2015 CDC STD Treatment Guidelines Update for Generalists

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Consultant:
GSK

Speakers Bureau:
None
Off-Label Disclosure

This presentation will include discussion of the following non-FDA-approved or investigational uses of products/devices:

- Oral and rectal testing for *N. gonorrhoeae* and *C. trachomatis* with NAAT
- Testing for *T. vaginalis* by NAAT (in men)
- Testing for *M. genitalium* utilizing NAAT
Sexually Transmitted Diseases
Treatment Guidelines, 2010
2015 CDC STD Treatment Guidelines

“Typical” Guidelines Subjects NOT Covered in This Talk

Adolescents

HPV

Tests You Do Not Do
  Darkfield Microscopy
  Gram Stain
2015 CDC STD Treatment Guidelines

Emerging Topics

STI Assessment and Management for the Generalist

Sex Partner Status – GLBTQ Awareness

*Mycoplasma genitalium*

Hepatitis C as an STI
Lecture Overview

I. Sexual Health - A subtle but high impact paradigm shift

II. Changes to the CDC Treatment Guidelines/Hot Topics
   A. Gonococcal Antimicrobial Resistance
   B. Extragenital Testing
   C. Urethritis Diagnosis
   D. Trichomoniasis – NAATs/ Males
   E. Syphilis Serologic Tests and Their Interpretation
   E. *Mycoplasma genitalium* - an emerging pathogen
Sexual Health
Changing the Paradigm

Why are rates of curable STIs (Gonorrhea, Chlamydia, Syphilis) Higher in the U.S Than in Any Other Developed nation on Earth??
Widely Held Beliefs About STDs

“Nice” (normal?) people do not get STDs

If you are not “promiscuous” you will not get STDs, unless your partner 

betrays you

Testing for STDs is warranted primarily for persons with risks for STD

When STDs are present, its obvious

Discussion of the need for STD testing is offensive to patients
Sexual Health
Changing the Paradigm

Sexually Transmitted Infections, Not Diseases

STD  STI
Consequences of STI-Related Stigma

Personal (Individual)
- Delays in using or seeking preventative health care
  - Condoms
  - Vaccines
  - Screening
- Delays in seeking care for perceived problems
- Ineffective partner notification

Provider
- Hesitancy in seeking relevant information
- Differential testing
- Changes to provider-client interactions

Population
- Guilt by association
- Differential Care
- Profiling
Sexual Health

Sexual health is a broad perspective that spans the entire lifespan encompassing topics which include:

- Sex Education
- STD/HIV Management
- Interpersonal Relationships
- Family Planning
- Reproductive Tract Care
- Erectile Dysfunction/
  Diminished Desire
A sexual health framework shifts the approach from a more traditional loss frame approach to a gain frame

Framing – influenced by context; anticipated to have selective influence on perception, encouraging certain interpretation, discouragement, others (Wikipedia)

Gain frame – Emphasizes positives, benefits

Loss frame – Emphasizes risks, potential harm, potentially fueling shame and stigma
Loss Frame/Gain Frame Examples
Sexual History

Loss Frame

Partner Type
Have you ever had homosexual sex?

Sites of exposure
Have you had oral or rectal sex, or just regular sex?

Gain Frame

Partner Type
Are your partners men, women or both?

Sites of exposure
When you have sex, what sites are exposed- oral, rectal or genital?
A Sexual Health “Litmus Test” for Clinicians

Have you ever apologized to a patient for making a diagnosis of chlamydia, trichomoniasis or HIV?
Three Question Sexual History for Adults

Take the history, assess risks

When was the last time you had sex?
How many partners have you had in the past year?
Were they men, women or both?

Don’t hesitate to screen. STI screening is not judgemental it is health promoting

Routinely provide STI prevention messages as part of continuing care
# Gonorrhoea—Rates by Age and Sex, United States, 2012

<table>
<thead>
<tr>
<th>Age</th>
<th>Rate (per 100,000 population)</th>
<th>Men</th>
<th>Women</th>
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<tr>
<td>10-14</td>
<td>25.3</td>
<td>462.8</td>
<td>521.2</td>
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<td>15-19</td>
<td>184.2</td>
<td>239.0</td>
<td>578.5</td>
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<tr>
<td>20-24</td>
<td>107.5</td>
<td>293.9</td>
<td></td>
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<tr>
<td>25-29</td>
<td>75.1</td>
<td>184.2</td>
<td></td>
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<tr>
<td>30-34</td>
<td>44.4</td>
<td>107.5</td>
<td></td>
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<tr>
<td>35-39</td>
<td>14.4</td>
<td>75.1</td>
<td></td>
</tr>
<tr>
<td>40-44</td>
<td>3.0</td>
<td>44.4</td>
<td></td>
</tr>
<tr>
<td>45-54</td>
<td>3.0</td>
<td>14.4</td>
<td></td>
</tr>
<tr>
<td>55-64</td>
<td>0.4</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>65+</td>
<td>0.4</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>108.7</td>
<td>105.8</td>
<td></td>
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</tbody>
</table>
DR. READ
EUREKA TONIC

DR. READ’S SYPHILORRHOEA “READY RELIEF REMEDY.” Antiseptic, Stimulant, Sedative, Diuretic, Healing. Relieves Coughs, Bronchial Catarrh, Gastritis, Inflammation, Piles, Sores, Burning, Muddy, Scalding, Itching Discharges, Pains, Weak Back, Kidney, Bladder troubles, etc. with this “AD.” $1 Value. Postpaid by EUREKA CO., 1618 South Street, Phila.

For Health, Happiness, Long Life, Try Dr. Read’s Young Youth Tonic Drink. Free Sample at Store.

SYPHILORRHOEA

Fig. 37.—Author's treatment outfit. Patient stands in front of the basin, which is placed lower than the average basin height: A, Position of jar for anterior irrigations; B, position of jar for posterior irrigations; C, dangerous pressure for gonococcal urethritis.
Fig. 39.—The compression of the middle and ring fingers is then released and the entire *anterior* urethra is irrigated.
Emerging Gonococcal Antimicrobial Resistance – Deja Vu

Pre-1937 Antiseptic Irrigation With Potassium Permanganate, Silver Salts, Mercurochrome

1937 Sulfonamide Therapy

1943 Penicillin Therapy (Mahoney et al)

1944 35% Treatment Failure With Sulfonamides

1972 Penicillin Regimen Increased to 4.8 Million Units Plus Probenecid
Previously Recommended Medications For Gonorrhea Therapy

- Sulfonamides
- Penicillins
- Macrolides
- Tetracyclines
- Aminoglycosides
- Spectinomycin
- Fluroquinolones
Penicillin, Tetracycline, and Ciprofloxacin Resistance, 2013

- PenR = penicillin resistant (β-positive or MIC ≥2 µg/ml)
- QRNG = ciprofloxacin MIC ≥1 µg/ml
- TetR = tetracycline resistant (MIC ≥2 µg/ml)

Susceptible 66.1%
Neisseria gonorrhoeae Treatment Failure and Susceptibility to Cefixime in Toronto, Canada

Cephalosporin-Resistant Gonorrhea in North America
Proportion of Isolates with MICs to Cefixime ≥ 0.25 μg/ml

n=52,785

Percentage of isolates

Gonococcal Isolate Surveillance Project (GISP)

* p_trend < 0.05
Preliminary data
Percentage of Isolates with Elevated Ceftriaxone MICs (≥ 0.125 µg/ml) by Gender of Sex Partner, 2008–2013
**N. Gonorrhoeae Treatment Failures to Cefixime, Toronto, Canada**

Rx failure overall – 6.8% (95% CI – 3.1-12.5%)

- If cefixime MIC $\geq 0.12$ – 25% (95% CI 10.7-44.9%)
- If cefixime MIC $< 0.12$ – 1.9% (95% CI 0.23-6.7%)

RR 13.13 (95% CI 2.9-59.72)

**Treatment failures:**
- 4 of 76 urethral (5.3%)
- 2 of 7 pharyngeal (28.6%)
- 3 of 39 rectal (7.7%)

2015 CDC STD TREATMENT GUIDELINES
Uncomplicated Gonorrhea

Ceftriaxone 250 mg IM

PLUS

Azithromycin 1.0 g Single Dose or
Doxycycline 100 BID x 7d
Even if chlamydia negative
### Proposed Alternative GC Treatment

#### 2015 CDC STD Treatment Guidelines

<table>
<thead>
<tr>
<th>Treatment Plan</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefixime 400mg po x 1 Plus Azithromycin 1gm po x 1</td>
<td>14d TOC</td>
</tr>
<tr>
<td>If cephalosporin allergy: Azithromycin 2gm po x 1</td>
<td>14d TOC</td>
</tr>
</tbody>
</table>
Salvage Therapy:
- Gentamycin 240 IM/ Azithromycin 2.0g PO (IM Administration/Toxicity)
- Gemifloxacin 340 mg/Azithromycin 2.0g PO (GI Toxicity)

On The Horizon:
- Solithromycin
- Delafloxacin
- AZ D0914
- Others
Reasons for STD Treatment Failure

Reinfection

Wrong Therapy
  Wrong diagnosis
  Wrong dosage/duration
  Self medication

Resistant Organisms

Other
Changing Paradigms For Urogenital Specimen Collection

Pre-NAAT’s: Specimen Quality Critical
- Endocervical Or Urethral Swabs
- Swab Order Impacts Test Results

: Culture > Non-Amplified Nucleic Acid Detection > Antigen Detection

NAAT’s: More Forgiving Specimen Collection
- Vaginal Swab > Endocervical Swab > initial Void Urine
How common are extra-genital sexual behaviors?

✦ Males:
  – Active oral
    • Lifetime 77%
    • Last sex 27%
  – Passive oral
    • Lifetime 79%
    • Last sex 28%

✦ Females
  – Active oral
    • Lifetime 68%
    • Last sex 19%
  – Passive oral
    • Lifetime 73%
    • Last sex 28%

# Performance of NAATs for Diagnosis of Pharyngeal *N. Gonorrhoeae* and Infections

<table>
<thead>
<tr>
<th></th>
<th>Pharyngeal Gonococcal Infections (N=961)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Sensitivity (95%)</td>
</tr>
<tr>
<td>ProbeTec (SDA)</td>
<td>97.1 (85.1-99.9%)</td>
</tr>
<tr>
<td>Amplicor (PCR)</td>
<td>91 (78.1-98.3%)</td>
</tr>
<tr>
<td>Aptima Combo2 (TMA)</td>
<td>100 (89.7-100%)</td>
</tr>
<tr>
<td>Culture</td>
<td>65.4 (50-78%)</td>
</tr>
</tbody>
</table>

Performance of NAATs for Diagnosis of Pharyngeal *N. Gonorrhoeae* and Infections

<table>
<thead>
<tr>
<th>Pharyngeal Gonococcal Infection By Site</th>
<th>No (%) Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genital and Oral</td>
<td>23 (28%)</td>
</tr>
<tr>
<td>Genital Only</td>
<td>28 (34.1%)</td>
</tr>
<tr>
<td>Oral Only</td>
<td>31 (37.8%)</td>
</tr>
<tr>
<td>Total Genital or Oral</td>
<td>82 (100%)</td>
</tr>
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</table>

Performance of NAATs for Diagnosis Rectal *N. Gonorrhoeae* Infections

<table>
<thead>
<tr>
<th>Site</th>
<th>No (%) Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genital and Rectal</td>
<td>12 (31.6%)</td>
</tr>
<tr>
<td>Genital Only</td>
<td>11 (28.9%)</td>
</tr>
<tr>
<td>Rectal Only</td>
<td>15 (39.5%)</td>
</tr>
<tr>
<td>Genital or Rectal</td>
<td>28 (100%)</td>
</tr>
</tbody>
</table>

## Performance of NAATs for Diagnosis of Rectal *C. trachomatis* Infection

<table>
<thead>
<tr>
<th>Chlamydial Rectal or Genital Infections By Site</th>
<th>No (%) Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site</td>
<td></td>
</tr>
<tr>
<td>Genital and Rectal</td>
<td>20 (40.8%)</td>
</tr>
<tr>
<td>Genital Only</td>
<td>6 (12.2%)</td>
</tr>
<tr>
<td>Rectal Only</td>
<td>23 (46.9%)</td>
</tr>
<tr>
<td>Genital or Rectal</td>
<td>49 (100%)</td>
</tr>
</tbody>
</table>

Bachmann, L et al. *J. Clin Microbiol.* 2010;48(5);1827-1832
Case 1

History: 29yo male presents to your office with urethral “itching” 7 days. Two weeks ago while at a business convention he had unprotected sex with a colleague.
Case 1 (Cont)

The most likely cause of his symptoms is:
1. Gonorrhea
2. Non gonococcal Urethritis (NGU)
3. Human Papillomavirus Infection
4. Post Coital Remorse
History: 29yo male presents to your office with urethral “itching” 7 days. Two weeks ago while at a business convention he had unprotected sex with a colleague.

Diagnosis: NGU
The further testing should include:

1. Urine testing for gonorrhea and chlamydia
2. Urine testing for gonorrhea, chlamydia and trichomoniasis
3. HIV testing
4. Syphilis testing
5. 1,3,4
6. 2,3,4
7. None of the above
Anticipated Urethritis Diagnosis Updates
2014 CDC STD Treatment Guidelines

- NGU cutoff will be lowered to \( \geq 2 \) WBC/hpf

- \( T. vaginalis \) testing could also be considered in areas or populations of high prevalence
  - No FDA-cleared NAAT for \( T. vaginalis \) detection in men in the U.S.
  - Several large reference labs have performed the necessary CLIA validation of a urine-based \( T. vaginalis \) NAAT for men

- Currently no commercially available diagnostic test for \( M. genitalium \) cleared by the FDA for use in the U.S.
  - Some medical centers and commercial labs have developed a \( M. genitalium \) NAAT

- Methylene Blue/Gentian Violet (MB/GV) smear should be considered as an alternative to Gram stain for clinical diagnosis of urethritis
Urethritis: Etiologies

✿ Infectious
  - *N. gonorrhoeae*
  - NGU
    • *C. trachomatis*
    • *U. urealyticum*
    • *M. genitalium*
    • *T. vaginalis*
    • HSV
    • Other bacteria (i.e. GNR, <5%)
    • UNKNOWN! (20-30%)
    • Dysbiotic Origin?

✿ Non-infectious
  - Chemical
  - Allergic
  - Autoimmune

✿ ? Frequency
# Gram stain PMN Cutoff for Clinical Diagnosis of Urethritis in Men with Urethral Signs and/or Symptoms

<table>
<thead>
<tr>
<th>Gram stain stratum</th>
<th>Number</th>
<th>CT+</th>
<th>%</th>
<th>95% CI</th>
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<tr>
<td>0</td>
<td>2612</td>
<td>126</td>
<td>4.8</td>
<td>4.0-5.7</td>
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<tr>
<td>1</td>
<td>1083</td>
<td>71</td>
<td>6.6</td>
<td>5.2-8.1</td>
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<tr>
<td>2</td>
<td>284</td>
<td>46</td>
<td>16.2</td>
<td>12.2-20.8</td>
</tr>
<tr>
<td>3</td>
<td>627</td>
<td>93</td>
<td>14.8</td>
<td>12.2-20.8</td>
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<td>4</td>
<td>753</td>
<td>136</td>
<td>18.0</td>
<td>15.4-20.9</td>
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<td>5</td>
<td>609</td>
<td>156</td>
<td>25.6</td>
<td>22.2-29.2</td>
</tr>
<tr>
<td>6</td>
<td>297</td>
<td>103</td>
<td>34.7</td>
<td>29.4-40.2</td>
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<tr>
<td>7</td>
<td>249</td>
<td>61</td>
<td>24.4</td>
<td>19.4-30.0</td>
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<td>8</td>
<td>358</td>
<td>122</td>
<td>34.0</td>
<td>29.3-39.0</td>
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<tr>
<td>9</td>
<td>139</td>
<td>54</td>
<td>38.8</td>
<td>31.0-47.1</td>
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<tr>
<td>10</td>
<td>533</td>
<td>220</td>
<td>41.2</td>
<td>37.1-45.4</td>
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<td>&gt;10</td>
<td>3878</td>
<td>1699</td>
<td>43.8</td>
<td>42.3-45.5</td>
</tr>
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</table>

Reitmeijer Sex Trans Dis 2012;39(1):18-20
Does MG cause Male Urethritis?

✨ Acute urethritis – 38 studies
  - 15% MG+ (median) in urethritis cases
  - 22% MG+ (median) in NCNGU cases

✨ Persistent urethritis – 6 studies
  - 12-14% MG+ men with persistent/recurrent urethritis

Compliments: Lisa Manhart
Anticipated NGU Treatment Updates
2014 CDC STD Treatment Guidelines

- Azithromycin and doxycycline regimens remain recommended for initial NGU treatment
- In areas with high *T. vaginalis* prevalence, heterosexual men with persistent/recurrent urethritis should be presumptively treated
- *M. genitalium* should be suspected in persistent/recurrent urethritis
  - Moxifloxacin 400mg daily x ≥7 days should be considered for subjects failing azithromycin treatment
- Persistent or recurrent NGU after presumptive treatment for *M. genitalium* or *T. vaginalis* should be referred to a urologist
Proposed Persistent/Recurrent Urethritis Treatment
2014 CDC STD Treatment Guidelines

If azithromycin NOT given for 1st episode:
- Azithromycin 1 g orally in a single dose PLUS
- Metronidazole 2 g orally in a single dose OR
- Tinidazole 2 g orally in a single dose

If azithromycin given for 1st episode:
- Moxifloxacin 400 mg orally qd x 7d PLUS
- Metronidazole 2 g orally in a single dose OR
- Tinidazole 2 g orally in a single dose
Case 2

A 40 YO male presents following notification that his recently tested blood donation tested positive for syphilis. He is a local businessman, unmarried, states he has been involved in a monogomous relationship for the past two years. He was treated with levofloxacin for a urinary tract infection by a colleague 6 months ago.

On further history, that sex partner is a male who works as a flight attendant. To the patient’s knowledge, neither has been tested for other STIs since their relationship began.

The laboratory reports the positive blood test was an EIA test for syphilis. Your next step should be:
Case 2 continued…

1. Order an TPHA test

2. Order an RPR test

3. Initiate treatment with benzathine penicillin G, 2.4 Mu

4. Request that the patient’s partner present for evaluation

5. Screen for gonorrhea and chlamydia at all recent sites of sexual exposure

6. Test for HIV
Reasons for Serological Testing For Syphilis

Screening

Diagnostic Testing

Monitoring Outcomes of Therapy
Serologic Tests for Syphilis

Nontreponemal Tests (VDRL, RPR)
- Antigen - cardiolipin-lecithin-cholesterol
  Quantitative

Treponemal Tests (FTA-ABS, MHA-TP, TPPA, EIAs)
- Treponemal Antigens
  Qualitative
EIA Serologic Tests for Syphilis

EIA= Enzyme Immunoassay

Pro’s
- Cloned Treponemal Antigens
- Easy to do in large numbers.
- Inexpensive

Con’s
- Limited data on specificity
- Positives need quantitative test to assess response to therapy and perhaps for confirmation
Reasons For EIA+/RPR- Test Results

- Past (treated) Syphilis
- Chronic Untreated Syphilis
- Very Early Syphilis
- False Positive
CDC-Recommended Algorithm for Reverse Sequence Syphilis Screening

CDC. MMWR 2011; 60 (5): 133-137
RPR is positive at a 1:16 dilution, HIV is negative, urine and rectal specimens are positive for *C. trachomatis*. The patient is treated with 2.4 Mu of benzathine penicillin and 1.0g of azithromycin for chlamydia. As follow-up, he should:

1. Have repeat syphilis testing in three months
2. Have repeat HIV testing in three months
3. Have repeat testing for chlamydia at 3 months
4. All of the above
Case 2 continued...

Three months later the patient returns for follow-up. Gonorrhea, chlamydia, and HIV tests are negative. The RPR is positive at a 1:8 dilution. Based on his test results, the patient is:

1. A treatment failure and should now be re-treated with 2.4 Mu of benzathine penicillin G for three weeks.

2. Successfully treated and can be followed routinely

3. Serofast
Interpretation of Changing STS Titers

Error of RPR VDRL Tests - ± 1 dilution

Meaningful change is 2 dilution (or 4-fold) change in titer
  e.g. 1:2 ↗ 1:4 or 1:1, no meaningful change
  1:2 ↗ 1:8, meaningful change

Quantitative RPR or VDRL test, results are not interchangeable

Two dilution decline in titer indicates response to therapy
however, failure to decline ≥ 2 dilutions does not necessarily
mean patient has failed treatment
Meaningful Change in STS Titers - +/- 2 Dilutions

- Two tube or fourfold dilution decrease
- \( \frac{128}{4} = 32 \)
Added Benefit of Nucleic Acid Amplification Testing for the Diagnosis of *Trichomonas vaginalis* Among Men and Women Attending a Sexually Transmitted Diseases Clinic

Christina A. Muzny,1 Reaford J. Blackburn,2 Richard J. Sinsky,3 Erika L. Austin,1 and Jane R. Schwebke1

1Division of Infectious Diseases, 2Department of Medicine, University of Alabama at Birmingham, and 3Quality, Improvement, and Decision Support, Jefferson County Department of Health, Birmingham, Alabama

(See the Editorial Commentary by Taylor on pages 842–4.)

**Background.** *Trichomonas vaginalis* (TV) is the most common nonviral sexually transmitted infection (STI) in the world. However, TV is not a reportable STI and, with the exception of HIV-positive women, there are no guidelines for screening in women or men. The objective of this study was to determine the added value of nucleic acid amplification tests (NAATs) for detection of TV in men and women at high risk for infection as well as correlates of infection.

**Methods.** This was a review of clinical and laboratory data of men and women presenting to the Jefferson County Department of Health Sexually Transmitted Diseases (STD) Clinic and receiving a TV NAAT.

**Results.** During 2012–2013, 6335 patients (3821 women and 2514 men) received a TV NAAT on endocervical, urethral, or urine specimens. Overall TV prevalence was 20.2%; 27.0% in women and 9.8% in men. Correlates of TV among men included age >40 years, African American race, and ≥5 polymorphonuclear cells per high-power field on urethral Gram stain. Age >40 years, African American race, leukorrhea on wet mount, elevated vaginal pH, positive whiff test, and concurrent gonococcal infection were positively associated with TV among women. TV NAAT detected approximately one-third more infections among women than wet mount alone.

**Conclusions.** TV prevalence among men and women was high in this study, suggesting that both groups should be routinely screened, including those aged >40 years. Improved detection of TV by routine implementation of NAATs
STI Prevalence in Women by Pathogen and Age

Proposed Trichomoniasis Treatment
2014 CDC STD Treatment Guidelines

New Episode
Tinidazole 2 g PO single dose OR
Metronidazole 2 g PO single dose
Metronidazole 500 mg po BID for 7d (alternative, rec if HIV+)

Treatment Failure of 2 g metronidazole single dose
Metronidazole 500 mg BID x 7d

Treatment Failure – Additional Options
Tinidazole or Metronidazole 2 g PO daily x 5d 7d
Tinidazole 2-3g PO daily x 14d plus intravaginal tinidazole

Treatment Failure – Alternative Additional Options
High-dose tinidazole + intravaginal paromomycin
Nitazoxanide PO
Intravaginal boric acid-
This presentation will include discussion of the following non-FDA-approved or investigational uses of products/devices:

- Oral and rectal testing for *N. gonorrhoeae* and *C. trachomatis* with NAAT

- Testing for *T. vaginalis* by NAAT (in men)

- Testing for *M. genitalium* utilizing NAAT
“Shhh, Zog! ... Here come one now!”
Acknowledgement

Laura Bachmann, MD, MPH
William M. Geisler MD, MPH

Resources

www.stdptc.org  www.nnptc.org