WHAT IS NEW WITH THE NEW 2015 CDC STD GUIDELINES

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Acknowledgments

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  ○ Emory University

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  ○ California Department of Public Health

• Lisa E. Manhart, PhD
  ○ University of Washington
Summary

These guidelines for the treatment of persons who have or are at risk for...
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- Introduction
- Methods
- Clinical Prevention Guidance
  - STD/HIV Risk Assessment
  - STD/HIV Prevention Counseling
  - Prevention Methods
  - Partner Services
  - Reporting and Confidentiality
- Special Populations
  - Pregnant Women
  - Adolescents
  - Children
  - Persons in Correctional Facilities
  - MSM
  - WSW
  - Transgender Men and Women
- Emerging Issues
U.S. Transgender Men and Women STD/HIV Epi

- Transgender women estimated HIV prevalence = 28%
  - 56% estimated HIV prevalence among black transgender women

- Transgender men
  - fewer data
  - lower HIV prevalence than transgender women
Transgender Men and Women

• Assess STD- and HIV-related risks based on current anatomy and sexual behaviors
  o diversity of transgender persons regarding surgical affirming procedures, hormone use, and their patterns of sexual behavior
  o providers must remain aware of common STD Sx and screen for STDs on basis of behavior and sexual practices
Have a History of Penicillin Allergy

- Persons in Correctional Facilities
- MSM
- WSW
- Transgender Men and Women

 Emerging Issues
- Hepatitis C
- *Mycoplasma genitalium*

 HIV Infection: Detection, Counseling, and Referral

 Diseases Characterized by Genital, Anal, or Perianal Ulcers
- Chancroid
- Genital HSV Infections
- Granuloma Inguinale (Donovanosis)
- Lymphogranuloma Venereum

 Syphilis
- Syphilis During Pregnancy
- Congenital Syphilis

 Management of Persons Who Have a History of Penicillin Allergy

 Diseases Characterized by Urethritis and Cervicitis
- Urethritis
- Nongonococcal Urethritis
- Cervicitis

 Pelvic Inflammatory Disease (PID)

 Epididymitis

 Human Papillomavirus (HPV) Infection

 Anogenital Warts

 HPV-Associated Cancers and Precancers

 Viral Hepatitis

 Proctitis, Proctocolitis, and Enteritis
HCV
HCV epi

- HCV most common U.S. chronic bloodborne infxn
  - ~2.7 million persons living with chronic HCV
- HCV not efficiently transmitted via sex
  - ↑ acute HCV incidence among MSM with HIV infection
- CDC and USPSTF recommended HCV screening
  - all persons born during 1945–1965
  - injection drug use
  - receiving a blood transfusion before 1992,
  - long-term hemodialysis,
  - being born to a mother with HCV infection
  - intranasal drug use
  - unregulated tattoo and other percutaneous exposures
Figure 4.2. Incidence of acute hepatitis C, by age group — United States, 2000–2013

Source: National Notifiable Diseases Surveillance System (NNDSS)
Mycoplasma genitalium

- First isolated in 1981
- Genital and reproductive tract disease
- Frequency
  - More common than *N. gonorrhoeae* but less common than *C. trachomatis*
**M. genitalium: More common than you think**

Young adults 18-24 yrs\(^1,2\)

<table>
<thead>
<tr>
<th></th>
<th>MG</th>
<th>CT</th>
<th>GC</th>
<th>TV</th>
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<tr>
<td></td>
<td>1.0%</td>
<td>3.8%</td>
<td>0.6%</td>
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STD Clinic/ED Attendees\(^3-9\)

<table>
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<tr>
<th>City</th>
<th>Men</th>
<th>Women</th>
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<tbody>
<tr>
<td>Seattle</td>
<td>13.4%</td>
<td>7.0%</td>
</tr>
<tr>
<td>New Orleans</td>
<td>12.1%</td>
<td></td>
</tr>
<tr>
<td>Cincinnati</td>
<td>15.2%</td>
<td>22.4%</td>
</tr>
<tr>
<td>Baltimore</td>
<td>19.2%</td>
<td></td>
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<tr>
<td>Durham</td>
<td>19.2%</td>
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</table>

\(^1\) Miller 2004; \(^2\) Manhart 2007; \(^3\) Totten 2001; \(^4\) Mena 2002; \(^5\) Manhart 2003; \(^6\) Huppert 2008; \(^7,8\) Gaydos 2009a & 2009b; \(^9\) Mobley 2012
Male urethritis & *M. genitalium*

- **Acute urethritis**¹
  - 15% MG+ in urethritis overall
  - 22% MG+ in CT-/GC- urethritis
  - Summary OR = 5.5 (4.3-7.0)

- **Persistent urethritis**²
  - 13 – 41% males w/ persistent/recurrent urethritis MG+

¹ Taylor-Robinson & Jensen, Clin Microbiol Rev, 2011;
² Sena et al, JID 2012
**M. Genitalium in females**

- *M. genitalium’s* pathogenic role less definitive in females vs males
  - Can be found in vagina, cervix, and endometrium
- *M. genitalium* in females commonly Asx
- Detected in clinical cervicitis and PID cases
  - Evidence suggests that *M. genitalium* can cause PID, but less frequently than *C. trachomatis*
M. genitalium Detection

No FDA-approved diagnostic test BUT…..

• Multiplex PCR assays available in Europe
  o Bio-Rad Dx/CT/NG/MG Assay®
  o Sacace Biotechnologies

• Commercial Laboratories’ PCR tests
  o CLIA certified

• Hologic Gen-Probe TMA assay (APTIMA Platform)
  o Commercially available as analyte-specific reagent (ASR) platform
    • Labs need to get CLIA approval
    • Information on web site or call customer service at 888.484.4747 or email at molecularsupport@hologic.com
**M. genitalium treatment**

- *M. genitalium* lacks cell wall
  - antibiotics that target cell-wall biosynthesis are ineffective
    - beta-lactams including penicillins and cephalosporins

- Given diagnostic challenges, most *M. genitalium* treatment will occur in context of management for STD syndromes
Treatment of *M. genitalium*

Randomized Controlled Trials

Doxycycline (100mg bid x 7d) vs. Azithromycin (1g)

<table>
<thead>
<tr>
<th></th>
<th>Doxycycline</th>
<th>Azithromycin</th>
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</thead>
<tbody>
<tr>
<td>Mena 2009</td>
<td>45%</td>
<td>87%</td>
</tr>
<tr>
<td>Schwebke 2011</td>
<td>31%</td>
<td>67%</td>
</tr>
<tr>
<td>Manhart 2013</td>
<td>30%</td>
<td>40%</td>
</tr>
</tbody>
</table>
**M. genitalium** and urethritis and cervicitis

- Consider *M. genitalium* Rx in persistent/recurrent urethritis and in persistent cervicitis and PID

- Azithromycin 1 gm more effective
  - Doxy ineffective
  - AZ Resistance emerging

- For Rx failures with azithro1 gm, Moxifloxacin (400 mg daily x 7-14 days)
HPV-Associated Cancers and Precancers
Viral Hepatitis
Proctitis, Proctocolitis, and Enteritis
Ectoparasitic Infections
Sexual Assault and Abuse and STDs
References
Terms and Abbreviations Used in This Report
Consultants
Evidence Tables
Screening Recommendations Referenced in Treatment Guidelines and Original Recommendation Sources

- Management of Persons Who Have a History of Penicillin Allergy
- Diseases Characterized by Urethritis and Cervicitis
  - Urethritis
  - Nongonococcal Urethritis
  - Cervicitis
- Chlamydial Infections
- Gonococcal Infections
- Diseases Characterized by Vaginal Discharge
  - Bacterial Vaginosis
  - Trichomoniasis
  - Vulvovaginal Candidiasis
- Pelvic Inflammatory Disease (PID)
- Epididymitis
- Human Papillomavirus (HPV) Infection
- Anogenital Warts
- HPV-Associated Cancers and Precancers
- Viral Hepatitis
  - Hepatitis A
  - Hepatitis B
- Proctitis, Proctocolitis, and Enteritis
- Ectoparasitic Infections
  - Pediculosis Pubis
Chlamydia treatment

- Rx not changed
- Effectiveness: azithromycin < doxycycline
  - Data from several studies and meta-analysis
    - Pooled cure rates: doxy=97.5% vs azithro=94.4%
    - Conclusion: doxy marginally superior to azithro
- Doxycycline delayed release 200 mg tabs (Doryx)
  - ↓ GI upset
  - Qday x 7 days
  - ↑$
Oropharyngeal Chlamydia

- Clinical significance unclear
- Routine oropharyngeal CT screening **not** recommended
- Can be sexually transmitted to genital sites
- Treat oropharyngeal chlamydia with azithro or doxy
Antibiotic-Resistant Gonorrhea
Gonorrhea Dual Therapy: Uncomplicated Genital, Rectal, or Pharyngeal Infections

- Ceftriaxone 250 mg IM in a single dose
- Azithromycin 1 g orally

- Doxy no longer recommended as 2nd antimicrobial for GC Rx
  - substantially ↑↑ prevalence of GC resistance to tetracycline vs azithromycin

www.cdc.gov/std/tg2015/gonorrhea.htm
What does dual therapy mean?

- Ceftriaxone and azithromycin administered on the same day
  - Preferably simultaneously and under direct observation
  - Challenge if ceftriaxone IM in office and Rx for azithro to fill in pharmacy
Gonorrhea Treatment Alternatives 2010
Anogenital Infections

**ALTERNATIVE CEPHALOSPORINS:**

- Cefixime 400 mg orally once
  
  PLUS
  
  - Dual treatment with azithromycin 1 g OR
  
  - doxycycline 100 mg BID x 7 days

ALTERNATIVE CEPHALOSPORINS:

- Cefixime 400 mg orally once
  
  **PLUS**

- Dual treatment with azithromycin 1 g

  OR

- doxycycline 100 mg BID x 7 days

  ➢ *Doxy removed as co-treatment*

www.cdc.gov/std/tg2015/gonorrhea.htm
IN CASE OF SEVERE ALLERGY:

- Azithromycin 2 g orally once
  (Caution: GI intolerance, emerging resistance)

Gentamicin 240 mg IM + azithromycin 2 g PO
OR
Gemifloxacin 320 mg orally + azithromycin 2 g PO

www.cdc.gov/std/tg2015/gonorrhea.htm
Alternative Urogenital GC Regimens

- Non-comparative randomized trial in adults with urethral or cervical gonorrhea
  1. Gentamicin 240 mg IM + azithromycin 2 g PO, or
  2. Gemifloxacin 320 mg PO + azithromycin 2 g PO

- Rationale for regimens
  - Additive effect between gentamicin and azithromycin (in vitro)
  - Gemifloxacin more active against GC with known ciprofloxacin resistance

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<table>
<thead>
<tr>
<th></th>
<th>Gentamicin / Azithromycin</th>
<th>Gemifloxacin / Azithromycin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>% (L 95% CI)</td>
</tr>
<tr>
<td>Urethra/Cervix</td>
<td>202/202</td>
<td>100% (98.5%)</td>
</tr>
<tr>
<td>Pharynx</td>
<td>10/10</td>
<td>100%</td>
</tr>
<tr>
<td>Rectum</td>
<td>1/1</td>
<td>100%</td>
</tr>
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Kirkcaldy, CID 2014
New regimen challenges

- Nausea common
  - 27% for gentamicin + AZ
  - 37% for gemifloxacin + AZ
  - 3% and 7% in each group vomited <1hr after administration

- Gemiflox no longer available
- FDA recently approved (6/15/2015) generic which may take several months to launch
- Updates on the availability can be found at: www.cdc.gov/std/treatment/drugnotices/gemifloxacin.htm
GC Test of Cure

• Patients with **pharyngeal** GC treated with an **alternative** regimen
  - Obtain test of cure 14 days after treatment, using either culture or NAAT

• Cases of suspected treatment failure
  - Culture and simultaneous NAAT
  - Call local health dept!!!!
Cephalosporin treatment failures

- Oral cephalosporin treatment failures reported worldwide
  - Japan, Hong Kong, England, Austria, Norway, France, South Africa, and Canada
- Ceftriaxone treatment failures in pharyngeal gonorrhea and a few isolates with high-level ceftriaxone resistance reported
Neisseria gonorrhoeae — Percentage of Isolates with Elevated Ceftriaxone Minimum Inhibitory Concentrations (MICs) (≥0.125 μg/ml), Gonococcal Isolate Surveillance Project (GISP), 2006–2013
Neisseria gonorrhoeae—Percentage of isolates with elevated cefixime minimum inhibitory concentrations (MICs) (≥0.25 μg/ml), Gonococcal Isolate Surveillance Project (GISP), 2006–2013

Suspected GC Treatment Failure After Recommended Dual Therapy: What do I do?

**REPORT:** State or Local Health Dept

**CULTURE:** if GC culture not available, call local health department

**REPEAT TREATMENT:** Gemifloxacin 320 mg + AZ 2g OR gentamicin 240 mg IM + AZ 2g

**TREAT PARTNERS:** Within 60 days with same regimen as patient receives

**TEST OF CURE (TOC):** Patient returns in 7-14 days for TOC culture and NAAT

*If reinfection suspected instead of treatment failure, repeat Tx with CTX 250mg + AZ 1g*
<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Pregnant Women</th>
<th>Men</th>
<th>Men Who Have Sex With Men (MSM)</th>
<th>Persons with HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CHLAMYDIA</strong></td>
<td>Sexually active women under 25 years of age [USPSTF]</td>
<td>All pregnant women under 25 years of age [USPSTF]</td>
<td>Consider screening young men in high prevalence clinical settings or in populations with high burden of infection (e.g., MSM)</td>
<td>At least annually for sexually active MSM at sites of contact (urethra, rectum) regardless of condom use [CDC]</td>
<td>For sexually active individuals, screen at first HIV evaluation, and at least annually thereafter [CDC]</td>
</tr>
<tr>
<td></td>
<td>Sexually active women aged 25 years and older if at increased risk [USPSTF]</td>
<td>Pregnant women, aged 25 years and older if at increased risk [USPSTF]</td>
<td>Retest during the 3rd trimester for women under 25 years of age or at risk [CDC]</td>
<td>Every 3 to 6 months if at increased risk [CDC]</td>
<td>More frequent screening might be appropriate depending on individual risk behaviors and the local epidemiology [CDC]</td>
</tr>
<tr>
<td></td>
<td>Retest approximately 3 months after treatment [CDC]</td>
<td>Pregnant women with chlamydial infection should have a test-of-cure 3-4 weeks after treatment and be retested within 3 months [USPSTF]</td>
<td></td>
<td>=password</td>
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<tr>
<td><strong>GONORRHEA</strong></td>
<td>Sexually active women under 25 years of age [USPSTF]</td>
<td>All pregnant women under 25 years of age and older if at increased risk [USPSTF]</td>
<td>At least annually for sexually active MSM at sites of contact (urethra, rectum, pharynx) regardless of condom use [CDC]</td>
<td>Every 3 to 6 months if at increased risk [CDC]</td>
<td>For sexually active individuals, screen at first HIV evaluation, and at least annually thereafter [CDC]</td>
</tr>
<tr>
<td></td>
<td>Sexually active women aged 25 years and older if at increased risk [USPSTF]</td>
<td>Retest 3 months after treatment [CDC]</td>
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<tr>
<td></td>
<td>Retest 3 months after treatment [CDC]</td>
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<td>=password</td>
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<tr>
<td><strong>SYPHILIS</strong></td>
<td>All pregnant women at the first prenatal visit [USPSTF]</td>
<td>All pregnant women at the first prenatal visit [USPSTF]</td>
<td>At least annually for sexually active MSM at sites of contact (urethra, rectum, pharynx) regardless of condom use [CDC]</td>
<td>Every 3 to 6 months if at increased risk [CDC]</td>
<td>For sexually active individuals, screen at first HIV evaluation, and at least annually thereafter [CDC, HRSA, IDSA, NIH]</td>
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<tr>
<td></td>
<td>Retest early in the third trimester and at delivery if [USPSTF]</td>
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Want to know more about STDs? There's an app for that.

CDC Treatment Guidelines
App for Apple and Android

http://www.cdc.gov/std/tg2015/
Wall chart

Sexually Transmitted Diseases

Updated Summary of 2010 CDC Treatment Guidelines

Sexually Transmitted Diseases

Updated Summary of 2010 CDC Treatment Guidelines

Pocket Guide


- Bacterial Vaginosis
- Cervicitis
- Chlamydial Infections
- Epididymitis
- Genital Herpes Simplex
- Genital Warts (Human Papillomavirus)
- Gonococcal Infections
- Lymphogranuloma venereum
- Non-Gonococcal Urethritis (NGU)
- Pediculosis Pubis
- Pelvic Inflammatory Disease
- Scabies
- Syphilis
- Trichomoniasis
STD Clinical Consultation Network (STDCCN)

8 Regional PTCs
Please fill in the form below including a descriptive question. A consultant will review your information and will contact you via the method you specify in the 'Reach Me By' field.

* = required field

Name (first) *
Name (last) *
Occupation *
Setting *
Reach Me By *
Need Answer *
Primary Phone *
Alt Phone *
Fax *
Email *
Facility *
Address *
Country *
City *
State *