Tricks for the Trade for Trichomonas

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Background: U.S. Estimates

Estimated Prevalence of Sexually Transmitted Infections in the U.S.
(Total 110,197,000)

Estimated New Sexually Transmitted Infections in the U.S. Each Year
(Total 19,738,800)


Objectives:

- To describe infections with Trichomonas vaginalis (TV), symptoms and their pathology
- To discuss diagnostic tools available
- To address the epidemiology of TV
- To mention associations with other infections
- To describe treatment and disclose some costs for TV
- To present research gaps

Trichomonas vaginalis 101

- More prevalent than CT or GC:
  - 4 million cases annually in U.S.
  - WHO global estimates are 173 million cases/yr
  - Not a reportable disease
  - True prevalence unknown
- Women:
  - Preterm birth, low birth weight (Choch STD 1997)
  - PID (Choch STD 2006)
  - Post-hysterectomy infection
  - HIV (VanDerPol OR 2.7, 2008; McClelland OR 1.5, 2008; Hughes OR 2.57, 2012)
  - ~50% asymptomatic or discharge
- Men:
  - ~50% asymptomatic, NCNGU
  - Prostatitis, epididymitis
  - Assoc w/ decrease in sperm motility and viability

Trichomonas Pathology

- Desquamation of vaginal epithelium
- Leukocytic inflammation; may persist for years

- Symptoms:
  - Women: asymptomatic or itching, burning, frothy discharge, worsens after menses, chronic, symptoms and parasite can be persistent
  - Men: asymptomatic or mild urethritis: rare to detect by wet prep in men due to urine flow
  - Strawberry hemorrhage in 5% of infected women w/ no discharge - pathogenesis is not well understood
Trichomonas Pathology

- Trichomonas attaches to epithelial cells
  - releases proteins which destroy the cell and elicits an intense local cellular immune response with inflammation resulting in
    - punctate mucosal hemorrhages
    - Lymphocyte recruitment including CD4+ cells
      - bind HIV to gain access
      - increases cervical HIV shedding
  - Inflammation-related factors
    - cytokines
      - implicated in pathology
      - prostate cancer

How do we diagnose TV

- Wet Preparation showing motile trichomonads
- Stained Trichomonas
- Electron microscope view of trichomonas on epithelial cell
- Wet Preparation
- Culture
- Affirm VPIII
- OSOM POC
- Amplified tests (NAAT)
  - Research PCRs
  - AptimaTV (ATV)
  - Becton Dickinson (TVQ)

Trichomonas Test Comparisons

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet prep</td>
<td>55%–65%</td>
<td>100%</td>
</tr>
<tr>
<td>Culture</td>
<td>75%*</td>
<td>100%</td>
</tr>
<tr>
<td>Affirm VPIII</td>
<td>46.3%**</td>
<td>100%</td>
</tr>
<tr>
<td>POCT (OSOM)</td>
<td>83-86%</td>
<td>&gt;97%</td>
</tr>
<tr>
<td>AmpliVue®TV POC</td>
<td>87.2-90.1%</td>
<td>98.2%</td>
</tr>
<tr>
<td>PCR (LDT)</td>
<td>83-92%</td>
<td>100%</td>
</tr>
<tr>
<td>TMA AptimaTV</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>ProbTec TVQ</td>
<td>98.3%</td>
<td>98.3%</td>
</tr>
</tbody>
</table>

Van Der Pol B, J Clin Microbiol. 2006; Van Der Pol, JCM 2011-02-088-089
Schwebke; Taylor: Posters STI & AIDS, 2013
** Affirm compared to nucleic acid amplification test, JCM, Carterright et al. (2013).
Gaydos, CVS 2015

Trichomonas NAAT Performance in Two Studies

In the evaluable cohort of 388 patients, the sensitivity for Trichomonas of ATV NAAT was 98.1% (53/54) versus 46.3% (25/54) for Affirm VPIII.

<table>
<thead>
<tr>
<th>Test</th>
<th>% positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet mount</td>
<td></td>
</tr>
<tr>
<td>Culture</td>
<td></td>
</tr>
<tr>
<td>OSOM</td>
<td></td>
</tr>
<tr>
<td>PCR</td>
<td></td>
</tr>
<tr>
<td>APTIMA</td>
<td></td>
</tr>
</tbody>
</table>


OSOM Rapid TV Antigen Test

- Immunochromato-graphic detection
- TV membrane proteins
- Mouse antibodies
- Latex beads/ capillary action

POSITIVE

NEGATIVE

Huppert et al.; JCM 2005; STI 2007: Sensitivity 83-90%, Specificity 98-100%
Rapid Trichomonas Test as a Model for Better STI Detection

- Trichomonas is an important pathogen
- An accurate rapid test is available
- Evaluate the rapid test as a non-invasive test in adolescents
- Opportunity to explore the impact of self-testing (using POC) on acceptability
- Apply this knowledge to other STIs as tests become available

Baseline acceptability of self vs. clinician testing

Mean total and sub-scale scores at baseline

Huppert et al. STI, 2011

Correlation Between Adolescent Self- and Clinician-POC TV Tests

<table>
<thead>
<tr>
<th>N=209</th>
<th>Clinician-POC test Positive</th>
<th>Clinician-POC test Negative</th>
<th>Kappa</th>
<th>% agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self–POC test Positive</td>
<td>38</td>
<td>4*</td>
<td>0.87</td>
<td>95.7</td>
</tr>
<tr>
<td>Self–POC test Negative</td>
<td>5†</td>
<td>162</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cells=number of subjects  *2 of 4 confirmed positive  †5 of 5 confirmed positive

Over 99% performed and interpreted the self test correctly

Huppert et al. STI 2007

AmpliVue® Trichomonas Assay

1) simple sample preparation with one-step dilution/heating
2) isothermal DNA amplification of target sequences specific to T. vaginalis by HDA
3) lateral-flow strip based colorimetric detection in a self-contained, disposable device

Sensitivity 100%; specificity 98.2% vs. culture/wet prep. Vs. NAAT PPA 87.2-90.1%


FDA Clearance of commercial TV NAAT assay (BD TVQ)

For the direct, qualitative detection of asymptomatic and symptomatic Trichomonas vaginalis DNA in females with
- clinician-collected female endocervical swabs
- patient-collected vaginal swabs in a clinical setting
- female urine specimens

TV Q* Performance vs. Culture

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Sensitivity % (95% CI)</th>
<th>Specificity % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neat Urine</td>
<td>95.5 (90.0-98.1)</td>
<td>98.7 (97.5-99.3)</td>
</tr>
<tr>
<td>Vaginal Swab</td>
<td>98.3 (93.9-99.5)</td>
<td>99.0 (98.0-99.5)</td>
</tr>
<tr>
<td>Endocervical Swab</td>
<td>96.3 (91.6-98.4)</td>
<td>99.4 (98.6-99.8)</td>
</tr>
<tr>
<td>Overall</td>
<td>96.7 (94.3-98.1)</td>
<td>99.1 (98.6-99.4)</td>
</tr>
</tbody>
</table>

From BD Trichomonas Qx for Viper XTR Package Insert

TVQ NAAT for Vaginal Trichomonas (BD)

<table>
<thead>
<tr>
<th>Assay</th>
<th># Test Pos/# true Pos</th>
<th>Sensitivity</th>
<th># Test Neg/# true Neg</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wet Mount</td>
<td>79/115</td>
<td>68.7%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Culture</td>
<td>113/116</td>
<td>97.4%</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>TVQ</td>
<td>114/116</td>
<td><strong>98.3%</strong></td>
<td>715/722</td>
<td>99%</td>
</tr>
<tr>
<td>ATV</td>
<td>115/115</td>
<td>100%</td>
<td>703/715</td>
<td>98.3%</td>
</tr>
</tbody>
</table>

Van Der Pol et al. JCM 2014;52:885-889
Comparison of Specimen Type for the Diagnosis of *Trichomonas vaginalis* (TVQ) using the BD Viper™ System in Extracted Mode (N=724)

Schwebke et al. STI & AIDS Global Congress, Vienna, Austria July 2013

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Number</th>
<th>Prevalence</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine</td>
<td>735</td>
<td>11.4%</td>
<td>95.2%</td>
<td>96.9%</td>
</tr>
<tr>
<td>Vaginal Swab</td>
<td>875</td>
<td>12.7%</td>
<td>100%</td>
<td>99.0%</td>
</tr>
<tr>
<td>CX Swab</td>
<td>920</td>
<td>12.4%</td>
<td>100%</td>
<td>99.4%</td>
</tr>
<tr>
<td>Thin Prep Pap</td>
<td>813</td>
<td>11.4%</td>
<td>100%</td>
<td>99.6%</td>
</tr>
</tbody>
</table>

**Epidemiology and Associations of *Trichomonas* with Other Infections**

- Sutton et al. CID 2007 Prev Tric: 2001-4
  - 3.1% in 3754 women; 13.3% Black, 1.3% White

- Allsworth et al. STD 2009 Trich & STDs: 2001-4
  - 3.2% in 3648 women; if Trich+ HSV more common; syphilis +6X; HIV 13X risk; attenuated after adjustment for race, age, PN

- Miller et al STD 2005;32:593-598
  - prevalence 2.3%; males 1.8%; females 2.8%; Black females 10.5%

**National Prevalence Study of *Trichomonas* Using NAAT**

- N = 7,593 women
  - ages 18-89 yr.
  - 21 States

- Overall Prevalence
  - TV 8.7%
  - CT 6.7%
  - NG 1.7%

Ginocchio et al. JCM, 50:2601-2608, 2012

**Prevalence Study of TV, CT, and GC Infections by Age (N=7,593; 21 states)**

- CT
- GC
- TV

Ginocchio et al. JCM 50:2601-2608, 2012
**Prevalence of TV: Infections by Collection Site**

- **ER**
- **Family Planning**
- **Family Practice**
- **Internist**
- **Jail**
- **OB/GYN**
- **Other/Unknown**
- **STD Clinic**

**Multivariant Analysis: Trichomonas Risk Factors, N=7,593**

<table>
<thead>
<tr>
<th>Clinic Type</th>
<th>% Prevalence</th>
<th>Multivariant OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Planning</td>
<td>5.36</td>
<td>1</td>
</tr>
<tr>
<td>ED, in pat.</td>
<td>16.63</td>
<td>3.50*</td>
</tr>
<tr>
<td>Family Practice, Int’l Med</td>
<td>6.12</td>
<td>1.27</td>
</tr>
<tr>
<td>OB/GYN</td>
<td>7.29</td>
<td>1.33</td>
</tr>
<tr>
<td>Jail, STD Clinic</td>
<td>16.41</td>
<td>2.59*</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>5.85</td>
<td>1.67</td>
</tr>
</tbody>
</table>

**Region**

- **Northeast**
- **Southwest**
- **Southeast**
- **Midwest**

P < 0.05  Ginocchio et al. JCM 50:2601-2608, 2012

**Female Trichomonas via Internet Recruitment (www.iwantthekit.org)**

- Of 1525 self collected vaginal swabs collected in the home using mailed kits
- Tested positive 2006-2010 using NAAT (Aptima) assays

TV 10.0%
CT 10.0%
GC 1.0%
Any STI 18.0%

Gaydos et al. STD 2011

**Female Trichomonas via Internet Recruitment using Vaginal swabs N = 1525**

TV 10%; CT 10%; GC 1.0%; Any STI 18.0%

Gaydos et al. STD 2011

**Table: Female Trichomonas via Internet**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Characteristic</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>14-19 yr</td>
<td>0.80 (0.43-1.46)</td>
</tr>
<tr>
<td></td>
<td>20-24 yr</td>
<td>0.62 (0.36-1.07)</td>
</tr>
<tr>
<td></td>
<td>25-29 yr</td>
<td>1.18 (0.64-2.17)</td>
</tr>
<tr>
<td></td>
<td>&gt;30 yr</td>
<td>1.00</td>
</tr>
<tr>
<td>Race</td>
<td>Black</td>
<td>2.69 (1.71-4.23)*</td>
</tr>
<tr>
<td></td>
<td>Health Insurance</td>
<td>1.67 (1.00-2.55)*</td>
</tr>
<tr>
<td>Education</td>
<td>Without BS Degree</td>
<td>1.23 (0.18-14.09)</td>
</tr>
<tr>
<td></td>
<td>Condom During Sex</td>
<td>1.04 (1.35-6.69)</td>
</tr>
<tr>
<td></td>
<td>Number PN Past Year</td>
<td>1.00 (0.03-2.51)*</td>
</tr>
<tr>
<td></td>
<td>&gt;16</td>
<td>1.61 (1.30-9.47)*</td>
</tr>
</tbody>
</table>

Other significant variables in Bivariate analysis which were Not Significant in Multivariate Analysis: Having TV previously, Having STI in past.
Trichomonas Home Test Analysis

<table>
<thead>
<tr>
<th>Question</th>
<th>Easy</th>
<th>Somewhat Easy</th>
<th>Not Easy</th>
</tr>
</thead>
<tbody>
<tr>
<td>How easy was it for you to collect the vaginal specimen correctly?</td>
<td>88 (95.6%)</td>
<td>3 (3.3%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>How easy was it for you to read the test strip and interpret (tell) the result?</td>
<td>84 (91.3%)</td>
<td>6 (6.5%)</td>
<td>2 (2.2%)</td>
</tr>
<tr>
<td>Overall, how easy was it for you to perform the test?</td>
<td>95 (92.4%)</td>
<td>5 (5.4%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Do you believe that the rapid Trichomonas test result was correct for the sample that you collected?</td>
<td>52 (56.5%)</td>
<td>39 (42.4%)</td>
<td>1 (1.1%)</td>
</tr>
</tbody>
</table>

Male Questionnaire Results

Home collection (N = 501) Chai et al.

- **Penile Swab**: 89.8%
- **Urine**: 95.3%
- **No swab**: 8; **No urine**: 2

Risk factors for *T. vaginalis* infection in men; N=919; Prevalence: 6.0%

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Categories</th>
<th>O.R.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>&gt;20</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>20-24</td>
<td>4.39</td>
</tr>
<tr>
<td></td>
<td>25-29</td>
<td>3.31</td>
</tr>
<tr>
<td></td>
<td>30-39</td>
<td>6.63</td>
</tr>
<tr>
<td></td>
<td>&gt;40</td>
<td>5.31</td>
</tr>
<tr>
<td>Race</td>
<td>African American</td>
<td>2.67</td>
</tr>
<tr>
<td>Age at first sex</td>
<td>&lt;15 yr</td>
<td>1.82</td>
</tr>
<tr>
<td>Penile discharge</td>
<td>Yes</td>
<td>2.25</td>
</tr>
</tbody>
</table>

Gaydos et al. STI April 2013

Associations of TV with other conditions/infections

- Adverse Birth outcomes
- HIV
- HPV
- PID
- Prostate Cancer
- Perinatal Transmission

Gaydos et al. STI April 2013

Trichomonas vaginalis infection in men who submit self-collected penile swabs after Internet recruitment

- Previous study indicated that self-collected penile-meatal swabs can be used for STI testing; Dize et al. STI, 2013
- From 2006-2012, 1699 men returned penile swabs after internet recruitment
- Age < 25 yr: 41%
- Black: 43%
- White: 45%
- TV prevalence: 3.7%
Association of Trichomonas with low birth weight / preterm delivery

Cotch et al. STD. 1997;24:353-360

Preterm premature rupture of membranes (RR, 1.41); 2 studies; n = 14,843; and small for gestational age infants (RR, 1.51); 2 studies; n = 14,843.

Sensitivity analyses of studies that accounted for coinfection with other sexually transmissible infection found a slightly reduced RR of 1.34 for preterm birth; 6 studies; n = 72,077; and in studies where no treatment was confirmed, the RR was 1.63; 3 studies; n = 1795.

Provides strong evidence that T. vaginalis in pregnancy is associated with an increased risk of preterm birth.

Based on fewer studies, there were also substantial increases in the risk of preterm premature rupture of membranes and small for gestational age infants.

Further studies that address the current gaps in evidence on treatment effects in pregnancy are needed.

Trichomonas and Risk for HIV

- Trichomonas treatment reduces vaginal HIV shedding

Kissinger et al. STD. 2009;36:11-16

- Of 60 HIV + women 18.3% were TV positive after 1 month vs. of 301 HIV – women, 8% were TV + at 1 month

Kissinger et al. Repeat infections with TV among HIV + and HIV – women CID 2008;46:994-999

Impact of Trichomonas on HIV Model

- HIV patients interviewed about risk factors baseline, 3 & 6 mo.

TV Therapy on Genital HIV Burden

- Estimated annual number new HIV transmissions in US attributable to TV cofactor effect of 2-5 fold increased risk (Shafir, Clin Micro Rev 2009; Chesson STD 2004)
- 557 women not receiving antivirals; 46 f/u; 80% cured; Plasma viral load not significantly different
- Genital viral load decreased significantly 0.5 \( \log_{10} \)
- After TV therapy, mean genital tract load decreased from 4.66 to 4.18 \( \log_{10} \) (\( p <0.01 \))

Association of Trichomonas with Duration of HPV Infection

- 3 city STD clinics 49 HPV-infected adolescents tested
- Concurrent infections were measured
- Prolonged HPV infection (during the HPV infection) was associated with
  - Oncogenic HPV AHR 0.58 (95%CI 0.39-0.84)
  - Low (<60%) condom use AHR 0.53 (95%CI 0.33-0.84)
  - Coinfection with CT AHR 0.58 (95% CI 0.31-0.89)
  - Coinfection with Trichomonas AHR 0.32 (95% CI 0.16-0.64)

Miscellaneous Associations

- Association with PID (Cherpes STD 2006) 2-fold increased risk
- Association of TV w/ increased PID in women with HIV. Moodley et al. Clin Infect Dis 2002
- Risk of subsequent Prostate Cancer (Sutcliffe et al. CA Epidemiol Bio Prev 2006) OR 1.43
- Perinatal transmission 5-6 case reports (Trintis et al. IJSA 2010;21::606-607)

T. vaginalis therapy

Recommended Regimen:
Metronidazole 2 g orally in a single dose
OR
Tinidazole 2 g orally in a single dose

Alternative Regimen:
Metronidazole 500 mg orally twice a day for 7 days

Estimates of Direct Cost/Case and Burden of Trichomonas in US

Extracted private insurance claims 2001-2005 MEDISTAT Market Scan database
Outpatient costs: visit $97; drug $9
Most common Dx wet prep
Avg. total cost for women 15-24 yr ($120) significantly higher all other ages (\( p<0.01 \))
Estimated: Overall annual economic burden of trichomoniasis to be $16.9 million among all U.S. women; Incidence rate: all ages 92/100,000 (higher 25-29 yr @185/100,000 )

Wineus-Eduelson et al. STD 2009;36:395-399
Estimates of Annual Number & Costs New HIV Attrb. to TV in US

- Mathematical Model to estimate probability woman w/TV would acquire HIV
- 746 new HIV cases attributed to TV/year
- Cost of $167 million
- Cost–effectiveness studies needed

Chesson et al. STD 31:547-551, 2004

Knowledge Gaps of TV Outcomes

- Studies linking trichomonas to adverse birth outcomes
- More studies on the link between TV and HIV, PID, and/or persistent HPV
- Persistence in older women
- Economic impact of untreated TV/cost savings associated with TV screening
- Public Awareness: Of ASHA survey of 1,000 females, ages 18-50, only 22% familiar with TV

TV Tricks for the Trade Needed

- More focus on how TV disrupts the vaginal ecology; natural history/rate of spontaneous clearance studies
- Better understanding of epidemiology of TV
- Studies to examine TV as a Public Health priority
- Better understanding of high prevalence of TV in older women and Black women
- Study on the impact of chronic TV infection in men and adverse health outcomes (possible link to prostatitis/BPH/prostate cancer)

Summary and Conclusion

- Trichomonas is highly prevalent in many populations studied; often associated with adverse birth outcomes, race, increased age, and acquisition of HIV
- Diagnostic tests are improving; there are now FDA cleared, commercial NAATs
- POC tests offer hope for rapid testing and immediate treatment
- Isn’t it Time to do Better for our Patients?

Acknowledgements

- Mary Jett-Goheen
- Mathilda Barnes
- Laura Dize
- Justin Hardick
- Jeff Holden
- Billie Jo Masek
- Perry Barnes
- Brianna Kyburz
We have the tools

- We have the diagnostic tests
- We have the epidemiologists
- We have the capability to perform C-E models
- We have the researchers
- We can obtain the data
- Do we have the will? The funds?
- How do we influence public health officials?

Priority Research Discussion

1. Adverse Birth outcomes
2. HIV Association
3. Why Persistence
4. TV in Older Women; Health Disparities
5. Public Health Cost
6. Public Health Reporting
7. Education and Public Awareness

Needs for a Promising Future

- Fund research for priority areas
  - HIV association, Adverse birth outcomes
- Learning how to effectively use new research to improve detection of TV and provide cost-effective ways to increase number of patients being treated
- Novel approaches include testing outside a clinic, new dx tests, and maybe self-testing (OTC)
- Yet, challenges will continue to remove barriers

Conclusions

- With new tools available for diagnostic tests, new methods for recruiting patients for STI testing, and new sample types available
- Shouldn’t public health officials consider more testing of trichomonas in patients in view of the potential sequelae such as low birth weight babies, PID, and association with HIV acquisition and transmission?
- Isn’t it Time to do Better for our Patients?

“Optimal prevention and control strategies for *T. vaginalis* infection should be further explored as a means of closing the racial disparity in prevalence and decreasing other adverse outcomes associated with this sexually transmitted infection”

Sutton et al. CID 2007 National Center HIV/AIDS, CDC

Persistence of Trichomonas

![Persistence of Trichomonas diagram]

“Optimal prevention and control strategies for *T. vaginalis* infection should be further explored as a means of closing the racial disparity in prevalence and decreasing other adverse outcomes associated with this sexually transmitted infection”

Sutton et al. CID 2007 National Center HIV/AIDS, CDC

Persistence of *Trichomonas vaginalis* infections detected among women in intervals during which they were not having sex. (3,6,9,12 mo f/u)

Each row represents the history of 1 woman. Shaded areas are intervals during which the woman reported not having sex.

Positive (+) and negative (−) culture test results for *T. vaginalis* are indicated for each woman.

Peterman et al. CID 48(2):259-260
Women do not know about: Trichomonas (ASHA SURVEY)

- Research Now, an independent research company
- Interviews conducted between January 28th – February 2nd, 2013
- Nationally representative sample, 1,000 females, ages of 18-50

<table>
<thead>
<tr>
<th>Disease</th>
<th>Very familiar</th>
<th>Somewhat familiar</th>
<th>Not very familiar</th>
<th>Not at all familiar</th>
<th>Don't know</th>
<th>Total familiar</th>
<th>Total not familiar</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>27%</td>
<td>52%</td>
<td>14%</td>
<td>4%</td>
<td>0%</td>
<td>79%</td>
<td>20%</td>
</tr>
<tr>
<td>Herpes or genital herpes</td>
<td>22%</td>
<td>40%</td>
<td>22%</td>
<td>7%</td>
<td>2%</td>
<td>88%</td>
<td>31%</td>
</tr>
<tr>
<td>Human papillomavirus or HPV</td>
<td>21%</td>
<td>43%</td>
<td>24%</td>
<td>13%</td>
<td>2%</td>
<td>64%</td>
<td>25%</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>15%</td>
<td>41%</td>
<td>28%</td>
<td>14%</td>
<td>2%</td>
<td>56%</td>
<td>42%</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>15%</td>
<td>39%</td>
<td>33%</td>
<td>14%</td>
<td>2%</td>
<td>53%</td>
<td>45%</td>
</tr>
<tr>
<td>Syphilis</td>
<td>13%</td>
<td>37%</td>
<td>34%</td>
<td>13%</td>
<td>2%</td>
<td>51%</td>
<td>47%</td>
</tr>
<tr>
<td>Trichomonias or trich</td>
<td>7%</td>
<td>15%</td>
<td>14%</td>
<td>8%</td>
<td>1%</td>
<td>79%</td>
<td>21%</td>
</tr>
</tbody>
</table>

Acceptability of self-testing increases with time

Acceptability of Self-testing for Trichomoniassis

- 15-item Survey: rated on a 3 point Likert scale, "not at all" "somewhat" "very"
- Four subscales:
  - comfort in collecting a self-swab
  - trust in test result
  - self-efficacy
  - confidence in ability to self-swab and perform the test.
- Compared
  - Self- to clinician-testing at baseline
  - Self-testing over time
  - Self-trust to clinician-testing over time

Huppert et al. STI, 2010, 2011

Trichomonas Home Test Analysis

<table>
<thead>
<tr>
<th>Question, N = 92</th>
<th>Trust Very Much</th>
<th>Trust Somewhat</th>
<th>Do Not Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>How much do you trust the result of the rapid trichomonas test that you collected and tested?</td>
<td>69 (65.2%)</td>
<td>31 (30.7%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Definitely Test</td>
<td>69 (65.2%)</td>
<td>31 (30.7%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Probably Test</td>
<td>14 (15.2%)</td>
<td>14 (15.2%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>Not Test</td>
<td>1 (1.1%)</td>
<td>1 (1.1%)</td>
<td>1 (1.1%)</td>
</tr>
</tbody>
</table>

Would you test yourself at home for trichomoniasis if the rapid trichomonas test were available over-the-counter?

<table>
<thead>
<tr>
<th>Maximum Price</th>
<th>10</th>
<th>20</th>
<th>30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Youself</td>
<td>62 (46.6%)</td>
<td>97 (40.2%)</td>
<td>3 (14.1%)</td>
</tr>
</tbody>
</table>

Trichomonias Home Test Analysis
### Trichomonas and Risk for HIV

<table>
<thead>
<tr>
<th>Relative Risks in per-Act Probability Transmission, N = 3297 couples</th>
<th>RR</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV Infected PN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma HIV copies.ml</td>
<td>2.89</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Condom Use in F/U</td>
<td>0.22</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>HIV Uninfected PN</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, per 5 yr</td>
<td>0.82</td>
<td>0.006</td>
</tr>
<tr>
<td>HSV-2 + enrollment</td>
<td>2.14</td>
<td>0.012</td>
</tr>
<tr>
<td>GUD</td>
<td>2.65</td>
<td>0.004</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>2.57</td>
<td>0.002</td>
</tr>
<tr>
<td>Cervicitis/vaginitis</td>
<td>3.63</td>
<td>0.005</td>
</tr>
<tr>
<td>Circumcision</td>
<td>0.53</td>
<td>0.37</td>
</tr>
</tbody>
</table>

Hughes et al. Determinants per-coital act HIV infectivity in African serodiscordant couples JID 2012;205:358-365. 86 transmissions; MTF 0.0019; FTM 0.0010

### Estimates of Sequelae Costs for Trichomonas in US?

- If direct overall annual economic burden of trichomonas is $18.9 M among all U.S. women, what about the population attributable cost for possible sequelae, if there are 4 million cases of TV/year?

- **Cost of premature infant’s hospitalization?** [550,000 babies/yr]
  - $49,000 in yr 1 (March of Dimes 2009)
  - $26 billion /yr (IOM)

- **Cost of PID?** [1378 (Rein-RTI & GH-CDC) - $1410 (IOM) /case]
  - $4 billion /yr (AHRQ) [1.2 million visits/yr]

- **Cost of HIV?** $618,900 /yr [50,000 new HIV infections /yr]
  - [1.1 million living with HIV/AIDS]

- **Cost of Cancer; association with HPV infection?**
  - Do we need a C-E study to convince public health officials and lawmakers of the necessity of a trichomonas control program in the US?

- Premature infant’s hospitalization? [550,000 babies/yr]
  - $49,000 in yr 1 (March of Dimes 2009)
  - $26 billion /yr (IOM)

- PID?
  - [1378 (Rein-RTI & GH-CDC) - $1410 (IOM) /case]
  - $4 billion /yr (AHRQ) [1.2 million visits/yr]

- HIV?
  - $618,900 /yr [50,000 new HIV infections /yr]
  - [1.1 million living with HIV/AIDS]