

Family PACT

STD Update for Family PACT Providers

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 CA Department of Health Services

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Sponsored by
 California Department of Health Services,
 Office of Family Planning

Family PACT

Tools you can use – Feedback Toolbar

Current Results
 Of 2 Participant(s)
 Yes: 1
 No: 1

Raise Hand
 Yes No
 Emoticons
 Feedback Results

Family PACT

Floating Icon Tray

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

Participant List
 Polling
 Q&A

Family PACT

Q&A -

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

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Polling -

Time elapsed: 1:23 Time left: 5:00
 Poll Questions:
 1) What information do you need to look up a record?
 A Customer name
 B Account number
 C Order number
 All Other A or B
 2) Which form fields are required?
 A Customer name
 B Phone number
 C Fax number
 D Delivery
 Submit
 Your answer will be anonymous

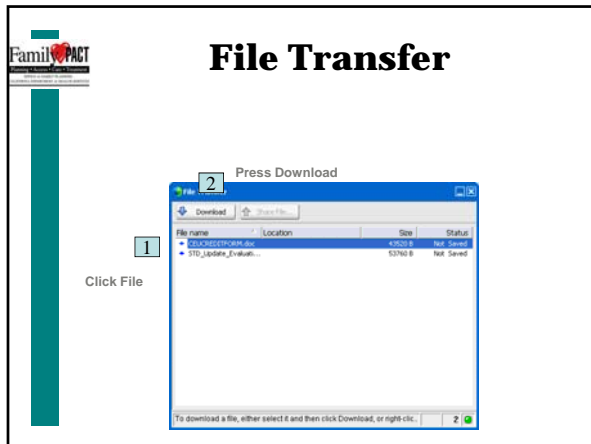
Family PACT

Evaluation and Continuing Education Forms

At the conclusion of session complete:

- Evaluation Form
- Continuing Education Form (if applicable)

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



Overview of Presentation

- Diagnosis and Treatment options:
 - Prevention and Screening
 - Chlamydia, Gonorrhea, and PID
 - Genital ulcers: Syphilis, HSV
 - Vaginitis: Trich, BV, Yeast
 - HPV
- Clinical Management Strategies
 - Screening Strategies
 - Partner Services
- Recent changes to the California Treatment Guidelines

Prevention & Screening Issues

- Sexual history taking and risk reduction client centered counseling including the 5 P's
 - Partners
 - Practices
 - Past History of STDs
 - Protection for STDs
 - Pregnancy prevention
- Patients should be informed about which STDs they are tested for (and which not) and if positive which must be reported to the local HD

Key Elements of Client Centered Counseling

- Establish rapport/maintain non-judgmental attitude
- Ask open-ended questions to gain understanding of client's risk
- Facilitate risk reduction on client terms (i.e.: what they can realistically do)
- Limit information giving to essential facts in order to reduce misinformation
- Encourage client to actively participate in session

Steps in Counseling: A client centered approach

- Conduct a personalized risk assessment (open ended questions)
 - “Actual” (provider assessed) risk
 - Self perceived (client assessed) risk
- Support client-initiated behavior change
 - *Listen* with an open mind, in a non-judgmental manner

Steps in Counseling: A client centered approach

- Help the client to recognize barriers to risk reduction (active listening)
- Negotiate an acceptable and achievable risk reduction plan (contract)
- Refer client to other specialized services, if needed (e.g. partner services, couples counseling, substance abuse treatment, etc.)

Family PACT Education and Counseling Codes

- E & C codes can be used for visits that are counseling in nature
- Counseling by clinician and/or counselor
- Following codes can be used instead of an E & M Office code
 - Z9752: 11-15 minutes**
 - Z9753: 16-30 minutes**
 - Z9754: 31-45 minutes**
- Call 1-877-FAMPACT for assistance

Asymptomatic STD Screening for Females 25 years or younger

Sexually experienced:

- Chlamydia test at least annually
- Gonorrhea test annually
- Pap test 3 yrs after sexual debut or by age 21

Depending high risk behaviors/partners:

- Syphilis test
- HIV test
- (HSV type-specific serology)

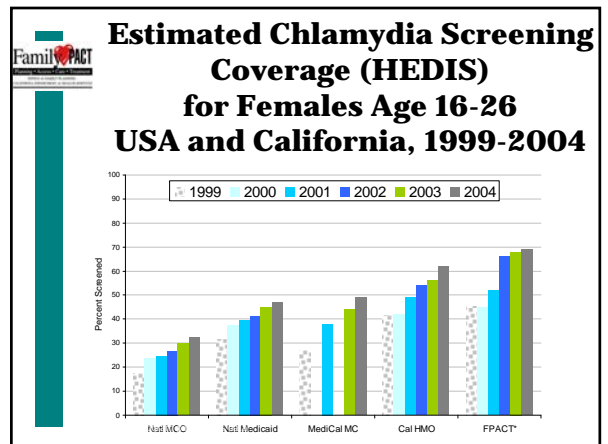
• What is the current Chlamydia test that you use to screen your female clients?

Current Chlamydia/Gonorrhea Diagnostic Tests

- Gram stain only for men
- Culture
- Antigen Detection Tests: EIA, DFA
- Nucleic Acid Non-amplified Detection Tests
 - ❖ **GenProbe PACE 2**
- Nucleic Acid Amplification Tests (NAATs)
 - ❖ **Roche AmpliCor (PCR)**
 - ❖ **GenProbe Aptima (TMA)**
 - ❖ **B-D ProbeTec (SDA)**

Nucleic Acid Amplification Tests Recommended

- Highest sensitivity
 - Able to detect up to 40% more Chlamydia infections
 - Less dependent on specimen collection and handling
- Noninvasive
 - Urine and self-collected vaginal swabs
- Non-clinical exam settings
 - Pelvic and genital exams not necessary
 - Clinic intake areas and pregnancy only tests
 - Home testing

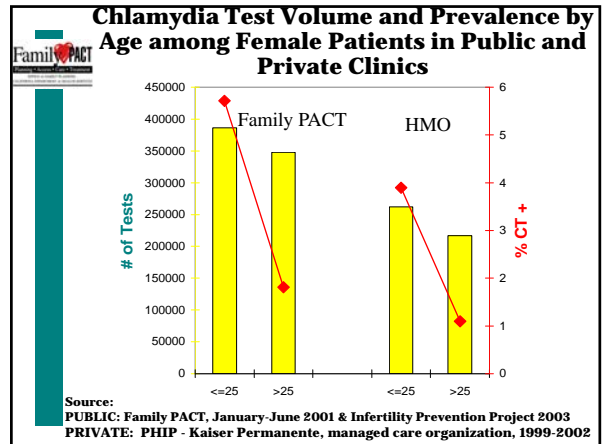



Are we screening the wrong women?

- The many 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
- Guidelines for screening women over 25 are not specific
 - Other women "at risk" such as prior history of STD, new or multiple partners, or inconsistent use of barrier contraception



California Gonorrhea Screening and Diagnostic Testing Guidelines for Non-Pregnant Female Patients

Annual Screening *

- All sexually active females 25 years and younger

Targeted Screening based on risk factors if over 25 yrs of age

- Hx of GC in 2 yrs, multiple partners in 12 mos, partner with other partner, African American women 26-30

Diagnostic Testing

- When clinical exam findings indicate gonococcal infection: cervicitis, pelvic inflammatory disease, or disseminated gonococcal infection.

Contact Testing

- For patients who report contact/exposure to any sexually transmitted disease (STD)

Testing for Co-Infections

- For patients with a newly diagnosed STD

Repeat Screening

- Three to six months after treatment, patients should have a repeat test for re-infection.

** Only if the prevalence is at least 1%.*

What about chlamydia screening among men?

- Obvious source of transmission
- Urine-based testing advantage
- Unpublished cost effectiveness analysis demonstrate community and future partner benefits; need > 5% prevalence
- Limited data on prevalence & outcomes in women
- No guidelines available

Chlamydia Treatment Adolescents and Adults

Recommended regimens:

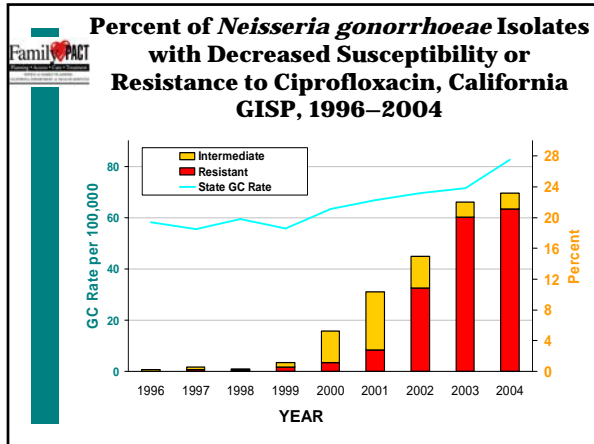
- ◆ Azithromycin 1 g PO x 1
- ◆ Doxycycline 100 mg PO BID x 7 d

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

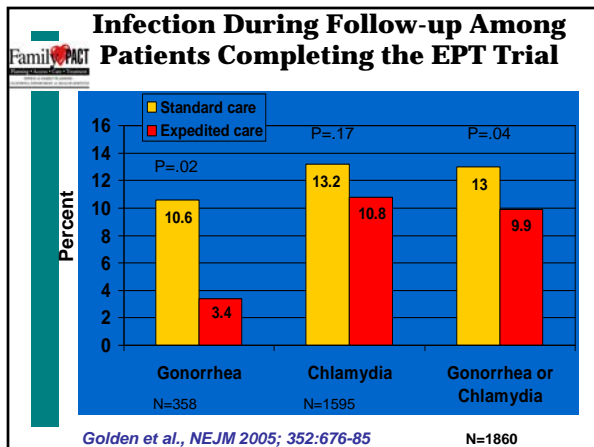
**** NO CHANGES FOR 2006 GUIDELINES ****

- Which is your first line treatment for gonorrhea?



- ### Gonorrhea Treatment in California
- Recommended regimens:**
- Ceftriaxone 125 mg IM x 1*
 - Cefixime 400 mg PO x 1
- Alternative oral regimen:**
- Cefpodoxime 400 mg po x 1
- Alternatives for Cephalosporin allergic:**
- Spectinomycin 2 g IM x 1
 - Azithromycin 2 gm x 1
- Co-treat for chlamydia unless ruled out by NAAT
- *Preferred and only recommended regimen for pharyngeal infection*

- ### Partner Treatment Options
- Patient referral
 - Provider or clinic referral
 - Health department referral
 - Expedited Partner Treatment (EPT)
 - Patient-delivered partner therapy (PDPT)
 - Health department-delivered therapy
 - Pharmacy-delivered therapy



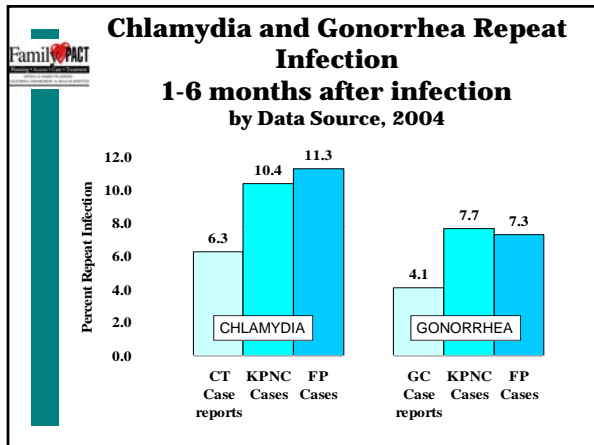
- ### Chlamydia and Gonorrhea Expedited Partner Treatment
- Expedited Partner Treatment (EPT) or Patient-Delivered Partner Treatment (PDPT)
 - Option for partner management for heterosexual men and women
 - Written materials should accompany medication and specially mention concern about PID in female partners
 - First line management is clinical evaluation
 - CDC has developed separate guidance on EPT/PDPT
- *PDPT is not a Family PACT benefit unless partner is also enrolled in the program**

Patient Delivered Partner Therapy Legislation in CA
(Ortiz bill SB 648 and Leno AB AB 2280)

- Enacted for CT January 1, 2001 and revised for GC January 2007
- Amendment to the Business and Professions and Health and Safety Codes
- Sets forth exceptions to the Medical Practice Act and is does not constitute unprofessional conduct
- “Notwithstanding any other provision of law, a physician, nurse practitioner, certified nurse-midwife, and physician assistant who diagnoses a sexually transmitted chlamydia **gonorrhea**, or other sexually transmitted infections dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient’s sexual partner or partners without examination of that patient’s partner or partners”

Recommendations for Chlamydia and Gonorrhea Re-Testing after Treatment

- Prefer “re-testing” to “re-screening”
- High rates of re-infection after treatment
- Recommend re-testing of females with CT; some experts suggest re-testing of males
- Consider re-testing of females with GC; some experts suggest re-testing of males
- Time frame: 3 months after treatment or whenever seek care within 12 months if did not return at 3 months
- TOC not routinely recommended unless treated initially with a fluoroquinolone and symptoms persist or recur after treatment



Pelvic Inflammatory Disease Issues

- Newest etiologic agent: *Mycoplasma genitalium*
 - Pathogenesis unclear
 - No recommendation for Mg testing
- If no evidence of cervicitis and no WBCs on wet mount the diagnosis of PID is unlikely
- Modify minimal criteria for presumptive treatment:
 - CMT **OR** uterine tenderness **OR** adnexal tenderness
- Clarify use of metronidazole*:
 - Treatment to cover anaerobes should be considered
 - If BV is present or cannot be ruled out, add metronidazole*
- Azithromycin treatment mentioned “outside the box”
 - Not recommended

Discussed PID: Oral Treatment Regimens *

Recommended Regimens *:

- Ofloxacin 400 mg PO BID x 14 d
- Levofloxacin 500 mg PO QD x 14 d
- Ceftriaxone 250 mg IM (or other parenteral 3rd generation cephalosporin) x 1
- plus*
- Doxycycline 100 mg PO BID x 14 d
- Cefoxitin 2 g IM *and* probenecid 1 g PO x 1
- plus*
- Doxycycline 100 mg PO BID x 14 d

* Plus metronidazole if BV or BV cannot be ruled out

* Discussed at the 2006 Guidelines Meeting

PID: Oral Treatment Regimens

Oral regimen A:

- Ofloxacin* 400 mg PO BID** x 14 d *or*
- Levofloxacin* 500 mg PO QD x 14 d
- plus (with or without)*
- Metronidazole 500 mg PO BID x 14 d

*Contraindicated pregnant or nursing women and in CA, Not recommended in CA and Hawaii

** typographical error in CDC guidelines- not once daily

PID: Oral Treatment Regimens Continued

Oral regimen B:

- Ceftriaxone 250 mg IM (or other parenteral 3rd generation cephalosporin) x 1 *or*
- Cefoxitin 2 g IM *and* probenecid 1 g PO x 1

plus

- Doxycycline* 100 mg PO BID x 14 d with or *without*
- Metronidazole 500 mg PO BID x 14 d

*Contraindicated pregnant or nursing women

Cervicitis

Causes:

- Infection CMV **STD:** GC, chlamydia, trich, HSV,
- Trauma **Other:** streptococci (GBS), TB
- Neoplasia **Chemical:** douches, spermicides
- Inflammatory systemic process (Behcet's, sarcoidosis) **Mechanical**
- Undefined local inflammatory process
 - Effect of persistent **pathogen** or **altered vaginal flora?**
 - Primary **host** response (independent of pathogen)?

Nyirjesy 2001

Diagnosis of Cervicitis

- Symptoms: nonspecific and insensitive; may include vaginal discharge, intermenstrual/postcoital bleeding
- Signs: specific, but insensitive. Include:
 - easily induced endocervical bleeding
 - mucopurulent discharge: swab test
- Inflammation detected on endocervical Gram stain is of limited usefulness in helping to define cervicitis

Diagnostic Evaluation of Cervicitis

- Consolidation of evidence supporting NAAT as preferred diagnostic assays for CT/GC
 - Accurate in presence of blood or mucus
- Availability of sensitive, rapid tests for *Trichomonas vaginalis*
 - Point-of-care Ag-based detection assay (OSOM rapid test, Genzyme); sens 83.3%, spec 98.8%
 - Affirm test
- Role of quantifying WBC in vaginal fluid
 - >5-10 WBC/HPF in vaginal fluid strongly associated with cervical CT/GC, high PPN (particularly in BV)

Johnson 2002, Marrazzo 2004
Huppert 2005
Geisler 2004, Hakakha 2002, Steinhilber 2002

Diagnostic Evaluation: Recommendations

NAAT for chlamydia and gonorrhea are preferred for the diagnostic evaluation of MPC, and may be performed on either cervical or urine samples. Women with MPC should also be evaluated for the presence of BV and trichomoniasis, and these conditions treated if present. A finding of >10 white blood cells in vaginal fluid may indicate endocervical inflammation caused by *C. trachomatis* or *N. gonorrhoeae*.

Empiric Therapy of Cervicitis

- Age- and risk-based empiric therapy:
 - Age < 25, treat for Ct and (usually) GC
 - Age > 25, treat for Ct based on risk factors and likelihood of follow-up, otherwise await Ct/GC test result
 - GC treatment should be based on risk, likelihood of follow-up, local (patient group/clinic/neighborhood) prevalence
- Evaluate for BV and trichomoniasis; treat if present
- If treatment is deferred, use NAAT results to direct future treatment for CT/GC

Chronic or Persistent MPC

- Prevalence, incidence, etiology, natural history and clinical significance are unknown
- Re-evaluate for all potentially associated organisms at least once
- The patient should be treated with azithromycin at least once
- Be sure partner was treated
- Ablative treatment (laser or cryotherapy) is often used, and is anecdotally successful; no data in literature
- No data on prolonged antibiotic use (2+ weeks) but some experts provide it

Vaginitis: Etiologies

| Etiology | Percentage |
|---------------------|------------|
| Bacterial vaginosis | 40% |
| Other | 20% |
| Trichomoniasis | 20% |
| Candidiasis | 20% |

"Other" includes atrophic, irritant/chemical, desquamative interstitial vaginitis; erosive lichen planus

Bacterial Vaginosis (BV)

- Overgrowth of commensal anaerobic flora (*G. vaginalis*, *Prevotella*, *Mobiluncus*, *M. hominis*) relative to H₂O₂-producing lactobacilli that predominate in the healthy vaginal ecosystem

Gram stain of normal vaginal fluid with many lactobacilli and normal epithelial cells

Gram stain of BV with no lactobacilli, many other bacteria, and clue cells

2006 CDC STD Treatment Recommendations Bacterial Vaginosis

Nonpregnant Women

- Recommended
 - Metronidazole 500 mg PO bid x 7 d
 - Metronidazole gel 0.75% intravag qHS x 5 d
 - Clindamycin cream 2% intravag qHS x 7 d
- Alternatives*
 - Clindamycin 300 mg PO bid x 7 d
 - Clindamycin ovules 100 g intravag qHS x 3 d

* Metronidazole 2 g PO, single dose deleted

Trichomoniasis

- Obligate human parasite
- May cause profuse, yellow-green, malodorous discharge, vulvar irritation, inflammatory infiltrate w/ punctate mucosal hemorrhages
 - "strawberry cervix"
- Symptoms may be absent or minimal (10-50%)
 - Can emerge as 'new' infection in post-menopausal women after antibiotics, change in estrogen status
- High prevalence in U.S. racial minorities and developing countries (especially where HIV common): 180 million worldwide (Swygard 2004)
- **New issues:**
 - Tinidazole
 - Rapid diagnostic testing

Trichomoniasis Treatment

Recommended regimen:

- Metronidazole 2 g PO x 1
- * (Tinidazole 2 g po x 1)

Alternative regimen:

- Metronidazole 500 mg PO BID x 7d

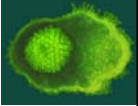
Treatment Failure and MTZ-resistance:

- Treatment failure (after MTZ 2 g po x 1):
 - Assure partner treatment
 - Treat with metronidazole 500 mg po BID x 7 d
 - If fail, tinidazole 2 g po x 1*
 - If fail, metronidazole or tinidazole 2 g po x 5 d
 - If fail, susceptibility testing
- Metronidazole-resistant trichomonas:
 - Tinidazole 500 mg PO QID (or 1 g BID) + 500 mg intravaginal bid x 14 d
 - Alternatives include paromomycin cream (can cause ulcers), 250 mg q d for 14 d; furazolidone; zinc oxide douche; N-9

Tinidazole (Tindamax)

- Second-generation nitroimidazole recently approved for
 - Trichomoniasis
 - Giardiasis: probably drug of choice
 - Amebiasis
- Highly active against anaerobic bacteria, some protozoa
 - Lower MIC's to trichomonas
 - Recent efficacy study in MTZ-R trich: 92% cure
- Elimination $\frac{1}{2}$ life twice that of MTZ (12-14 h vs. 6-7 h)
- Excellent tissue penetration
- Better safety and tolerance profile relative to MTZ
 - Less nausea/vomiting
- No alcohol during and 3 days after treatment, Category C in pregnancy, don't use

Genital Herpes



- 50 million in U.S. likely have genital HSV
- 90% of infections unrecognized
- 95% of people with genital HSV-2 have intermittent subclinical shedding
 - Present 5-30% of days in persons with genital HSV-2
 - Frequency highest in first year after infection (20 - 30% of days), then declines; ~ 4 - 6% of days for many years
 - Accounts for most HSV-2 transmission
 - Uncommon if genital herpes due to HSV-1
 - Similar frequency in persons with and without recognized symptoms

Genital Herpes

What's New:

- Overall declines in HSV-2 seroprevalence in U.S.
- Availability of affordable type-specific serology
 - ❖ Glycoprotein G type-specific HSV-2 serology tests:
 - HerpeSelect- 1 or 2 ELISA, HerpeSelect- 1 and 2 Immunoblot and HSV-2 ELISA, Biokit HSV-2, and SureVue HSV-2
- Role in enhancing HIV transmission
- Prevention of transmission with antiviral therapy and condoms
- ↑ Proportion of genital herpes due to HSV-1
- Trends toward shorter courses of treatment

Uses of Herpes Serology

Definite Indications:

- Diagnosis of genital ulcers or lesions, especially when lesions cannot be sampled or are unlikely to yield virus
- Management of sex partners of persons w/ herpes
 - Implications for counseling, antiviral therapy in infected partner
- Screen persons at risk for HIV transmission (HIV+)

Other Uses:

- Pregnant women and partners (select vs. all)

AJOG 2005

Cost-effectiveness of herpes simplex virus type 2 serologic testing and antiviral therapy in pregnancy

- Patient request
- Not clear whether all sexually active persons should be screened (cost vs. benefit) but currently not recommended

David Baker, MD,* Zane Brown, MD,* Lisa M. Huttler, MD,* George D. Wendel, Jr., MD,* Lisa Holmes,* Genevieve A. Griffiths, MD, PhD,* Jacqueline Manauzoff, PhD,*

Guerry CID 2005, Strick CID 2006

Genital Herpes – Treatment Issues

- Added episodic treatment regimens:
 - Acyclovir 800 mg PO TID for 2 days
 - Famciclovir 1000 mg PO BID for 1 day
 - Valacyclovir 500 mg PO BID for 3 days
- Prevention of sexual transmission:
 - Antiviral treatment at suppression dose
 - Indications may include: discordant couples, persons with multiple partners, MSM
 - Reassess discordant partner annually for seroconversion
 - Counsel regarding condoms, disclosure, abstinence

2006 CDC Guidelines

2006 CDC STD Treatment Guidelines Genital Herpes

First Episode

- Acyclovir 400 mg TID x 7-10 d
- Acyclovir 200 mg 5x/d x 7-10 d
- (Famciclovir 250 mg TID x 7-10 d)
- (Valacyclovir 1.0 g BID x 7-10 d)

Episodic Treatment

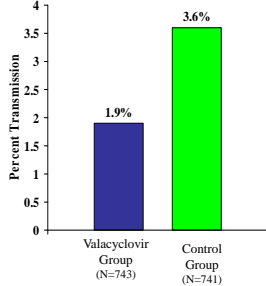
- Acyclovir 400 mg TID x 5 d
- Acyclovir 800 mg BID x 5 d
- Acyclovir 800 mg TID x 2 d
- (Famciclovir 125 mg bid x 5 d)
- (Famciclovir 1 g BID x 1 d)
- (Valacyclovir 500 mg BID x 3 d)
- (Valacyclovir 1 gm q D x 5 d)

Suppressive Treatment

- Acyclovir 400 mg bid
- (Famciclovir 250 mg bid)
- (Valacyclovir 500 mg or 1000 mg once daily)

Rates of Transmission of HSV-2 to Susceptible Partners is Reduced with Once-Daily Suppressive Therapy

- 1484 heterosexual couples randomly assigned to take 500 mg of valacyclovir or placebo once daily for 8 months
- Serum samples collected monthly from susceptible partners for HSV analysis
- The valacyclovir group showed
 - decreased transmission
 - lower frequency of shedding
 - fewer copies of HSV-2 DNA when shedding occurred



Corey et al, NEJM 2004; 350:11-20

Genital Herpes: Prevention of Sexual Transmission, 2006 CDC STD Treatment Guidelines

- Antiviral treatment: valacyclovir 500 mg PO QD
- Indications may include:
 - Discordant couples (the only evidence-based indication)
 - Persons with multiple partners
 - Men who have sex with men
 - HIV-infected
- Reassess discordant partner annually for seroconversion
- Counsel regarding condoms, disclosure, abstinence

Syphilis Issues

- Recommend against the use of azithromycin
- Penicillin usage problems
 - BIC shortage
 - Specify use of Bicillin L-A (NOT Bicillin C-R)
- Diagnostic issues
 - New EIA testing algorithms: reflexive quantitative RPR/VDRL, alternative treponemal test for discrepancies

2006 CDC Guidelines

Syphilis Treatment
Primary, Secondary & Early Latent

Recommended regimen for adults:

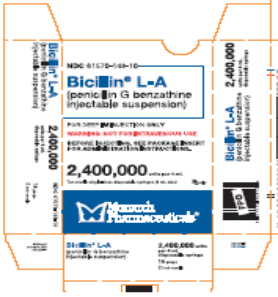
- Benzathine penicillin G 2.4 million units IM in a single dose

Alternatives (non-pregnant PCN-allergic adults):

- Doxycycline 100 mg po bid x 2 weeks
- Tetracycline 500 mg po qid x 2 weeks
- Ceftriaxone 1 g IV or IM qd x 8-10 d
- **DELETED Azithromycin 2 g po in a single dose**


2006 CDC Guidelines

Penicillin G Usage Problems



- Benzathine penicillin G shortage
- Inadvertent use of Bicillin C-R (Bicillin L-A is the appropriate drug)

HPV Issues



- Clarify uses of HPV DNA test
- No change in diagnosis or treatment of external genital warts
- No discussion of HPV vaccine

Clinical Indications for HPV DNA Testing

Proven to be clinically useful for:

- Triage of ASCUS Pap smears
- Adjunct screening in women age 30 and over
- 12-month f/u of LSIL in adolescents
- Post-colposcopy and post-treatment follow-up

NO proven benefit for:

- Triage of ASC-H, LSIL in adults or higher grade lesions
- STD screening in the general population
- Evaluation of sex partners
- Evaluation of genital warts

FPACT HPV Test Reimbursement

- Reflex testing for women with ASC-US
- F/u of LSIL in women <21 yrs old (HPV DNA testing at 12 months in lieu of cytology at 6 & 12 months is an option)
- F/u post colpo in women with Atypical squamous, ASC-H, LSIL or HPV DNA positive ASCUS with no CIN on colpo
- F/U of women with biopsy proven CIN I (HPV DNA testing at 12 months in lieu of cytology at 6 & 12 months is an option)
- F/U of women post treatment CIN II & III (HPV DNA testing at least 6 months after treatment in lieu of 3 f/u Paps is an option)

* Only for those over age 15

Q & A

STD Resources

California STD/HIV Prevention Training Center

- www.stdhivtraining.org

National Network of STD/HIV Prevention Training Centers

- www.stdhivpreventiontraining.org

CDC Treatment Guidelines

- www.cdc.gov/std/treatment

Processing Forms

Download Now:

- Evaluation Form
- Continuing Education Form

No Web Access Now:

- Call 1-877-FAMPACT for forms

- All participants that return an evaluation form will receive a Certificate of Participation
- Those requesting CE credit must return evaluation and CE form-indicate CE requesting

Complete forms and fax to 213 368-4410

Thank you for your participation!