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**Hepatitis C and STIs**  
An Update

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**Hep C Statistics**

- 170 million infected worldwide
- 4 million infected in the US
- 1/3 of HIV+ patients also have Hep C
- Many people unaware of being infected

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**Are There Different Types of Hep C?**

**Genotypes 1-6**

- Genotype 1: 80% of patients in US – Most difficult to treat
- Genotype 2 and 3: 16% of patients in US
- Other genotypes: 4% of patients in US

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**Goals of Treatment**

- Sustained Virologic Response (SVR) = clear Hep C from the body
- Slow or stop damage to the liver
- Prevent complications like cirrhosis, liver failure and liver cancer

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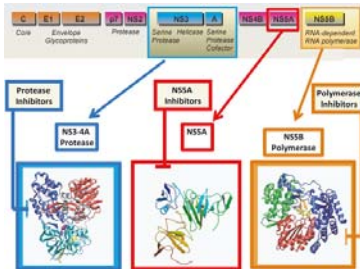
**What Treatment is Available?**

- **Peg-interferon**  
– taken once a week, injectable
- **Ribavirin**  
– Taken 2-3 times a day, oral
- **Boceprevir or Telaprevir** **NEW!**  
– Taken 3 times a day, oral




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**HCV Genome and DAAs**



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**What is Telaprevir (Incivek)?**



- Approval**  
FDA Approved May 23, 2011
- Indications**  
In combination with Peg-interferon and ribavirin  
Chronic Hep C genotype 1 infection  
Adults with compensated liver disease, including cirrhosis  
Treatment-naïve or prior interferon-based treatment  
Not currently FDA approved for HIV/Hep C coinfectd
- Dosing**  
750 mg (two 375-mg tablets) three times daily with fatty food  
Treat with peg/riba for 12 weeks (followed by additional 12 or 36 weeks peg/riba)

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**What is Boceprevir (Victrelis)?**



- Approval**  
FDA Approved May 13, 2011
- Indications**  
In combination with Peg-interferon and ribavirin  
Chronic Hep C genotype 1 infection  
Adults with compensated liver disease, including cirrhosis  
Treatment-naïve or prior interferon-based treatment  
Not currently FDA approved for HIV/Hep C coinfectd
- Dosing**  
800 mg (four 200-mg tablets) three times daily with food (not fatty)  
Treat with peg/riba for 28 weeks (might need additional 8 or 20 weeks with or without peg/riba)

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**Side Effects of Interferon & Ribavirin**

Common Side Effects:

- Flu-like symptoms**
  - Headache
  - Fatigue
  - Muscle & joint aches
  - Fever, chills
- Psychiatric symptoms**
  - Depression
  - Difficulty sleeping
  - Difficulty concentrating
  - Irritability

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**Side Effects of Interferon & Ribavirin**

Less Common Side Effects:

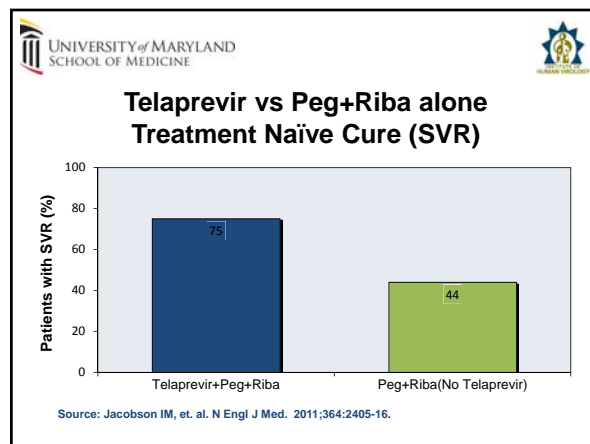
- Hair loss
- Weight loss
- Thyroid problems
- Predisposition to infections
- Fetal malformations ([need for contraception!](#))

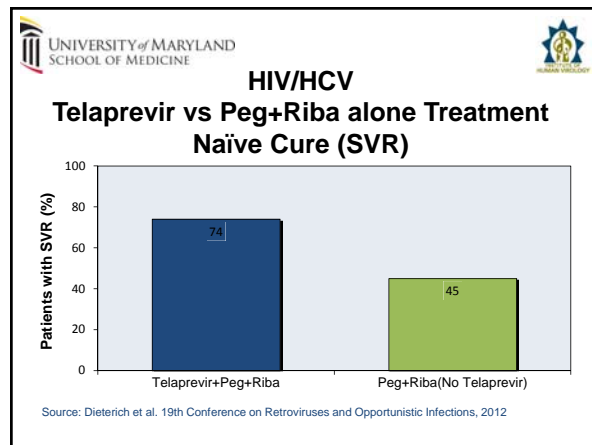
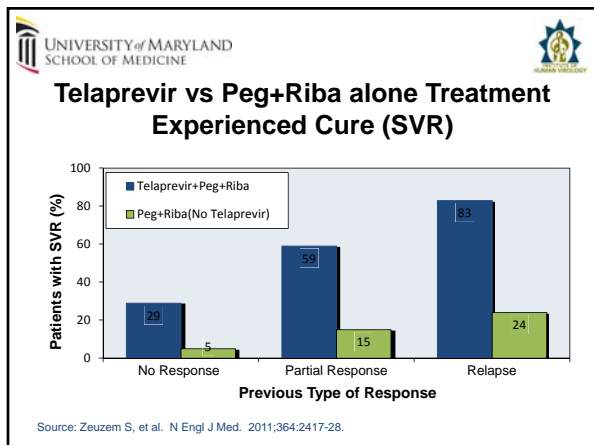
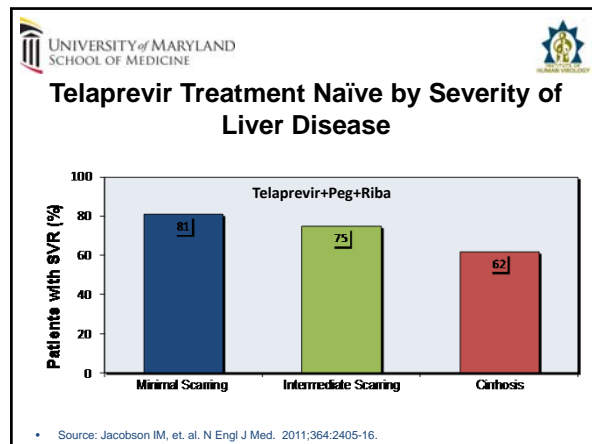
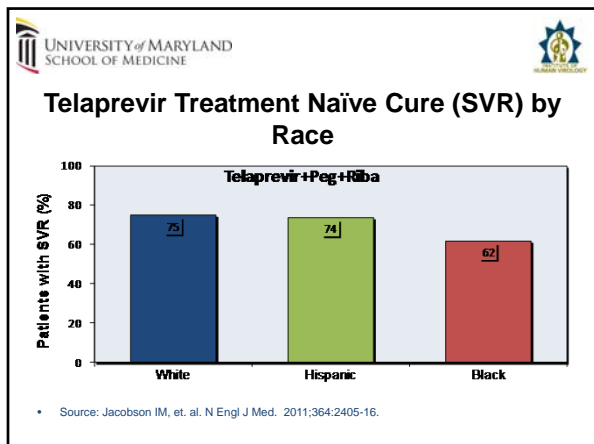
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**Side Effects of Telaprevir/Boceprevir**

Common Side Effects:

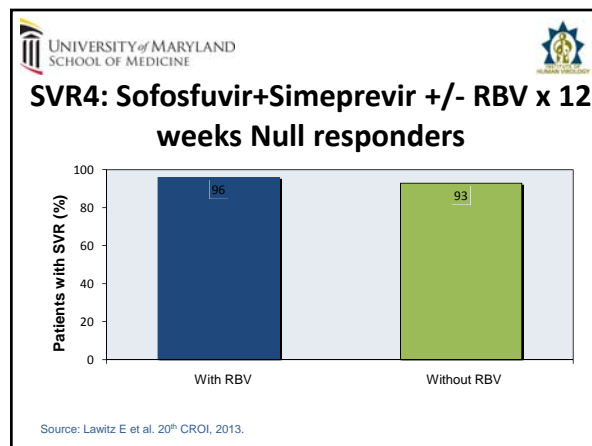
- Telaprevir**
  - Rash
  - Ano-rectal burning
  - Low red cell count (Anemia)
  - Low white cell count
  - Nausea/diarrhea
- Boceprevir**
  - Altered taste
  - Low red cell count
  - Low white cell count
  - Nausea/diarrhea

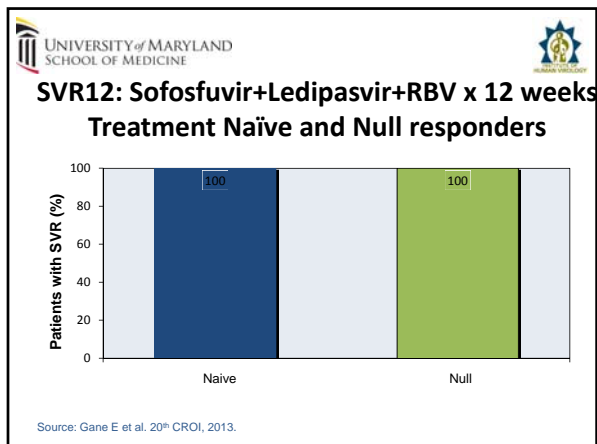




**Future of Hep C**

- Over 25 new drugs in advanced development
  - Including 9 in phase 3 trials
- Several interferon-free combination treatments
- Cure rates as high as 100%
- New wave of drugs coming out to market expected in late 2013-2014

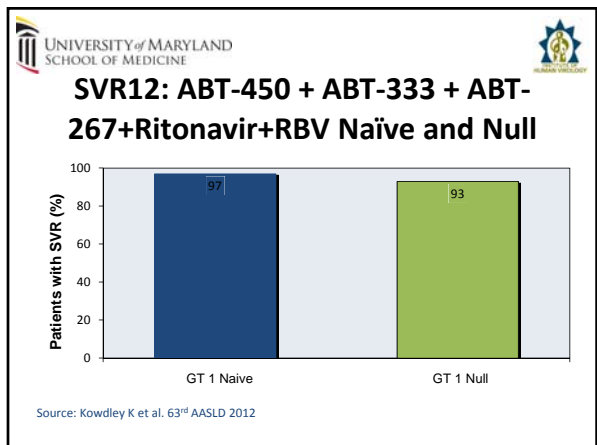




**SVR12: Sofosbuvir+Ledipasvir+RBV x 12 weeks**  
Results: Adverse Events

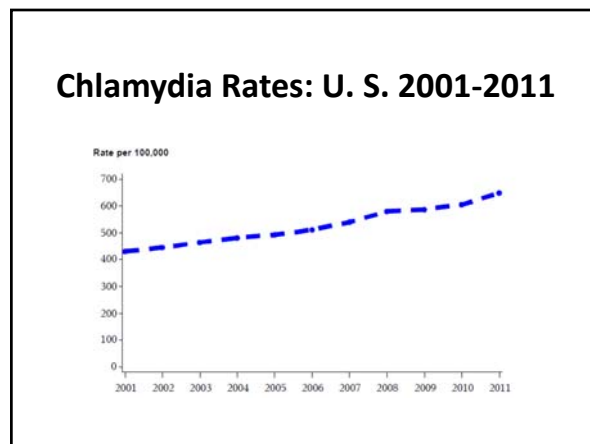
	SOF + RBV		SOF + LDV + RBV	
	Treatment-naïve (n = 25)	Null responder (n = 10)	Treatment-naïve (n = 25)	Null responder (n = 9)
SAR <sup>a</sup>	1 (4)	0	2 (8)	0
AEs that led to discontinuation	0	0	1 (4) <sup>b</sup>	0
≥Grade 2 AEs <sup>c</sup>	10 (40)	3 (30)	12 (48)	2 (22)
Anemia	0	1 (10)	5 (20)	0
Depression	0	1 (10)	2 (8)	0
Headache	1 (4)	0	1 (4)	0
Ligament sprain	1 (4)	1 (10)	0	0

<sup>a</sup>SARs considered unrelated to SOF (urinary injury, pyelonephritis, ototoxicity, otitis • skin rashes • dizziness • peripheral neuropathy)  
<sup>b</sup>Stopped all treatment at Week 8 at time of partial colectomy for diverticular perforation.  
<sup>c</sup>More than 1 patient.  
 AE: adverse event; LDV, ledipasvir; RBV, ribavirin; SAR, serious adverse event; SOF, sofosbuvir.



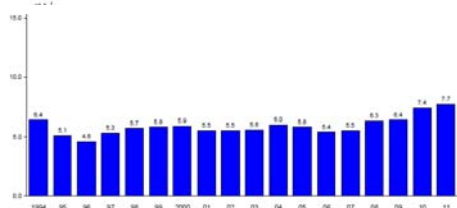
- Common STDs**  
**Estimated U.S. Annual Incidences**
- Human Papillomavirus: 5.5 million
  - Trichomoniasis: 5 million
  - Chlamydia: 3 million
  - Genital herpes: 1 million
  - Gonorrhea: 650,000
  - Hepatitis B: 120,000
  - Syphilis: 70,000

- Chlamydia Infection**
- Most common reportable disease in the U.S.
    - Incidence is highest among sexually active adolescents and young adults
  - Most infections are asymptomatic
  - Leading cause of preventable infertility in women
  - Direct and indirect costs estimated at \$1.7 billion annually



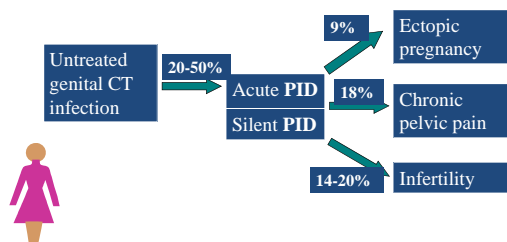
## Chlamydia — Rates in Maryland Region 1994-2011

Figure A. Chlamydia - Trends in Positivity Among Women Aged 15-24 Years Tested in Family Planning Clinics, Intensity Prevention Project, United States, Region II, 1994 - 2011

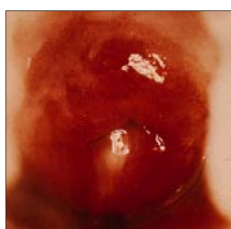


(Guam, Puerto Rico and Virgin Islands) was 293.6 per 100,000 population.

## Genital Chlamydia in Women: Complications



## Chlamydia Infection Clinical Manifestations



## Chlamydia Screening & Treatment

- Decreases community prevalence
- Prevents pelvic inflammatory disease
  - Scholes et al., NEJM, 1996; 334:1362-6
- Cost effective
  - CDC estimates that "for every dollar spent on chlamydia screening, we could save \$12"
- Opportunity to increase awareness and provide risk reduction counseling

## Chlamydia Screening Recommendations

- CDC, NCQA HEDIS, USPSTF, ACOG and others are similar
- All sexually active women under 26 yoa
  - Initial screen
  - Repeat annually
  - Consider repeat with new or multiple sex partners
  - Repeat 2-3 months after an infection
- All pregnant women under 26 yoa
- Men, and women 26 and older, consider with
  - New or multiple sex partners,
  - Inconsistent condom use



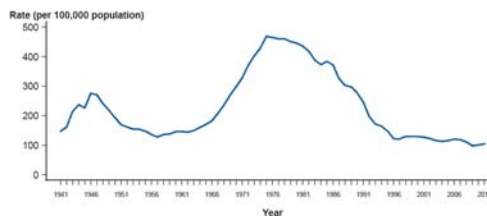
## Chlamydia Treatment Recommendations

- Azithromycin 1gm single dose or Doxy x 7 days
- Alternative regimens
  - Erythromycin x 7 days
  - Ofloxacin or Levofloxacin x 7 days

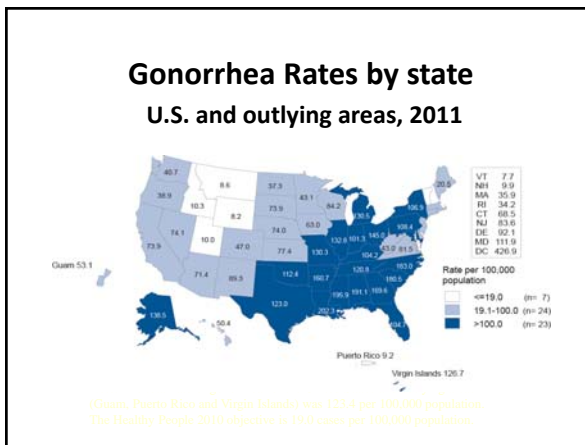
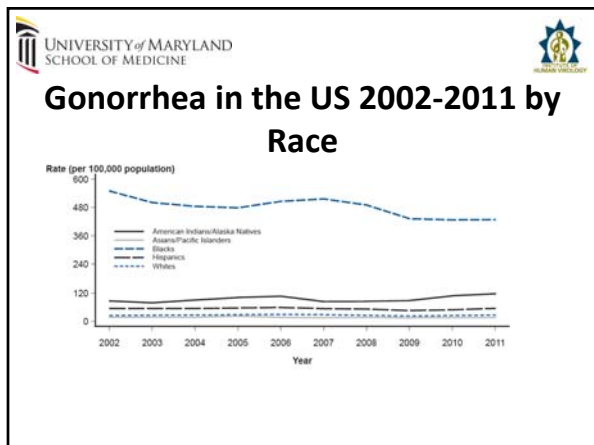
## Gonorrhea

- Most common in young adults and adolescents
- CT co-infection of GC cases remains at about 40%
- Resistance to medication is an spreading problem

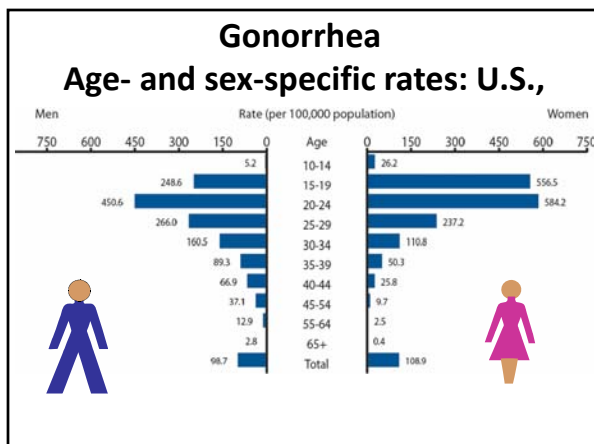
## Gonorrhea Rates: U.S. 1941–2011



Note: The Healthy People 2010 objective for gonorrhea is 19.0 cases per 100,000 population.

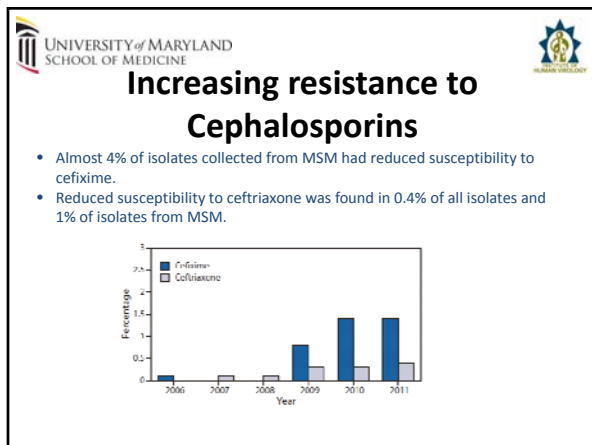
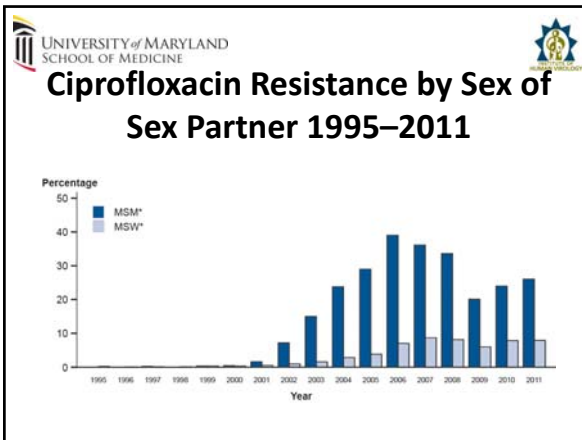
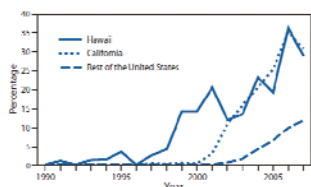


(Guam, Puerto Rico and Virgin Islands) was 123.4 per 100,000 population. The Healthy People 2010 objective is 19.0 cases per 100,000 population.

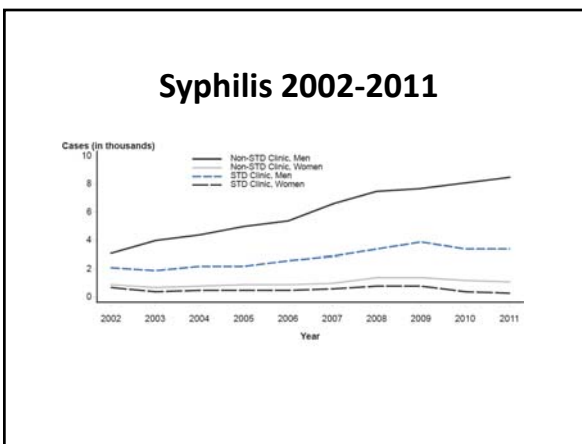
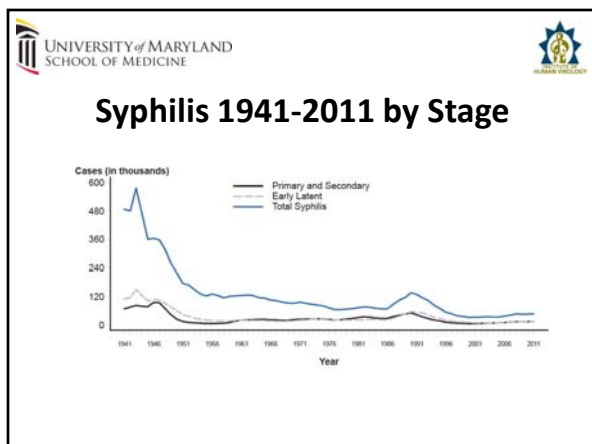


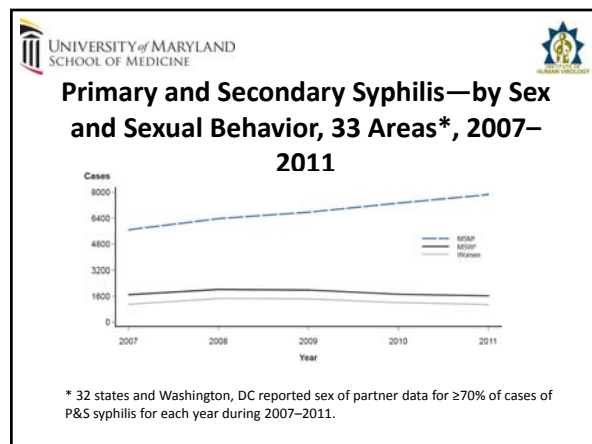
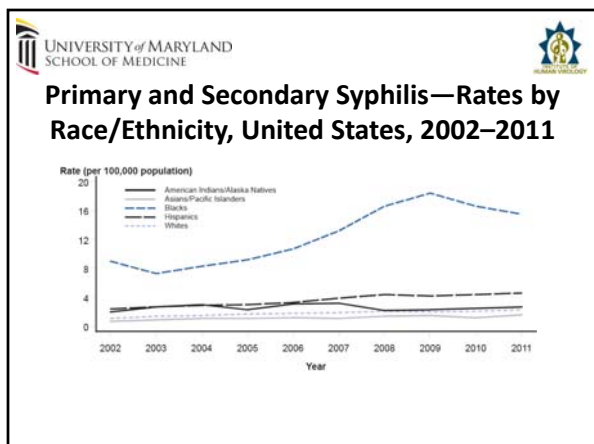
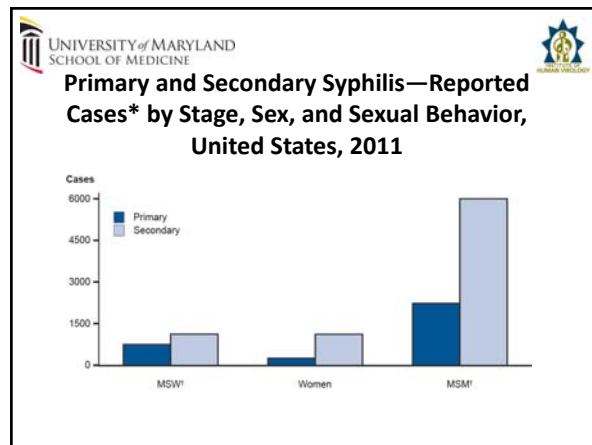
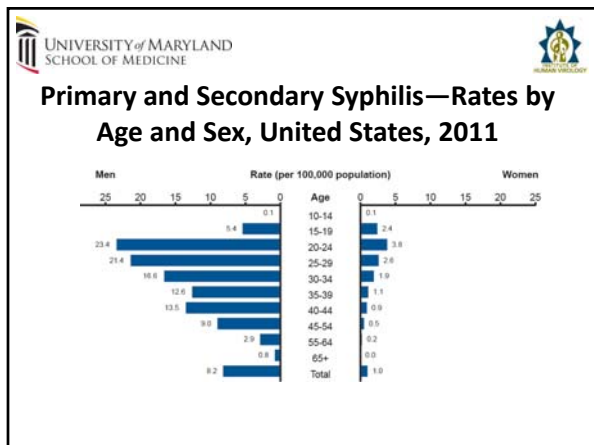
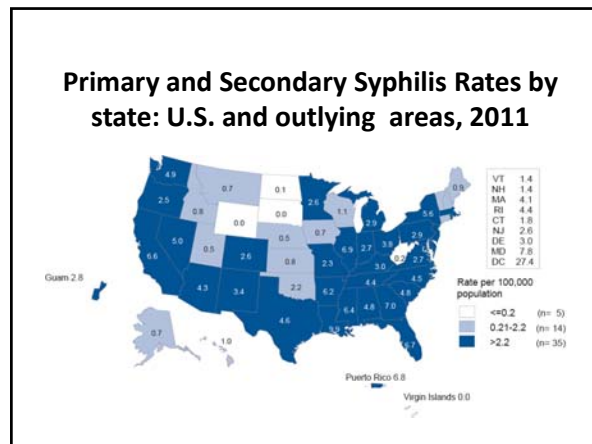
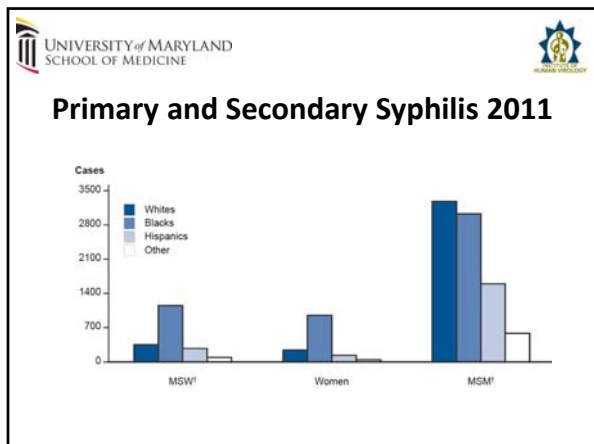
### Increasing Antibiotic Resistance in the U.S.

- Almost all GC isolates in Asia are resistant to Cipro
- In the US, the resistance to Cipro is 10-30%

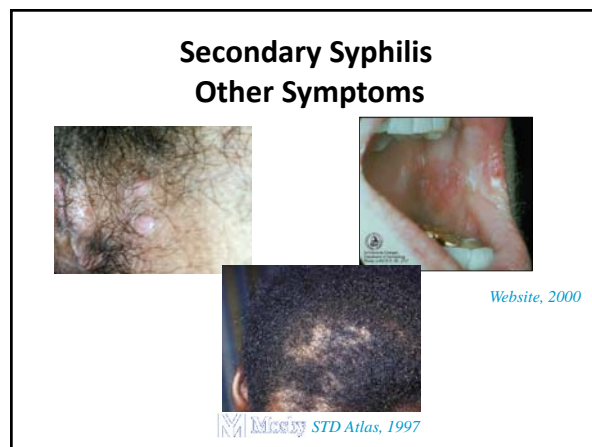
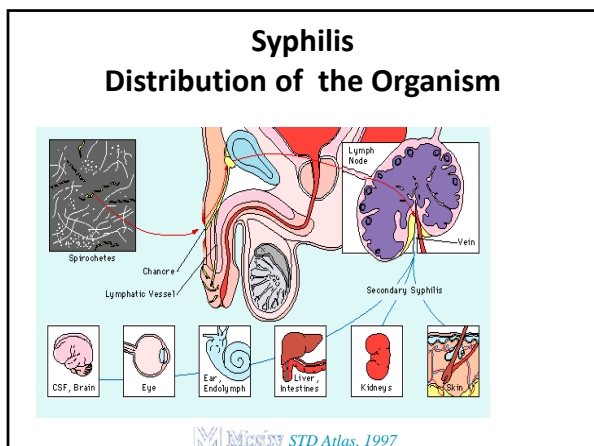


- ### Gonorrhea Screening Recommendations
- Targeted screening: consider in
    - Populations with prevalence of 1-2% or more
    - MSM
    - High-risk women
      - Young age
      - New or multiple partners
      - Pregnant women





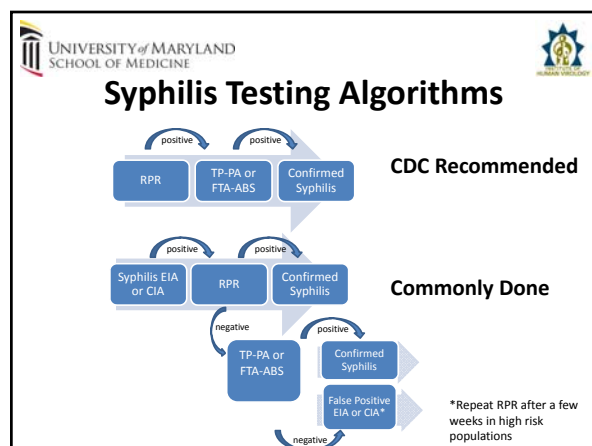




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## Syphilis testing

- Primary Syphilis: serology might be negative, do dark field microscopy
- CDC recommends to start with a non-treponemal test (RPR, VDRL)
  - confirm positives with a treponemal test (TP-PA, FTA-ABS)
- Many labs use *T. Pallidum* EIA or CIA as screening
  - Confirm positives with quantitative RPR
  - If RPR is negative (56%), do TP-PA or FTA-ABS
    - If TP-PA or FTA-ABS are also negative->false positive (36% of discordant sera)



## Syphilis Treatment

- Penicillin G (an injectable) remains the first line treatment
  - Only possible treatment for pregnant women and neurosyphilis
- Doxycycline can be used as alternative treatment in PCN allergic
- Azithromycin 2gm single dose can be effective for early syphilis however resistance might occur
- Limited data supports ceftriaxone x 4 days but optimal dose or duration of therapy has not been defined



## Summary

- New drugs are available for HCV, increasing likelihood of cure, but less toxic and more efficacious drugs are in the pipeline
- Chlamydia is on the rise in the US, and screening should be implemented in appropriate groups, as treatment decreases complications
- GC is increasingly becoming drug resistant, in the US the oral treatment is no longer recommended, and ceftriaxone should be used
- Syphilis has made a comeback, especially among African-Americans and MSM. There are 2 ways to go about testing, and treatment of choice is still PCN