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Clinical Practice Alert: Chlamydia & Gonorrhea Screening & Treatment June 20, 2019

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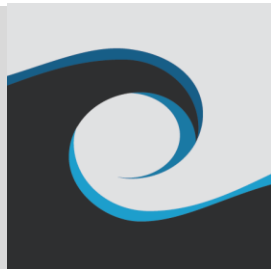
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REMINDER: If an individual or group members have not pre-registered, please register using this link for same day registration:

https://www.ofpregistration.org/presentation_description.html?id=170

After the webinar, you will receive an email with the materials and evaluation link.

Chlamydia and Gonorrhea Screening and Treatment



California PTC

Today's speakers



Ina Park, MD, MS

UCSF School of Medicine

California Prevention Training Center



Michael Policar, MD, MPH

UCSF School of Medicine

Family Planning Access and Treatment

Question 1:

- Please explain the difference between routine GC and CT screening compared to targeted testing?
- What are the criteria for targeted testing of women 25 and older?
- Are they any different for males? Should any males be screened routinely?

Who gets screened for CT/GC?

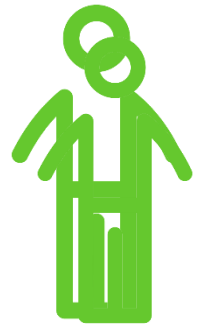


Cis-women

- <25 yrs. annually* if ever sexually active
- ≥25 yrs. **if at risk**
- All pregnant <25 yrs.
- Pregnant ≥25 yrs. **if at risk**

Men who have sex with women

- **High prevalence settings** (teen clinics, corrections, STD clinics, family planning clinics)



Men who have sex with men (MSM)

- At least annually*
 - Exposed sites: genital, rectal, pharyngeal
- TG men/women as well

After treatment

- All patients should be re-tested ~3 months after being treated for a CT/GC infection



*At least annually and more frequent if new/ongoing risk

Risk factors for CT/GC infection

- History of chlamydia or gonorrhea infection w/in past 2 years
- Multiple sex partners within the past year
- A recent sex partner who had suspected concurrent sex partners
- Exchanging sex for money/drugs/safety/housing
- Sex in conjunction with drug use

Question 2:

- What about screening females in high prevalence practice sites? Do the CDPH guidelines about routine screening when practice-site specific rates of CT are $\geq 3\%$ and GC are $\geq 1\%$ still apply?
- How can a clinic or a practice determine what the positivity rates for GC and CT are for different age strata at their site?

Screening in high prevalence sites

- Sites that have rates of CT $\geq 3\%$ and GC $\geq 1\%$ among women ≥ 25 years of age (e.g., 25-29 yr olds) may chose to perform routine screening in this age group
- For certain time period (e.g., 1 month), screen all sexually active women between the ages of 25-29
- Pull data for women based on DOB during study period
- $\% \text{ positivity} = \# \text{ positive test results} / \# \text{ of women screened}$
 - Calculate $\% \text{ positivity}$ for 25, 26, 27, 28, 29 year olds



Question 3:

- Are there any new data on CT/GC transmission?
- Could kissing alone spread CT/GC?

Kissing and Oropharyngeal STIs?

- N=3000 MSM in Australia completed surveys about sexual behavior including tongue-kissing, oral sex, anal sex

Compared to MSM with 0-1 partners

- Men with 4 or more partners, kissing-only: 46% increased risk for GC in throat
- Men with 4 or more partners, kissing-and-sex: 81% increased risk for GC in throat
- Sex without kissing (no association found)
- Data are cross-sectional, not prospective, so certainly not definitive

Question 4:

- What is the optimal way to obtain genital tract samples GC and CT in females and males?
- What about screening after vaginoplasty in transgender women?
- Any specific tips regarding how clinicians should obtain and transport samples to maximize the accuracy of test results?

**Recommendations for the Laboratory-Based
Detection of *Chlamydia trachomatis* and
Neisseria gonorrhoeae — 2014**

Nucleic acid amplification tests (NAATs) are recommended for detection of genital tract infections in men and women

- highly sensitive and specific compared to culture
- less dependent on specimen collection and handling

Optimal specimen types are:

- First catch **urine** for men
- **Self collected vaginal swabs from women**

NAATs are recommended for: detection of rectal and oropharyngeal infections

- As of **May 2019**, FDA approved for rectal or pharyngeal specimens. Preferred testing method over culture

Optimal specimen collection/handling

- For first-catch urine, patients shouldn't urinate an hour before they provide a specimen for GC/CT
 - If patient urinated < 1 hr before, ok to use specimen, but sensitivity may be reduced
- What if we only have a midstream urine?
 - 96/100 participants with first-void urine + for CT also had a positive midstream urine (CI 90-99%)
 - Ok to use the specimen, but sensitivity may be slightly reduced

(Mangin et al J Fam Pract 2012)

STI screening after vaginoplasty?

- Penile inversion technique – skin lined vagina
 - ? Urethral mucosa used
 - Reasonable to screen urine instead of neovagina but optimal specimen type is unknown
- Sigmoid colon vaginoplasty
 - Less common
 - Mucosal epithelium can be infected with CT/GC
 - Swab the neovagina

Question 5:

- When an individual discloses oral or anal-receptive sexual contact, how should multi-site screening be performed?
- Does it happen often that a female is GC or CT negative in the genital site, but positive in the oropharynx or rectum?
- Should both tests be requested from oropharynx and anus?
- Is there a “best way” to obtain a throat or anal sample?
- Do any national guidelines recommend routine oropharyngeal or anal sampling when exposure at either of these sites has not been disclosed?

What about rectal CT/GC in women?

- Rectal CT positivity in women overall: **6%** (95% CI, 3.2-8.9%)
- Rectal CT positivity in women reporting anal sex: **25.9%** (95% CI 8.5-43.3)
- % of rectal infections that would be missed with only urogenital screening: **18-23%**

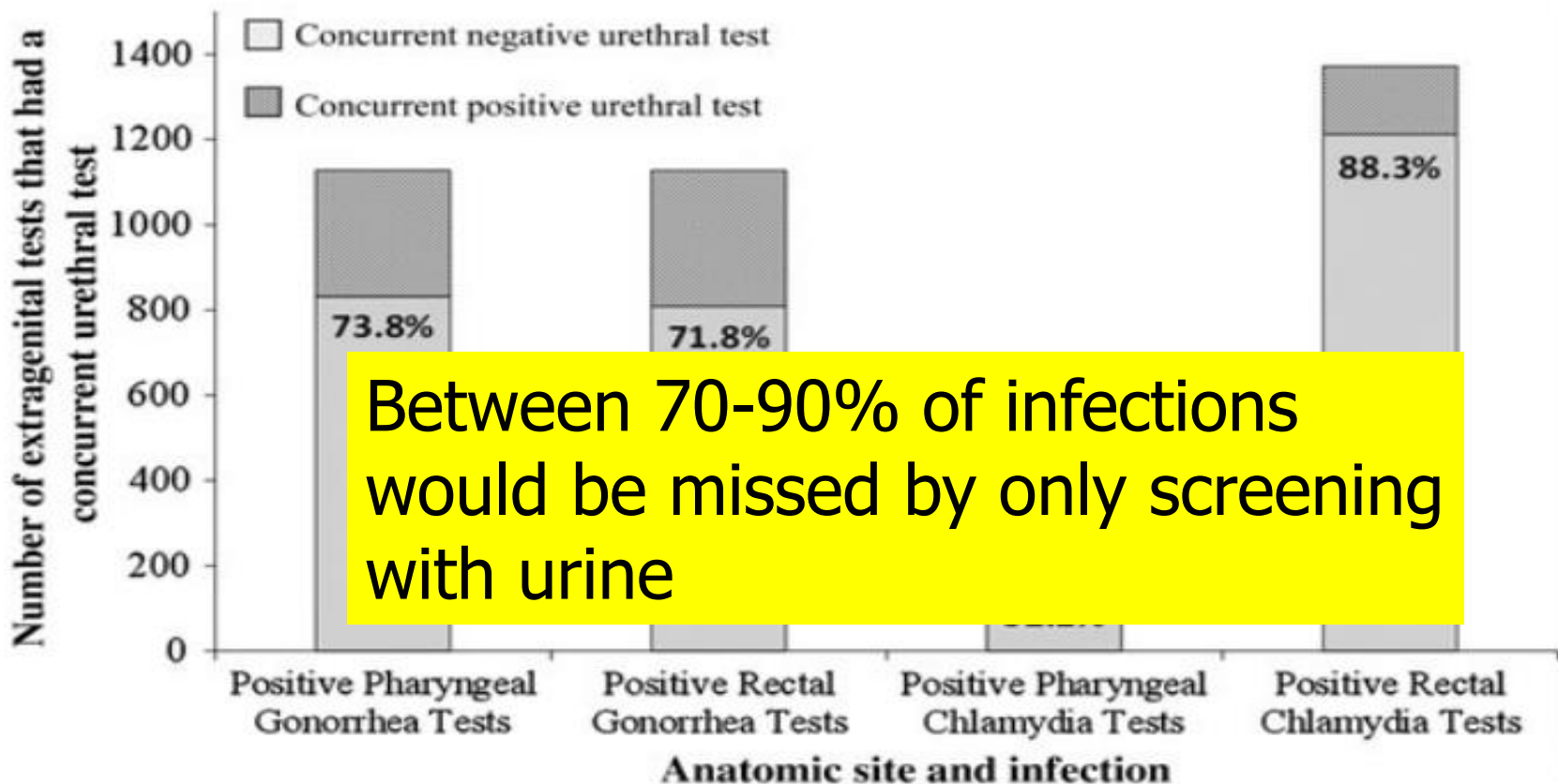
Chandra et al, STI 2018

Bamberger et al, STD 2019

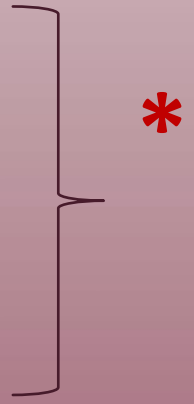
Cosentino et al, J Clin Microbiol 2017

Llata et al Obstet Gynecol 2018

Pharyngeal and Rectal CT/GC Often Associated with Negative Urine Test, STD Surveillance Network (n=21994)



STI Screening for MSM

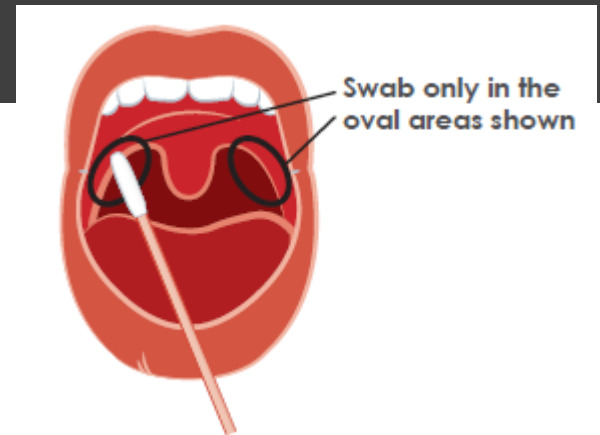
- HIV
 - Syphilis
 - Urethral GC and CT
 - Rectal GC and CT (if RAI)
 - Pharyngeal GC (if oral sex)
 - Hepatitis B (HBsAg, freq not specified)
 - Hepatitis C (for HIV+ MSM, at least annual)
- 

Anal Cancer in HIV+ MSM: Data insufficient to recommend routine screening, some centers perform anal Pap and HRA

* At least annually, more frequent (3-6 months) if at high risk (multiple/anonymous partners, drug use, high risk partners)

Let's talk about technique

- Throat: Swab both tonsillar pillars (watch out for gagging)
- For rectal swab:
Insert 3-4 cm and twirl the wrist 360°





Question 6:

- What should providers do when a GC or CT test result is positive regarding public health surveillance reporting?

Reporting

- Both CT and GC are reportable conditions to the California Department of Public Health (CDPH)
- Positive CT/GC results automatically reported laboratories to CDPH
- CDPH will send a Confidential Morbidity Report (CMR) to provider to fill in key missing information: Race/ethnicity, pregnancy status, treatment
- CMR data helps state monitor disparities, adherence to treatment recommendations. **Please complete CMRs**

Question 7:

- What are the recommended treatments for GC and CT?
- Is gonococcal antibiotic resistance a major issue in California? Are management recommendations any different (i.e., more stringent) in any parts of the state?
- How important is it for a clinic that currently does not do IM injections to develop that capability in order to make treatment with ceftriaxone available?

Chlamydia Treatment: Adolescents and Adults

Recommended regimens (non-pregnant):

- ❖ Azithromycin 1 g orally in a single dose
- ❖ Doxycycline 100 mg orally twice daily for 7 days

Recommended regimens (pregnant*):

- ❖ Azithromycin 1 g orally in a single dose

* Test of cure at 3-4 weeks only in pregnancy

Chlamydia Treatment

Updates to STD Treatment Guidelines in 2015

Alternative Regimen (non-pregnant):

- ❖ Doxycycline (delayed release) 200 mg QD x 7 d
- Equally efficacious to BID doxy, ↓ GI side effects
- More \$\$\$

Alternative Regimen (pregnant):

- ❖ Amoxicillin* 500 mg po TID x 7 days
- CT persistence documented in vitro after treatment prompted removal from recommended to alternate

* Moved from recommended to alternative regimen.

Gonorrhea Dual Therapy

Uncomplicated Genital, Rectal, or Pharyngeal Infections

Ceftriaxone 250 mg IM in
a single dose

PLUS*

Azithromycin 1
g orally
(preferred)
or
~~Doxycycline 100
mg BID x 7 days~~

- Regardless of CT test result

Gonorrhea Treatment Alternatives

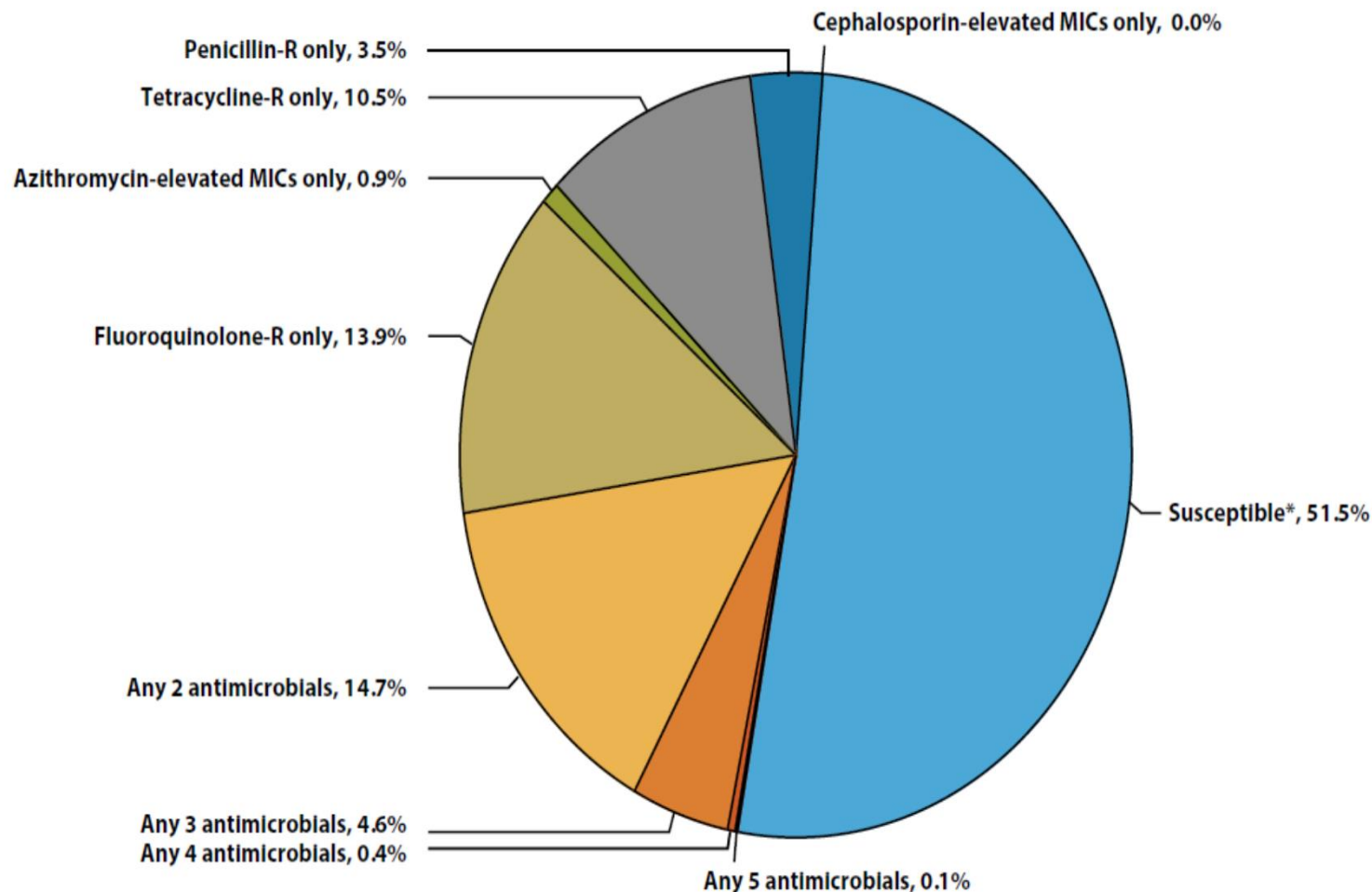
Anogenital Infections

ALTERNATIVE CEPHALOSPORINS:

- ❖ Cefixime 400 mg orally once
PLUS
- ❖ Azithromycin 1 g (preferred)

Half of Gonococcal Isolates have resistance to at least one antibiotic

Gonococcal Isolate Surveillance Project, 2017



Multidrug resistant gonorrhoea

- Hawaii: Sept 2016 (7 cases)
 - Canada: November 2017 (1 case)
 - **England: March 2018 (1 cases)**
 - Australia: April 2018
 - **England: January 2019 (2 cases)**
-
- Two cases from England required hospital admission for IV therapy (!) with ertapenem

Question 8

- How common is penicillin or cephalosporin allergy?
- How should a person with gonorrhoea be managed if they have this allergy?
- Is there still a role for using azithromycin 2 grams in treating gonorrhoea in persons who are penicillin allergic?

Is it really a penicillin allergy?

Is it Really a Penicillin Allergy?

Evaluation and Diagnosis of Penicillin Allergy for Healthcare Professionals

Did You Know?

5 Facts About Penicillin Allergy (Type 1, Immunoglobulin E (IgE)-mediated)

1. Approximately 10% of all U.S. patients report having an allergic reaction to a penicillin class antibiotic in their past.
2. However, many patients who report penicillin allergies do not have true IgE-mediated reactions. When evaluated, fewer than 1% of the population are truly allergic to penicillins.¹
3. Approximately 80% of patients with IgE-mediated penicillin allergy lose their sensitivity after 10 years.¹
4. Broad-spectrum antibiotics are often used as an alternative to penicillins. The use of broad-spectrum antibiotics in patients labeled "penicillin-allergic" is associated with higher healthcare costs, increased risk for antibiotic resistance, and suboptimal antibiotic therapy.¹
5. Correctly identifying those who are not truly penicillin-allergic can decrease unnecessary use of broad-spectrum antibiotics.¹

10% of the population reports a penicillin allergy but <1% of the whole population is truly allergic.



Before prescribing broad-spectrum antibiotics to a patient thought to be penicillin-allergic, evaluate the patient for true penicillin allergy (IgE-mediated) by conducting a history and physical, and, when appropriate, a skin test and challenge dose.

10% of Americans report having a PCN allergy

>90% of these are not true allergies

Kaiser Southern CA: > 1 million patients exposed to cephalosporins:
Chance of anaphylaxis 1/100,000-1/1,500,000

NOT related to history of PCN allergy

Gadde, JAMA 1993

Sacco, Allergy 2017

Macy, J Allergy Clin Immunol 2015

<https://www.cdc.gov/antibiotic-use/community/pdfs/penicillin-factsheet.pdf>

Gonorrhea Treatment Alternatives

Anogenital Infections

ALTERNATIVE CEPHALOSPORINS:

- ❖ Cefixime 400 mg orally once
- PLUS***
- ❖ Azithromycin 1 g (preferred)

IN CASE OF SEVERE ALLERGY:

Gentamicin 240 mg IM + azithromycin 2 g PO

OR

Gemifloxacin 320 mg orally + azithromycin 2 g PO

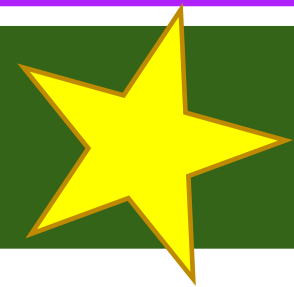
Question 9:

- When a person is found to have gonorrhea or chlamydia, how should their partner(s) be notified and treated?
- Could you please explain what patient-delivered partner therapy (PDPT) is and how it can be accomplished?
- Is there a “best approach” to maximize the likelihood that partner(s) will complete treatment?

Partner Management Options

Patient brings partner with them to clinic for treatment
(concurrent patient partner therapy)

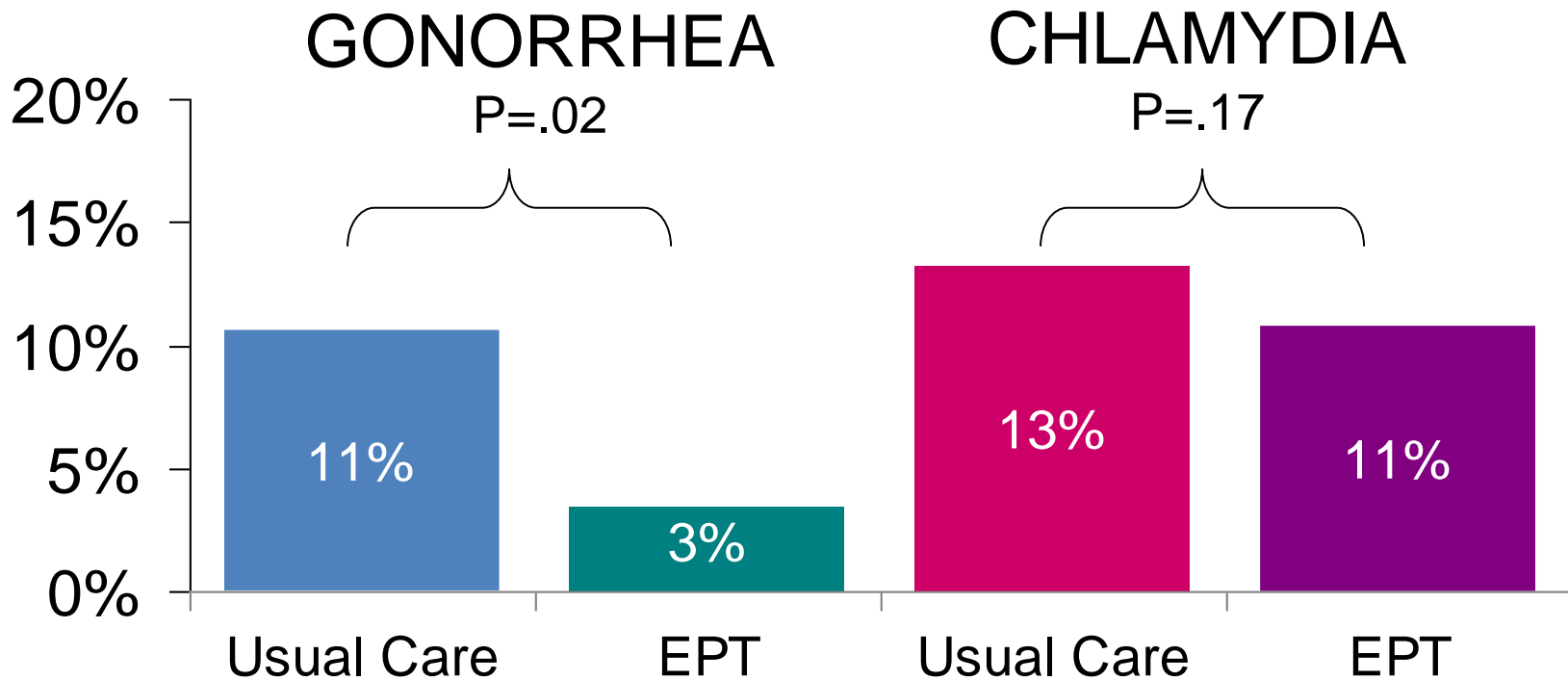
Expedited partner therapy (EPT)
via Patient-Delivered Partner Therapy (PDPT)



Other options with less demonstrated effectiveness:

- Patient telling partner to get tested (“patient referral”)
- Anonymous partner notification
- Local health department referral

The Effectiveness of Expedited Partner Treatment (EPT) on Re-Infection Rates



Essential Access Health's CT/GC Patient Delivered Partner Therapy Program

- Program provides **free CT/GC medication** to eligible clinic sites + local health jurisdictions (LHJs)
- Participating clinic sites dispense **pre-packaged medication** to patients diagnosed with CT/GC who give the medication to their sex partner(s) for treatment



www.essentialaccess.org/pdpt

Partner Management: Take Home points

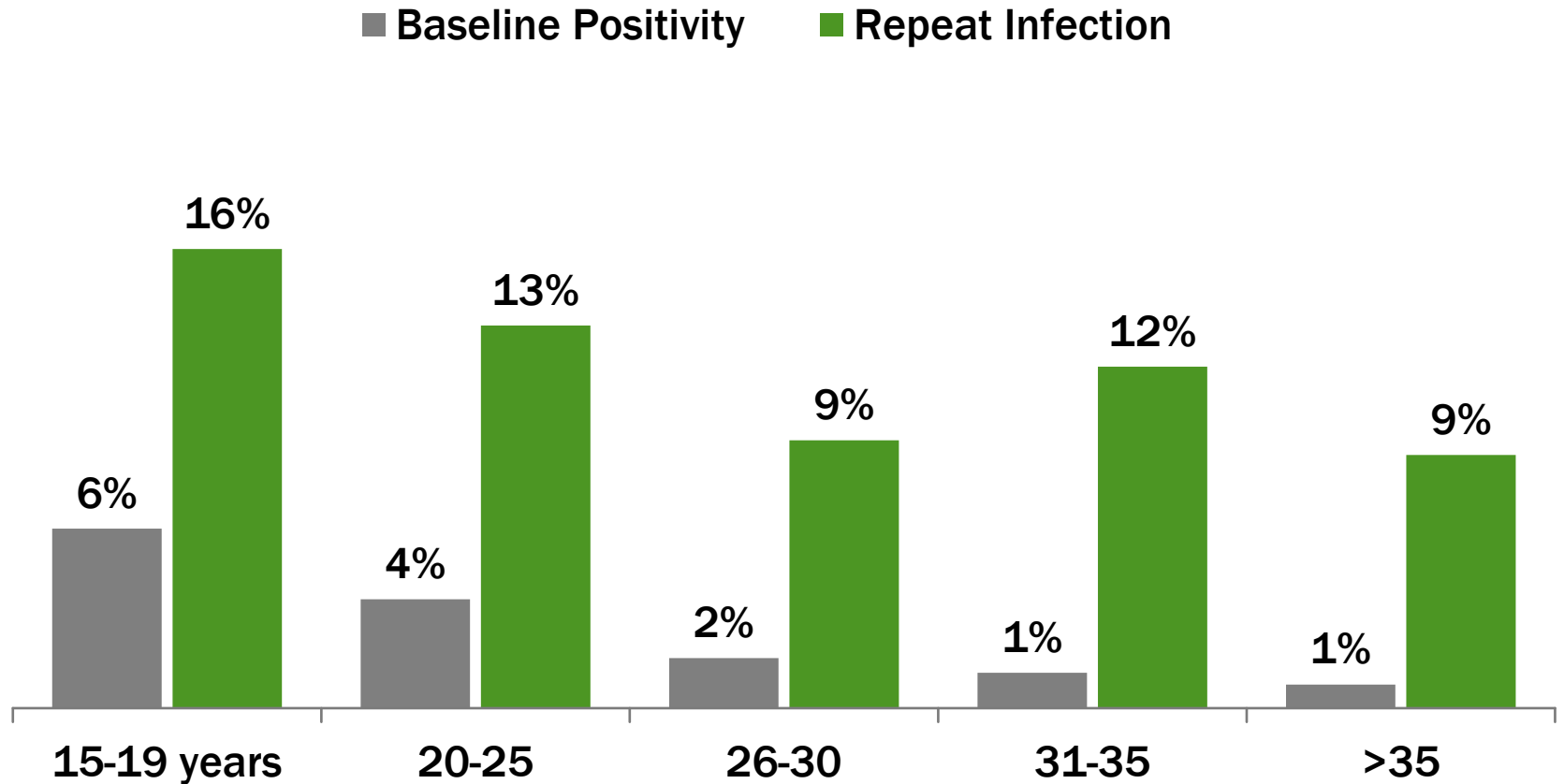
For patients being treated for a chlamydia and/or gonorrhea infection:

- Clinical evaluation of recent/current sex partners is first-line option
 - Concurrent patient-partner therapy (CPPT) – asking the patient to bring his/her partner to treatment appointment -- can be effective for one primary partner
- Offer expedited partner treatment (EPT/PDPT) routinely to patients for partner(s) who cannot be promptly treated
 - Offering prepackaged medication is most effective; giving a Rx also an option

Question 10

- When a person has been diagnosed and treated for GC or CT, when should re-testing occur? Any advice regarding how to get patients to return for retesting?
- Are there any situations when the patient who has been treated for gonorrhea or chlamydia should be advised to return for a “test of cure”?
- When should this be done (i.e., how many weeks after treatment)?
- What are the next steps when the test-of-cure is positive?

Reinfection is common: regardless of age, rates often 2-3 times higher than baseline positivity rates.



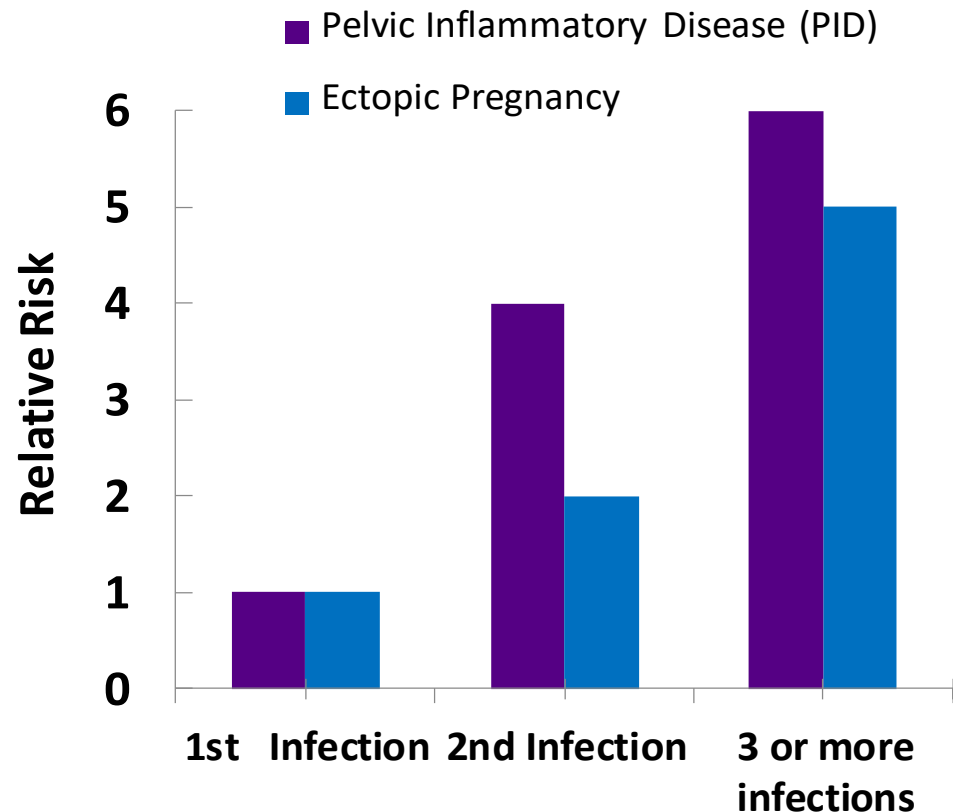
Reinfection is dangerous: highly associated with increased risk for adverse reproductive health consequences.

2nd infection:

- 4x risk of PID
- 2x risk of ectopic pregnancy

3+ infections:

- 6x risk of PID
- 5x risk of ectopic pregnancy



Retesting is not the same as Test-of-Cure.

Retesting/Rescreening = screening to identify reinfection

Test-of-Cure = testing to confirm that treatment was effective

Test-of-Cure for chlamydia is only recommended in limited circumstances:

- **All pregnant females**
 - 3-4 weeks after completion of recommended therapy
- **Non-pregnant females only if:**
 - Compliance is in question or symptoms persist

Retesting is not the same as Test-of-Cure.

Retesting is recommended for ALL patients who have tested positive for chlamydia (or gonorrhea) ~3 months after treatment

- *or opportunistically at next visit*
- especially important for adolescents; high prevalence of repeat infection
- Timing: need to wait at least 3 weeks after treatment to re-test for chlamydia with NAAT because of risk for false positives (continued presence of nonviable organisms)

Effective ways to counsel patients to return for chlamydia/gonorrhea retesting

Counsel patients about **why** they need to prioritize retesting:
“reinfections are common and dangerous”



Ask patients how they can help themselves **remember** their retest
(i.e., cell phone reminder)

Chlamydia TOC positive after azithro?

Recommended regimens (non-pregnant):

- ❖ Azithromycin 1 g orally in a single dose
- ❖ Doxycycline 100 mg orally twice daily for 7 days

Recommended regimens (pregnant*):

- ❖ Azithromycin 1 g orally in a single dose

* Test of cure at 3-4 weeks only in pregnancy

Suspected GC Treatment Failure

TEST WITH CULTURE AND NAAT:

- If GC culture not available, call your local health department

REPEAT TREATMENT:

- Gemifloxacin 320 mg + AZ 2g OR Gentamicin 240 mg IM + AZ 2g
- If reinfection suspected, repeat treatment with CTX 250 + AZ 1g

REPORT:

- To your local health department within 24 hours

TEST AND TREAT PARTNERS:

- Treat all partners in last 60 days with same regimen

TEST OF CURE (TOC):

- TOC 7-14 days with culture (preferred) and NAAT

Question 11:

- If a person who was treated for GC or CT returns a week later stating that they have had sexual contact with an untreated partner, should the patient be tested, empirically treated, or both?

Treatment after re-exposure

- No specific guideline in this circumstance
- If patient has a primary partner that is likely source of repeat infection, reasonable to treat empirically
- If patient had multiple partners and its unknown who was the source of the infection, reasonable to test and then await results, but also ok to treat!

Question 12:

- There has been a lot of discussion about *Mycoplasma genitalium*, but many clinicians are confused about screening and treatment of this infection in women.
- Can you summarize what is known about this topic and what guidelines recommend?

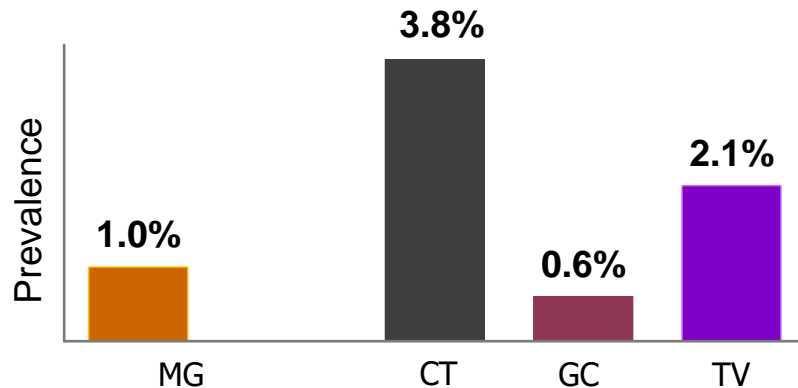
Mycoplasma genitalium



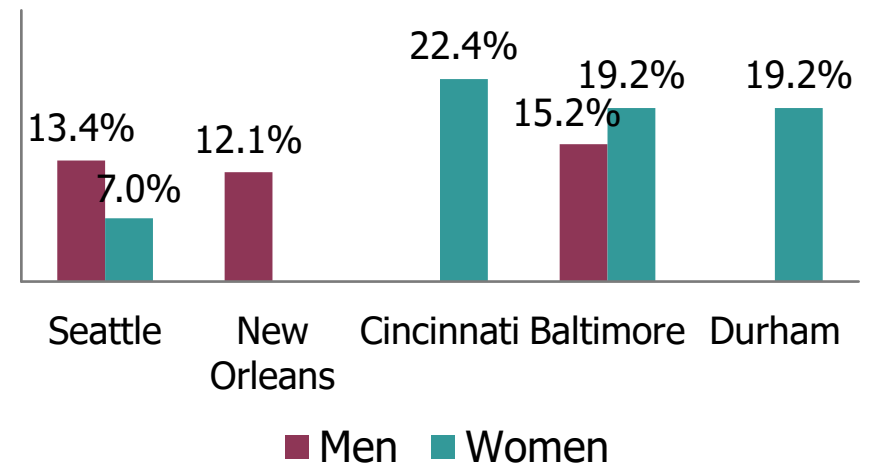
M. genitalium

More common than you think

Young adults 18-24 yrs^{1,2}



STD Clinic/ED Attendees³⁻⁹



¹ Miller 2004; ² Manhart 2007

³Totten 2001; ⁴Mena 2002; ⁵Manhart 2003; ⁶Huppert 2008; ⁷-
⁸Gaydos 2009a & 2009b; ⁹Mobley 2012

M. genitalium & Reproductive Tract Disease

- Definitely associated with NGU in men, Likely associated with PID in cis-women
- Association with cervicitis is weaker
- Systematic review of association with:
 - Cervicitis
 - PID
 - Infertility
 - Preterm delivery
- **Increased odds of adverse outcomes = ~2.0 fold higher for all conditions**

Screening and Diagnostic Testing

- No national guidelines on screening or diagnostic testing currently
- Reasonable to test for *M. genitalium* in cases of NGU treatment failure in cis-men, cervicitis treatment failure, or PID treatment failure.

Detecting MG infections?

FINALLY: An FDA-approved diagnostic test (1/2019)

- **Nucleic Acid Amplification Test (Hologic GenProbe)**
 - Urine, urethral, penile meatal, endocervical, vaginal
- **Commercial Laboratories (in house PCR tests)**
 - Limited test-performance information



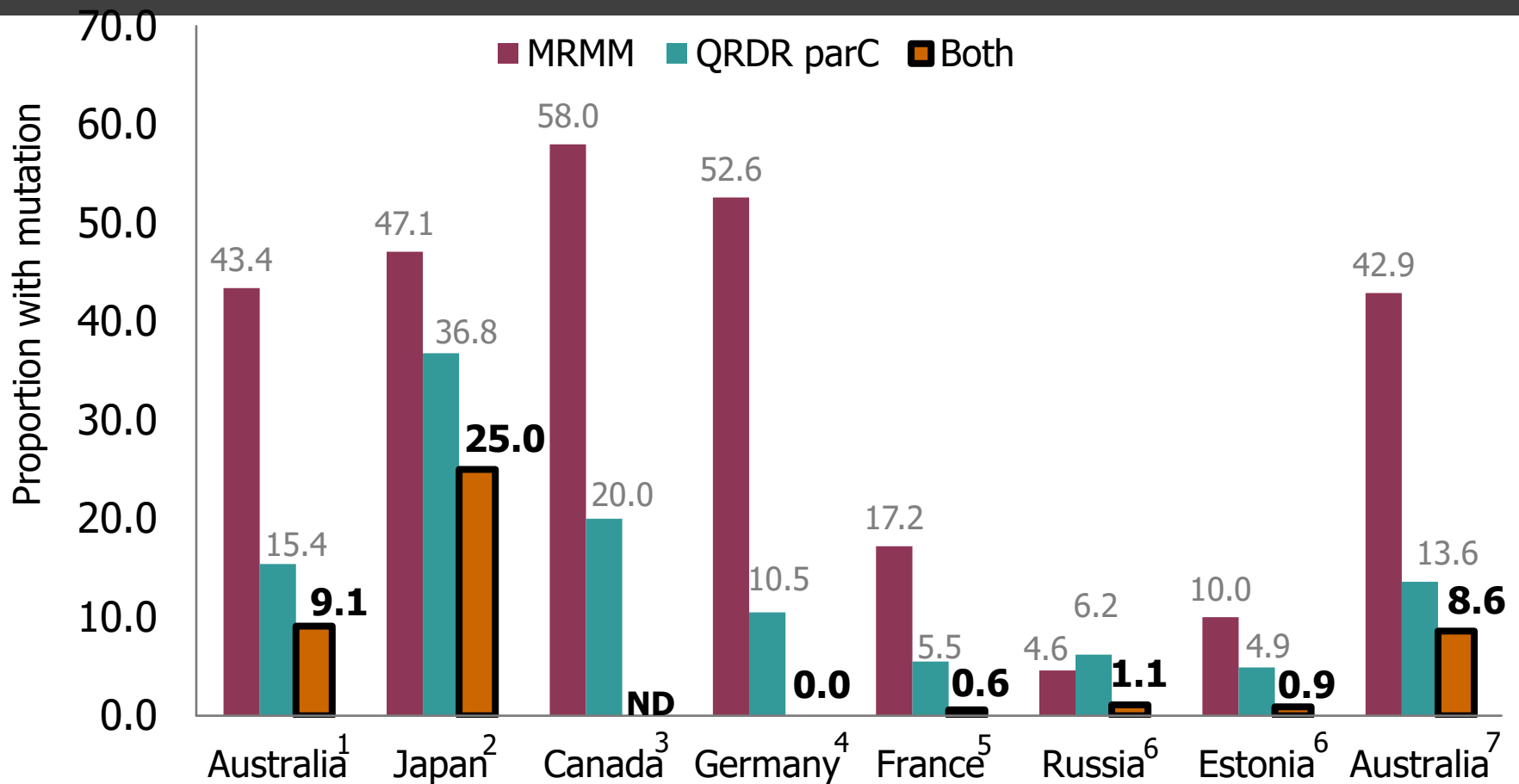
M. Genitalium Treatment



Moxifloxacin 400mg po x 7-14d

- Highly effective for treatment failures
 - 100% cure rates in most places
- Public health 340b pricing available
 - Usual price for 7 day course ~ \$100+
 - Negotiated price to **\$1.21/pill**
- ***Caveat:*** Moxifloxacin treatment failures emerging
(Japan, Seattle, Australia)

Emergence of Dual Resistance Macrolides-fluoroquinolones



¹Tagg 2013, ²Deguchi 2015, ³Gesink 2016, ⁴Dumke 2016, ⁵LeRoy 2016, ⁶Shipitsnya 2017, ⁷Murray 2017

Question 12:

- When sending a GC or CT sample to the lab, which ICD-10 codes must be included on the laboratory request?
- Why is this necessary?

Beyond the ICD-10 code for the client's contraceptive method, when is it necessary to include an additional ICD-10 code on a lab request for CT and GC NAAT tests?



FEMALES

- **<25 years:** Routine annual screening, any provider. No additional ICD-10-CM code required
- **<25 years:** Screening more than 1x per year, same provider, additional ICD-10-CM code is required
- **≥25 years:** Additional ICD-10-CM code required



**ACCEPTABLE
ADDITIONAL ICD-10-CM
DIAGNOSIS CODES**

- **Screening:** Z11.3, Z11.8, Z20.2, Z22.4, Z72.51 – Z72.53, Z86.19
- **Diagnostic CT:** A56.01, A56.09, A56.3, A56.4, N70.03, N70.93, N72, N89.8, N94.10 – N94.12, N94.19, N94.89, R30.0, R30.9
- **Diagnostic GC:** A54.01, A54.03, A54.5, A54.6, N34.2, N70.03, N70.93, N72, N89.8, N94.10 – N94.12, N94.19, N94.89, R30.0, R30.9



**MALES OF ANY AGE
(ADDITIONAL ICD-10-CM
CODE IS REQUIRED)**

- **Screening:** Z11.3, Z11.8, Z20.2, Z22.4, Z72.51 – Z72.53, Z86.19
- **Diagnostic CT:** A56.01, A56.3, A56.4, N34.2, N45.3, R30.0, R30.9
- **Diagnostic GC:** A54.01, A54.22, A54.5, A54.6, N34.2, N45.3, R30.0, R30.9

Sexually Transmitted Infection Screening Females and Males

PPBI (Lab Services, page 26, 28)

ICD-10	Description
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission (includes GC)
Z11.8	Encounter for screening for chlamydia
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z22.4	Carrier of infections with sexual mode of transmission
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior
Z86.19	Personal history of other infectious and parasitic diseases

Sexually Transmitted Infection Screening Females and Males

ICD-10	Description
Z11.3	“Screen me for everything” or “I live in a high CT prevalence location”
Z11.8	“I live in a high GC prevalence location”
Z20.2	“My partner(s) screened positive for an STD
Z22.4	“I have one STD already”...screen me for others
Z72.51	Targeted screening...e.g. multiple or new partners” (hetero)
Z72.52	Targeted screening...e.g. multiple or new partners (lesbian, gay)
Z72.53	Targeted screening...e.g. multiple or new partner (bisexual)
Z86.19	“I’ve had GC or CT within the past 2 years”

Sexually Transmitted Infection Testing

Examples of Female Presumptive Diagnoses

ICD-10	Description
N89.8	Leukorrhea NOS
N72	Mucopurulent cervicitis
N94.10	Unspecified dyspareunia
N94.12	Deep dyspareunia
R30.0	Dysuria

Sexually Transmitted Infection Re-testing Females and Males

ICD-10	Description
A56.01	Chlamydial cystitis and urethritis (M and F)
A56.09	Chlamydial cervicitis (F)
A56.3	Chlamydial infection of anus and rectum (M and F)
A56.4	Chlamydial infection of pharynx (M and F)
A54.01	Gonococcal cystitis and urethritis, (M and F)
A54.03	Gonococcal cervicitis, unspecified (F)
A54.22	Gonococcal prostatitis (M)
A54.6	Gonococcal infection of anus and rectum (M and F)
Z86.19	Personal history of other infectious and parasitic diseases



Question 13:

- Does Family PACT cover multi-site screening, as clinically indicated?
- Are there any limits on how often this will this be covered?

Family PACT Benefits

Multi-site GC and CT Screening and Testing

- Persons who disclose a history of having anal-receptive sex should have GC and CT NAAT samples taken at the rectal site
- Those having oral sex should be screened for oropharyngeal GC and CT
- Men who have sex with men (MSM) should be screened for GC and CT at least annually, based on sites of exposure.
- Family PACT (and Medi-Cal) frequency limits for GC and CT are up to three tests per recipient, per day (as of Sept, 2018)
- ***Routine*** multi-site screening is not recommended

Question 14:

- Questions come up regarding Family PACT coverage of patient delivered partner therapy. Obviously, if the patient's partner has, or obtains, Family PACT eligibility, treatment can be covered for him or her. Is there any other way that partner therapy for GC or CT can be covered by Family PACT?
- **Answer:** Not at the present time. Under current Family PACT policy, PDPT for GC or CT is not a covered benefit.

Question 15:

- Does Family PACT cover antibiotic treatment for the consequences of GC or CT infection: pelvic inflammatory disease in females and epididymitis in males?

GC and CT Infection Complications

Females and Males

ICD-10	Description
N70.03	Acute salpingitis and oophoritis (F)
N70.93	Salpingitis and oophoritis, unspecified (F)
N45.3	Epididymo-orchitis (M)

Pelvic Inflammatory Disease

- Lab: GC/CT NAAT, ESR, CBC
- Meds: ceftriaxone + doxycycline \pm MTZ, cefoxitin + doxy \pm MTZ, ceftriaxone + azithromycin, ofloxacin + metronidazole

Epididymo-orchitis

- Meds: ceftriaxone + doxycycline

Question 16:

- Does Family PACT cover testing for *Mycoplasma genitalium* or antibiotic treatment for presumed *M genitalium* in cases of NGU or cervicitis treatment failure?
- **Answer:** Family PACT covers moxifloxacin 400mg PO daily for 7 days for persistent and recurrent cervicitis in females and nongonococcal urethritis in males that has not responded to treatment with doxycycline or azithromycin
 - Pharmacy dispensing only; requires a TAR
 - Reference: ben grid, page 22.



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We greatly appreciate your feedback.

Evaluation link:

<https://www.surveymonkey.com/r/RQVKL37>