ashp MIDYEAR 2018
Clinical Meeting & Exhibition

The Rise of Sexually Transmitted Infections: An Alarming Trend of a Familiar Foe

Thomas D. Chiampas, Pharm.D., AAHIVP, BCPS
Clinical Assistant Professor/Clinical Pharmacist
University of Illinois at Chicago College of Pharmacy
Chicago, IL

Disclosures

All planners, presenters, reviewers, and ASHP staff of this session report no financial relationships relevant to this activity.

The Rise of Sexually Transmitted Infections: an Alarming Trend of a Familiar Foe

Session Learning Objectives:

- **Explain recent updates to the sexually transmitted infection (STI) treatment guidelines.**
- **Identify reasons behind the increase in STIs in the United States over the last three years.**
- **Given a patient case, develop an appropriate treatment strategy for a patient with an STI.**

Patient Case

CJ is a 25 year old bisexual black male living with HIV who presents to clinic for a 6 month follow up appointment. He reports several casual sex partners for oral, receptive, and insertive anal sex since last visit. States he/his partners wear condoms "when we can remember." He tolerates his medication well, reports 100% adherence, and has no complaints today.

Allergies: NKDA

Current medications:
Bictegravir/emtricitabine/tenofovir alafenamide 50/200/25 mg PO daily

Patient Case

Pertinent PMH:
HIV – diagnosed 1/2017; risk factor = bisexual; CD4 nadir = 532 cells/mm^3
Chlamydia – 1/2017, treated
Gonorrhea – 1/2017, treated
Syphilis – 1/2017 (RPR 1:256), treated; most recent RPR = 1:2 on 4/2018

Pertinent Labs from 11/20/18 (2 weeks prior to appointment date):
HIV-RNA = <20 copies/mL CD4/% = 711/35 cells/mm^3 RPR = 1:64

GC/Chlam (rectal, throat, oral) = POS/POS; neg/neg; POS/neg
Comprehensive metabolic panel = WNL

Pre-Test Question 1

Based on CJ's labs from 11/2018, what treatments, if any, are recommended?

A. Amoxicillin + benzathine penicillin G + doxycycline
B. Azithromycin + benzathine penicillin G + ceftriaxone
C. Azithromycin + ceftriaxone
D. Benzathine penicillin G + ceftriaxone
E. None, as he was treated previously 1/2017

Pre-Test Question 2

Due to increased resistance concerns, which is the most appropriate treatment for gonococcal infections based on the most recent STI guidelines?

A. Amoxicillin + cefixime
B. Azithromycin
C. Azithromycin + ceftriaxone
D. Cefixime
E. Ceftriaxone

“Nearly 2.3 million cases of chlamydia, gonorrhea, and syphilis were diagnosed in the United States in 2017, according to preliminary data…

This surpassed the previous record set in 2016 by more than 200,000 cases and marked the fourth consecutive year of sharp increases in these sexually transmitted diseases.”

https://www.cdc.gov/nchhstp/newsroom/2018/press-release-2018-std-prevention-conference.html. Accessed September 4, 2018.

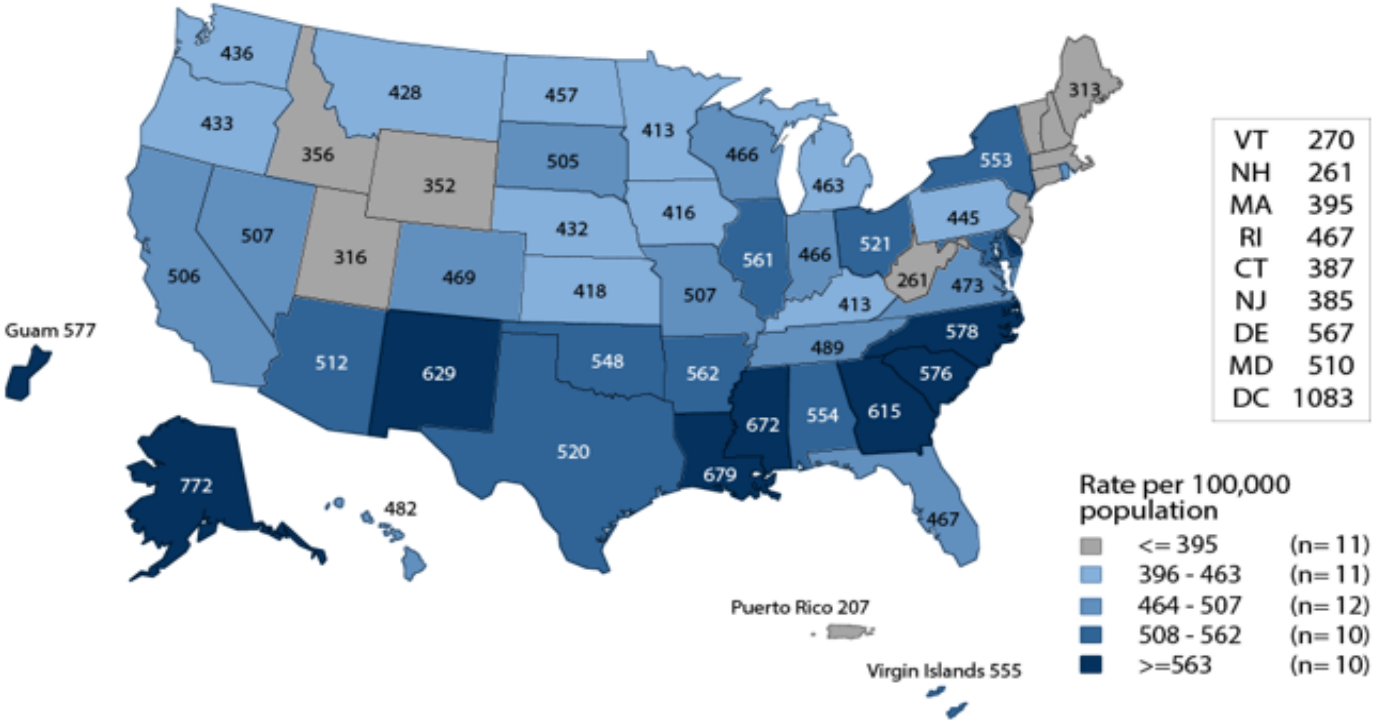
STD DIAGNOSES AMONG KEY U.S. POPULATIONS, 5-YEAR TRENDS

	2013	2014	2015	2016	2017*
Chlamydia	1,401,906	1,441,789	1,526,658	1,598,354	1,708,569
Among young women (aged 15 to 24)	715,983	709,170	724,709	735,027	771,340
Gonorrhea	333,004	350,062	395,216	468,514	555,608
Among women	163,208	162,608	173,514	197,499	232,587
Among men	169,130	186,943	221,070	270,033	322,169
Primary & secondary syphilis	17,375	19,999	23,872	27,814	30,644
*Among MSM***	10,451	12,226	14,229	16,149	17,736
Combined cases	**1,752,285**	**1,811,850**	**1,945,746**	**2,094,682**	**2,294,821**

*Preliminary data
**Men who have sex with men

https://www.cdc.gov/nchhstp/newsroom/docs/2018/table-data-2018-STD-Prevention-Conference.pdf. Accessed September 4, 2018.

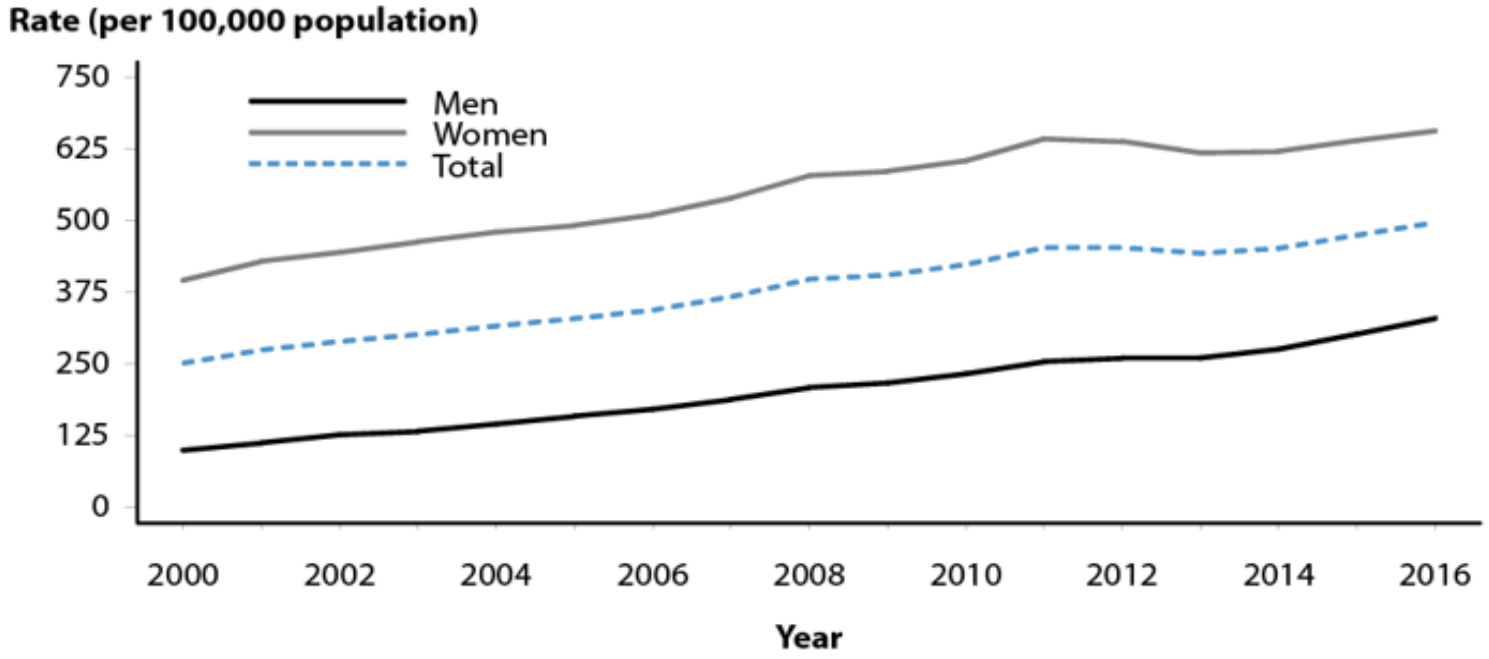
Chlamydia — Rates of Reported Cases by State, United States and Outlying Areas, 2016



NOTE: The total rate of reported cases of chlamydia for the United States and outlying areas (Guam, Puerto Rico, and Virgin Islands) was 494.2 per 100,000 population.

https://www.cdc.gov/std/stats16/slides.htm. Accessed May 12, 2018.

Chlamydia — Rates of Reported Cases by Sex, United States, 2000–2016



NOTE: Data collection for chlamydia began in 1984 and chlamydia was made nationally notifiable in 1995; however, chlamydia was not reportable in all 50 states and the District of Columbia until 2000. Refer to the National Notifiable Disease Surveillance System (NNDSS) website for more information: https://wwwn.cdc.gov/nndss/conditions/chlamydia-trachomatis-infection/.

https://www.cdc.gov/std/stats16/slides.htm. Accessed May 12, 2018.

Chlamydia trachomatis Recommended Treatments

Adults and Adolescents

- **Azithromycin 1 g PO as a single dose**
- **-OR-**
- **Doxycycline 100 mg PO twice daily for 7 days**

Pregnancy

- **Azithromycin 1 g PO as a single dose**

g = gram; mg = milligram; PO = by mouth

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Chlamydia trachomatis Treatment Updates

<u>Updates</u> from the Guidelines from 2010-2015

- **Amoxicillin 500 mg PO three times daily for 7 days acceptable alternative in pregnancy**

- **Data are limited on the effectiveness and optimal dose of azithromycin for chlamydial infection in infants and children < 45 kg (urogenital, rectal)**

- **Azithromycin 20 mg/kg/day PO daily for 3 days (neonates: ophthalmia, neonatorum, pneumonia)**

kg = kilogram; mg = milligram; PO = by mouth

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Chlamydia trachomatis Goals of Therapy

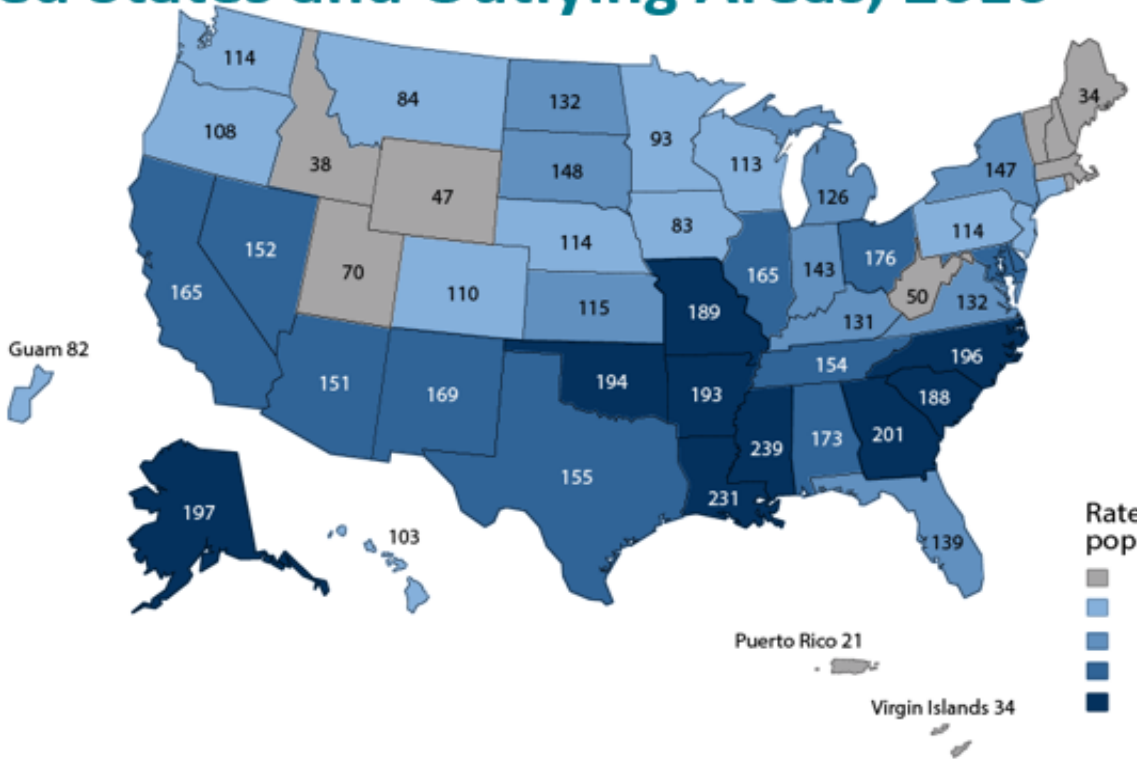
Goal of therapy = CURE INFECTION!

Test of cure (3-4 weeks s/p treatment):

- **Adults and adolescents <u>not advised</u> unless adherence is in question, symptoms persist, or re-infection suspected**
- **Repeat testing should occur about 3 months s/p treatment**
- **Pregnant, infants, and children <u>is recommended</u>**

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Gonorrhea — Rates of Reported Cases by State, United States and Outlying Areas, 2016



VT	20
NH	34
MA	73
RI	68
CT	76
NJ	91
DE	180
MD	159
DC	480

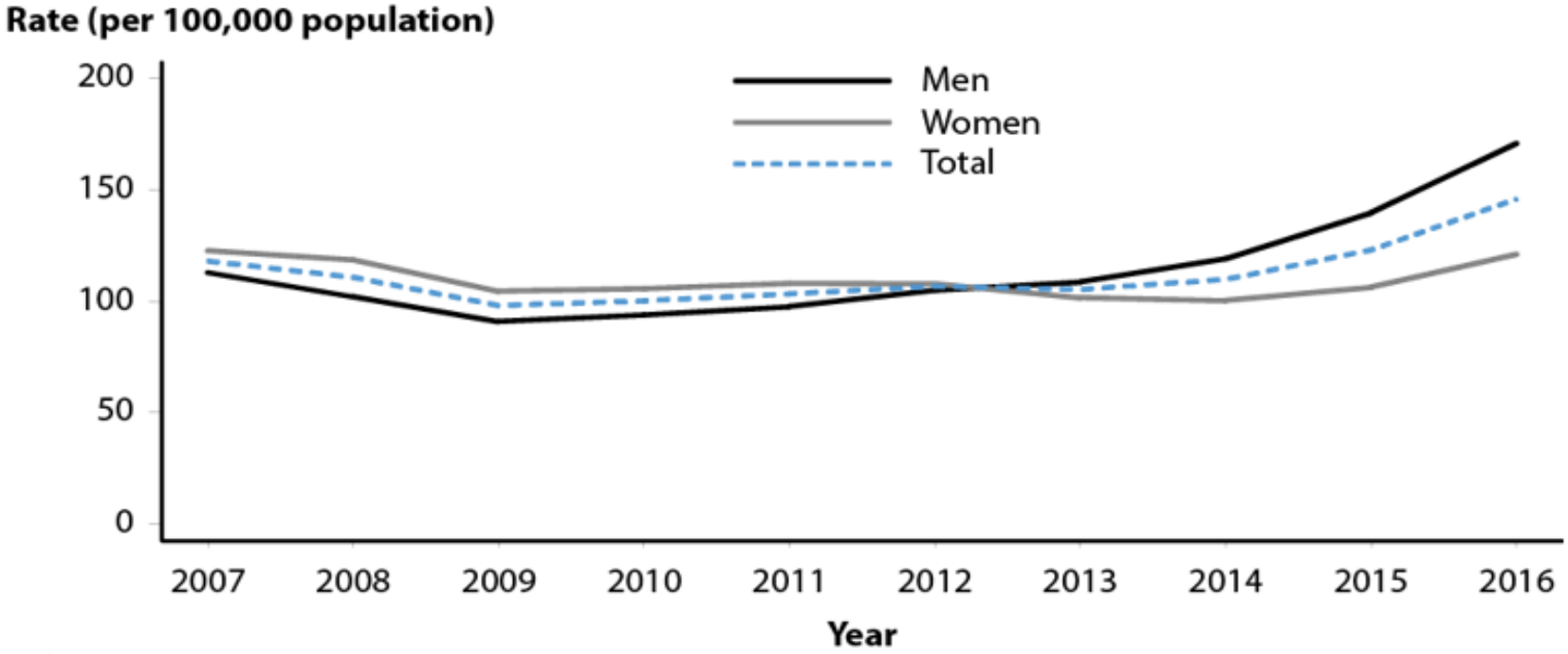
Rate per 100,000 population

<= 73	(n= 11)
74 - 114	(n= 13)
115 - 148	(n= 9)
149 - 180	(n= 11)
>=181	(n= 10)

NOTE: The total rate of reported cases of gonorrhea for the United States and outlying areas (Guam, Puerto Rico, and Virgin Islands) was 144.4 per 100,000 population.

https://www.cdc.gov/std/stats16/slides.htm. Accessed May 12, 2018.

Gonorrhea — Rates of Reported Cases by Sex, United States, 2007–2016



https://www.cdc.gov/std/stats16/slides.htm. Accessed May 12, 2018.

Neisseria Gonorrhea Treatments and Updates

Adults, adolescents, and children >45 kg; uncomplicated gonococcal infections of the cervix, urethra, and rectum

- **Ceftriaxone 250 mg IM as a single dose PLUS one dose of azithromycin 1 g PO**

Alternative Regimens (also updates in treatment guidelines from 2010-2015)

- **Ceftriaxone is unavailable:**
  - **One dose each of cefixime 400 mg PO PLUS azithromycin 1 g PO**
- **Cephalosporin allergy:**
  - **One dose each of gemifloxacin 320 mg PO PLUS azithromycin 2 g PO**
  - **One dose each of gentamicin 240 mg IM PLUS azithromycin 2 g PO**

g= gram; IM = intramuscular; mg = milligram; PO = by mouth

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Neisseria Gonorrhea Goals of Therapy

Goal of therapy = CURE INFECTION!

Test of cure (14 days s/p treatment):

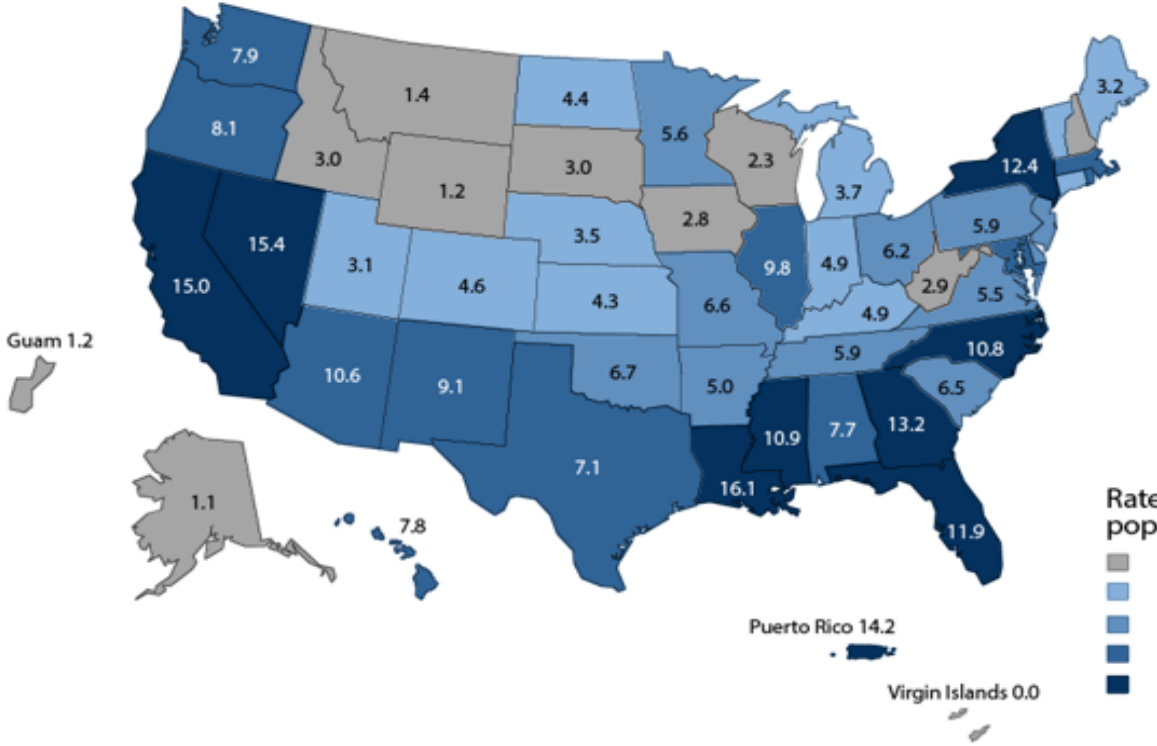
- **Adults and adolescents <u>not needed</u> unless treated with alternative regimen for pharyngeal gonorrhea**
  - **If positive, susceptibility testing should be performed**
  - **Should retest about 3 months s/p treatment**

- **Pregnant, infants, and children test-of-cure <u>is recommended</u>**

- **If symptoms persist s/p treatment → susceptibility testing**

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Primary and Secondary Syphilis — Rates of Reported Cases by State, United States and Outlying Areas, 2016



VT	3.7
NH	3.0
MA	7.2
RI	8.5
CT	3.1
NJ	5.3
DE	6.1
MD	8.5
DC	24.0

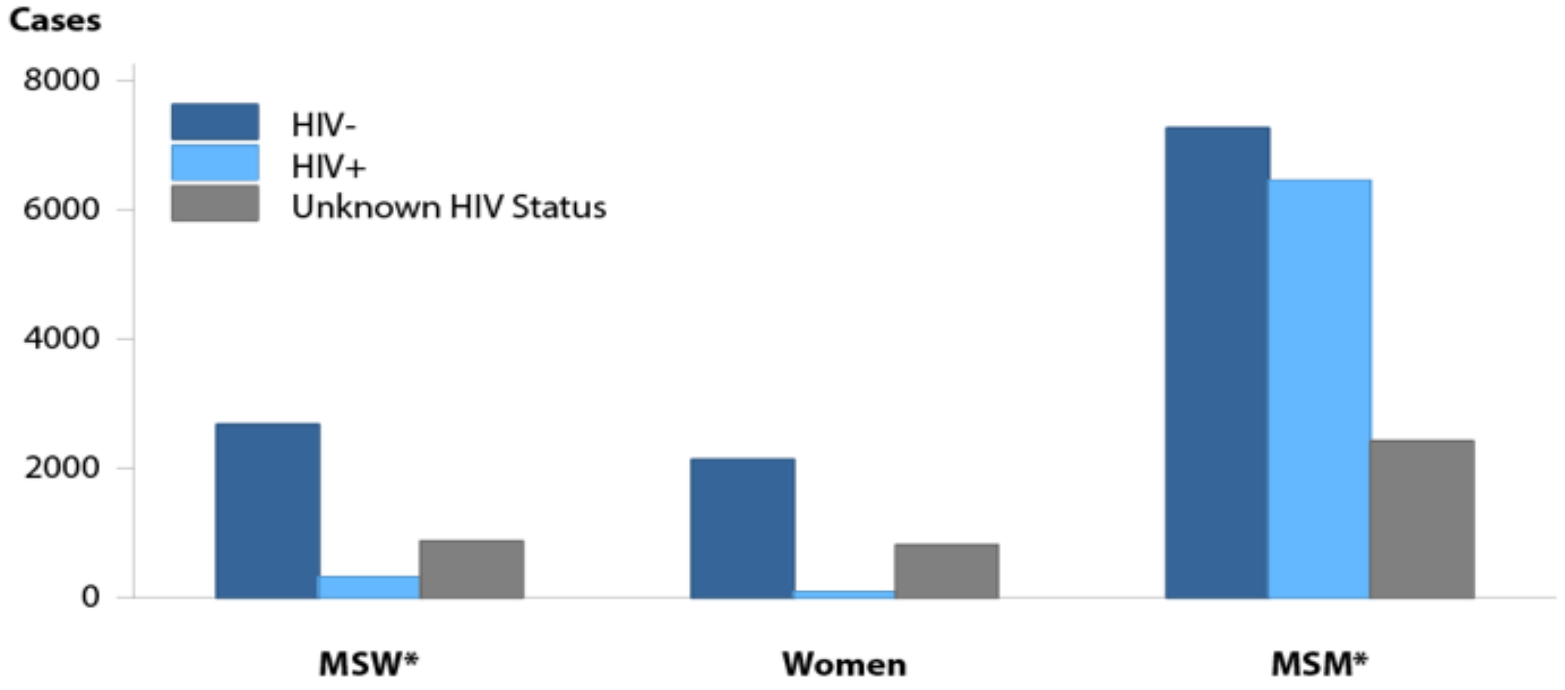
Rate per 100,000 population

<= 3.0	(n= 11)
3.1 - 4.9	(n= 11)
5.0 - 6.7	(n= 11)
6.8 - 10.6	(n= 11)
>=10.7	(n= 10)

NOTE: The total rate of reported cases of primary and secondary syphilis for the United States and outlying areas (Guam, Puerto Rico, and Virgin Islands) was 8.7 per 100,000 population.

https://www.cdc.gov/std/stats16/slides.htm. Accessed May 12, 2018.

Primary and Secondary Syphilis — Reported Cases by Sex, Sexual Behavior, and HIV Status, United States, 2016



* MSM = Gay, bisexual, and other men who have sex with men (collectively referred to as MSM); MSW = Men who have sex with women only.

https://www.cdc.gov/std/stats16/slides.htm. Accessed May 12, 2018.

Syphilis *Treponema pallidum* Recommended Treatments

Primary, secondary, or early latent <1 year

- **Benzathine penicillin G 2.4 million units IM as a single dose**

Latent >1 year, latent of unknown duration

- **Benzathine penicillin G 2.4 million units IM for 3 doses given 1 week apart**

IM = intramuscular

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Syphilis *Treponema pallidum* Alternative Treatments

Primary, secondary, or early latent <1 year

- Doxycycline 100 mg PO twice daily for 14 days
- Tetracycline 500 mg PO four times daily for 14 days

Latent >1 year, latent of unknown duration

- Doxycycline 100 mg PO twice daily for 28 days
- Tetracycline 500 mg PO four times daily for 28 days

mg = milligram; PO = by mouth

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

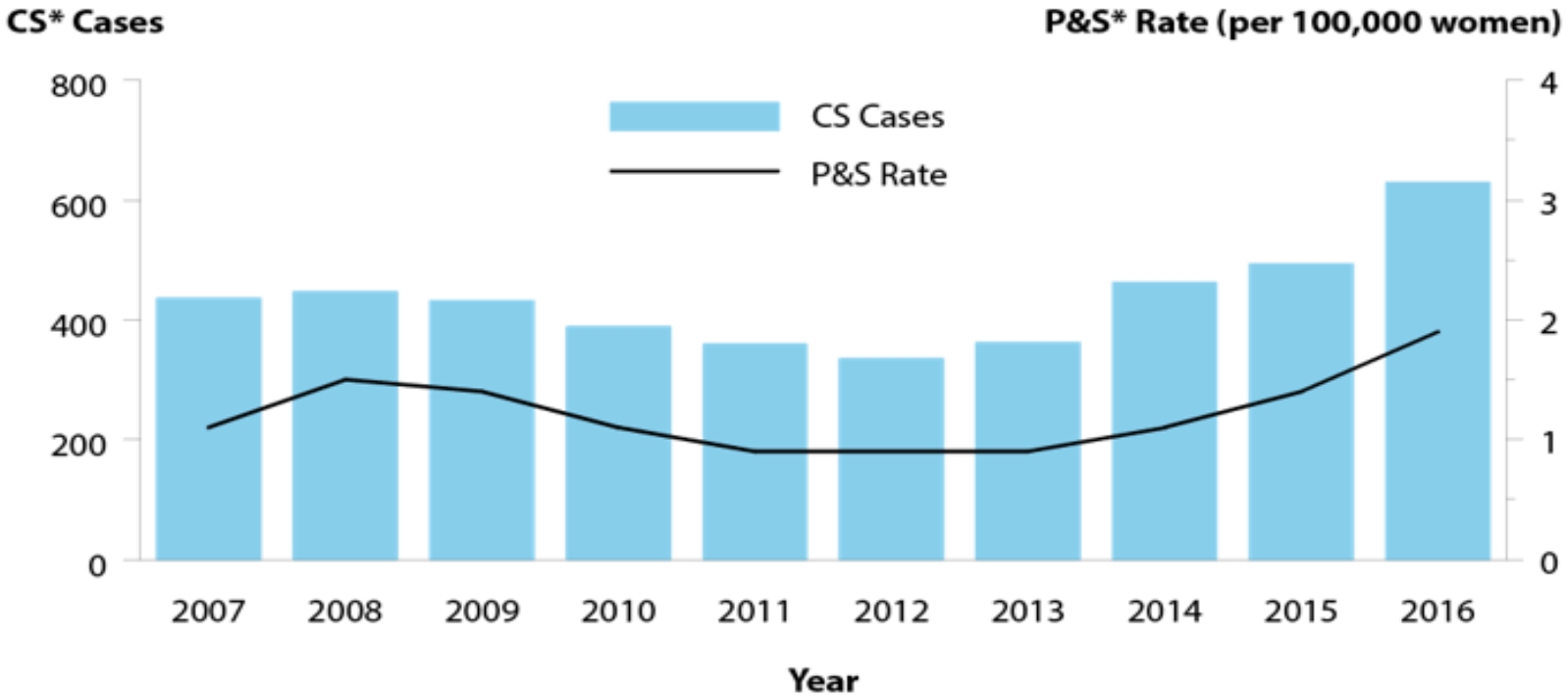
Syphilis *Treponema pallidum* Goals of Therapy

Goal of therapy = at least a 4-fold (2 dilution) decline within 6-12 months after therapy for primary or secondary (e.g. 1:256 → 1:64 or 1:32 → 1:8)

- **15-20% may not achieve the 4-fold/2 dilution decrease within 1 year**
- **Factors associating: person's stage of syphilis (earlier more likely to decline 4 -fold) and initial lower titer**
- **Clinical Pearl: 1 dilution variation may be lab variation, therefore, typically want to see at least 2 dilution positive change to alter or re-treat**

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Congenital Syphilis — Reported Cases by Year of Birth and Rates of Reported Cases of Primary and Secondary Syphilis Among Women, United States, 2007–2016



* CS = Congenital syphilis; P&S = Primary and secondary syphilis.

https://www.cdc.gov/std/stats16/slides.htm. Accessed May 12, 2018.

Updates in STI Treatment Guidelines From 2010 to 2015

Congenital Syphilis

Proven or highly probable (1 of 2 treatment options)

- Aqueous crystalline penicillin G 100,000 – 150,000 units/kg/day, administered as 50,000 units/kg/dose IV every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days
- Procaine penicillin G 50,000 units/kg/dose IM in a single daily dose for 10 days

Probable (1 of 3 treatment options)

- Above 2 treatment options
- Benzathine penicillin G 50,000 units/kg/dose IM in a single dose

IM = intramuscular; IV = intravenous; kg = kilogram

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

Updates in STI Treatment Guidelines From 2010 to 2015
Congenital Syphilis

Less Likely

- Benzathine penicillin G 50,000 units/kg/dose IM x 1 dose
- If mother's titer decreased 4-fold after appropriate treatment for early syphilis, or remained low/stable for latent syphilis may also NOT treat, and provide close serologic follow-up every 2-3 months for 6 months

Unlikely

- No treatment required
- If needed, benzathine penicillin G 50,000 units/kg as a single IM dose might be considered, particularly if follow-up is uncertain

2015 Sexually Transmitted Diseases Treatment Guidelines - Gonococcal Infections. Centers for Disease Control and Prevention website. www.cdc.gov/std/tg2015/gonorrhea.htm. Accessed May 12, 2018.

IM = intramuscular; kg = kilogram

KEY TAKEAWAYS

1) **PREVENTABLE STIS CONTINUE TO RISE ACROSS THE USA**
   Some regions and patients are being impacted more aggressively than others.

2) **CONCERNS FOR RESISTANCE**
   Treating gonorrhea should include BOTH ceftriaxone 250 mg intramuscularly as well as azithromycin 1 g by mouth.

3) **THESE STIS ARE CURRENTLY PREVENTABLE AND CURABLE!!!**
   This cannot be emphasized enough.

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The Rise of Sexually Transmitted Infections: An Alarming Trend of a Familiar Foe

Danielle Colayco, Pharm.D., M.S.
Director, Health Outcomes & Value Strategy
Komoto Healthcare

Why is this Happening?!

- Low condom use
- Increased numbers in populations/demographics with usually lower incidence (i.e. newborns)
- Dating apps
- More people are getting tested
- Cuts to public health funds
- Antibiotic resistance
  - Concerns with gonorrhea

What can be done?

CDC

- **Train frontline health workers, provide STI prevention resources to state and local health departments**

State and local health departments

- **Direct resources to STI investigation and clinical service infrastructure for rapid detection and treatment for people living in areas with high epidemic**

What can be done?

Providers

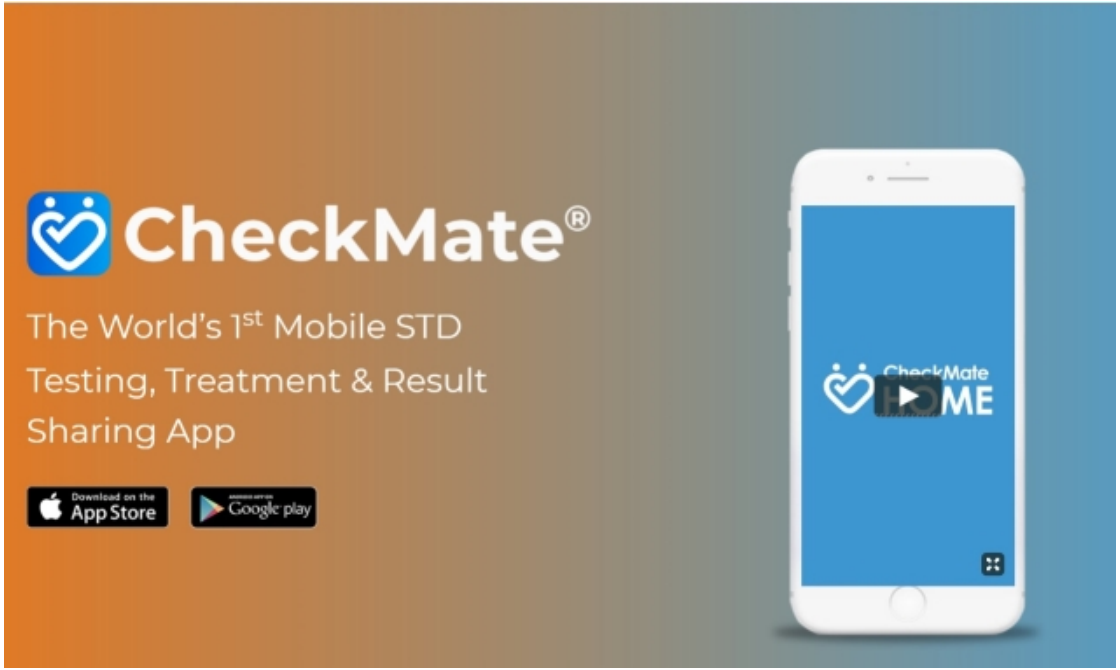
- **STI screening and timely treatment standard part of practice, especially for pregnant women and MSM**
  - **Integrate STI screening and treatment into prenatal care in addition to HIV prevention and PrEP when necessary**

Everyone

- **Talk openly about sexual health, use condoms, get tested regularly (Q3-12 months, depending on risk factors)**

https://www.cdc.gov/std/tg2015/screening-recommendations.htm. Accessed September 12, 2018.

New App Lets Consumers Order STI Tests and Get Treatment via Telemedicine



https://www.empr.com/news/sexually-transmitted-disease-app-home-testing-telemedicine-prescription/article/776663/. Accessed September 12, 2018.

A Community Pharmacy Perspective

- **Opportunities for involvement**
  - **Sexual health services**
  - **Community-wide coalitions**
  - **Public health initiatives**

How can community pharmacists make a difference?

- Condom and medication distribution
- Local data collection
- Counseling and referral
- Collaborative practice: testing & prescribing
- Community partnerships

How can community pharmacists make a difference?

Condom and medication distribution

Local data collection

Counseling and referral

Collaborative practice: testing & prescribing

Community partnerships

Komoto Healthcare, 1981

Demographics: Delano, CA

Parameter	Delano	United States
Population size, n	55,659	325,719,178
Hispanic or Latino	72.2%	17.3%
Median household income	$36,949	$55,322
Below poverty level	29.0%	15.1%
High school graduate or higher	54.5%	87.0%

Factfinder.census.gov
Facebook.com/JasmineVineyards

Komoto Healthcare, 2018

Condom and medication distribution

Komoto Pharmacy

Komoto Medical Pharmacy

Integrated Care Systems

Synergy Pharmacy Solutions

Komoto Family Foundation

Risk behaviors and perceptions

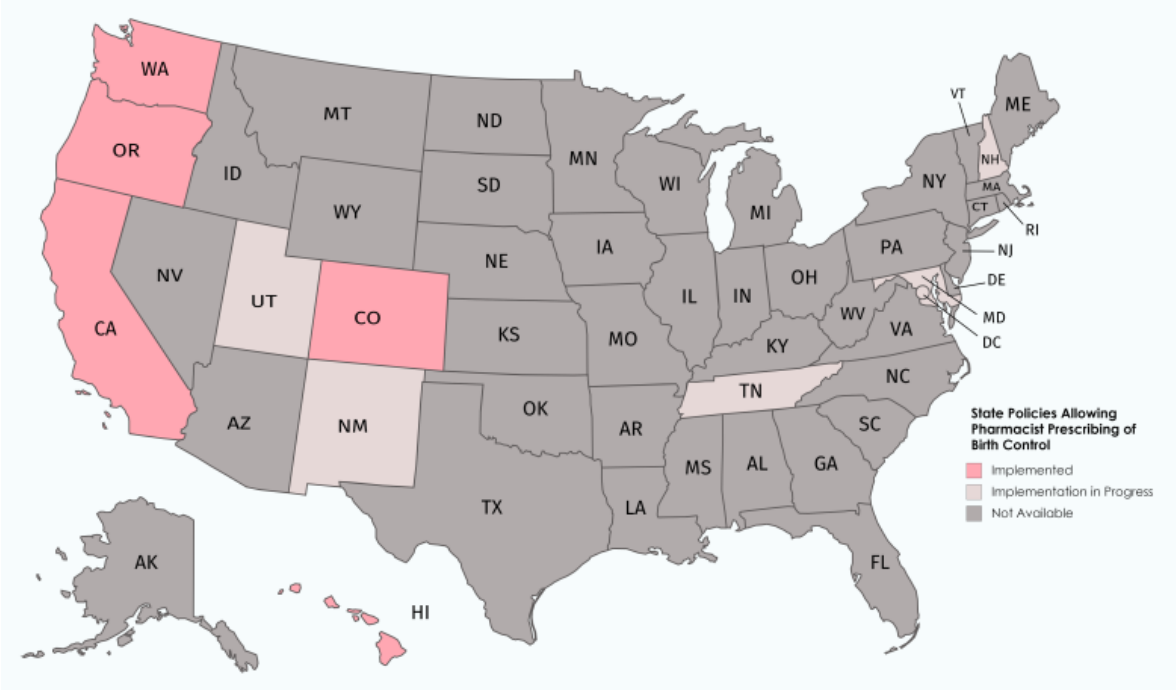
- **At a local community college, 63% rarely or never used a condom during vaginal intercourse during last 30 days (n=676)**

- **Community pharmacy survey (n=97)**
  - **44% had first intercourse < age 17**
  - **At first intercourse, 53% used no method of contraception**
  - **55% had first pregnancy < age 20**
  - **60% had at least one unplanned pregnancy**
  - **47% of those who do not desire pregnancy used contraception inconsistently**

Local data collection

Data on file; publications in progress

Contraceptive Prescribing: an opportunity to discuss STI prevention



Birthcontrolpharmacies.com

STI Counseling and Referral

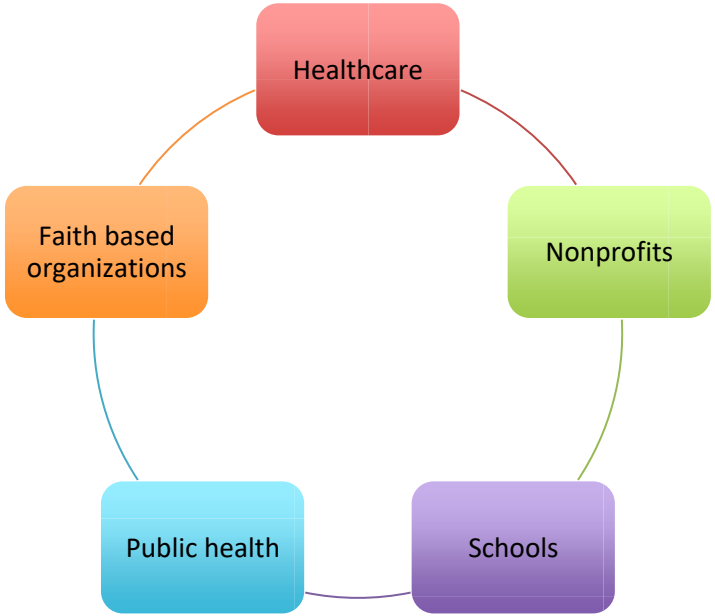
- Referral to local clinics
  - Primary care/gynecologists
  - Publicly funded
    - Planned Parenthood
    - Federally Qualified Health Clinics
    - Public Health Departments
- Counseling on risk reduction
  - Condom use
  - Testing with each new partner
- Cultural humility
  - Avoid making assumptions (monogamy, gender identify, sexual orientation, etc)
  - Reserve judgments

Social Determinants of Health

https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health. Accessed September 12, 2018.

Community Partnerships

- Kern County STI Action Team
  - Phase 1: Know your risk
  - Phase 2: Parents, talk to kids.
    - "Be the first voice"
  - Phase 3: Get tested
- Delano Sexual Health Task Force
  - Farmworker outreach
  - Peer health educators



Local STI prevalence

Kernpublichealth.com.

Re-imagining the “Sexual Health” Aisle

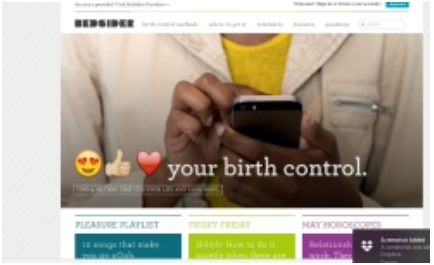
Accessibility

Inclusivity: “I am a gay man. The sex I have is non-reproductive by definition.” –Jamie Lawson

Variety

Patient-friendly Resources

www.teensource.org



www.bedsider.org

www.talkwithyourkids.org

Children's books: It's NOT the Stork, It's So Amazing, It's Perfectly Normal

KEY TAKEAWAYS

1) **THE ROLE OF COMMUNITY PHARMACISTS**
Community pharmacists can reduce the burden of STIs through various means, including condom and medication distribution, counseling and referral for STI testing and treatment, local data collection, community partnerships, and collaborative practice arrangements.

2) **OPPORTUNITIES TO ENGAGE PATIENTS IN STI CONVERSATIONS**
Pharmacists can counsel patients on STI prevention, testing, and treatment through various encounters, including medication dispensing and contraception prescribing.

3) **COMMUNITY PARTNERSHIPS**
Pharmacists can participate in community-wide coalitions as part of a cross-functional collaboration to prevent and reduce the incidence of STIs.

Patient Case Revisited

CJ is a 25 year old bisexual black male living with HIV who presents to clinic for a 6 month follow up appointment. He reports several casual sex partners for oral, receptive, and insertive anal sex since last visit. States he/his partners wear condoms "when we can remember." He tolerates his medication well, reports 100% adherence, and has no complaints today.

Allergies: NKDA

Current medications:
Bictegravir/emtricitabine/tenofovir alafenamide 50/200/25 mg po daily

Patient Case Revisited

Pertinent PMH:
HIV – diagnosed 1/2017; risk factor = bisexual; CD4 nadir = 532 cells/mm^3
Chlamydia – 1/2017, treated
Gonorrhea – 1/2017, treated
Syphilis – 1/2017 (RPR 1:256), treated; most recent RPR = 1:2 on 4/2018

Pertinent Labs from 11/20/18 (2 weeks prior to appointment date):
HIV-RNA = <20 copies/mL CD4/% = 711/35 cells/mm^3 RPR = 1:64

GC/Chlam (rectal, throat, oral) = POS/POS; neg/neg; POS/neg
Comprehensive metabolic panel = WNL

Post-Test Question 1

Based on CJ's labs from 11/2018, what treatments, if any, are recommended?

A. Amoxicillin + benzathine penicillin G + doxycycline
B. Azithromycin + benzathine penicillin G + ceftriaxone
C. Azithromycin + ceftriaxone
D. Benzathine penicillin G + ceftriaxone
E. None, as he was treated previously 1/2017

Assessment/Plan:

1. **Early non-primary, non-secondary syphilis – RPR 1:64 (11/2018) vs. 1:2 (4/2018). Pt is asymptomatic, no chancre, no rash; ≥ 2 fold positive change in RPR**
    1. **Plan = benzathine penicillin G 2.4 million units IM x 1 dose.**
    2. **F/up RPR ~6-12 months; minimal acceptable response, RPR = ≤ 1:16**
2. **Gonorrhea – positive rectal and oral. Pt asymptomatic.**
    3. **Plan = ceftriaxone 250 mg IM x 1 dose PLUS azithromycin 1 gm PO x 1 dose.**
    4. **F/up test unnecessary unless symptoms present.**
3. **Chlamydia – positive rectal on lab. Pt asymptomatic.**
    5. **Plan = azithromycin 1 gm PO x 1 dose.**
    6. **F/up test of cure ~3 months.**
4. **HIV – undetectable with good immunologic function**
    7. **Plan = continue present management with BIC/FTC/TAF PO daily**
    8. **F/up HIV labs ~6 months**
5. **Sexual Health**
    9. **Condoms!! Encourage partner(s) get tested/treated.**

Post-Test Question 2

Due to increased resistance concerns, which is the most appropriate treatment for gonococcal infections based on the most recent STI guidelines?

A. Amoxicillin + cefixime
B. Azithromycin
C. Azithromycin + ceftriaxone
D. Cefixime
E. Ceftriaxone