

Top STI Updates: Pandemic Considerations and Beyond ...

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June 19, 2020



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PANDEMICS INCENTIVIZE MEDICAL CREATIVITY



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Telehealth Barriers Smashed

- Triage upscaled and improved
 - Who REALLY needs to be seen?
- Face time reduced for routine care
 - Blood work still needs to be drawn
 - Self-swabbing can be used
- Face time even reduced for urgent care
 - Self-swabbing can be used in conjunction with exams
 - Reduction in parenteral treatment are fair game
 - Prioritize patients where an exam and testing change the DDX significantly (vaginal discharge! Proctitis!)
BUT filter through – what's the harm in a trial of presumptive outpatient therapy, vs. benefits?



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

Let's Take A "Selfie": Self-Collected Samples for Sexually Transmitted Infections

Charlotte A. Gaydos, MS, MPH, DrPH

The use of self-collected samples for the diagnosis of sexually transmitted infections (STIs) has been around for a long time and predates by many years the popular use of the word "selfie" to describe the practice of taking a picture of oneself.^{1,2} Both examples might be called a "selfie" because the person is in charge of producing a product, but the potential benefits are different. The picture is often intended for posting on social media. Benefits from self-collecting one's own specimen are more practical. The privacy associated with self-collection, compared with provider-collected specimens, may be highly valued. Additionally, convenience may be important. Self-collection can be time-saving, because a provider appointment is not always necessary, and in some cases it may be done at home and the specimen mailed to a laboratory. Five commercial companies have been granted FDA clearance for self-collected vaginal swabs for women and urine for men when nucleic acid amplification tests are performed. The Centers for Disease Control and Prevention recommend vaginal swabs, either self- or clinician-collected, for screening women and urine for screening men for chlamydia (CT) and gonorrhea (NG).³ Many investigations have reported that self-collected urogenital specimens were acceptable to men and women and provided accurate results.⁴⁻¹¹

Although urine has been well accepted for screening men, the adoption of vaginal swabs has been slower. In this journal, Habel et al.¹² report the acceptability and uptake of self-collected urogenital samples among university students who were offered the option of participating in an innovative "selfie" program. They used the term "self-testing" but "self-collection" is more appropriate. Self-testing suggests the patients performed the tests themselves, which may be possible in the future. Semantics aside, allowing university students to self-collect samples for testing for CT and NG was acceptable, efficient, and effective.¹² The authors did not report which assay was used, but it probably was a nucleic acid amplification test, as recommended by the Centers for Disease Control and Prevention.

The reported overall increase in uptake of any testing in 2015, compared with a 2013 baseline, was 28.5% for men and 13.7% for women.¹² For women opting for the "selfie," the specimen changed from a clinician-collected cervical swab to the self-collected vaginal swab. The urine specimen offered to men opting for the "selfie" did not change. What did change for these students was the dispensing of the specimen for an appointment with a clinician. They found 31.0% of men and 13.6% of women opted for the "selfie." Less than one fourth of those opting for the "selfie" program. Interestingly, women were more likely to test positive for CT/NG when they selected the self-collected specimen (12.4%, compared to 4.8% for those with clinician collected specimens, $p < .01$). No significant difference in positivity for testing option was observed for men (12.9% vs 12.4%). Clinician testing for 2015, compared with 2013, declined 11.3% for men and 1.8% for women.

It is interesting to note that a higher percentage of men were in favor of the "selfie" than women. The reasons are not apparent. Perhaps, women were more used to seeing clinicians for reproductive health issues. Convenience may have contributed to the male choices. Although the student response to the "selfie" program was modest, the results presented are encouraging in that more people got tested. Continued assessment of the option program may show greater selection of the "selfie" as more students learn of the benefits.

Increasing the options for getting tested for STIs is expected to increase testing of those at risk. Innovative programs are being developed, implemented and evaluated. Although home collection of urogenital samples with mail transport to a testing site has not yet been cleared by the Federal Drug Administration,¹³ many such programs have been implemented and evaluated and found acceptable to participants.¹⁴⁻¹⁹ Self-collected vaginal swabs appear to be cost-effective.^{20,21} Pharmacy

on the Department of Medicine, The Johns Hopkins University, Baltimore, MD
outcomes of funding: USA-E80007958, NIDDK, NIAID.
conflict of interest: None declared.
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received for publication: December 28, 2017, and accepted January 2, 2018.
DOI: 10.1097/STB.0000000000000785
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Gaydos. *Sex Trans Dis*, 2018



staff, students, and health care organizations.

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CDC DSTDP Dear Colleague Letter (1)

April 6, 2020

- Guidance provided for “flexible and pragmatic approach that minimizes reductions in STD care and treatment”
- [STD] clinics that remain open but are limiting number of patients seen should prioritize:
 - patients with STD symptoms
 - those reporting STD contact, and
 - individuals at risk for complications (i.e. women with vaginal discharge and abdominal pain, pregnant women with syphilis, individuals with symptoms concerning for neurosyphilis)
- Routine [STD] screening visits should be deferred until the emergency response is over



CDC DSTDP Dear Colleague Letter (2)

April 6, 2020

- Phone or telemedicine-based triage, including syndromic management of male urethritis, suspected primary or secondary syphilis, vaginal discharge, and proctitis, could be implemented
 - A triage protocol that includes identification and referral for additional evaluation of individuals at risk for complications is essential.
- If an STD program is considering closing clinics, they should try to establish relationships with other clinics and/or pharmacies that can still provide preferred treatments (e.g., injections of ceftriaxone, penicillin G benzathine [Bicillin L-A[®]], or gentamicin)
 - Symptomatic patients and their known contacts could be referred to these sites for syndromic treatment
 - CDC encourages development of innovative testing protocols for self-collected clinical laboratory specimens
- Some STD programs have already implemented home or non-clinic-based testing programs



CDC DSTDP Dear Colleague Letter

April 6, 2020

Table 1. Therapeutic options to consider for symptomatic patients and their partners when in person clinical evaluation is not feasible

Table Footnotes

*When possible, clinics should make arrangements with local pharmacies or other clinics that are still open and can give injections:

&Alternative regimens should be considered when recommended treatments from the 2015 CDC STD Treatment Guidelines are not available

++All pregnant women with syphilis must receive Benzathine penicillin G. If clinical signs of neurosyphilis present (e.g. cranial nerve dysfunction, auditory or ophthalmic abnormalities, meningitis, stroke, acute or chronic altered mental status, loss of vibration sense), further evaluation is warranted

#Consider adding therapy for herpes simplex virus if pain present

Syndrome	Preferred Treatments In clinic, or other location where injections can be given*	Alternative Treatments When only oral medications are available&	Follow-up
Male urethritis syndrome	Ceftriaxone 250mg intramuscular (IM) in a single dose PLUS Azithromycin 1g orally in a single dose (If azithromycin is not available and patient is not pregnant, then doxycycline 100 mg orally twice a day for 7 days is recommended). If cephalosporin allergy is reported, gentamicin 240 mg IM in a single dose PLUS azithromycin 2 g	Cefixime 800 mg orally in a single dose PLUS Azithromycin 1g orally in a single dose (If azithromycin is not available and patient is not pregnant, doxycycline 100 mg orally twice a day for 7 days is recommended). OR Cefpodoxime 400 mg orally q12 hours x 7 doses PLUS A	For alternative oral regimens, patients should be counseled that if their symptoms do not improve or resolve within 5-7 days, they should follow-up with the clinic or a medical provider.
Genital ulcer disease, primary or secondary			Patients should be counseled to be tested for STIs once clinical care is resumed in the jurisdiction. Health departments should make an effort to remind clients who have been referred for oral treatment to return for comprehensive testing and screening and link them to services at that time.
Vaginal discharge without lower abdominal pain or other signs of inflammatory disease			All patients receiving regimens other than Benzathine penicillin for syphilis treatment should have repeat serologic testing performed 3 months post-treatment.
Proctitis syndrome		Cefpodoxime 400 mg orally q12 hours x 2 doses PLUS doxycycline 100 mg orally bid for 7 days (if doxycycline not available or the patient is pregnant, azithromycin 1g orally in single dose recommended).	

Follow-Up

For alternative oral regimens, patients should be counseled that if their symptoms do not improve or resolve within 5-7 days, they should follow-up with the clinic or a medical provider.

Patients should be counseled to be tested for STIs once clinical care is resumed in the jurisdiction. Health departments should make an effort to remind clients who have been referred for oral treatment to return for comprehensive testing and screening and link them to services at that time.

All patients receiving regimens other than Benzathine penicillin for syphilis treatment should have repeat serologic testing performed 3 months post-treatment.

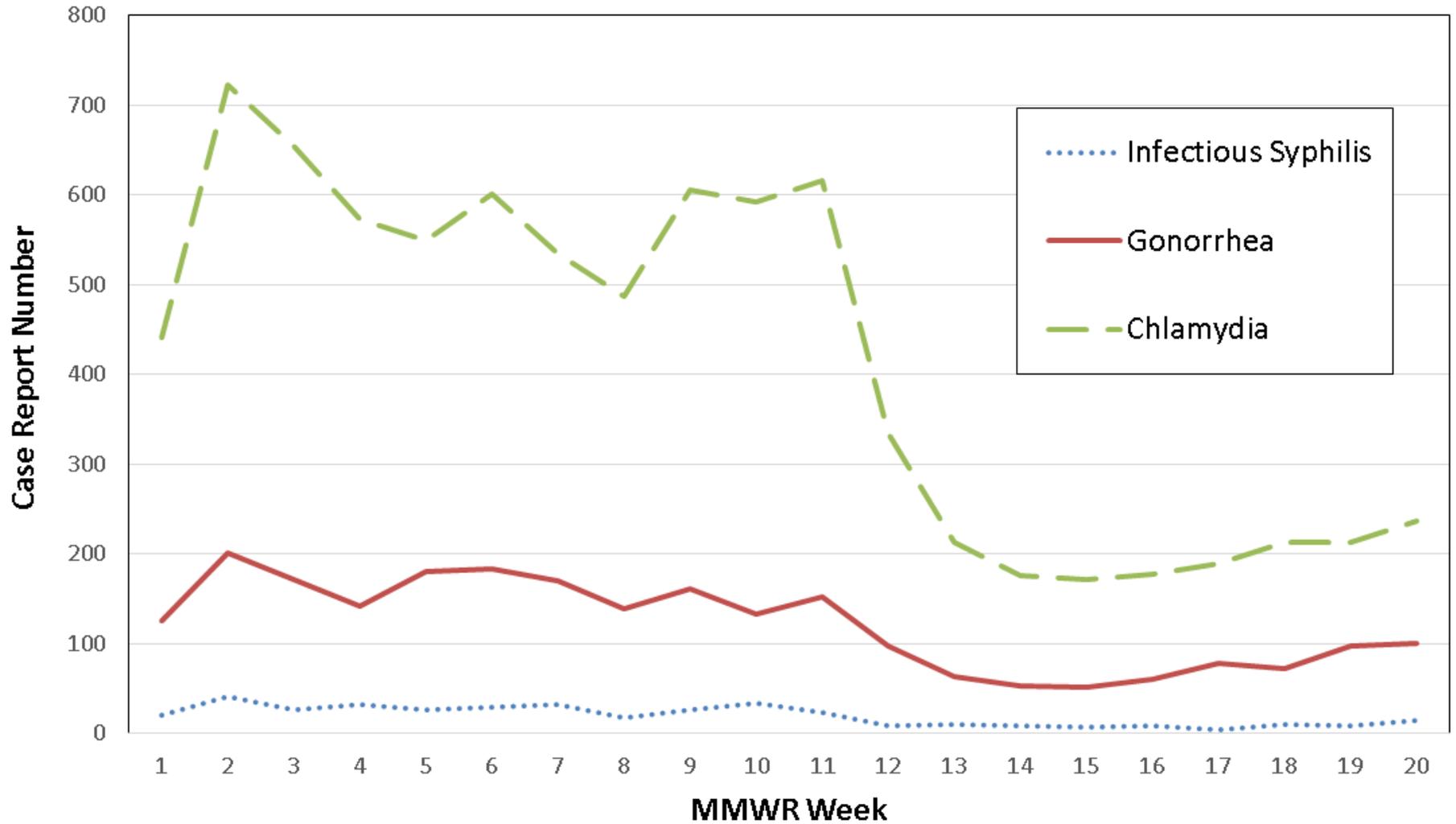
PANDEMICS HIDE ENDEMIC DISEASE



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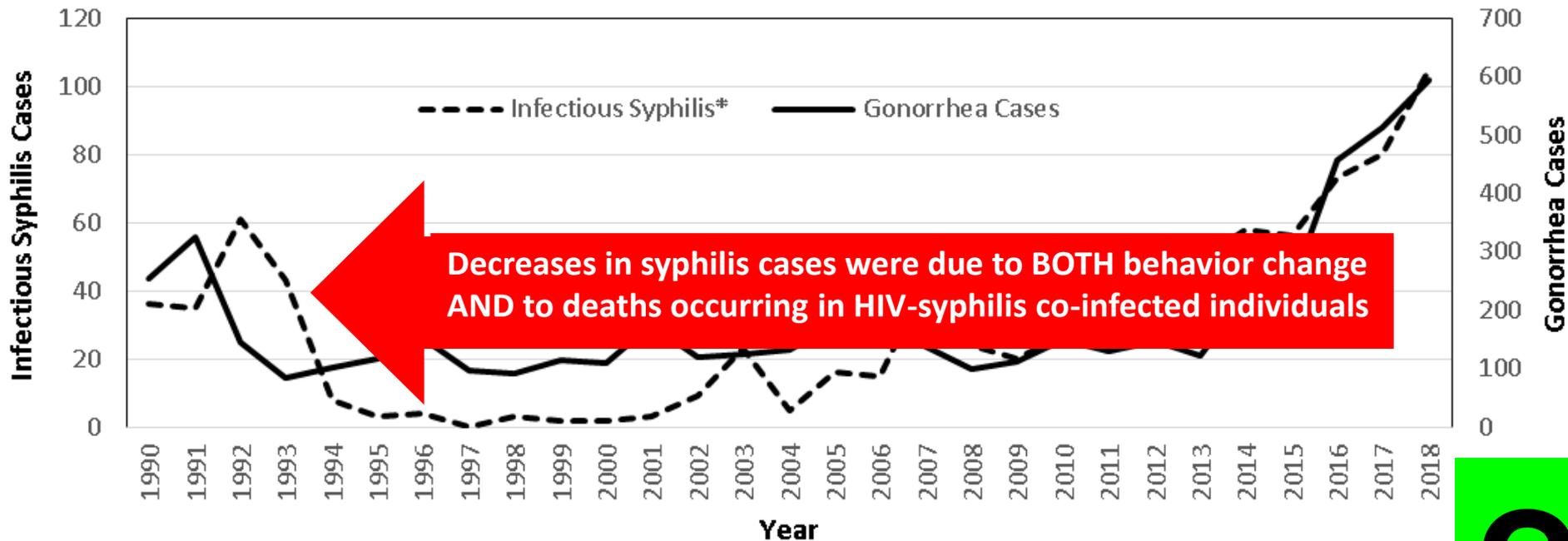
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Massachusetts Weekly STI Case Counts



Syphilis and Gonorrhea Over Time

Infectious Syphilis and Gonorrhea Cases New Hampshire 1990-2018



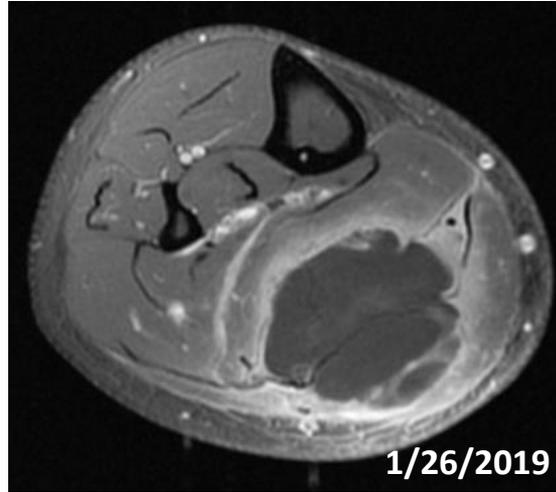
Decreases in syphilis cases were due to BOTH behavior change AND to deaths occurring in HIV-syphilis co-infected individuals



*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 2018. Atlanta: U.S. Department of Health and Human Services; 2019.

STI COMPLICATIONS **LIKELY EVEN** MORE COMMON



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AMERICA'S LEADING GAY NEWS SOURCE

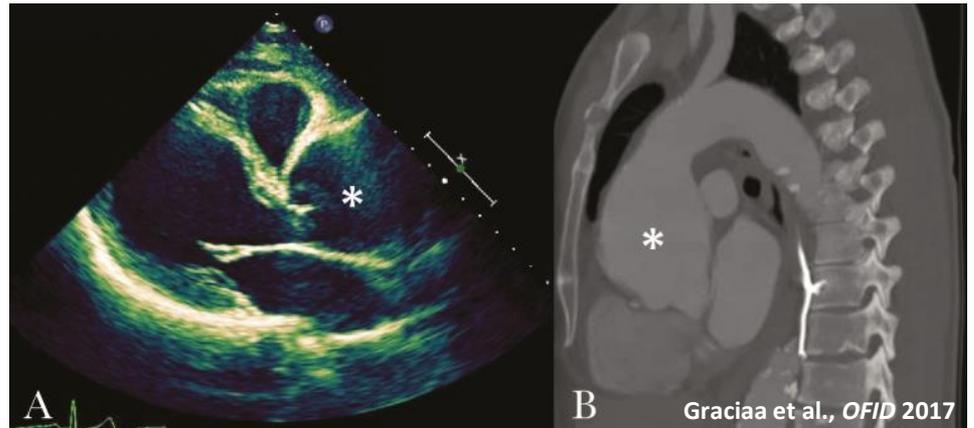
March 13, 2015 | by Staff reports

Gay men blinded by ocular syphilis outbreak

148 94 3 0 Google+ 0

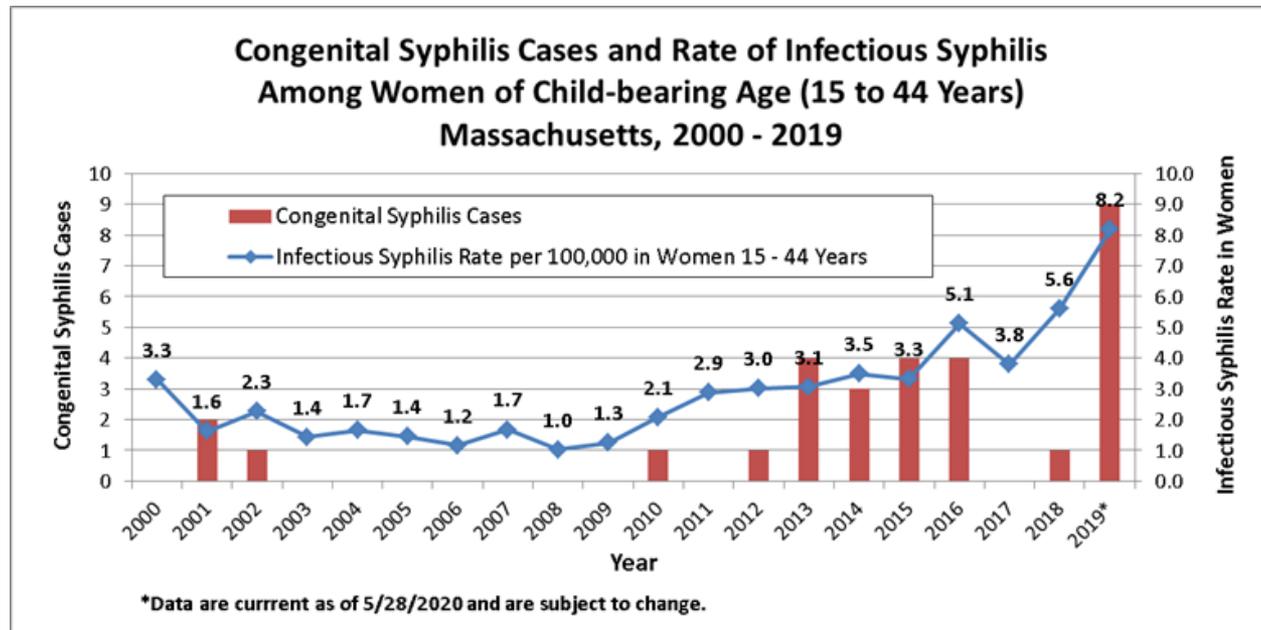


Seven cases of ocular syphilis have been reported in San Francisco, five among MSM and six of whom were HIV-positive, the AIDS Healthcare Foundation reports.



MA Congenital Syphilis Stillbirth Alert

- **Two stillbirths with syphilis and a congenital syphilis case exhibiting symptoms of rash, jaundice and hepatosplenomegaly at birth have been reported to MDPH in 2020.**
 - One stillbirth occurred in woman with limited prenatal care who delivered at 28 wks gestation.
 - Other stillbirth occurred in a woman who delivered at 33 wks with negative 1st trimester syphilis screening, no history of risk to prompt 3rd trimester re-screening, but in retrospect had a rash compatible with secondary syphilis at 27 wks.
 - Symptomatic congenital syphilis case was born at 37 wks to a woman with negative 1st trimester syphilis screening, no history of syphilis symptoms, and no history of risk to prompt 3rd trimester re-screening.



- **Will Massachusetts recommend *universal syphilis screening early in 3rd trimester (~27-28 weeks gestation), in addition to routine syphilis screening performed at first prenatal visit?***

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 because the base case number is growing
- **Are these increases reflective of increased**
 - Screening
 - Reporting
 - True increases in underlying incidence in specific sexual networks
 - All of the above?
- **What will happen when the pandemic “ends”?**
 - Will we have missed more cases of PID or other syndromes, where patients may not have come in when they otherwise would have?
 - Will there be a surge of cases from backlog of asymptomatic screening that will need to be done?

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



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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 June 2019; published ? 2020
- www.cdc.gov/std/treatment
 - Pocket guides, teaching slides, charts, app

CONTENTS

Introduction.....	1
Methods.....	1
Clinical Prevention Guidance.....	2
Special Populations.....	9
Emerging Issues.....	17
Hepatitis C.....	17
<i>Mycoplasma genitalium</i>	20
HIV Infection: Detection, Counseling, and Referral.....	21
Diseases Characterized by Genital, Anal, or Perianal Ulcers.....	25
Chancroid.....	26
Genital HSV Infections.....	27
Granuloma Inguinale (Donovanosis).....	32
Lymphogranuloma Venereum.....	33
Syphilis.....	34
Management of Persons Who Have a History of Penicillin Allergy.....	49
Disease Characterized by Urethritis and Cervicitis.....	51
Chlamydia.....	51
Gonorrhea.....	52
Cervicitis.....	53
Chlamydial Infections.....	55
CONTENTS (Continued)	
Gonococcal Infections.....	60
Diseases Characterized by Vaginal Discharge.....	69
Bacterial Vaginosis.....	69
Trichomoniasis.....	72
Vulvovaginal Candidiasis.....	75
Pelvic Inflammatory Disease.....	78
Epididymitis.....	82
Human Papillomavirus Infection.....	84
Anogenital Warts.....	86
HPV-Associated Cancers and Precancers.....	90
Viral Hepatitis.....	94
Hepatitis A.....	94
Hepatitis B.....	95
Proctitis, Proctocolitis, and Enteritis.....	100
Ectoparasitic Infections.....	101
Pediculosis Pubis.....	101
Scabies.....	102
Sexual Assault and Abuse and STDs.....	104
References.....	110
Terms and Abbreviations Used In This Report.....	135

Sexually Transmitted Infection (?) Guidelines, 2020

Misnomer!

- Prevention
- Screening
- Counseling
- Management

AND

•Treatment Guidelines



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