Can we use postal surveys with anonymous testing to monitor chlamydia prevalence in young women in England? Pilot study incorporating randomised controlled trial of recruitment methods.

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ABSTRACT

Objectives

Chlamydia prevalence in the general population is a potential outcome measure for the evaluation of chlamydia control programmes. We carried out a pilot study to determine the feasibility of using a postal survey for population-based chlamydia prevalence monitoring.

Methods

Postal invitations were sent to a random sample of 2,000 17-18 year-old women registered with a general practitioner in two pilot areas in England. Recipients were randomised to receive either a self-sampling kit (n=1,000), a self-sampling kit and offer of £5 voucher on return of sample (n=500), or a self-sampling kit on request (n=500). Participants returned a questionnaire and self-taken vulvovaginal swab sample for unlinked anonymous *Chlamydia trachomatis* testing. Non-responders were sent a reminder letter three weeks after initial invitation. We calculated the participation rate (number of samples returned/number of invitations sent) and cost per sample returned (including cost of consumables and postage) in each group.

Results: A total of 155/2,000 (7.8%) samples were returned with consent for testing. Participation rates varied by invitation group: 7.8% in the group who were provided with a self-sampling kit, 14% in the group who were also offered a voucher and 1.0% in the group who were not sent a kit. The cost per sample received was lowest (£36) in the group who were offered both a kit and a voucher.

Conclusions: The piloted survey methodology achieved low participation rates. This approach is not suitable for population-based monitoring of chlamydia prevalence among young women in England.

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KEY MESSAGES

- We investigated the feasibility of using a postal survey with anonymous testing for population-based chlamydia prevalence monitoring in two pilot areas in England.

- 17-18 year-old women were either sent a self-sampling kit, sent a kit and offered a £5 voucher or asked to request a kit.

- The piloted survey methodology achieved low participation rates. Participation was highest in the group offered a £5 voucher to provide a specimen (14%).

- Due to potential for selection bias and high costs of delivery, surveys of chlamydia prevalence using postal invitations are not suitable for population-based monitoring of chlamydia prevalence among young women in England.

INTRODUCTION

Chlamydia trachomatis ('chlamydia') is a common bacterial sexually transmitted infection. The National Chlamydia Screening Programme (NCSP) was introduced in England in 2003 and aims to control chlamydia and reduce the sequelae of infection through opportunistic screening of sexually active under 25-year olds. The majority of chlamydia infections are asymptomatic, with potential of serious complications if left untreated.[1]

Routine monitoring of population prevalence of chlamydia would provide an important indicator of success of chlamydia control programmes, but presents a substantial challenge. The percentage testing positive measured using routinely-collected data from populations accessing testing cannot be extrapolated to the general population as individuals tested for chlamydia tend to have different risks of infection than those who have not been tested[2] and symptomatic patients are likely overrepresented. Previous studies have measured chlamydia prevalence among young adults in the general population[2], but their estimates are of limited use for monitoring changes in the levels of infection in relation to chlamydia screening as timely and regularly repeated measurements of chlamydia prevalence are needed.

Between June and August 2011, we piloted a survey methodology to recruit and test young women for chlamydia. Our aim was to determine whether repeat cross-sectional surveys using postal invitations and anonymous testing (i.e. without return of test result) could be a feasible method of population-based chlamydia prevalence monitoring in England.

METHODS

Selection and recruitment

The pilot was carried out in two Primary Care Trusts (PCTs, local health administrations at the time of the study) in England. Eligible participants were identified using lists of patients registered with general practices (GPs). Women aged 17 to 18 years old were eligible. This age group was selected to maximise the expected proportion sexually active[3] and prevalence of infection[3] as well as the reliability of address data, given that the proportion of young adults living with their parents declines steeply with age over 16 years[4]. Only 18 year-old women were included in one of the two PCTs in order to comply with local guidance about research involving children. The pilot study was limited to women as the most serious complications of chlamydia such as PID, ectopic pregnancy and infertility occur in women, thus making prevalence monitoring in women a higher priority.

One thousand women were randomly selected from each PCT (from 7,544 eligible participants). The sample size was sufficient to identify a minimum 5% difference in response rate between three different types of postal invitation. The selected women were randomly allocated into three groups (Table 1). Group A were sent a self-sampling kit, consisting of an information leaflet, a short questionnaire including questions on sexual behaviour and ticked consent (to retain anonymity) for anonymous testing of their sample, a vulvovaginal swab to self-sample at home and a pre-paid return envelope (n=1,000). Group B were sent a self-sampling kit and also offered a £5 voucher on return of sample (n=500). Group C were invited to contact the study team by text message, email or return of postcard to obtain a self-sampling kit (n=500). All invitations included details of where they could be screened at a local clinical service. A reminder letter was sent to non-responders three weeks after the initial invitation. Individuals who did not wish to participate were asked to

complete and return a pre-paid postcard to the research team, indicating the reason they did not want to participate.

Biological sample

Participants returned the self-taken vulvovaginal swab to the Health Protection Agency (now part of Public Health England) where they were anonymised and unlinked from all personal identifying information. Samples were stored cold (4°C) before being tested (in batches) for chlamydia using the APTIMA COMBO 2 (Gen-Probe, San Diego, CA) assay.

Participation rates

Participation rates (the number of samples returned with consent to test divided by the total number of invitations sent) and reported sexual behaviours were compared between invitation groups using a chi-square test. An area-level indicator of deprivation (the Index of Multiple Deprivation, IMD[5]) was assigned to all invited individuals using their postcode of residence. Ranked IMD scores were grouped into quintiles. The potential for participation bias in each group was investigated by comparing the profile of participants to that of the invited population in terms of IMD quintile of residence.

Cost per sample received

The costs per invitation and per sample received for each randomisation group were estimated. This cost was defined as the total of the unit costs of all consumables, postage, testing and vouchers where relevant, divided by the number of invitations sent or the number of samples returned with consent for testing. Staff and overhead costs were not included, as these were assumed to be equivalent for all recruitment methods.

Regulatory approvals

The study was approved by North London Research Ethics Committee (ref:10/H0717/57). Research governance approval was obtained from the two participating PCTs. Ethics and research governance approvals were obtained on the basis of the study being categorised as study type 'other' on the Integrated Research Application System (the system for applying for the permissions and approvals for health care research in the UK). Thus the study was not categorised as a clinical trial. We sought clarification from the Medicines and Healthcare Products Regulatory Agency (MHRA, the body responsible for approval of clinical trials of investigational medicinal products in the UK) about the status of this study. MHRA confirmed that they considered the study to be "a health survey with no therapeutic intervention" and did not therefore require MHRA approval (personal communication, MHRA). The study was registered on the UK Clinical Research Network (CRN) portfolio (UKCRN ref: 10913) but was not registered as a clinical trial.

RESULTS

A total of 155 samples were returned with consent, equivalent to a 7.8% participation rate overall (Table 1). Thiry-three (21%) of the samples were returned after receipt of a reminder letter. A further 30 invitations (1.5%) were returned as undelivered. Participation rates varied by invitation group, with the highest participation rate (14%) achieved in the group offered a voucher, and very few responses received from the group invited to request a sampling kit (Group C). This group was therefore excluded from further comparative analyses. All samples received were adequate for testing. Three samples tested positive for chlamydia (1 in Group A, 2 in Group B).

Table 1: Participation rates and reported sexual behaviour by randomisation group

	A: Kit (n=1,000)		B: Kit + voucher (n=500)		p value (A v B)^	C: No kit (n=500)		Overall (n=2,000)	
	n	%	n	%		n	%	N	%
Participation rates									
Primary Care Trust 1$	47/500	9.4%	41/250	16%	0.005	2/250	0.8%	90/1,000	9.0%
Primary Care Trust 2	31/500	6.2%	31/250	12%	0.004	3/250	1.2%	65/1,000	6.5%
Overall	78/1,000	7.8%	72/500	14%	<0.001	5/500	1.0%	155/2,000	7.8%
Reported sexual behaviour among participants*									
Ever had sex	58/77	75%	58/72	81%	0.44	4/5	80%	120/154	78%
More than 1 sexual partner in the past 12 months#	19/58	33%	26/58	45%	0.18	1/4	25%	46/120	38%
At least 1 new sexual partner in the past 12 months#	38/58	66%	37/58	64%	0.85	1/4	25%	76/120	63%
More than 1 sexual partner in the past 3 months#	5/58	8.6%	7/58	12%	0.54	0/4	0%	12/120	10%
At least 1 new sexual partner in the past 3 months#	23/58	40%	23/58	40%	1.00	0/4	0%	46/120	38%
Condom used at last intercourse#	17/55	31%	18/57	32%	0.94	3/4	75%	38/116	33%

$ *Included women aged 18 years only, to comply with local guidance about research involving children.*
* *Variations in denominators represent item non-response. Percentages are calculated among women who returned a swab for testing and who had non-missing responses on the variable of interest*
# *Among those reporting at least 1 sexual partner by the time of participation.*
^ *X^2 test*

A total of 48 women declined consent by returning the pre-paid postcard (3% of all women who did not return a sample). The most commonly cited reasons for non-participation were that women did not want to use the swab (19/48, 40%), did not have the time (12/48, 25%), were not sexually active (9/48, 19%) or were not interested in chlamydia (7/48, 15%). Two respondents (4%) indicated that they wanted to receive their results.

A total of 78% participants were sexually-experienced in terms of reporting at least one sexual partner by the time they participated (Table 1). There were no significant differences in reported sexual behaviour between participants in Groups A and B. In both groups, women living in less deprived areas were over-represented among participants compared to the invited population (Online supplementary Figure 1). The profile of IMD quintile of residence among participants in Group B was more similar to that seen in the invited

population than the distribution of participants by IMD quintile in Group A, suggesting less participation bias in the group offered a voucher.

The cost per invitation/sample received was £3.00/£51 for group A, £3.10/£36 for Group B and £0.50/£93 for Group C.

DISCUSSION

Our pilot of a postal survey of young women with anonymous testing for chlamydia resulted in low participation rates. Offering a small financial incentive increased participation, and reduced the cost per sample received.

The main strength of this pilot study was that invitations were randomly allocated into different groups to allow investigation of the response rates that could be expected given different approaches. The study was subject to limitations. Firstly, we could not determine whether non-response was due to the invitation having not reached the intended person. In a previous study of chlamydia screening using GP lists, 27% of 16 to 39 year-olds could not be contacted at their registered address[6]. Our participation rates probably include some instances of this, as well as non-response among recipients. Secondly, while there was some indication that offering a £5 voucher recruited a more representative population in terms of deprivation, the sample size in this pilot was insufficient to explore this in detail.

Given the small number of PCTs included it is possible that participants would have been higher in other areas. However, PCTs were selected to vary by geographical area (London/non-London) and background levels of chlamydia screening and there is no reason to think rates would have been higher in other PCTs. It was not possible to determine

whether participation rates would have been higher if participants had been offered their results. As people who take part in named chlamydia testing are, on average, at higher risk of infection than the general population[7], participants were not provided with their test results to reduce potential non-response bias. Furthermore, the batch-testing used in the study meant that tests would not have met diagnostic standards of time between testing and result.[8] Only 2/48 individuals cited non-provision of results as a reason not to take part in the survey. Although this is a small sample and only indicative of potential reasons for non-participation in the overall population, this suggests that providing test results would not have led to substantially higher response rates. The low participation rates are also consistent with those reported in other recent studies of chlamydia screening using postal invitations where named testing was used. For example, Bracebridge et al reported a participation rate of 13.2% in women invited by post to take a chlamydia screening test[9] and in their trial of chlamydia screening using postal invitations to order a home-sampling kit via the internet, van den Broek et al found that <20% of women aged 16 to 29 years invited for testing ordered and returned a home-sampling kit.[10]

In summary, this pilot study showed that cross-sectional studies of chlamydia prevalence using postal invitations with anonymous testing for chlamydia are not a suitable method for measuring chlamydia prevalence in the general population in England. Other methods for monitoring chlamydia infection are therefore required.

Author contributions

SW, TN, SA, CI, NG and KS contributed to the design of the study. SW acted as study coordinator, led on the analysis and interpretation of the data and wrote the first draft of the manuscript; TN provided statistical support. FCS carried out the laboratory testing. CM, NG, KS, CI and SW contributed to the interpretation of the study. All authors contributed to the drafting of the manuscript.

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Competing interests

None declared

Data sharing statement

No additional data available.

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