

Resurgence of STIs: Who, What, Why, and What Public Health & Clinical Medicine Can Do Together

Katherine Hsu, MD, MPH, FAAP*

Medical Director, Div. of STD Prev., Mass. Dept. of Pub. Health

Associate Professor of Pediatrics, Boston Univ. Med. Ctr.

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Disclosures

- In the past 12 months, Dr. Hsu has had the following significant financial interests or other relationships with manufacturer(s) of product(s) or provider(s) of service(s) that will be discussed in this presentation:
 - None
- This presentation will include discussion of pharmaceuticals or devices that have not been approved by the FDA
 - “Off-label” use of extra-genital (rectal and pharyngeal) nucleic acid amplification tests (NAATs) for gonorrhea and chlamydia

Goals

- Distinguish relevant updates to STI epidemiology, management, and prevention
 - Identify highest risk individuals in need of STI screening
 - Utilize correct screening and prevention strategies
 - Describe reasoning behind need for speed and accuracy in treating STIs
- Highlight areas of 2015 CDC STD Treatment Guidelines that should be read carefully for detailed recommendations
- Provide new clinical resources (smartphone applications, STD Clinical Consultation Network) to access expert guidance on STD management at the point of care

4. STIs HAVE REACHED NEW HIGHS

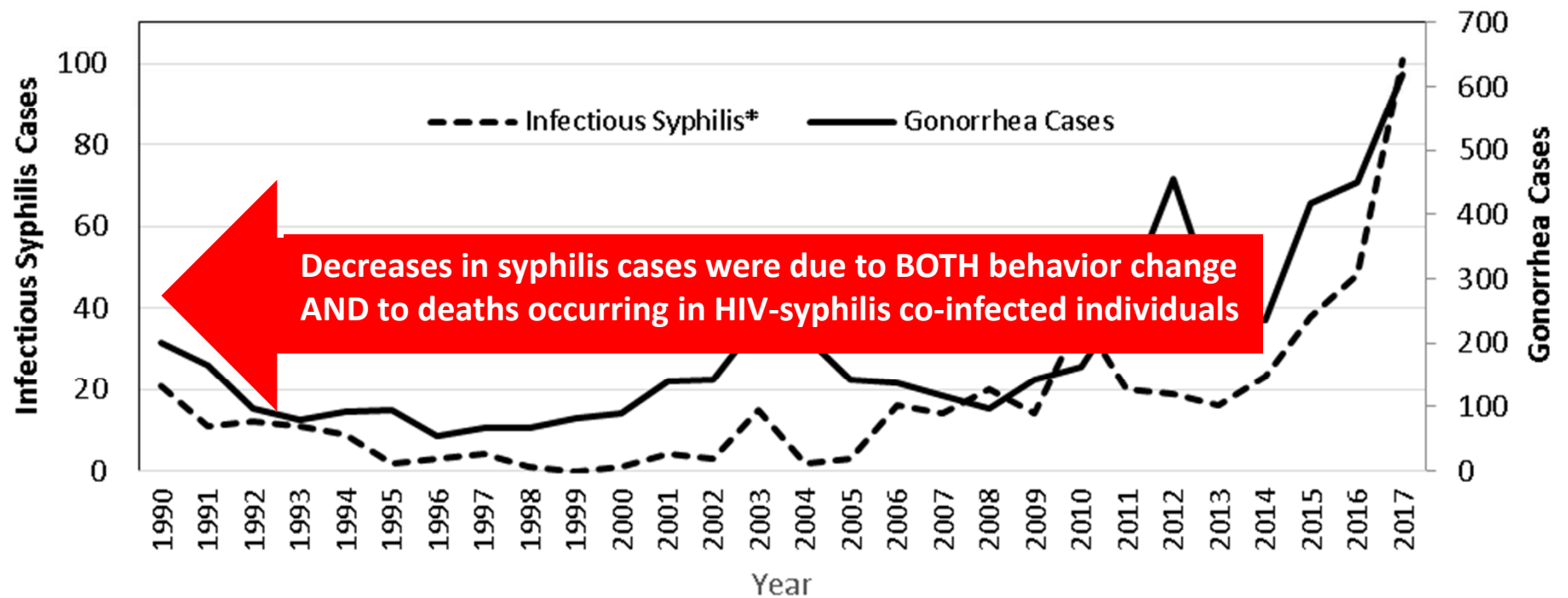


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Syphilis and Gonorrhea Over Time (ME)

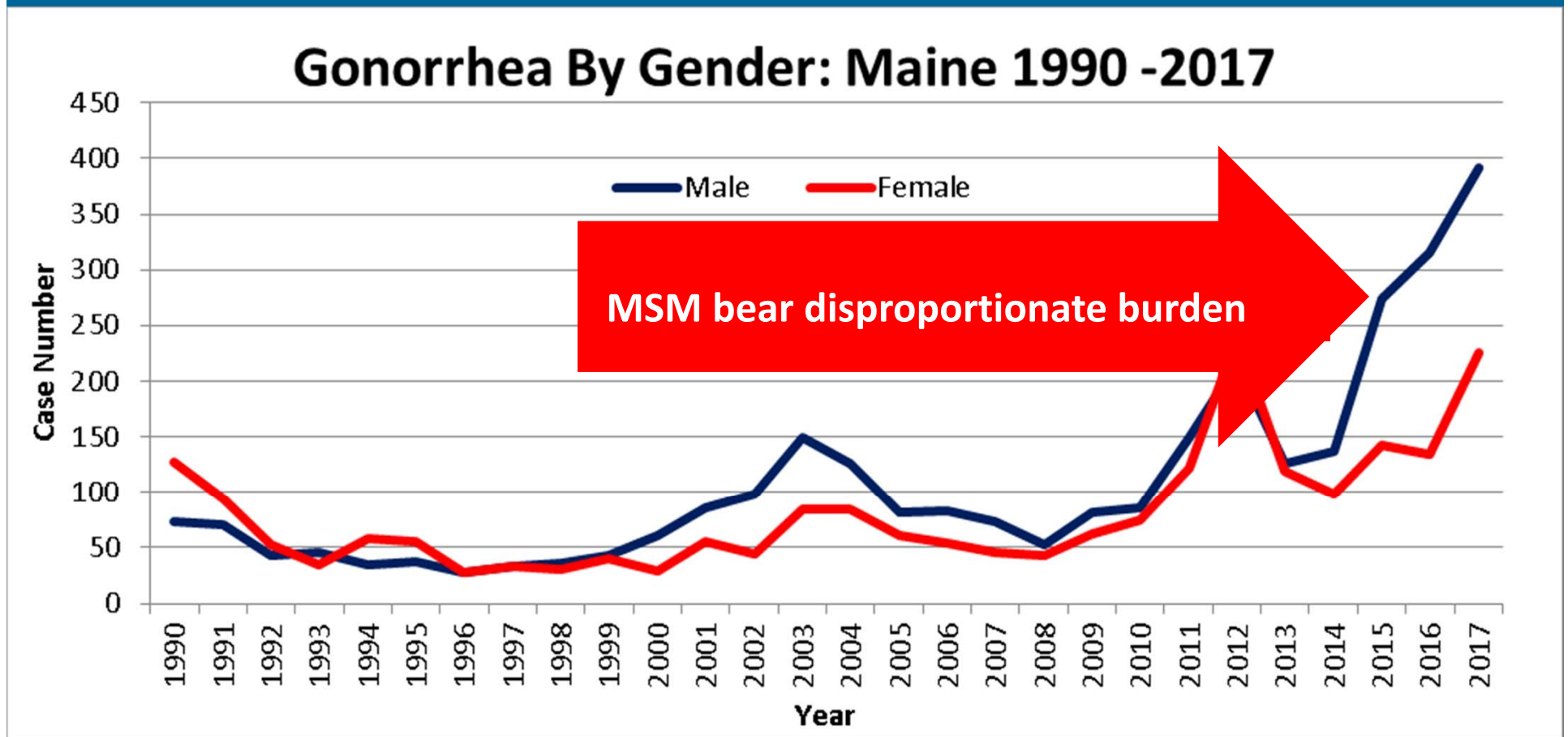
Infectious Syphilis and Gonorrhea Cases
Maine 1990-2017



*Infectious syphilis is defined as primary, secondary and early latent stages of syphilis within one year of infection.

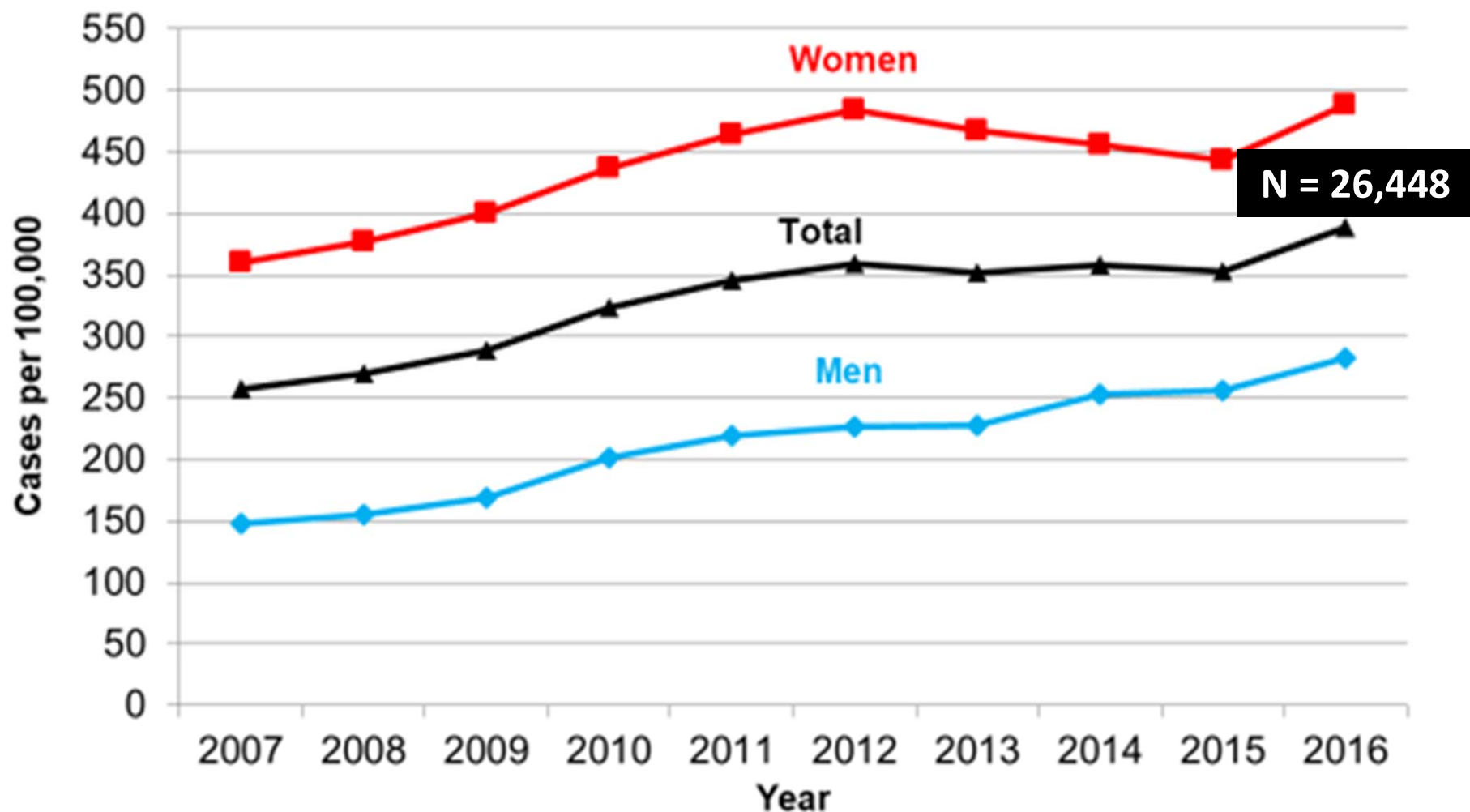
Data Source: CDC. Sexually Transmitted Disease Surveillance 2017. Atlanta: U.S. Department of Health and Human Services; 2018.

Gonorrhea Trends by Gender Identity (ME)



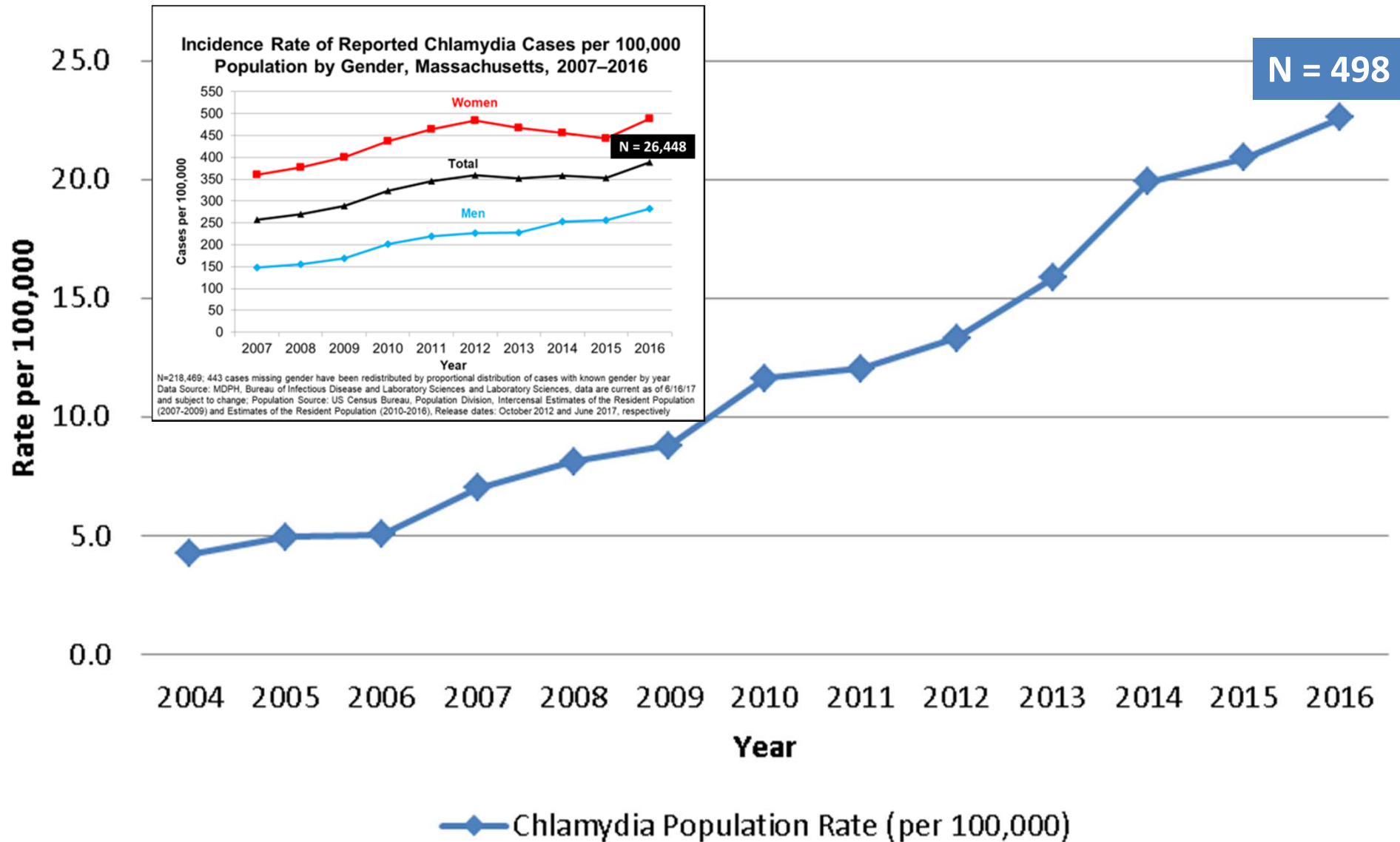
Data Source: CDC. Sexually Transmitted Disease Surveillance 2017. Atlanta: U.S. Department of Health and Human Services; 2018.

Incidence Rate of Reported Chlamydia Cases per 100,000 Population by Gender, Massachusetts, 2007–2016



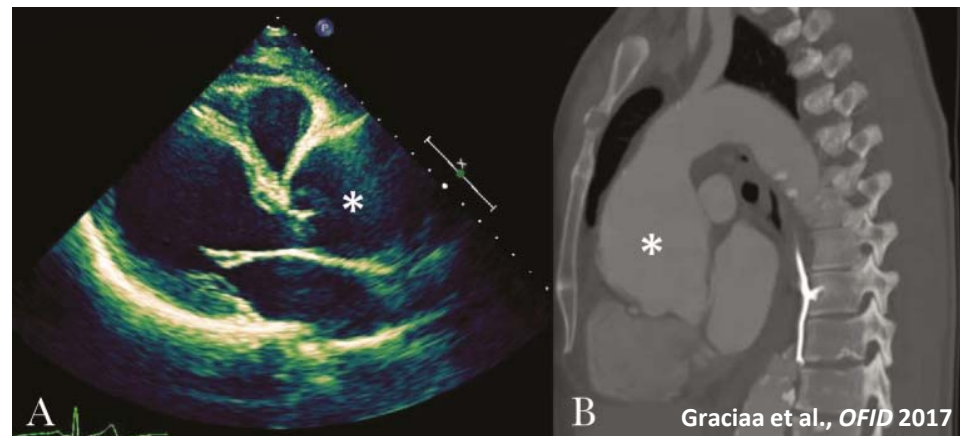
N=218,469; 443 cases missing gender have been redistributed by proportional distribution of cases with known gender by year
Data Source: MDPH, Bureau of Infectious Disease and Laboratory Sciences and Laboratory Sciences, data are current as of 6/16/17 and subject to change; Population Source: US Census Bureau, Population Division, Intercensal Estimates of the Resident Population (2007-2009) and Estimates of the Resident Population (2010-2016), Release dates: October 2012 and June 2017, respectively

Chlamydia Incidence Rate per 100,000 Among Individuals 50 and older, Massachusetts, 2004 - 2016



Data Source: MDPH Bureau of Infectious Disease, data as of 6/30/2017

STI COMPLICATIONS ARE THEREFORE MORE COMMON



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Epi Take Home Points

- **STI rates are at record highs**
 - Reflective of national and regional trends
 - Male signal dominating reporting trends for syphilis and gonorrhea
 - Increases not limited to those ≤ 25 years of age
 - We are seeing more STI complications

- **Are these increases reflective of increased**
 - Screening
 - Reporting
 - True increases in underlying incidence in specific sexual networks
 - All of the above?

3. FOCUS SCREENING ON HIGH-RISK POPULATIONS FOR HIGHEST YIELD



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Population-level Control of STIs

Basic Reproductive Rate

$$R_0 = T \cdot C \cdot D$$

Transmissibility

No. of Sexual Contacts

Duration of infectiousness

Screening decreases D
(duration) of carriage
and therefore transmission

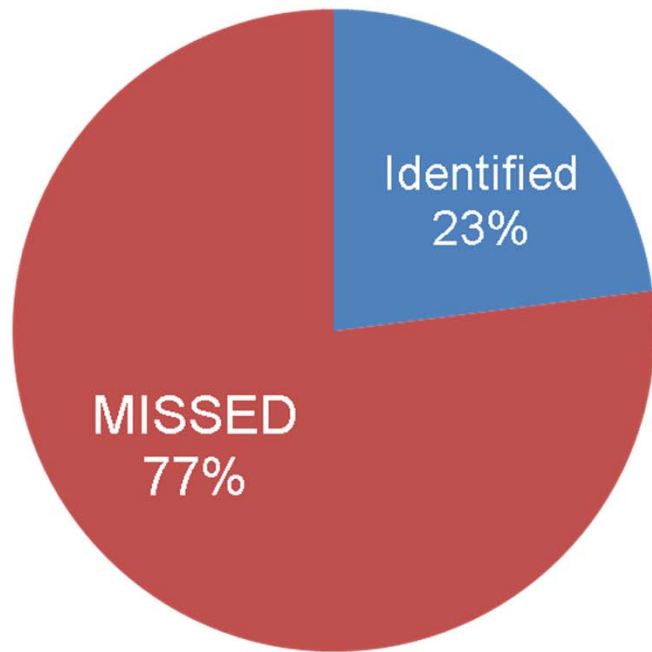
3A. MSM STI SCREENING IS IMPORTANT FOR MAINTAINING MALE SEXUAL HEALTH



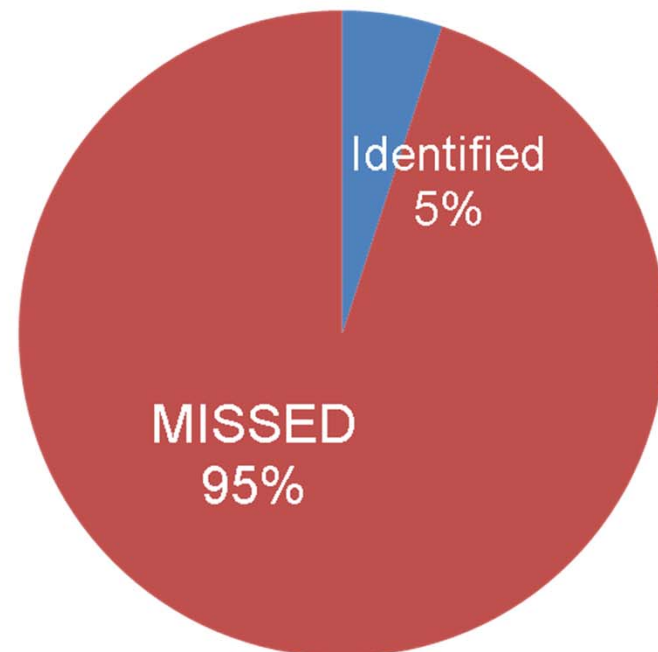
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Proportion of CT and GC infections **MISSED** among 3398 asymptomatic MSM if screening only urine/urethral sites, San Francisco, 2008-2009



Chlamydia



Gonorrhea

The q3mth “Triple Dip” for at-risk MSM



← HIV/Syphilis/
HepC* Serologies

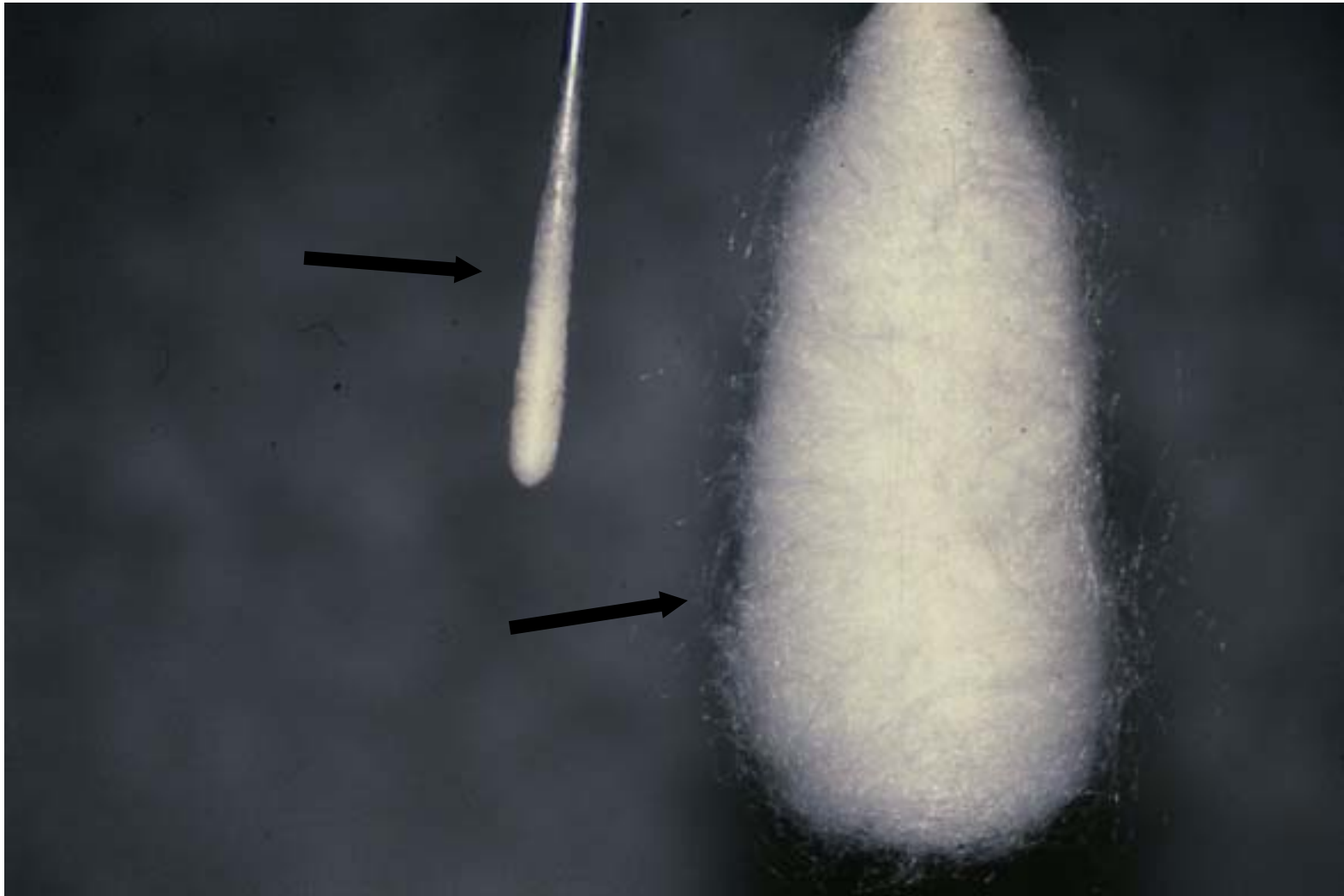
← Pharyngeal GC NAAT**

← Urine GC/CT NAAT

← Rectal GC/CT NAAT**

*In HIV-coinfected individuals, screen hep C at least annually

**Off-label use - not FDA-approved for testing at extragenital sites, but many reference labs have validated the assay for use



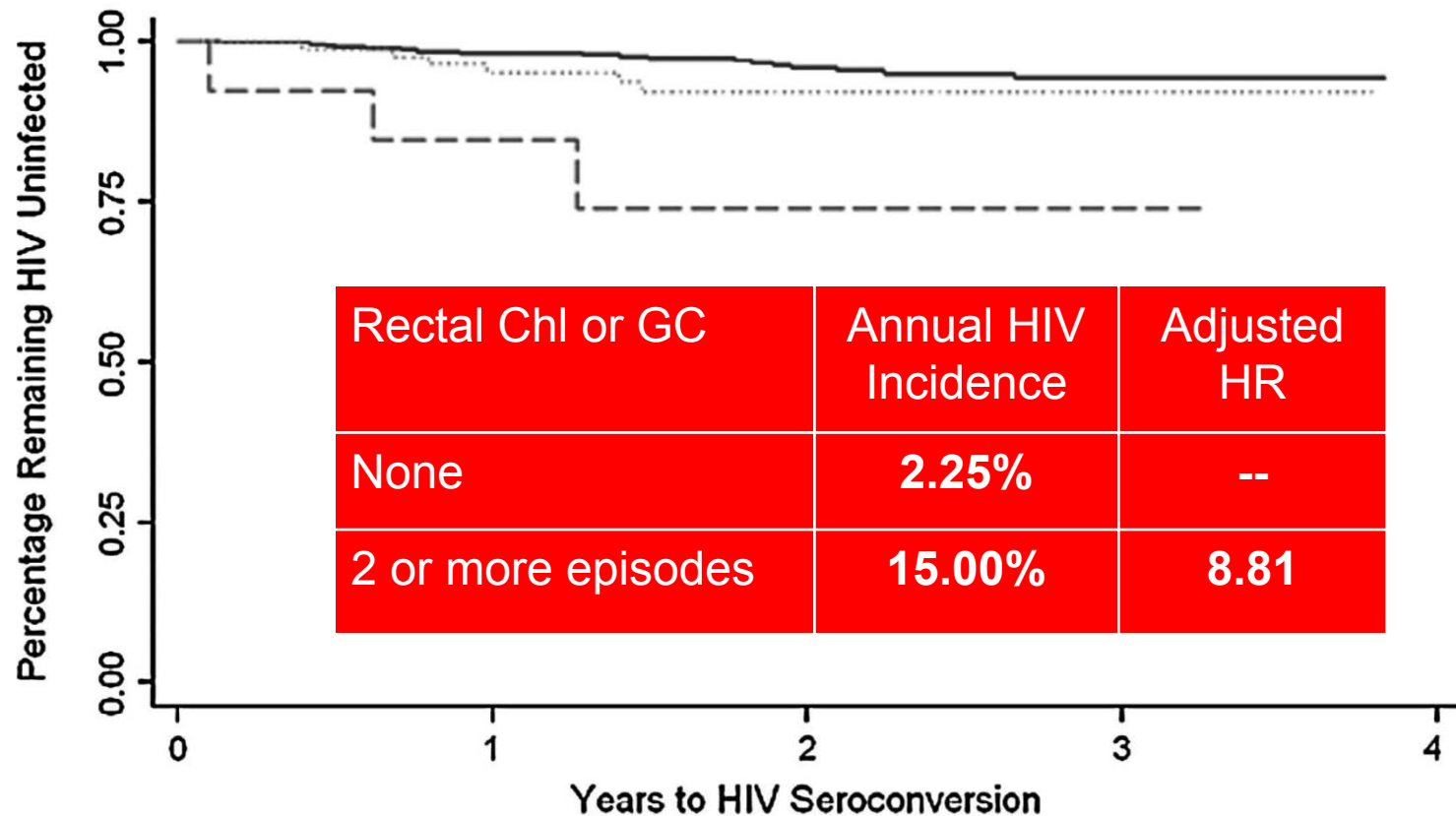
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MSM in SF City Clinic Diagnosed with Rectal Chlamydia or Gonorrhea 2003-05

HIV Seroconversion by Number of Prior Rectal Infections



— No Prior Rectal Infections One Prior Rectal Infection
 - - - Two Prior Rectal Infections



Consider HIV PrEP



National Network of
STD Clinical Prevention
Training Centers

*Tenofovir/emtricitabine now licensed for
HIV PrEP in adolescents weighing ≥ 35 kg

HIV Treatment as Prevention

Antiretroviral treatment should be offered to all HIV-infected persons not only to provide benefit to individual health but also to reduce transmission to sex partners.

HIV pre-exposure prophylaxis should be available to HIV-negative men and women who are sexually active or injecting illicit drugs who are at substantial risk of HIV infection.

NEW REFERENCE: CDC, USPHS. Preexposure prophylaxis for the prevention of HIV infection in the U.S. – 2017 Update.

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>



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Prescribing PrEP: CDC Guidance for MSM, Heterosexual Couples, IDUs

<u>Component</u>	<u>Recommendation</u>
Risk assessment	<ul style="list-style-type: none">▪ PrEP indicated for those at high HIV risk▪ FDA-approved for adults and adolescents weighing ≥ 35kg
Eligibility	<ul style="list-style-type: none">▪ HIV negative, adequate renal function
Dosing	<ul style="list-style-type: none">▪ 1 tenofovir/emtricitabine tablet, once daily
Follow-up	<ul style="list-style-type: none">▪ Testing for HIV/STI every 3 mos, even if asymptomatic▪ Counseling on risk reduction and testing creatinine at 3 mos and then annually
Discontinuation	<ul style="list-style-type: none">▪ PrEP not meant for lifelong administration but rather for periods of highest risk

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

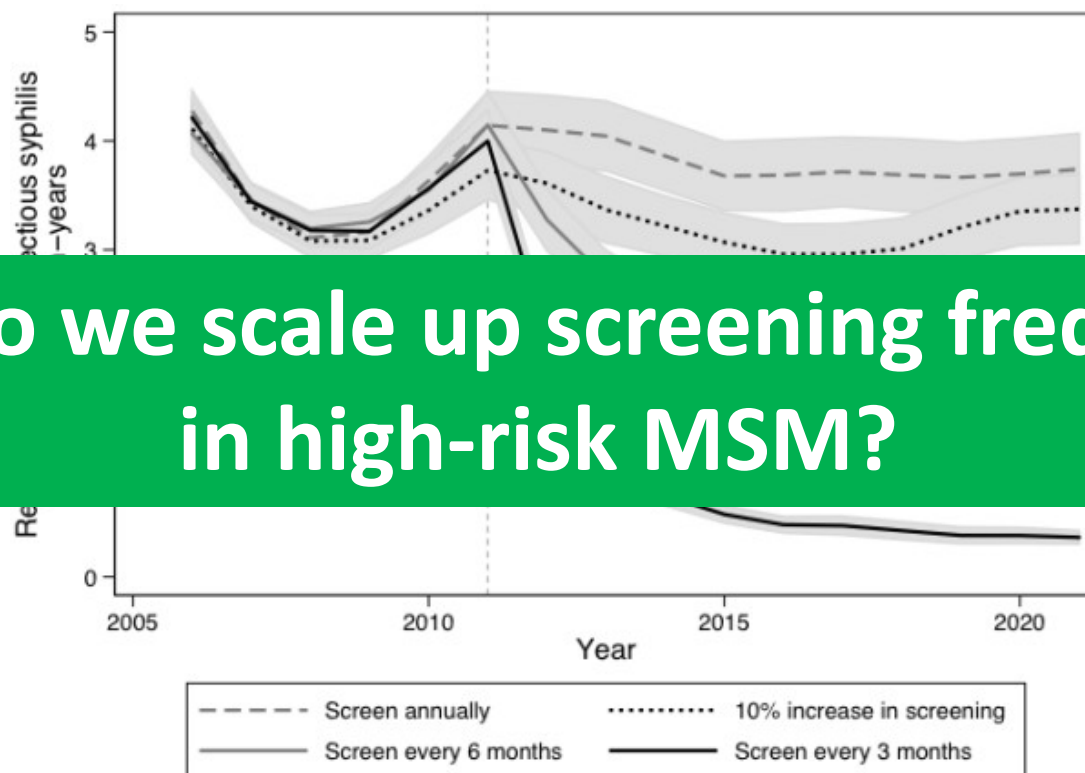


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Screen more or screen more often?

- Agent-based model of syphilis transmission representing 2,000 high-risk MSM from Toronto, Canada data



How do we scale up screening frequency in high-risk MSM?

Figure 2. Model-projected annual rates of reported infectious syphilis. Results are based on 1000 realizations of each intervention scenario and are presented as mean values with corresponding 95% uncertainty bounds. Prior to 2011, all scenarios included annual screening only, with the specified interventions implemented at the start of 2011 (indicated by a dashed line).

Evolution of Syphilis Test



Traditional syphilis tests - Manual

- Nontreponemal
- Treponemal



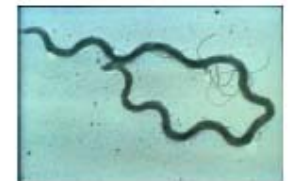
Automated Test platforms

- Treponemal



Rapid syphilis test

- Nontreponemal
- Treponemal



... but concerns about sensitivity & specificity abound

Fakile Y, STD Prevention Conference, 2016

<https://cdc.confex.com/cdc/std2016/webprogram/Paper38173.html>

Self-collected STI Testing



- Acceptable to many patient populations
- FDA-approved for certain GC/CT/trich NAAT testing platforms and sample types
- Equivalent or greater sensitivity than clinician-collected samples
- Improved uptake of STI screening

Gaydos. *Sex Trans Dis*, 2018



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Dean St Express Clinic, Soho, London



- Walk-ins
 - Treatment for positive gonorrhoea and chlamydia tests
 - If you've had sex with a person who tells you they had gonorrhoea or chlamydia
 - HIV PrEP three monthly monitoring
 - Follow up for people who started emergency HIV PEP at 56 Dean Street
 - Vaccines
- Appointments
 - Sexual health screening for people without symptoms (STI/STD and HIV tests) with results in 6 hours



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3B. RE-SCREENING FOR STIs IN THOSE PREVIOUSLY INFECTED, REACHES THOSE AT HIGHEST STI RISK



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Characteristics of Cases With Repeated Sexually Transmitted Infections, Massachusetts, 2014–2016

Katherine K. Hsu,^{1,2} Lauren E. Molotnikov,¹ Kathleen A. Roosevelt,¹ Heather R. Elder,¹ R. Monina Klevens,³ Alfred DeMaria, Jr.,⁴ and Sevgi O. Aral⁵

¹Division of STD Prevention and HIV/AIDS Surveillance, Massachusetts Department of Public Health, Jamaica Plain, ²Section of Pediatric Infectious Diseases, Boston University Medical Center, Massachusetts, and ³Office of Research and Evaluation and ⁴Bureau of Infectious Disease and Laboratory Sciences, Massachusetts Department of Public Health, Jamaica Plain; and ⁵Division of STD Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

Background. Persons with prior sexually transmitted infections (STIs) are at high risk for reinfection. No recent studies have examined frequency with which persons are diagnosed and reported with multiple bacterial STIs over time.

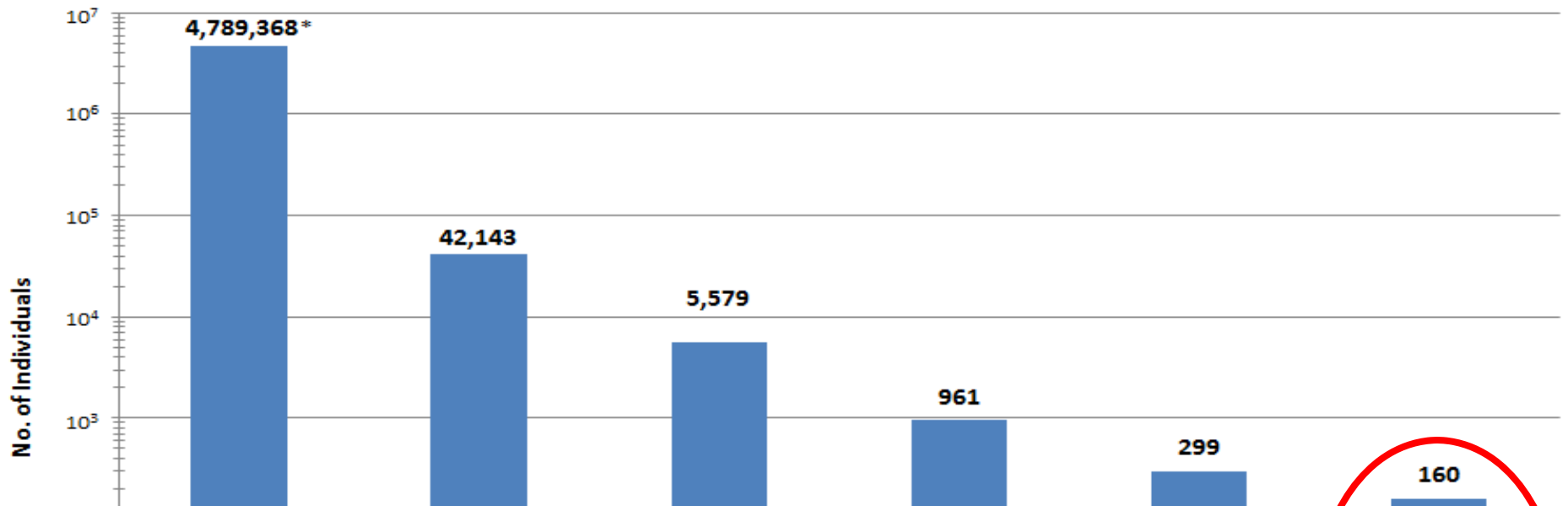
Methods. We conducted a retrospective, of confirmed syphilis, gonorrhea, and chlamydial infections reported to Massachusetts state surveillance system within a 2-year period, 28 July 2014–27 July 2016.

Results. Among Massachusetts population aged 13–65 years (4 847 510), 49 142 (1.0%) were reported with ≥ 1 STIs; 6999 (14.2% of those with ≥ 1 STI) had ≥ 2 STIs, accounting for 27.7% of STIs. Of cases with ≥ 5 or more STIs (high-volume repeaters), 118 (74%) were men and 42 (26%) were women. Men spanned the age spectrum and were predominantly non-Hispanic white; 87% reported same-sex contacts. Women were younger, predominantly nonwhite, and without known same-sex contacts. Women were reinfected with gonorrhea and chlamydia or chlamydia alone; none had syphilis or human immunodeficiency virus (HIV) infection. All men with syphilis also had gonorrhea and/or chlamydia; 35% were diagnosed with HIV before, during, or within 10 months after study period. The majority (56%) of high-volume repeaters were seen at more than 1 care site/system.

Conclusions. In Massachusetts, a large proportion of bacterial STIs are reported from a small subpopulation, many of whom have repeated infections and are likely to have higher impact on STI and HIV rates. Public health can play a crucial role in reaching high-volume repeaters whose STI histories may be hidden from clinicians due to fragmented care.

Keywords. repeated sexually transmitted infections; population-based surveillance.

Results: Cases of Confirmed Chlamydia, Gonorrhea, and Infectious Syphilis, Massachusetts 2014-2016



Of 13-65 year olds in Massachusetts (N = 4,847,510):

- 1% (49,142) were reported with bacterial STI
- 0.1% (6,999) accounted for 28% of all reported bacterial STIs
- 56% of high-volume repeaters sought care in >1 clinical system

Massachusetts July 1, 2015 population estimate for male and females 13 to 65 years of age minus number of individuals diagnosed with at least one STD between July 28, 2014 and July 27, 2016. Population estimate derived from Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: April 1, 2010 to July 1, 2015, Source: U.S. Census Bureau, Population Division; Release Date: June 2016. <http://www.census.gov/programs-surveys/popest.html>

Source: MDPH BIDLS Division of STD Prevention. Data are current as of 2/15/2017 and are subject to change.

Conclusions

- Repeaters are a small portion of the overall population, but contribute a large volume of STIs
 - Disproportionately high impact on circulation of STIs and HIV infection in the population
 - Representative of chronic poor sexual health?
- Infections in high volume repeaters may be hidden from clinicians and clinical systems due to fragmented care
- Public health can play a crucial role in identifying and reaching these individuals
 - State & local jurisdictions have sufficient identifying information to act

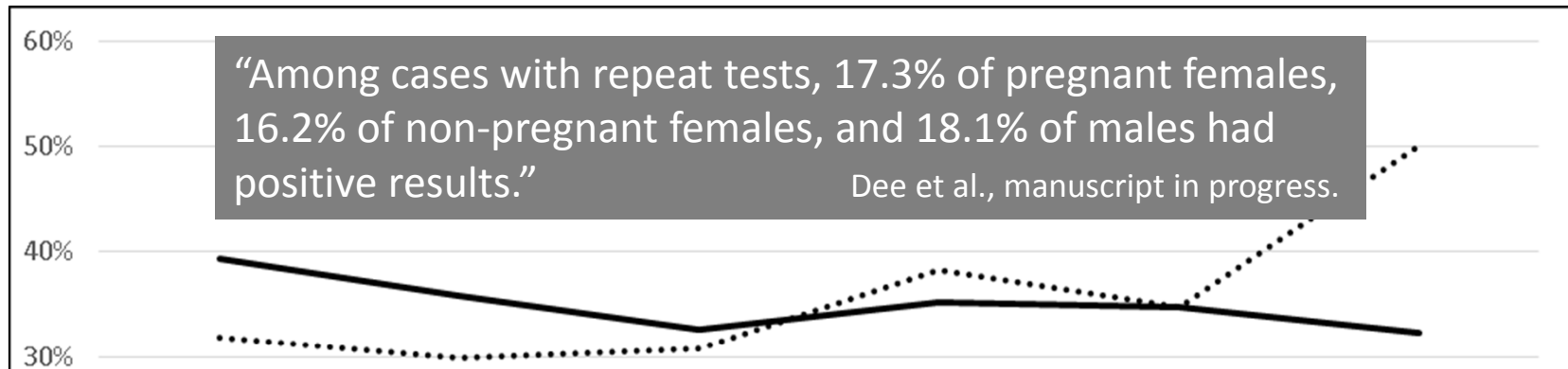
Next Steps

- **New Model for Field Follow-up**
 - Need a greater understanding of the underlying sexual network
 - In order to intervene in the spread of STIs and HIV
 - Provide Pre-Exposure Prophylaxis (PrEP) referrals and other services to repeatedly infected HIV-negative cases
 - Help reduce risk to reproductive-aged females
 - Infertility prevention
 - Contact tracing, treatment, and prevention during pregnancy results in double benefit (mother and infant)

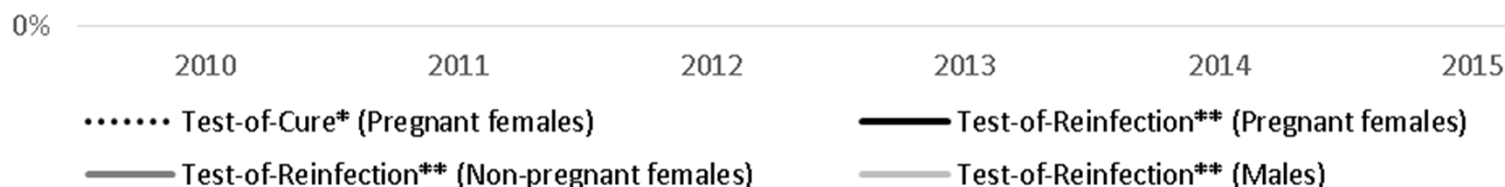
Repeat Screening After STI

- *Women with CT, GC or trich should be rescreened at 3 months after treatment.*
- *Men with CT or GC should be rescreened at 3 months after treatment.*
- *Patients diagnosed with syphilis should undergo follow up serologic serology per current recommendations.*

One Massachusetts ACO: Percent of *Chlamydia trachomatis* cases retested within recommended time period



We are underutilizing repeat testing as a tool for identifying higher risk patients



*Test-of-cure includes repeat tests occurring 3 to 5 weeks following the index positive, regardless of whether a test-of-reinfection occurs.
**Test-of-reinfection includes repeat tests occurring 8 to 16 weeks following the index positive. For pregnant women, tests are included regardless of whether a test-of-cure occurred.



Many thanks to Laura Bachmann and IDWeek 2016!

2. TREAT STI SYNDROMES QUICKLY



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Population-level Control of STIs

Basic Reproductive Rate

$$R_0 = T \cdot C \cdot D$$

Transmissibility

No. of Sexual Contacts

Duration of infectiousness

Screening and RAPID APPROPRIATE treatment decrease D (duration) of carriage and therefore transmission

Principles of STI Treatment

- Symptomatic
 - Test AND treat **immediately**, based on STI syndrome
- Reports contact
 - Test AND treat **immediately**, according to reported exposure
- Asymptomatic, no specific contact
 - Screen and treat according to results

Delays in Gonorrhea Treatment Massachusetts 2015-2017

- 599/2523 randomized cases agreed to interview
 - Symptomatic/contact cases
 - Median time to treatment = 0 days
 - **BUT 42% not treated on day 0**
 - Asymptomatic
 - Median time to treatment = 4 days
 - **BUT 51% treated ≥ 5 days after sample collection**
 - Delays more common in symptomatic women, asymptomatic MSM

Symptomatic/contact cases had shorter time to treatment compared to asymptomatic cases, who may contribute more to population transmission of gonorrhea.

BUT, in both groups, treatment delays are common.

2A. NEW CONSIDERATIONS FOR PERSISTENT URETHRITIS



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Case

**20yo M treated with doxycycline for NGU
2 weeks prior ...**

- **His initial chlamydia and GC tests were negative. His urethral symptoms never fully resolved and he now returns for evaluation. NGU is demonstrated again.**
- **He reports compliance with treatment and sexual abstinence.**
- **He reports only female partners.**

What's next on your differential for persistent urethritis?

1. *T. vaginalis*
2. *M. genitalium*
3. *U. urealyticum*
4. HSV
5. *N. meningitidis*



Recurrent and Persistent Urethritis

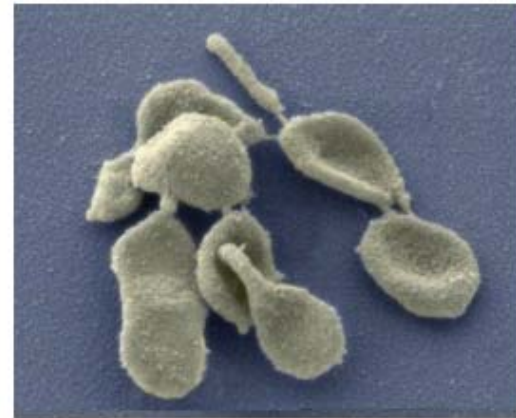
- Check first for objective signs of urethritis
 - Mucoid, mucopurulent, or purulent discharge on exam
 - Gram, methylene blue, or gentian violet stain of urethral secretions: ≥ 2 WBC per oil immersion field
 - Positive leukocyte esterase test on first void urine
 - Urine micro of first void urine sediment: ≥ 10 WBC per high-power field
- If urethritis confirmed, re-treat with initial regimen if initially non-compliant or if re-exposed to untreated partner
 - Not this patient's case, but this is the usual next step

DDx for Recurrent or Persistent Urethritis

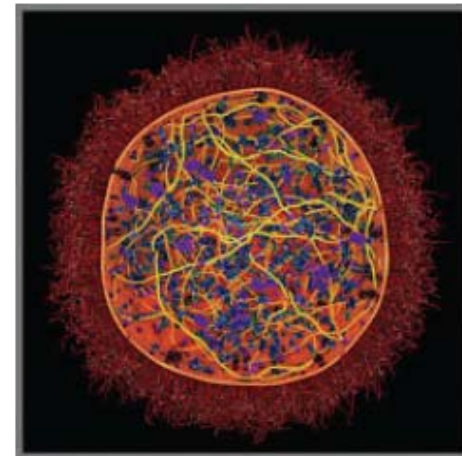
- Consider azithromycin or doxycycline-resistant *U. urealyticum* or *M. genitalium*
 - May benefit from treatment with moxifloxacin 400 mg orally once daily for 7 days
- Consider *T. vaginalis*
 - More common in heterosexual men
 - Test using first-void urine or urethral swab, send for culture (not always available) or NAAT (now commercially available)
 - May benefit from treatment with metronidazole or tinidazole
 - Low probability in MSM
- Consider HSV if recurrent

What is *Mycoplasma genitalium*?

- Mollicute
 - Lacks a cell wall
- Smallest known genome^{1,2}
 - 580 kb translating to <500 genes
- First identified in 1981 from 2 of 13 men with NGU³
- Extremely fastidious
 - Culture only achieved by ~3-4 laboratories worldwide
 - Takes ~6 months⁴



Scanning electron micrograph



Computer assembled & generated 3D model

Slide courtesy of LE Manhart

Mycoplasma genitalium: Epidemiology

- First identified in the early 1980's
- Cause of male urethritis
 - 15-20% of non-gonococcal urethritis (NGU) cases
 - 20-25% of non-chlamydial NGU
 - 30% of persistent or recurrent urethritis
 - More common than *N. gonorrhoeae* but less common than *C. trachomatis*
 - Co-infection with *C. trachomatis* is not uncommon
- Unknown whether it can cause male infertility or other male anogenital tract disease syndromes
- Pathogenic role in women also less clear

Mycoplasma genitalium: Diagnostics

- Very slow-growing organism
 - Culture can take up to 6 months
 - Only a few laboratories in the world are able to recover clinical isolates
- Nucleic acid amplification testing (NAAT) is the preferred method to detect *M. genitalium*
 - Research settings
 - In-house PCR assays (?)
 - None commercially available (YET)



Treatment of MG: RCTs Comparing Doxycycline vs. Azithromycin

Study	Year	N	Drugs & Dosages	Micro Cure
Mena	2009	36	DOXY 100mg PO bid X 7d	45% ←
		42	AZM 1g PO X1	87%
Schwebke	2011	39	DOXY 100mg PO bid X 7d	31% ←
		45	AZM 1g PO X 1 +/- Tinidazole	67%
Manhart	2013	35	DOXY 100mg PO bid X 7d	30% ←
		35	AZM 1g PO X 1	40%

Mena 2009 *Clin Inf Dis*; 48:1649; Schwebke 2011 *Clin Inf Dis*; 52:163; Manhart 2013 *Clin Inf Dis*;56:934

- Doxycycline largely ineffective against *M. genitalium*: median cure rate of ~31%
- Resistance to azithromycin appears to be emerging: median cure rate for men and women ~85%, but only 40% in most recent trial
- Longer courses of AZM (e.g. 500 mg PO X1 followed by 250 mg QD X 4d) yield higher cure rates and may lead to decreased emergence of resistance

CDC 2015 STD Treatment Guidelines

“The **1-g single dose of azithromycin** was significantly more effective against *M. genitalium* than doxycycline in two randomized urethritis treatment trials and is **preferred over doxycycline**. However, **resistance** to azithromycin appears to be **rapidly emerging**....

Moxifloxacin (400mg daily x 7, 10, or 14 days) has been successfully used to treat *M. genitalium* in men and women with previous treatment failures....

Although generally considered effective, studies in Japan, Australia, and the United States have reported **moxifloxacin treatment failures after the 7 day regimen.**”

Take Home Points

- **Use strict objective criteria to define recurrent or persistent urethritis**
- **Likely pathogens depend on sexual behaviors and risk history**
- **Management is difficult if neither gonorrhea nor chlamydia are diagnosed on subsequent testing**
 - Rule out reinfection
 - Test for *T. vaginalis* using NAAT
 - Strongly consider *M. genitalium* in DDx (may be difficult to test for and treat)
 - Consider referral to urologist

**2B. RECURRENT BACTERIAL VAGINOSIS IS
COMMON, CAN BE TREATED WITH PROLONGED
THERAPY, BUT OPTIMAL MANAGEMENT IS IN
EVOLUTION**



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Center
Boston, MA

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Case

- **JG is a 21 yo F who presents with 3d history of abnormal vaginal discharge and odor**
- **PMH – BV diagnosed 6 times in the last year (at least 3 of 4 Amsel Criteria fulfilled at each diagnosis)**

Bacterial Vaginosis Diagnosis: Amsel Criteria

**Amsel Criteria:
Must have at least
three of the
following
findings:**

- **Vaginal pH >4.5**
- **Presence of >20% per HPF of "clue cells" on wet mount examination**
- **Positive amine or "whiff" test**
- **Homogeneous, non-viscous, milky-white discharge adherent to the vaginal walls**

Recurrent BV

- **Recurrent disease remains common**
 - Rates up to 70% within 3 months
- **Reasons for recurrence unclear**
 - Re-infection
 - Failure of lactobacilli to re-colonize
 - Inadequate length of therapy
 - Persistence of unidentified host factor
 - ?Resistance
- **Despite comparable early cure rates, higher recurrence rates associated with shorter treatment**
 - Single-dose 2 g metronidazole no longer recommended
 - 3-day clindamycin course no longer first-line

What strategy should this patient employ to prevent future BV recurrence?

- 1. Initiate suppression with twice weekly intravaginal metronidazole gel following treatment of current episode**
- 2. Get a new partner**
- 3. Use condoms 100% of time for vaginal sex**
- 4. Pull out the boric acid!**
- 5. All of the above**



Present Day Recurrent BV Management

- **Suppression with metronidazole gel twice weekly for 4-6 months**
- **Oral metronidazole, then intravaginal boric acid, then suppressive metronidazole gel twice weekly for 4-6 months**
- **Oral metronidazole administered monthly with fluconazole**

Adherent Biofilms in Bacterial Vaginosis

G. vaginalis

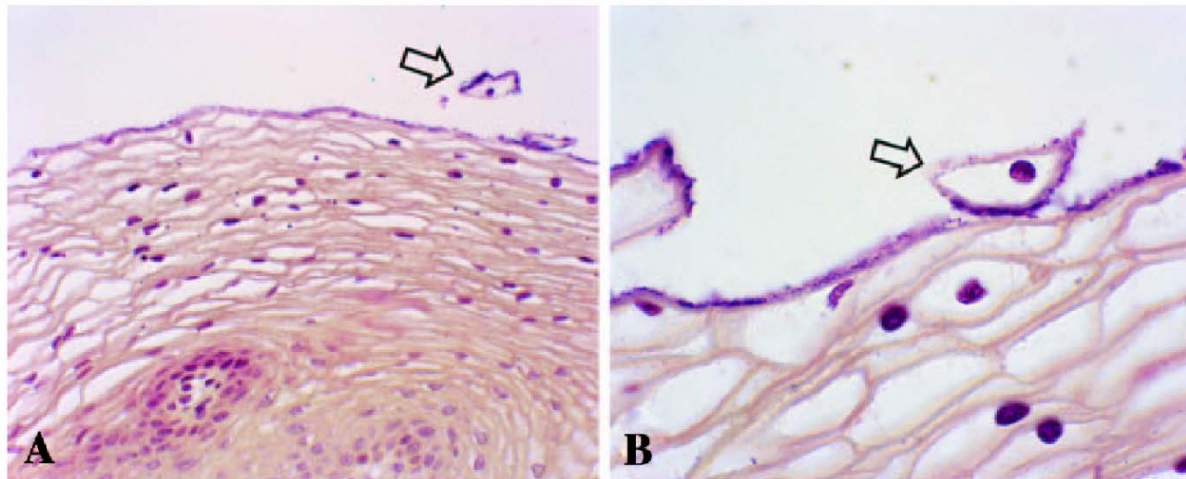
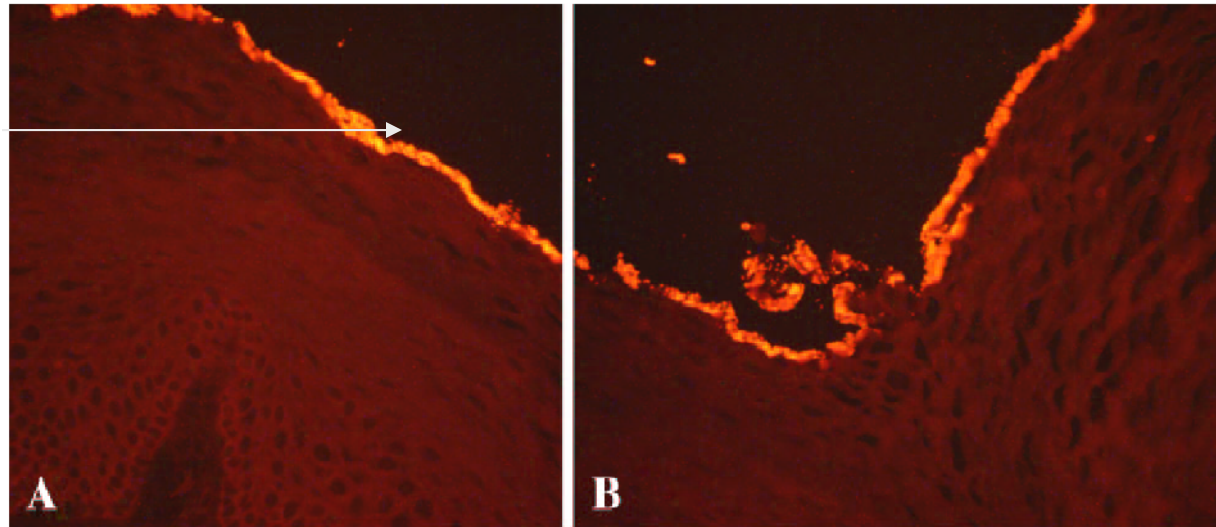


Fig. 4. A continuous biofilm can be detected histologically on the vaginal epithelial surface in patients with bacterial vaginosis (Brown-Hopps modification of the Gram stain). Original magnifications: left panel, x100 (A); right panel, x250 (B). Note the desquamation of surface epithelial cells containing the biofilm that can be detected as "clue cells" in the vaginal smear (arrows).

Swidsinski. *Biofilms in Bacterial Vaginosis*. *Obstet Gynecol* 2005.

Swidsinski,
Obstet. Gynecol
2005



National
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Slide courtesy of Marrazzo, IDSA 2011



What is new with BV?

- **Biofilm disrupters – boric acid, octenidine, retrocyclin, quorum sensing inhibitors?**
- **New data presented in Durban, South Africa at the 21st International AIDS Conference**
 - **Follow-up studies of women in CAPRISA (PrEP study of vaginal gel)**
 - **Association of specific pathogens with increased inflammation/susceptibility**
 - *P. bivia*
 - *G. vaginalis*
 - **Lack of *Lactobacilli***

Partner Management

- **Treatment of male sex partners has not been found to reduce BV recurrence**
- **?Evaluate and treat female partners**
- **Patients should also be advised to refrain from douching and either abstain from sex or use a condom during and for a month after treatment**

Take Home Points

- **BV is a common clinical entity**
- **Understanding of BV continues to evolve**
 - **Biofilms may be important**
- **Use of appropriate diagnostic tests are critical for management**
- **Several strategies exist to treat recurrent BV, but more work is needed**

4. STIs HAVE REACHED NEW HIGHS (COMPLICATIONS ARE MORE COMMON)

THEREFORE, TO REDUCE TRANSMISSION ...

3. FOCUS SCREENING ON HIGH-RISK POPULATIONS FOR HIGHEST YIELD

3A. MSM STI SCREENING IS IMPORTANT FOR MAINTAINING MALE SEXUAL HEALTH

3B. RE-SCREENING FOR STIs IN THOSE PREVIOUSLY INFECTED, REACHES THOSE AT HIGHEST STI RISK

2. TREAT STI SYNDROMES QUICKLY

2A. NEW CONSIDERATIONS FOR PERSISTENT URETHRITIS

2B. RECURRENT BV IS COMMON, CAN BE TREATED WITH PROLONGED THERAPY, BUT OPTIMAL MANAGEMENT IS IN EVOLUTION

Drum roll please ...

1. CDC STD TREATMENT GUIDELINES: A ROSE BY ANY OTHER NAME ...



Sylvie Ratelle
STD/HIV
Prevention Training
Center of New England

A Project of the Division of STD Prevention
Massachusetts Department of Public Health
Funded by the CDC

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- Harmony with USPSTF screening guidelines on gonorrhea/chlamydia in adolescents
- New hepatitis C screening recommendations for HIV+ MSM
- New information on clinical management of transgender men and women

**Sexually Transmitted Diseases
 Treatment Guidelines, 2015**

Misnomer!

- Prevention
- Screening
- Counseling
- Management

AND

- Treatment Guidelines

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CDC STD Treatment Guidelines Development

- Evidence-based on principal outcomes of STD therapy
 1. Microbiologic eradication
 2. Alleviation of signs & sx
 3. Prevention of sequelae
 4. Prevention of transmission
 - Recommended regimens preferred over alternative regimens
 - Alphabetized unless there is a priority of choice
 - Reviewed April 2013; published 2015
 - www.cdc.gov/std/treatment
 - Pocket guides, teaching slides, charts, app
- Language in yellow highlighted boxes reflects changes between 2010 and 2015 guidelines**



Want to know more about STDs? *There's an app for that.*



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This curriculum was funded by a grant from the CDC and developed by the
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