

Supplementary online material

Figure A1 Recruitment of patients in genitourinary medicine and primary care clinics with exclusions applied.

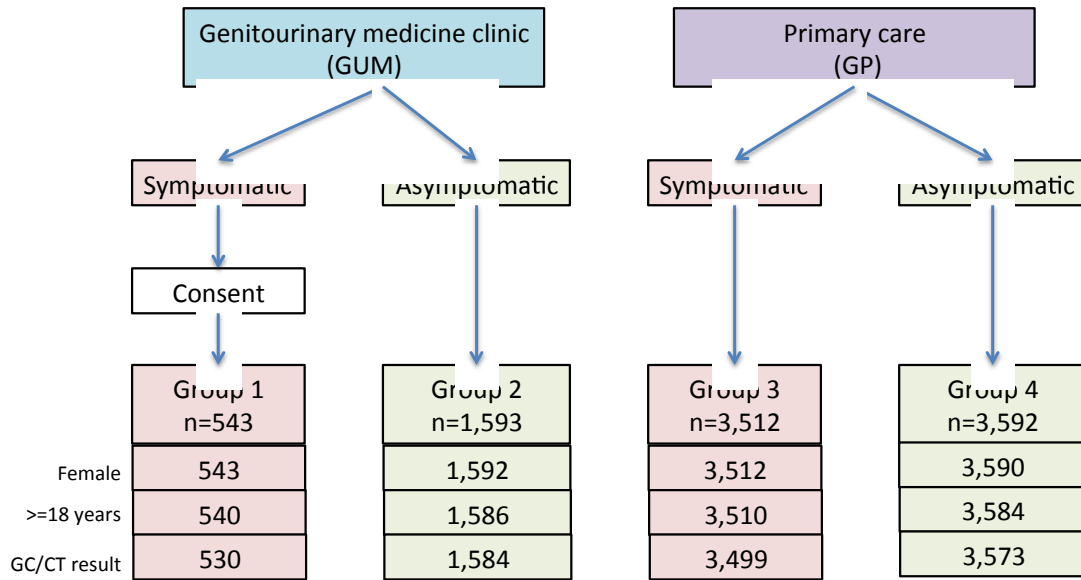


Table A1 Diagnoses of sexually transmitted infections; *T. vaginalis*, *C. trachomatis* and *N. gonorrhoeae* by study group

| | | Group 1 | Group 2 | Group 3 | Group 4 | Total | |
|-----------------------|---------------|------------|--------------|--------------|--------------|--------------|---------------------|
| | | GUM | | Primary care | | n | Confidence interval |
| | | Symptoms | No symptoms | Symptoms | No symptoms | | |
| Total (n) | | 530 | 1,584 | 3,499 | 3,573 | 9,186 | |
| <i>T. vaginalis</i> | Number | 24 | 27 | 94 | 41 | 186 | |
| | Percentage | 4.5% | 1.7% | 2.7% | 1.2% | 2.0% | 1.78% to 2.34% |
| | Mean age | 30.7 | 33.2 | 36.1 | 33.3 | 34.3 | 32.5 to 25.9 |
| | Median age | 28 | 33 | 35 | 31 | 31 | |
| <i>C. trachomatis</i> | Number | 26 | 60 | 74 | 90 | 250 | |
| | Percentage | 4.9% | 3.8% | 2.1% | 2.5% | 2.7% | 2.43% to 3.11% |
| | Mean age | 24.0 | 24.2 | 25.3 | 25.3 | 24.9 | 23.9 to 25.6 |
| | Median age | 22.5 | 23 | 22 | 23 | 23 | |
| <i>N. gonorrhoeae</i> | Number | 10 | 5 | 7 | 12 | 34 | |
| | Percentage | 1.9% | 0.3% | 0.2% | 0.3% | 0.4% | 0.26% to 0.53% |
| | Mean age | 30.4 | 24 | 21.4 | 24.6 | 25.6 | 22.8 to 27.9 |
| | Median age | 26.5 | 23 | 21 | 23.5 | 24 | |
| Any STI | Number | 52 | 88 | 168 | 138 | 446 | |
| | Percentage | 9.8% | 5.6% | 4.8% | 3.9% | 4.9% | |
| Coinfection | TV and CT | 1 | 3 | 6 | 2 | 12 | |
| | CT and NG | 4 | 1 | 1 | 3 | 9 | |
| | TV, CT and NG | 2 | 0 | 0 | 0 | 2 | |

Key: TV = *Trichomonas vaginalis*; CT = *Chlamydia trachomatis*; NG = *Neisseria gonorrhoeae*;
STI = Sexually transmitted infection; GUM = Genitourinary medicine

Table A2 GUM groups only (group 1 and group 2) logistic regression of risk factors for *T. vaginalis* diagnosis adjusted odds ratios (n=2,114)

| | Variable | Number (n=2,114) | TV positive (n=51) | Unadjusted OR | P value | 95% CI Lower | 95% CI Upper | Adjusted OR* | P value | 95% CI Lower | 95% CI Upper |
|--------------|----------------|---------------------|-----------------------|------------------|---------|-----------------|-----------------|-----------------|------------------|-----------------|-----------------|
| Symptoms | Absent | 1,557 | 27 | Ref | | | | | | | |
| | Present | 530 | 24 | 2.74 | <0.001 | 1.56 | 4.78 | 2.36 | 0.004 | 1.31 | 4.26 |
| Age group | 18 to 24 | 868 | 14 | Ref | | | | | | | |
| | 25 to 34 | 911 | 18 | 1.23 | 0.565 | 0.61 | 2.49 | 1.10 | 0.795 | 0.53 | 2.31 |
| | 35 to 44 | 208 | 12 | 3.73 | 0.001 | 1.70 | 8.20 | 3.48 | 0.003 | 1.52 | 7.99 |
| | 45 and over | 127 | 7 | 3.56 | 0.007 | 1.41 | 8.99 | 3.35 | 0.017 | 1.25 | 9.00 |
| Chlamydia | Negative | 2,028 | 45 | Ref | | | | | | | |
| | Positive | 86 | 6 | 3.05 | 0.008 | 1.37 | 7.97 | 3.18 | 0.035 | 1.08 | 9.36 |
| Gonorrhoea | Negative | 2,099 | 49 | Ref | | | | | | | |
| | Positive | 15 | 2 | 6.44 | 0.016 | 1.41 | 29.29 | 3.01 | 0.208 | 0.54 | 16.79 |
| Ethnic group | White | 1,786 | 29 | Ref | | | | | | | |
| | Black | 134 | 16 | 8.21 | <0.001 | 4.34 | 15.55 | 5.28 | <0.001 | 2.65 | 10.50 |
| | Asian | 37 | 0 | - | | | | <0.01 | 0.990 | 0 | - |
| | Mixed | 95 | 6 | 4.09 | 0.002 | 1.65 | 10.10 | 2.58 | 0.068 | 0.93 | 7.13 |
| | Other | 27 | 0 | - | | | | <0.01 | 0.992 | 0 | - |
| | Prefer not say | 24 | 0 | - | | | | <0.01 | 0.994 | 0 | - |
| | Missing | 11 | 0 | - | | | | <0.01 | 0.995 | 0 | - |
| IMD score | Mean | 23.4 | 33.3 | 1.03 | <0.001 | 1.02 | 1.05 | 1.03 | 0.003 | 1.01 | 1.04 |

*In the adjusted analysis ethnic groups Asian, Other, Prefer not to say and Missing have no observations.

Table A3 General practice groups only (group 3 and group 4) logistic regression of risk factors for *T. vaginalis* diagnosis adjusted odds ratios (n=7,017)

| | Variable | Total (n=7,017) | TV positive (n=133) | Unadjusted OR | P value | 95% CI Lower | 95% CI Upper | Adjusted OR* | P value | 95% CI Lower | 95% CI Upper |
|---------------------------|-------------|--------------------|------------------------|------------------|---------|-----------------|-----------------|-----------------|------------------|-----------------|-----------------|
| Symptoms | Absent | 3,553 | 41 | Ref | | | | | | | |
| | Present | 3,464 | 92 | 2.36 | <0.001 | 1.61 | 3.39 | 2.02 | <0.001 | 1.38 | 2.93 |
| Age group | 18 to 24 | 2,640 | 33 | Ref | | | | | | | |
| | 25 to 34 | 2,457 | 38 | 1.24 | 0.368 | 0.78 | 1.98 | 0.88 | 0.609 | 0.55 | 1.43 |
| | 35 to 44 | 1,139 | 27 | 1.92 | 0.013 | 1.14 | 3.21 | 1.46 | 0.154 | 0.87 | 2.47 |
| | 45 and over | 781 | 35 | 3.71 | <0.001 | 2.29 | 6.00 | 3.16 | <0.001 | 1.93 | 5.19 |
| Chlamydia | Negative | 6,854 | 128 | Ref | | | | | | | |
| | Positive | 163 | 8 | 2.78 | 0.006 | 1.35 | 5.78 | 3.32 | 0.002 | 1.56 | 7.05 |
| Gonorrhoea | Negative | 6,998 | 19 | Ref | | | | | | | |
| | Positive | 19 | 0 | Empty | | | | | | | |
| IMD practice score (2012) | Mean | 26.9 | 35.7 | 1.05 | <0.001 | 1.03 | 1.06 | 1.05 | <0.001 | 1.03 | 1.06 |

55 individuals did not have identifiable practice codes and were dropped from this analysis.

There were no cases of TV diagnosed in primary care in patients with gonorrhoea therefore this was dropped from the adjusted analysis.

Table A4 Comparison of existing test methods (wet mount/culture) and NAAT test using Chi-squared

a) All test results

| | Aptima TV TMA | | Total |
|----------------------------|---------------|--------------|--------------|
| | Positive | Negative | |
| Wet mount/culture positive | 32 | 0 | 32 |
| Wet mount/culture negative | 65 | 3,327 | 3,392 |
| Total | 97 | 3,327 | 3,424 |

Pearson chi2 = 1.1e03, p<0.001

Sensitivity of wet mount/culture = 33.0% (23.8% to 43.3%)

Specificity 100% (99.9% to 100.0%)

b) Genitourinary medicine tests

| | Aptima TV TMA | | Total |
|----------------------------|---------------|------------|------------|
| | Positive | Negative | |
| Wet mount/culture positive | 13 | 0 | 13 |
| Wet mount/culture negative | 10 | 479 | 489 |
| Total | 23 | 479 | 502 |

Pearson chi2 = 277.9, p<0.001

Sensitivity of wet mount/culture = 56.5% (34.8% to 76.1%)

Specificity 100% (99.0% to 100%)

c) Primary care tests

| | Aptima TV TMA | | Total |
|----------------------------|---------------|--------------|--------------|
| | Positive | Negative | |
| Wet mount/culture positive | 19 | 0 | 19 |
| Wet mount/culture negative | 55 | 2,848 | 2,903 |
| Total | 74 | 2,848 | 2,922 |

Pearson chi2 = 736.0, p<0.001

Sensitivity of wet mount/culture = 25.7% (16.5% to 37.3%)

Specificity 100% (99.8% to 100%)

Table A5. Comparison of clinician-collected and self-collected vaginal swabs for detecting *Trichomonas vaginalis* using the Aptima TV NAAT

| Women with both samples taken (GUM, symptomatic only n=518) | | |
|---|--------------------------|--------------------------|
| | Clinician Taken Negative | Clinician Taken Positive |
| Self taken Negative | 494 | 1 |
| Self taken Positive | 3 | 20 |
| P=0.8778, Fisher's exact test | | |
| Women where self-taken swab collected first (first n=257) | | |
| Self taken Negative | 241 | 0 |
| Self taken Positive | 2 | 14 |
| P=0.8511, Fisher's exact test | | |
| Women where clinician-taken swab collected first (first n=249) | | |
| Self taken Negative | 242 | 1 |
| Self taken Positive | 1 | 5 |
| P=1.00, Fisher's exact test | | |

We investigated whether self-taken vaginal swabs performed as well as clinician taken, using the Aptima TV NAAT test in symptomatic women (Group1) attending a department of Genitourinary Medicine.

The order of the swabs being taken was randomised such that half took the self-taken swab before the clinician (262) and half swabbed afterwards (255), order not reported (13).

Definitive test results were available for both self and clinician taken swabs in 518/530 eligible women (Table A5). No difference in test performance was observed between self-taken and clinician taken swabs.