices (Box 5). Of the 2047 Pap screens carried out during the study, 173 (8.4%) were performed at visits made by women aged < 20 years.

DISCUSSION

Our study demonstrates that the simple intervention of asking GPs to combine chlamydia screening with Pap screening (without a risk assessment) doubled the odds of chlamydia screening per general practice visit for women aged 16–39 years. Combined CT/Pap screening has been shown to increase chlamydia screening rates in the context of gynaecological and obstetric practice in the US,[20] but, to our knowledge, ours is the first study to demonstrate this effect in a primary care setting.

Despite a higher screening rate for chlamydia in our intervention group, the absolute rate of 6.9% per year was still low (although it represents about half the annual Pap smear screening rate in the population studied). The prevalence of chlamydia among tested women was 4.3%, with no statistically significant difference between the rates in the two groups, highlighting the difficulty in identifying those at greater risk of infection. Moreover, there was no statistically significant difference between the 16–19-years age group, the 20–25-years age group and the 25–30-years age group in overall rates of chlamydia infection detected. This suggests that there may be benefit in screening women up to the age of 30 years, even though prevalence and notification data indicate that chlamydia infection rates fall after the age of 25 years.[2-4] As the rate in the group aged over 30 years was 0.8%, we would not recommend implementing combined testing in this group.

The pragmatic design and minimal number of inclusion criteria for our study enabled participants to reflect the population of GPs

5 Chlamydia and Pap screening rates during the study

	Intervention practices		Control practices		Total	
	Number	% (95% CI)	Number	% (95% CI)	Number	% (95% CI)
Chlamydia screening rate per visit*	1107/16082	6.9%† (6.5%–7.3%)	486/10794	4.5%† (4.1%–4.9%)	1593/26876	5.9% (5.6%–6.2%)
Pap screening rate per visit*	2047/16082	12.7% (12.2%–13.2%)	1397/10794	12.9% (12.3%–13.6%)	3444/26876	12.8% (12.4%–13.2%)
Chlamydia screening rate per Pap smear‡	1107/2047	54.1% (51.9%–56.3%)	486/1397	34.8% (32.2%–37.3%)	1593/3444	46.2% (44.6%–47.9%)

* Total number of screens divided by total number of visits made by eligible women to the general practices during the study period. † Calculated by averaging rates per cluster. ‡ Total number of chlamydia screens divided by total number of Pap screens. ◆

6 Age-specific rates of positive chlamydia tests*

	Intervention		Control		Total	
Test	Number	% (95% CI)	Number	% (95% CI)	Number	% (95% CI)
CT/Pap						
16–19 years	0/52	0 (6.8%†)	4/40	10.0% (2.8%–23.7%)	4/92	4.3% (1.2%–10.8%)
20–25 years	13/207	6.3% (3.4%–10.5%)	8/94	8.5% (3.7%–16.1%)	21/301	7.0% (4.4%–10.5%)
26–30 years	4/167	2.4% (0.7%–6.1%)	2/48	4.2% (0.5%–14.2%)	6/218	2.8% (1.0%–6.0%)
31–39 years	1/182	0.5% (0.0%–3.0%)	0/70	0 (4.9%†)	1/252	0.4% (0.0%–2.2%)
All ages	18/608	3.0% (1.8%–4.6%)	12/252	4.8% (2.5%–8.2%)	30/860	3.5% (2.4%–4.9%)
CT alone						
16–19 years	5/60	8.3% (2.8%–18.4%)	1/44	2.3% (0.1%–12.0%)	6/104	4.2% (1.5%–8.8%)
20–25 years	12/185	6.5% (3.4%–11.1%)	4/90	4.4% (1.2%–11.0%)	16/275	5.8% (3.4%–9.3%)
26–30 years	10/157	6.4% (3.1%–11.4%)	2/50	4.0% (0.5%–13.7%)	13/207	6.3% (3.4%–10.5%)
31–39 years	2/97	2.1% (0.3%–7.6%)	0/47	0 (7.5%†)	2/144	1.4% (0.2%–4.9%)
All ages	29/499	5.8% (3.9%–8.2%)	7/231	3.0% (1.2%–6.1%)	36/730	4.9% (3.5%–6.8%)
Total CT						
16–19 years	5/112	4.5% (1.5%–10.1%)	5/84	5.9% (2.0%–13.3%)	10/196	5.1% (2.5%–9.2%)
20–25 years	25/392	6.4% (4.2%–9.3%)	12/184	6.5% (3.4%–11.1%)	37/576	6.4% (4.6%–8.7%)
26–30 years	15/324	4.6% (2.6%–7.5%)	4/98	4.1% (1.1%–10.1%)	19/425	4.5% (2.7%–6.9%)
31–39 years	3/279	1.1% (0.2%–3.1%)	0/120	0 (3.0%†)	3/396	0.7% (0.2%–2.2%)
All ages	48/1107	4.3% (3.2%–5.7%)	21/486	4.0% (2.4%–6.2%)	69/1593	4.3% (3.4%–5.5%)

CT = chlamydia testing. CT/Pap = combined chlamydia and Pap testing. * Rate = total number of positive chlamydia screens divided by total number of screens in each age group. † One-sided 97% CI. ◆

and women who would provide and receive the simple intervention of combined CT/Pap screening. However, the fact that two-thirds of the general practices approached declined to participate and only some doctors in some practices participated increases the likelihood of selection bias and reduces the generalisability of our findings. Furthermore, the requirement for written consent may have been a disincentive for participation.

Randomisation by practice meant that there was variation in the number of participating doctors. Six more doctors were enrolled in the intervention practices, resulting in a higher number of eligible women patients in that group. Although the overall number of male and female GPs in our study was similar, there were significantly fewer male than female doctors in the control practices. Some studies have found that female doctors are more likely to perform Pap smears[21,22] and to screen both men and women for STIs, including chlamydia.[23,24] It is possible that this sex bias explains some of the difference in the number of chlamydia tests performed in the two arms and the relatively high rate of CT/Pap testing in the control group. The high rate of CT/Pap testing in the control group may also be partly explained by "contamination" of the control group (as the ACT general practice community is relatively small), but also highlights increasing recognition among practitioners of the value of combined testing.

Local ACT and national data indicate that 59%–70% of women aged 16–39 years have a Pap test every 2 years and that, in the 2-year period 2000–2002, 1300 ACT 16–19-year-olds had Pap smears, representing a Pap screening rate in this subpopulation of about 14%.[25,26] In light of these figures, the Pap screening rate per visit in our study, although the same for intervention and control groups, was low. This discrepancy may be at least partially explained by the number of Pap smears performed outside general practice (eg, in sexual health and family planning clinics), particularly among women aged 16–39. Adoption of a combined CT/Pap screening approach by all women's health practitioners, including sexual health and family planning clinics, obstetricians and gynaecologists, is needed to maximise the public health benefit.

A coordinated public health approach to chlamydia control must target a broader audience than just women who undergo Pap smears. Nevertheless, with more than half of women aged 20–30 years having a Pap smear each year, the combined CT/Pap screen offers an obvious way of reaching a substantial proportion of the sexually active population. CT/Pap screening would also increase chlamydia testing among men if proper contact tracing of sexual partners of chlamydia-positive women were carried out.

Although there is considerable debate about the use of nucleic acid amplification testing for detecting human papillomavirus and a vaccine is now available, it is likely that the current guidelines for Pap screening in Australia will continue for the next 10 years, securing the value of a combined CT/Pap testing strategy for the near future at least.

Many countries have raised the recommended age of first Pap smear to 25 years.[27] If Australia adopted this policy, it would present the ideal opportunity to consider using the existing cervical cancer screening registration and callback infrastructure to implement chlamydia screening for women under 25 years. Women could move from a chlamydia-only screen in their early twenties to a combined CT/Pap screen in their late twenties to a Pap-only screen in their thirties.

CONCLUSION

Combined CT/Pap screening is feasible, increases chlamydia screening and would require little additional infrastructure support in settings where there is an existing cervical screening program. Implementation of this approach could represent an important public health innovation.

7 Odds ratios for chlamydia testing, by randomisation status, adjusted for stratifying variables and clustering by general practice

	OR (95% CI)	*P*	AOR* (95% CI)	*P*
Randomisation status				
Intervention	1.7 (1.5–1.9)	< 0.001	2.1 (1.3–3.4)	0.003
Control	RF		RF	
Number of doctors in each practice enrolled in the study				
1	RF		RF	
2	1.1 (0.9–1.2)	0.6	1.0 (0.5–2.1)	0.9
3	0.8 (0.6–0.9)	< 0.001	0.7 (0.4–1.3)	0.3
4	1.3 (1.1–1.6)	0.006	1.2 (0.5–2.8)	0.7
⩾ 5	1.0 (0.8–1.1)	0.7	0.8 (0.5–1.5)	0.5
Female general practitioners				
Males only enrolled	RF		RF	
At least one female doctor from practice enrolled	1.1 (0.8–1.3)	0.7	1.1 (0.6–2.1)	0.8

AOR = adjusted odds ratio. OR = odds ratio. RF = reference group.
* OR was adjusted for size of practice, having at least one female doctor in practice enrolled, and clustering (estimated intraclass correlation coefficient for total chlamydia tests, 0.025). Size of general practice was controlled for during randomisation through stratification to small, medium and large practice sizes. ◆

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COMPETING INTERESTS

None identified.

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