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ORIGINAL ARTICLE

Cross-sectional study to evaluate *Trichomonas vaginalis* positivity in women tested for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, attending genitourinary medicine and primary care clinics in Bristol, South West England

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ABSTRACT

Background Highly sensitive, commercial nucleic acid amplification tests (NAAT) for *Trichomonas vaginalis* have only recently been recommended for use in the UK. While testing for *T. vaginalis* is routine in symptomatic women attending genitourinary medicine (GUM) clinics, it is rare in asymptomatic women or those attending primary care. The aim of this study was to evaluate the positivity of *T. vaginalis* using a commercial NAAT, in symptomatic and asymptomatic women undergoing testing for chlamydia and gonorrhoea in GUM and primary care settings.

Methods Samples from 9186 women undergoing chlamydia and gonorrhoea testing in South West England between May 2013 and Jan 2015 were also tested for *T. vaginalis* by NAAT alongside existing tests.

Results *T. vaginalis* positivity using NAAT was as follows: in GUM 4.5% (24/530, symptomatic) and 1.7% (27/1584, asymptomatic); in primary care 2.7% (94/3499, symptomatic) and 1.2% (41/3573, asymptomatic). Multivariable regression found that in GUM older age, black ethnicity and deprivation were independent risk factors for *T. vaginalis* infection. Older age and deprivation were also risk factors in primary care. Testing women presenting with symptoms in GUM and primary care using TV NAATs is estimated to cost £260 per positive case diagnosed compared with £716 using current microbiological tests.

Conclusions Aptima TV outperforms existing testing methods used to identify *T. vaginalis* infection in this population. An NAAT should be used when testing for *T. vaginalis* in women who present for testing with symptoms in primary care and GUM, based on test performance and cost.

BACKGROUND

Trichomonas vaginalis is the most common non-viral STI worldwide with an estimated 276 million new cases annually.[1] In the USA, 3.15% of women of reproductive age are estimated to be infected, corresponding to 2.31 million prevalent infections.[2–4] *T. vaginalis* infection is associated with female gender, non-Hispanic black race/ethnicity, older age, a greater number of lifetime sex partners, lower educational level and poverty.[2–4]

T. vaginalis infection is associated with adverse pregnancy outcomes including premature rupture of membranes, preterm labour and low birth weight.[2 5] There is increasing recognition that *T. vaginalis* increases the likelihood of HIV acquisition, HIV shedding and onward transmission.[2 6–9] This interaction with HIV could increase the cost-effectiveness of *T. vaginalis* testing in areas or populations with moderate to high HIV incidence.[2 10 11]

Highly sensitive nucleic acid amplification tests (NAATs) for *T. vaginalis*, approved by the FDA, are available in Europe and the USA.[2 12 13]

Data from Public Health England in 2015 showed 6396 new diagnoses of *T. vaginalis* compared with >200 000 chlamydia diagnoses.[14] The Natsal-3 study estimated the British general population *T. vaginalis* positivity as 0.3%.[15]

At the start of this study, routine clinical practice in the UK was to test symptomatic women attending genitourinary medicine (GUM) clinics for *T. vaginalis* infection, using culture and wet mount microscopy. In 2014, updated BASHH guidelines recommended *T. vaginalis* NAAT testing in GUM for symptomatic women, where resources allow;[16] however, availability remains limited.

One such NAAT, the Aptima *T. vaginalis* transcription-mediated amplification test (Aptima TV; Hologic, San Diego, USA), has shown acceptable performance characteristics in the UK and USA.[12 17 18] It is not known which other patient groups could benefit from *T. vaginalis* testing using NAAT or whether testing would be considered good value for money.

In this study, we evaluate the positivity of *T. vaginalis* in symptomatic and asymptomatic women undergoing testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in GUM and primary care. We compare the new test with existing testing practice and validate self-collected vaginal swabs.

Finally, we consider the economic implications in each clinical setting of changing testing protocol, to inform how best to implement *T. vaginalis* NAAT nationally.

METHODS

Setting

Bristol has a population of 442 500,[19 20] with 16% black minority ethnic. We recruited patients from the Bristol GUM clinic (Bristol Sexual Health Centre) and primary care practices in central and South Bristol, Bath and Weston-Super-Mare.

Study period
Data were collected from May 2013 to January 2015.

Eligibility
All females undergoing *C. trachomatis* and *N. gonorrhoeae* NAAT testing were eligible. We excluded women who were pregnant or under 18 years old.

Recruitment
GUM clinic
Women presenting for testing in GUM were asked about symptoms (vaginal discharge irritation, dysuria, pain).

Patients were managed according to routine clinical practice:

Group 1 (symptomatic) underwent speculum examination and was asked to provide a self-collected vaginal swab. Genital swabs were also collected by a health professional.

Group 2 (asymptomatic) provided a self-collected vaginal swab.

Primary care
Women were recruited from GP practices served by University Hospitals Bristol, Weston General Hospital or Royal United Hospital Bath laboratories.

Healthcare professionals submitting an electronic request for chlamydia and gonorrhoea NAAT were offered Aptima TV automatically. The test was offered consistently across all practices served by the above laboratories for the duration of the study. However, it was not possible to obtain information about patients who opted out.

Women were asked about symptoms and assigned to group 3 (symptomatic) or group 4 (asymptomatic). Women from group 3 and 4 provided self-collected or clinician collected swabs according to routine clinical practice in primary care.

Testing of samples
Aptima swab samples were tested for *C. trachomatis* and *N. gonorrhoeae* using the Aptima Combo 2 *C. trachomatis* and *N. gonorrhoeae* test (Hologic). The residual sample was tested using Aptima TV. All test kits were provided free of charge by Hologic.

Genital swabs in standard microbiological media were tested for *T. vaginalis* using wet mount and culture according to existing testing protocols: All symptomatic patients with GUM had a wet mount and culture for *T. vaginalis*. Samples from primary care were tested using wet mount and culture, prepared from charcoal transport swabs, dependent on the clinical details provided according to routine laboratory practice.

Consent
Written consent was obtained from patients in group 1, because an additional sample was collected for validation of self-collection swabs. Patients in groups 2–4 were notified of the study using posters in the waiting rooms and clinical areas and were included unless they opted out of the study.

Ethics
Ethical approval for this study was obtained from the NHS Health Research Authority NRES Committee South West, Cornwall and Plymouth (REC Reference: 12/SW/0181).

Data governance
All patient identifiable data were converted to suitable proxy variables and then removed from the study database prior to statistical analysis.

Analysis
Information on age, symptoms (present/absent) and the results of all diagnostic tests performed for *T. vaginalis, C. trachomatis* and *N. gonorrhoeae* was collected for all participants. In addition, ethnicity and symptom details were collected for GUM participants only (groups 1 and 2).

The index of multiple deprivation (IMD) is a composite score indicating relative socioeconomic disadvantage, published by the UK Office for National Statistics (ONS),[21] used under open license (http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/).

Deprivation scores were assigned to study individuals by matching the LSOA codes to IMD scores from ONS data. For GUM (groups 1 and 2) participants, the LSOA code was derived from postcode of residence and for GP (groups 3 and 4) participants on their GP practice postcode.

All analyses were performed in STATA V.14 (Stata LP).

Sample size
We used group1 to examine the diagnostic accuracy of Aptima TV compared with wet mount and culture. We estimated the number of positive cases required (n=24) to show with 95% power at an α of 0.05 that the diagnostic accuracy of Aptima TV was the same as that of wet mount and culture. We calculated the sample size (n=800 tests) based on the estimated number positive and the positivity of *T. vaginalis* in this population by existing tests prior to the study (3%). Since the interim analysis in December 2014 indicated a higher observed positivity of *T. vaginalis* (4.6%), we revised our sample size calculation (n=510 tests).

Collection of samples for groups 2–4 continued until we had recruited the required number from group 1.

Statistical analysis
The following multivariable logistic regression analyses of factors associated with *T. vaginalis*-positive test result were performed:

1. *All participants*: independent variables: age, setting (GP or GUM), symptoms (presence/absence), chlamydia diagnosis (positive/negative), gonorrhoea diagnosis (positive/negative)
2. *GUM only (groups 1 and 2)* as above, IMD score (based on postcode of residence), ethnic group)
3. *Primary care only (groups 3 and 4)* as above, IMD score (based on practice postcode)
4. *Performance* of existing tests was compared with Aptima TV using the χ^2 test.

Economic evaluation
The costs of current and new testing methods were estimated. These estimates took into account reagents and staff costs. Two scenarios of costs for implementing *T. vaginalis* NAAT testing were considered:

Scenario 1: using same NAAT platform,

additional test added to chlamydia and gonorrhoea NAAT, where Aptima NAAT platform is in use (assumes Aptima TV test cost £7.62).

Scenario 2: using different NAAT platform, stand-alone test with a *different* sample from that used for chlamydia and gonorrhoea NAAT, where another NAAT platform is in use (assumes Aptima TV cost £15.19).

The number of additional diagnoses, number of tests performed, total cost of testing, cost per positive and cost per additional positive in each group were calculated.

RESULTS

A total of 9241 women were recruited to the study: 9220 were eligible and 9186 had complete data on age and definitive test results for *T. vaginalis*, *C. trachomatis* and *N. gonorrhoeae* summarised in table 1. Study recruitment and exclusions are shown in online supplementary appendix figure A1.

During the study period May 13 to January 15, there were a total of 46 188 chlamydia/gonorrhoea NAATs performed on female patients in the three laboratory areas. A total of 14 367 tests were performed in GUM of which 2114 (14.7%) were included in the analysis and 31 821 were performed in primary care of which 7072 (22.2%) were included in the analysis.

The positivity of *T. vaginalis, C. trachomatis* and *N. gonorrhoeae* is shown in figure 1 and online supplementary appendix table A1.

Overall, the *T. vaginalis* positivity was 2.0% (95% CIs 1.75% to 2.33%) compared with *N. gonorrhoeae* 0.4% (95% CIs 0.26% to 0.52%) and *C. trachomatis* 2.7% (95% CIs 2.4% to 3.08%).

The observed *T. vaginalis* positivity was highest in symptomatic patients with GUM 4.5% (24/530), followed by symptomatic women attending primary care (2.7%, 27/1584). In symptomatic women attending primary care, the positivity of *T. vaginalis* (2.7%) was higher than *C. trachomatis* (2.1%).

Risk factor analysis

In multivariable logistic regression of risk factors (n=9186), the presence of symptoms, attendance at GUM, age over 35 and chlamydia diagnosis were all significantly associated with diagnosis of *T. vaginalis* at 5% significance level (table 2).

In subgroup analysis in GUM, black ethnicity was associated with increased odds of diagnosis with *T. vaginalis* (adjusted OR 5.28, CI 2.65 to 10.50, p<0.001) compared with white ethnicity (see online supplementary appendix table A2).

In the primary care analysis, increasing risk with age remained (see online supplementary appendix table A3). The effect of deprivation was significant in both settings (GUM and primary care) with more deprived (higher) IMD scores associated with higher risk of *T. vaginalis*.

Performance of new test compared with existing testing practice

A total of 3424 (of the total 9186) patients were tested both by Aptima TV and existing testing methods (either wet mount microscopy, culture or both). The majority were symptomatic (group 1: 485, group 2: 17, group 3: 2133, group 4: 789).

In the GUM clinic, where wet mount microscopy is undertaken on site in addition to culture, existing testing methods were 56.5% (13/23) sensitive compared with the Aptima TV test.

In primary care, sensitivity was 25.7% (19/74), which may reflect deterioration of samples in transit. There were no cases identified by existing test methods which were not also identified by Aptima TV, which significantly outperformed existing testing methods in GUM and primary care (p<0.001, χ^2 test) see online supplementary appendix table A4.

Clinician and self-collected swabs had equivalent performance (details in online supplementary appendix table A5).

Economic evaluation

Table 3 shows the number of tests performed for *T. vaginalis* in symptomatic and asymptomatic women in primary care and GUM clinics (Row B), number of diagnoses (A) compared with numbers tested under current testing policy (E) and diagnosed by Aptima TV (C) or wet mount/culture (D). These results were used to calculate the positivity and number of additional diagnoses and the cost implications of different testing strategies.

Compared with baseline estimates, for women currently tested for *T. vaginalis* (3424) using Aptima TV would result in an additional 45 diagnoses (97 compared with 32). If all women who are currently tested for chlamydia/gonorrhoea (9186) were also tested for *T. vaginalis,* this would result in 186 diagnoses (2.0% positivity).

Scenario 1 (using same testing platform) compared with baseline

The total cost of universal testing for *T. vaginalis* in women currently receiving chlamydia/gonorrhoea testing assuming use of existing NAAT platform is estimated at £69 997 over 21 months, equating to approximately £40 000 per year,

Table 1 Demographics of women in each study group

	Group 1 GUM, symptomatic Total (%)	Group 2 GUM, asymptomatic Total (%)	Group 3 Primary care, symptomatic Total (%)	Group 4 Primary care, asymptomatic Total (%)	All groups Total (%)
n	530	1584	3499	3573	9186
Age <25	214 (40.4%)	654 (41.3%)	1113 (31.8%)	1545 (43.2%)	3526 (38.4%)
Age ≥25	316 (59.6%)	930 (58.7%)	2386 (68.2%)	2028 (56.8%)	5660 (61.6%)
Age range	18 to 66	18 to 72	18 to 72	18 to 80	18 to 80
Mean age	28.0	27.8	31.5	28.6	29.5
Median age	26	26	29	26	27
Ethnic group*			N/A	N/A	N/A
White	434 (81.9%)	1352 (85.4%)			
Black	46 (8.7%)	88 (5.6%)			
Asian	12 (2.3%)	25 (1.6%)			
Mixed	27 (5.1%)	68 (4.3%)			
Other	9 (1.7%)	18 (1.1%)			
Prefer not to say	0 (0.0%)	24 (1.5%)			
Missing	2 (0.4%)	9 (0.6%)			
Residence IMD mean score	24.5	23.0	–	–	–
Practice IMD mean score	N/A	N/A	28.5	25.5	26.9

*Ethnic categories following Office for National Statistics grouping, white ('A', 'B', 'C'), black ('M', 'N'), Asian ('H', 'J', 'K', 'L'), mixed ('D', 'E', 'F', 'G'), other ('R', 'S'), prefer not to say ('Z').
GUM, genitourinary medicine; IMD, Index of Multiple Deprivation.

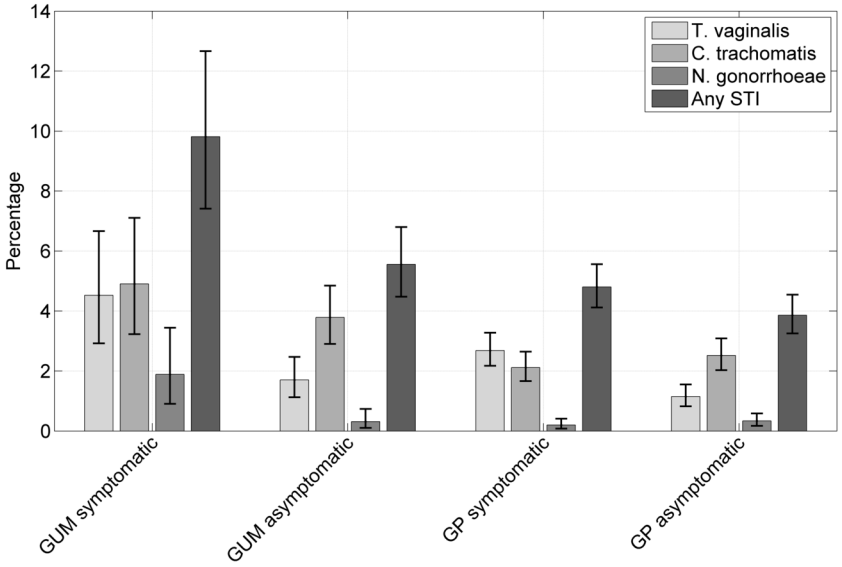

Figure 1 Positivity of *Trichomonas vaginalis*, *Chlamydia trachomatis*, *Neisseria gonorrhoeae* or any STI in different patient groups. GUM, genitourinary medicine.

depending on test volume. The overall cost per positive is £376, compared with £849 per positive using current tests (table 3). If only symptomatic women are tested (ie, combining group 1 and 3), the cost per positive would be £260=(530+3499)×£7.62/(24+94) compared with £716=(485+2133)×£7.93/(12+17) using current tests.

Scenario 2 (using a different testing platform) compared with baseline

For clinics with different testing platforms, the total cost of universal testing for *T. vaginalis* is £139 535 (21 months study period) or £79 700 per year. Correspondingly, the cost per positive is also nearly doubled.

This only includes the test cost and excludes equipment purchase, lab overheads, training and other opportunity costs associated with implementing a new laboratory test which should also be considered.

DISCUSSION

Summary of main findings

In women attending primary care and at risk of STIs, positivity of *T. vaginalis* infection was 2.7% (symptomatic) and 1.1% (asymptomatic), using the Aptima TV test.

In women attending GUM, the positivity of *T. vaginalis* was 4.5% (symptomatic) and 1.7% (asymptomatic) which is consistent with comparable UK NAAT estimates.[22]

Aptima TV outperformed existing testing methods, identifying additional cases of *T. vaginalis* in GUM and primary care settings.

T. vaginalis positivity was 11.9% (16/134) in patients of black ethnicity in GUM and 1.6% (29/1789) in those who self-identified as white. However, as the absolute number of cases was higher in women of white ethnicity, 69% (35/51) of *T. vaginalis* NAAT-positive cases in GUM would not have been identified had testing been targeted based on black ethnicity alone.

Table 2 Logistic regression of risk factors for *T. vaginalis* diagnosis, with unadjusted and adjusted ORs (n=9186)

Variable	Number (n=9186)	TV positive (n=186)	Positivity % (CI)	Unadjusted OR (CI)	p Value	Adjusted OR	p Value
Setting							
Primary care	7072	135	1.91 (1.60 to 2.26)	Ref			
GUM	2114	51	2.41 (1.80 to 3.16)	1.27 (0.92 to 1.76)	0.150	1.73 (1.23 to 2.45)	0.002
Symptoms							
Absent	5157	68	1.32 (1.03 to 1.67)	Ref			
Present	3911	118	2.93 (2.43 to 3.50)	2.26 (1.67 to 3.05)	<0.001	2.28 (1.66 to 3.12)	<0.001
Age group							
18 to 24	3526	47	1.33 (0.98 to 1.76)	Ref			
25 to 34	3387	58	1.71 (1.30 to 2.21)	1.29 (0.88 to 1.90)	0.20	1.29 (0.87 to 1.90)	0.208
35 to 44	1359	39	2.87% (2.05 to 3.90)	2.19 (1.42 to 3.36)	<0.001	2.26 (1.46 to 3.50)	0.001
45 and over	914	42	4.60 (0.33 to 6.16)	3.56 (2.34 to 5.44)	<0.001	3.67 (2.38 to 5.67)	<0.001
Chlamydia							
Negative	8936	172	1.92 (1.65 to 2.23)	Ref			
Positive	250	14	5.60 (3.09 to 9.22)	3.02 (1.73 to 5.29)	<0.001	3.64 (2.02 to 6.54)	<0.001
Gonorrhoea							
Negative	9152	32	2.01 (1.73 to 2.32)	Ref			
Positive	34	2	5.89 (0.72 to 19.68)	3.05 (0.72 to 12.81)	0.128	1.70 (0.37 to 7.75)	0.492

In the adjusted analysis, *T. vaginalis* positivity was the outcome adjusted for all variables (setting, symptoms, age group, chlamydia and gonorrhoea status).
GUM, genitourinary medicine.

Table 3 Economic implications for use of nucleic acid amplification test (NAAT) technology in different clinic settings (May 2013 to January 2015, 21 months)

			Genitourinary medicine		Primary care		Total
		Row	Symptomatic Group 1	Asymptomatic Group 2	Symptomatic Group 3	Asymptomatic Group 4	
All women in the study (tested for STI plus TV)	Positive, TMA (percentage)	A	24 (4.5%)	27 (1.7%)	94 (2.7%)	41 (1.1%)	186 (2.0%)
	Total	B	530	1584	3499	3573	9186
Women tested under current protocol	Positive, TMA	C	22	1	62	12	97
	Positive, wet mount/ culture	D	12	1	17	2	32
	Total tested	E	485	17	2133	789	3424
	Difference in diagnoses	F=A–D	12	26	77	39	154
Positivity	TMA test	G=C/E	4.5%	5.9%	2.9%	1.5%	2.8%
	Wet mount/culture	H=D/E	2.5%	5.9%	0.8%	0.3%	0.9%
Baseline (current situation)	Current cost	I=E×£7.93	£3846	£135	£16 915	£6257	£27 152
	Cost per positive (£7.93)	J=I/D	£321	£135	£995	£3128	£849
Scenario 1	Total cost (TMA test)	K=B×£7.62	£4039	£12 070	£26 662	£27 226	£69 997
TMA costs £7.62 using existing diagnostic platform	Difference in cost	L=K–I	£193	£11 935	£9748	£20 969	£42 845
	Cost per additional positive	M=L/F	£16	£459	£127	£538	£278
	Cost per positive	N=K/A	£168	£447	£284	£664	£376
Scenario 2	Total cost (TMA test)	O=B×£15.19	£8051	£24 061	£53 150	£54 274	£139 535
TMA costs £15.19, different test platform	Difference in cost	p=O–I	£4205	£23 926	£36 235	£48 017	£112 383
	Cost per additional positive	Q=P/F	£350	£920	£471	£1231	£730
	Cost per positive	R=O/A	£335	£891	£565	£1324	£750

TMA, transcription-mediated amplification.

T. vaginalis infection was independently associated with deprivation, and positivity was higher in older women in all clinical settings.

The current cost of wet mount/culture is comparable to the cost of an additional test in the existing testing platform in the Bristol clinic, and the higher detection rate makes it relatively more cost-effective as well as more accurate, especially for patients in primary care.

Strengths and weaknesses

The study is a large, cross-sectional study of *T. vaginalis* infection diagnosed with NAATs in over 9000 women undergoing STI testing and is the first to report on *T. vaginalis* positivity in primary care in the UK.

Study limitations

An important limitation of the study is that it does not include any information about patient's sexual behaviour, their partners and their risks. It would have been useful to know partner's ethnicity for those patients testing positive for *T. vaginalis*. In primary care, ethnicity information is not consistently recorded at patient or practice level.

Patients tested for STIs in primary care are likely at increased risk compared with the general population and positivity would be expected to be higher. In primary care, opportunistic chlamydia screening is recommended for sexually active women under 25 years. Older women are not routinely screened and might be more likely to present in the event of symptoms or perceived risk. A limitation of this study is that it does not distinguish between patients in primary care who present in response to symptoms or a perceived need to test and those who are screened opportunistically. It was only possible to distinguish those who presented with and without symptoms.

We only included women over 18 so cannot comment on the risk in younger women. We did not recruit patients from community sexual health clinics, where positivity might be lower than GUM but higher than primary care.

We do not have information on women who withheld consent so cannot define the representativeness of the women in each study group. We used opt-out consent method, other than in symptomatic patients with GUM, which should reduce participation bias.

The economic evaluation did not consider factors such as indirect effects on population prevalence, such as reducing risk of outcomes or the effect on HIV transmission. Local commissioning decisions are likely to be based on pragmatic considerations of cost and detection rate, which was the focus of this study.

Findings compared with other studies

In the USA in 2001–2004, the National Health and Nutrition Examination Survey observed that 3.1% (n=3754) of women of reproductive age were infected with *T. vaginalis*, with highest rates in women of non-Hispanic black ethnicity (13.3%).[3] Additional factors associated with infection were older age (especially in black women), lower educational achievement and poverty.[3]

In the Netherlands, a comparative cohort study observed *T. vaginalis* infection in women in 1.6% of a general practice cohort (n=554) and 0.8% of a nationally representative chlamydia screening study (n=566).[23] In Australia, a retrospective analysis of community samples tested with NAAT found 1.5% (n=37 137) of women positive for *T. vaginalis*.[24] Indigenous referrals accounted for 48% of positive cases in this sample.[24]

The positivity in a general practice population is comparable with the Netherlands and Australian findings[23 24] and somewhat lower than in USA, as expected. Findings from the GUM study groups were also consistent with other comparable populations in the UK.[22]

The positivity is much higher than that found in the recently published Natsal-3 data[15] which showed a 0.3% positivity in

4396 urine samples obtained from men and women aged 16–44 years. This suggests that the population who present for testing in primary care is at higher risk than the general population.

The Aptima TV test outperformed wet mount and culture in the GUM clinic and particularly in primary care. Sensitivity of wet mount and culture was 56.5% compared with NAAT when performed in the GUM clinic but was only 25.7% in primary care. This could be due to deterioration of samples in transit, calling into question the use of traditional microbiological testing methods for *T. vaginalis* outside the GUM setting where near patient wet mount microscopy is routinely available.

As has been shown previously for gonorrhoea and chlamydia, self-collected swabs are as good as clinician-taken swabs for *T. vaginalis* NAAT testing, and this is the preferred method for sample collection.[25]

The association with black ethnicity has been documented previously in the UK and USA[3 22 26] The findings are consistent with previous UK surveillance data which shows a higher proportion of the absolute number of *T. vaginalis* diagnoses in those of white ethnicity, but much higher rate of infection in those of black ethnicity.

What this study means?

The positivity of *T. vaginalis* in women with symptoms in GUM and in primary care was higher than anticipated using Aptima TV. Opportunities for diagnosis of *T. vaginalis* may be being missed in GUM and in primary care, and this could have implications for onward transmission and population positivity.

Use of sensitive NAATs such as Aptima TV will identify additional cases, and is likely to be cost-effective for symptomatic patients, especially when performed using the same sample and diagnostic platform as that used for chlamydia and gonorrhoea testing.

Use of NAATs in asymptomatic patients is more expensive. Complex testing strategies based on a combination of risk factors could help to optimise detection of *T. vaginalis* in the community. These would need to be easy to implement in practice.

Local epidemiology and locally relevant cost data will influence commissioning decisions regarding *T. vaginalis* testing in future in the UK.

Key messages

- Positivity of *Trichomonas vaginalis* determined by nucleic acid amplification tests (NAATs) is high in women with symptoms presenting for STI testing in genitourinary medicine (GUM) (4.5%) and in primary care (2.7%).
- In this UK population, deprivation increases the risk of *T. vaginalis* independent of ethnicity.
- Based on cost, NAATs for *T. vaginalis* are recommended for symptomatic women presenting for STI testing both in GUM and primary care.

Handling editor Jackie A Cassell

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Contributors JEN, PJH and PM conceived the study idea; wrote the protocol with input from KMET, MTM and JM. MTM calculated sample sizes based on data from KG and had overview of the statistical analysis. JEN, KG and PM ran the study in the lab and in primary care. JEN and PJH ran the study in the GUM clinic. RF wrote the ICE programme to offer Aptima TV testing and record consent in primary care. PN was responsible for extracting and summarising the data from LIMS throughout the study. KT performed the data linkage and data analysis on data from PN and MTM provided statistical support. KMET undertook the economic evaluation. JN wrote the first draft with input from KMET, PJH and PM. Subsequent drafts followed critical review by all authors. All authors approved the final version.

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Competing interests Hologic provided test kits free of charge during the study. In addition, PJH, JEN and KMET received expenses (travel, conference fee and accommodation) to attend ISSTDR 2015 (Brisbane). JEN received expenses to attend ECCMID 2016 (Amsterdam) and RICAI 2017 (Paris). No other consultancy fees or payments were received for this study and Hologic was not involved in the study design or analysis.

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REFERENCES

1 World Health Organisation. Global Incidence and Prevalence of selected curable sexually transmitted infections 2008. http://apps.who.int/iris/bitstream/10665/75181/1/9789241503839_eng.pdf accessed 2 April 2016.
2 Meites E, Gaydos CA, Hobbs MM, *et al*. A review of evidence-based care of symptomatic trichomoniasis and asymptomatic trichomonas vaginalis infections. *Clin Infect Dis* 2015;61(Suppl 8):S837–48.
3 Sutton M, Sternberg M, Koumans EH, *et al*. The prevalence of Trichomonas vaginalis infection among reproductive-age women in the United States, 2001-2004. *Clin Infect Dis* 2007;45:1319–26.
4 Satterwhite CL, Torrone E, Meites E, *et al*. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. *Sex Transm Dis* 2013;40:187–93.
5 Cotch MF, Pastorek JG II, Nugent RP, *et al*. Trichomonas vaginalis associated with low birth weight and preterm delivery. The Vaginal Infections and Prematurity Study Group. *Sex Transm Dis* 1997;24:353–60.
6 Anderson BL, Firnhaber C, Liu T, *et al*. Effect of trichomoniasis therapy on genital HIV viral burden among African women. *Sex Transm Dis* 2012;39:638–42.
7 Kissinger P, Amedee A, Clark RA, *et al*. Trichomonas vaginalis treatment reduces vaginal HIV-1 shedding. *Sex Transm Dis* 2009;36:11–16.
8 Hughes JP, Baeten JM, Lingappa JR, *et al*. Determinants of per-coital-act HIV-1 infectivity among African HIV-1-serodiscordant couples. *J Infect Dis* 2012;205:358–65.
9 Mavedzenge SN, Pol BV, Cheng H, *et al*. Epidemiological synergy of Trichomonas vaginalis and HIV in Zimbabwean and South African women. *Sex Transm Dis* 2010;37:460–6.

10 Owusu-Edusei K Jr, Chesson HW, Gift TL, *et al*. The estimated direct medical cost of selected sexually transmitted infections in the United States, 2008. *Sex Transm Dis* 2013;40:197–201.
11 Chesson HW, Blandford JM, Pinkerton SD. Estimates of the annual number and cost of new HIV infections among women attributable to trichomoniasis in the United States. *Sex Transm Dis* 2004;31:547–51.
12 Schwebke JR, Hobbs MM, Taylor SN, *et al*. Molecular Testing for Trichomonas vaginalis in Women: Results from a Prospective U.S. Clinical Trial. *J Clin Microbiol* 2011;49:4106–11.
13 Van Der Pol B, Williams JA, Taylor SN, *et al*. Detection of trichomonas vaginalis DNA by use of self-obtained vaginal swabs with the BD ProbeTec Qx assay on the BD viper system. *J Clin Microbiol* 2014;52:885–9.
14 Public Health England. Sexually Transmitted Infections (STIs) annual data tables 2015 [Table 4]. http://www.gov.uk/government/statistics/sexually-transmitted-infections-stis-annual-data-tables
15 Field N, Clifton S, Alexander S, *et al*. Trichomonas vaginalis infection is uncommon in the British general population: implications for clinical testing and public health screening. *Sex Transm Infect* 2016; ■■■.
16 Sherrard J, Ison C, Moody J, *et al*. United Kingdom National Guideline on the Management of Trichomonas vaginalis 2014. *Int J STD AIDS* 2014;25:541–9.
17 Nathan B, Appiah J, Saunders P, *et al*. Microscopy outperformed in a comparison of five methods for detecting Trichomonas vaginalis in symptomatic women. *Int J STD AIDS* 2015;26:251–6.
18 Andrea SB, Chapin KC. Comparison of Aptima Trichomonas vaginalis transcription-mediated amplification assay and BD affirm VPIII for detection of T. vaginalis in symptomatic women: performance parameters and epidemiological implications. *J Clin Microbiol* 2011;49:866–9.
19 Council BC. The Population of Bristol: 2015 2015. https://www.bristol.gov.uk/documents/20182/33904/Population%20of%20Bristol%20September%202014.pdf/d916c075-26f3-4d5e-9ef3-5aba2788e7df
20 Slater W, Sadler K, Cassell JA, *et al*. What can be gained from comprehensive disaggregate surveillance? The avon surveillance system for sexually transmitted infections. *Sex Transm Infect* 2007;83:411–15.
21 Statistics OoN. 2016 [August 2016]. http://www.ons.gov.uk/
22 Hathorn E, Ng A, Page M, *et al*. A service evaluation of the Gen-Probe APTIMA nucleic acid amplification test for Trichomonas vaginalis: should it change whom we screen for infection? *Sex Transm Infect* 2015;91:81–6.
23 Geelen TH, Hoebe CJ, Dirks A, *et al*. Low positivity rate after systematic screening for Trichomonas vaginalis in three patient cohorts from general practitioners, STI clinic and a national population-based chlamydia screening study. *Sex Transm Infect* 2013;89:532–4.
24 Bygott JM, Robson JM. The rarity of Trichomonas vaginalis in urban Australia. *Sex Transm Infect* 2013;89:509–13.
25 Gaydos CA, Cartwright CP, Colaninno P, *et al*. Performance of the Abbott RealTime CT/NG for detection of Chlamydia trachomatis and Neisseria gonorrhoeae. *J Clin Microbiol* 2010;48:3236–43.
26 Mitchell HD, Lewis DA, Marsh K, *et al*. Distribution and risk factors of Trichomonas vaginalis infection in England: an epidemiological study using electronic health records from sexually transmitted infection clinics, 2009-2011. *Epidemiol Infect* 2014;142:1678–87.