STI Hot Topics:
What’s New in Sexually Transmitted Infections

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Disclosures

No relevant financial disclosures
Overview
Epidemiology
Gonorrhea
HIV/AIDS
Hepatitis C
Human Papilloma Virus
Conclusions
PATHOGENS

- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Treponema pallidum*
- Human Immunodeficiency virus (HBV, HCV, HPV, CMV, HSV, HAV, MCV, Crabs, Scabies, Mycoplasma)
PATHOGENS

- *Chlamydia trachomatis*
- *Neisseria gonorrhoeae*
- *Treponema pallidum*
- *Human Immunodeficiency virus* (HBV, HCV, HPV, CMV, HSV, HAV, MCV, Crabs, Scabies, Mycoplasma)
STI HOT TOPICS

HIV/AIDS
- Prevention
- Test →
Engage care

N. gonorrhoeae
- Antibiotic
Resistance

HPV
- Vaccine

(Hepatitis C)
- Test
- Treat
STI HOT TOPICS

Overview

Epidemiology

Gonorrhea

HIV/AIDS

Hepatitis C

Human Papilloma Virus

Conclusions
Chlamydia—Rates by County, United States, 2010

Rate per 100,000 population:
- ≤300.0 (n = 1,962)
- 300.1–400.0 (n = 418)
- >400.0 (n = 762)
Gonorrhea—Rates by County, United States, 2010

Rate per 100,000 population

- ≤19.0 (n = 1,408)
- 19.1–100.0 (n = 1,107)
- >100.0 (n = 627)
NOTE: In 2010, 2,167 (69.0%) of 3,141 counties in the United States reported no cases of primary and secondary syphilis.
<table>
<thead>
<tr>
<th></th>
<th>Rate</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>US</td>
<td>MD</td>
</tr>
<tr>
<td>AIDS</td>
<td>10.3</td>
<td>20.1</td>
</tr>
<tr>
<td>HIV</td>
<td>19.1</td>
<td>30.6</td>
</tr>
<tr>
<td>Syphilis congenital**</td>
<td>8.5</td>
<td>31.1</td>
</tr>
<tr>
<td>Syphilis 1° &amp; 2°</td>
<td>4.5</td>
<td>7.8</td>
</tr>
<tr>
<td>GC</td>
<td>104.2</td>
<td>111.9</td>
</tr>
<tr>
<td>C. trachomatis</td>
<td>457.6</td>
<td>471.3</td>
</tr>
</tbody>
</table>

*Per 100,000 pop.
**Per 100,000 live births

Source: CDC; Maryland Department of Health and Mental Hygiene/Prevention and Health Promotion Administration
### STI RATES: Maryland Trends*

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2007</th>
<th>2011</th>
<th>Change (10 yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>C. trachomatis</em></td>
<td>314.1</td>
<td>412.0</td>
<td>471.3</td>
<td>+49%</td>
</tr>
<tr>
<td><em>N. gonorrhoea</em></td>
<td>174.0</td>
<td>120.5</td>
<td>111.7</td>
<td>-36%</td>
</tr>
<tr>
<td><em>T. pallidum</em></td>
<td>4.2</td>
<td>6.1</td>
<td>7.8</td>
<td>+86%**</td>
</tr>
</tbody>
</table>

*Per 100,000 population

**Baltimore increase 19 → 38

Source: Center for STI Prevention, Maryland Department of Health and Mental Hygiene (DHMH); Baltimore City Health Department (BCHD)
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Gonorrhea—Rates, United States, 1941–2010

Source: CDC
Gonorrhea—Rates by Race/Ethnicity, United States, 2001–2010

Source: CDC
Gonococcal Isolate Surveillance Project (GISP) Percentage of Urethral *Neisseria gonorrhoeae* Isolates Obtained from MSM* Participating STD Clinics, 1990–2011

* MSM = men who have sex with men
Source: CDC
The Elephant in the Room: GC Resistance

Rates: 1976-96 ↓ 76%
1996-2009 Plateau
2010-2011 ↑ 2.8%

Demographics – AA:White = 18.7

Resistance:
- Ceftriaxone: Only drug left (2011)
- Cefixime, azithro or quinolones resistance – MSM
- Resistance now with ceftriaxone 0.5-1% (2013)
- Epidemiology: Highest rates – MSM
TIMELINE OF RESISTANCE TO GONORRHEA TREATMENT

1938 - Protargol no longer recommended
1936 - Sulphonamides
1943 - Penicillin
1949 - Streptomycin and Chloramphenicol
1952 - Erythromycin
1958 - Penicillin and Streptomycin clinical resistance first reported
1961 - Spectinomycin
1962 - Tetracycline
1976 - Beta-lactamase plasmids first reported (high-level Penicillin resistance)
1977 - Erythromycin resistance widespread
1980 - Ceftriaxone
1985 - Chromosomal Penicillin resistance elucidated
1985 - Ceftriaxone recommended (ciprofloxacin alternative)
1986 - Tetracycline no longer recommended
1987 - Spectinomycin resistance reported to rapidly emerge when widely used
1989 - Fluoroquinolone resistance first reported in USA (Hawaii) - already a problem in Asia
1991 - Cefixime out of production
2002 - Cefixime available again
2007 - Azithromycin no longer recommended
2008 - Cefixime available again
2010 - Cefixime clinical failures verified beyond Japan (in Europe)
2011 - First high-level cefixime resistant strain fully characterized
2011 - Super Bug Status!!

Doxycycline

US Food and Drug Administration (FDA) issued a shortage alert on January 18, 2013

- Four pharmaceutical companies supply:
  - Mutual – available as of 3/22/13
  - Mylan – available as of 4/5/13
  - Watson – only available to contracted customers
  - West-Ward – not available as of 4/3/13

- Costs have escalated
  - $4.60 for a 60-day supply to $165

Sources: FDA
http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm314739.htm#doxycycline and
N. Gonorrhoeae : TREATMENT

1937: Sulfonamides
1940: Penicillin
1972: Penicillin dose ↑ and probenecid
1987: Sentinel surveillance
1990 – 08: Resistance
2006: Ceftriaxone, Cefixime, Cipro/Levo/Oflox + Azithro/Doxy

Current: Ceftriaxone 250 mg IM + Azithro 1 gm or Doxycycline 100 bid x 7 d
MEDICAL DISPATCHES

SEX AND THE SUPERBUG

The rise of drug-resistant gonorrhea

By JEROME GROOPMAN

THE NEW YORKER, OCT 01, 2012
2008: **Kyoto prostitute:** pharyngeal GC → failed ceftriaxone x 2 → strain resistant to ceftriaxone → postulated transmitted resistance from pharyngeal Neisseria.

≈

2009: **Ceftriaxone – resistant GC in France and Germany:** Strain identify with Kyoto strain

≈

2013: **Ceftriaxone resistant strain in Europe, Asia and US** – Must get TOC

**GC Surveillance Project:** Most resistance in MSM

Resistance of *Neisseria gonorrhoeae* isolates to cephalosporins in the Gonacoccal Isolate Surveillance Project 2006-11 (MMWR 2013;62:103)
**Screen:** All sexually active MSM and high risk women at exposed sites at least annually

**Treatment:** Ceftriaxone 250 mg IM x 1 + Azithromycin 1 gm po x 1 or doxycycline 100 mg bid x 7 days

**Alternatives:**
- Cefixime 400 mg po x 1 + azithromycin or doxycycline
- Azithromycin 2 gm po

**FU:** TOC at one week
Issue: How important is POC testing to detect GC?

Method: Cincinnati STI database for 187 female visits for over/under Rx based on NAAT*

Results of treatment:
Correct 933/1,877 (50%)
Under Rx 49/168 (30%)
Over Rx 895/711 (52%)

*NAAT – Nucleic Acid Amplification Test
POC DIAGNOSTIC TESTING FOR N. GONORRHOEAE & C. TRACHOMATIS
(Gaydos C. JCM 2013;3/3/13)

**Standard**: NAAT (CDC recommended)

**Disadvantage**: Time (? 1-2d) & place (lab)

**GeneXpert advantage**: Time (<2 hr) & place (potentially POC)

**Test**: Comparison with NAAT in 3,109 specimens for NG & CT

**Results**: Sensitivity: >97.4-99.4%
Specificity: >99.8%
## GeneXpert:
Results for detection of NG and CT*

<table>
<thead>
<tr>
<th>Group</th>
<th>No.</th>
<th>NG</th>
<th>CT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Female</td>
<td>1,387</td>
<td>3.6%</td>
<td>5.8%</td>
</tr>
<tr>
<td></td>
<td>1,722</td>
<td>1.3%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Sx Yes</td>
<td>27%</td>
<td>6.7%</td>
<td>9.9%</td>
</tr>
<tr>
<td>Sx No</td>
<td>73%</td>
<td>0.7%</td>
<td>3.5%</td>
</tr>
</tbody>
</table>

*(Gaydos C. J Clin Micro 2013;3/3/13)*
STI HOT TOPICS

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Reported Adult/Adolescent HIV Diagnosis Trends by Exposure Category

Year of HIV Diagnosis

- MSM
- IDU
- MSM/IDU
- HetSex
- Other

Using data as reported through 12/31/2011
HIV/AIDS: MARYLAND

Reported Adult/Adolescent HIV Diagnosis Trends by Race/Ethnicity

Using data as reported through 12/31/2011
HIV/AIDS: MARYLAND

Reported Adult/Adolescent HIV Diagnosis Trends by Age at Diagnosis – MSM Exposure

Using data as reported through 12/31/2011
HIV/AIDS: MARYLAND

Reported Adult/Adolescent HIV Diagnosis Trends by Race/Ethnicity – MSM Exposure

Using data as reported through 12/31/2011
HIV/AIDS: MARYLAND

Reported Adult/Adolescent HIV Diagnosis Trends by Race/Ethnicity – Heterosexual Exposure

Using data as reported through 12/31/2011
**HIV/AIDS: MARYLAND**

**Rank:** #3 state (2011, ranked by rate)
- **Rate:** 2 x national average

**Regional assets:**
- MADAP, Maryland Department of Health and Mental Hygiene, Baltimore City Health Department
- Clinical services

**State of HIV science:**
- Treatment (done-Fauci/2008)
- Priorities: Prevention and TLC

**Challenges:**
- Prevention
- Test → link → retain
HIV: WHAT’S NEW AND IMPORTANT

Testing

≈

Treatment recommendations

≈

Generic ART

≈

Gardner cascade

≈

Prevention

≈

Cure
Who gets tested?

- **2005**: CDC – all persons ages 13-64 years; repeat annually with risk
- **2006**: USPSTF: Risk based test only (Payment issue)
- **2012**: USPSTF: Endorses CDC recommendations

**Legislated test regulations**: State-based

**Test**: 1985-2012 – Specificity 2012 – sensitivity

**Where**: Hospital/Clinic → Consumer
GUIDELINES: INDICATIONS FOR ART –

**Who:** Everyone – “for individual health and public health”

**Other guidelines:** (CD4 count)

- BHIVMA <350 (+ tx risk)
- European <350-500
- WHO <350 + tx risk; Everyone when affordable
## Dynamics of HIV Viremia
*(Fiebig EW. AIDS 2003;17:1871)*

<table>
<thead>
<tr>
<th>Stage</th>
<th>Day</th>
<th>RNA</th>
<th>P24Ag</th>
<th>Ab</th>
<th>WB</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>5</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>II</td>
<td>10</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>III</td>
<td>14</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>IV</td>
<td>19</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>V</td>
<td>88</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>VI</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
Early ART: Reducing the Size of Initial Reservoir?

Week 24 Results on ART

Almost all Fiebig I Subjects had Undetectable Integrated HIV DNA in PBMC

Ananworanich J, et al. 20th CROI; Atlanta, GA; March 3-6, 2013. Abst. 47.
Testing: Why 30% of persons who test positive for HIV do not know it, and nobody is diagnosed until Fiebig V

HIV Ab test positive
WHY 30% OF PERSONS WHO TEST POSITIVE FOR HIV DO NOT KNOW IT and nobody is diagnosed until Fiebig V

HIV Ab test positive
↓
HIV Ag/Ab positive (4th generation HIV test)
↓
Directly to HIV care with ART:

WP

Sensitivity vs. specificity
Early detection (Ag) to:
1) Preserve immune function
2) Prevent tx
3) Avoid false positives
4) Achieve cure
5) Improve LTC
6) Catch up with Europe
Almost all Fiebig I Subjects had Undetectable Integrated HIV DNA in PBMC
| **Sensitivity:** 93% |
| **Specificity:** 99.8% |
| **Distribution:** Walmart, CVS, Walgreens, RiteAid, Kroger, etc. |
| **Sales:** 4,000/wk |
| **Cost:** $40 |

**Note:** EW data
- 20-25% test by CDC guidelines
- Charge is $50 – $500/test
Do you know if you have HIV or an STI?
Do you want to test yourself?
Consumer accuracy: 100%
ENGAGEMENT IN HIV CARE
(Gardner EM. CID 2011;52:793)
Does it work?
Answer: Significant benefit in all chronic diseases tested

Is IRB approval needed?
Answer: No, unless trial

Size of award?
Answer: No guidance. Most cost-effective is lottery ticket

Do non-recipients resent status?
Answer: They offer it to all and many reject it.

Are there any studies in HIV patients?
Answer: Only HPTN-65

- Establish care -- $125
- Labs -- $25
- Complete visit -- $100
- VL<400 -- $70 every 3 months
# COST OF CARE

## Contemporary costs/yr.
*(AIDS 2010;24:2705)*

<table>
<thead>
<tr>
<th>Service</th>
<th>Cost</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAART</td>
<td>$12,600</td>
<td>(76%)</td>
</tr>
<tr>
<td>Meds – other</td>
<td>$2,100</td>
<td></td>
</tr>
<tr>
<td>In-patient</td>
<td>$600</td>
<td></td>
</tr>
<tr>
<td>Out-patient</td>
<td>$400</td>
<td>(2.4%)</td>
</tr>
<tr>
<td>Other</td>
<td>$900</td>
<td></td>
</tr>
<tr>
<td><strong>Total (Meds)</strong></td>
<td><strong>$16,600</strong></td>
<td><strong>(88%)</strong></td>
</tr>
</tbody>
</table>

400,000 in care (Gardner) = $5B for ART and $160M for provider
*(Gebo K. AIDS 2010;24:2705)*
US Patent Expirations

AZT/3TC
NVP
ABC/3TC
TDF
AZT/3TC/ABC
ABC/3TC
TDF/FTC
(19)
EPV
GS7340 = 2025
RAL 2022-5

AZT ddC ddi d4T 3TC

SQV
RTV IDV
LFV
TPV DRV
LPV/RTV caps
RTV boosting

LPV/RTV tabs CVC= 2023+
## COST-EFFECTIVENESS OF GENERIC ART
*(Walensky R. Ann Intern Med 2013;158:84)*

<table>
<thead>
<tr>
<th>Category</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFV /TDF/FTC (Branded ART)</td>
<td>$15,300</td>
</tr>
<tr>
<td>EFV + TDF/FTC (&quot;Generic 2 pill&quot;)</td>
<td>$11,600</td>
</tr>
<tr>
<td>EFV + TDF + 3TC (&quot;Generic 3 pill&quot;)</td>
<td>$ 9,200</td>
</tr>
</tbody>
</table>

*75% AWP

**Red=Generic; Black=Brand**
Comparison:
Atripla (EFV/FTC/TDF)
Generic (EFV/3TC/TDF)

Cost:
Atripla: $15,300/year
Generic: $9,200/year
Viral failure: Generic – 6%
Longevity: Generic – reduced 4 months
Estimated savings: $920 million/yr (US)
Rate of new cases: 50,000-55,000/yr in US 1990-present

Prevention “bundle”
- Condoms: Variable use
- Circumcision: 60-70% effective US rates: 60% ACA – not covered but recommended AAP
- Needle exchange: IDU rates ↓
- PrEP: 62-91% effective (in trials)
- Universal treatment of HIV to prevent transmission
## EFFECT OF STI ON HIV SUSCEPTIBILITY

<table>
<thead>
<tr>
<th>STI</th>
<th>M to F</th>
<th>F to M</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUD</td>
<td>2.8</td>
<td>4.4</td>
</tr>
<tr>
<td>HSV</td>
<td>insuff data</td>
<td>2.7</td>
</tr>
<tr>
<td>Syphilis</td>
<td>2.1</td>
<td>2.5</td>
</tr>
<tr>
<td>Chancroid</td>
<td>2.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>2.6</td>
<td>3.9</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>2.8</td>
<td>ns</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>1.5</td>
<td>--</td>
</tr>
<tr>
<td>Candida</td>
<td>2.2</td>
<td>--</td>
</tr>
<tr>
<td>Bacterial Vaginosis</td>
<td>1.4</td>
<td>--</td>
</tr>
</tbody>
</table>

*Summary Estimates (ORs) from Cohort Studies*

STI Screening: First Visit

- **All patients**
  - Ask about STI symptoms
  - Syphilis serology
  - Hepatitis A/B/C tests

- **Men**
  - Chlamydia
    - Urine specimen for urethral infection
    - Rectal specimen, if report receptive anal sex
  - Gonorrhea
    - Urine specimen for urethral infection
    - Rectal specimen, if report receptive anal sex
    - Pharyngeal specimen, if exposed

STI Screening: First Visit

- **Women**
  - **Chlamydia**
    - Vaginal swab, urine or cervical specimen
    - Rectal specimen, if exposed
  - **Gonorrhea**
    - Vaginal swab, urine or cervical specimen
    - Rectal and pharyngeal specimens, if exposed
  - **Trichomoniiasis**
  - **Pregnancy**
    - LMP, current pregnancy, interest in future pregnancy, need for contraception

**HIV TREATMENT FOR PREVENTION:**
**HPTN 052 M. Cohen (PI)**
(Cohen MS. NEJM 2011;365:493)

**Protocol:** Discordant couples, CD4 350-550: Randomized to ART vs. no ART until CD4 <250

**Results:** N=1,763 (M=890, F=873)

<table>
<thead>
<tr>
<th></th>
<th>ART</th>
<th>No Art</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>886</td>
<td>877</td>
</tr>
<tr>
<td>HIV transmission*</td>
<td>1**</td>
<td>27</td>
</tr>
</tbody>
</table>

*Linked cases
**Protection with ART = 96% -- Study continues to determine durability
HIV PREVENTION WITH ART

Quinn, et al (NEJM 2000)
No transmission if VL <1500

↓

Swiss Federal Statement 1/8/2008
No sexual tx if VL undetectable

↓

Granich (Lancet, 2009)
WHO: Universal ART for prevention

↓

Cohen M: HPTN 052 2012
Discordant couples: 96-100%

↓

BHIVA: No confirmed HIV tx with NDV (“never”) January, 2013
Tanser F, et al. 19th CROI; Seattle, WA; March 5-8, 2012. Abstr. 136LB.
# Efficacy of Daily Oral FTC/TDF PrEP

<table>
<thead>
<tr>
<th>Trial</th>
<th>Pop.</th>
<th>Efficacy</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>MSM</td>
<td>42%</td>
<td>18 to 60%</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>Men</td>
<td>83%</td>
<td>49 to 94%</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>62%</td>
<td>19 to 82%</td>
</tr>
<tr>
<td>TDF2</td>
<td>Men</td>
<td>80%</td>
<td>25 to 97%</td>
</tr>
<tr>
<td>FemPrep*</td>
<td>Women</td>
<td>49%</td>
<td>-22 to 81%</td>
</tr>
<tr>
<td>VOICES*</td>
<td>women</td>
<td>TDF only arm discontinued</td>
<td></td>
</tr>
</tbody>
</table>

*DSMB recommended discontinuation for futility; drug level testing is in progress.

PrEP TRIALS: CONCLUSION

**Trials:** TDF2, Partners, IPrEx (FEM – PrEP)

**Risk:** MSM, discordants, commercial sex

**Data:** n=6,956 x 13-23 months

**Results:**

- Prevention efficacy: 62-91% (renal & bone)
- Side effects: GI 5-10%; ? Long term
- Resistance: 3/3,900 (<10.1%)
- Adherence: FEM – PrEP
PrEP CDC RECOMMENDATIONS

**Who:** MSM & Discordant couples plus “very high risk”

**Screening:** HIV, pregnancy, HBV, CrCl >50 cc/mL, STDs; Partner – on ART? (Refer)

**Rx:** TDF/FTC script only with negative HIV test q 3 months

**Follow up:** Every 2-3 months

Each visit: HIV, pregnancy, STD sx, STD screen q 6 months, CrCl at 3 months, then q 6 months
CHALLENGES OF PrEP

**Adherence**: Huge Issue

**Cost**: TDF/FTC AWP = $1391.45/mo -- $12,600/yr + medical care

**CDC recs (?)**: 4 medical visits/yr for drug toxicity and HIV serology

**Long term toxicity**: Bone and renal

**What will happen (?)**: Selective use but may not reach the most vulnerable
HIV PREVENTION 2009-12

<table>
<thead>
<tr>
<th>Prevention Technologies</th>
<th>Effect size (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrEP</td>
<td>96% (73-99)</td>
</tr>
<tr>
<td>PrEP</td>
<td>73% (49-85)</td>
</tr>
<tr>
<td>PrEP</td>
<td>63% (21-84)</td>
</tr>
<tr>
<td>Circumcision</td>
<td>54% (38-66)</td>
</tr>
<tr>
<td>PrEP</td>
<td>44% (15-63)</td>
</tr>
<tr>
<td>PrEP</td>
<td>42% (21-58)</td>
</tr>
<tr>
<td>Microbide</td>
<td>39% (6-60)</td>
</tr>
<tr>
<td>Vaccine</td>
<td>31% (1-51)</td>
</tr>
</tbody>
</table>

IMPACT OF COMBINATION PREVENTION ON HIV INCIDENCE
(Cremin I. AIDS 2013;27:447)

- Baseline
- ART CD4 200
- ART CD4 350
- Male circumcision
- Early ART
- PrEP

Annual number of new infections

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HCV INCIDENCE IN MSM

Amsterdam Cohort
(Wandeler G. CID 2012;55:1408) n=3333
Incidence 1998 – 0.23/100 PY & 2011 – 4.09/100 patient

MACS (Witt M. CID 3/26/13)
- Incidence (n=5,310) 1984 – 2011 2.08/patient year
- Incident cases 115
- RR HIV: 5.5 (p=0.001)
- RR Unprotected receptive sex -- >1 partner: 3.37 (p=0.001)
HEPATITIS C**

No. infected: 2.7-3.9 million

No. who know it: 40% (NHANES)
- Tested for perceived risk (13%)
- Tested and F/U: 22/170 (13%)

Risk: Birth 1945-65 >75%
- IDU, tx <1992, hemodialysis

CDC: Screen birth cohort and “at risk”

Deaths/yr: 15,106 (2007)

Treatment → SVR (cure): 75% (2014)

Drugs in phase II/III: 37

*MMWR 2012;61 RR4:1
NHANES Hepatology 2012;55:1653
HOW WILL HCV TREATMENT CHANGE?

HCV Treatment

1991: Interferon
1995: PegINF/rib
2011: PegINF/rib/PI (TPV, BOC) + 57 drugs in development
2012: Pipeline – 37 agents
2014: No INF/r, all oral, high cure rates, high cost
MORTALITY RATES DUE TO HIV, HCV AND HBV IN US 1999-2007
HEPATITIS C

**Testing:**
- Screening: All at risk* and all born 1946-64 (CDC)
- HCV-Ab → VL, genotype, LFT → Refer

**Treatment:** Now or later?
Decision – Fibrosis score and cost/trials

*Is MSM a “significant” risk and ? frequency of testing
STI HOT TOPICS

Overview
Epidemiology
Gonorrhea
HIV/AIDS
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Human Papilloma Virus
Conclusions
**Vaccines:**  Cervarix (HPV2) 16/18  
Gardasil (HPV4) 6/8/16/18

**Recommendations:**
- **Females:** HPV2 or HPV4; 3 doses at age 11-12, catch-up 13-26
- **Males:** HPV4; 3 doses at age 11-12, catch-up 13-26
- **Immunocompromised:** To age 26
- **MSM:** HPV4 to age 26
**Issue:** Australia – quadravalent HPV vaccine for women 12-26 yrs 2007-09 – ? Impact

**Method:** Cervical cytology Registry data for 2003-09 vs. 2007-09

**Results:** Significant decrease in incidence of high grade cervical abnormalities in girls <18 years
TRENDS IN INCIDENCE: HGCA  

<table>
<thead>
<tr>
<th></th>
<th>Age &lt;18</th>
<th></th>
<th>Age 18-20</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Incidence</td>
<td>P</td>
<td>Incidence</td>
<td>P</td>
</tr>
<tr>
<td>Pre-vaccine</td>
<td>0.99</td>
<td></td>
<td>0.99</td>
<td></td>
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<tr>
<td>Post vaccine</td>
<td>0.87</td>
<td>0.05</td>
<td>1.00</td>
<td>NS</td>
</tr>
<tr>
<td>Before vs. after</td>
<td>1.14</td>
<td></td>
<td>0.99</td>
<td>NS</td>
</tr>
</tbody>
</table>

**Note** the importance of early vaccine  
**Potential**: Cervical cancer – 529,000/yr – 85% in developing countries
HPV VACCINE AGAINST ANAL HPV INFECTION AND ANAL INTRAEPITHELIAL NEOPLASIA
(Palefsky JM. NEJM 2011;365:1576)

**Issue:** 1) HPV 16/18 are highly associated with anal cancer; 2) anal cancer rates increasing and 3) MSM are at high risk

**Method:** Double blind randomized trial HPV vaccine for 608 MSM (ages 16-26). Efficacy based on anal intraepithelial neoplasia (AIN) and anal cancer

**Results:** Rate of grade 2/3 AIN reduced 75%; rate of infection reduced 49%
INCIDENCE OF HPV-6, 11, 16, OR 18 RELATED AIN.
(Palefsky. NEJM 2011;365:1576)

B  HPV-6, 11, 16, or 18–Related AIN in the ITT Population

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>qHPV vaccine</th>
<th>Placebo</th>
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<tbody>
<tr>
<td>0 months</td>
<td>275</td>
<td>276</td>
</tr>
<tr>
<td>6 months</td>
<td>264</td>
<td>263</td>
</tr>
<tr>
<td>12 months</td>
<td>225</td>
<td>236</td>
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<tr>
<td>18 months</td>
<td>208</td>
<td>218</td>
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<tr>
<td>24 months</td>
<td>191</td>
<td>192</td>
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<tr>
<td>30 months</td>
<td>148</td>
<td>146</td>
</tr>
<tr>
<td>36 months</td>
<td>45</td>
<td>38</td>
</tr>
</tbody>
</table>
Why HPV 6 & 11?
May cause some low grade AIN but “Cervirax should be just as good”*

*Note: Survey of teenagers – far greater concern for genital warts

Age limit of 26 in MSM?
Agree with CDC but “reasonable to individualize”
Presentations with warts in men and women <21 years, and MSM all ages, July 2004 to end June 2011. Vaccination program commences.

Read T R H et al. Sex Transm Infect 2011;87:544-547
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<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Cost Single dose</th>
<th>Vaccine Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV Gardasil</td>
<td>$155 (x3)</td>
<td>21% (F)</td>
</tr>
<tr>
<td>Cervarix</td>
<td>$134 (x3)</td>
<td></td>
</tr>
<tr>
<td>Influenza</td>
<td>$ 32</td>
<td>44%</td>
</tr>
<tr>
<td>Pneumococcal Pneumovax</td>
<td>$ 74</td>
<td>60% (&gt;65 yrs)</td>
</tr>
<tr>
<td>Prevnar 13</td>
<td>$145</td>
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</tr>
<tr>
<td>Zoster</td>
<td>$192</td>
<td>14%</td>
</tr>
<tr>
<td>Tdap</td>
<td>$ 47</td>
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</tr>
</tbody>
</table>
STI HOT TOPICS

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HEALTHCARE REFORM

- What will happen to STD clinics, HIV care programs & RWCA?
- Provider: Computer QC, EPR, cost, outcome, patient satisfaction
- Transition will be rough
- No attempt at single payer system or medical-legal issue
CONCLUSIONS

**Epidemiology**: MSM, black race and poverty

**HIV**: Emphasis on Testing, Gardner Cascade, Prevention and Cure

**GC**: Resistance, TOC, POC test

**HCV**: Test and Treat (for cure)

**HPV**: Vaccine to prevent cancer and warts

**HCR?** Impact potentially great
Questions/Discussion