

Optimizing STD Management in HIV-Infected Individuals: Challenging Areas in the CDC 2006 STD Treatment Guidelines

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December 14, 2007

Overview of Challenging Areas in STD Management Issues

- **Diagnostic Issues**
 - ◆ STD screening recommendations
 - ◆ New treponemal EIA test
 - ◆ Criteria for CSF exam
- **Treatment Issues**
 - ◆ GC options
 - ◆ Syphilis recommended regimens
 - ◆ Syphilis follow-up

Case #1

A 45 year-old HIV-infected man comes into see his primary care clinician for a routine visit. He has no complaints and his physical exam is normal. His last CD4 count was 300. During the visit he states that he and his partner are going through a difficult time, and he has had sex with “a few” other partners in the past few months. He reports protected receptive anal intercourse, but unprotected oral sex (both ways).

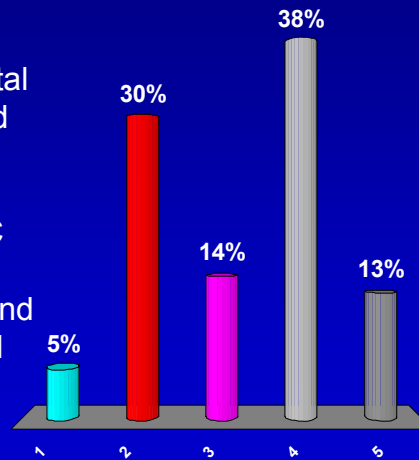
What STD screening tests would you order?

Question: What STD screening tests would you order?

- a. Pharyngeal GC and CT, Urine for GC and CT, HSV-2 and syphilis serology
- b. Pharyngeal GC and CT, Rectal GC and CT, Urine for GC and CT and HSV-2 and syphilis serology
- c. Pharyngeal GC, Urine for GC and CT and syphilis serology
- d. Pharyngeal GC, Rectal GC and CT, Urine for GC and CT and syphilis serology
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STD Screening for MSM

STD	Site	Type of Sex
HIV	blood	oral, anal
Syphilis	blood	oral, anal
GC/CT	urethra or urine	oral, anal
GC/CT	rectum	receptive anal
GC	pharynx	receptive oral
HSV-2*	blood	

* Some experts recommend

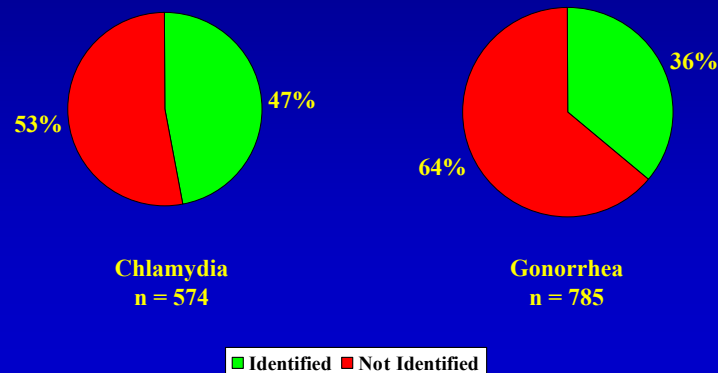
FREQUENCY: At least at the initial visit then annually or more frequently based on risk

Indications for More Frequent Screening in MSM

- Increased prevalence of STDs in area or patient population
- Symptoms or recent history of any STD in patient or partner
- Risky sexual behavior
 - ◆ Multiple or anonymous partners
 - ◆ Substance abuse especially methamphetamine
- Risky sexual behavior in partner
- If any of the above, then screen q 3-6 months

MMWR 2003 52: RR 12

Proportion of unidentified CT and GC infections if only urine/urethral screening performed among MSM: San Francisco – 2003



Kent, CK et al. ISSTD, July 2005

C. trachomatis NAAT Testing

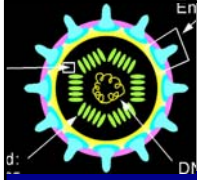


...*not* FDA-cleared for rectal
or pharyngeal specimens

Rationale for Glycoprotein G type-specific HSV-2 serology tests in HIV- infected individuals

- At least 90% of genital HSV-2 infections are unrecognized and/or asymptomatic
 - ◆ General U.S. seroprevalence 17.4%; MSM ~50%
- Genital HSV-2 (even asymptomatic) increases risk of transmitting and acquiring HIV
- Suppressive therapy aimed at HSV-2 suppresses not only genital HSV-2, but also genital HIV
 - ◆ More data needed, but convincing recent study
- Cost-effectiveness depends on assay, suppressive drug, prevalence of HSV-2/HIV
 - ◆ Complex; may require setting-specific decisions
- Contradictions/omissions: USPSTF (no), & CDC STD Treatment Guidelines (some experts recommend)

Nagot NEJM 2007; Xu JAMA 2006; Kapiga CID 2007; Reynolds et al JID 2003



Type-specific gG-based HSV-2 Serology: Commercial Kits 2007

<u>FDA-Approved Tests</u>	<u>Sensitivity</u>	<u>Specificity</u>
HerpeSelect-2™ ELISA Focus	96-100	94-98
HerpeSelect™ Immunoblot Focus	97-100	96-97
biokit™HSV-2 biokitUSA	93-96	94-97
Cobas®-HSV-2 Roche	93	98
Captia Select-HSV-2 Trinity	90-92	91-98

- Cost varies; \$20-\$140
- Western blot assay, considered gold standard, not commercially available
- *Older non-specific tests are still on the market*

Case #1 (continued)

The pharyngeal GC culture comes back positive.

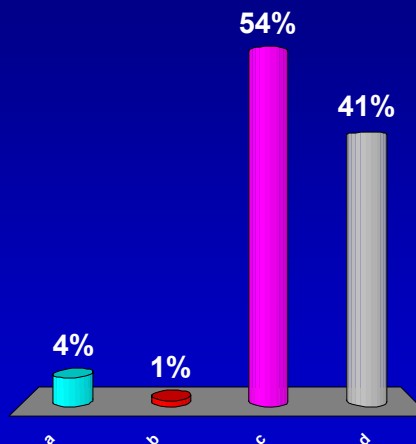
How would you manage this patient?


Question: How would you manage this patient?

- a. Prescribe a single dose of ciprofloxacin 500 mg and obtain of test of cure
- b. Repeat the test, because gonorrhea in the pharynx is usually symptomatic, and you do not believe the result
- c. Treat with a single intramuscular injection of ceftriaxone, 125 mg
- d. Prescribe a single dose of cefpodoxime 400 mg and a second dose to take home to his partner.

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

In the United States, gonorrhea is the second most commonly reported notifiable disease, with 339,593 cases docu-

Gonorrhea Treatment, 2007

Recommended regimens:

- Ceftriaxone 125 mg IM x 1
- Cefixime 400 mg PO x 1
- Ciprofloxacin 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*

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., ISSTD 2007; Abstract P-459

Gonorrhea – Treatment Issues

- Limited options in cephalosporin allergic patients:
 - ◆ Spectinomycin is no longer manufactured
 - ◆ CDC recommends desensitization
 - ◆ Could be a special case to consider azithromycin, but
 - Requires 2 grams; GI tolerance issues
 - Resistance to azithro likely increasing and treatment failures have been seen
 - ◆ If fluoroquinolones are the only option, obtain culture if possible prior to treatment to document FQ sensitivity; if not possible, obtain test-of-cure (3-5 days if culture, 3 weeks if NAAT)

Case #1 (continued)

When ordering the STD screening tests, you noticed that a new syphilis serologic test, an EIA, has been added to the lab requisition slip.

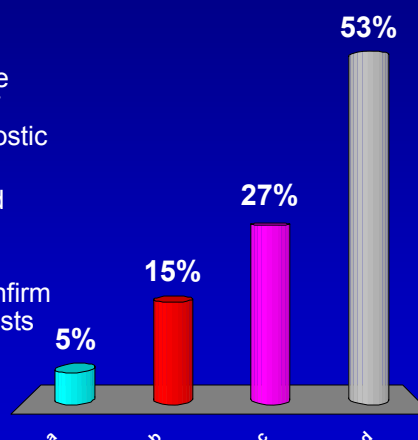
Which answer best reflects available guidance and evidence about the clinical use of the syphilis EIA test?

Question: Which answer best reflects available guidance and evidence about the clinical use of the syphilis EIA test?

- a. The syphilis EIA has no clinical utility and is only approved for blood bank screening.
- b. The syphilis EIA is the most sensitive serologic test at the primary stage of syphilis is recommended as a diagnostic test for syphilis.
- c. The syphilis EIA is an FDA approved serologic screening test for syphilis.
- d. The syphilis EIA is a treponemal serologic test that is only used to confirm nontreponemal serologic screening tests such as the RPR or VDRL.

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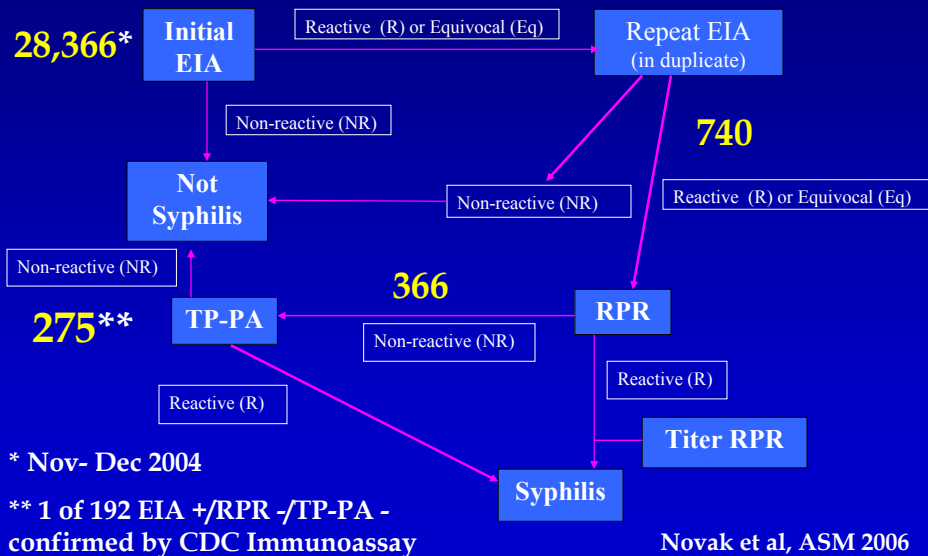
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Syphilis EIA Treponemal Tests

- ◆ Treponemal tests FDA cleared for clinical use
 - Captia, Trep-Chek, Trep-Sure, Liaison
- ◆ Can be used for screening but if positive then need quantitative reflexive RPR/VDRL for clinical management
- ◆ Both IgM and IgG tests available
 - No clinical value of IgM in adult early syphilis diagnosis
- ◆ Advantages
 - No prozone, low cost, automated, and less lab occupational hazard (pipeting)
- ◆ Disadvantages
 - Studies to compare test performance with other serologic tests are needed
 - Sensitivity and Specificity concerns regarding Captia
 - Specificity concerns regarding Trep-Chek
 - Limited utility as a screening test in previously treated patients

Syphilis EIA Trep- Chek Testing Algorithm: Southern Kaiser



Kaiser Syphilis EIA Screening Algorithm, 2005

- Screen with EIA and repeat positives/equivocals
- If positive x 2, reflexive quantitative RPR/VDRL
- If negative RPR/VDRL, reflexive TP-PA
- Positive predictive value of a positive EIA for syphilis with a negative RPR and TP-PA is low
- Lab reports as unconfirmed positive EIA test which most likely represents a false positive results
- If patient is low risk for syphilis no further follow-up
- If patient is high risk for syphilis, advise to repeat serologic test in one 1 month

Which Serologic Test is Best? Sensitivity According to Stage

<u>Test</u>	<u>1^o</u>	<u>2^o</u>	<u>Latent</u>	<u>Tertiary</u>
VDRL/ RPR	74-87%	100%	88-100%	37-94%
FTA-ABS	70-100%	100%	100%	96%
MHA-TP*	69-90%	100%	97-100%	94%

*MHA-TP and TP-PA probably perform equivalently

Diagnostic Tests for Syphilis

- Darkfield / DFA-TP
- Multiplex PCR
- VDRL/RPR
- FTA-abs / TP-PA (MHA-TP)
- EIA

Case # 1 (continued)

Since the patient had no past history of syphilis, an EIA and a reflexive RPR was ordered. The EIA comes back positive with a quantitative RPR titer of 1:128. He reports his last RPR was about one year ago and was negative.

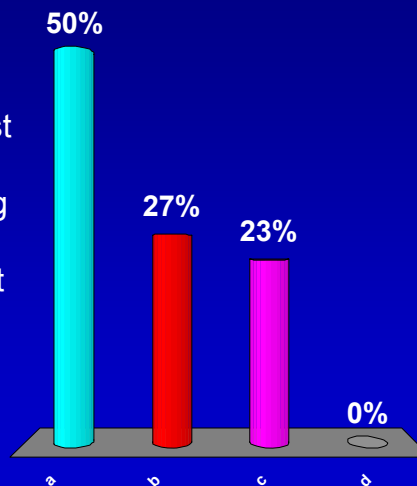
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Question: How would you manage this patient?

- a. Treat with three shots of Benzathine PCN G
- b. Tell him you would like to first schedule an LP to rule out neurosyphilis before deciding what is the best treatment
- c. Order another RPR and treat with one shot of Benzathine PCN G
- d. Give him a prescription for doxycycline 100 mg bid for 2 weeks.

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Syphilis Management Issues in HIV Infected Patients

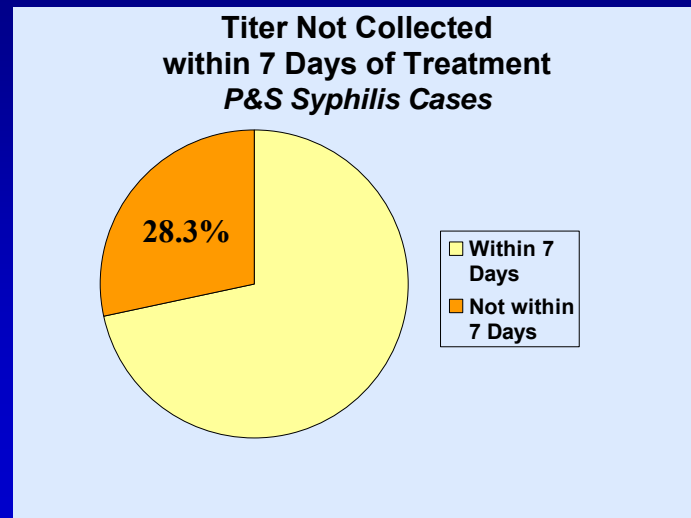
1. Which RPR/VDRL titer should be followed to assess treatment success as defined by the serologic criteria of a four-fold decrease?
2. When is an LP indicated?
3. What is the recommended treatment regimen for early syphilis in HIV-infected individuals?

Which RPR/VDRL titer should be followed?

Answer: The RPR/VDRL titer at the time of treatment

- Studies defining serologic criteria for successful treatment used this titer
- Other titers are dependent on when the specimen is collected
 - ◆ Before treatment depends on the stage of disease
 - ◆ After treatment depends on the stage of disease and immunologic response

Missed Opportunities in California, 2003 Titer not collected near treatment date



When is an LP indicated?

Answer: The CDC 2006 criteria for CSF examination are the following:

- Neurologic or ophthalmic symptoms/signs
- Evidence of tertiary disease
- HIV infection with late latent or latent of unknown duration
- Treatment failure
- **Some experts recommend a CSF exam in:**
 - **Patients with latent syphilis and an RPR titer \geq 1:32**
 - **HIV-infected patients with CD4 count \leq 350**

Proposed Criteria for Performing LP in HIV-Infected Patients with Newly Diagnosed Syphilis

<u>Stage of Syphilis</u>	<u>CD4-Cells</u>	<u>Recommendation</u>
Primary or early latent with RPR \leq 1:32	\geq 350 <350	No LP Consider LP
Any stage with RPR >1:32	Any	Consider LP
Late-latent or syphilis of unknown duration	Any	LP indicated
Positive RPR/confirmatory test with neurologic or ophthalmic symptoms and/or signs	Any	LP indicated

Source: AIDS Clinical Care, 2003 Vol. 15, No 2

Evidence for CSF Examination if RPR \geq 1:32 or CD4 count \leq 350

- One study of 326 patients with syphilis referred for LP because they met the 1993 CDC criteria- *Marra et al, JID 2004; 189:369-76*
 - ◆ 125/326 had symptoms of syphilitic meningitis or ocular syphilis
 - ◆ 65/125 with Sx NS met the laboratory case definition of NS
 - Positive CSF VDRL or
 - CSF WBCs > 20 cells/ μ L
- Lab diagnosis of NS was not more common in patients with Sx NS

Questions Regarding the Recommendation for LP if RPR \geq 1:32 or CD4 count \leq 350 ?

- Who are the patients affected by this recommendation?
 - ◆ HIV negative aSx patients with latent syphilis and RPR \geq 1:32
 - ◆ HIV positive aSx patients with early latent and RPR \geq 1:32 and/or with early syphilis and CD4 \leq 350
- How large is this group and how common is aSx NS?
- What is the clinical benefit of treating aSx NS in this group?
 - ◆ The clinical and prognostic significance of these lab abnormalities remain unknown
- What is the cost and potential negative consequences of the recommendation?
 - ◆ e.g.- hospitalization, delay in treatment of infectious cases to schedule LPs which furthers the spread of syphilis in the community
- Why change the LP criteria based on one study after years of conventional treatment of many patients and very limited number reported adverse neurologic events after treatment?

What is the recommended treatment for early syphilis in HIV infected adults?

Answer:

- ◆ Benzathine penicillin G 2.4 million units IM in **a single dose**
and
- ◆ Follow titers for fourfold decrease !

Follow-up and Serologic Response after Treatment for Early Syphilis

- Follow-up titers should be compared to the nontreponemal titer obtained on day of treatment
- Primary, secondary and early latent syphilis
 - ◆ Examine at ~1-2 weeks to confirm improvement of symptoms (1^o and 2^o)
 - ◆ Repeat titers at:
 - 3, 6, 9, 12, and 24 months for HIV-infected
 - 6, 12 and 24 months for HIV negative
 - ◆ Expect fourfold decrease in serology within 6-12 months
 - ◆ Serologic response is slower in HIV-infected patients

Serologically Defined Treatment Failure in an Observational Cohort, 1991-1994

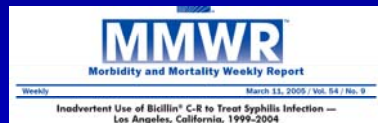
	<u>3 Months</u>	<u>6 Months</u>	<u>12 Months</u>
Total Patients (n=553)	23 % (364)	17% (329)	13% (281)
Syphilis Stage & HIV infection			
Primary			
HIV +	17% (18)	22% (8)	14% (14)
HIV -	6% (66)	5% (59)	8% (53)
Secondary			
HIV +	36% (42) ^a	23% (35)	19% (32)
HIV -	15% (141)	10% (121)	6% (96)
Early Latent			
HIV +	40% (15)	19% (16)	13% (15)
HIV -	49% (78)	35% (77)	29% (69)

Management of Suspected Syphilis Treatment Failures

- Treatment failure is defined as:
 - ◆ Slow resolution or relapse of mucocutaneous signs
 - ◆ Sustained (greater than 2 weeks) fourfold increase in nontreponemal titers
 - Reinfection may be difficult to rule out
 - ◆ Failure of nontreponemal titers to decrease fourfold
- Management of treatment failure includes:
 - ◆ LP to rule out neurologic site of infection
 - ◆ Benzathine Penicillin G 7.2 million units (2.4 mu weekly x 3)
 - ◆ Follow serofast titers annually but additional therapy/repeat LP not warranted
 - ◆ Fluctuating high titers have been observed in HIV-infected patients

Early Syphilis Treatment

- Recommended Regimen
 - Benzathine PCN G (L-A) 2.4 million units IM single dose
 - Do not use other PCN formulations!
 - E.g. PCN G (C-R)
- Alternative Regimens
 - Doxycycline 100 mg PO bid x 14 days (inferior)
 - Ceftriaxone 1 g IV or IM daily x 8-10 days (inferior)
 - Do not use azithromycin



Case # 2

A 30 year-old HIV-infected men presented to an urgent care center with a painful, erythematous rash on his groin. He was treated with ketoconazole. Six days later, he returned to the clinic with a rash over 50% of his body and an RPR test was ordered. One week later, he returned again because the rash was not getting better and another serologic test was ordered. Three weeks after he was originally seen the local health department received a lab report of RPR 1:8 and reactive TP-PA.

Case # 3

A 40 year old HIV-infected male sees his doctor because of rash on his buttocks. Three weeks later, he returns to the provider, this time with rash over his full body and scalp, in addition to the unresolved rash on buttocks. His provider believes the rash to be herpes zoster and treats with Valacyclovir. One week later, he returns to the provider because rash is not healing. Having done independent web-based research, patient requests a syphilis test. An RPR was order and the titer was 1:128, no treponemal confirmatory test was done. Provider reports positive result to health department within two days but the lab never reported the positive result.

Case # 4

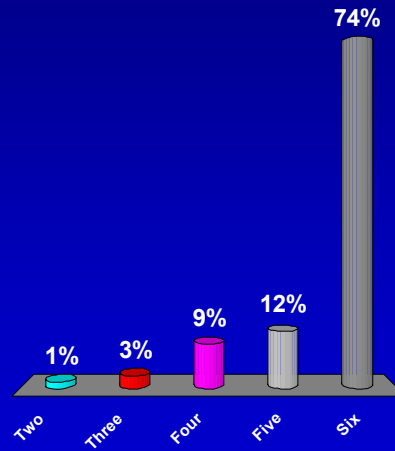
A 34 year-old theology student presented to the student health center with reddish, crusted lesions on his penis. He was treated with fungal cream. One week later, he returned because the lesions were not getting better and he was prescribed dicloxacillin. Three months later he returned with a rash on his trunk. An RPR test was ordered and he was treated with one shot of Benzathine PCN G.

Question: How many missed opportunities in clinical management occurred in these cases?

- a. Two
- b. Three
- c. Four
- d. Five
- e. Six

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Syphilis Management Issues in HIV Infected Patients

Answer: Five

1. Sexual history taking absent
2. Misdiagnosis of primary and secondary lesions
3. Lack of empiric treatment on initial visit
4. Delayed or absent provider reporting
5. Delayed or absent lab reporting

Missed Opportunities in California, 2003 and 2005

Symptoms: Missed or Misdiagnosed

Primary and Secondary Syphilis Cases with Symptoms Present But Missed or Misattributed to a Non-syphilis Etiology

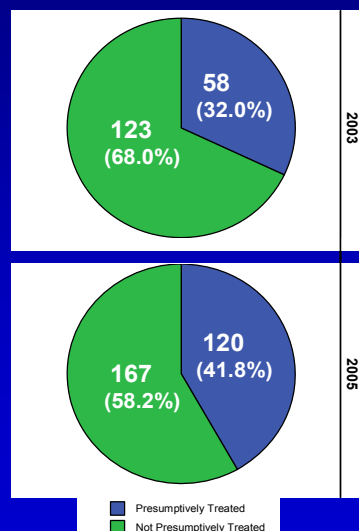
		2003	2005
Yes	N	32	31
	%	22.1%	14.0%
Total presenting with symptoms		145	221

Statistically significant difference across the two time periods (X^2 yields $p < 0.05$).

Missed Opportunities in California, 2003 and 2005

Lack of Empiric Treatment

No empiric
treatment on initial
visit for suspected
cases of primary
and secondary
syphilis



Principles of Empiric or Epidemiologic STD Treatment

- Core STD Control strategy
 - “suspected cases” based on epidemiology
 - syndromes and contacts (“epi treat”) or other risk factors
 - principle is to over treat the individual for the health of the community
 - independent of test results
- Threshold for empiric treatment is unclear
 - 20 – 30 % ?
- Balance public health benefit with:
 - individual costs
 - prudent antimicrobial use

Syphilis

Treponema pallidum

The Three “R”s of Syphilis



- Recognize
- Rx
- Report

Primary Syphilis

■ Chancre:

- ◆ Appears 10-90 days after infection
- ◆ Typically single, painless, indurated, clean-based lesion with rolled edges
- ◆ More likely to be multiple lesions and persisting at the time of secondary Sx in HIV-infected patients

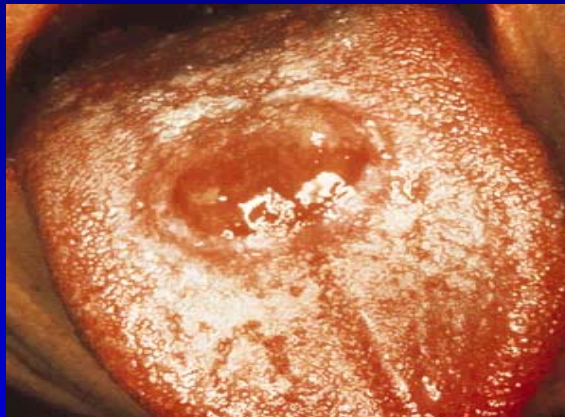


M Mosby *STD Atlas, 1997*



Dr. Joseph Engelman, San Francisco City Clinic

Primary Syphilis Chancre, Tongue



M Mosby *STD Atlas, 1997*

Rashes of Secondary Syphilis



Macular



Palmar

Dr. Joseph Engelman, San Francisco City Clinic



Papular

DDx of the Rash of 2° Syphilis

- Tinea versicolor
- Pityriasis rosea
- Erythema multiforme
- HAART Drug reaction

 Mosby STD Atlas, 1997

Other Manifestations of 2° Syphilis



Condyloma lata



Condyloma lata

Dr. Joseph Engelman, San Francisco City Clinic



Mucous patches



Patchy Alopecia

 Mosby STD Atlas, 1997

Case #5

A 41 year old HIV infected male presents to his primary care doctor with blurring of vision in his right eye. He reports no trauma to the eye and no other neurologic symptoms, including headache, neck stiffness, pain in the eye. On exam, his visual acuity in the affected eye is reduced (20/100) and although you cannot get a great look at his eyegrounds, you are pretty sure you do not detect papilledema or retinal abnormalities.

Case #6

A 35 year old HIV-infected male presented to a urgent care clinic complaining of painful red nodules on his face and shoulders and blurring of vision. He was treated with with prednisone and referred to an optometrist. Three weeks later, he saw the optometrist who thought he had a possible detached retina. RPR was ordered and was reactive at 1:32 with a positive TP-PA. Patient was started on IV PCN one week later- one month after his initial visit. Three weeks after the RPR was obtained and two weeks after treatment was started the health department received the lab report.

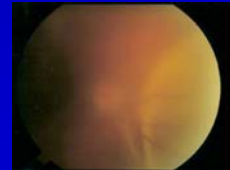
Syphilis Management Issues in HIV-Infected Patients

1. Visual complaints (especially unilateral) in HIV infected patients even with well-controlled HIV should prompt consideration of ocular syphilis
 - ◆ Symptoms: blurred vision, loss of vision, central scotomas
 - ◆ Posterior chamber uveitis is typical, but retinitis, retinal detachment, CSF inflammation also possible



Optic nerve edema & retinitis (L)
Retinal detachment & vitreous
inflammation (R)

Balba Am J Med 2006



Syphilis Management Issues in HIV Infected Patients (continued)

2. Neurologic complaints in HIV infected patients even with well-controlled HIV should prompt consideration of neurosyphilis
 - ◆ Symptoms: visual changes, hearing loss, facial weakness, stuttering stroke symptoms
 - ◆ Early forms of neurosyphilis are most common

Neurosyphilis

- Central nervous system invasion occurs early in infection in 30-40% of patients
 - Vast majority are asymptomatic
- Neurosyphilis can occur at any stage of syphilis
 - Early symptomatic forms (months to a few years)
 - Acute syphilitic meningitis (CN VI, VII, VIII)
 - Meningovascular (stuttering stroke)
 - Late symptomatic forms (> 2 years)
 - General paresis and Tabes dorsalis
- Ocular syphilis
 - CSF inflammation may occur

Neurosyphilis Diagnosis

- *T. pallidum* detection correlates poorly with the usual CSF findings
- Use the CSF VDRL as diagnostic guide
 - ◆ very specific but may not be sensitive
 - ◆ only test approved for CSF specimen
- In the CSF VDRL negative patients, consider neurosyphilis treatment if no other etiology is identified and CSF WBCs >5 in HIV negative patients and CSF WBCs >10-20 in HIV infected patients
- CSF FTA-abs is not specific but a negative test result may help rule out neurosyphilis

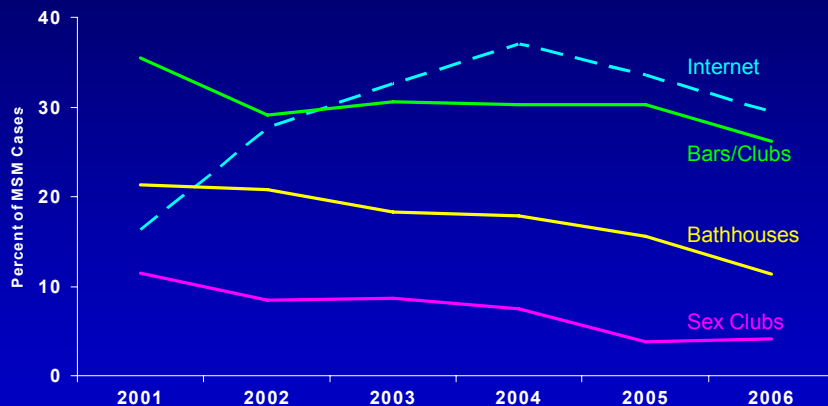
Syphilis: Treatment Neurosyphilis

- Recommended regimen:
 - ◆ Aqueous Crystalline Penicillin G 18-24 million units IV daily administered as 3-4 million IV q 4 hr for 10-14 days
- Alternative regimen:
 - ◆ Procaine Penicillin G 2.4 million units IM daily plus Probenecid 500 mg PO q d, both for 10-14 days
- Non-pregnant penicillin-allergic adults
 - ◆ Ceftriaxone 2 gm IM or IV x 10-14 d
- *Some experts recommend additional treatment with benzathine penicillin 2.4 million units IM once per week for up to 3 weeks after completion of 10-14 day course*

Public Health Management of Infectious Syphilis Cases

- Report all suspected or confirmed syphilis cases to the local Public Health Department within 24 hours of diagnosis
- Evaluate contacts with history, exam, serology and treat empirically on day of visit if possible exposure within the past 3 months

Percent of Interviewed Men who Have Sex with Men Primary & Secondary Syphilis Cases Reporting Meeting Partners by Venue, California, 2001–2006



Note: The difference between bathhouses and sex clubs is the presence of private rooms; sex clubs do not have private rooms.

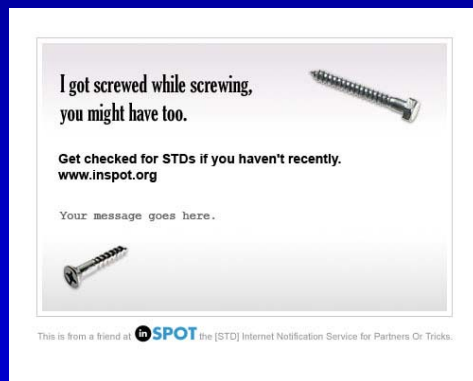
CA DPH STD Control Branch (rev 7/2007)

Innovation in Partner Notification via Internet

Individuals use Web site to notify partners

- anonymous
- free
- referrals for testing provided

<http://www.inspot.org>



Questions?

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