Who is being tested by the English National Chlamydia Screening Programme? A comparison with national probability survey data

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ABSTRACT

Objectives We compare data collected by England's National Chlamydia Screening Programme (NCSP) with national probability survey data to examine demographic and behavioural differences that may be important in understanding who the NCSP is reaching and interpreting chlamydia positivity.

Methods Data for 538 119 men and women aged 16—24 years who were screened in 2008 and data collected from 2180 interviewees in Britain's second National Survey of Sexual Attitudes and Lifestyles 1999—2001 (Natsal-2), of whom 644 were tested for chlamydia, were compared using the χ^2 statistic and logistic regression.

Results Compared with Natsal-2, the NCSP tested more women (67% vs 49%). NCSP participants were more likely to be younger: 29% were 16—17 years versus 16% of men and 15% of women in Natsal-2; from ethnic minority groups: 17% of men and 14% of women versus 8% and 6%, respectively, in Natsal-2; not to have used condoms at last sex: 66% of men and 68% of women versus 48% and 63%, respectively, in Natsal-2: and more likely to report two or more partners in the last year: 62% of men and 47% of women versus 47% and 30%, respectively, in Natsal-2. In multivariate analyses, higher AOR of chlamydia positivity were found for those reporting non-use of condoms and for those reporting multiple partners in both the NCSP and Natsal-2.

Conclusions The NCSP is testing young people at increased risk of chlamydia. The impact of this testing bias on the effectiveness of the programme should be evaluated.

INTRODUCTION

Genital *Chlamydia trachomatis* infection is the most commonly diagnosed bacterial sexually transmitted infection in the UK.[1] It is commonly thought, based on experience in genitourinary medicine (GUM) clinics, that around 50% of infections in men and 60—70% of infections in women are asymptomatic, although some data put this higher at around 90% in men.[2] If left untreated genital chlamydial infections can have serious long-term consequences, including pelvic inflammatory disease, ectopic pregnancy and tubal factor infertility in women, and urethritis, epididymitis and Reiter's syndrome in men.[3–5] The National Chlamydia Screening Programme (NCSP) was launched in England in 2003 to control chlamydial infection through early detection and treatment of predominantly asymptomatic infections to prevent

onward transmission and the development of sequelae.[6] Unlike the cervical, breast or bowel screening programmes in England where medical registers are used to invite eligible subgroups of the population, the NCSP was not implemented as a call-recall register-based programme. Instead, the NCSP was set up as an opportunistic programme offering testing and treatment to men and women under the age of 25 years in healthcare and non-healthcare based settings. The proportion of those testing positive through the programme has been higher than the prevalence observed in the general population[7 8] and is likely to be influenced by factors associated with who is offered and who accepts chlamydia testing.

Between 1999 and 2001, Britain's second National Survey of Sexual Attitudes and Lifestyles (Natsal-2), a population-based probability sample survey, was carried out. In addition to collecting data on sexual behaviour and attitudes, the survey collected urine samples from a subset of sexually active adults and estimated the population-based prevalence of genital chlamydia. At the time of writing, the Natsal-2 data are the most up-to-date and well-characterised population-based chlamydia prevalence data available for Britain. Therefore, these data provide an opportunity to explore differences between those who are tested through the NCSP and a nationally representative general population sample. The aims of this study are to (i) compare the demographic and behavioural profiles of those participating in the NCSP relative to a general population sample (Natsal-2); (ii) examine whether the same demographic and behavioural risk factors for chlamydia are seen in both the NCSP and the general population; and (iii) consider how this comparison informs interpretation of NCSP positivity rates.

METHODS
Data sources
NCSP

The NCSP tests sexually active young men and women aged less than 25 years for chlamydia outside of GUM clinics. Altogether, 542 052 tests were recorded in the NCSP database for 2008. Reported data do not necessarily include a unique patient identifier. In total, 2450 test records matched other records by sex, date of birth, ethnicity and postcode of residence. These were considered highly likely to be repeat tests of the same individual and were excluded from our analysis. The first test was retained unless a subsequent test was positive in which case the first positive

test was retained. An additional 1483 tests were excluded due to unknown sex. Data for 538 119 men and women aged 16—24 years (an estimated 8.6% of the English population aged 16—24 years) who were tested for chlamydia through the programme in 2008 entered analysis. The programme collects sociodemographic data (age, gender both 100% completeness and ethnicity with around 76% completeness) and sexual behavioural data (two or more sexual partners in the last year with around 67% completeness) for each test conducted. Information about condom use at last sex is additionally requested of NCSP participants in less than 20% of programme areas. Where asked, this question is completed with a 'yes' or 'no' response for around 50% of participants.

Natsal-2

Natsal-2 involved a stratified probability sample of 11 161 male and female British residents aged 16—44 years interviewed between 1999 and 2001 based on addresses drawn using a multistage probability cluster design from the Postcode Address File. Because the prevalence of many HIV risk factors had been found to be higher in London relative to the rest of the country in the first Natsal survey conducted a decade earlier, addresses in Greater London were over sampled in Natsal-2.[9] Information was collected by face-to-face computer-assisted personal interviews with the more sensitive questions asked through computer-assisted self-interviews (CASI). In addition, a random half of sexually active respondents aged 18—44 years were asked to provide a urine sample to test for *C trachomatis* using ligase chain reaction. Natsal-2 achieved a response rate of 65% for participation in the survey which is in line with other major surveys conducted in Britain.[10—12] The urine sample achieved a response rate of 71%, which did not vary significantly by age group.[13] Further details of the survey methodology and questionnaire are published elsewhere.[8 13—15] As described in other publications,[14 15] the Natsal-2 questionnaire data were weighted for differential selection and response probabilities and the urine sample data were given an additional weight to take account of non-response in providing a urine sample calculated as the inverse probability of providing a urine sample.[8] Details regarding the factors found to be associated with providing a urine sample are given in the paper by McCadden *et al*.[13]

Data analyses

We compared data collected by the NCSP throughout 2008 and Natsal-2. Two analyses were conducted: first, we compared the demographic and behavioural characteristics of those participating in the NCSP with those respondents aged 16—24 years who participated in the national probability survey with regards to five factors for which data were available from the two data sources: gender, age, ethnicity, condom use at last sex and having two or more sexual partners in the last year (expressed hereon for brevity as 'multiple partners'). Due to the large proportion of the NCSP participants for whom data on condom use was not available (see above), we compared the characteristics of NCSP participants with and without data for this variable to see whether there were any differences. We also compared the NCSP and Natsal-2 data limited to those participants with data for all five factors as the multivariate analyses (described below) also focused on these sub-samples. In the bivariate analyses, the χ^2 statistic was used to determine whether any differences between the NCSP and the Natsal-2 data sources were statistically significant, which was considered as $p<0.05$ for all analyses.

Second, we investigated how testing positive for chlamydia is associated with the five factors for each of the two data sources.

We used binary logistic regression to do this calculating the OR for testing positive for those in a particular category relative to the reference category—for example, among those aged 20—24 years relative to those aged 18—19 years. To take account of any confounding, we also used multivariate binary logistic regression to enable us to calculate the OR adjusting for the other variables we had data for. The denominator for this second analysis was limited to those Natsal-2 participants aged 18—24 years who had met the sample selection criteria for providing a urine sample,[8] who had agreed to do so and whose result had been tested for chlamydia (n=644). Only those people for whom we had data on all five variables were included in this analysis. This corresponds to 627 of the eligible Natsal-2 participants (97% of 644) and 17 259 NCSP participants aged 18—24 years (4%). We also ran this multivariate analysis excluding the condom use variable; thus, including those participants who had data available for gender, age, ethnicity and multiple partners (630 (98%) of eligible Natsal-2 participants; 234 034 (61%) of NCSP participants aged 18—24 years) to see if the results differed to the first multivariate model described.

To account for clustering, weighting and stratification of the Natsal-2 data, all analyses were performed in STATA 9.2 using the complex survey analysis functions.[16] The NCSP data were considered as a simple sample with no weighting (ie, a weight of one).

RESULTS
Demographic and behavioural characteristics

Compared with Natsal-2, the NCSP tested larger proportions of women (67.2%, 95% CI 66.8% to 67.2% vs 49.3%, 95% CI 46.5% to 52.1%) (data not shown in tables). Table 1 compares the demographic and behavioural characteristics of NCSP participants relative to the general population aged 16—24 years, according to Natsal-2, by gender. Relative to Natsal-2 respondents, men and women participating in the NCSP were more likely to be younger, specifically aged 16—17 years: 29% of men and women in the NCSP versus 16% of men and 15% of women in Natsal-2. NCSP participants were also more likely to be from ethnic minority groups: 17% of men and 14% of women versus 8% and 6%, respectively, in Natsal-2, and particularly from black ethnic groups: 8% of men and 7% of women in contrast to 2% and 1%, respectively, among Natsal-2 participants. NCSP participants were also more likely to report not having used condoms at last sex than their counterparts in the general population: 66% of men and 68% of women versus 48% and 63%, respectively in Natsal-2. NCSP participants were also more likely to report multiple partners in the last year: 62% of men and 47% of women versus 47% and 30%, respectively, in Natsal-2.

Due to the large proportion of NCSP participants for whom data on condom use were not available (see above), we compared the characteristics of NCSP participants with and without data for this variable to see whether there were any differences. While statistically significant differences do exist, reflecting the size of these two groups, the magnitude of these differences are slim, typically within four percentage points (see online table 1). One notable exception though is that the proportion of women from ethnic minority groups is larger among those for whom data on condom use were not collected: 15% in contrast to 5% of women for whom these data were collected. Given these differences, we also compared the NCSP and Natsal-2 participants limited to those with data for all four factors (see online table 2). We found that the differences between the

Table 1 A comparison of the demographic and behavioural characteristics of National Chlamydia Screening Programme (NCSP) participants relative to the general population aged 16—24 years, according to Natsal-2, by gender

Gender, data source, all	Natsal-2 (2000) 1289, 995* n (%)†	Men NCSP (2008) 176 430 n (%)	p Value	Natsal-2 (2000) 1251, 1185* n (column %)†	Women NCSP (2008) 361 689 n (column %)	p Value
Age, y						
16—17	207 (16)	51 453 (29)	p<0.001	193 (15)	103 568 (29)	p<0.001
18—19	267 (21)	51 600 (29)		276 (22)	96 126 (27)	
20—24	815 (63)	73 377 (42)		782 (63)	161 995 (45)	
Ethnicity						
White	1182 (92)	103 303 (83)	p<0.001	1180 (94)	245 053 (86)	p<0.001
Black	27 (2)	9397 (8)		9 (1)	19 348 (7)	
Other minority	76 (6)	11 112 (9)		60 (5)	20 680 (7)	
Condoms used at last sex‡						
Yes	661 (52)	2744 (34)	p<0.001	456 (37)	6051 (32)	p=0.007
No	602 (48)	5347 (66)		782 (63)	12 639 (68)	
2+ sexual partners, last year‡						
<2	655 (53)	40 234 (38)	p<0.001	845 (70)	137 253 (53)	p<0.001
2+	586 (47)	64 721 (62)		363 (30)	120 303 (47)	

*Weighted, unweighted denominators in Natsal-2.
†Natsal-2 counts and percentages are weighted.
‡Condom use at last sex is asked about in less than 20% of NCSP areas, in which it is completed by around 50% of participants. 2+ sexual partners is asked of all NCSP participants, with around 67% completeness.

two data sources shown in table 1 persisted, although there were smaller differences in the proportions of participants of non-white ethnicity.

Factors associated with chlamydia positivity

Overall, both men and women (aged 18—24 years) who tested in the NCSP had higher chlamydia positivity than those tested in the general population sample: among men: 9.4% (95% CI 9.2% to 9.5%) versus 2.9% (95% CI 1.3% to 5.2%) and among women: 8.5% (95% CI 8.4% to 8.6%) versus 3.1% (95% CI 1.6% to 5.7%). The corresponding numbers of positive chlamydia cases were 11 454 men and 21 316 women in the NCSP; 8 men and 16 women in the Natsal-2 sample.

Table 2 shows the factors associated with increased risk of chlamydia infection in each data source for men and women separately. Age was only significantly associated with having chlamydia among women in the NCSP with lower odds for those aged 20—24 years relative to those aged 18—19 years (AOR 0.84, 95% CI 0.74 to 0.96). Ethnicity appeared significantly associated for women in the NCSP (only) with lower odds for black women relative to white women (AOR 0.34, 95% CI 0.15 to 0.76). However, NCSP women of black ethnicity who responded to the question regarding condom use (and were therefore included in our analysis) had a lower prevalence of chlamydia infection than all NCSP women of black ethnicity (3% vs 9.5%), which will have introduced bias into our analysis with respect to ethnicity. When the multivariate model was run for those participants with data for the other factors, excluding condom use (online tables 3A and 3B), the AOR for these women increased to 1.19 (95% CI 1.11 to 1.27) and a similar relationship was observed for men in the NCSP of black ethnicity: AOR 1.42 (95% CI 1.30 to 1.54).

In terms of sexual risk behaviours, for both genders in both data sources the AOR was greater than one for participants who reported not using condoms at last sex: among men, AORs of 1.53 for NCSP participants and 10.3 for men in Natsal-2; among women, AORs of 1.23 and 1.31, respectively. Similarly, NCSP participants who reported multiple partners in the year prior to testing for chlamydia were significantly more likely to test positive: AORs of 1.62 and 1.81 for men and women,

respectively. This relationship was also observed among Natsal-2 women but was not statistically significant (AOR 2.85, 95% CI 0.88 to 9.22). Among men in Natsal-2 sample, none of those reporting at most one partner in this time-frame tested positive for chlamydia, while prevalence was 6.7% (95% CI 3.0% to 14.1%) among those reported multiple partners.

DISCUSSION

This study has shown that the NCSP is testing individuals at higher risk of chlamydia than those in the general population. Similar behavioural risk factors for testing positive for chlamydia were identified for both populations. In line with previous published figures,[17] [18] individuals reporting not having used a condom at last sex and those having multiple partners had higher odds of testing positive for chlamydia.

Strengths and weaknesses of the study

This study included a large sample size, particularly for NCSP records, with over half a million records used in these analyses. The use of nationally representative data allowed us to investigate the disparities that exist between those testing through the NCSP in contrast to a random sample of the general population.

There are several limitations with this study. First, the two data sources used different methods to collect genital samples and detect *C trachomatis*. Natsal-2 used the most sensitive and specific nucleic acid amplification assay (NAAT) available at the time of that study—the ligase chain reaction on participant-collected urines posted to the laboratory.[8] NCSP testing in 2008 was by more recently developed NAAT assays conducted on a mixture of patient-collected and clinician-collected samples. Natsal samples may have suffered more loss of sensitivity as a result of greater specimen transport delays.[8] This may have increased the difference in observed prevalence of chlamydia in the two populations but should not affect the differences in behaviours or risk factors associated with the infection in each of the two populations.

The response rate for Natsal-2 was consistent with other major social surveys,[10—12] and the data were weighted to be broadly representative of the British general population with respect to the age, gender and regional distribution[14] [15] and to

Table 2 Percentages, crude and adjusted ORs for demographic and behavioural risk factors associated with testing positive for chlamydia, by data source: men and women

Data source	Natsal-2				NCSP			
Demographic and behavioural risk factors	% (95% CI) testing positive	Crude OR (95% CI)	Adjusted OR‡ (95% CI)	Denominator*†	% (95% CI) testing positive	Crude OR (95% CI)	Adjusted OR‡ (95% CI)	Denominator†
Men								
All	3.0% (1.4% to 6.6%)	—	—	270, 342	9.8% (9.0% to 10.6%)	—	—	5491
Age group (y)		p=0.986	p=0.744			p=0.118	p=0.175	
18—19	3.1% (0.7% to 11.9%)	1	1	68, 79	9.1% (8.0% to 10.3%)	1	1	2517
20—24	3.0% (1.2% to 7.6%)	0.98 (0.17 to 5.69)	1.36 (0.21 to 8.79)	202, 263	10.4% (9.3% to 11.5%)	1.15 (0.96 to 1.38)	1.13 (0.95 to 1.35)	2974
Ethnic group		p=0.535	p=0.056			p=0.333	p=0.123	
White	3.0% (1.3% to 6.9%)	1	1	243, 310	9.7% (8.9% to 10.5%)	1	1	4943
Black	0.0%	NA	NA	11, 12	12.3% (9.0% to 16.6%)	1.31 (0.91 to 1.89)	1.47 (1.02 to 2.13)	285
Other minority groups	5.8% (0.8% to 32.9%)	2.03 (0.22 to 19.0)	9.13 (0.94 to 88.6)	16, 20	9.1% (6.2% to 13.3%)	0.94 (0.61 to 1.44)	1.00 (0.65 to 1.55)	263
Condom use at last sex		p=0.033	p=0.070			p<0.001	p<0.001	
Yes	0.5% (<0.01% to 3.5%)	1	1	125, 151	7.5% (6.3% to 8.9%)	1	1	1617
No	5.0% (2.2% to 11.3%)	10.4 (1.21 to 89.3)	10.3 (0.82 to 127.8)	145, 191	10.7% (9.8% to 11.8%)	1.49 (1.20 to 1.84)	1.53 (1.23 to 1.89)	3874
≥2 sexual partners in last year		NA	NA			p<0.001	p<0.001	
No	0.0%	NA	NA	140, 187	7.8% (6.8% to 8.9%)	1	1	2491
Yes	6.7% (3.0% to 14.1%)	NA	NA	130, 155	11.4% (10.3% to 12.6%)	1.53 (1.27 to 1.84)	1.62 (1.34 to 1.96)	3000
Women								
All	2.8% (1.6% to 4.9%)	—	—	357, 337	9.0% (8.5% to 9.5%)	—	—	11768
Age group (y)		p=0.967	p=0.809			p=0.001	p=0.010	
18—19	2.9% (0.9% to 8.8%)	1	1	87, 85	10.0% (9.2% to 10.9%)	1	1	4773
20—24	2.8% (1.5% to 5.3%)	0.97 (0.25 to 3.74)	1.18 (0.30 to 4.73)	270, 252	8.2% (7.6% to 8.9%)	0.80 (0.71 to 0.91)	0.84 (0.74 to 0.96)	6995
Ethnic group		p=0.147	p=0.145			p=0.011	p=0.030	
White	2.5% (1.3% to 4.5%)	1	1	323, 309	9.1% (8.6% to 9.7%)	1	1	11129
Black	13.7% (2.6% to 48.5%)	6.31 (0.95 to 41.8)	5.85 (0.96 to 35.8)	11, 7	3.0% (1.3% to 6.4%)	0.30 (0.13 to 0.69)	0.34 (0.15 to 0.76)	203
Other minority groups	5.1% (1.1% to 20.6%)	2.12 (0.38 to 11.7)	2.01 (0.37 to 10.9)	23, 21	7.8% (5.6% to 10.7%)	0.84 (0.59 to 1.21)	0.91 (0.64 to 1.31)	436
Condom use at last sex		p=0.759	p=0.034			p=0.016	p=0.004	
Yes	2.5% (1.0% to 6.1%)	1	1	110, 97	8.0% (7.2% to 8.9%)	1	1	3636
No	3.0% (1.5% to 5.8%)	1.20 (0.37 to 3.86)	1.31 (0.43 to 3.93)	247, 240	9.4% (8.8% to 10.0%)	1.19 (1.03 to 1.37)	1.23 (1.07 to 1.42)	8132
≥2 sexual partners in last year		p=0.068	p=0.079			p<0.001	p<0.001	
No	1.9% (0.8% to 4.6%)	1	1	244, 241	6.6% (6.0% to 7.2%)	1	1	6070
Yes	5.3% (2.7% to 10.1%)	2.92 (0.92 to 9.22)	2.85 (0.88 to 9.22)	113, 96	11.5% (10.7% to 12.3%)	1.83 (1.61 to 2.09)	1.81 (1.58 to 2.06)	5698

*Unweighted, weighted denominators. Percentages and ORs are based on weighted data for Natsal-2.
†Denominator corresponds only to respondents with data available for all factors shown in table 2.
‡Adjusted for all other factors in table 2.
NA, not applicable; NCSP, National Chlamydia Screening Programme.

account for non-response to the urine sample collection.[13] Nevertheless, response bias cannot be completely eliminated and remains a limitation of these data. The possibility of response bias also applies to the NCSP data since these data were also not 100% complete. Our inclusion of data on condom use at last sex appears to have introduced such a response bias in our analysis by ethnic group rather than to have improved the adjustment for confounding that we hoped it would. Our analysis of risk without this variable, and associated response bias, finds an elevated risk for individuals with black ethnicity as reported by a previous NCSP study.[7]

We had limited power due to the relatively small Natsal-2 sample size for the age group of interest, as noted above. There are also differences in terms of how the behavioural data were collected as Natsal-2 used CASI while the NCSP used a self-administered or clinician completed pen-and-paper questionnaire. However, it is worth noting that in a randomised comparison of administering the Natsal-2 questionnaire as a CASI versus pen-and-paper self-completion, no consistent evidence of an increased willingness to report sensitive behaviours was observed.[19]

It would have been interesting to examine whether the strength of the associations found in both populations differed in the NCSP relative to the general population. For example, it is possible that the relationship between a single, binary risk behaviour variable on the probability of infection is less discriminating in the NCSP than in the general population. Unfortunately there were too few chlamydia cases in the Natsal-2 (8 among men, 16 among women) and, thus, insufficient statistical power to test this hypothesis.

Finally, data for the two populations being compared were also collected during two different time periods with the general population sample collected around 8 years before the NCSP sample. However, at the time of writing, Natsal-2 data are the most up-to-date data available on chlamydia prevalence in the general population. As has been previously reported,[14] it is possible that sexual behaviour in the British population has changed since the interviews for Natsal-2, which may account, at least in part, for the differences detected between those tested through the screening programme and Natsal-2. If the young British population has become more sexually active since Natsal-2 was conducted it is possible that the results from this study, which describe the NCSP population as being more at risk, reflect this change. A comparison of NCSP participants and participants in Britain's third National Survey of Sexual Attitudes and Lifestyles (Natsal-3), being conducted in 2010—2012, should further our understanding of who is being tested by England's chlamydia screening programme.

Comparison with other studies

Others have compared certain characteristics of young people undergoing screening to those of young people more generally. For example, Sheringham et al have analysed residence-based Index of Multiple Deprivation scores (a variable we did not investigate) for young people screened through the NCSP in comparison to total population data and found that in 2008 the NCSP tested a larger proportion of individuals who resided in deprived areas compared to those in more affluent areas.[20] We are not aware of any studies prior to ours that have compared behavioural data of young people assessing opportunistic chlamydia screening in England with a representative sample of the general population. This is probably because there are no population-based behavioural data with chlamydia status that are comparable to Natsal for this purpose.

Key messages

► Condom non-use and having multiple sexual partners is strongly associated with testing positive for chlamydia among both National Chlamydia Screening Programme (NCSP) participants and the general population.
► The NCSP is testing individuals at higher risk of chlamydia than those in the general population.
► As chlamydia screening becomes more widespread, further study of who is being tested would inform evaluation of screening effectiveness.

Interpretation of the findings

Our findings suggest that the testing venues delivering opportunistic NCSP chlamydia screening, and/or testing offers, have been preferentially accessed, and/or accepted, by sexually active young adults at higher than average risk of infection. The reasons for this, whether selection by attendance at screening venues, by health professionals offering of tests or by acceptance of test offers, or a combination of these potential selection pressures, are a matter for separate research.

Implications of the findings

Models used to explore the effectiveness of chlamydia screening in England have assumed that those accepting testing are a random sample of the population eligible for chlamydia testing.[21] However, the results from this study suggest that those participating in the screening programme are at higher risk than the general population. The consequent higher yield of infections detected (and treated) by screening is an important feature that should be factored in when evaluating the impact of chlamydia screening in England. This could be done by incorporating test-positivity and population prevalence into models as two separate variables. Assuming all other model assumptions were correct, this bias to higher risk participants in screening that we have observed in England suggests that the effectiveness of chlamydia screening in England might have been higher than 'random sample' models would have predicted for the observed levels of coverage. Further analysis of this kind should be conducted as opportunities arise to monitor who is accessing screening and to inform modelling studies.

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LETTER

Fourth generation point of care testing for HIV: validation in an HIV-positive population

Identification of primary HIV infection is valuable to reduce onward transmission and consider early antiretroviral therapy (ART). Fourth generation (4G) HIV tests detect p24 antigen in addition to antibody and therefore allow detection of HIV before antibody development. 4G point of care tests (POCTs) have been widely adopted despite an absence of prospective evidence and reports of reduced antigen sensitivity in primary HIV infection.[1] The performance of the p24 component has not been evaluated in chronic infection and it is not known whether detection is influenced by factors such as illness or vaccination. Further evaluation of the p24 aspect of the 4G POCT is therefore required to allow accurate interpretation of test findings.

The Determine HIV-1/2 Ag/Ab Combo POCT (Alere Medical, Stockport, UK) was tested on whole blood samples obtained by finger prick from patients attending for routine HIV care at St Thomas' Hospital, London. Patients presenting with early p24 antigen-only infection had been diagnosed using the ARCHITECT HIV Ag/Ab Combo (Abbott Diagnostics, Germany) 4G serological assay, VIDAS p24 antigen test (Biomerieux, France) and Immunocomb II Bispot HIV 1 and 2 antibody test (Orgenics, Israel).

One hundred and forty seven HIV-infected patients were recruited prospectively between June and October 2010; 19/147 (13%) POCTs were excluded because the visual control line on the test strip was absent. Of the remaining 128 individuals, 94 (73%) were men, mean age 41 years (range, 24—73), mean CD4 count 515 cells/μl (46—1186), mean time since diagnosis 67 months (0—326); 90 (70%) were on ART, 5 (3.9%) had primary HIV infection and 42 (33%) had concomitant illness (30 patients), vaccination (9 patients) or sexually transmitted infection (STI, 17 patients).

Five out of 128 (3.9%) tested positive for p24 antigen by 4G POCT. Of these, 3/5 reported recent influenza-like symptoms and had been diagnosed with primary HIV infection in the previous 2 months (p24 antigen positive and HIV antibody negative). The two remaining patients had no history of concomitant illness, vaccination or STI, had been diagnosed HIV positive more than 5 years previously and were taking ART with a viral load of <20 copies/ml.

CONCLUSION
In a real life setting, the p24 antigen component of the Determine HIV-1/2 Ag/Ab Combo POCT has an acceptably low positive rate in chronic infection and is not affected by concomitant illness, vaccination or STI. The detection of p24 is therefore suggestive of early HIV infection and should guide clinicians accordingly. The high rate of void tests is of concern and needs further investigation.

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