

**EXPEDITED PARTNER THERAPY :**

GIVING ADOLESCENTS DIAGNOSED WITH STIs MEDICATION FOR THEIR PARTNERS:

- 1) Is this feasible?
- 2) Is this effective?
- 3) Will I go to jail?

Gale R Burstein, MD, MPH, FAAP, FSAHM  
 University at Buffalo Pediatrics Associates  
 Erie County Department of Health  
 Buffalo, NY

The short answer...

- Yes.
- Sometimes.
- Not if you do it right.

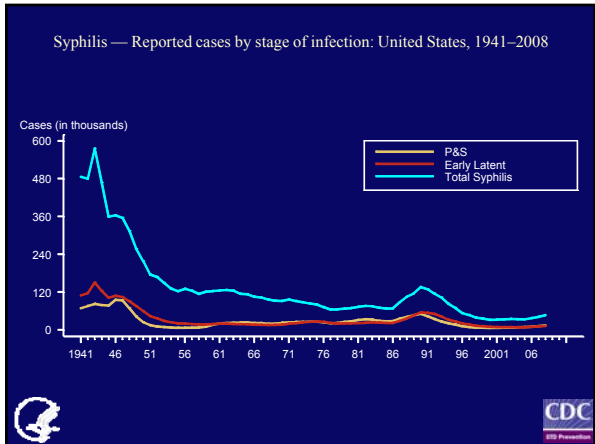
The Long Answer

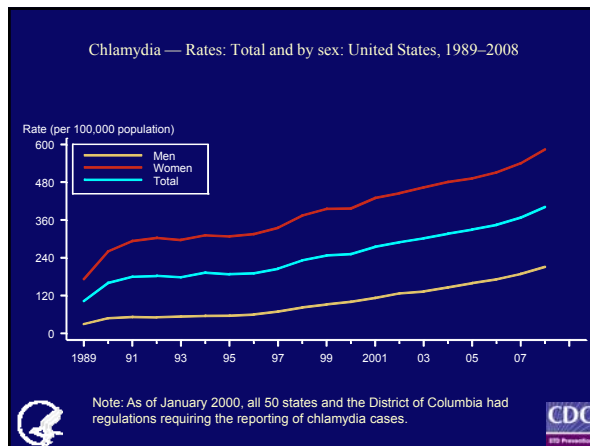
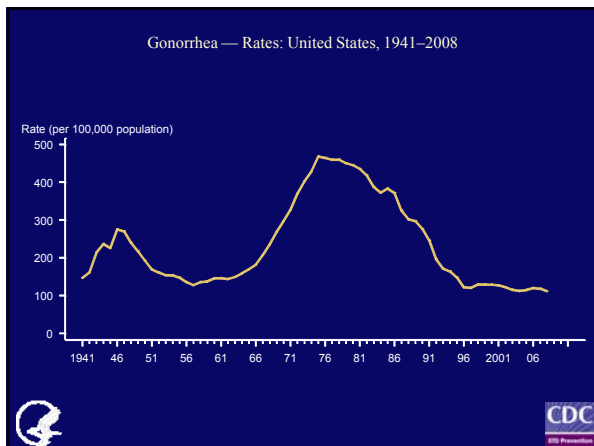
Treatment of STI-infected persons' sex partners

- Central component of prevention and control of bacterial STIs in the U.S. for six decades
- Treatment recommended for all sexually exposed partners within a specified time interval
- Initially developed for syphilis control
  - Now recommended for gonorrhea, chlamydia, and HIV infection

Traditional STI partner management strategies

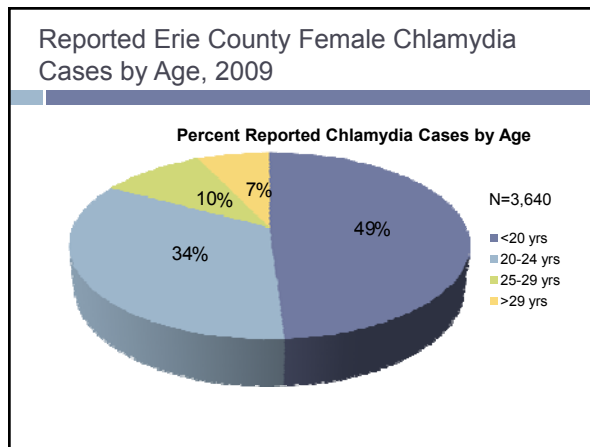
- *Provider Referral:* Partners directly contacted by index patient's provider or by a health department disease intervention specialist (DIS).
- *Patient Referral:* Index patient assumes primary responsibility to notify and refer his/her partners at risk.





### Reported Communicable Diseases, Erie County, 2009 (N= 7,186)

□ Chlamydia	4,979
□ Gonorrhea	1,406
□ All other 65 diseases	801



### EXPEDITED PARTNER THERAPY (EPT)

Treatment of sex partners without a prior health care provider exam or assessment.

- ### EPT Methods
- Patient-Delivered Partner Therapy:
    - Providers (1) give patients medication intended for the partners, or (2) prescribe extra doses of medication in the index patients' names, or (3) write partners prescriptions for medication
  - Partners collect medication at public health clinics or other venues
  - Public health workers deliver medication to partners in non-clinical settings

## EPT Effectiveness

- Published data
- Real time experience

### EPT for CT: infection rates at follow-up

- Multi-center, multi-venue, randomized clinical trial
- 728 women with CT randomized to PDPT; 726 to patient referral
- Rate of reinfection 20% lower in PDPT group (12% vs 15%, p=.102)

Schillinger et al., STD 2003 30:49-56

### Behaviors affecting EPT effectiveness

- EPT-specific
  - ▣ Patients did not give Rx to any/all partners
- General non-compliance
  - ▣ Patients noncompliant with Rx
  - ▣ Patients did not contact partner(s)
  - ▣ Partners noncompliant with Rx
  - ▣ Resumed sex <7 days after case and partner treatment
  - ▣ Sex with new partner(s)

### EPT for GC and CT: infection rates at follow-up

- RCT of EPT vs standard partner referral
- 929 pts in EPT arm vs 931 pts in standard referral arm
- ♂ & ♀ index cases
- Rate of reinfection lower in EPT groups
  - ▣ Not robust effect for CT

Golden, NEJM, 2005

### Persistent chlamydia infection

- At follow-up, among patients who denied sex after Rx in both study arms:
  - ▣ *C. trachomatis* infection found in 8% of ♀
  - ▣ *N. gonorrhoeae* found in 3% of ♀
  - ▣ No CT or GC infections were found among ♂
- Suggests that CT infection in ♀ may persist following Rx more frequently than GC

Golden, et al. NEJM 2005;352:676-685.

### Baltimore City Health Department EPT Experience: Effectiveness Data

- Implementation in January, 2009
  - ▣ STD clinics
  - ▣ Medications dispensed for GC/CT Rx
    - ▣ ≥3 extra dose/case
- Evaluation
  - ▣ Uptake = 1046/1533 (68%)
  - ▣ Modal extra doses: ♀ = 1; ♂ = 2
  - ▣ No adverse events
  - ▣ Repeat infection rate
    - ▣ 2.3% in 2008 (after EPT implemented)
    - ▣ 3.9% in 2007 (w/o EPT); p = .10
    - ▣ **41% reduction!!!**

## EPT Barriers

- Liability concerns
- Adverse drug effects
- Cost challenges
- Administrative challenges
- Missed Counseling and STI evaluation opportunities

## Liability Concerns

- Providers may *perceive* substantial legal liability risk from prescribing or dispensing antibiotics to pt's sexual partners to prevent GC or CT reinfection without a prior exam of those partners.
- *Perceptions may not match reality.*

## Liability Concerns

- A provider's duty of care is to prevent disease
  - ▣ Where EPT is legal a provider would not likely be considered negligent for practicing EPT when indicated
- However.....*
- If a provider neglected to offer EPT and pt develops multiple reinfections and chronic pelvic pain, infertility, or other sequelae....
  - ▣ provider could be found liable for negligence in failing to practice EPT

## Liability Concerns

- CDC, AMA, AAP and SAHM published guidelines\* recommend EPT when indicated
- American Bar Association\* supports CDC EPT guidelines and recommends removal of legal barriers
- In cases of medical liability, legal authorities would review these medical recommendations to determine whether EPT is practiced in a manner that is consistent with these guidelines.

\*Available at: [www.cdc.gov/std/ept/](http://www.cdc.gov/std/ept/)

## Liability Concerns

- In a litigious medical environment, providing any medical Rx to a patient who has not been evaluated or examined could be considered a medical liability risk for the treating provider.
- In EPT programs in which adverse events have been monitored since 2001, no drug-related adverse effects or lawsuits arising from this type of care have been documented.

## Liability Concerns

- Other precedents for cases where Rx is offered without prior medical examination.
  - ▣ Close contacts to meningococemia routinely prescribed prophylaxis antibiotics without clinical evaluation.
  - ▣ Influenza vaccine administered to persons without prior medical examination.
- In situations where a Rx medication is provided to exposed or at-risk persons to prevent illness, providers cannot be considered negligent.

### NYC healthcare providers STD partner management strategies

- Methods: cross-sectional survey
- Results (N= 695 respondents)
  - ▣ Frequent patient referral reported by 94%
  - ▣ Frequent provider referral reported by 20%
  - ▣ Overall 49% reported ever using PDPT
    - Peds = 50%
    - **OB/GYN= 62%**
    - IM = 53%
    - FM = 49%
  - ▣ 27% reported using PDPT frequently

Rogers ME., et al. *Sex Transm Dis* 2007;34:88-92.

### Adverse drug effects

- Adverse drug and allergic reactions in sexual partners treated without direct medical supervision are potential problems for all medications likely used for EPT
- However, serious adverse reactions are rare with recommended chlamydia and gonorrhea treatment regimens
  - i.e., doxycycline, azithromycin and cefixime
- Transient gastrointestinal side effects more common but rarely result in severe morbidity

Pichichero ME. *Pediatrics* 2005;115:1048-1057.

### Strategies to decrease adverse reaction risk

- Provide educational info with Rx regarding possible drug side effects
- Provide partners with tel # to call if experience severe adverse effects
- Order on prescription for pharmacist to screen for drug allergies before dispensing meds

### Cephalosporins use among penicillin-allergic

- Apprehension about dispensing cephalosporins to unexamined partners based on belief that penicillin-allergic patients may experience adverse drug reaction to cephalosporins
- No evidence of increased anaphylaxis risk with 2<sup>nd</sup> & 3<sup>rd</sup>-generation cephalosporins used to treat *N. gonorrhoeae* among penicillin-allergic patients
  - 1<sup>st</sup> generation cephalosporin package inserts suggest 10% cross-sensitivity risk as possible contraindication to cephalosporin use among penicillin-allergic patients
- Anaphylaxis with cephalosporins is a rare event

### Cost challenges

- EPT cost issues:
  - ▣ cost of the additional medication
  - ▣ reimbursement for time spent implementing EPT
- Currently no billing codes to cover expenses related to extra medication or counseling time for sexual partners

### Cost challenges

- Substantial number of adolescents and young adults uninsured
  - ▣ reimbursement opportunities for partner services are tenuous
- Providers can develop relationship with local STD clinic to develop strategy to treat all partners, regardless of insurance status
- Doxycycline costs \$4 at discount pharmacies

## Administrative challenges

- How to record medication dispensed or Rx provided to pts not directly under provider's care?
  - ▣ Maintaining medical records for all patients prescribed medication is standard of care
- In NYS EPT regulations, documenting partner name on Rx is not necessary
  - ▣ Providers can document # EPT Rx or med doses gave to pt in pt's medical record

## Missed care opportunities

- Missed STI coinfections
  - ▣ Counseling materials accompanying Rx or dispensed medication should encourage partners to receive complete STI evaluations despite receiving Tx
- Missed PID
  - ▣ Counseling materials should recommend females with abdominal pain seek medical care immediately
- Missed prevention counseling opportunity
  - ▣ Pharmacist may provide counseling when Rx is filled

## CDC GUIDANCE FOR EPT

- Ideal for STI contacts to receive comprehensive STI evaluation and treatment for exposure, but...
- When partners may not seek evaluation and treatment, providers should offer EPT to patients diagnosed with CT or GC
  - ▣ unless prohibited by state or local law
  - ▣ unless patients decline or indicate they are unlikely to deliver EPT
- Meds and Rx for EPT should be accompanied by
  - ▣ treatment instructions
  - ▣ appropriate warnings about taking medications if pregnant
  - ▣ general health counseling
  - ▣ advise that partners should seek medical evaluations, particularly ♀ with STD or PID symptoms

[www.cdc.gov/std/treatment/EPTFinalReport2006.pdf](http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf)

## EPT has potential role for Trichomonas

- Randomized trial to compare 3 partner strategies to prevent trichomonas reinfection (N=484 women)
  - ▣ self-referral of partners (PR)
  - ▣ partner-delivered therapy (PDPT)
  - ▣ public health disease intervention (DIS) locating partners and delivering medication in the field for partner notification

Schwebke JR, Desmond RA. *Sex Transm Dis* 2010;37:392-6.

## EPT for Trichomonas

- Initial cure rates = 95%.
- PDPT group had a lower repeat infection rate at 1 month f/u
  - ▣ 6% for PDPT
  - ▣ 15% for DIS
  - ▣ 12.5% for PR/DIS combined
- 80% in PDPT-arm reported delivering medication
  - ▣ 89% thought partners took medication
  - ▣ No serious adverse events reported

## CDC GUIDANCE FOR EPT

- No data support EPT for routine syphilis management
- No experience with EPT for GC or CT infection among MSM
  - ▣ data lacking on the efficacy among MSM
  - ▣ high risk of co-morbidity in partners, especially undiagnosed HIV infection

Resources at: [www.cdc.gov/std/ept](http://www.cdc.gov/std/ept)

#### EPT Resources from States

- [Illinois Department of Health EPT Resources](#) (29 January 2010)
- [Texas Department of State Health Services EPT Resources](#) (1 August 2008)
- [Guidelines for Expedited Partner Therapy](#) from New Mexico Department of Health (2 April 2008)
- [Background and Recommendations for Incorporating Patient-Delivered Partner Therapy \(PDPT\) by Health Care Providers](#) from Washington State Department of Health (20 February 2008)
- [Expedited Partner Therapy \(EPT\) for Chlamydia and Gonorrhea Infections](#) from Washington State Department of Health (20 February 2008)
- [Patient-Delivered Partner Therapy for Chlamydia trachomatis and Neisseria gonorrhoeae: Guidance for Medical Providers in California](#) California Department of Health Services STD Control Branch, March 27, 2007

#### Other Resources

- [A Position Paper of the Society for Adolescent Medicine](#) (29 January 2010)
- [American Bar Association resolution supporting removal of legal barriers to the provision of EPT](#) (15 August 2008)
- [Batling a Silent Enemy](#) (see pages 28-31) - An article on expedited partner therapy in the March edition of *State News*, a publication of CDC partner, The Council of State Governments. (22 March 2007)
- [American Medical Association Update on Expedited Partner Therapy \(Patient-delivered Partner Therapy\)](#) June 2006

## Conclusion

- STI Partner Services resources are very limited.
- EPT offers an opportunity to prevent reinfection in settings where partner(s) would otherwise not receive STI treatment.

NYS Public Health Law: EPT for *Chlamydia trachomatis*

- NYS Public Health Law
- “Expedited Partner Therapy” (“EPT”) means a practice whereby a health care practitioner chooses to provide a patient with either antibiotics or a written prescription for antibiotics for the sexual partner(s) to be delivered by the patient to the sexual partner(s) for treatment *Chlamydia trachomatis* exposure.

## Liability

- A health care practitioner who reasonably and in good faith **renders EPT in accordance with section 2312 of the Public Health Law** and this section, and a pharmacist who reasonably and in good faith dispenses drugs pursuant to a prescription written in accordance with section 2312 of the Public Health Law and this section, **shall not be subject to civil or criminal liability or be deemed to have engaged in unprofessional conduct.**

## EPT in NY State

- Officially legal to treat partners of chlamydia-infected patients with EPT on January 26, 2009 as per NYSDOH regulations
- NYSDOH posted proposed regulations on April 7, 2010 at:
  - <http://www.dos.state.ny.us/info/register/2010/apr7/pdfs/rules.pdf>
- 45 day comment period ended May 22, 2010

## Eligibility criteria for EPT

- Only for partner(s) of a patient diagnosed with *C. trachomatis* infection;
- **Not** for any partner(s) of patients who are gonorrhea or syphilis coinfectd

### Educational material requirements

- In addition to Abx or Rx, each patient provided with EPT must be given informational materials to give to his/her sexual partner(s)
- Each patient shall be counseled to inform partner(s) that it is important to read informational materials prior to taking meds
- NYSDOH developing provider, patient and partner informational materials that will be available on NYSDOH web site

### EPT Educational Materials and Counseling Messages

- Encourage partner(s) to seek complete STI evaluation regardless of whether take EPT meds;
- Disclose risks of potential adverse drug reactions, including allergic reactions, and dangerous drug interactions;
- Inform partner that he/she may be infected with other STIs that may not be treated by EPT meds;
- Inform partner that if Sx c/w more serious infxn (i.e., abdominal, pelvic, or testicular pain, fever, nausea or vomiting) he/she should seek medical care ASAP;
- Recommend that if partner may pregnant, should seek medical evaluation ASAP;
- Instruct patient and partner to abstain from sex for  $\geq 7$ days after both treated to decrease the risk of recurrent infection;
- Inform partner who is high risk of HIV that he/she should consult a health care practitioner for a complete medical evaluation including HIV and STI testing;
- Inform patient and partner how to prevent repeated chlamydia infection.

### Prescription format

- "EPT" must be written in the body of the Rx form above the med name and dosage for all Rx's issued;
- Name, address, and DOB of sexual partner should be written in the designated area of the prescription form; but...
- If sexual partner's name, address, and DOB are not available, the written designation "EPT" shall be sufficient for the pharmacist to fill the Rx.

### Providers reporting *C. trachomatis* cases

- Reports of *C. trachomatis* cases who are provided with EPT shall include the added designation of "EPT" and # of sexual partners for whom a Rx or meds was provided.

### What is next?

- Public Health Council needs to approve at July 23<sup>rd</sup> meeting →
- NYSDOH then needs to approve →
- Law and regulations is posted on State Register again →
- Becomes final two weeks later

### What is next?

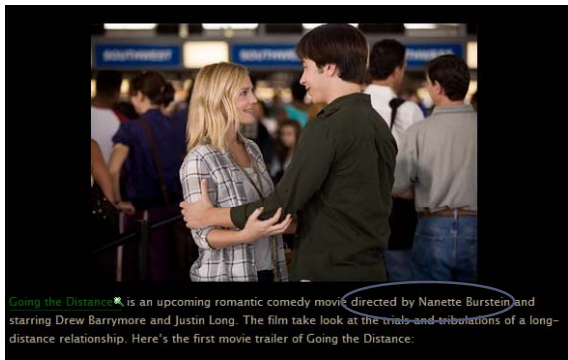
- NYSDOH will send out "Dear Colleague" letters to inform providers about EPT availability
- AAP NYS District II Planning dissemination strategy
  - Partner with NYSDOH and other NYS medical professional organizations
  - Developing EPT Fact Sheet
  - Webinar?

### What can you do?

- Ask a *confidential* sexual history of ALL adolescent patients
- Screen all sexually active adolescent females for chlamydia and gonorrhea
- Retest CT+ and GC+ patients
- Offer EPT for CT when available in NYS
- Become active in community and AAP chapter!

### Questions?

And now a commercial.....



Going the Distance is an upcoming romantic comedy movie directed by Nanette Burstein and starring Drew Barrymore and Justin Long. The film take look at the trials-and-tribulations of a long-distance relationship. Here's the first movie trailer of Going the Distance:

Coming to theaters on August 27, 2010!!!!

<http://going-the-distance.warnerbros.com/>