New Directions in the Clinical Management of Bacterial Sexually Transmitted Infections

Gail Bolan, M.D., Chief
Sexually Transmitted Disease Control Branch
CA Department of Public Health

May 26, 2010

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Tools you can use – Feedback Toolbar

Raise Hand
Feedback Results
Yes
No
Emoticons

2

Floating Toolbar

- Use the floating toolbar to communicate in today's session.

Participant List
Q&A
You are sharing G202.3_TeenLARC...
Chat

3

Q&A

Q&A
All (0)
Type Question
Type your question here. There is a 256 character limit.
Send
Ask: All Panelists
Click Send

4

Polling

Polling
Time elapsed: 1:23 Time limit: 5:00
Poll Questions:
1.What information do you need to look up a record?
a.Customer name
b.Account number
c.Order number
d.Either A or B
2.Which form fields are required?
a.Customer Name
b.Address
c.Phone number
d.Fax number
e.Birthday
Submit
Your answer will be anonymous

5

Sample Polling Questions:

1. Describe your professional background?
2. What is your principal employment setting?

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Evaluation and Other Forms

At the conclusion of session complete:

- Evaluation Form
- Post Test
- Continuing Education Form
- Sign-in Sheet

Forms can be downloaded at the end of this session by file transfer.

Those without web access can get forms by calling 1-877- FAMPACT

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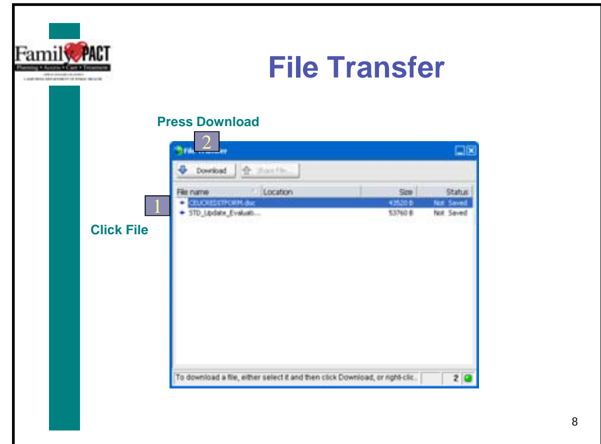
File Transfer



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Overview

- Novel specimen collection for screening
- Partner management strategies
- Repeat CT and GC testing
- Over screening in "older females"
- GC treatment challenges
- New syphilis screening algorithm
- Cervicitis and PID management

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Case # 1

Young woman for routine gyn visit

- 17 year-old G_0P_0 female presents for a gynecologic exam and is interested in starting OCs
- She has no complaints
- New male partner within past 3 months and they use condoms "most of the time"
- No symptoms
- LMP 2 weeks prior

Should she be screened for chlamydia?
Should any other STD tests be done?

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Clinic-based Chlamydia Screening Recommendations- Non Pregnant Women

- US Preventive Services Task Force, 2007
  - Sexually active women age 24* and younger should be screened annually

Endorsed by the CDC, ACOG & other medical associations

As of 2000, NCQA HEDIS measure **

- Family PACT recommends that sexually active women age 25 and younger should be screened annually

* In 2001, the age cut off was 25 years

** Measures women screened 15 through 25 years

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Current Chlamydia Diagnostic Tests: Test Performance

	Specificity	Sensitivity
EIA	> 99%	40-60%
DFA	> 99%	50-70%
DNA probe GenProbe PACE 2	> 99%	40-65%
Culture	> 99%	50-90%
NAATs *	> 99%	**>90%**

Roche *Amplicor* (PCR) **
GenProbe *Aptima* (TMA) **
B-D *ProbeTec* (SDA)

* Able to use urine and vaginal swabs specimens
** FDA cleared for liquid pap transport media

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Question: What is the best specimen collection method to detect chlamydial infections in young women?

1. Provider collected cervical swab specimen
2. Provider collected liquid-based cytology specimen
3. Patient collected vaginal swab specimen
4. Patient collected urine specimen

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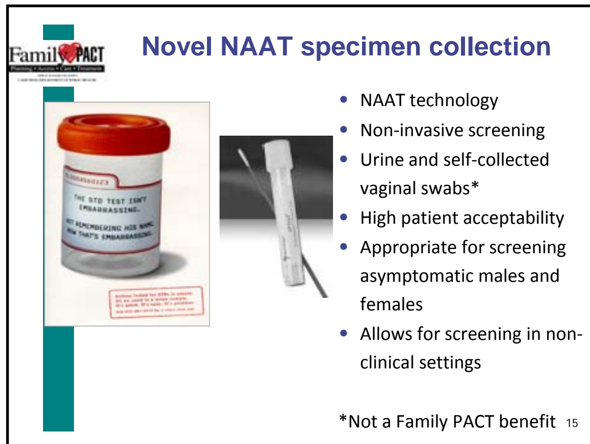

STD Screening Recommendations for Sexually Experienced Adolescents

Females:
- Chlamydia and gonorrhea annually
- Pap smear (3 yrs after sexual debut or age 21)
- HIV screening should be discussed and offered
- No recommendations regarding syphilis, HSV, trich

Males:
- Chlamydia screening if a high prevalence setting
- HIV screening should be discussed and offered

Don't forget:
- Contraception needs
- Immunizations- HBV and HPV

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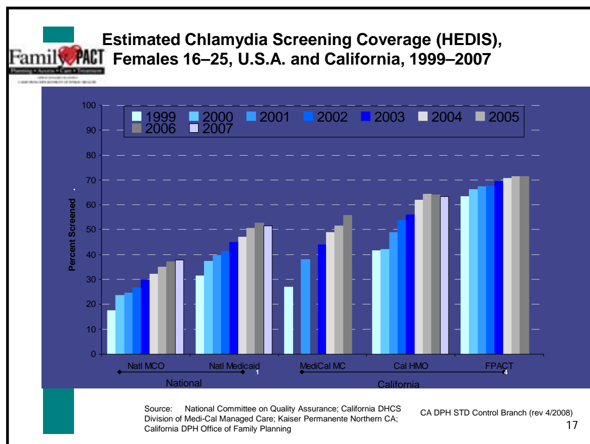

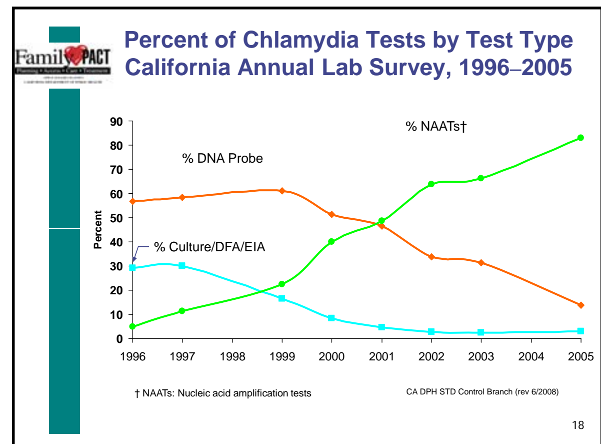

Case # 1 continued

- Physical and genital/pelvic exam normal
- Chlamydia and gonorrhea tests done using a vaginal swab NAAT
- 3 days later, her test results are reported:
  - Chlamydia positive
  - Gonorrhea negative

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Check List for the Management of Chlamydia Cases

- Ensure timely and appropriate treatment
  - Within 14 days of specimen collection
- Testing for other STDs
  - GC, syphilis, HIV
- Patient education and counseling
- Ensure that sex partners are treated
  - All partners in the past 2 months
- Schedule follow-up test in 3 months
- Report case to the local health department

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Chlamydial Infection
Treatment in Adolescents and Adults

Recommended regimens:

- Azithromycin 1 g PO x 1
- Doxycycline 100 mg PO BID x 7 d

Alternative regimens*:

- Erythromycin base 500 mg PO QID x 7 d
- Erythro ethylsuccinate 800 mg PO QID x 7 d
- Ofloxacin 300 mg PO BID x 7 d
- Levofloxacin 500 mg PO QD x 7 d

NO need for test of cure unless pregnant

*Alternative regimens not a Family PACT benefit

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Chlamydia Patient Counseling

- Abstain from sex for at least 7 days during treatment (even with single dose) and until all partners are treated
- Nature of transmission, methods of protection
- Potential long term and neonatal complications
- Treatment of partners prevents reinfection
- Repeat test in 3 months for reinfection

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Question: In your clinical setting, what is the most common method you use to treat partners?

1. Encourage the patient to bring their partner(s) in with them when they return for treatment
2. Give the patient extra medication to give to their partner(s)
3. Give the patient a prescription for their partner(s)
4. Counsel the patient about the need to self refer their partner(s) for treatment
5. Call the Health Department for assistance with partner services
6. None of the above because that is a Health Department responsibility

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Partner Treatment Options for Chlamydia and Gonorrhea

- Patient referral
- Provider/clinic referral
- Health department referral
- Expedited partner treatment (EPT)*
  - Patient-delivered partner therapy (PDPT)*
- Asking patient's to bring partner to clinic (BYOP)**

* Not a Family PACT benefit

** Eligible partners that enroll in Family PACT can receive treatment.

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Patient-Delivered Partner Therapy for Chlamydia Infection

- Untreated infection in male partner is a risk factor for repeat infection in women
- Repeat infections place women at increased risk of upper tract complications
- Single dose therapy is very safe and easy to administer
- PDPT reduces the rate of re-infection compared to patient referral
- PDPT legislation enacted January 1, 2001

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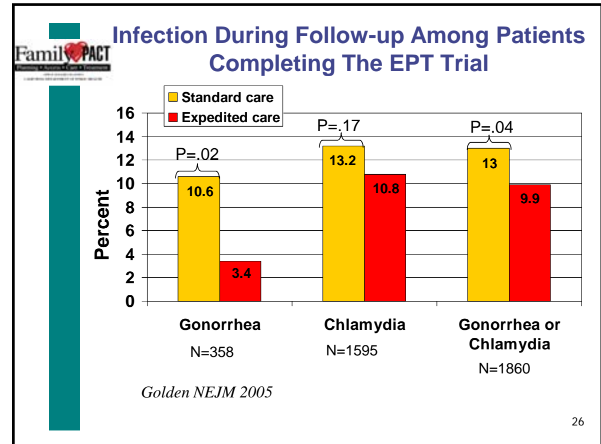
Infection During Follow-up Among Patients Completing The EPT Trial



Golden NEJM 2005

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Expedited Partner Treatment: PDPT for CT and GC

- CDC: "PDPT can prevent reinfection of index case and has been associated with a higher likelihood of partner notification…"[1] www.cdc.gov/std/ept for CDC EPT guidelines
- EPT for CT and GC is safe and effective option for partner management for heterosexual men and women
  - Written materials should accompany medication and specially mention concern about PID in female partners
  - Not recommended in MSM because of concern regarding co-morbidities (e.g., HIV and other STDs)
- First line management is clinical evaluation

1 - CDC 2006 STD Tx Guidelines www.cdc.gov/std/treatment

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Expedited Partner Treatment: Barriers and Concerns

- Adverse drug effects
- Missed opportunities for prevention counseling
- Legal status of EPT
- Litigation
- Funding
- Co-morbidities
- Minor consent
- Drug delivery/ packaging
- Providers'/agencies' attitudes & beliefs, etc.

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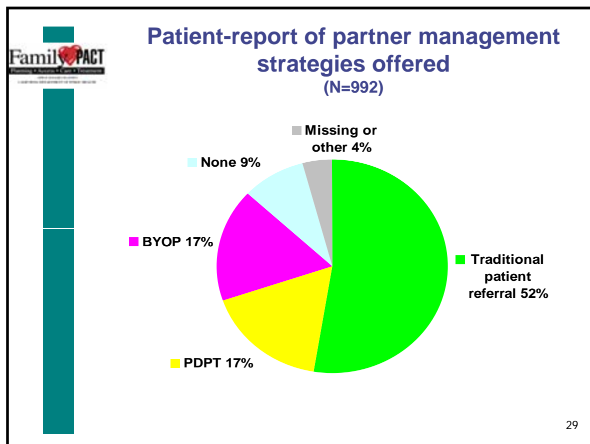
Patient-report of partner management strategies offered

(N=992)



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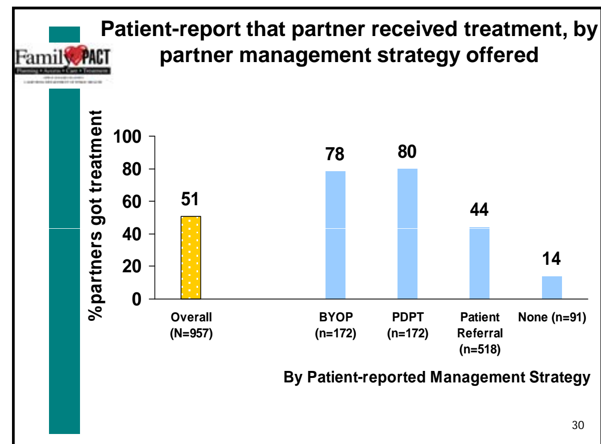
Patient-report that partner received treatment, by partner management strategy offered



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FamilyPACT

Summary of Partner Management Strategies in FP Clinics

- Traditional patient referral least effective, yet most commonly used
- BYOP and PDPT both very effective for steady partners
- PDPT most effective strategy for non-steady partners
- Casual/non-steady/multiple partners often missed during partner mgmt counseling
- Only moderate retesting rate among patients who returned to clinic 1-6 mos post-treatment

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FamilyPACT

Reinfection of Women with Chlamydia Within 12 Months of Initial Infection

Reinfection (%)
40
30
20
10
0
0 2 4 6 8 10 12
Months Follow-up

Review of 17 active cohort studies

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FamilyPACT

Reinfection of Women with Gonorrhea Within 12 Months of Initial Infection

Reinfection (%)
40
30
20
10
0
0 2 4 6 8 10 12
Months Follow-up

Review of 7 active and passive cohort studies

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FamilyPACT

Chlamydia and Gonorrhea Repeat Infection 1-6 months after infection

by Data Source, 2004

Percent Repeat Infection
12.0
10.0
8.0
6.0
4.0
2.0
0.0

CHLAMYDIA: CT Case reports 6.3; KPNC Cases 10.4; FP Cases 11.3

GONORRHEA: GC Case reports 4.1; KPNC Cases 7.7; FP Cases 7.3

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FamilyPACT

Retesting Rates in FP Clients who Returned after Chlamydia Treatment

- No Return Visit
- Returned and Retested
- Returned, Not Retested

21%
42%
37%

Female CT+ Clients
(N = 4,963)

2006 data from Family PACT-Quest Diagnostics, prepared by the CA STD Control Branch

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FamilyPACT

Remember to Get Re-tested

If you are TREATED for CHLAMYDIA, GONORRHEA, or SYPHILIS today, it is important that you return to the clinic in 3 MONTHS to get TESTED AGAIN.

Even if you feel fine, re-testing is necessary to make sure you have not been re-infected.

Re-Testing Poster available

www.sfcityclinic.org

Click on

"For Providers"

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Retesting at 3 Months

- Return rates are low
  - Generally 20-40%
- Reminder methods
  - Telephone
  - Mail
  - Email or text
- Flag chart for retest at any subsequent visit

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Case # 2

Woman for a check up

- 35 yo women comes in to your clinic and is about to start a new relationship
- She wants to restart OCs.
- She also says "I'd just like to be tested for everything."
- She was recently divorced, 2 lifetime partners, no history of STDs or drug use.
- Her physical and genital/pelvic exam was normal.

Should she be screened for chlamydia?

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Question: What is the most common reason you obtain a chlamydia test in a woman over the age of 25?

1. Patient requests the test
2. Patient is about to start a new relationship
3. Patient has multiple partners
4. Patient is concerned partner has another partner
5. I test all sexually active women for chlamydia

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Clinic-based Chlamydia Screening Recommendations- Non Pregnant Women

US Preventive Services Task Force, 2007

- Sexually active women age 24* and younger should be screened annually
- Women age 25* and older should be screened "if increased risk"
  - Risk factors: Previous CT or other STDs, new or multiple partners, inconsistent condom use, sex work
  - Demographics: African Americans and Hispanics
- Family PACT recommends that sexually active women age 25 and younger should be screened annually

* In 2001, the age cut off was 25 years

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Are we screening the wrong women?

- The majority of women in the target age range (25 and younger) are NOT being screened

Meanwhile

- A large proportion of current testing is being done for women over age 25

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Chlamydia Test Volume and Prevalence by Age among Female Patients in Public and Private Clinics

Source: PUBLIC: Family PACT, January-June 2001 & Infertility Prevention Project 2003
PRIVATE: PHIP - Kaiser Permanente, managed care organization, 1999-2002

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How to design a cost-effective screening program

- What is your goal of screening?
  - to test apparently well people to find those at increased risk of a disease or disorder
  - inappropriate screening is harmful- injurious, costly and stigmatizing
- When Earlier Diagnosis is Worth the Cost?
- What factors do you need to consider?
  - Prevalence of disease in population
  - Sensitivity and specificity of screening criteria
  - Test performance characteristics of diagnostic test
  - Cost of test, treatment and complications

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Question: What is the cost-effective prevalence threshold for chlamydia screening in a clinic setting?

1. .5 percent
2. 1 percent
3. 3 percent
4. 5 percent
5. 10 percent

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The Over 25 Chlamydia Evaluation Results: Women Age 26-44 by Clinical Presentation

Total CT-tested Participants
N = 2,634 n_{CT+} = 83
3.2 % CT+

Patients with clinical indications for CT testing:
N = 346 n_{CT+} = 24
- STD contacts
- Cervicitis or PID
- New STD dx

6.9 % CT+

29 % of CT Cases
13 % of Pop. Tested

Patients screened for CT:
N = 2,287 n_{CT+} = 59
- No STD contact
- No cervicitis or PID
- No new STD dx

2.6 % CT+

71 % of CT Cases
87 % of Pop. Tested

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Factors associated with Chlamydia in Non-Pregnant Women > Age 25 in California Family Planning Clinics

- Partner(s) possibly having had other concurrent partners (during past 12 mos) was the strongest predictor of CT infection;
- Other fairly consistent behavioral predictors of CT included:
  - > 1 partners in past 12 mos
  - New partner in past 2-3 mos
- Younger age, specifically age 26-30, was a strong demographic predictor of CT

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The Over 25 Study

"Partner possible other partners" Actual Question Studied:

Q: At anytime within the past 12 months*, did any of your male partners have sex (of any type) with someone else while they were still in a sexual relationship with you?

A:
- ❑ Yes, definitely
- ❑ Not sure, it is possible
- ❑ No, it is very unlikely

Answers combined (Yes, definitely; Not sure, it is possible)

* Also asked about the past 3 months in a separate question.

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Proposed CT Testing Guidelines for Women greater than age 25 in California

- Diagnostic testing based on clear clinical indications:
  - Current contact (exposure) to any STD
  - Clinical signs of cervicitis or PID
  - Newly confirmed or presumptively treated other STD dx
- Targeted Screening based on risk factors:
  - Partner possible other partners during past 12 mos!!!
  - More than 1 partner during past 12 mos
  - New partner during past 2-3 mos
- Use age-based prevalence data to guide age criteria is available
  - Request positivity reports by age from your lab

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Case # 3

Woman returns for gonorrhea treatment

- 22 yo women returns to your clinic for gonorrhea treatment after being tested 1 week ago.
- She says she feels fine and has had no vaginal discharge or abdominal or pelvic pain since her exam one week ago.
- She reports no recent travel.

How do you usually treat your patients for gonorrhea?

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Question: In a patient with uncomplicated gonococcal infection, which of the following treatment options do you usually recommend?

1. Ceftriaxone 125 mg IM
2. Ciprofloxacin 500 mg po and obtain of test of cure
3. Ceftriaxone 250 mg IM
4. Cefpodoxime 400 mg po and a second dose to take home to her partner
5. Ceftriaxone 250 mg IM plus doxycycline 100 mg po BID or azithromycin 1 g po

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MMWR

Update to CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006: Fluoroquinolones No Longer Recommended for Treatment of Gonococcal Infections

Gonorrhea Treatment, 2007

Recommended regimens for pharyngeal infections:
- Ceftriaxone 125 mg IM x 1
- ~~Ciprofloxicin 500 mg PO x 1~~

Alternative regimens:
- None

Recommended regimens for urogenital infections:
- Ceftriaxone 125 mg IM x 1
- Cefixime 400 mg PO x 1
- ~~Ciprofloxicin 500 mg PO x 1~~
- ~~Ofloxacin 400 mg PO x 1~~
- ~~Levofloxacin 250 mg PO x 1~~

Alternative regimens:
- Cefpodoxime 400 mg po x 1
- Cefuroxime 1 g po x 1
- Spectinomycin 2 g IM x 1

Co-treat for chlamydia unless ruled out *with highly sensitive test NAAT*

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Efficacy Data for Agents with Activity Against GC Infection

Agent, dose, route	Site	Studied	Cured	% Cure (95%CI)
Ceftriaxone 125 IM	SS	442	438	99.1 (98.7, 99.8)
	PH	63	59	93.7 (84.5, 98.2)
Cefixime 400mg PO	SS	344	336	97.7 (96.1, 99.3)
Cefpodoxime 200 PO (*)	SS	284	274	96.5 (94.3, 98.6)
	PH	19	15	78.9 (54.5, 94.0)
Cefpodoxime 400 PO (**)	SS	316	305	96.5 (93.9, 98.2)
	SS §	287	281	97.9 (95.5, 99.2)
	PH	35	26	74.3 (56.7, 87.5)
Cefuroxime 1 gm PO	SS	469	454	96.8 (95.2, 98.4)
	PH	29	16	55.2 (37.1, 73.3)

Site: SS - single urogenital or rectal; PH - pharynx; MS - multiple or unspecified.
SS § - urogenital, with sex in treatment interval excluded

John Moran, William Levine. CID 1995; 20 (Suppl 1): S47-65
* Novak et al., Antimicrob Agents Chemother 1992; 36: 1764-5
** Hall et al., ISSTDR 2007; Abstract P-459

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Gonorrhea Treatment in 2010

Recommended regimen**:
- Ceftriaxone 250 mg IM x 1 plus treatment for chlamydia *

Alternative oral regimen:
- Cefixime 400 mg PO x 1 plus treatment for chlamydia *

Alternatives for Cephalosporin allergic:
- Azithromycin 2 gm x 1

* Co-treat "for chlamydia" even if NAAT is negative

**Preferred and only recommended regimen for pharyngeal infection

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Gonorrhea – Treatment Issues

Limited options in cephalosporin allergic patients:
- Spectinomycin is no longer manufactured
- CDC recommended desensitization but now states it is impractical
- Consider azithromycin, but
  - Requires 2 grams; GI tolerance issues
  - Resistance to azithro likely increasing and treatment failures have been seen

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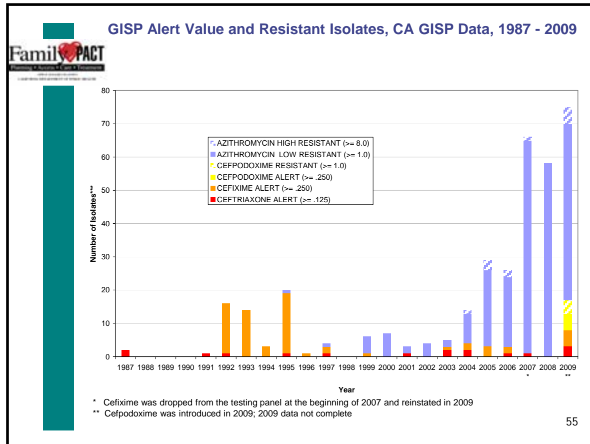

Gonorrhea – Treatment Issues

- Suspected cephalosporin treatment failures should be cultured, and if positive:
  - perform susceptibility testing,
  - consult a specialist for treatment guidance
  - Report case to CDC through state and local HD
  - HD should prioritize partner notification
- The CDC website or state HD can provide the most current information

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Case # 4

Woman for prenatal visit

- 35 yo female comes in for her first prenatal visit.
- When ordering the syphilis prenatal tests, you noticed that a new syphilis screening serologic test, an EIA, has been added to the lab requisition slip.
- The EIA comes back positive. What do you do with this result?

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Syphilis Screening Paradigm

TRADITIONAL

Non-treponemal tests (i.e., RPR, VDRL)
- **Non-specific to TP**
- **Quantitative**
- **Reactivity declines with time**

reflex to →

Treponemal tests (i.e., TPPA, FTA-Abs)
- **Specific to *TP***
- **Qualitative**
- **Reactivity persists over time**

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Syphilis Screening Paradigm

EMERGING / NEW…

Treponemal tests (i.e., TPPA, FTA-Abs)
- **Specific to *TP***
- **Qualitative**
- **Reactivity persists over time**

reflex to →

Non-treponemal tests (i.e., RPR, VDRL)
- **Non-specific to *TP***
- **Quantitative**
- **Reactivity declines with time**

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Why switch to EIA/CLIA for Screening?

- Automated (high throughput)
- Low cost in high volume settings
- Less lab occupational hazard (pipetting)
- No false negatives due to prozone reaction
- Objective results

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Low tech vs. high tech

180 tests per hour, no manual pipetting

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Challenges and limitations of the EIA/CLIA

- Cannot distinguish between active disease and old disease (treated/untreated)
- Studies to compare test performance with other serologic tests are lacking
- Confusion re: management of patients with discrepant serology (e.g., positive EIA/CLIA and a negative RPR)

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California EIA/CLIA Algorithm- Draft

Treponemal Test *
(EIA/CLIA or TP-PA)

⊖ → No infection or Incubating syphilis

⊕ → Quantitative Non-trep test (RPR)

⊕ →
- Clinical assessment: (history of syphilis, sx/signs)
- If untreated: stage and treat
- If treated and 4X increase of titer: assess for re-infection or Rx failure

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California EIA/CLIA Algorithm-Draft

Treponemal Test *
(EIA/CLIA)

⊕ → Quantitative non-trep Test (RPR)

⊖ → 2nd trep test

⊖ →
- Probable false positive EIA
- If high risk: repeat trep EIA (and non-trep test if EIA still+)

⊕ →
- Assess for hx of treated syphilis, sx/signs
- If treated, no further action
- If untreated, consider rx for latent syphilis F/U in 1 week for RPR & J-Herx reaction
- If low risk, consider repeat trep EIA in 1 month (and non-trep test if EIA still +)

* Not useful if history of treated syphilis or neonatal

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Cervicitis

STD Atlas, 1997

- Clinically-evident cervical inflammation
- Associations
  - upper tract disease
  - increased HIV shedding
  - poor pregnancy outcomes
- Is cervicitis a reliable predictor of CT or GC infection?

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What causes cervicitis?

- Infectious
  - Chlamydia
  - Gonorrhea
  - Genital herpes
  - Trichomoniasis
  - *Mycoplasma genitalium*
  - Others?
    - Cytomegalovirus
    - Streptococcus species
- Non-infectious
  - Chemical irritants
  - Trauma
  - Abnormal host immune response
  - Persistent disruption of healthy vaginal flora
- Co-infections are common

A significant proportion have no etiology confirmed

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Cervicitis Single and Co-infections

Coinfection in women with cervicitis

47.4%, 18.8%, 12.0%, 4.5%, 1.5%, 6.8%, 3.0%, 1.5%, 1.5%, 2.3%, 0.8%

Coinfection in women without cervicitis

72.3%, 7.3%, 9.4%, 2.1%, 1.0%, 3.1%, 1.0%, 0.5%, 0.5%, 1.0%, 1.6%

Neg, MG+, TV+, TV+MG+, NG+, CT+, CT+MG+, CT+MG+, CT+TV+MG+, CT+NG+, CT+NG+MG+

unpublished data from the C. Gaydos group at JHU

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Cervicitis: Diagnosis

- Imprecise diagnosis
- Widely-used criteria
  - Mucopurulent endocervical exudate
  - Easily-induced cervical bleeding (friability)
- Other possible diagnostic criteria
  - Erythema
  - Elevated # of WBCs
    - Gram stain
    - Vaginal wet mount

Positive Swab Test

Negative Swab Test

Mosby STD Atlas, 1997

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Cervical Ectopy or Erythema?

Ectopy

Minimal ectopy

Mosby STD Atlas, 1997

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Cervicitis Diagnostic Workup

- Pelvic exam- evaluate for PID
- Swab test
  - Endocervical mucopus
    OR
  - Cervical friability
- Saline wet mount for BV, *Trichomonas*
- NAATs for CT and GC

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Is cervicitis a sensitive predictor of CT or GC infection?

- Most CT and GC infections do not cause cervicitis
- In most cases of cervicitis, CT and GC tests are negative

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Cervicitis – Treatment

- Treat for CT if:
  - Age 25 or younger
  - STD risk: new/multiple partners, unprotected sex
  - Follow-up unlikely
- Treat for GC if:
  - Local prevalence is high (>5%)
- Treat BV if present
- Management of lower-risk women?
  - Can try 1 course of antibiotics
  - Choice of antibiotic unclear- azithromycin 1 gm po

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Challenges in Diagnosis of PID

- No single historical, physical or laboratory diagnostic test both sensitive and specific
- Clinical diagnosis has PPV of only 65-90%
  - Highest in young, sexually active women
  - Highest in areas of high prevalence of STDs
- Symptoms vary
  - Pelvic pain or pressure
  - Abnormal/post-coital bleeding
  - Dyspareunia

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PID Minimum Diagnostic Criteria

- **Uterine tenderness OR**
- **Adnexal tenderness OR**
- **Cervical motion tenderness**

- Err on the side of over-treatment
  - Because of high risk of adverse outcomes
- Test for CT and GC
- Evaluate for BV and trich
- If no evidence of cervicitis and no WBCs on wet mount the diagnosis of PID is unlikely

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PID: Oral Treatment Regimens

Recommended regimens:

- Ceftriaxone 250 mg IM x 1 ***or***
- Cefoxitin 2 g IM ***with*** probenecid 1 g PO x 1 ***or***
- Other parenteral 3rd generation cephalosporin

PLUS
- Doxycycline 100 mg PO BID x 14 d

WITH OR WITHOUT
- Metronidazole 500 mg PO BID x 14 d

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With or Without Metronidazole???

- BV associated with PID and other upper tract abnormalities
- Assess for BV
  - Wet mount, use metronidazole if present
  - If no wet mount available, use metronidazole

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Alternate Oral PID Regimens

- Fluoroquinolone regimens may be considered only if:
  - Cephalosporin can not be used and
  - If low GC prevalence and
  - Follow-up is likely
  - If FQ are used and GC NAAT is positive:
    - Change to non-FQ regimen
      - or
    - Retest with NAAT and culture and get sensitivity
      - how and where?
- No oral cephalosporins are recommended
- Azithromycin mentioned but not really recommended except if QRNG and cephalosporin can not be used
- Amoxicillin/clavulinic acid (Augmentin) and doxycycline

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STD Resources
California of STD/HIV Prevention Training Center
www.stdhivpreventiontraining.org
CDC Treatment Guidelines
www.cdc.gov/std/treatment
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Questions?
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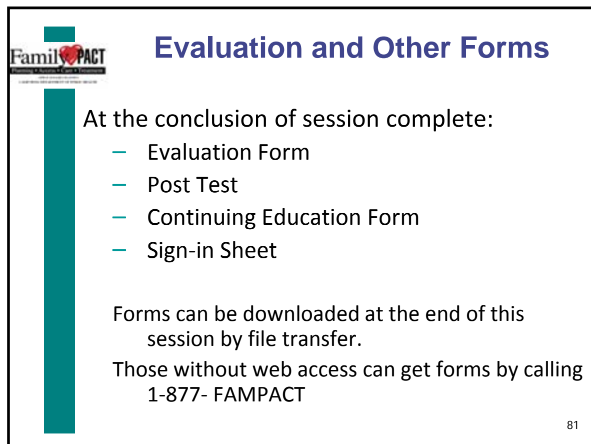
Evaluation and Other Forms
At the conclusion of session complete:
– Evaluation Form
– Post Test
– Continuing Education Form
– Sign-in Sheet
Forms can be downloaded at the end of this session by file transfer.
Those without web access can get forms by calling 1-877- FAMPACT
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