Expedited Partner Therapy for Chlamydia in New York State

What every pharmacist needs to know

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Todays talk

- Background
  - Expedited Partner Therapy (EPT) defined
  - *Chlamydia trachomatis*: biology/clinical manifestations, complications, epidemiology
- EPT, from concept to policy
  - Overview of traditional partner management strategies
  - Rationale for EPT
- What every New York State pharmacist needs to know
  - New York State EPT law, regulations
- Challenges to EPT implementation - pharmacy perspective

What is Expedited Partner Therapy (EPT)?

- A strategy for treating the sex partners of patients diagnosed w/ a sexually transmitted infection (STI)
- Clinician provides medication or prescription to patient, who brings it to his/her partner(s)
- Partner treatment given without the health care provider first examining the sex partner

What is the legal status of EPT in NYS?

EPT legal in NYS for *Chlamydia trachomatis* (Ct) only

- Law passed January 2009
- Regulations adopted October 2010
- Provider guidelines finalized March 2011

Chlamydia trachomatis
Biology, Genital tract infections

- Ct targets columnar epithelial cells
  - Conjunctivitis, pharyngitis, proctitis
- Genital tract infection
  - Lower genital tract: urethritis, cervicitis
  - Upper genital tract: epididymitis, salpingitis
  - Most genital infections are asymptomatic
  - Increases risk for HIV acquisition

Chlamydial infection Sequelae, adverse outcomes

- Sequelae: pelvic inflammatory disease, chronic pelvic pain, ectopic pregnancy, infertility

- Each repeat Ct infection ↑'s risk for sequelae
  - Repeated infection common
    - NYC: 25% 15-19 year old girls re-infected w/in one year
  - <50% of male partners get treated
  - Repeat infection often attributable to resuming sex w/ untreated sex partner

Chlamydial infection
Screening and treatment

National screening recommendations:

- Women: annual Ct screening for all sexually active women 15-25
- Men: Recommended only for males in certain venues/setting

Treatment:

- Single dose therapy: azithromycin 1 gram orally highly effective; no evidence of resistance

Epidemiology of *Chlamydia trachomatis* in New York City (NYC)

NYC Health

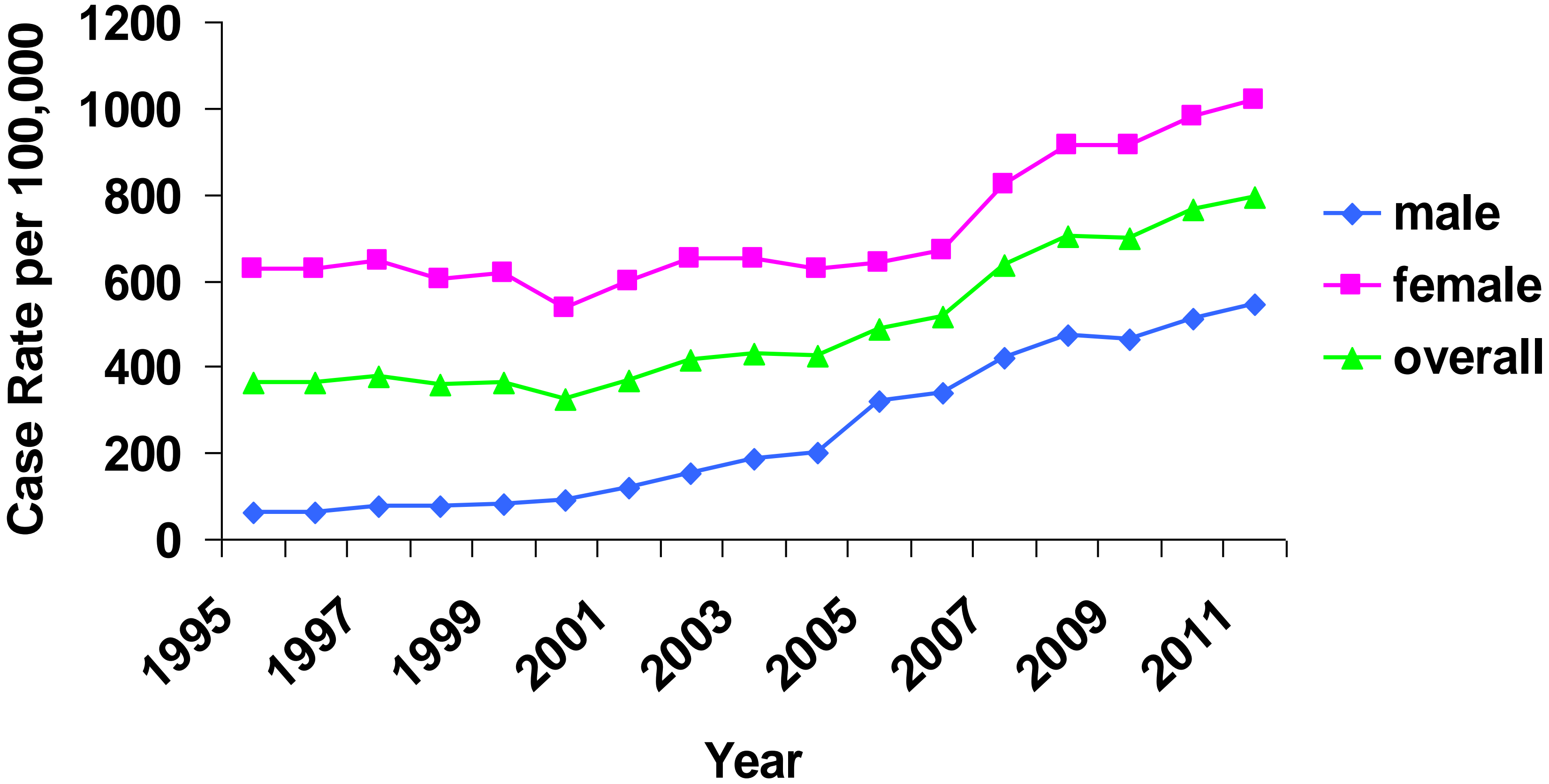
Chlamydia trachomatis
A reportable disease in NYS

- By law, Ct is a reportable disease in NYS, NYC
  - Laboratories report all positive Ct test results
  - Health care providers report diagnosed Ct

- Ct is highly prevalent
  - Most commonly reported disease in US, NYS, NYC
  - In NYC, 64,966 cases reported in 2011

- Majority of infections among adolescents, young adults
  - 69% female Ct is among 15-19, 20-24 year olds (55% male)
  - In NYC public high schools, ~7% girls tested are Ct infected

Chlamydia
Rates by Sex
New York City, 1995-2011



EPT; from concept to policy

NYC Health

Traditional partner management strategies *Provider referral*

- Definition: health care provider (or public health agency) takes responsibility for notifying sex partners; provider performs partner elicitation and notification
  - Most efficacious method of getting partners tx'd
  - Labor/resource intensive, requires special expertise
- National surveys – practiced by Health Depts for syphilis, HIV, sometimes gonorrhea
- Provider referral in NYC for Ct
  - DOHMH STD clinics: perform provider referral for Ct cases detected through HS Screening
  - 'Private providers' ~20% (80/401 surveyed) do provider referral frequently

Traditional partner management strategies
Patient (self) referral

- Definition: index (infected) patient given responsibility for contacting and notifying sex partner(s)
    - Less efficacious than provider referral
    - Most common strategy employed for Ct, GC

- Patient (self) referral in NYC for Ct
    - DOHMH STD clinics: all Ct cases dx'd in our clinics
    - 'Private providers': ~94% (368/393) do patient referral frequently

What is Expedited Partner Therapy (EPT)?

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- Partner treatment given without the health care provider first examining the sex partner

EPT – from concept to policy

- Studies demonstrated:
  - High rates of Ct re-infection in 4-6 mos after tx
  - Repeat Ct infection ↑ risk for PID/ other sequelae
  - Low tx rates for male partners to Ct
  - Most female re-infections attributable to resuming sex with an untx'd sex partner
- EPT practiced for decades for Trichomoniasis
- Observational studies suggested EPT for Ct effective in preventing Ct re-infection in women[1,2]

[1]Ramstedt K, Forssman L, Johannisson G. Contact tracing in the control of genital *Chlamydia trachomatis* infection. *Int J STD AIDS* 1991;2:116-8.
[2]Kissinger P, Brown R, Reed K, et al. Effectiveness of patient-delivered partner medication for preventing recurrent *Chlamydia trachomatis*. *Sex Transm Inf* 1998;74:331-3

RCTs: biologic outcomes

- Randomized controlled trials (RCT) in heterosexuals
- Compared EPT to routine patient (self) referral
- Main outcome: repeated Ct infection
  - Women with Ct[1]
  - Men & women with GC and/or Ct[2]
  - Men with non-gonococcal urethritis (NGU)[3]
- All 3 studies found lower rates of repeat CT infection among persons given EPT

1.Schillinger et al. Sex Trans Dis 2003. 30:49-56)
2.Golden et al. NEJM 2005. 352:676-85
3.Kissinger et al. Clin Infect Dis 2005; 41(5): 630-3

RCTs: behavioral Outcomes

- Patients in EPT arm reported higher or equivalent frequencies of partner notification and partner treatment
  - Increases proportion sex partners treated
- Lower frequencies of behaviors that could pose risk re-infection

CDC White Paper (2006), in brief

- Supports EPT for Chlamydia *and* Gonorrhea (NOT Trichomonas, NOT syphilis)
- Recommends for heterosexual population only

Concerns addressed in CDC White Paper

- EPT evaluated in select populations only
  - Not studied among men or women with same-sex sex partners
- STD co-morbidity in sex partners
  - Ct and *Trichomonas vaginalis* are most common STD diagnosed in sex partners to people with Ct
- Effect on antimicrobial resistance
  - Azithromycin given as EPT adds very small fraction to overall azithromycin use (~55 million doses prescribed in US/year)
- Adverse reactions to medication
  - Azithromycin well tolerated, adverse reactions rare
- Missed opportunities for prevention counseling
  - Partners willing, able to see health care provider should be encouraged to do so

National professional society endorsements

American Medical Association (June, 2006)

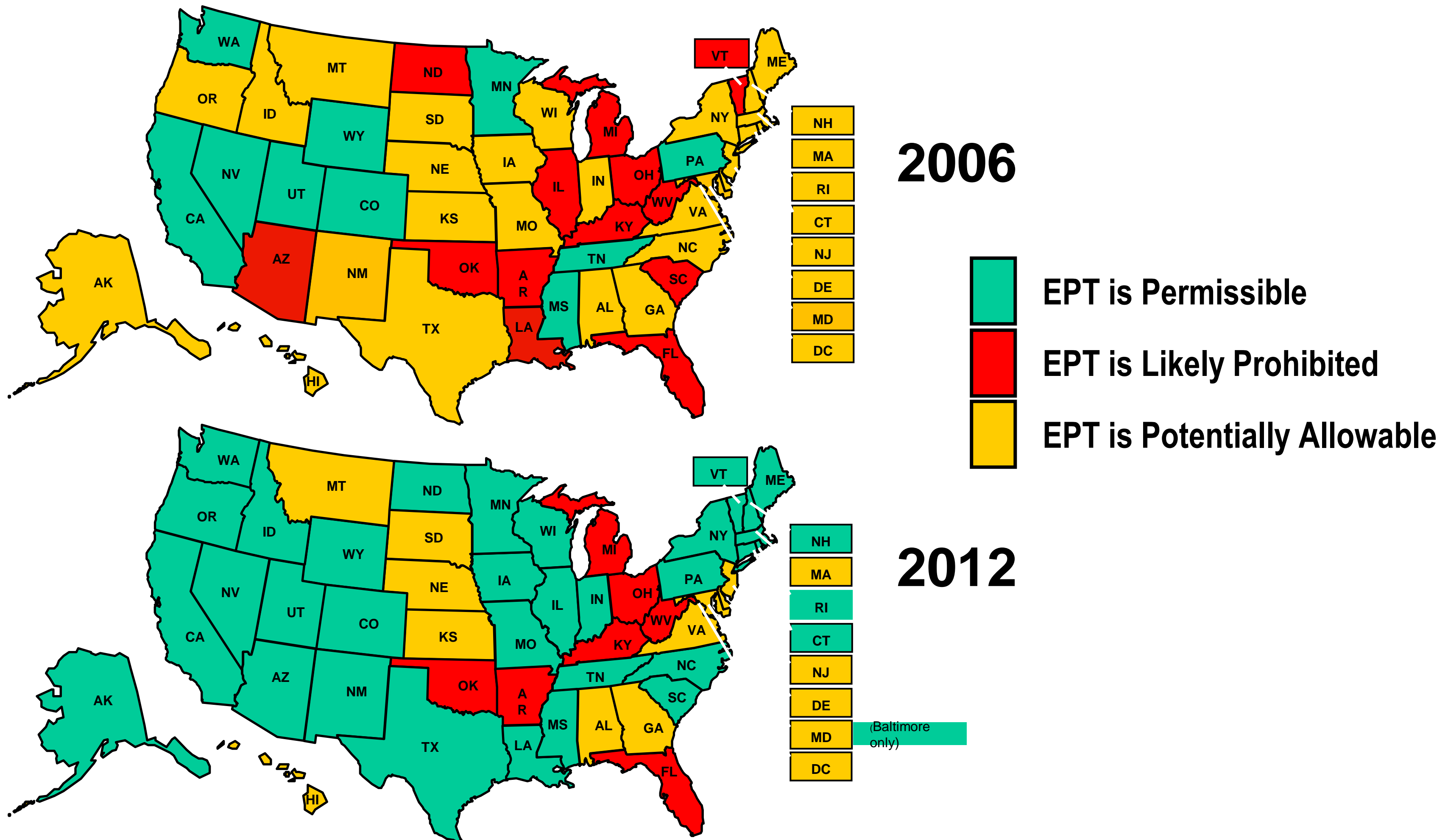
American Bar Association (August, 2008)

American Academy of Pediatrics (March, 2009)

Society for Adolescent Medicine (September, 2009)

American College of Obstetricians and Gynecologists (August, 2011)

Evolving Landscape of EPT: Legal Status Summary



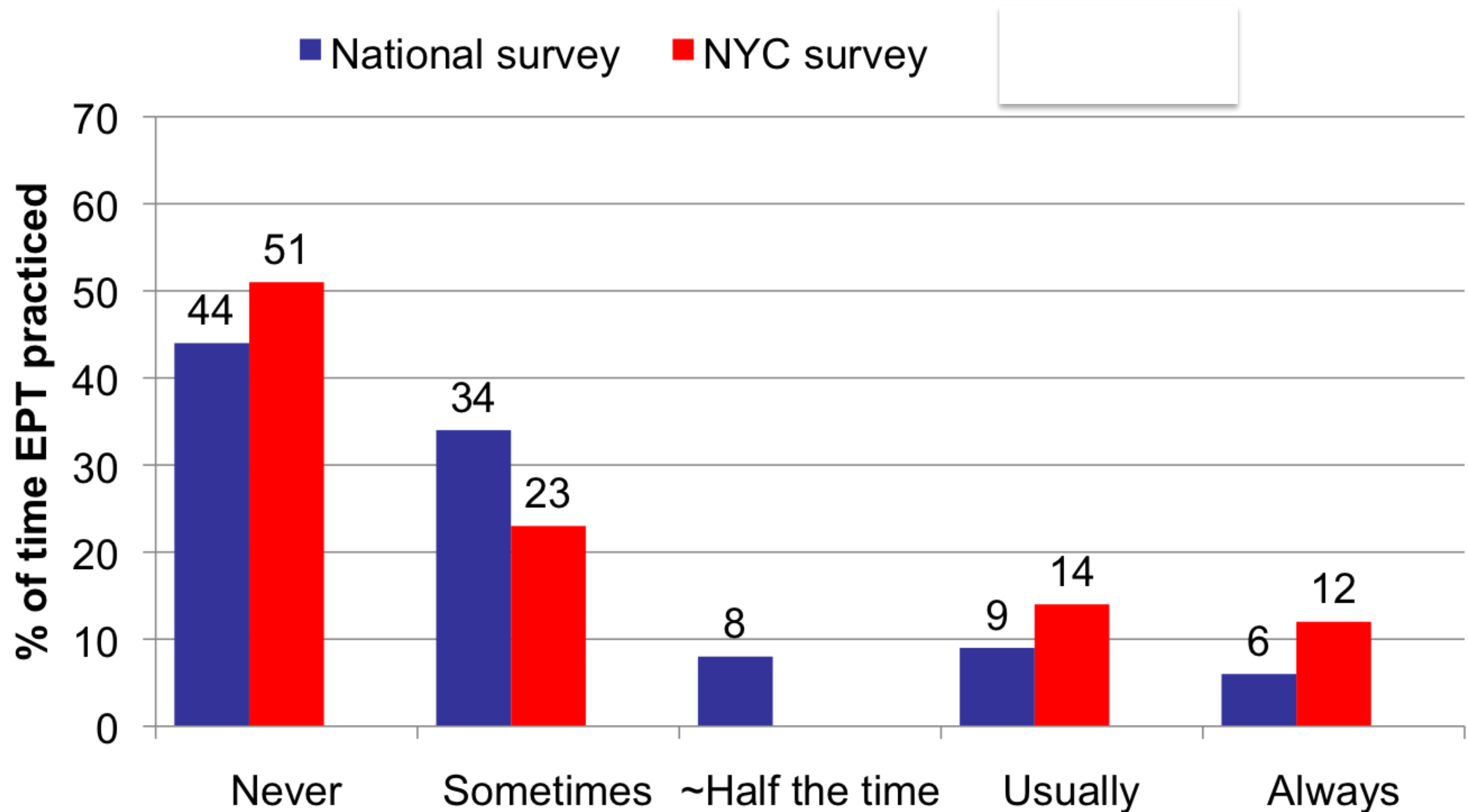
Legalizing EPT for Chlamydia in NY State; rationale

- RCTs show efficacy for reducing repeat infection
- High disease burden, limited resources
- Repeat infection common; inadequate partner management
- Asymptomatic - partners may not seek care
- Can be treated w/ single dose therapy (Azithromycin, 1 gram), which is well tolerated
- No evidence of Azithromycin-resistance

NYC Health

National v. local findings re MD practice of EPT:

% frequency with which MDs give Ct patients meds for sex partners



From: Hogben et al. Sex Transm Dis. 2005, and Rogers et al. STD. 2007.

What every NYS pharmacist needs to know about EPT

NYC Health

NYS EPT Law – 1

1. "….a health care practitioner who… diagnoses a sexually transmitted chlamydial infection in an individual patient may prescribe, dispense, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners without examination of that patient's partner or partners."

NYS EPT Law – 2

2. "A health care practitioner who reasonably and in good faith renders expedited partner therapy in accordance with this section and following the rules and regulations promulgated by the commissioner <u>shall not be subject to civil or criminal liability or be deemed to have engaged in unprofessional conduct.</u>"

NYS EPT Law – 3

3. "The commissioner shall promulgate rules and regulations concerning the implementation of this section and shall also develop forms for patients and their partners explaining expedited partner therapy for a chlamydia trachomatis infection. Such forms shall be written in a clear and coherent manner using words with common, everyday meanings."

NYS EPT Law – Sunset clause

"This act shall take effect on the one hundred twentieth day after is shall have become a law and shall expire and be deemed repealed January 1, 2014."

Summary of NYS EPT law

- Permissible for Ct only
- Ct may be lab-confirmed *or* presumptive/clinical dx
- Health care practitioner (HCP) may dispense medication, or prescription
- HCP protected from liability
- Regulations specify how to practice EPT
- EPT law expires 2014

NYS EPT regulations
Summary

- Do *not* use EPT if index patient co-infected w/ GC or syphilis
- Each patient being given medication or prescription for sex partners, must be given EPT informational materials to give to sex partner
- HCP must counsel patient to tell partner that it is important to read said materials before taking medication
- Specifies content of informational materials
- Prescription format for EPT
- Pharmacist may fill EPT prescription missing name, dob, address
- Pharmacists protected from liability

NYS EPT regulations
Informational materials for partner*

Materials shall:

(1) Encourage partner to consult HCP for full eval as preferred alternative to EPT & regardless of whether take med

(2) Disclose risk of potential adverse drug reactions/ interactions

(3) Inform partner possible co-morbidity - could go untx'd

(4) Inform partners - seek care if sx of more serious infection

(5) Recommend partner who could be pregnant consult HCP asap

(6) Instruct patient and partner to abstain >= 7 days after each tx'd to avoid reinfection

(7) Inform partner at high risk for HIV to consult HCP for full eval and HIV/STD testing

(8) Inform patient and partner how to avoid repeat Ct

*Informational materials available at: www.nyc.gov/health/ept

NYS EPT regulations
Prescription format

(1) Designation "EPT" must be written in body of script

(2) Name, address, DOB of sex partner should be written in designated section *if available*

NYS EPT regulations
Prescriptions missing patient name may be filled and dispensed by pharmacists

- If name, address, dob of sex partner not available, the written designation “EPT” *shall be sufficient* for a pharmacist to fill the prescription

NYS EPT regulations
Pharmacists protected from liability

"…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."

*Section 23.5 of Title 10 New York Codes, Rules and Regulations

Other prescribing and dispensing issues (not in NYS EPT law or regulations)

- Azithromycin 1 gram orally x 1 is recommended treatment regimen
- Allergies
  - partner allergic to azithromycin, erythromycin, clarithromycin, any macrolide or ketolide: *EPT should not be used (direct partner to HCP for alternative tx)*
- Potential drug interactions
  - if index patient suggests sex partner at risk for possible drug interactions w/ EPT med: *do not dispense. Partner should be referred to HCP.*

Other prescribing and dispensing issues (not in NYS EPT law or regulations)

- Separate prescription must be written for each partner
  - HCP should not prescribe for a partner by writing extra doses of medication on an index patient prescription

- Payment for EPT
  - By person picking up the medication or by sex partner's insurance or prescription plan
  - Pharmacists should not bill EPT under index patient's name

Other prescribing and dispensing issues (not in NYS EPT law or regulations)

- Record keeping for EPT prescriptions
  - File like prescriptions for any non-controlled substances

EPT is being prescribed in NYC
Survey of 52 health care providers diagnosing a high volume of Ct cases, 2011

Characteristic	**n/N**	**(%)**
Aware of EPT	44/52	(84)
Know EPT legal in NYS	41/44	(93)
Used EPT in 2011	28/44	(64)
By prescription	20/28	(71)

Survey conducted by Touro School of Pharmacy students Eileen Sordo and Christina Lau, 10/2011

EPT is being prescribed in NYC

Survey of federally qualified health center clinics in NYC; 41 clinics providing EPT, 2012

Characteristic	**n/N**	***(%)***
EPT is dispensed by prescription	38/41	*(93)*

~800,000 patient visits/year at these 38 clinics

Survey of 51 Federally Qualified Health Centers, 2012

Challenges to EPT implementation

Pharmacists not aware of the law

Addressing the gap:

- Partnered w/ Board of Pharmacy
- Article in professional org. newsletter
- Attend key NYS pharmacy conferences/meetings
- Outreach to Schools of Pharmacy (add to curriculum, email alum)
- Partnership w/ NYC-based School of Pharmacy
- Webinar offering continuing education credits

Challenges to EPT implementation

Electronic health records (EHR) systems will not generate prescription for person not in the EHR

Possible work around(s):

- dispense medication rather than prescription
- use conventional prescription pad
- create ‘dummy’ patient record for “EPT partner” and use when generating EPT prescriptions

Challenges to EPT implementation

E-prescribing systems cannot e-prescribe for person not in office EHR

Possible work around(s)

- dispense medication
- call in prescription
- e-prescribe from ‘dummy’ patient record

Challenges to EPT implementation

Prescriptions missing name – prescriptions cannot be entered into pharmacy software without name

Possible work around(s):

- Keep a log book of EPT prescriptions
- Enter into software using “EPT partner” as patient name, w/ an unique identifier (eg. “EPT partner – SM9271201”

Challenges to EPT implementation

Who will pay for partner treatment?

- Provider may dispense medication at no cost
- Medication may be “self-pay” (paid for by the person who picks up the prescription)
- Medication may be paid for by partner’s health insurance
  - billing sex partner’s medication under index patient’s name would be considered fraudulent

Summary - 1

- EPT is an effective partner management strategy, equivalent or superior to patient (self) referral
  - Decreases re-infection in index patient
  - Increases proportion sex partners tx'd
  - Gets tx to sex partners unlikely to seek care
- EPT for Chlamydia <u>legal</u> in NY State

Summary - 2

- NYS EPT regulations:
  - Contraindication to EPT - index patient co-infected with Ct and gonorrhea or syphilis
  - Specify that prescription must include “EPT”
  - pharmacist may fill, and dispense a prescription missing name, dob, address
  - Protect pharmacists from liability
  - Require that information for sex partners must be provided to patients given EPT

Summary - 3

- Pharmacist should not bill EPT under index patient name
- Obstacles to EPT use include:
  - Lack of awareness of law among pharmacists
  - Operational and technical issues, eg. how to fill and dispense prescriptions without name

On the horizon

- Survey of knowledge, attitudes, practice related to EPT among pharmacists in NYC neighborhoods with high Ct rates
- Sentinel surveillance in pharmacies receiving EPT prescriptions (EPT prescriptions received, filled, dispensed, number missing name?)
- EPT on legislative agenda

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Resources

NYC DOHMH EPT Webpage: www.nyc.gov/health/ept

Key materials available:

→ Law

→ Regulations

→ Dear colleague letter from Commissioners of Health

→ Provider guidelines

→ Pharmacist FAQ

→ Patient information

→ Partner information

→ EPT brochure for HCP

→ Links to other sites, including CDC, White paper

Questions

or

Comments?

Could EPT with azithromycin increase drug resistance?

Among Chlamydia?

- Chlamydial resistance to azithromycin is rare, if it occurs at all
- Azithromycin 1 gram is recommended treatment for Ct

Among other organisms, for example *Neisseria gonorrhoeae*?

- ~55 million prescriptions written each year in the US for azithromycin and other antibiotics in the same drug family.
- estimated 3 million US cases of CT
- If EPT was performed for each of those 3 million cases, the use of azithromycin would only increase by about 5%.
- In reality, EPT would be used only for a fraction of CT cases, so would have very little impact on overall antibiotic use.

Why is EPT not permitted for Gonorrhea in NY State?

- *At the time law developed*: recommended GC treatment regimens: cephalosporins (po, IM), alternative, azithro
- Significant concerns about oral cephalosporins for EPT
  - Anticipation that GC would develop drug resistance to cephalosporins
  - Potential for serious drug reaction
- Concerns about azithromycin 2 grams
  - Anticipation that G would develop drug resistance to azithromycin
  - Not well tolerated
- *Since 2010:* GC isolates showing decreased susceptibility to cephalosporins
  - In 2012, IM cephalosporins only recommended GC tx