

Detection of *Chlamydia trachomatis* infection in early pregnancy using self-administered vaginal swabs and first pass urines: a cross-sectional community-based survey

Pippa Oakeshott, Phillip Hay, Sima Hay, Frances Steinke, Elizabeth Rink, Brenda Thomas, Penny Oakeley and Sally Kerry

SUMMARY

A cross-sectional survey of 1216 newly pregnant women (mean age = 31 years) from 32 general practices and five family planning clinics was conducted to find the prevalence of chlamydial infection and to evaluate self-administered vaginal swabs and first-pass urines for detection of *Chlamydia trachomatis* by ligase chain reaction assay. Overall prevalence of infection was 2.4% (95% CI = 1.5 to 3.3) but in women aged less than 25 years it was 8.6% (95% CI = 4.1 to 12.9) and in pregnant teenagers it was 14.3% (95% CI = 3.7 to 24.9). In 1161 women with both swab and urine results, 25 women were positive on both specimens, three on swab alone, and one on urine alone. When asked which they preferred to provide, 47% said urine, 5% swab and 48% preferred both equally. This is the first study to show that non-invasive screening in early pregnancy is feasible in the community. Although swabs detected 10% more infections, nearly half the women preferred providing urine specimens.

Keywords: chlamydia screening; pregnancy; non-invasive testing.

Introduction

THERE have been no primary care-based studies of *Chlamydia trachomatis* infection in early pregnancy.¹ Screening has been made easier by the advent of new non-invasive tests, which can be self-administered and may be more acceptable to asymptomatic women.² Our aims were to find the prevalence of chlamydial infection in newly pregnant women in the community, and to evaluate self-administered vaginal swabs and first-pass urines for detection of *C trachomatis* by ligase chain reaction assay in early pregnancy.

Method

Recruitment of practices and patients

Following ethical approval, 32 general practices and five family planning clinics in south London agreed to take part in the study. All practices and clinics were given posters, patient information sheets and specimen packs, and were asked to recruit consecutive pregnant women presenting at less than ten weeks gestation. Women intending to have a termination were excluded. Women giving informed consent were requested to provide a self-administered vaginal swab and first-pass urine immediately and to complete a confidential postal questionnaire at 16 weeks gestation. This asked about demographic characteristics, medical history, and women's opinions about providing the specimens.

Analysis of specimens

Specimens were taken by routine courier to the local hospital laboratory and frozen at -70° until they were tested for *C trachomatis* by ligase chain reaction (LCR, Abbott Diagnostics, Maidenhead). Positive results were confirmed by direct immunofluorescence (Syva MicroTrak, California).

Statistical methods

Possible predictors of infection found in other studies³⁻⁵ were examined in women with and without infection. Multiple logistic regression was used to adjust for age less than 25 years or for age 25 years or more.

P Oakeshott, MD, senior lecturer in general practice; S Hay, RM, research midwife; F Steinke, MSc, research health visitor; E Rink, MPhil, senior lecturer in primary care; S Kerry, MSc, senior lecturer in medical statistics, Department of General Practice; P Hay, FRCP, senior lecturer in genitourinary medicine; P Oakeley, MFFP, consultant in family planning, Department of Genitourinary Medicine, St George's Hospital Medical School, London. B Thomas, PhD, senior medical laboratory scientific officer, Public Health Laboratory Service Communicable Disease Surveillance Centre, London.

Address for correspondence

Dr Pippa Oakeshott, Department of General Practice and Primary Care, St George's Hospital Medical School, Hunter Wing, Cranmer Terrace, London SW17 0RE. E-mail: oakeshot@sghms.ac.uk

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HOW THIS FITS IN*What do we know?*

The advantages of the new *C trachomatis* nucleic acid amplification tests on first-pass urines or vaginal swabs are that they are more sensitive and less invasive than enzyme immunoassay on endocervical specimens and can be self administered. Although *C trachomatis* prevalence studies have been conducted among pregnant women attending hospital antenatal clinics, there have been no community-based studies.

What does this paper add?

Despite possible anxieties about screening during pregnancy, we found that women were able and willing to provide self-administered vaginal swabs and first-pass urines for detection of *C trachomatis*. Although half of the women found the two methods of providing the specimens equally easy, women who expressed a view preferred providing urine specimens. Since the prevalence of *C trachomatis* was 9% in women aged less than 25 years, and 14% in pregnant teenagers, it may be worth offering screening to these groups.

**Results***Participants*

Between June 1998 and July 2000, 1216 newly pregnant women (mean age = 31 years, range = 17 to 48 years) were recruited. Median gestation was 49 days (range = 12 to 69 days). The response rate to the questionnaire was 91% (1108/1216). Of the responders ($n = 1107$), 78% described their ethnic group as white, 7% as black Caribbean, 4% as black African, 6% as Indian subcontinent origin and 5% as other ethnic groups.

Prevalence of chlamydial infection

Overall prevalence of chlamydial infection in newly pregnant women was 2.4% (29/1214, 95% CI = 1.5 to 3.3). Prevalence of infection was 2.0% (23/1124, 95% CI = 1.2 to 2.9) in general practices, and 6.7% (6/90, 95% CI = 1.5 to 11.8) in family planning clinics. The prevalence was higher in younger women: 8.6% (13/152, 95% CI = 4.1 to 12.9) in women aged less than 25 years and 14.3% (6/42, 95% CI = 3.7 to 24.9) in pregnant teenagers. Infection was also more common in women of black Caribbean or black African ethnic origin (Table 1). Multiple logistic regression confirmed that being less than 25 years of age (odds ratio 3.2, 95% CI = 1.3 to 7.9, adjusted for ethnicity) and being of black ethnicity (5.7, 95% CI = 2.4 to 13.7, adjusted for age) were independent predictors of infection.

Evaluation of self-administered vaginal swabs and first-pass urines

Paired *C trachomatis* specimens of adequate quality were available for 1161 (95%) women (Table 2). When asked which specimen they preferred to provide, 47% of 1057 responders said urine, 5% said swab, and 48% said both the same.

Discussion

This is the first United Kingdom study to use self-administered vaginal swabs and first-pass urines for detection of chlamydia in early pregnancy. Despite possible anxieties about screening during pregnancy, we found that women were able and willing to do their own swabs, although nearly half of them preferred to provide urine specimens.

Strengths and weaknesses of the study

The main strength of the study is its community basis. Recruitment was done during routine appointments by nurses and doctors who would be most likely to be involved in any future national screening programme. Participants were normal healthy women attending local practices and clinics. Apart from instructions to put specimens in clinic refrigerators while awaiting collection,¹ we used routine specimen storage and transport facilities.

The main limitation was that although practices were asked to recruit consecutively we were unable to obtain reliable information on women who were not recruited. Prevalence estimates should therefore be treated with caution. However, the high prevalence of infection found in women aged less than 25 years (9%) and pregnant teenagers (14%) was almost identical with that found in the primary care screening pilots.³ Furthermore, the mean age (31 years) of women in the study was comparable to the mean age (30 years) of women delivering at St George's Hospital in 1999; and their ethnic distribution was similar to that in the 1991 census in Wandsworth where 80% of study practices were located.

Other limitations include the small number of *C trachomatis* positives detected and that the study was not set up to assess the sensitivity and specificity of the tests used. However, the performance of LCR on first-pass urines has been favourably evaluated in a similar low prevalence UK general practice population.⁴ Finally, the exclusion of women intending to have a termination probably reduced the prevalence rate.¹

Comparison with other studies

There have been no other community-based studies of prevalence of *C trachomatis* in early pregnancy. However, similar prevalences have been obtained in non-pregnant women aged less than 35 years attending inner-London general practices^{4,5} with higher rates in younger women and women of Afro-Caribbean ethnic origin. Although studies of UK antenatal clinic attenders have found a slightly higher median prevalence of 5% (range = 2 to 7),¹ these were mainly screening a younger population.

In line with a recent primary care-based study of home screening,² most women who expressed a definite view preferred to provide a first-pass urine. However, in our survey first-pass urines missed 10% (2 to 27) of infections and there is controversy about their sensitivity during pregnancy. Compared with cervical swabs, reported sensitivities of DNA tests during pregnancy are 97% for vaginal swabs and 83% for urines.⁶

Conclusions

This study shows that even during pregnancy, non-invasive

Table 1. Demographic and behavioural characteristics of 1214 newly pregnant women participating in the study – comparison of women with and without chlamydial infection.

Risk factor	Percentage (number) of women with positive <i>Chlamydia</i> result ^a	Odds ratio (95% confidence interval)	Odds ratio adjusted for age <25 years or 25 years
Age group (years) (n = 1214)			
<25	8.6 (13/152)	6.1 (2.9 to 13.0)	
≥ 25	1.5 (16/1062)	1	
Marital status (n = 1105)			
Single, widowed, divorced	4.2 (4/96)	2.4 (0.8 to 7.2)	1.3 (0.4 to 4.2)
Married or cohabiting	1.8 (18/1009)	1	
Contraception (n = 1095)			
Oral contraception or none	1.9 (13/687)	1.1 (0.4 to 2.8)	1.1 (0.4 to 2.8)
Other	1.7 (7/408)	1	
Ethnic group (n = 1106)			
Black Caribbean or Black African	9.2 (11/119)	7.6 (3.3 to 17.5)	5.7 (2.4 to 13.7)
Other ethnic group	1.3 (13/987)	1	
Social class (n = 1045)			
Social class 3–5	2.6 (11/419)	1.8 (0.8 to 4.5)	1.3 (0.5 to 3.4)
Social class 1 or 2	1.4 (9/626)		
Ever had termination of pregnancy (n = 1097)			
Yes	2.9 (8/274)	2.0 (0.8 to 5.0)	2.0 (0.8 to 5.0)
No	1.5 (12/823)	1	

^aWomen were defined as *C trachomatis*-positive if they had a confirmed positive result on either a swab or a urine specimen. In two of the total of 1216 women both *C trachomatis* specimens were missing.

Table 2. *Chlamydia* ligase chain reaction tests in 1161 newly pregnant women who provided paired self-administered vaginal swabs and first-pass urines.

	First-pass urine +	First-pass urine –
Vaginal swab +	25	3
Vaginal swab –	1	1132

In the remaining patients, 13 vaginal swabs could not be tested as there was no liquid left in the tube, 8 swabs were of inadequate quality, and 14 swabs and 22 urines were missing.

chlamydial screening is feasible in the community. The high prevalence found in younger women supports recent recommendations for routine chlamydial screening for all asymptomatic pregnant women aged 25 years or less.

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