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# A service evaluation of the Gen-Probe APTIMA nucleic acid amplification test for *Trichomonas vaginalis*: should it change whom we screen for infection?

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## Abstract

**Objective—**A service evaluation of the new Gen-Probe APTIMA nucleic acid amplification test was performed to determine the prevalence of *Trichomonas vaginalis* (TV) infection in a UK sexual health clinic and identify risk factors to inform an appropriate TV screening strategy.

**Method—**Unselected patients presenting with a new clinical episode were offered TV testing with Gen Probe transcription-mediated amplification (TV TMA) in addition to routine sexually transmitted infection screening. Asymptomatic females provided a self-collected vulvovaginal specimen and asymptomatic men a first-void urine sample. Symptomatic patients were examined and a urethral swab taken from men and two posterior vaginal swabs from females; one for culture and one for TV TMA testing. Demographic and clinical data were collected on all patients positive for TV infection and 100 randomly selected TV-negative controls.

**Results—**3503 patients underwent TV TMA testing during the evaluation period. The prevalence of TV infection was 21/1483, 1.4% (95% CI 0.9% to 2.2%) in men and 72/2020, 3.6% (95% CI 2.8% to 4.5%) in women. The rate of TV positivity was higher in Black Caribbean



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**Contributors** JDCR developed the concept and was involved in all aspects of the study. AN was involved in study design, data collection and analysis. CG performed repeat TV testing using an alternative primer target in the USA. JH performed the statistical analysis. EH developed the manuscript. All authors contributed to, reviewed and approved the final manuscript.

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patients compared with Caucasian patients (men 5.4% vs 0.1%, p<0.001; women 9.0% vs 1.2%, p<0.001). TV TMA detected an additional 16 infections (38%) in symptomatic women compared with culture.

**Conclusions—**While screening all patients with TV TMA will identify more TV infections, the UK prevalence remains low and this approach is unlikely to be cost effective. In addition to testing symptomatic patients, targeted testing of high-risk asymptomatic groups using TV TMA should be considered.

## INTRODUCTION

### Background

Trichomoniasis is a sexually transmitted infection (STI) caused by the flagellated protozoan *Trichomonas vaginalis* (TV). TV infects the vagina, urinary tract and paraurethral glands of women and may be asymptomatic (10–50% cases) or result in vaginal discharge, vaginal itching and dysuria.[1] Men are usually asymptomatic but may report urethral discharge and/or dysuria and may have signs of a balanoposthitis.[1] Complications are uncommon but include adverse pregnancy outcomes (premature rupture of membranes, preterm delivery, low birth weight),[2,3] enhanced HIV-1 acquisition and transmission,[4–6] cervical neoplasia,[7] pelvic inflammatory disease[8] and infertility[9] in women, and prostatitis in men.[1]

### Local problem

The number of TV diagnoses made by Genitourinary Medicine (GUM) clinics in England rose by 6% from 2011 (6280 diagnoses) to 2012 (6638 diagnoses).[10] Most infections are diagnosed in women, and older age and non-white ethnicity are identified risk factors.[11] There are limited data on the prevalence of TV infection in men in the UK presenting with non-specific urethritis (NSU), although a study comparing culture and PCR for the detection of TV in urethral, urine and semen samples from male partners of TV infected women in the USA identified at least one positive test in 73.2% (205/280) of men.[12]

Current UK guidance advocates selective testing for TV infection. The British Association for Sexual Health and HIV (BASHH) recommends testing women with vaginal discharge and men who have persistent urethral symptoms after infection with Neisseria gonorrhoeae, *Chlamydia trachomatis* and *Mycoplasma genitalium* have been excluded.[13] While TV culture is recognised as the ‘gold standard’ diagnostic test, clinics often favour wet mount microscopy that is inexpensive and permits rapid identification of infection. The sensitivity of direct visualisation by wet mount microscopy and culture of vaginal samples is 45–60% and 73%, respectively, and even lower in men.[12,14,15]

Whittall Street Clinic (WSC) is a large (21 684 new patients attended in 2011) inner city sexual health clinic in Birmingham, UK, that serves a diverse ethnic population (43% white British, 20% black Caribbean, 6% black African, 27% other, 3% unknown). TV screening by wet mount microscopy with confirmation by culture of vaginal secretions was offered to all symptomatic women up to and including January 2011.

### Intended improvement

A nucleic acid amplification test (NAAT) for TV has recently been licensed in the UK (Gen-Probe APTIMA TV assay) that uses transcription mediated amplification (TMA) and has a high sensitivity (96.7%) and specificity (97.5%).[16] It can be performed on male and female specimens (vaginal fluid, self-taken vaginal swab, urine, urethral swab) and has a rapid turnaround time compared with culture. In view of the increased sensitivity in both male and female patients, screening of unselected patients using TV NAATwas introduced at WSC in February 2011.

This evaluation aimed to determine the prevalence of TV infection using NAAT and identify risk factors for TV infection to inform an appropriate screening strategy.

## METHODS

### Ethical issues

The project was assessed as being a service evaluation on the basis that it involved routine testing of patients using a licensed test and that only standard demographic and clinical data were collected. The national guideline on patient testing refers to TV microscopy and culture, but published studies show a significantly higher sensitivity for the newer TV NAAT and we considered it unreasonable to delay the introduction of an existing licensed test for patients while waiting for the guideline to be updated. The data from patients undergoing routine TV NAAT testing were therefore evaluated to ensure that the test was being used in an appropriate care pathway. In accordance with current National Research Ethics Service advice, the evaluation was designed and conducted solely to define current care and judge how the new TV NAAT performed.[17] No allocation to treatment or testing was undertaken.

### Intervention

Unselected patients presenting to WSC as a new clinical episode between 21 February 2011 and 7 April 2011 were prospectively offered screening for TV, in addition to screening for syphilis, HIV, gonorrhoea and chlamydia. Specimen collection was strati-fied according to gender and presence of symptoms. Two specimens were obtained for TV testing from the posterior vaginal fornix in symptomatic females; one for wet mount microscopy and direct inoculation into Diamond's culture medium, and one for TV NAAT. Wet mount microscopy was performed in line with local clinic policy to assist rapid diagnosis; however, culture was used as the standard diagnostic test against which NAAT was compared.[13] A urethral NAAT was taken from symptomatic men undergoing examination. Asymptomatic patients were not routinely examined and were instructed to provide a non-invasive sample; a self-collected vulvovaginal specimen for women and first-void urine sample for men.

All NAAT samples were tested for TV infection using TV TMA. Repeat testing using an alternative primer target was performed on all positive specimens and 99 negative control specimens. Laboratory staff randomly selected the control group; one negative sample selected to match each positive sample. The second confirmatory assay was an alternative TMA assay (Alt TV TMA) for TV (Gen-Probe Inc.) exclusively used in research studies.[18]

Clinical and demographic data (age, ethnicity, country of birth, sexual orientation, self-reported symptoms, clinical signs on examination, concurrent STI diagnosed on the day of attendance and number of sexual partners in the last 3 months) were reviewed for all patients diagnosed with TV infection and 100 negative control patients randomly selected by computer generation.

### Data analysis

All analyses were performed using SPSS V.19 (IBMSPSS Inc.) with $p<0.05$, or the corresponding Bonferroni adjusted value ($p<0.005$), deemed significant. Fisher's exact tests were used to compare the rates of positive test results across demographic factors (age and ethnicity), with the analysis split by gender. Where factors were found to be significant, post hoc paired analysis was performed to determine between which groups significant differences were present. Subgroup analysis was subsequently performed on all TV-positive patients and 100 negative controls in order to identify significant predictors of a positive TV TMA test. To account for the potentially confounding effects of these risk factors, a multivariable binary logistic regression was performed that considered the factors simultaneously. The small number of patients and unequal patient distribution across categories resulted in several cases of zero counts and ORs were therefore not calculable. To overcome this, factors were recategorised to ensure that each contained at least one positive and negative test. Sexual orientation was removed from this model due to the paucity of non-heterosexual patients.

Kappa and McNemar's tests were performed to determine the level of agreement between TV TMA and culture results in symptomatic women.

## RESULTS

In total, 3547 patients presented as a new clinical episode during the study period. Of these, 3503 (98.8%) underwent TV TMA testing (1483 male (42%); 2020 female (58%); table 1). Forty-three eligible patients did not have TV screening by TV TMA performed, accounting for 1.2% of the overall eligible clinic population.

The overall prevalence of TV infection using TV TMA was 2.7% (93/3503). The rate of infection differed significantly by gender ($p<0.001$), with rates of 1.4% in males (21/1483; 95% CI 0.9% to 2.2%) and 3.6% in females (72/2020; 95% CI 2.8% to 4.5%). Infection rates were found to differ significantly by ethnicity for both genders (table 1). Subsequent post hoc paired analysis found that black Caribbean patients were significantly more likely to have a positive TV TMA test than white patients (males: 5.4% black Caribbean vs 0.1% white, $p<0.001$; females: 9.0% black Caribbean vs 1.2% white, $p<0.001$). The rate of positive TV test differed significantly by age in females ($p=0.041$), with a trend towards a higher rate with increasing age, but no post hoc paired comparisons between age groups were found to be significant after Bonferroni adjustment.

Subgroup analysis was performed on all TV-positive patients and 100 negative controls in order to identify further predictors of a positive TV TMA test (table 2). Ethnicity and country of birth were the only demographic factors found to be significantly associated with

TV infection. The presence of self-assessed symptoms was a significant predictor of TV infection in men with an infection rate of 25% (95% CI 13.2% to 40.3%) identified in men who reported no symptoms compared with 66.7% (95% CI 38.4% to 88.2%) in men reporting symptoms. Post hoc analysis found urethral discharge to be the only symptom significantly associated with a positive TV test (6 of 7 men reporting urethral discharge had a positive TV test, p=0.006). Diagnosis of an additional STI on the day of attendance was not associated with a positive TV test; however, two men reporting urethral discharge were diagnosed with a concurrent STI (chlamydia=1; NSU=1) that could explain their presentation.

In multivariate analysis (table 3), ethnicity remained a signifi-cant predictor of TV infection. Infection rates were highest in black female and male patients with ORs, relative to white patients, of 4.5 (95% CI 1.8 to 11.7; p=0.002) and 22.4 (95% CI 1.6 to 317.5; p=0.022), respectively.

In total, 1105 women screened using TV TMA had an additional TV culture performed due to the presence of symptoms (table 4). The culture and TV TMA results were in agreement in 1088 cases (98.5%, $\kappa$=0.824, 95% CIs 0.735 to 0.843). Sensitivity of TV TMA in females compared with culture was 97.7% (87.7% to 99.9%). Where the results did not agree, the NAAT was significantly more likely to be positive (McNemar p<0.001); an additional 16 symptomatic women were diagnosed with infection using TV TMA. All samples positive on TV TMA testing were confirmed as positive using an alternative primer target (Alt TV TMA) (table 4). Ninety-nine negative samples by TV TMA were also retested of which four samples tested positive by Alt TV TMA.

## DISCUSSION

The overall prevalence of TV infection using NAAT in an inner city sexual health clinic population in Birmingham, UK, was 2.6% using TV TMA. TV prevalence was higher in women (3.6% women; 1.4% men) and in those of black Caribbean ethnicity (9.0% women; 5.4% men). There was a trend towards increased age as a risk factor for infection in women, but this did not reach significance when comparisons were performed across age groups. Culture and TV TMA results were in good agreement in women (98.5%). In the 17 cases where the tests did not agree, TV TMA detected 16 additional infections, 38% more than culture in symptomatic women.

A lower prevalence of TV infection (0.8%; 95% CI 0.0% to 1.7%) was recently reported in a cohort of 1009 women screened using TV TMA on vulvovaginal or first-void urine specimens at Macclesfield GUM clinic, its satellite prison and community clinic.[19] Ethnicity data were not presented for the overall study population and fewer women of black ethnicity may account for the lower prevalence rate reported (3/32 TV infections were diagnosed in black African women cf. 27 white British/Irish and 2 Chinese). In contrast, significantly higher rates have been reported in specific female cohorts in the USA; prevalence rates up to 8.7% in women aged 18–89 years[20] and even higher in African-American drug users (38%)[21] and incarcerated pregnant women (47%).[22]

Comparable UK prevalence data are not available for men; however, a rate of 0.2% (4/89 infections identified) was previously reported from a retrospective case note review of 38 774 patients screened for TV infection using wet mount microscopy and culture.[23] This is significantly lower than the prevalence rate in our male population (1.4%) and from American cohorts using TV NAAT for diagnosis; 3.7% in asymptomatic men[24] and 5.2% in men presenting with urethritis.[25] The availability of a sensitive NAAT test provides the opportunity to obtain more accurate data on the frequency of TV as a cause of NSU in men presenting to UK sexual health services to better inform local management protocols.

A number of risk factors in addition to gender have been associated with TV infection. Ethnicity has consistently been associated with TV infection,[112627] and the majority of participants with TV infection in our cohort were black Caribbean based on self-disclosed ethnicity (76% of infection in men and 56% in women). This is consistent with data from the UK Genitourinary Medicine Clinic Activity Dataset (GUMCAD),[11] which identified older age, non-white ethnicity, in particular black Caribbean ethnicity (adjusted OR 4.23, 95% CI 3.98 to 4.50 in women; adjusted OR 8.00, 95% CI 6.48 to 9.87 in men) and birth in the Caribbean compared with the UK (adjusted OR 1.27, 95% CI 1.16 to 1.38 in women; adjusted OR 1.63, 95% CI 1.28 to 2.09 in men) as risk factors for TV infection. The high rate of TV infection observed in women of black Caribbean ethnicity may in part be explained by racial differences in social and sexual behaviour. First, it may reflect a higher incidence of TV infection[28] or a lower rate of condom use in men of black ethnicity.[29] Second, vaginal douching is reportedly more common in black ethnicities[30] (Web reference 1, appendix 1) and is associated with proportional loss of vaginal lactobacilli and relative overgrowth of anaerobic organisms, which is observed in women with TV infection (Web reference 2, appendix 1). Lastly, it may reflect a lack of access to health-care services in ethnic minority women due to social, educational or structural barriers.

Previous studies have failed to identify specific symptoms that are strongly associated with TV infection.[2628] Self-reported urethral discharge in men was the only significant predictor of a positive TV test in our cohort; 86% of symptomatic men who were positive by TV NAAT reporting discharge. While discharge is a common presentation of STI, only two men with a positive TV NAAT were diagnosed with an alternative concurrent infection, which might have explained their symptoms. Of concern, 32% of TV infections were in patients who reported no symptoms (46.3% women, 25.0% men) and would not therefore have been tested if following current BASHH guidance. All men diagnosed with TV infection were heterosexual, and it may be that asymptomatic women act as a significant reservoir of infection.

TV TMA was more sensitive than TV culture in symptomatic women and identified an additional 38% of infections. All TV-positive samples by TV TMA were confirmed as true positives by an alternative testing platform. The positive predictive value of TV TMA in our low prevalence cohort was 72.4% (65% to 74%). In addition, the rapid turnaround time of TV TMA has the potential to reduce the time to diagnosis, treatment and partner notification in affected individuals and would support the replacement of culture with NAAT as the preferred test for TV diagnosis. The cost of implementing a point of care test (POCT) and in-house PCR have been compared to microscopy, and although initial outlay costs for

POCT and PCR were high (Web reference 3, appendix 1), some savings in labour costs are possible when using an automated NAAT platform. Further information on cost-effectiveness will be available from an ongoing study assessing Aptima TV TMA in high-risk and low-risk populations in England using self-taken swabs compared with standard diagnostic methods (Web reference 4, appendix 1).

Our evaluation has a number of limitations. First, samples were collected in line with local testing guidelines and patients self-reporting as asymptomatic were not examined. This approach may have missed clinical signs of TV infection, such as vaginitis. Second, an evaluation of the performance of TV TMA between samples was not performed and an optimal sample cannot be recommended. Third, the performance of TV TMA in comparison to wet microscopy has not been performed, which may have been more relevant to clinics where culture is unavailable. Lastly, while all positive TV TMA samples were confirmed using a second assay (Alt TV TMA) and are therefore likely to represent true positives, 4 out of 100 TV TMA-negative samples subsequently tested positive by Alt TV TMA. In a study to determine the specificity of the alternate probe assay, 266 negative specimens by TV TMA were tested using Alt TMA (Web reference 5, appendix 1). Four urine specimens tested negative by TV TMA and PCR, but positive by Alt TV TMA. These were classified as false positives, resulting in a specificity of the Alt TV TMA of 98.5% in contrast to the 100% specificity reported for TV TMA. Although our uncon-firmed infections were not from urine samples (three urethral samples from symptomatic men and one vaginal specimen from an asymptomatic woman), this previous report is consistent with either some Alt TV TMA results being false positives or that the Alt TV TMA has a higher sensitivity than the TV TMA.

### Interpretation

This service evaluation was performed in a sexual health clinic serving a large black Caribbean population, which may explain the higher TV prevalence identified compared with other UK cohorts described. Following a review of the performance of the new TV TMA, symptomatic women presenting to our clinic continue to be offered screening for TV infection with TV NAAT. However, in a low-prevalence setting such as the UK, targeted screening of high-risk asymptomatic patients using risk factors such as female gender and black Caribbean ethnicity may be a more cost-effective approach to reduce the prevalence of TV.

## CONCLUSION

Screening all patients attending a sexual health clinic by TV TMA detects more infections than using culture due to its higher sensitivity. However, the overall prevalence of TV infection in the UK population remains low and routine screening in this setting is probably not justified. TV TMA may have a role in screening high-risk populations who have an increased prevalence of asymptomatic TV infection, in particular black Caribbean women. In addition, TV TMA testing of symptomatic women will detect over a third more infections than culture. TV TMA is significantly more expensive than microscopy and culture, but its

targeted use has the potential to identify a significant number of previously undiagnosed infections.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**Key messages**

▶ *Trichomonas vaginalis* (TV) transcription-mediated amplification (TMA) is more sensitive than microscopy or culture for detecting TV.

▶ The prevalence of TV infection in a sexual health clinic population remains low and probably does not justify the expense of routine TV screening.

▶ Screening of specific high-risk groups that have a high prevalence of asymptomatic infection, such as black Caribbean women, should be considered.

▶ TV TMA is significantly more expensive than microscopy/culture, but its targeted use can increase diagnostic accuracy and improve patient care.

## Table 1

*Trichomonas vaginalis* transcription-mediated amplification (TV TMA) result stratified for age and ethnicity

| | Female (N=2020) | | | Male (N=1483) | | |
|---|---|---|---|---|---|---|
| **TV TMA result** | **Positive N=72 (3.6%)** | **Negative N=1948 (96.4%)** | **Fisher's exact test p value** | **Positive N=21 (1.4%)** | **Negative N=1462 (98.6%)** | **Fisher's exact test p value** |
| Age | | | 0.041* | | | 0.877 |
| <20 | 9 (2.7%) | 329 (97.3%) | | 2 (1.6%) | 127 (98.4%) | |
| 21-24 | 19 (2.5%) | 741 (97.5%) | | 5 (1.3%) | 382 (98.7%) | |
| 25-29 | 17 (4.0%) | 408 (96.0%) | | 4 (1.1%) | 368 (98.9%) | |
| 30+ | 27 (5.4%) | 470 (94.6%) | | 10 (1.7%) | 585 (98.3%) | |
| Ethnicity | | | <0.001 | | | <0.001 |
| White | 12 (1.2%) | 959 (98.8%) | | 1 (0.1%) | 679 (99.9%) | |
| Black Caribbean | 40 (9.0%) | 403 (91.0%) | | 16 (5.4%) | 281 (94.6%) | |
| Black African | 3 (2.4%) | 124 (97.6%) | | 0 (0.0%) | 111 (100.0%) | |
| Asian | 2 (1.1%) | 177 (98.9%) | | 2 (0.9%) | 213 (99.1%) | |
| Mixed/other† | 15 (5.9%) | 238 (94.1%) | | 2 (1.5%) | 129 (98.5%) | |
| Not specified | 0 (0.0%) | 47 (100.0%) | | 0 (0.0%) | 49 (100.0%) | |

*Significant at $p<0.05$.

†Mixed white/black Caribbean or white/black African or mixed white/Asian or Middle Eastern.

## Table 2

Univariable analysis of factors associated with a *Trichomonas vaginalis* transcription-mediated amplification (TV TMA) test result

| | Female TV NAAT result | | | Male TV NAAT result | | |
|---|---|---|---|---|---|---|
| | **Positive (N=72)** | **Negative (N=62)** | **Fisher's exact test p value** | **Positive (N=21)** | **Negative (N=38)** | **Fisher's exact test p value** |
| Age | | | 0.327 | | | 0.439 |
| Not known | 0 (0.0%) | 0 (0.0%) | | 0 (0.0%) | 0 (0.0%) | |
| <20 | 9 (40.9%) | 13 (59.1%) | | 2 (33.3%) | 4 (66.7%) | |
| 20-24 | 19 (48.7%) | 20 (51.3%) | | 5 (23.8%) | 16 (76.2%) | |
| 25-29 | 17 (65.4%) | 9 (34.6%) | | 4 (36.4%) | 7 (63.6%) | |
| 30+ | 27 (57.4%) | 20 (42.6%) | | 10 (47.6%) | 11 (52.4%) | |
| Ethnicity | | | 0.001* | | | <0.001* |
| Not known | 0 (0.0%) | 0 (0.0%) | | 0 (0.0%) | 1 (100.0%) | |
| White | 12 (30.0%) | 28 (70.0%) | | 1 (5.6%) | 17 (94.4%) | |
| Black Caribbean | 40 (69.0%) | 18 (31.0%) | | 16 (69.6%) | 7 (30.4%) | |
| Black African | 3 (50.0%) | 3 (50.0%) | | 0 (0.0%) | 2 (100.0%) | |
| Asian | 2 (33.3%) | 4 (66.7%) | | 2 (33.3%) | 4 (66.7%) | |
| Mixed/other† | 15 (62.5%) | 9 (37.5%) | | 2 (22.2%) | 7 (77.8%) | |
| Country of birth | | | 0.027* | | | 0.001* |
| Not known | 0 (0.0%) | 0 (0.0%) | | 0 (0.0%) | 0 (0.0%) | |
| UK | 54 (52.9%) | 48 (47.1%) | | 15 (34.9%) | 28 (65.1%) | |
| Europe‡ | 1 (16.7%) | 5 (83.8%) | | 0 (0.0%) | 4 (100.0%) | |
| Africa | 1 (20.0%) | 4 (80.0%) | | 0 (0.0%) | 3 (100.0%) | |
| Caribbean | 14 (73.7%) | 5 (26.3%) | | 6 (100.0%) | 0 (0.0%) | |
| Asia Pacific | 2 (100.0%) | 0 (0.0%) | | 0 (0.0%) | 3 (100.0%) | |
| Sexual orientation | | | 0.438 | | | 0.500 |
| Not known | 4 (30.8%) | 9 (69.2%) | | 0 (0.0%) | 10 (100.0%) | |
| Heterosexual | 68 (56.7%) | 52 (43.3%) | | 21 (44.7%) | 26 (55.3%) | |
| Same sex partner | 0 (0.0%) | 0 (0.0%) | | 0 (0.0%) | 2 (100.0%) | |
| Bisexual | 0 (0.0%) | 1 (100.0%) | | 0 (0.0%) | 0 (0.0%) | |
| Self-assessed symptoms | | | 0.266 | | | 0.005* |
| Not known | 0 (0.0%) | 0 (0.0%) | | 0 (0.0%) | 0 (0.0%) | |
| Yes | 53 (57.5%) | 40 (43.0%) | | 10 (66.7%) | 5 (33.3%) | |
| No | 19 (46.3%) | 22 (53.7%) | | 11 (25.0%) | 33 (75.0%) | |
| Clinically identified signs | | | 0.158 | | | 0.057 |
| Not known | 17 (42.5%) | 23 (57.5%) | | 9 (28.1%) | 23 (71.9%) | |
| Yes | 44 (62.9%) | 26 (37.1%) | | 7 (70.0%) | 3 (30.0%) | |
| No | 11 (45.8%) | 13 (54.2%) | | 5 (29.4%) | 12 (70.6%) | |
| Other sexual infection§ | | | 0.224 | | | 0.754 |

| | Female TV NAAT result | | | Male TV NAAT result | | |
|---|---|---|---|---|---|---|
| | **Positive (N=72)** | **Negative (N=62)** | **Fisher's exact test p value** | **Positive (N=21)** | **Negative (N=38)** | **Fisher's exact test p value** |
| Not known | 0 (0.0%) | 0 (0.0%) | | 0 (0.0%) | 0 (0.0%) | |
| Yes | 28 (47.5%) | 31 (52.5%) | | 4 (30.8%) | 9 (69.2%) | |
| No | 44 (58.7%) | 31 (41.3%) | | 17 (37.0%) | 29 (63.0%) | |
| Number of partners in the last 3 months | | | 0.355 | | | 1.000 |
| Not known | 4 (36.4%) | 7 (63.6%) | | 0 (0.0%) | 6 (100.0%) | |
| 0 or 1 | 53 (53.0%) | 47 (47.0%) | | 13 (39.4%) | 20 (60.6%) | |
| More than 1 | 15 (65.2%) | 8 (34.8%) | | 8 (40.0%) | 12 (60.0%) | |

NAAT, nucleic acid amplification test; NSU, non-specific urethritis.

*Significant at $p<0.05$.

†Mixed white/black Caribbean or white/black African or mixed white/Asian or Middle Eastern.

‡Rest of Europe excluding UK.

§Chlamydia, gonorrhoea, HIV, syphilis, PID, warts, BV, NSU, Candida, HSV.

## Table 3

Multivariate analysis of factors associated with a *Trichomonas vaginalis* transcription-mediated amplification (TV TMA) test result

| | Female | | Male | |
|---|---|---|---|---|
| | **OR (95% CI)** | **p Value** | **OR (95% CI)** | **p Value** |
| Age | | 0.622 | | 0.903 |
| <20 | 1 | - | 1 | - |
| 20-24 | 1.86 (0.57 to 6.07) | 0.305 | 0.96 (0.06 to 15.33) | 0.978 |
| 25-29 | 2.16 (0.60 to 7.78) | 0.239 | 2.30 (0.09 to 57.96) | 0.613 |
| 30+ | 1.97 (0.63 to 6.19) | 0.245 | 1.48 (0.08 to 28.43) | 0.795 |
| Ethnicity | | 0.007* | | 0.025* |
| White | 1 | - | 1 | - |
| Black | 4.53 (1.75 to 11.73) | 0.002* | 22.38 (1.58 to 317.49) | 0.022* |
| Mixed/other† | 3.20 (1.08 to 9.52) | 0.036* | 2.33 (0.12 to 43.95) | 0.571 |
| Country of birth | | 0.557 | | 0.204 |
| UK | 1 | - | 1 | - |
| Other | 0.75 (0.28 to 1.99) | 0.557 | 0.28 (0.04 to 1.98) | 0.204 |
| Self-assessed symptoms | | 0.610 | | 0.201 |
| No | 1 | - | 1 | - |
| Yes | 0.54 (0.05 to 5.77) | 0.610 | 6.29 (0.37 to 105.65) | 0.201 |
| Clinically identified signs | | 0.247 | | 0.969 |
| No | 1 | - | 1 | - |
| Yes | 1.95 (0.66 to 5.78) | 0.226 | 1.24 (0.09 to 16.09) | 0.872 |
| Not known | 0.42 (0.03 to 5.60) | 0.511 | 1.25 (0.14 to 11.64) | 0.842 |
| Other sexual infection‡ | | 0.054 | | 0.415 |
| No | 1 | - | 1 | - |
| Yes | 0.43 (0.18 to 1.01) | 0.054 | 0.39 (0.04 to 3.73) | 0.415 |
| More than one partner in the last 3 months | | 0.519 | | 0.229 |
| No | 1 | - | 1 | - |
| Yes | 1.65 (0.59 to 4.62) | 0.345 | 0.18 (0.03 to 1.27) | 0.086 |
| Not known | 0.65 (0.14 to 3.04) | 0.585 | N/A | N/A |

NSU, non-specific urethritis.

*Significant at $p<0.05$.

†Mixed white/black Caribbean or white/black African or mixed white/Asian or Middle Eastern.

‡Chlamydia, gonorrhoea, HIV, syphilis, PID, warts, BV, NSU, Candida, HSV.

**Table 4**

TV result by *Trichomonas vaginalis* transcription-mediated amplification (TV TMA), alt TV TMA and culture

| | TV TMA | |
|---|---|---|
| **Female patients** | **Positive** | **Negative** |
| TV culture | | |
| Positive | 42 | 1 |
| Negative | 16 | 1046 |
| Alt TV TMA | | |
| Positive | 93 | 4 |
| Negative | 0 | 95 |