STI’s: What’s New and Different

Donna E. Sweet, MD, AAHIVS, MACP
Professor of Medicine
The University of Kansas
School of Medicine - Wichita
that nearly 20 million new STIs occur every year in this country
that undiagnosed STIs cause 24,000 women to become infertile each year
The total estimated direct cost of STIs annually in the U.S. is about $16 billion

http://www.ashasexualhealth.org/stdsstis/statistics/
STIs Are More Common Among Adolescents and Young Adults

- **Americans aged 15-24 years** make up just 25% of the sexually active population, but incidence and prevalence estimates suggest they acquire **half all new STIs**\(^1\)

- **In 2015, most reported chlamydia and gonorrhea infections occurred among 15-24 year-olds**\(^2\):

  - **Chlamydia**: 64.3%
  - **Gonorrhea**: 49.7%

**Total infections all ages:**
- **Chlamydia**: 1,526,658
- **Gonorrhea**: 395,216

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Young people account for a substantial proportion of new STIs

- **Gonorrhea**: 70% of total infections (820,000)
- **Chlamydia**: 63% (2.9 million)
- **HPV**: 49% (14.1 million)
- **Genital Herpes**: 45% (776,000)
- **HIV**: 26%* (47,500, Ages 13-24)
- **Syphilis**: 20% (55,400)

https://www.cdc.gov/std/products/infographics.htm
Youth At Risk

One in two sexually active persons will contract an STI by age 25

Half of the new STIs diagnosed occur in young people aged 15–24.

Even though young people account for half of new STI cases, a recent survey showed only about 12% were tested for STIs in the last year.

http://www.ashasexualhealth.org/stdsstis/statistics/
Importance of Extragenital Screening for STIs

Proportion of CT and GC infections that would be missed among 3398 asymptomatic MSM if screening only urine/urethral sites, San Francisco, 2008-2009

• **Rectal chlamydia and gonorrhea infections are asymptomatic 85% of the time** supporting the need for routine screening

CT, chlamydia; GC, gonorrhea.
Misconceptions About STIs Among Patients, Clinicians

Among young women:
86% do not see themselves at risk for chlamydia and gonorrhea
51% do not want to bring up sex or STIs with their health care provider
27% overall and 43% of those 15 to 17 years of age are not completely honest with their health care provider about sexual history
49% were not offered STI testing by their health care provider

Source: Infectious Disease News. June 2018. Pg. 44. Healio.com/Id
Misconceptions About STIs Among Patients, Clinicians

According to Survey results from health care providers:

24% agreed they are uncomfortable discussing STI risks with their female patients

27% said they can accurately diagnose an STI based on patients’ symptoms

74% would order chlamydia testing and 72% would order gonorrhea testing for an asymptomatic, sexually active female patient

Source: Infectious Disease News. June 2018. Pg. 44. Healio.com/Id
Among sexually active adults who were not tested:

- 49% said they do not need routine STI testing
- 33% said testing was too expensive
- 26% said they had no time
- 19% were worried about confidentiality
- 17% were not offered testing
- 16% were not sure where they could get tested

Source: Infectious Disease News. June 2018. Pg. 44. Healio.com/Id
Youth At Risk

• Young people ages 15 to 24 years old accounted for 65% of chlamydia diagnoses and 50% of gonorrhea diagnoses in 2015.

• While CDC and the U.S. Preventive Services Task Force recommend annual chlamydia screening for sexually active young women ages 15-24, fewer than half of eligible women are screened according the guidelines.

http://www.ashasexualhealth.org/stdsstis/statistics/
Normal Adolescent Cognitive and Behavioral Factors Can Affect Sexual Behavior

Adolescents' heightened propensity for risky behavior is thought to reflect maturational imbalance between cognitive control systems and affective reward processing.1

Cognitive2

- Myth of invulnerability
- Lack of knowledge of STIs and associated signs/symptoms
- Fear of disclosure of sexual activity to parent/guardian

Behavioral2

- Multiple partners, new partner in past 3 months, older partners, bisexual partners, partners who have been incarcerated
- Known sex with HIV-positive partner or partner with a history of IDU
- Inconsistent or lack of use of barrier method
- Oral contraceptive use (increases risk of chlamydia)
- Past history of STIs

Today we will Discuss...

Chlamydia
Gonorrhea
Syphilis
Hepatitis C
HIV
Chlamydia: 2016 United States

- Chlamydia 1,598,354
  - Rate per 100,000 people: 497
Chlamydia: United States

• The approximately 1.5 million reported cases to the CDC of chlamydia represent the highest number of annual cases of any condition ever.

http://www.ashasexualhealth.org/stdsstis/statistics/
Figure 8. Chlamydia incidence, United States & South Dakota 1994-2016
(Cases per 100,000 population)

### South Dakota Infectious Disease Summary 2018

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YTD: Year-to-Date  Rate: Cases per 100,000 population  5-Year Median: 2013–2017  ‡ Unstable rate based on <20 observations

**2017 Total of 1,267 Chlamydia Cases In South Dakota**
Chlamydia: Treatment of Uncomplicated Genital Chlamydial Infections

CDC-recommended regimens

• Azithromycin 1 g orally in a single dose, or
• Doxycycline 100 mg orally twice daily for 7 days

Alternative regimens

• Erythromycin base 500 mg orally 4 times a day for 7 days, or
• Erythromycin ethylsuccinate 800 mg orally 4 times a day for 7 days, or
• Ofloxacin 300 mg orally twice a day for 7 days, or
• Levofloxacin 500 mg orally once a day for 7 days

Chlamydia: Repeat Testing after Treatment

- **Pregnant women**
  - Test of cure, by NAAT, 3 weeks after completion of therapy
  - Repeat testing for reinfection 3 months after completion of therapy

- **Non-pregnant women and men**
  - Repeat testing 3 months after treatment is recommended to detect re-infection with *C. trachomatis*
    - If not possible, then repeat testing should be performed at next presentation for care within 12 months
  - Test of cure (3 weeks after therapy) is not recommended, but can be considered when
    - compliance is in question,
    - symptoms persist,
    - re-infection is suspected, or
    - erythromycin is used.

Screening of sexually-active young men should be considered in clinical settings with a high prevalence of chlamydia and when resources permit.

Repeat testing is recommended for all men 3 months after treatment for *C. trachomatis* infection

– If not possible, then repeat testing should be performed at next presentation for care within 12 months.
Gonorrhea: 2016 United States

- Gonorrhea 468,514
- Rate per 100,000 people: 146

Figure 2. Gonorrhea incidence, South Dakota & United States, 1941-2016
(Cases per 100,000 population)

- United States
- South Dakota

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2017 1,267 Gonorrhea Cases In South Dakota
Gonorrhea: Treatment

Gonorrhea treatment guidelines have been revised twice in the last 6 yrs and now recommend...

• Dual therapy of intramuscular ceftriaxone (250mg) and oral azithromycin (1g) for the best patient outcomes and to help prevent antimicrobial resistance.

Source: Infectious Disease News. June 2018. Pg. 44. Healio.com/Id
1 in 5 Patients With Gonorrhea Gets Wrong Treatment

• Data showed that in 2016 at 7 surveillance sites in the United States 81% of patients received the recommended first-line treatment.

• Most who were treated with other regimens only received one antimicrobial, including 3% of all patients who received azithromycin monotherapy, which is not recommended because of concerns about emerging resistance and case reports of treatment failures.

• The most frequently prescribed inappropriate regimen in 2016 was Ceftriaxone 250mg alone – almost 6% of the time.

Source: Infectious Disease News. June 2018. Pg. 44. Healio.com/ld
Syphilis: 2016 United States

- Syphilis (primary and secondary) 27,814
  - Rate per 100,000 people: 9
- Syphilis (congenital) 628
  - Rate per 100,000 live births: 16

Figure 15. Syphilis incidence, United States and South Dakota 1995-2016

(Cases per 100,000 population)

- USA primary & secondary
- SD primary & secondary
- USA early latent
- SD early latent
- USA late & late latent
- SD late & late latent

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</tr>
<tr>
<td>Shigella</td>
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<td>0.5†</td>
<td>3</td>
<td>33%</td>
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<tr>
<td>Syphilis, early</td>
<td>7</td>
<td>0.8†</td>
<td>13</td>
<td>-46%</td>
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<tr>
<td>Toxic shock syndrome</td>
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<td>0.1†</td>
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<tr>
<td>Tuberculosis</td>
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<td>2</td>
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<td></td>
<td>6</td>
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2017
75 Cases of Syphilis (all stages)
Syphilis: Treatment
Primary, Secondary, and Early Latent Syphilis

- Benzathine penicillin G 2.4 million units intramuscularly in a single dose (Bicillin L-A®)

- If penicillin allergic
  - Doxycycline 100 mg orally twice daily for 14 days, or
  - Tetracycline 500 mg orally 4 times daily for 14 days

Source: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2010. MMWR 2010;59 (No. RR-12).
Syphilis: Treatment Therapy for Late Latent Syphilis

- Benzathine penicillin G 7.2 million units total, administered as 3 doses of 2.4 million units intramuscularly each at 1-week intervals
- If penicillin allergic
  - Doxycycline 100 mg orally twice daily for 28 days or
  - Tetracycline 500 mg orally 4 times daily for 28 days

Source: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2010. MMWR 2010;59 (No. RR-12).
Syphilis: Treatment Therapy for Tertiary Syphilis

• Benzathine penicillin G 7.2 million units total, administered as 3 doses of 2.4 million units intramuscularly each at 1-week intervals

• If penicillin allergic
  – Doxycycline 100 mg orally twice daily for 28 days or
  – Tetracycline 500 mg orally 4 times daily for 28 days

Source: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2010. MMWR 2010;59 (No. RR-12).
Syphilis: Treatment Therapy for Neurosyphilis

• Aqueous crystalline penicillin G 18–24 million units per day, administered as 3–4 million units intravenously every 4 hours or continuous infusion for 10 to 14 days intravenously

• Alternative regimen (if compliance can be ensured)
  – Procaine penicillin 2.4 million units intramuscularly once daily PLUS Probenecid 500 mg orally 4 times a day, both for 10 to 14 days

Source: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2010. MMWR 2010;59 (No. RR-12).
**Syphilis: Treatment**

**Therapy for Syphilis in Pregnancy**

- Treat with penicillin according to stage of infection.
- Erythromycin is no longer an acceptable alternative drug in penicillin-allergic patients.
- Patients who are skin-test-reactive to penicillin should be desensitized in the hospital and treated with penicillin.
- Some evidence suggests that additional therapy can be beneficial for pregnant women in some settings.

*Source: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines 2010. MMWR 2010;59 (No. RR-12).*
Procaine Penicillin G is currently unavailable. See recommended options to treat congenital syphilis:

**Congenital Syphilis**

- **Proven or highly probable congenital syphilis**
  
  **Recommended Regimen**
  
  Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days

**Possible Congenital Syphilis**

- **Recommended Regimens**
  
  Aqueous crystalline penicillin G 100,000–150,000 units/kg/day, administered as 50,000 units/kg/dose IV every 12 hours during the first 7 days of life and every 8 hours thereafter for a total of 10 days

  OR

  – Benzathine penicillin G 50,000 units/kg/dose IM in a single dose

https://www.cdc.gov/std/treatment/drugnotices/procaine-peng.htm
Procaine Penicillin G is currently unavailable.

See recommended options to treat neurosyphilis/ocular syphilis:

**Neurosyphilis/Ocular Syphilis**

- Aqueous crystalline penicillin G 18–24 million units per day, administered as 3–4 million units IV every 4 hours or continuous infusion, for 10–14 days

https://www.cdc.gov/std/treatment-drugnotices/procaine-peng.htm
• 2,436 cases of acute hepatitis C were reported to CDC from 41 states.

• The overall incidence rate for 2015 was 0.8 cases per 100,000 population, an increase from 2011–2012.

• Actual acute cases are estimated to be 13.9 times the number of reported cases in any year.

• After adjusting for under-ascertainment and under-reporting, an estimated 33,900 acute hepatitis C cases occurred in 2015 (95% CI=26,800–115,000).
  – (Data for 2015 were unavailable for Alaska, Arizona, Connecticut, the District of Columbia, Hawaii, Iowa, Mississippi, New Hampshire, Rhode Island, and Wyoming.)
Hepatitis C virus infection is the most common bloodborne infection in the United States and South Dakota.

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†Rate: cases per 100,000 population.
MSA: Metropolitan Statistical Area.


Disease fact sheets: [http://doh.sd.gov/diseases/infectious/diseasefacts](http://doh.sd.gov/diseases/infectious/diseasefacts)

South Dakota Department of Health
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Hepatitis C

• Of the more than 3 million people living with Hepatitis C, 3 out of every 4 are “Baby Boomers,” born from 1945-1965.

• Baby boomers are five times more likely to have Hepatitis C than other adults.

http://www.ashasexualhealth.org/stdsstis/statistics/
Testing Recommendations by Risk

- Baby boomer cohort (born between 1945-1965)
  - One-time screening for all members of baby boomer cohort
  - No prior HCV risk attainment recommended

- People who inject drugs
  - Those currently injecting drugs
  - Those who have ever injected drugs, even once

- HIV-positive persons
  - At initial HIV-related medical visit
  - Annually for all HIV-positive MSM

- Children born to HCV-positive mothers
  - After 18 months if using an antibody screening
  - At 1–2 months if using an RNA test, and repeated subsequently to confirm

3. CDC. Hepatitis C FAQ for Health Professionals. http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section1
Initial Testing for Hepatitis C Has Three Parts

- HCV antibody testing
- Qualitative HCV RNA testing
- HCV Genotypic Testing

https://www.hepmag.com/basics/hepatitis-c-basics/hepatitis-c-testing
Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

1. **HCV antibody**
   - Nonreactive: No HCV antibody detected
     - STOP*  
     - Stop testing for HCV infection
   - Reactive: HCV RNA
     - Not Detected: No current HCV infection
       - Additional testing as appropriate†
     - Detected: Current HCV infection
       - Link to care

* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

In a study, approximately 45% of untreated HCV patients were projected to develop cirrhosis by 2030\(^2\). Patients who develop cirrhosis are at greater risk for developing liver cancer and other liver-related complications\(^3\).

---

## Current All-Oral Regimens for HCV Infection

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Component Classes</th>
<th>Approved Genotypes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grazoprevir/elbasvir (Zepatier)</td>
<td>Protease inhibitor + NS5A inhibitor</td>
<td>1, 4</td>
</tr>
<tr>
<td>Ombitasvir/paritaprevir/ritonavir (Technivie)</td>
<td>Protease inhibitor + NS5A inhibitor</td>
<td>4</td>
</tr>
<tr>
<td>Ombitasvir/paritaprevir/ritonavir + dasabuvir (Vikera Pak)</td>
<td>Protease inhibitor + NS5A inhibitor + polymerase inhibitor</td>
<td>1</td>
</tr>
<tr>
<td>Sofosbuvir + daclatasvir (Darvoni, Sovodak)</td>
<td>Nucleotide polymerase inhibitor + NS5A inhibitor</td>
<td>1, 3</td>
</tr>
<tr>
<td>Sofosbuvir/ledipasvir (Harvoni)</td>
<td>Nucleotide polymerase inhibitor + NS5A inhibitor</td>
<td>1, 4, 5, 6</td>
</tr>
<tr>
<td>Simeprevir + sofosbuvir</td>
<td>Nucleotide polymerase inhibitor + protease inhibitor</td>
<td>1</td>
</tr>
<tr>
<td>Sofosbuvir/velpatasvir (Epclusa)</td>
<td>Nucleotide polymerase inhibitor + NS5A inhibitor</td>
<td>1, 2, 3, 4, 5, 6</td>
</tr>
<tr>
<td>Glecasprevir/pibrentasvir (Mavyret)</td>
<td>NS3/4A protease inhibitor + NS5A inhibitor</td>
<td>1, 2, 3, 4, 5, 6</td>
</tr>
<tr>
<td>Sofosbuvir, Velpatasvir, and Voxilaprevir (Vosevi)</td>
<td>Nucleotide analog NS5B polymerase inhibitor/NS5A replication complex inhibitor/NS3/4A protease inhibitor.</td>
<td>1, 2, 3, 4, 5, 6</td>
</tr>
</tbody>
</table>

Slide credit: clinicaloptions.com/ Mavyret & Vosevi package inserts
# Overall Cure Rates Of Commonly Used Treatment Regimens for Hepatitis C

<table>
<thead>
<tr>
<th>Treatment</th>
<th>% Overall Cure</th>
<th>Genotype</th>
<th>Length Of Tx</th>
</tr>
</thead>
<tbody>
<tr>
<td>sofosbuvir/Velpatasvir – (Epclusa)</td>
<td>99%</td>
<td>GT 1-6</td>
<td>12 weeks</td>
</tr>
<tr>
<td>ledipasvir/sofosbuvir – (Harvoni)</td>
<td>99%</td>
<td>GT1,4,5,6</td>
<td>12 weeks</td>
</tr>
<tr>
<td>glecasprevir/pibrentasvir – (Mavyret)</td>
<td>98%</td>
<td>GT1-6</td>
<td>8 weeks</td>
</tr>
<tr>
<td>elbasvir/grazoprevir - (Zepatier)</td>
<td>97%</td>
<td>GT1</td>
<td>12 weeks</td>
</tr>
<tr>
<td>sofobuvir, vlepatasvir and voxilaprevir (Vosevi)#</td>
<td>96-97%</td>
<td>GT 1-6</td>
<td>12 weeks</td>
</tr>
<tr>
<td>paritaprevir/r/ombitasvir + dasabuvir + ribavirin – (Viekira Pak)**</td>
<td>90%</td>
<td>GT1</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

# - for patients with GT1 who have been previously treated with the DAA drug sofosbuvir or other drugs for HCV that inhibit NS5A
** - includes compensated cirrhosis. Limitations of use include decompensated liver disease.

Recommended regimens for HIV/HCV-coinfected individuals.

HIV/HCV-coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications (see Initial Treatment of HCV Infection and Retreatment of Persons in Whom Prior Therapy Has Failed sections).

Rating: Class I, Level B
HIV: 2016 United States

• There were an estimated 38,500 new HIV infections in 2015.
• Pre-exposure prophylaxis, or PrEP, involves taking a daily medication to prevent HIV infection in people who are HIV-negative.
  – When taken consistently, PrEP has shown to reduce HIV infection risk by up to 92%.

Rates of HIV Diagnoses Among Adults and Adolescents in the US by State, 2016

# South Dakota Infectious Disease Summary 2018

<table>
<thead>
<tr>
<th>Disease/Agent</th>
<th>Cases YTD</th>
<th>Rate</th>
<th>5-Year Median YTD</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter</td>
<td>33</td>
<td>3.8</td>
<td>15</td>
<td>+120%</td>
</tr>
<tr>
<td>Carbapenem-resistant Enterobacteriaceae</td>
<td>6</td>
<td>0.7‡</td>
<td>4</td>
<td>+50%</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>695</td>
<td>80.3</td>
<td>727</td>
<td>-4%</td>
</tr>
<tr>
<td>Cryptosporidiosis</td>
<td>14</td>
<td></td>
<td></td>
<td>-50%</td>
</tr>
<tr>
<td>E. coli, shiga toxin-producing</td>
<td>4</td>
<td></td>
<td></td>
<td>200%</td>
</tr>
<tr>
<td>Giardiasis</td>
<td>14</td>
<td></td>
<td></td>
<td>-50%</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>163</td>
<td></td>
<td></td>
<td>+38%</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>--</td>
<td></td>
<td></td>
<td>--</td>
</tr>
<tr>
<td>Hepatitis B, chronic</td>
<td>11</td>
<td></td>
<td></td>
<td>-73%</td>
</tr>
<tr>
<td>Hepatitis C, acute and chronic</td>
<td>86</td>
<td>9.7</td>
<td>86</td>
<td>-2%</td>
</tr>
<tr>
<td>HIV, including Stage III (AIDS)</td>
<td>3</td>
<td>0.3‡</td>
<td>5</td>
<td>-40%</td>
</tr>
<tr>
<td>Legionellosis</td>
<td>1</td>
<td>0.1‡</td>
<td>0</td>
<td>NA</td>
</tr>
<tr>
<td>MRSA, invasive</td>
<td>28</td>
<td>3.2</td>
<td>20</td>
<td>+40%</td>
</tr>
<tr>
<td>Pertussis</td>
<td>7</td>
<td>0.8‡</td>
<td>6</td>
<td>+17%</td>
</tr>
<tr>
<td>Pneumococcal disease, invasive</td>
<td>22</td>
<td>2.5</td>
<td>19</td>
<td>16%</td>
</tr>
<tr>
<td>Rabies, animal</td>
<td>2</td>
<td></td>
<td>2</td>
<td>0%</td>
</tr>
</tbody>
</table>

**YTD**: Year-to-Date  
**Rate**: Cases per 100,000 population  
**5-Year Median**: 2013–2017  
‡ Unstable rate based on <20 observations

2017 Total Cases of HIV/AIDS in South Dakota
South Dakota Residents Infected by HIV, by Gender

1985 - 2017
HIV Co-infection with Chlamydia, Gonorrhea, Hepatitis C, Syphilis and TB by Sex and Age, 2013-2017

<table>
<thead>
<tr>
<th>Co-Infection</th>
<th>Total</th>
<th>Sex</th>
<th>13-24 Years</th>
<th>25-44 Years</th>
<th>45-65 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlamydia</td>
<td>43</td>
<td>13</td>
<td>30</td>
<td>11</td>
<td>28</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>29</td>
<td>4</td>
<td>25</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>27</td>
<td>8</td>
<td>19</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Syphilis</td>
<td>45</td>
<td>1</td>
<td>44</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>TB</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>147</td>
<td>27</td>
<td>120</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Many people have HIV for years before they know it.

In 2015, nearly 40,000 people in the US received an HIV diagnosis.

1 in 2 had been living with HIV 3 years or more.

1 in 4 had been living with HIV 7 years or more.

1 in 5 already had the most advanced stage of HIV (AIDS).

Many people at high risk* for HIV aren’t getting tested every year.

*People at high risk for HIV include: 1) sexually active gay and bisexual men, 2) people who inject drugs, and 3) heterosexuals who have sex with someone who is at risk for or has HIV.
South Dakota Late Testers

Persons who are diagnosed with AIDS within 12 months of their initial HIV diagnosis are known as “late testers”

2010 thru 2015: 32% of all cases were “late testers”.

USPSTF Recommends an “A” grade for Routine HIV Screening: April 2013

- The USPSTF statement recommends clinicians screen for HIV in all adolescents and adults aged 15-65 years.
- It also recommends...
  - Repeat HIV screenings for those who are at increased risk for HIV infection, including men who have sex with men and people who inject drugs.
  - Younger adolescents and older adults who are at increased risk for HIV infection should also be screened.

- These updated USPSTF recommendations align with CDC’s 2006 guidelines which state that HIV testing should be a routine part of medical care for all American adults and adolescents.

http://www.cdc.gov/hiv/dhap/ehap/fyi/050113.html
HIV Testing: Current Algorithm

To “close the window”, current testing algorithm:

- Sensitive HIV-1/2 Immunoassay (4th Generation)
  - HIV-1/2 Ab Differentiation assay
    - (+) Patient is infected
    - (-) Check HIV RNA

**Advantages:**
- RNA testing identifies patients with acute HIV
  - Averted missed diagnoses in 8 – 32% of HIV patients
- All antibody-positive specimens tested for HIV-2
  - Same day turnaround

4th gen. immunoassay: HIV-1/HIV-2 antibodies and p24 antigen

Branson B, Stekler J. JID. 2012; MMWR June 21, 2013
Laboratory Testing for the Diagnosis of HIV Infection, Updated CDC Recommendations, June 27, 2014.
Caveat emptor!

- Although current algorithm more likely to detect HIV during routine screening, if acute HIV suspected, check immunoassay (IA) and HIV RNA

- If IA negative and HIV RNA low (<10,000), repeat RNA testing to rule out false positive result.

- If very recent exposure (<10-15 d), repeat testing 1-2 wks later, particularly if symptoms develop
Point-of-Contact (Rapid) 4th Generation HIV Testing

**Alere Determine HIV-1/2 Ag/Ab Combo**

- 4th generation for fingerstick or venous whole blood, serum or plasma
- Can be used to detect acute (early) HIV infection before antibody detection
- Distinguish between the detection of p24 antigen and HIV antibodies
- Results in about 20 minutes

STIs Lead to Increased Susceptibility for HIV Acquisition

- STIs that cause ulcers or inflammation greatly increase the efficiency of HIV transmission by increasing both the infectiousness of, and the susceptibility to HIV infection.

**MSM With an STI Diagnosis in New York City**

(New York City HIV/AIDS and STD Surveillance Registries, 2000-2010\(^2\) or New York City Public STD Clinics\(^3\))

- 1 in 20 HIV positive within 1 year of a syphilis diagnosis\(^2\)
- 1 in 15 HIV positive within 1 year of a rectal gonorrhea diagnosis\(^3\)

**Adolescents With an STI Diagnosis in Philadelphia**

(Philadelphia High School STD Screening Program, 2003-2010\(^4\))

- 2x HIV risk for adolescents who had an STI reported
- 3x HIV risk for female adolescents who had multiple gonococcal infections\(^a\)
- 5x HIV risk for female adolescents who had 3 or more chlamydia episodes\(^a\)

---

\(a\). Compared with those with none.

Self Perception of HIV Risk Is Low in At-Risk Populations

Persons undergoing HIV rapid testing in Philadelphia surveyed between May 2012 and December 2014 (N=5606; >90% African American)

**SELF Perception Of Risk**

<table>
<thead>
<tr>
<th>Gender</th>
<th>SELF</th>
<th>Tester's Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>57%</td>
<td>72%</td>
</tr>
<tr>
<td>Female</td>
<td>8%</td>
<td>60%</td>
</tr>
</tbody>
</table>

A large proportion of patients at moderate or high risk for HIV infection, especially women, do not perceive themselves to be at high risk.

Appearances May Be Deceiving When It Comes to Seniors With STIs

Nearly 75% Of those aged 57-64 and 26% Of those aged 75-85 Are sexually active.
Sexual activity continues into older age: be prepared to screen and treat

Key results

- 40% of women aged 65-74 years report that they are sexually active.
- <20% of women aged 75-85 years report that they are sexually active.
- Decline in sexual activity may result from physical problems and lack of available partners.
- Menopause symptoms can cause vaginal dryness and painful intercourse but can be treated with lubricants and hormonal therapy.
- Older women are at risk for HIV and sexually transmitted infections (STIs) and need counseling for screening and prevention.
- Medical conditions in the patient or partner may affect sexuality through fears of hurting a partner during sexual activity, physical barriers, and side effects of medications.
- Providers should acknowledge the importance of sexuality and openly discuss these issues with patients.


JAGS 2018. Women’s Sexual Health and Aging. Lisa Granville, MD, and Janet Pregler, MD
Sexual activity continues into older age: be prepared to screen and treat

**Takeaway**

- Sexual health in older women is rarely studied or addressed by physicians.

**Why this matters**

- Sexual history is infrequently addressed in older women, despite treatable challenges.
- Physicians lack training in caring for this aspect of older women.

We offer HIV testing to all patients.

If we fail to ask, ask us.
“Antiretroviral therapy (ART) is recommended for all HIV-infected individuals. . . . Individualizing treatment with involvement of the patient in decision making is the cornerstone of any treatment plan.”
### Changing Criteria for Antiretroviral Therapy Initiation in DHHS Guidelines

<table>
<thead>
<tr>
<th><strong>CD4+ Count, cells/mm³</strong></th>
<th><strong>1998</strong></th>
<th><strong>2001</strong></th>
<th><strong>2006</strong></th>
<th><strong>2008</strong></th>
<th><strong>2009</strong></th>
<th><strong>2012</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 500</td>
<td>Offer if VL &gt; 20K</td>
<td>Offer if VL &gt; 20K</td>
<td>Consider if VL ≥ 100K</td>
<td>Consider in certain groups*</td>
<td>Consider†</td>
<td>Treat</td>
</tr>
<tr>
<td>350-500</td>
<td>Offer if VL &gt; 20K</td>
<td>Consider if VL &gt; 55K</td>
<td>Consider if VL ≥ 100K</td>
<td>Consider in certain groups*</td>
<td>Treat</td>
<td>Treat</td>
</tr>
<tr>
<td>200-350</td>
<td>Offer if VL &gt; 20K</td>
<td>Offer, but controversy exists</td>
<td>Offer after discussion with patient</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
</tr>
<tr>
<td>&lt; 200 or symptomatic</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
<td>Treat</td>
</tr>
</tbody>
</table>

*Pregnant women, patients with HIV-associated nephropathy, and patients with HBV that requires treatment.
†50% of panel members recommended starting antiretroviral therapy; 50% of members viewed treatment as optional.
### Cancer Events With Immediate vs Deferred ART

<table>
<thead>
<tr>
<th>Cancer Event, n</th>
<th>Immediate ART (n = 2326)</th>
<th>Deferred ART (n = 2359)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>14</td>
<td>39</td>
</tr>
<tr>
<td>Kaposi’s sarcoma</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Lymphoma, NHL + HL</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Anal cancer</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Cervical or testis cancer</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>


**Time to Cancer Event**

Rate/100 PY: immediate, 0.20; deferred, 0.56 (HR: 0.36; 95% CI: 0.19-0.66; P = .001)


Slide credit: clinicaloptions.com
What to Use
HIV Replication Cycle and Sites of Drug Activity

1. Attachment
2. Uncoating
3. Reverse Transcription
4. Integration
5. Transcription
6. Translation
7. Assembly and Release

- **Attachment Inhibitors**
- **Entry Inhibitors**
- **Reverse Transcriptase**
- **Integrase**
- **Protease**
- **Integrase Inhibitors**
- **NRTIs**
- **NNRTIs**
- **Protease Inhibitors**
- **New HIV particles**
- **Capsid proteins and viral RNA**
- **HIV Virions**
- **CD4 Receptor**
- **CCR5 or CXCR4 co-receptor**
- **HIV Virions**
- **Viral RNA**
- **Unintegrated double stranded Viral DNA**
- **Integrated viral DNA**
- **Viral mRNA**
- **gag-pol polyprotein**
- **Nucleus**
- **Cellular DNA**
- **NRTIs**
- **NNRTIs**

<table>
<thead>
<tr>
<th>Year</th>
<th>Drug</th>
<th>Date</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1987:</td>
<td>zidovudine (Retrovir)</td>
<td>8/11/11</td>
<td>rilpivirine/ tenofovir/ emtricitabine (Complera)</td>
</tr>
<tr>
<td>1991:</td>
<td>didanosine (Videx)</td>
<td>7/16/12</td>
<td>emtricitabine/tenofovir</td>
</tr>
<tr>
<td>1992:</td>
<td>zalcitabine (Hivid)</td>
<td>8/28/12</td>
<td>emtricitabine/ tenofovir/ elvitegravir/ cobicistat. (Stribild)</td>
</tr>
<tr>
<td>1994:</td>
<td>stavudine (Zerit)</td>
<td>8/12/13</td>
<td>dolutegravir (Tivicay)</td>
</tr>
<tr>
<td>1995:</td>
<td>lamivudine (Epivir)</td>
<td>8/30/14</td>
<td>abacavir/dolutegravir/lamivudine (Triumeq)</td>
</tr>
<tr>
<td>1996:</td>
<td>saquinavir (Invirase)</td>
<td>1/29/15</td>
<td>atazanavir 300 mg and cobicistat /150 mg</td>
</tr>
<tr>
<td>1997:</td>
<td>ritonavir (Norvir)</td>
<td>11/5/15</td>
<td>elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide. (Genvoya)</td>
</tr>
<tr>
<td>1998:</td>
<td>indinavir (Crixivan)</td>
<td>3/1/16</td>
<td>rilpivirine+emtricitabine+tenofovir alafenamide (Odefsey)</td>
</tr>
<tr>
<td>1999:</td>
<td>nevirapine (Viramune)</td>
<td>4/6/16</td>
<td>emtircitabine+tenofovir alafenamide</td>
</tr>
<tr>
<td>1999:</td>
<td>efavirenz (Sustiva)</td>
<td>11/21/2017</td>
<td>dolutegravir sodium / rilpivirine hydrochloride (Juluca)</td>
</tr>
<tr>
<td>1999:</td>
<td>amprenavir (Agenerase)</td>
<td>2/7/2018</td>
<td>bictegravir 50 mg /emtricitabine 200 mg/tenofovir alafenamide 25 mg (Biktarvy)</td>
</tr>
<tr>
<td>2000:</td>
<td>lopinavir/ritonavir (Kaletra)</td>
<td>3/6/2018</td>
<td>Trogarzo (ibalizumab-uiyk) IV 2,000mg/800mg</td>
</tr>
<tr>
<td>2003:</td>
<td>enfuvirtide (Fuzeon)</td>
<td>7/17/2018</td>
<td>Symtuza (darunavir 800 mg/cobicistat 150 mg/ emtricitabine 200 mg/ tenofovir alafenamide 10 mg)</td>
</tr>
<tr>
<td>2007:</td>
<td>tipranavir (Aptivus)</td>
<td>5/20/11</td>
<td></td>
</tr>
</tbody>
</table>
Treatment Is Effective, Safe, Simple, and Tolerable

Once-daily, single-tablet regimens

• EFV/TDF/FTC (Atripla®)[a]
• RPV/TDF/FTC (Complera®)[b]
• RPV/TAF/FTC (Odefsey®)[c]
• EVG/Cobi/TDF/FTC (Stribild®)[d]
• EVG/Cobi/TAF/FTC (Genvoya®)[e]
• DTG/ABC/3TC (Triumeq®)[f]
• DTG/RPV (Juluca®)[g]
• BIC/TAF/FTC (Biktarvy®)[h]

a. Atripla PI; b. Complera PI; c. Odefsy PI; d. Stribild PI; e. Genvoya PI; f. Triumeq PI, g. Juluca PI, h. Biktarvy PI.
Increase Awareness of Effective Biomedical Interventions to Help Prevent HIV\textsuperscript{1-6}

### Prevent HIV Acquisition

<table>
<thead>
<tr>
<th><strong>PrEP\textsuperscript{1}</strong></th>
<th><strong>PEP\textsuperscript{2}</strong></th>
<th><strong>TasP\textsuperscript{3}</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Pre-Exposure Prophylaxis)</td>
<td>(Post-Exposure Prophylaxis)</td>
<td>(Treatment as Prevention)</td>
</tr>
<tr>
<td>PRIOR TO EXPOSURE</td>
<td>Time of EXPOSURE</td>
<td>AFTER INFECTION</td>
</tr>
</tbody>
</table>

- **PrEP\textsuperscript{1}** (Pre-Exposure Prophylaxis): Use of daily ARV medications in combination with safer sex practices to help reduce the risk of HIV infection in HIV-negative individuals at high risk for acquiring HIV-1.

- **PEP\textsuperscript{2}** (Post-Exposure Prophylaxis): Use of ARV medications after an uninfected person has come into contact with bodily fluids that represent a substantial HIV risk.

- **TasP\textsuperscript{3}** (Treatment as Prevention): Use of ART by an HIV-positive individual in order to suppress viral load in bodily fluids, thereby reducing the chances that HIV will be transmitted to an HIV-negative partner.

---

FTC/TDF (TRUVADA) FOR PrEP INDICATION

- FTC/TDF is indicated in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV-1 in adults at high risk
- This indication is based on clinical trials in MSM at high risk for HIV-1 infection and in heterosexual serodiscordant couples

emtricitabine (FTC) 200 mg
tenofovir disoproxil fumarate (TDF) 300 mg

Pill image is for illustration only.
TRUVADA FOR PrEP: USPHS/CDC GUIDELINES FOR ASSESSING RISK OF HIV-1 ACQUISITION

The risk categories listed in the USPHS/CDC guidelines include:

**MSM:**
- HIV-positive sexual partner
- Recent bacterial STI
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work

**Heterosexual Men and Women:**
- HIV-positive sexual partner
- Recent bacterial STI
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work in high-prevalence area or network

CONTRAINDICATIONS, DOSAGE AND ADMINISTRATION, AND HBV TESTING

Contraindications:

● Do not use TRUVADA for PrEP in individuals with unknown or positive HIV-1 status

Dosage and Administration:

● TRUVADA for PrEP in HIV-1 uninfected adults: one tablet once daily with or without food

HBV Testing

● It is recommended that all individuals be tested for the presence of chronic HBV before initiating TRUVADA
PCPs often prescribe PrEP before ordering HIV testing

Only 77% of patients were tested for HIV and 81% were tested for STIs before initiating PrEP

Components of a Comprehensive STI/HIV Prevention Approach for All Patients

- **Initiate a Sexual History Discussion**:  
  - Take a sexual history during a patient's initial visit, at routine preventive exams, and at the first signs of STIs  
  - Allows for the identification of individuals at risk for STIs, including HIV

- **Regular STI and HIV Testing**:  
  - It is recommended that individuals at risk get tested for STIs every 3 to 6 months, depending on their risk factors
  - Test for chlamydia and gonorrhea at least annually for sexually active MSM at sites of contact (urethra, pharynx, rectum) regardless of condom use

- **Sex and Prevention Education**:  
  - Educate patients with up-to-date information about STIs, HIV, and safer-sex practice options  
  - Discuss the appropriate use of condoms with every sexually active individual

How many Sex partners Have you had?

Maybe 5 or 6? I don’t really remember

Yes, that wasn’t my best week

Hmmm… Not that many!