Disclosures

- CDC, our planners, and our presenters wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters, with the exception of:
 - Edward W. Hook III, University of Alabama at Birmingham, wishes to disclose receipt of research support as an investigator for: Astra Zeneca, GSK, Becton Dickinson, Roche Molecular, and Cepheid.
 - Jeanne Marrazzo, University of Washington, wishes to disclose receipt of research funding to institution for Clinical trial conduct from Symbiomix and receipt of research funding to institution for Diagnostic trial conduct from Cepheid; GenProbe Hologics.

Disclosures

- Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception of:
 - Gail Bolan, Edward W. Hook III, Jeanne Marrazzo, and Kim Workowski will discuss some diagnostic tests and treatment regimens for which there is not currently an FDA indication. This is relevant to discussions on the use of extra-genital nucleic acid amplification tests and the management of non-gonococcal urethritis and pelvic inflammatory disease.

Continuing Education Accreditation

Continuing Medical Education (CME):

- The Centers for Disease Control and Prevention is accredited by the Accreditation Council for Continuing Medical Education (ACCME®) to provide continuing medical education for physicians.
- The Centers for Disease Control and Prevention designates this live activity for a maximum of 1.5 AMA PRA Category 1 Credits™.
 Physicians should only claim credit commensurate with the extent of their participation in the activity.

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- The Centers for Disease Control and Prevention is accredited as a provider of Continuing Nursing Education by the American Nurses Credentialing Center's Commission on Accreditation.
- This activity provides 1.5 contact hours.

Continuing Education Accreditation (cont'd)

IACET Continuing Education Units (CEU):

 The Centers for Disease Control and Prevention is authorized by IACET to offer 0.2 CEUs for this program.

Continuing Education Contact Hours in Health Education (CECH):

Sponsored by the Centers for Disease Control and Prevention, a designated provider of continuing education contact hours (CECH) in health education by the National Commission for Health Education Credentialing, Inc. This program is designed for Certified Health Education Specialists (CHES) and/or Master Certified Health Education Specialists (MCHES) to receive up to 1.5 total Category 1 continuing education contact hours. Maximum advanced level continuing education contact hours available are 0. CDC provider number 98614.

Continuing Education Accreditation (cont'd)

Continuing Pharmacy Education (CPE):



- The Centers for Disease Control and Prevention is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
- This program is a designated event for pharmacists to receive 0.15 Contact Hours in pharmacy education. The Universal Activity Number 0387-9999-15-130-L04-P/0387-9999-15-130-H04-P.
- Course Category: This activity has been designated as Knowledge-Based.

Learning Objectives

- Discuss clinical significance of the sexual health/clinical issue.
- Describe epidemiological trends related to the sexual health/clinical issue.
- Identify key screening and treatment recommendations for management of the sexual health/clinical issue, in accordance with CDC 2015 STD Treatment Guidelines.
- Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of health care providers.

Gail Bolan, MDDirector, Division of STD Prevention, CDC



Welcome to the 2015 STD Treatment Guidelines Webinar:

An Overview by the CDC and the National Network of STD Clinical Prevention Training Centers (NNPTC)

June 22, 2015

Webinar Overview

Intended Audience:

This webinar is for clinicians and other staff who provide clinical care for persons with or at risk for STDs in public and private health care settings.

This webinar will:

- Emphasize the importance of diagnosis and treatment of STDs and the clinicians' role in STD prevention
- Explain the NNPTC's role in STD prevention
- Provide an overview of the 2015 STD Treatment Guidelines with:
 - Highlights of key recommendations
 - Important changes from 2010 Guidelines
- Include:
 - Time for Questions and Answers
 - Additional resources



Your questions submitted during the Webinar will help determine the focus of future 2015 STD Treatment Guidelines Webinars.

Instructions on how to receive CME are available at http://www.cdc.gov/std/training/webinars.htm.

An archived version of the Webinar will be available at http://nnptc.org/ and at www.cdc.gov/std/tg2015 within a few days.

If you have questions about the 2015 STD Treatment Guidelines following the Webinar you may contact the NNPTC clinical consultation network at https://www.STDCCN.org/.

STD Clinical Consultation Network (STDCCN)

- Provides STD clinical consultation services within 1-3 business days, depending on urgency, to healthcare providers nationally
- Your consultation request is linked to your regional PTC's expert faculty
- We are just a click away! https://www.STDCCN.org/



National Network of STD Clinical Prevention Training Centers (NNPTC)

- Dedicated to increasing the quality of STD care in the areas of the diagnosis, treatment, and prevention of STDs
- Target the individual health care clinician, clinical organization, and health care system levels
- Training content and priorities based on the most current CDC STD Treatment Guidelines and STD epidemiological trends and scientific advancements
- Program outcome measures aligned with STD prevention program funding

www.nnptc.org









WWW.NNPTC.ORG 12

Why Diagnose and Treat STDs?

- >19 million STDs in U.S. annually
- Health consequences of untreated STDs
 - Women's reproductive health
 - Untreated Chlamydia (CT) or gonorrhea (GC) may lead to pelvic inflammatory disease (PID)
 - Leading infectious cause of infertility in the U.S.
 - Infant mortality/morbidity
 - Neonatal HIV, herpes simplex virus (HSV) and congenital syphilis
 - HIV transmission
- Health care cost
 - \$15.6 billion

Populations at Greatest Risk for STDs

Youth

Nearly 50% of STDs estimated to occur in 15-24 year olds

Racial/ethnic minorities

- STDs among highest of all racial/ethnic health disparities
- African-Americans:
 - CT: 5.8 times the rates among whites
 - GC: 12.4 times the rate among whites
 - P&S: 5.6 times the rates among whites

MSM

- Account for 75% of syphilis cases in 2013
- High rates of HIV co-infection

STD Prevention – Key Principles

- Counseling to reduce STD acquisition
- Screening of asymptomatic persons
- Diagnosis and treatment of symptoms
- Management of sex partners
- Vaccination
 - Human papillomavirus
 - Hepatitis A and B

STD Prevention: Clinicians' Role

- Provide a welcoming environment
- Take a routine sexual history and risk assessment
- Screen, appropriately
 - Alcohol, drug use, tobacco, depression, and intimate partner violence
- Vaccinate for Human papillomavirus, Hepatitis A & B
- Prevention messages--condoms, medications, Preexposure prophylaxis for HIV (PrEP), and Postexposure prophylaxis (PEP)
- Diagnosis and treatment
- Provide or refer (partner management/ services)
- Report STD/HIV cases in accordance with state and local statutory requirements and keep reports confidential

Purpose of 2015 STD Treatment Guidelines

- To advise clinicians on most effective
 - Risk assessment
 - Diagnostic evaluation
 - Treatment regimens
 - Prevention and vaccination strategies
- Client centered services
- Guidelines are tools not rules
- Critical approach to STD prevention





2015 Sexually Transmitted Treatment Guidelines

Kimberly Workowski, MD, FACP, FIDSA

Lead Author, CDC STD Treatment Guidelines
Professor of Medicine, Division of Infectious Diseases, Emory University

Overview

Guidelines Process

Screening

- Chlamydia and Gonorrhea (U.S. Preventative Services Task Force)
- Sexually transmitted infections in Men who have sex with Men

New Directions

- Clinical Prevention guidance
- Special Populations
- Emerging Issues (M. genitalium, Hepatitis C)
- Treatment and management concerns



Clinical Practice Guidelines We Can Trust

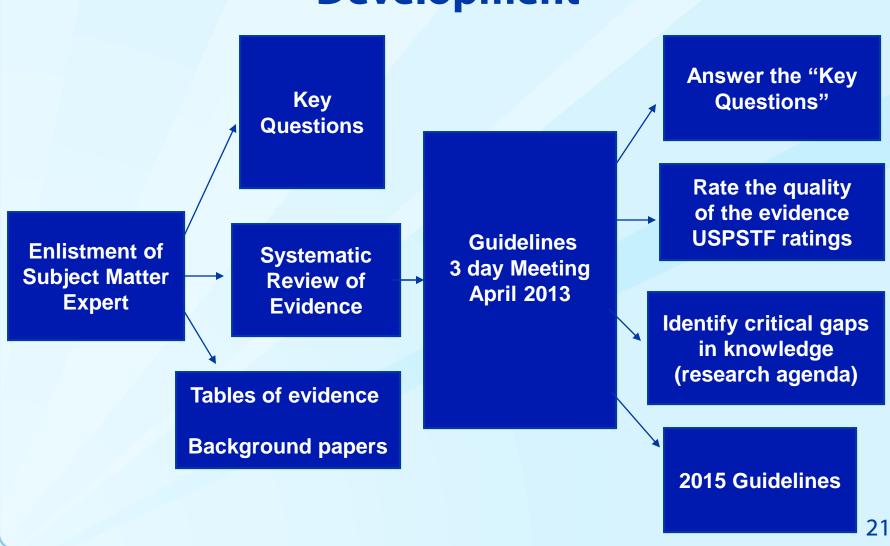
Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, and Earl Steinberg, Editors; Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Institute of Medicine

ISBN: 0-309-16423-0, 300 pages, 6 x 9, (2011)

This PDF is available from the National Academies Press at: http://www.nap.edu/catalog/13058.html

- Be based on a systematic review of the existing evidence;
- Be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- Consider important patient subgroups and patient preferences, as appropriate;
- Be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- Provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and
- Be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

Evidence-based Approach to Guideline Development



Clinical Prevention Guidance

- Behavioral and biologic risk assessment
- High intensity behavioral counseling (USPSTF)
- Pre-exposure vaccination (Human Papillomavirus, Hepatitis A, Hepatitis B)
- Male latex condoms
- Male circumcision
- Microbicides
- Emergency contraception
- Preexposure prophylaxis for HIV
- Retesting (chlamydia, gonorrhea, trichomonas)

Chlamydia and Gonorrhea Screening

- USPSTF categorizes chlamydia/gonorrhea screening as level "B" evidence
- Women: Annual screening for chlamydia/gonorrhea
 - Women < age 25 (harmonized)
 or older women with risk factors
- Heterosexual men
 - Chlamydia, consider screening in high prevalence settings (adolescent clinics, corrections, STD clinics)
 - Gonorrhea screening not recommended

Screening in MSM

- Sexually active MSM (at least yearly) including HIV
 - HIV serology
 - Syphilis serology
 - Urethral infection (insertive intercourse), gonorrhea/chlamydia (nucleic acid amplification), urine is preferred
 - Rectal infection (receptive anal intercourse), gonorrhea/chlamydia (nucleic acid amplification)
 - Pharyngeal infection (receptive oral intercourse), gonorrhea (nucleic acid amplification)
- Hepatitis A, B (vaccination if nonimmune)
 - Sexual transmission of Hepatitis C (MSM with HIV)
- Recent or concurrent STI and HIV

More frequent STI screening dependent on risk behavior (3-6 months)

Special Populations

- Pregnant women
- Adolescents
- Children
- Persons in Correctional Facilities
- MSM
- WSW
- Transgender Men and Women
 - Screen on basis of behavior and sexual practices

Emerging Issues

Hepatitis C, sexually transmitted

- Especially among MSM with HIV infection
- High risk and traumatic sexual practices
- Concurrent ulcerative disease or proctitis (syphilis, lymphogranuloma venereum)

Annual screening

- Initial evaluation of HIV
- At least yearly testing in MSM with HIV infection; repeat test (HCV prevalence, high risk behavior, ulcerative sti or proctitis)

Acute HCV may be HCV Ab negative with low CD4

HCV viral load with LFT elevation

Emerging Issues

Mycoplasma genitalium

- Recognized cause of urethritis
- Role in cervicitis and PID emerging
- No diagnostic test FDA cleared for use
 - Nucleic acid amplification tests available in some large medical centers and commercial laboratories
- Suspect in persistent or recurrent urethritis and consider in persistent cervicitis and PID
- Treatment implications
 - azithromycin>doxycycline
 - emerging resistance to azithromycin
 - Moxifloxacin for recurrence

Diagnostic and Treatment Concerns

- Urethritis
- GC
- CT
- Syphilis
- HPV
- Trichomonas

Urethritis

Diagnostic Considerations

- Discharge on examination
- Gram stain <u>> 2 WBCs</u>, methylene blue or gentian violet on urethral secretions
- +leukocyte esterase on first void urine

Gram stain not available

- At least one diagnostic criteria
- Testing and treatment, gonorrhea/chlamydia

Symptoms without signs

- Chlamydia/gonorrhea testing may identify infection
- Empiric treatment for high risk or unlikely follow-up

NGU Treatment

- Azithromycin or doxycycline
- Limited data on the public health impact of M genitalium to demote doxycycline
- Persistent or recurrent urethritis
 - M. genitalium most common cause
 - Higher azithromycin doses not effective
 - Moxifloxacin 400 mg x 7 d for azithromycin failure
 - T. vaginalis
 - Nitroimidazole (men who have sex with women in areas of high prevalence)
 - Urology referral with persistence after treatment

GONORRHEA

Criteria for GC Treatment Recommendations

Antimicrobial resistance has effected treatment recommendations

- Antimicrobial resistance surveillance (GISP)
- Change in antimicrobial if resistance prevalence >5%

GC treatment efficacy

- >95% and 95% CI lower bound 90%
- >95% and 95% CI lower bound 95%

Pharmacokinetic/pharmacodynamic factors

- Serum concentration at least 4x MIC₉₀ x 10 hrs after peak
- At least twice the minimum efficacious dose

Other factors

- Mechanism of action
- Side effects and safety

- Cost

Uncomplicated Gonococcal Infections of Cervix, Urethra & Rectum

Ceftriaxone 250 mg as a single intramuscular dose

PLUS **Azithromycin 1 g orally**

Alternatives:

If Ceftriaxone is not available:

Cefixime 400 mg PLUS azithromycin 1 gram

GC Treatment

- Dual therapy recommended
 - Enhance treatment effectiveness
 - Prevent transmission of resistant organism
 - Azithromycin preferred over doxycycline due to high prevalence of tetracycline resistance (23.7% in 2013)
- No clinical data to support increasing dose of ceftriaxone or azithromycin as part of dual therapy
- Ceftriaxone treatment failures rare, all outside U.S.
- Azithromycin monotherapy not recommended due to ease of resistance
- Test of cure **not** needed after treatment for urogenital or rectal infection; **recommended for pharynx (alternative)**

Expedited Partner Therapy (EPT)

- EPT effective in reducing chlamydia and gonorrhea reinfection rates among women
- Providers should routinely offer EPT to heterosexual patients with chlamydia or gonorrhea when the provider cannot ensure the sex partners from the prior 60 days will be treated, unless prohibited by law or other regulations

New Treatment Option

- NIH sponsored RCT (Kirkaldy, CID 2014)
 - Gentamicin 240 mg IM + azithromycin 2 g PO, OR
 - Gemifloxacin 320 mg PO + azithromycin 2 g PO
- Rationale
 - Additive effect, gentamicin and azithromicin in vitro
 - Gemifloxacin more active against cipro resistance or GyrA and ParC mutations

	Gentamicin / Azithromycin		Gemifloxacin / Azithromycin	
	n/N	% (L 95% CI)	n/N	% (L 95% CI)
Urethra/Cervix	202/202	100% (98.5%)	198/199	99.5% (97.6%)
Pharynx	10/10	100%	15/15	100%
Rectum	1/1	100%	5/5	100% 37

Suspect Treatment Failures

- Most treatment failure likely due to reinfection
- If treatment failure suspect, obtain culture/ susceptibility test
 - If reinfection likely (ceftriaxone/azi); Rx ceftriaxone 250 mg
 +azithromycin 1 gram
 - If reinfection likely (cefixime/azi), Rx ceftriaxone 250 mg + azithromycin 2 gram
 - If treatment failure suspected, Rx gemifloxacin 320 mg
 +azithromycin 2 g or gentamicin 240 lM + azithromycin 2g
- Report to local or state health department
- Test of cure 7-14 days after retreatment (culture/susceptibility test with NAAT)
- Ensure partner treatment

CHLAMYDIA

Chlamydia Treatment

- Effectiveness of azithromycin < doxycycline
 - Data from one nongonococcal urethritis trial and several rectal infection studies
- Doxycycline delayed release 200 mg tablets (Doryx)
- Amoxicillin moved to alternative regimen in pregnancy
 - In vitro studies demonstrate penicillin induces persistent viable noninfectious chlamydia that can revert to a replicative form after penicillin removal
 - Early amoxicillin studies in pregnancy had major limitations
 - RCT by Kacmar et al showed higher test of cure using azithromycin vs. amoxicillin (95% vs. 80%)

Treatment of Genital Chlamydia Infection

Hocking et al (University of Melbourne)

- Meta-analysis of 23 RCTs (through 2012): 1065 individuals treated with azithromycin, 850 with doxycycline
- Pooled cure rates: doxy 97.5%, azithro 94.4%
- Pooled estimate favored doxy (2.2% 2.7% more efficacious) especially in men
- Conclusion: doxy <u>marginally</u> superior to azithro
- Caveats in interpreting and comparing RCTs:
 - Differences in when endpoint was measured
 - Only 4 studies were double blind
 - Most studies performed in high-risk population

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Lymphogranuloma venereum

- MSM presenting with protocolitis should be tested with rectal NAATs (chlamydia)
 - Additional molecular testing (PCR based genotyping) can be used to differentiate LGV vs. non LGV strains
 - Clinical syndrome consistent with protocolitis should receive presumptive treatment (doxy 100 mg bid x 21 d)
 - In addition if painful perianal ulcers or mucosal ulcers (anoscopy) presumptive therapy for herpes

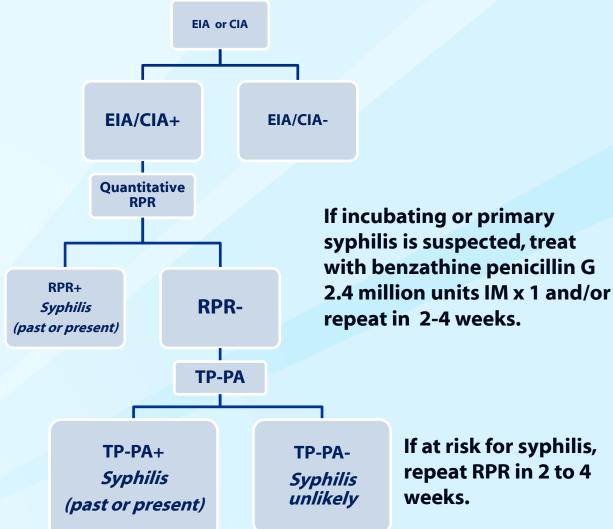
SYPHILIS

Syphilis

- Darkfield examination/tests to detect T pallidum from lesion exudate or tissue are definitive methods for diagnosis but not readily available
- Serological response to treatment
 - Stage (earlier stage more likely to decrease 4x)
 - titer (low titer less to decline than higher titer)
- Time between Benz penicillin doses (LL)
 - <9 days based on limited PK (nonpregnant)</p>
 - 7 days in pregnant women
 - 40% are below treponemicidal levels after 9 days
 - If a dose is missed, the entire series must be restarted

Reverse Screening Algorithm

Evaluate clinically, determine if treated for syphilis in the past, assess risk of infection, and administer therapy according to guidelines if not previously treated.



Syphilis Treatment Primary, Secondary, Early Latent

- Penicillin treatment of choice (HIV)
 - Benzathine penicillin 2.4 mu IM x 1
- No benefit of additional therapy
 - Enhanced (IM+oral)
- Penicillin alternatives
 - Doxycycline, ceftriaxone
 - Azithromycin 2 gm (A2058G mutation/treatment failure)
 - MSM>MSW
 - Not recommended in MSM or pregnancy

Evaluation of CNS Involvement

- Clinical signs (neurologic, ocular, auditory, meningitis, stroke) warrant investigation
- CNS invasion in early syphilis is common
 - CSF abnormalities
 - Unknown clinical significance in absence of signs or symptoms
- Neurosyphilis: CSF tests + reactive RPR + signs/sx
- Lumbar puncture (LP): neuro/ocular symptoms, serologic treatment failure, tertiary
 - Some studies in HIV+ showed association with CSF abnormalities*
 - RPR ≥ 1:32 and/or CD4 ≤350
 - Unless neurologic signs/symptoms, value of LP unknown.

Genital Herpes

- Increasing proportion of anogenital infections HSV-1 (young females, MSM)
- IgM testing not useful
- Type specific serologic tests
 - HerpeSelect HSV-2 ELISA may be false + at low index values (1.2-3.5)confirm with Biokit or Western Blot
 - HerpeSelect HSV-1 ELISA insensitive for HSV-1 (80%)
 - Head to head comparison of type specific assays vs. Western Blot
- No change in recommended therapy



HPV Vaccine Recommendations

- Routine vaccination at age 11 or 12 years*
- Vaccination recommended through age 26 for females and through age 21 for males not previously vaccinated
- Vaccination recommended for men who have sex with men and immunocompromised men (including persons HIV-infected) through age 26
- Vaccination of females is recommended with 2vHPV, 4vHPV, or 9vHPV
- Vaccination of males is recommended with 4vHPV or 9vHPV

Genital Warts

- Treatment
 - Imiquimod (3.75%) applied daily for genital warts
 - Case reports of inflammatory responses to 5% imiquimod
 - Worsened inflammatory and autoimmune skin disease
- Demote to alternative
 - Podophyllin resin 10-25%, reports of systemic toxicity (including death)
 - No clear efficacy benefit when compared with podophyllotoxin

Risk to Healthcare Workers Treating Genital Warts

- HPV DNA can be found in smoke plumes after laser or electrosurgical therapy on external genital warts, cervical intraepithelial neoplasia, common warts
- Case reports of laryngeal papillomas reported in health care workers exposed to smoke plumes during treatment
- Appropriate infection control to prevent possible transmission for anogenital warts and anogenital intraepithelial neoplasias with CO2 laser or electrosurgical procedures (local exhaust ventilation- smoke evacuator)

Anal Cancer Screening

Primary Prevention

- HPV vaccination of MSM 4v or 9v
- 3 dose schedule

Secondary Prevention

- Anal cytology in high risk populations
- High risk HPV tests not clinically useful (high HPV prevalence)
- No studies have shown that treatment of anal HSIL reduces the incidence of anal cancer

T vaginalis

- Testing in women with vaginal discharge
- Consider screening in high prevalence settings (STD clinics, corrections) or asymptomatic persons at high risk of infection
 - Lack data on screening/treatment reduces adverse health events or reduces community burden of infection
- Diagnostic testing (nucleic acid amplifications test)
 - APTIMA T vaginalis; BD Probe Tec TV Qx amplified DNA Assay
 - A molecular test-resolved algorithm (negative wet prep followed by NAAT)
- Retesting 3 months after treatment
- Treatment, Metronidazole or Tinidazole 2 gm
- Management of persistent infection (resistance)

T vaginalis and HIV infection

- Women should receive screening at entry to care and annually if sexually active
 - Associated with PID
 - Treatment reduces genital HIV shedding
- Longer treatment course better in women
 - metronidazole 500mg BID x7d
 - Potential factors- bacterial vaginosis, antiretrovirals, vaginal ecology
- No data to recommend extended treatment in men
- Retesting 3 months after treatment

Bacterial Vaginosis

Treatment- metronidazole oral or gel, clindamycin cream

Recurrent BV

- Biweekly suppressive MTZ gel (RCT) for 4-6 mo
- Oral metronidazole followed by boric acid and suppressive metrogel
- Metronidazole (10-14 days with vaginal gel or oral tablets) or a weeklong course of oral tinidazole (limited data)
- No data on suppressive tinidazole, oral clindamycin/vaginal cream
- No support of any available probiotic as adjunctive or replacement therapy to antibiotics in BV

Awaiting more data

- Vitamin D, contraceptives and BV risk
- L. crispatus vaginal capsule (LACTIN-V) for prevention

Sexual Assault in Adults

Initial exam individualized

- Nucleic acid amplification test (gonorrhea/chlamydia) and test for trichomonas
- HIV, syphilis, hepatitis B

Prophylaxis

- Empiric treatment for gonorrhea, chlamydia, trichomonas
- Emergency contraception
- Post exposure hepatitis B vaccination
- HPV vaccination
- HIV Post exposure prophylaxis according to risk





2015 STD Treatment Guidelines Resources

- The 2015 Guidelines updates the previous 2010 Guidelines with new STD diagnostic, treatment, and prevention recommendations
- Print the full MMWR, Evidence Tables,
 Screening Recommendations, and wall chart now, at www.cdc.gov/std/tg2015
- Limited copies of the MMWR, pocket guide, and wall chart will be available for order this summer
- Updated STD Treatment Guide app for Apple and Android Devices will be available this summer



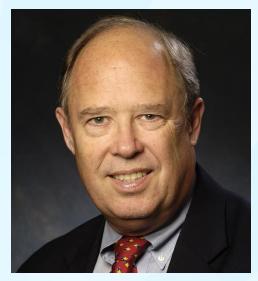
www.cdc.gov/std/treatment



Reminders

- Stay tuned for additional STD Treatment Guidelines Webinars in the future
 - www.nnptc.org
 - www.cdc.gov/std/treatment
- If you have questions about the 2015 STD Treatment Guidelines following the Webinar you may submit them to stdtraining@cdc.gov.

Questions and Answers



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Continuing Education Information

- Complete the CME evaluation for credit
 - Instructions are available at http://www.cdc.gov/std/training/webinars.htm

- To receive CE credit, an evaluation must be completed at CDC's Training and Continuing Education Online site: http://www2a.cdc.gov/TCEOnline/.
- If you have not previously registered as a participant on the CDC Training and Continuing Education Online site, click on New Participant to create a user ID and password; otherwise click on Participant Login.

- Once logged on to the CDC Training and Continuing Education Online site, you will be on the *Participant Services* page. Click on *Search* and *Register*.
- For those viewing the webinar between June 22, and July 22, 2015 enter EC1956 into the Keyword Search box and then click on View.
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- Select the title of the webinar that you viewed. The course information page will come up. Scroll down to the *Register* Here section of the page.
- Click on the type of continuing education credit that you would like to receive and then Submit.
- Complete and Submit the demographic questions. A message will come up thanking you for registering for the course.
- Complete and Submit the post-test and the evaluation.

- A record of your course completion and your CE certificate will be located in the *Transcript and Certificate* section of the *Participant Services* page.
- Print out a copy of your certificate and send it to the appropriate accrediting agency (ACCME, ACPE, ANCC, NCHEC, etc.) so that they will have a record of your certificate.





For more information please contact Centers for Disease Control and Prevention

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