Trichomonas Vaginalis (TV)
Is there more out there than we think?

Aptima TV NAAT Study
Jane Nicholls & Katy Turner
BASHH Glasgow 2015
Trichomonas Vaginalis (TV)

Is it common?
UK Cases TV (2013)\(^1\)  6475
UK cases Chlamydia  101,179 (16x)

Is it clinically important?
✓ Premature labour
✓ Increased susceptibility to HIV
?? Pelvic inflammatory disease
?? Infertility

1. PHE Table 5 ALL STI diagnoses 2009-13
TV in Primary Care

- Rarely tested for in GP
- Highest rates found in BME population
- Presumed ‘negligible’ in white population

Bristol situation: what we knew...

- 3% in symptomatic women (Bristol Sexual Health Centre)
- ~0.3% in primary care (local sample 2010)
- Bristol has large Caribbean population 16 % BME

Prevalence too low for testing to be cost effective?

1. Black Minority Ethnic, source Census 2011, Office for National Statistics
Bristol TV study: 4 Groups

Symptomatic GUM
Asymptomatic GUM
Symptomatic GP
Asymptomatic GP

Highest Risk

Lowest Risk
Q1: Who should we test for TV?

?? True TV Prevalence in Clinic & GP
using leftover samples from dual NAAT tests

?? Aptima® TVNAAT, vs wet prep and culture
(92%, 38% and 88% sensitivity respectively\(^1\))

Q2: Is it worth it?

?? Extra Cost:
   cost per additional positive

?? Cost Effectiveness:
   targeted or universal TV testing strategy
### 4 Study Groups – female patients

<table>
<thead>
<tr>
<th></th>
<th>Group 1 GUM Symptomatic</th>
<th>Group 2 GUM Asymptomatic</th>
<th>Group 3 GP Symptomatic</th>
<th>Group 4 GP Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-GUM</strong></td>
<td></td>
<td></td>
<td><strong>S-GP</strong></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>Discharge, irritation, pain</td>
<td>Nil or Nil revealed</td>
<td><strong>Vaginal discharge selected on ICE</strong></td>
<td><strong>STI risk selected on ICE</strong></td>
</tr>
<tr>
<td>Eligibility</td>
<td>All women attending GUM</td>
<td></td>
<td>All women for whom GP requested chlamydia/gonorrhoea test</td>
<td></td>
</tr>
<tr>
<td>Consent</td>
<td>Written</td>
<td>Posters</td>
<td>Opt-out consent using ICE + Posters</td>
<td></td>
</tr>
<tr>
<td>Samples</td>
<td>Self- &amp; physician-Remnant sample</td>
<td>collected swabs</td>
<td>No extra needed</td>
<td></td>
</tr>
<tr>
<td>Exclusions</td>
<td>&lt;18, pregnant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient data</td>
<td>Age, ethnicity, postcode</td>
<td></td>
<td>Age, GP practice location</td>
<td></td>
</tr>
<tr>
<td>Timeframe</td>
<td>21 months, May 2013 - Jan 2015</td>
<td></td>
<td>Total Sample n=9240</td>
<td></td>
</tr>
</tbody>
</table>

4 clicks!
Opt out consent request (ICE)

REQUEST ACCEPTED!
# Summary results – All groups

<table>
<thead>
<tr>
<th></th>
<th>S-GUM</th>
<th>A-GUM</th>
<th>S-GP</th>
<th>A-GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>N =</td>
<td>543</td>
<td>1593</td>
<td>3512</td>
<td>3592</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>444 (84%)</td>
<td>1,360 (85%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>58 (11%)</td>
<td>135 (9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>25 (6%)</td>
<td>39 (4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;25</td>
<td>220 (41%)</td>
<td>660 (41%)</td>
<td>1,117 (32%)</td>
<td>2,395 (68%)</td>
</tr>
<tr>
<td>&gt;=25</td>
<td>323 (59%)</td>
<td>933 (59%)</td>
<td>1,559 (43%)</td>
<td>2,034 (57%)</td>
</tr>
<tr>
<td>Total positive</td>
<td>26 (4.8%)</td>
<td>28 (1.8%)</td>
<td>95 (2.7%)</td>
<td>41 (1.1%)</td>
</tr>
</tbody>
</table>
### TV NAAT Positivity Rate %

<table>
<thead>
<tr>
<th></th>
<th>S-GUM</th>
<th>A-GUM</th>
<th>S-GP</th>
<th>A-GP</th>
</tr>
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<tr>
<td>%</td>
<td>N =  543</td>
<td>1593</td>
<td>3512</td>
<td>3592</td>
</tr>
</tbody>
</table>

- **Actual**
  - S-GUM: 4.8
  - A-GUM: 2.7
  - S-GP: 1.8
  - A-GP: 1.1

- **Expected**
  - S-GUM: 2.7
  - A-GUM: 1.1

- **9x**
  - Actual is 9 times the Expected
<table>
<thead>
<tr>
<th></th>
<th>S-GUM</th>
<th>S-GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subset</td>
<td>N = 491</td>
<td>2149</td>
</tr>
</tbody>
</table>

**Sensitivity:**

- **NAAT+**
  - S-GUM: 61%
  - S-GP: 27%

- **Micro Cult+**
  - S-GUM: 23
  - S-GP: 17
## STI Positivity Rate %

<table>
<thead>
<tr>
<th></th>
<th>S-GUM</th>
<th>A-GUM</th>
<th>S-GP</th>
<th>A-GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>N = 543</td>
<td>1593</td>
<td>3512</td>
<td>3592</td>
</tr>
</tbody>
</table>

TV CT NG

TV > CT
<table>
<thead>
<tr>
<th>Age Group</th>
<th>S-GUM</th>
<th>A-GUM</th>
<th>S-GP</th>
<th>A-GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>543</td>
<td>1593</td>
<td>3512</td>
<td>3592</td>
</tr>
<tr>
<td>TV</td>
<td>&lt;25</td>
<td>&gt;25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Age + STI Positivity Rate %

<table>
<thead>
<tr>
<th></th>
<th>S-GUM</th>
<th>A-GUM</th>
<th>S-GP</th>
<th>A-GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>7.8%</td>
<td>543%</td>
<td>1593%</td>
<td>3512%</td>
</tr>
</tbody>
</table>

CT

<25

>25
### Ethnicity + TV Positivity Rate %

<table>
<thead>
<tr>
<th></th>
<th>S-GUM</th>
<th>A-GUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>15.5</td>
<td>7.4</td>
</tr>
<tr>
<td>N</td>
<td>43</td>
<td>1593</td>
</tr>
</tbody>
</table>

35/54 (65%) TV+ identify as non black
Black Caribbean Ethnicity - Bristol

- Montpelier HC: 3.9% TV+
- Easton FP: 3.7% TV+
- Lennard Surgery: 5.8% TV+
- Hartcliffe HC: 3.1% TV+

Census 2011
Black Caribbean Ethnicity - Weston

Census 2011

Longton Grove
4.2% TV+

Bourneville LP
4.3% TV+
High TV rates: link to deprivation?

Deprivation Index (IMD) by practice fingertips.phe.org.uk
**6 practices with highest TV rates**

Positivity >3% + >130 patients tested

<table>
<thead>
<tr>
<th>Practices N &gt; 130 pt</th>
<th>Positives / tested</th>
<th>% BME</th>
<th>Dep Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montpelier</td>
<td>3.9% (26/672)</td>
<td>21%</td>
<td>33.8%</td>
</tr>
<tr>
<td>Easton</td>
<td>3.7% (5/136)</td>
<td>34%</td>
<td>43.5%</td>
</tr>
<tr>
<td>Hartcliffe</td>
<td>3.1% (10/321)</td>
<td>&lt;1%</td>
<td>50.2%</td>
</tr>
<tr>
<td>Bourneville (WSM)</td>
<td>4.3% (12/277)</td>
<td>&lt;1%</td>
<td>54.1%</td>
</tr>
<tr>
<td>Lennard</td>
<td>5.8% (9/155)</td>
<td>&lt;1%</td>
<td>24.5%</td>
</tr>
<tr>
<td>Longton Grove (WSM)</td>
<td>4.4% (6/144)</td>
<td>&lt;1%</td>
<td>24.9%</td>
</tr>
<tr>
<td>Student Health</td>
<td>0.1% (2/1370)</td>
<td>&lt;1%</td>
<td>12.9%</td>
</tr>
</tbody>
</table>

Deprivation Index Bristol average IMD = 25.2
Should I care about TV in 1°Care? .... not my problem

- Total cases diagnosed in GUM 54
- Total cases diagnosed in GP 136
- GUM + GP populations overlap
Main Study Findings

- Substantial TV rate in GUM women
  - 4.8% sympt. 1.8% asympt. – 2.5% overall
- TV rate much higher in GP than expected
  - 2.7% sympt. 1.1% asympt. - 1.9% overall
- Some findings consistent with known epidemiology
  - Age >25, Black Caribbean ethnicity
- TV rate varies greatly by practice:
  - Deprivation is an independent risk
  - Any other “Mystery” factors ??
Question: Is it worth it?

Extra Cost: cost per additional positive

Cost Effectiveness: targeted or universal TV testing strategy

Katy Turner PhD, University of Bristol
Considerations

- Clinical problem
- Prevalence
- Cost of testing and management (£, £/positive)
- Benefit of diagnosis & treatment (QALY)
- Transmission dynamics
- Cost-effectiveness (£/QALY)
Considerations

- Clinical problem
- Prevalence
- Cost of testing & management (£, £/positive)
- Benefit of diagnosis & treatment (QALY)
- Transmission dynamics
- Cost-effectiveness (£/QALY)
Methods

• Calculate costs associated with TV testing
• Compare existing testing with different testing scenarios using TV NAAT
• Calculate total cost of each scenario
• Calculate cost per positive test
Current testing strategy (TV Micro/Cult)

Women tested for GC/CT
N=9,240

Attending GUM
2,136

GP
7,104

Symptomatic
543 (25%)
Test
497 (92%)
12
2.4%

Asymptomatic
1,593
Test
17 (1%)
1
5.9%
New testing strategy (TV NAAT)

Women tested for GC/CT
N=9,240

Attending GUM
2,136
- Symptomatic
  - 543 (25%)
  - Test 26 (4.8%)
- Asymptomatic
  - 1,593
  - Test 28 (1.8%)

GP
7,104
- Symptomatic
  - 3,512 (49%)
  - Test 95 (2.7%)
- Asymptomatic
  - 3,592
  - Test 41 (1.1%)
Costs

TV test

Added to CT/GC NAAT = £7.62

Standalone = £15.19

Microscopy + Culture = £7.93

Sexual health screen

Asymptomatic £79.77*

Symptomatic £99.38*

Testing scenarios

1. All samples sent for STI testing
2. Symptomatic samples (GUM/GP)
3. Targeted high prevalence GPs
4. Combination
Cost of universal TV NAAT test

- GUM sympt: £4,138
- GUM asympt: £12,139
- GP sympt: £26,761
- GP asympt: £27,371
Adjusted total cost

-£105
£12,004
£9,791
£21,090

GUM sympt
GUM asympt
GP sympt
GP asympt

Additional cases found
Cost per additional positive positive

- £8.7
- £444.6
- £125.5
- £540.8

GUM sympt
GUM asympt
GP sympt
GP asympt
Testing scenarios

<table>
<thead>
<tr>
<th>Cases Found</th>
<th>Tests Done</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>£30,000</td>
</tr>
<tr>
<td>80%</td>
<td>£25,000</td>
</tr>
<tr>
<td>60%</td>
<td>£20,000</td>
</tr>
<tr>
<td>40%</td>
<td>£15,000</td>
</tr>
<tr>
<td>20%</td>
<td>£10,000</td>
</tr>
<tr>
<td>0%</td>
<td>£5,000</td>
</tr>
<tr>
<td>All</td>
<td>£-</td>
</tr>
</tbody>
</table>
Primary Care TV Testing

Test all patients with TV NAAT, stop doing microbiology testing

Advantages
- Equitable
- Simple

Disadvantages
- High cost
- Loss of lab capability
Prevalence affects Cost* per TV +

*Assumptions: Existing APTIMA Platform, add TV NAAT, No change to microbiology
Future Plans for Bristol...

GUM

- TV NAATs for symptomatic women ✔
- TV NAATs for asymptomatics too expensive ?
- Target high risk patients: age + ethnicity ?
- NAAT urine for male contacts of TV+ women ?

GP

- TV NAATs for symptomatic women ✔
- How to identify other high risk General Practices ?
  - further study !
Conclusions

• First UK study in primary care     N= 9240
• High TV positivity found (2.7% GP symptoms+)

Targeting?

• Testing symptoms+ is most cost effective
• Ethnicity alone misses >65% of cases
• Deprivation is independent risk factor
• Is there another Mystery Factor?
Mystery X-Factor
West Country
ENTHUSIASM!
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