Optimizing STD Prevention & Care in the U.S.
What’s Hot in the STD Treatment Guidelines

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## Disclosure

<table>
<thead>
<tr>
<th>Gail Bolan, M.D.</th>
<th>Role</th>
<th>Status</th>
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<tbody>
<tr>
<td>Commercial Interest</td>
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<tr>
<td>Nothing to disclose</td>
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Objectives

- Identify four areas of STD clinical uncertainty in the 2015 STD Treatment Guidelines
- List three STD treatment recommendation changes in the 2015 STD Treatment Guidelines
- Discuss two new STD diagnostic options in the 2015 STD Treatment Guidelines
Overview

- STD treatment guidelines history
- Changing landscape of STDs in the United States
- What’s hot in STD treatment and management
  - USPSTF chlamydia screening for young females
  - Treatment concerns for gonorrhea
  - Syphilis in pregnancy
  - Mycoplasma genitalium
- Provision of quality STD clinical services
2015 STD TREATMENT GUIDELINES
Clinical Practice Guidelines We Can Trust

Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, and Earl Steinberg, Editors; Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Institute of Medicine
This PDF is available from the National Academies Press at:
http://www.nap.edu/catalog/13058/clinical-practice-guidelines-we-can-trust

- Be based on a systematic review of the existing evidence;
- Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- Consider important patient subgroups and patient preferences, as appropriate;
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and
- Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.
STD Prevention – Key Principles

- Risk Assessment and counseling to reduce STD acquisition
- Screening of asymptomatic persons
- Diagnosis and treatment of symptoms
- Management of sex partners
- Vaccination
  - HPV
  - Hepatitis A & B
STD Prevention - The Clinicians’ Role

- A welcoming environment
- Routine sexual history and risk assessment
- Screen, appropriately
  - Appropriate anatomic sites with recommended tests
  - Alcohol, drug use, tobacco, depression, intimate partner violence
- Assure appropriate vaccination status (HPV, HBV/HAV)
- Prevention messages—condoms, HIV pre- and post-exposure prophylaxis (PrEP, PEP)
- Diagnosis and treatment
- Provide or refer partner services
- Report cases in accordance with state and local statutory requirements; keep reports confidential
Want to know about 2015 STD Treatment Guidelines? There's an app for that.

- CDC Treatment Guidelines App for Apple and Android
- Available now, FREE!
  - (accept no competitors)
STD Tx Guide Mobile app – New look

- Gonorrhea
- Bacterial Vaginosis
- Candidiasis - Vulvovaginal
- Cervicitis
- Chancroid
- Chlamydia
- Epididymitis
- Granuloma Inguinale
- Hepatitis

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

Alternative Regimen
- Cefixime 400 mg orally in a single oral dose
- Azithromycin 1 g orally in a single dose
2015 DocStyles Provider Survey: Preliminary Results

- **Web-based quota survey:**
  - Total n=1,500
  - 1000 primary care – internists and family practice, 250 peds, 250 OB/GYN
  - 76.8% response rate

- **Sample frame:** SERMO's Global Medical Panel of 330,000 US medical professionals. Random sample.

- **Respondents:**
  - US based
  - In practice for at least 3 years
  - Double validated
  - Paid $35-$80

### Table: Physician Type

<table>
<thead>
<tr>
<th>Physician Type</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Family Practice</td>
<td>31%</td>
</tr>
<tr>
<td>Internist</td>
<td>35%</td>
</tr>
<tr>
<td>Pediatrician</td>
<td>17%</td>
</tr>
<tr>
<td>OB</td>
<td>17%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100% (1500)</td>
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</tbody>
</table>

### Table: Practice Region

<table>
<thead>
<tr>
<th>Practice Region</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Midwest</td>
<td>23%</td>
</tr>
<tr>
<td>South</td>
<td>31%</td>
</tr>
<tr>
<td>Northeast</td>
<td>25%</td>
</tr>
<tr>
<td>West</td>
<td>21%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100% (1500)</td>
</tr>
</tbody>
</table>

### Key descriptions

- Seeing STD at-risk patients 91%
- Low volume providers* 60%
- High volume providers* 30%
- Correctly identified recommended GC treatment 62%

Fielded in June 2015. Results are preliminary.

* Low volume providers were defined as those who saw 1-19 patients for STD screening, diagnosis, or treatment in the past 30 days. High volume saw 20+. 
“If you needed to look up information on STD treatment for a patient you saw today, which source would you check first?”

Data come from DocStyles 2015, fielded in June 2015. Results are preliminary.
CHANGING LANDSCAPE OF STDS IN THE UNITED STATES
Main Messages:

1. CDC’s annual STD report finds that overall reported cases for chlamydia, gonorrhea and syphilis are increasing; some at an alarming rate.

2. Young people are still at the highest risk of acquiring an STD and most vulnerable to their damaging effects.

3. Greater awareness and action is needed at all levels to ensure good health for the nation’s youth and others disproportionately impacted by STDs.
2014 Surveillance Report Overview

Case rate increases seen from 2013 - 2014:

- **Chlamydia**: 2.8% with 1,441,789 cases reported in 2014
  - Driven by a 6.8% increase among men
  - 1.3% increase among women
- **Gonorrhea**: 5% with 350,062 cases reported in 2014
  - Driven by a 10.5% increase among men
  - 0.4% decrease among women
- **P & S syphilis**: 15.1% with 19,999 cases reported in 2014
  - Increases seen in MSM, MSW, women
  - MSM accounted for 83% of P & S cases
- **Congenital syphilis**: total of 458 cases
  - Decreased from 2008-2012, increased slightly in 2013 and then rose by 27.5% in 2014
  - Increased in all regions with largest increases in the NE and West
WHAT’S HOT IN STD TREATMENT AND MANAGEMENT
Chlamydia—Rates of Reported Cases Among Women by Age Group, 2004–2015*

Average annual percent change during 2011–2015

20–24: ↓0.1%
15–19: ↓4.4%
25–29: ↑4.1%
30+: ↑5.5%

*2015 data preliminary as of March 7, 2016
Chlamydia — Screening Coverage Trends Among Sexually-Active Women,* by Age and Plan, HEDIS, 2001–2014

*Among women enrolled in commercial or Medicaid plans who had a visit where they were determined to be sexually active

Number of female family planning users aged 15–19 years tested for chlamydia and proportion tested, Title X Family Planning, 2005–2014

No change

- 10.6%
Chlamydia and Gonorrhea Screening

- Annual screening of sexually active women <25
- Screening of older women at increased risk
  - New sex partner, partner with concurrent partners or more than one partner, or partner with an STI
- Screening older women at low risk of infection not recommended
- CT screening sexually active men
  - Insufficient evidence for general screening; Consider in high prevalence (adolescent clinics, corrections, STD clinics)
- GC screening in men not recommended
Chlamydia & Gonorrhea Diagnostic Tests

- Nucleic acid amplification tests (NAAT) recommended for men & women
- Optimal specimen: first-catch urine in men and vaginal swabs in women
- NAAT optimal for rectal and pharyngeal testing; not FDA approved but commercially available & validation protocols available for local labs
- Limitations: no antibiotic resistance testing with NAAT (need culture)

http://www.cdc.gov/mmwr 2014
Evolving Landscape of EPT, 2006 – February 2016: Legal Status Summary

2006
EPT is Permissible
EPT is Likely Prohibited
EPT is Potentially Allowable

February 2016
TREATMENT CONCERNS FOR GONORRHEA
Percentage of *Neisseria gonorrhoeae* isolates with reduced cefixime susceptibility†

Gonococcal Isolate Surveillance Project (GISP), 2006–2015*

†Minimum inhibitory concentration (MICs) $\geq 0.25 \, \mu g/ml$
*2015 data are preliminary as of March 7, 2016
†† Cefixime susceptibility not tested in 2007 and 2008

Revised Tx Recommendations
12/2010
Increased Ceftriaxone to 250 mg from 125 mg

Revised Tx Recommendations
8/2012
Dual therapy for GC
2015 CDC Treatment Recommendations for Gonococcal Infections

- Ceftriaxone 250 mg IM x 1
  PLUS
- Azithromycin 1 g po x 1

Alternatives
If ceftriaxone not available or for EPT:
- Cefixime PLUS azithromycin 1 g
If cephalosporin allergy:
- Gentamicin (240mg IM or 5 mg/kg IM) / azithro 2 g PO or
- Gemifloxacin 320 mg PO / azithro 2 g PO

TOC if alternative regimen used for pharyngeal GC at ~14 days
If treatment failure, perform culture, AST and retreat

1998
2000
2002
2004
2006
2008
2010
2012
2015
SYphilis in Pregnancy
Congenital Syphilis (CS) Rate and Rate of Primary and Secondary (P&S) Syphilis Among Females, United States, 2008–2015*

*2015 data are preliminary as of March 7, 2016
### Characteristics of Mothers Who Gave Birth to Infants with Congenital Syphilis, United States, 2014

<table>
<thead>
<tr>
<th>Category</th>
<th>Number (N=458)</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not receive prenatal care</td>
<td>100</td>
<td>21.8%</td>
</tr>
<tr>
<td>Received prenatal care (N=314, 68.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No treatment</td>
<td>135</td>
<td>29.5%</td>
</tr>
<tr>
<td>Treated &lt;30 days prior to delivery</td>
<td>78</td>
<td>17.0%</td>
</tr>
<tr>
<td>Non-penicillin therapy</td>
<td>3</td>
<td>0.7%</td>
</tr>
<tr>
<td>Inadequate regimen for stage</td>
<td>13</td>
<td>2.8%</td>
</tr>
<tr>
<td>Adequate treatment</td>
<td>43</td>
<td>9.4%</td>
</tr>
<tr>
<td>Unknown treatment status</td>
<td>42</td>
<td>9.2%</td>
</tr>
<tr>
<td>Unknown prenatal care status</td>
<td>44</td>
<td>9.6%</td>
</tr>
</tbody>
</table>
### Characteristics of Mothers Who Gave Birth to Infants with Congenital Syphilis and Did Not Receive Treatment, United States, 2014

<table>
<thead>
<tr>
<th>Mothers with prenatal care but no treatment</th>
<th>Number (N=135)</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never tested during pregnancy</td>
<td>21</td>
<td>15.6%</td>
</tr>
<tr>
<td>1\textsuperscript{st} test negative, later test positive</td>
<td>52</td>
<td>38.5%</td>
</tr>
<tr>
<td>Positive test, but not treated</td>
<td>62</td>
<td>45.9%</td>
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</tbody>
</table>
Algorithm for reverse sequence syphilis screening

If incubating or primary syphilis is suspected, treat with benzathine penicillin G 2.4 million units IM x 1 and/or repeat in 1-2 weeks.

Evaluate clinically, determine if treated for syphilis in the past, assess risk of infection, and administer therapy according to CDC's STD Treatment Guidelines if not previously treated.

If at risk for syphilis, repeat RPR in 2 to 4 weeks.
Syphilis Treatment
Primary, Secondary, Early Latent

- Penicillin treatment of choice +/- HIV
  - Benz PCN 2.4 mu IM x 1
- Penicillin is the only recommended treatment in pregnancy
- PCN alternatives in non-pregnant patients
  - Doxycycline, ceftriaxone
  - Azithromycin 2 gm (A2058G mutation/tx failure)
    - MSM>MSW
    - Do not use azithromycin in MSM or pregnancy
EMERGING ISSUES:

MYCOPLASMA GENITALIUM
Role of *Mycoplasma genitalium*

- Good evidence for role in urethritis (20%)
- May play role in cervicitis, PID, infertility, preterm delivery
- No commercially-available test for *M. genitalium* (in house NAATs)
- Treatment implications
  - Azithromycin > doxycycline because of resistance to doxycycline but concerns of emerging resistance to Az
  - Conflicting data on single dose vs extended dosing
  - Moxifloxacin 400 mg po for 7-14 days has been studied as an alternative (cure rates 85-100%)
Guidelines for the Provision of Quality STD Clinical Services
Levels of STD Clinical Care Definitions

- **Basic STD Care:** Delivery of basic recommended STD clinical preventive services:
  - RA, screening and treatment of those with asymptomatic infection
  - Basic partner services (BYOP, EPT) and counseling, as needed
  - Treatment of patients with non-complex symptomatic infection

- **Specialized STD Care:** Delivery of more comprehensive and complex STD clinical services- including basic care plus:
  - On-site stat diagnosis (e.g. Gram stain, RPR)
  - Advanced diagnostics (e.g. gonorrhea culture, extra genital GC/CT NAATS)
  - On site injectable antibiotics to treat syphilis and gonorrhea
  - Offers same day service for those likely to be infected (those with symptoms suggestive of an acute STD and those who report a partner with an acute STD)
  - Offers culturally expert care to those at highest risk of STD (youth and LGBT)
  - Ensures protection of confidentiality
Regional NNPTC Coverage
Save the Date!
2016 STD Prevention Conference

Atlanta, GA
September 20-23, 2016
www.cdc.gov/stdconference/

A collaborative conference between
- Centers for Disease Control & Prevention
- American Sexually Transmitted Diseases Association
- National Coalition of STD Directors
- American Sexual Health Association
- Pan American Health Organization
- Public Health Agency of Canada