

HCET
ARH Series Part II - STD Updates

Good morning, and welcome to the second of five free webinars on Adolescent Reproductive Health: Focus on Indiana. I'm Monique Hensley, Program Manager with Health Care Education and Training; and I'm pleased to welcome you all today. This webinar is sponsored by the New York City STD/HIV Prevention Training Center, the Indiana Chapter of the American Academy of Pediatrics, and Health Care Education and Training.

Today's webinar offers Continuing Medical Education credits for physicians and Continuing Nursing Education credits as well. This information will be sent to you at the conclusion of today's webinar. If you are interested in receiving this information when you receive your e-mail, please follow the instruction and you will be able to access that information.

If you have a question during the presentation, please feel free to send it to us. On this slide, you can see where we have our Chat feature. You can type your question into the Chat box, which is located within the sidebar as seen on this slide. Make sure the drop down menu is set to ask "All Panelists" and then hit Send. You can send in questions at any time during the presentations, and they will be answered during the Q&A period at the end of the webinar.

If you are accessing the audio portion of the presentation on your phone, your lines will be muted throughout the presentation. I would also recommend that if you are accessing via phone and your computer to turn down your speakers or only access it through your computer speakers so that you're not receiving feedback.

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It is with great pleasure that I introduce our two presenters for today's webinar. Dr. Weaver is an Assistant Professor of Clinical Medicine and Pediatrics at the Indiana University School of Medicine and Riley Hospital for Children. She is board certified in Internal Medicine, Pediatrics and Infectious Diseases. Her clinical work has been in inpatient and outpatient infectious diseases, consultations, and caring for adults and children living with HIV. Her research has included human papillomavirus in adolescent men and women, as well as STI prevention in adolescents and young adults.

Dr. Margaret Blythe is a Professor of Pediatrics and Adjunct Professor of Gynecology at the Indiana University School of Medicine and Riley Hospital for Children. She is board certified in Pediatrics and Adolescent Medicine. Her clinical work has been in general adolescent medicine, reproductive health care of young women and juvenile justice. Her research and publications have included the areas of reproductive health including menstrual disorders, contraception and sexually transmitted infections.

It is with great pleasure that I welcome you both, Dr. Weaver and Dr. Blythe. And I will now turn it over to you.

Thank you.

Thank you for joining us for Part II of the five-part webinar series focusing on issues related to the reproductive health of adolescents. The topic of this presentation is Screening and Treatment of Sexually Transmitted Infections as it relates to the care that primary care pediatricians may offer teens in Indiana.

Analysis of the National Ambulatory Medical Care Survey data indicates that the proportion of general office visits to general pediatricians has grown steadily over the last two decades. Thus, pediatricians are the most important health care providers that have opportunity to offer anticipatory guidance around the topic of reproductive health and provide routine screening for sexually-transmitted infections for teens.

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So our objectives today for the talk will include to know the Indiana law that addresses testing and treatment of sexually transmitted infections in minors; to discuss the incorporation of such testing into the medical home as recommended by the American Academy of Pediatrics as well as by other professional organizations such as the Centers for Disease Control or the CDC, the US Preventative Services Task Force and the National Committee for Quality Assurance.

As such, pediatricians should be familiar with the different STI testing modalities, especially Nucleic Acid Amplification Tests, or NAATS, and should understand how these tests can be used and why they are favored over other tests. Pediatricians should be aware that gonorrhea treatment guidelines have changed in response to increasing antibiotic resistance and that expedited partner therapy, or EPT, is potentially available to ensure partner treatment.

In Indiana, minors may consent for services if they are emancipated by the court, which is not a common practice and honestly requires an official legal judgment. Minors may consent if they are at least 14 years of age, can prove they are not dependent on and are living apart from parents or guardians. This generally fails proof of practice as parents will still claim their teens on their tax forms as exemptions even if the teens are living with others, have a job and totally providing their own support.

If an adolescent is married or has been a member of the armed services, they may consent to their own care. The only common scenario in which all minors may consent for care is for sexually-transmitted infections, whether within the context of a preventative health care visit or a problem-focused visit with symptoms and/or concerns about such infections.

Adolescents may consent for such STI services actually in every state, including Indiana, and the District of Columbia. And this is important as estimates indicate that U.S. youth, ages 15 to 24 years, account for approximately 25% of the sexually experienced population, but nearly 50% of all new sexually transmissible infections diagnosed each year.

Although adolescents should be encouraged to include parents or guardians in health care concerns or questions, many times it may not be possible, particularly around care indicated for these sensitive issues. And we know from surveys that teens have indicated they would forego accessing such services if having to disclose to parents or guardians.

So how does one incorporate STI testing and treatment into the medical home? AAP and its many collaborating partners have developed Bright Futures as a set of guidelines and recommendations for health promotion and preventative care for infants, children and teens. Bright Futures now serves as a template of services that should be provided for teens through the Affordable Care Act. There are visit forms especially developed for each age group, including teens and young adults. There are screening tools that address adolescent care including immunizations, substance abuse, and specifically one that addresses sexual health.

The beginning of the section in Bright Futures that addresses teen care indicates that a policy addressing confidentiality should be in place and clearly communicated to teens and their parents. As part of the policy, teens should be encouraged to have open communication with their parents. Yet on the other hand, parents should be encouraged to respect the confidential nature of their teens' conversations with their health care providers.

This topic was addressed in the first webcast. An example of setting policy is this handout that could be provided to both parents and the youth about the next upcoming well child visit. This allows questions and any potential concerns to be addressed before this type of care begins. The example included is available electronically upon request. The statistics here within the handout reflect the most recent youth risk behavior surveillance data from Indiana and indicate that over half of teens attending high school in Indiana have had sex.

Several of the recent guidelines published in the last three years by the American Academy of Pediatrics have included the gynecological visit, male sexual reproductive health, health care for youth in the

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Juvenile Justice System, care in school-based centers, emergency contraception, and office-based care for gay and lesbian youth. All of these have embedded within them the need to provide confidential care. Again, confidential care was one of the major topics discussed in the first of this webinar series, which occurred in October and has been archived for your convenience.

Different agencies and organizations have published recommendations for STI testing for adolescents. We will discuss the recommendations from the Centers for Disease Control and Prevention, the U.S. Preventative Services Task Force, and the National Committee for Quality Assurance. There is very little difference among these guidelines when it comes to testing females. The differences are in the recommendations for routinely screening males.

The CDC's most recent guidelines were published in 2010, but the recommendations on these slides also reflect updates that have occurred since then. For asymptomatic sexually active females under 25 years old, the CDC recommends chlamydia screening each year. Gonorrhea screening is recommended for the same group, females under 25, only if the patient is pregnant, lives in a highly endemic area, or has had a partner that has gonorrhea.

For males, chlamydia and gonorrhea screening is recommended for high-risk groups. Adolescents as a group are included in the definition of high risk, as well as males participating in Job Corps, those who are incarcerated, and men who have sex with men regardless of age.

The reasons for the recommendations to screen adolescents and high-risk groups are that these individuals have the highest rate of infection, many of which are asymptomatic. Any untreated infection in females can result in serious sequelae such as pelvic inflammatory disease, infertility, ectopic pregnancy and chronic pelvic pain.

Both gonorrhea and chlamydia screening should be accompanied by HIV and syphilis testing when the adolescents are asking to be tested for everything. According to the CDC, 13 to 29 year olds accounted for 39% of all new HIV infections in 2009; but persons aged 15 to 29 comprised only 21% of the U.S. population then. Young men who have sex with men are at increased risk for HIV. In 2009, they accounted for 27% of new HIV infections in the U.S. and 69% of new infections among 13 to 29 year olds.

HIV testing offers an opportunity to provide education to the adolescent about HIV transmission and prevention. Syphilis testing should also be performed for adolescents seeking STI screening, for men who have sex with men, and/or for those with risky behaviors such as exchanging sex for drugs or money. According to 2011 statistics from the CDC, the rates of primary and secondary syphilis are highest among 20 to 24 year olds.

The Affordable Care Act, or the ACA, has indicated that all preventative services which have A or B recommendation by the U.S. Preventative Services Task Force will be included as covered services retroactive as September 2010 for new plans, and subsequently in 2014 for other plans. The recommendation for screening young women for chlamydia is really very specific: all sexually active young women, 24 years and younger. But for gonorrhea, the recommendation is limited to those young women pregnant and those young women at increased risk, which is clinically interpreted as being a teen or young adult and/or living in a community where gonorrhea is prevalent.

For young women, as mentioned, screening for chlamydia and gonorrhea are cost-effective ways to prevent pelvic inflammatory disease. Estimates suggest that 10% to 20% of untreated chlamydia and gonorrhea can lead to pelvic inflammatory disease for women, which may lead to infertility for 20%, ectopic pregnancy for 9%, and chronic pelvic pain for 18% of those with PID. Any of these diagnoses certainly leads to much higher costs for care, both physically and emotionally.

For young men, the consequences to them of having untreated infection compared to being incorrectly diagnosed with these infections has not yet led to the recommended routine screening of asymptomatic males.

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The National Committee for Quality Assurance is a private, 501(c)(3), not-for-profit organization that holds health care plans accountable. Each year, they develop a set of more than 80 standards, referred to as the HEDIS measures that health care plans use to measure performance on important dimensions of care. More than 90% of U.S. health plans utilize these standards as tools to determine where they need to focus on improving the health of their participants. These measures are often derived from the U.S. Preventative Services Task Force Recommendations A or B.

Reporting data on chlamydia screening is available from 2011 and looks at chlamydia screening in young, sexually active women who are enrolled in both commercial plans and Medicaid Managed Care programs. Over the last decade, percentages have consistently increased but still need to improve. These sets of data suggest that female enrollees on commercial plans, regardless of age, have a lower likelihood of chlamydia screening than those enrolled in Medicaid. One stated concern has been the lack of confidentiality for enrollees on commercial plans through the provision of explanation of benefits, or EOBs, to the primary insured on the plan.

Regardless, screening for both groups needs to improve. In this effort, CDC will soon start testing a new approach of universal opt out chlamydia screening for teen and young adult women in the 15- to 24-year-old age group. Low screening rates, particularly for the younger age group undoubtedly reflect the fear of disclosing risk for such infections for a variety of reasons.

A great resource for you to have when testing and treating your patients is the CDC STD Treatment Guidelines. This evidence-based guideline is updated about every three years and is available in print, online, and as an app for your Smart phone or iPad.

The first step a pediatrician can take is to provide a confidential risk assessment if the adolescent so chooses. This would include details of the patient's sexual practices including age at first intercourse; number of sexual partners; if they have sex with males, females, or both; the types of sex including oral, vaginal and anal sex they have; use of barrier and hormonal contraception; prior STI testing and results; and history of sexual abuse. This allows for testing of all anatomic sites where sexual contact may result in infection.

There are multiple testing options to diagnosis both gonorrhea and chlamydia. Gram staining of male urethral specimens is very sensitive and specific for diagnosing gonorrhea in men with symptoms, such as discharge, but has lower sensitivity when it's used for asymptomatic screening – approximately 20%. Use of this technique is primarily limited to STD clinics. Gram staining can show the presence of white blood cells, supporting a diagnosis of NGU or non-gonococcal urethritis, but cannot diagnosis chlamydia specifically.

Culture has the advantage of providing the capability for antibiotic susceptibility testing and is recommended for children where sexual abuse is suspected. Enzyme immunoassays, or EIAs, and nucleic acid hybridization tests were the first type of test developed not requiring vital organisms. But the nucleic acid amplification tests, or NAATs, are preferred because they are more sensitive than other options. NAATs are the recommended tests for the detection of both gonorrhea and chlamydia in asymptomatic and symptomatic males and females.

For males, the preferred sample type is urine; and for females, the preferred sample type is a vaginal swab. Vaginal swabs are equal or superior to endocervical swabs and are superior to urine samples, depending on the study. These are easily collected or obtained, particularly if the female is instructed to self-swab. Female urine, while acceptable, may have reduced performance when compared to genital swab samples.

NAATs, the superior and recommended tests for both gonorrhea and chlamydia, are FDA cleared for endocervical, vaginal, male and female urine, and male urethral samples. They are not FDA cleared for rectal or pharyngeal specimens, but many local public health departments, hospitals and commercial laboratories use them. This is possible because these labs have obtained clinical laboratory improvement amendment, or CLIA waivers, to show that the lab can reliably perform this test.

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NAAT testing is considered superior, although sensitivity and specificity may vary according to the individual test. In general, all NAATs are considered superior to culture especially in the asymptomatic patient, which represents over 95% of the infected patients.

I mentioned a technique that can be offered to a teen or young adult, the opportunity to obtain self-collected samples. For females, self-collected vaginal swabs are generally considered more sensitive than urine samples and are well accepted by patients.

One of the most important changes to the CDC's most recently published STD Treatment Guidelines is the recommendation for dual therapy, two antibiotics for gonorrhea treatment. The reason for this recommendation is the evolution of resistant organisms over the last two decades or so. Information about susceptibility of gonorrhea to various antibiotics is obtained systematically by the Gonococcal Isolate Surveillance Project, or GISP, which was established in 1986. This program collects 25 gonorrhea isolates each month from men attending STD clinics in 28 cities. The emergence of fluoroquinolone resistance in the 1990s and early 2000s led to the removal of any fluoroquinolone from the first-line treatments recommended by the CDC. Additionally, over the last few years, organisms with decreased susceptibility to cephalosporin, such as oral cefixime, have been noted.

Last year, the CDC removed cefixime as a first-line treatment with notation made of increasing MICs for ceftriaxone. This means that the minimal inhibitory concentration of antibiotic needed to kill gonorrhea was increasing to the point where that it would be difficult to achieve high enough antibiotic levels in patients' bodies to treat their infections.

This figure shows the increasing percentage of isolates with elevated MICs on the Y axis, over time on the X axis for both cefixime in light blue and ceftriaxone in dark blue. Of note, a similar pattern was seen over time with the emergence of fluoroquinolone resistance. This data predicts resistance to cefixime occurring prior to resistance to ceftriaxone.

In an effort to slow the emergence of drug-resistant gonorrhea, the CDC recommends dual therapy for gonorrhea – two antibiotics instead of one. The current regimen recommended for the treatment of urogenital, pharyngeal and rectal gonorrhea is ceftriaxone, 250 mg in a single intramuscular dose plus azithromycin 1 g orally in a single dose; or doxycycline, 100 mg orally twice daily for seven days. Either azithromycin or doxycycline is recommended regardless of what a patient's chlamydia test shows. For example, if your patient has a positive urine gonorrhea NAAT and a negative urine chlamydia NAAT, that patient still receives ceftriaxone and either azithromycin or doxycycline.

You may recall that the dose of ceftriaxone for gonorrhea in the 2007 guidelines was 125 mg intramuscularly once, but is now 250 mg. Oral cefixime is no longer recommended as a first-line treatment for treating gonorrhea.

However, if ceftriaxone is not available for the treatment of urogenital or rectal gonorrhea, cefixime may be used with azithromycin or doxycycline. Cefixime is not an option for pharyngeal gonorrhea since it poorly penetrates the infected tissue. If the patient has a known severe cephalosporin allergy, 2 g of azithromycin in a single dose is recommended. If either of these second-line treatment is used, a test-of-cure one week after treatment is recommended. Ideally, this test-of-cure would be a culture so that if there is viable organism after treatment, susceptibility testing can be performed to guide retreatment. However, a NAAT can be performed and if positive, should then be followed up with a confirmatory culture. A test-of-cure is not recommended if the first-line treatment is used.

The recommended regimen for chlamydia has not changed. The recommended treatment is either azithromycin 1 g, given once, or seven days of doxycycline. There are alternative regimens listed on the slide if allergies to both of these medications are documented or if availability of these medications is an issue.

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Just an additional word about pharyngeal chlamydia -- the clinical significance of finding chlamydia in the throat and the transmissibility of such an infection is unclear. In addition, the efficacy of different antibiotic regimens in resolving pharyngeal chlamydia remains unknown. Thus, the current recommendation is to screen only for pharyngeal gonorrhea, as infection can be either symptomatic or asymptomatic and can lead to disseminated gonorrhea infection if untreated.

For follow-up care, the CDC STD Treatment Guidelines have increased their emphasis on tests of reinfection three months following initial diagnosis of gonorrhea or chlamydia. Rescreening three months after diagnosis and treatment is recommended for both of these. Retesting to see if an initial infection has been cured is only suggested for pregnant women or if compliance is an issue, if symptoms persist, or if reinfection may have occurred.

We will now discuss partner treatment and a rather new model of care now available for providers in Indiana. The CDC STD Treatment Guidelines recommend that all sex partners who have had contact with an infected patient in the preceding 60 days get evaluated and treated when a test is found to be positive for chlamydia and/or gonorrhea, the two infections we specifically discussed today, though clinically care of sexual partners may need to include sexual contact beyond the 60 day recommendation.

Routine care has been for patients to notify their partners of the infection or leave the task of notification of the partner to the local health department and hope the partner will access appropriate care, including testing and treatment. But we know that most often, particularly for male partners of females, they are asymptomatic; thus incorrectly feel they are not infected and not the source of the infection or frankly may not even understand how to access care.

One model of care that has been studied as expedited partner treatment is referred to as EPT. This means that the provider will write a prescription for the partner of the patient they are treating, or give the patient additional medicine for the patient to give to their partner without the partner being examined or being a person who has received care by that provider. The practice of EPT is allowable in 34 states, including Indiana.

This practice was first discussed in the literature from 2003 to 2005. The studies included the results of three randomized controlled clinical trials of patients mainly attending STD clinics. The patients enrolled in EPT were 20% less likely to have a repeat positive test for chlamydia on a follow-up test compared to those enrolled in routine care or partner notification and self-referral. The rates of repeat gonorrhea infections for the EPT arm of the study were even lower, at 50%. The studies only addressed those patients with diagnosed genital chlamydia and/or gonorrhea. The study results cannot be extended to other scenarios as clinical syndromes of NGU and PID that did not have the specific finding of one or both of these infections.

Also these studies addressed most often females who were in heterosexual relationships; and thus at the time, the results of these studies cannot be used as a treatment modality for homosexual relationships. We know still the best outcome is for the partner to get his or her own evaluation and treatment as a contact of another person with chlamydia or gonorrhea. Thus allow for education of the partner and a more thorough evaluation for other STDs.

We already mentioned that Indiana since 2011 is now one of 34 states allowing EPT. EPT is also potentially allowable in ten other states, as well as Puerto Rico and District of Columbia. But for six states -- Florida, Kentucky, Michigan, Ohio, Oklahoma, and West Virginia -- EPT is specifically not allowed. As mentioned, currently this practice is not recommended for men who have sex with men. The concern is the high rate of HIV among that group and missing the opportunity for screening and education.

On this slide, we've included the CDC website, the Indiana State Department of Health website, and the Indiana Standards of Professional Conduct which specifically includes the legislation allowing this practice.

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The specifics of EPT outlined by the State Department of Health include that the physician has to have examined one's own patient and done the testing. The next step is fairly simple in that the treatment of the patient and the partner should be in line with recommendations of the CDC, and that for partner management of the patient or the partner, both the patient and the partner should have been notified of the need to be treated.

And also for partner management, written materials to the partner include that a clinical evaluation for that partner is the most desirable modality of care. In other words, if that partner has a primary care provider, it's important to access care; that for the medications that are prescribed or provided, there are potential side effects and responses. The written materials also include fact sheets regarding the SDIs diagnosed, emergency contact information in case of allergic concerns, also that the patient should seek evaluation for any symptoms or signs that suggest complications; that being, testicular pain in men and pelvic or abdominal pain in women. Finally document in the patient's record should occur regarding the prescriptions given to the patient for the partner of the actual medications provided.

Again, materials provided by the State Board of Health actually include examples of inserts that might be included in a patient's chart regarding the care offered to the patient's partner or partners.

In summary, under the Affordable Care Act, screening and treatment for STIs should come without a deductible or copay. Indiana law allows minors to access STD care from pediatricians without parental permission. Also, it's important for providers to be aware of updated recommendations for screening and treatment for common sexually transmitted infections and to be knowledgeable about the legality of practicing expedited partner therapy, or EPT, in Indiana.

These are some guidelines and resources that may be helpful to you. Thank you very much.

Thank you, Dr. Weaver and Dr. Blythe.

We are going to open up for questions, and if you will remember to use the Question box located on the bottom right side of your screen. If you would just type your question into the Chat box, you make sure to use the Dropdown menu and that it is set to Ask All Panelists and hit Send, we will then go ahead and proceed with answering some questions.

It appears that our first question is: "Although the patient is a minor, may they consent to diagnosis and treatment; and can the parent be told of the results of the test?"

That's a good question, and this is Maggie. Actually, the patient is protected by the law for both not only screening but treatment. And the parents do not need to be knowledgeable about the fact the test was even done or that medications were given to that patient. I think the logistics of that sometimes is difficult; and so really as providers we have to process with patients, "How are you going to do this? How are you going to get to the pharmacy to pick up these prescriptions? How are you going to talk to your partner about these infections and make sure they take these medications?"

And so it's more than just screening and giving them medication by prescription. It's really a lot of discussion about negotiation of the way that you access care or the medicine. This is often the first time that minors have had to access care themselves. As we know, oftentimes parents or guardians are the ones who go to the pharmacy, pick up the prescriptions; so this is oftentimes the first time that they've this opportunity to access care in this way for themselves.

Okay, thank you. It appears that the next question is: "Can you discuss screening and testing of women for STDs that have had a hysterectomy?"

So this is Bree; this is Dr. Weaver. I'll take this question. That's an interesting question. We don't often see in our patient population adolescents or young adults who have had a hysterectomy, so this isn't something that we have as much experience with. However, if the woman for some reason has had a hysterectomy under the age of 25, the CDC screening recommendations would apply to her regardless of

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what surgery she's had. For older women who have had a hysterectomy, screening for STDs such as gonorrhea, chlamydia, syphilis, HIV, have to be taken on a case-by-case basis based on their risk – if they've had new partners, if they've had multiple partners, if they've exchanged sex for drugs or money. So they would have to be then reassessed based on their individual risk. So I think that's what you would have to do is look at the individual patient rather than whether or not they had had a hysterectomy.

Okay, thank you, Dr. Weaver. Another question that we have had submitted is: "Is EPT allowed for chlamydia or for gonorrhea or for both?"

I think it's specifically written for both. And so it affords us the opportunity to not only screen but screen appropriately, as Bree mentioned on her slides, of taking an appropriate history so we know where to screen. It's not unusual – in fact, if you look at survey data for teens, the percentage of teens who have experienced oral sex is actually higher than those who have experienced vaginal sex. So appropriate history taking is really important.

And kids are very savvy. I've been impressed as we talk to them that they know there's a risk for the behavior that they are having with their partner, but they also want to get appropriate care to make sure that they are not somehow being exposed to an infection that needs to be treated.

Wonderful, thank you.

And if anyone has any further questions, please feel free to submit them now.

There appear to be no more questions at this time. So we will go ahead and end the call.

Once again, Dr. Weaver and Dr. Blythe, thank you so much for your time. As I finish up these last few slides, if I happen to see any further questions come in, we can always address those.

The information on how to obtain CMEs and CNEs will be emailed to all of the participants after the webinar has concluded. If you are interested in receiving Continuing Education for this live activity, you must complete the online evaluation by December 4th of 2013.

This information will be archived, and this slide will actually give participants the information they need going forward if they want to see the archived webinar. If you happen to miss the deadline of December 4th for the live activity, you can receive your Continuing Education by accessing the archived webinar that was just shown.

And please join us for upcoming webinars or to view the archived webinars. The next webinar in our series is Providing Primary Care to GLTB Youth. This will be in December. The date for this webinar is to be announced soon, so please check back. Registration for this event will open when the date has been announced. You can find more information at this link for the New York City Training Center.

Thank you to everyone for your participation.

Thank you, Dr. Weaver and Dr. Blythe.

And have a great weekend.