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: AstraZeneca, 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.
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IACET Continuing Education Units (CEU):

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Continuing Education Accreditation (cont’d)

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- 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.
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 (STDCCCN)

- 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.STDCCCN.org/](https://www.STDCCCN.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
8 Regional PTCs

STD Clinical Prevention Training Centers

University of Washington PTC
Denver PTC
St. Louis PTC
California PTC
AL/NC PTC
New York City PTC
PTC at Johns Hopkins
Ratelle PTC
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

Satterwhite et al, 2013; Owusu-Edusei et al, 2013
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


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

Enlistment of Subject Matter Expert

Key Questions

Systematic Review of Evidence

Tables of evidence

Background papers

Guidelines 3 day Meeting April 2013

Answer the “Key Questions”

Rate the quality of the evidence USPSTF ratings

Identify critical gaps in knowledge (research agenda)

2015 Guidelines
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 $\geq 2 \text{ WBCs, methylene blue or gentian violet}$ 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 MIC$_{90}$ 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 azithromycin *in vitro*
  - Gemifloxacin more active against cipro resistance or GyrA and ParC mutations

<table>
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<tr>
<th></th>
<th>Gentamicin / Azithromycin</th>
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<tr>
<td></td>
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<td>% (L 95% CI)</td>
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<td>202/202</td>
<td>100% (98.5%)</td>
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<tr>
<td>Pharynx</td>
<td>10/10</td>
<td>100%</td>
</tr>
<tr>
<td>Rectum</td>
<td>1/1</td>
<td>100%</td>
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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 IM + 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 marginally 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
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)
  - 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.

If incubating or primary syphilis is suspected, treat with benzathine penicillin G 2.4 million units IM x 1 and/or repeat in 2-4 weeks.

If at risk for syphilis, repeat RPR in 2 to 4 weeks.
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.

* Marra 2004; Libois A, *STD* 2007; Ghanem CID; Marra CID 2008
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
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

*Vaccination series can be started at 9 years of age  
MMWR 2015;64:300-4
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
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](http://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.
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Jeanne Marrazzo, MD, MPH

- Professor, University of Washington Division of Allergy & Infectious Diseases
- Medical Director, University of Washington’s STD Prevention Training Center
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- Complete the CME evaluation for credit
  - Instructions are available at http://www.cdc.gov/std/training/webinars.htm
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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.

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- 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.

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