Audit of *Trichomonas vaginalis* test requesting by community referrers after a change from culture to molecular testing, including a cost analysis

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**ABSTRACT**

**AIMS:** *Trichomonas vaginalis* (TV) prevalence varies among different communities and peoples. The availability of robust molecular platforms for the detection of TV has advanced diagnosis; however, molecular tests are more costly than phenotypic methodologies, and testing all urogenital samples is costly. We recently replaced culture methods with the Aptima *Trichomonas vaginalis* nucleic acid amplification test on specific request and as reflex testing by the laboratory, and have audited this change.

**METHODS:** Data were collected from August 2015 (microbroth culture and microscopy) and August 2016 (Aptima TV assay) including referrer, testing volumes, results and test cost estimates.

**RESULTS:** In August 2015, 10,299 vaginal swabs, and in August 2016, 2,189 specimens (urogenital swabs and urines), were tested. The positivity rate went from 0.9% to 5.3%, and overall more TV infections were detected in 2016. The number needed to test and cost for one positive TV result respectively was 111 and $902.55 in 2015, and 19 and $368.92 in 2016. Request volumes and positivity rates differed among referrers.

**CONCLUSIONS:** The methodology change was associated with higher overall detection of TV, and reductions in the numbers needed to test/cost for one TV diagnosis. Our audit suggests that there is room for improvement with TV test requesting in our community.

*Trichomonas vaginalis* (TV) is a globally important sexually transmitted infection responsible for an estimated 250 million new infections annually; more than those attributable to *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) combined. Infections are more commonly detected in women than men. Clinical manifestations of this parasitic infection range from asymptomatic carriage through to vaginitis and pelvic inflammatory disease. Infection may also lead to serious reproductive health outcomes, including pregnancy complications, pelvic inflammatory disease and infertility. Infection is also associated with an increased risk of HIV transmission in both males and females.

Labtests is the sole community laboratory in Auckland, New Zealand, and provides community (outpatient) testing for a population of approximately 1.5 million. Here, we present data of an audit of changes to our TV diagnostics.

**Methods**

In April 2016 we moved from testing for TV using microtitre broth culture to performing a nucleic acid amplification test using the Aptima *Trichomonas vaginalis* (ATV) assay for the detection of TV-specific 18S rRNA on the Hologic Panther system (Hologic, San Diego, CA), as the laboratory had changed to the Aptima assay for CT/NG.
detection, a singleplex assay. Nucleic acid amplification tests such as the ATV assay are significantly more sensitive than other methods of testing for TV. Before April 2016, culture was performed on all vaginal swabs received from female patients aged 13–60 years and on TV specimens from males if requested.

Prior to introducing the ATV assay, referrers were provided with education on the epidemiology of TV in Auckland with prevalence rates of 424/100,000 and 21/100,000 population among females and males, respectively (unpublished data), with significant differences among genders, ethnicities and socio-economic groups. For females, prevalence rates peaked at 15–29 years (1,622/100,000), while for males prevalence rates peaked later at 30–39 years (109/100,000). These data also demonstrated the superior sensitivity of the Aptima assay compared with culture for detection of TV; where both tests were performed, culture was positive in only 48% of cases that were positive for TV by Aptima. Referrers were consulted on the change from routine culture to ATV testing, and after feedback the laboratory protocol was changed to ATV testing only in the following circumstances: 1) TV specifically requested on the laboratory request form; 2) specimens received from urogenital sites of females aged 13–17 years old; and 3) specimens found to be positive for *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) (reflex testing). The second and third criteria were added after consultation with referrers and at the request of a number of practitioners who work in high-risk areas of Auckland, including high schools.

Data for TV detection in our laboratory for the months of August 2015 and August 2016 were collected from the laboratory information system, including patient age, gender, unique identifying number, laboratory number, referrer and results of CT, NG and TV testing. In August 2015, 10,299 specimens were cultured for TV. Almost all (10,273, 99.7%) specimens were from females; the median age was 30 years (range 13–60). Of the 10,299 specimens tested, 93 (0.9%) specimens from 93 patients were positive. In August 2016, 2,189 specimens were tested by the Aptima; 1,922 patients were female (88%) and the median age was 21 years (range 6–77). Of the 2,189 specimens tested, 116 (5.3%) specimens from 116 patients were positive. Of the 2,189 specimens tested by ATV, 740 (33.8%) were on request, 816 (37.3%) were reflex tests and 577 (26.4%) were tested because of female gender and age (13–17 years).

Of the 2,189 tested by the Aptima in August 2016, 348 (15.9%) of the specimens were urine; 268 from males and 80 from females. Of the urine samples from males, five (1.5%) were positive, and of the urine samples from females, seven (8.8%) were positive for TV.

Specimens with a specific request for TV were received from 740 referrers; the median number of tests per referrer was 1 (range 1–65). Positivity rates for referrers ranged from 0% to 100% with a median of 0%. Some examples of apparent misalignment between requesting and rates

The Aptima Combo 2 (AC2) assay was used for the detection of CT-specific 23S rRNA, NG-specific 16S rRNA and the ATV assay for the detection of TV-specific 18S rRNA. All testing was performed on one of three Panther systems according to the package inserts. In order to perform a cost analysis, the current price charged to the public funder (Auckland Regional District Health Boards) of the ATV was used ($19.55). As there was no price for standalone TV culture, we estimated that the cost attributable to TV culture and microscopy was used ($8.15). All prices are in New Zealand dollars. Positivity rates and total number of requests per referrer were used to estimate possible over- and under-requesting of TV testing. As this was an audit of referrer TV requesting and laboratory processes, no formal ethics approval was sought in accordance with the New Zealand Ethics Committee guidelines.

**Results**

In August 2015, 10,299 specimens were cultured for TV. Almost all (10,273, 99.7%) specimens were from females; the median age was 30 years (range 13–60). Of the 10,299 specimens tested, 93 (0.9%) specimens from 93 patients were positive. In August 2016, 2,189 specimens were tested by the Aptima; 1,922 patients were female (88%) and the median age was 21 years (range 6–77). Of the 2,189 specimens tested, 116 (5.3%) specimens from 116 patients were positive. Of the 2,189 specimens tested by ATV, 740 (33.8%) were on request, 816 (37.3%) were reflex tests and 577 (26.4%) were tested because of female gender and age (13–17 years).

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of TV identified include a family planning clinic and a general practice where relatively high numbers of requests (16 and 29 requests, respectively) were associated with no positive results. In contrast, a family planning clinic in an area of Auckland where TV prevalence is expected to be relatively high (based on population demographics), only 10 tests were requested in August 2016, with a positivity rate of 20%. Similarly, a female correctional facility requested TV testing on 12 patients, and had a 50% positivity rate.

We performed a cost analysis to compare the cost per positive for culture and ATV (Table 1).

In August 2015, the total cost of samples tested by culture was calculated to be $83,936.85, with a cost per positive result of $902.55. In August 2016, the total cost for ATV was $42,794.95, with a cost per positive result to $368.92. Reflex testing was most cost-effective with a cost per positive result of $332.35. We also estimated the numbers needed to test for one positive result; for culture the NNT was 111, compared with 19 for ATV. Routine testing for specimens collected from females in aged 13–17 years was not as effective as reflex testing of CT/NG positive samples from both females and males (Table 1).

### Discussion

The Centers for Disease Control STI Guidelines recommend testing symptomatic women for TV.\(^1\) In addition, they recommend asymptomatic screening on patients who are at risk (based on history) or are receiving care in a high-prevalence setting. They also comment that “decisions about screening might be informed by local epidemiology”. However, it is noted that the epidemiology of TV in the US differs from that in New Zealand, with high rates (>10%) reported among socio-economically deprived African-Americans, and peaking in older patients, compared with CT/NG.\(^1\) The epidemiology of TV infection in New Zealand has not been well studied. Using culture for diagnosis, 2.2% of women attending Auckland Regional Sexual Health Clinic were positive.\(^5\)

Prior to the introduction of ATV testing we were testing for TV by culture, by a labour intensive and time-consuming method, in a largely indiscriminate fashion on all females aged 13–60 years who had a vaginal swab collected. It is probable that we were culturing TV on specimens from many asymptomatic women with no or minimal risk factors, and we were testing almost no males. Routine screening is not indicated by our epidemiology (unpublished data), and would be expensive using molecular

### Table 1: Price (New Zealand dollars) and number needed to test per positive for different approaches to testing for *Trichomonas vaginalis* (TV).

<table>
<thead>
<tr>
<th></th>
<th>Culture</th>
<th>ATV(^1) (all specimens)</th>
<th>TV(^2) request</th>
<th>TV reflex on basis of positive CT/NG</th>
<th>TV on 13–17 year old females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total specimens tested</td>
<td>10,299</td>
<td>2,189</td>
<td>740</td>
<td>816</td>
<td>77</td>
</tr>
<tr>
<td>Price per specimen</td>
<td>$8.15</td>
<td>$19.55</td>
<td>$19.55</td>
<td>$19.55</td>
<td>$19.55</td>
</tr>
<tr>
<td>Total cost</td>
<td>$83,936.85</td>
<td>$42,794.95</td>
<td>$14,467.00</td>
<td>$15,952.80</td>
<td>$11,280.35</td>
</tr>
<tr>
<td>Number positive</td>
<td>93</td>
<td>116</td>
<td>39</td>
<td>48</td>
<td>22</td>
</tr>
<tr>
<td>Percentage positive</td>
<td>0.9%</td>
<td>5.3%</td>
<td>5.3%</td>
<td>5.9%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Cost per positive</td>
<td>$902.55</td>
<td>$368.92</td>
<td>$370.95</td>
<td>$332.35</td>
<td>$512.74</td>
</tr>
<tr>
<td>NNT(^3) per positive</td>
<td>110.7</td>
<td>18.9</td>
<td>19.0</td>
<td>11.4</td>
<td>26.2</td>
</tr>
</tbody>
</table>

\(^1\)ATV, Aptima *Trachomonas vaginalis* assay; \(^2\)TV, *Trichomonas vaginalis*; \(^3\)NNT, Numbers needed to test.
technology, and so the laboratory relies on referrers to identify patients in whom TV testing is indicated by either clinical presentation or risk factors. Changing our methodology to the ATV assay, with its superior sensitivity and turn-around times, has allowed us to improve efficiencies in the laboratory by testing fewer samples but detecting a greater number of TV infections overall. While these data indicate a cost saving to the laboratory, we expect that over time numbers of requests will increase as the change in approach is embedded among referrers.

A limitation of this audit is that we did perform reflex (on basis of positive CT and/or NG) and on-request testing on specimens from males, for which the assay does not have a label. Review of our data indicate that positivity rates for urines from males are low and we plan to review this practice; however, we will continue to test urethral swabs from males. In addition, we will be reviewing our routine testing for TV on all specimens received from females aged 13–17 years.

These data suggest possible over- and under-requesting by referrers, resulting in inefficiencies in resource allocation and barriers to testing and treatment for some at-risk patients. We will continue to engage with our referrers to improve the quality of this vital pre-analytical step; appropriate test selection.

**Competing interests:**
Nil.

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