

Implementation of Expedited Partner Therapy (EPT)

Joint Commission on Health Care Meeting
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Study Mandate

- House Joint Resolution 147 (Delegate Herring, 2012) directed the Joint Commission on Health Care to study options for implementing expedited partner therapy in the Commonwealth
 - The study resolution was left in the House Rules Committee, but agreed to by JCHC members

Study Mandate

- During the 2012 JCHC work plan meeting, members agreed to a guest presentation on EPT, possibly in lieu of further study by JCHC staff
 - Robin Hills, Clinical Assistant Professor at VCU's School of Nursing, gave the presentation at the September 18th Healthy Living/Health Services Subcommittee meeting
 - Three policy options were provided for consideration by JCHC members
 - Members voted to include a staff study on the implementation of expedited partner therapy in Virginia in the 2013 JCHC work plan

Background

- Gonorrhea and chlamydia are highly infectious and among the most common sexually transmitted diseases
- Chlamydia and gonorrhea infections in women can lead to serious consequences including pelvic inflammatory disease (PID), tubal factor infertility, ectopic pregnancy, and chronic pelvic pain
 - Effects are more closely linked to re-infection than to initial infection
- If left untreated, gonorrhea can cause epididymitis in men, a painful condition of the testicles that may lead to infertility; and it can affect the prostate gland and cause scarring in the urine canal
- In rare cases, gonorrhea can spread to the blood and cause disseminated gonococcal infection (DGI) which is usually characterized by arthritis, tenosynovitis, and/or dermatitis
- Untreated chlamydia and gonorrhea can increase a person's risk of acquiring or transmitting HIV

Source: www.cdc.gov/std

New Chlamydia Diagnoses in Virginia (2008-2012), and Percent of Diagnoses that are Repeat Infections (2012)

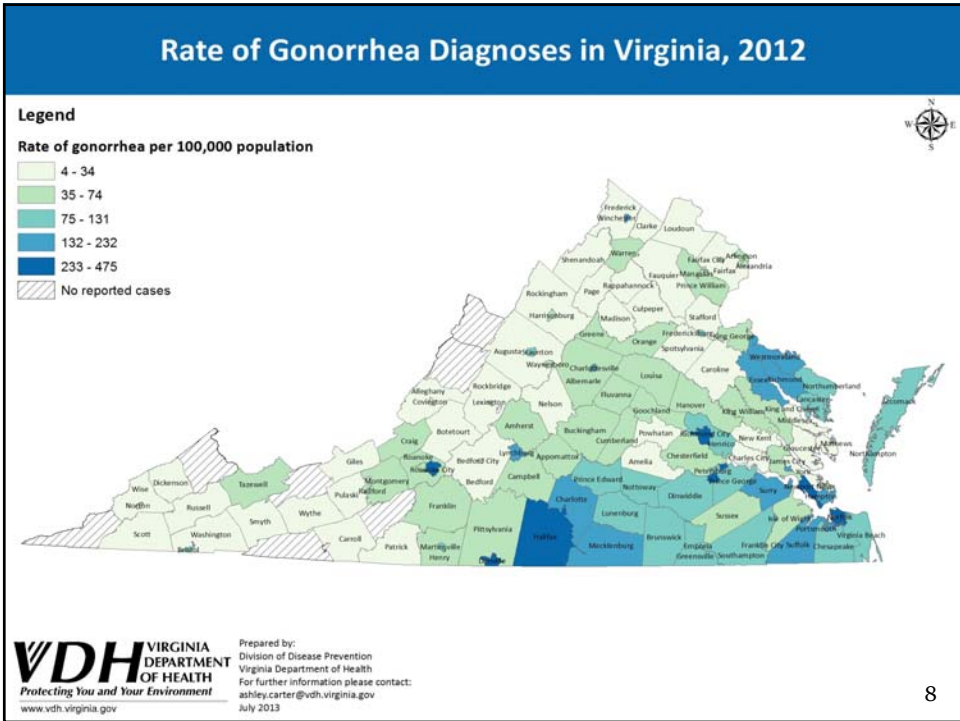
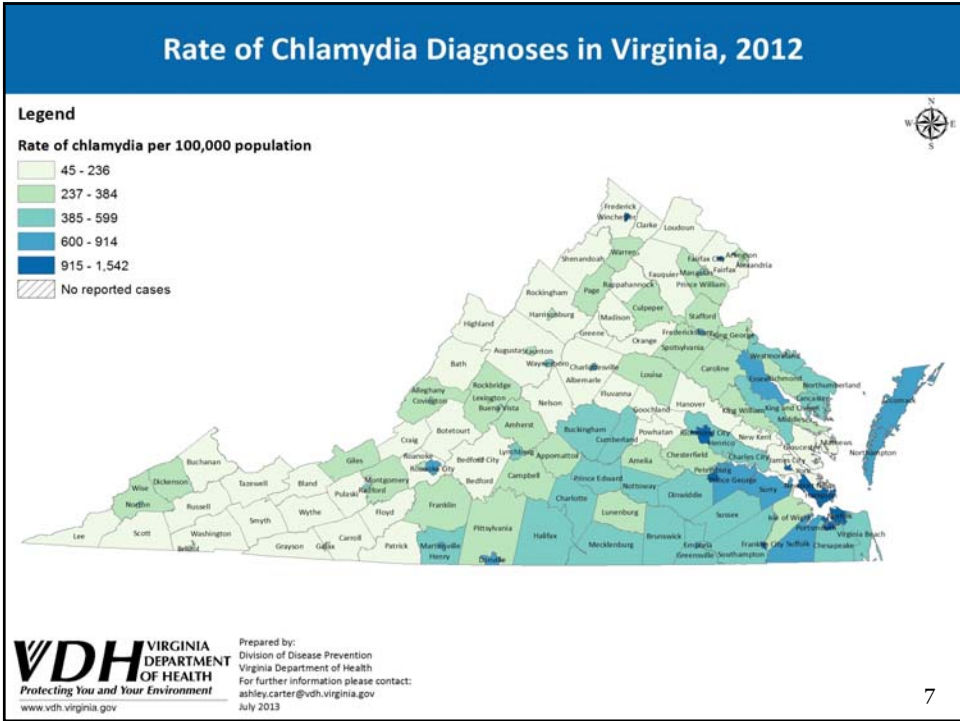
	New Diagnosed Cases					% Repeat Infections
	2008	2009	2010	2011	2012	2012
Male	8,042	8,391	8,576	9,704	10,149	7%
Female	22,286	22,756	22,818	25,146	24,431	14%
Unknown	48	63	48	96	43	2%
Total	30,376	31,210	31,442	34,946	34,623	12%

Source: Virginia Department of Health (VDH), data available as of July, 2013

New Gonorrhea Diagnoses in Virginia (2008-2012), and Percent of Diagnoses that are Repeat Infections (2012)

	New Diagnosed Cases					% Repeat Infections
	2008	2009	2010	2011	2012	2012
Male	4,381	3,472	3,152	2,861	3,095	8%
Female	5,655	4,326	4,004	3,722	3,678	8%
Unknown	9	10	5	13	6	0%
Total	10,045	7,808	7,161	6,596	6,779	8%

Source: VDH, data available as of July, 2013



Expedited Partner Therapy

- The clinical practice of treating the sex partners of patients diagnosed with chlamydia or gonorrhea by providing prescriptions or medications to the patient to take to his/her partner(s) without the health care provider first examining the partner

www.cdc.gov/ept

Expedited Partner Therapy

CDC Recommendations:

- Every effort should be made to ensure that a patient's sex partners from the past 60 days (or most recent sex partner if none in the previous 60 days) are evaluated by a health practitioner and treated with a recommended regimen of antibiotics
- However, if a partner of a patient cannot be linked to evaluation and treatment in a timely fashion, EPT should be considered, "as not treating partners is significantly more harmful than practicing EPT"

Source: www.cdc.gov/std

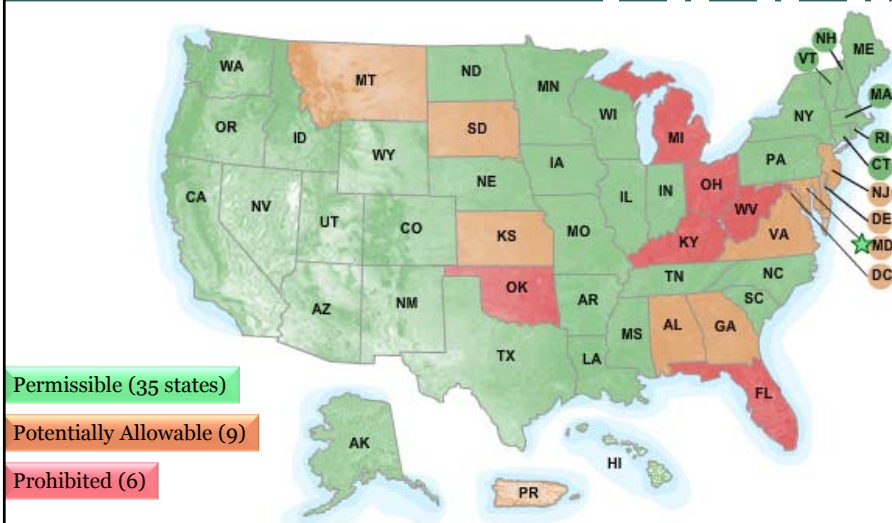
Expedited Partner Therapy

CDC Recommendations:

- The partner’s prescription or medication should be accompanied by an informational flyer containing:
 - Treatment instructions
 - Appropriate warnings about possible side effects and allergic reactions
 - Statement advising that the partner should seek personal medical evaluation, particularly women who are pregnant and individuals experiencing negative symptoms
 - Health education about STDs and counseling information
 - For gonorrhea, a recommendation that the partner receive a test-of-cure approximately one week after finishing medication
 - Information on where the partner can receive care if uninsured (i.e. local health department or STD clinic)

If EPT is approved, VDH would post English and Spanish versions of the informational flyers on the agency’s website for practitioner use

Legal Status of EPT as of August, 2013



Organizations that Support EPT

National

- U.S. Centers for Disease Control and Prevention
- American Medical Association
- American Congress of Obstetrics and Gynecology
- Society for Adolescent Health and Medicine
- American Academy of Pediatrics
- American Bar Association

Virginia

- American Academy of Pediatrics, Virginia Chapter
- Virginia College of Emergency Physicians

EPT Effectiveness

- Determining the effectiveness of EPT based on reductions in the rates of chlamydia and gonorrhea in states that legally allow the treatment is difficult given that increased efforts (including EPT) to reduce the rate of STDs in an area also results in an increase in the number of STDs reported, thereby masking or dampening any effect that EPT has on STD rates.
- However, in published clinical trials comparing EPT to traditional patient referral, EPT was associated with fewer persistent or recurrent infections in the index patient, and a larger reported number of partners treated

Source: "Expedited Partner Therapy for Adolescents Diagnosed with Chlamydia or Gonorrhea: A Position Paper of the Society for Adolescent Medicine." *Journal of Adolescent Health*, 45 (2009) 303-309. Also see: Mickiewicz, Theresa. 2012. "Implementation and Effectiveness of an Expedited Partner Therapy Program in an Urban Clinic." *Sexually Transmitted Diseases*. Vol. 39, Num. 12, December.

Antibiotic Resistant Strains of Gonorrhea

- The CDC continues to recommend EPT for gonorrhea when the partner is unlikely to seek treatment in a timely manner, “as not treating partners is significantly more harmful than is practicing EPT for gonorrhea”
- Currently, antibiotic resistant strains are primarily a problem in Europe, with the only a few cases in the U.S. being found in Hawaii

Antibiotic Resistant Strains of Gonorrhea

- The Gonococcal Isolate Surveillance Project (GISP) was established in 1986 to monitor trends in antibiotic resistant strains of gonorrhea in the United States in order to establish a rational basis for the selection of gonococcal therapies. GISP is a collaborative project among selected sexually transmitted disease (STD) clinics, five regional laboratories, and the Centers for Disease Control and Prevention (CDC).
- Richmond, Virginia is currently a sentinel site providing a mechanism to monitor for emergence of drug resistant strains. VDH is looking at additional strategies to continue this type of surveillance.

Side Effects & Allergic Reactions

- Serious adverse reactions are rare with recommended chlamydia and gonorrhea treatment regimens (Azythromycin & Cefixime)⁺
 - Anaphylaxis with cephalosporins is a rare event*
 - A recent review of cephalosporin use in penicillin-allergic patients found that there is no evidence of an increased risk of anaphylaxis with second- and third-generation cephalosporins that are used to treat gonorrhea among penicillin-allergic patients*
 - Transient gastrointestinal side effects are more common but rarely result in severe morbidity*

+Sources: Sources: 1. Adimora, A.A. 2002. "Treatment of Uncomplicated Genital Chlamydia Trachomatis Infections in Adults. *Journal of Clinical Infectious Diseases*. Vol. 35. Pgs 183-6. 2. Rubinstein E. 2001. "Comparative Safety of the Different Macrolides. *International Journal of Antimicrobial Agents*. Vol. 18. Pgs. 71-76. *Source: Pichichero, M.E. 2005. "A Review of Evidence Supporting the American Academy of Pediatrics Recommendation for Prescribing Cephalosporin Antibiotics for Penicillin-Allergic Patients." *Pediatrics*. Vol 115. Pgs. 1048-57.

Side Effects & Allergic Reactions

- "In EPT programs in which adverse events have been monitored since 2001, no drug-related adverse effects or lawsuits arising from the type of care have been documented"*
- All medications used in EPT include information about possible side effects and allergic reactions on the label
- An order can be placed on the prescription for the pharmacist to screen for drug allergies before dispensing medications

Source: **Expedited Partner Therapy for Adolescents Diagnosed with Chlamydia or Gonorrhea: A Position Paper of the Society for Adolescent Medicine." *Journal of Adolescent Health*, 45 (2009) 303-309.

Practitioner Responsibility & Liability

- If legalized, providers will have the *option*, but will not be legally required, to administer EPT
- Other states include liability protections for practitioners and pharmacists within the EPT Code section
 - Suggested language: *All health care providers involved in the prescribing or dispensing of Schedule VI antibiotics to partners under this section shall be immune from criminal and civil liability absent gross negligence or willful misconduct*

Estimate of State Cost for EPT

- Fiscal Impact Statement was completed in 2011 for HB 2083
 - In December 2010, the Department of Planning and Budget (DPB) conducted a survey of local health departments
 - Estimated that, if allowable, 30% of patients would be offered EPT, with an average of 1.3 partners per patient
 - Total estimated annual cost to VDH for EPT of Chlamydia and Gonorrhea: \$9,033
 - DPB determined that no General Funds would be necessary because VDH would absorb cost as part of clinic operations

DPB Estimate of Annual Cost to VDH for EPT (2010)

	Chlamydia	Gonorrhea
# Public Cases Treated in 2009	7768	2399
Estimated # of Partners Receiving EPT*	3029	936
CDC Recommended Regimen	Azythromycin 250mg x 4	Cefixime 400mg x 1
Cost per Treatment	\$0.85	\$6.90
Estimated Cost to Treat Partners via EPT	\$2,575	\$6,458

*Based on an estimated usage of EPT for 30% of public cases and an estimated average of 1.3 partners per case.

Source: 2011 Fiscal Impact Statement for HB 2083 by the Department of Planning and Budget

Estimate of Annual Cost to VDH for EPT (2012)

	Chlamydia	Gonorrhea
# Public Cases Treated in 2012 eligible for EPT	8,449	1,666
Estimated # of Partners Receiving EPT*	3,295	650
CDC Recommended Regimen	Azythromycin 1g x 1	Cefixime 400mg x 1 + Azythromycin 1g
Cost per Treatment	\$0.58	\$14.92 + \$0.58
Estimated Cost to Treat Partners via EPT	\$1,911	\$10,075

*Based on an estimated usage of EPT for 30% of public cases and an estimated average of 1.3 partners per case.

Source: VDH

Screening for Pregnancy & PID

- The CDC-recommended treatment regimens for pregnant women with chlamydia and/or gonorrhea are the same antibiotics that are recommended for EPT
- Practitioners typically do not test for pregnancy prior to prescribing antibiotics for chlamydia and gonorrhea for the index patient unless pregnancy is suspected (i.e. the patient indicates that she is/may be pregnant)
- As a precaution, educational materials provided to the partner include a statement that women experiencing symptoms of PID and/or that are pregnant should be seen by a provider prior to being treated for their STD

Potential Effect of EPT on STD Tracking

- According to VDH, averting infection and preventing re-infection are desired outcomes of EPT
 - A resulting decline in lab confirmed cases would potentially demonstrate this outcome and would not hamper STD control efforts
- Tracking is possible by creating a new field for the number of EPT prescriptions written
 - This would provide an account of EPT cases without counting them as “suspected” cases
 - Partner treatment would be noted in the index patient’s medical record

Treatment of Uninfected Partners

- According to VDH, while treating an uninfected partner has not been shown to contribute to antibiotic resistant gonorrhea, inadequately treating an infected partner may increase this risk. One rationale for EPT is to increase the number of partners who are adequately treated.

Policy Options

Option 1: Take no action

Option 2: Introduce legislation to amend § 54.1-3303 of the *Code of Virginia* to authorize the use of Expedited Partner Therapy to treat chlamydia and gonorrhea and to provide immunity from civil and criminal liability, absent gross negligence or willful misconduct, to health care providers involved in the prescribing or dispensing of Schedule VI antibiotics to partners under Expedited Partner Therapy

Public Comments

- Written public comments on the proposed options may be submitted to JCHC by close of business on October 8, 2013. Comments may be submitted via:
 - E-mail: sreid@jchc.virginia.gov
 - Facsimile: 804-786-5538 or
 - Mail to: Joint Commission on Health Care
P.O. Box 1322
Richmond, Virginia 23218
- Comments will be summarized and presented during the JCHC meeting on October 22nd

Internet Address

Visit the Joint Commission on Health Care website:
<http://jchc.virginia.gov>



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