

### October 17, 2017

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#### Agenda

- Didactic: Paul Pottinger, Fluoroquinolone Update
- Case Discussions
- Open Discussion

This presentation is intended for educational use only, and does not in any way constitute medical consultation or advice related to any specific patient.



### Fluoroquinolone Update

Paul Pottinger, MD, FIDSAAssociate ProfessorUW Medical Center &The University of Washington School of Medicine

October 17, 2017

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### Disclosures

 No financial conflicts of interest

 Everything we discuss is QI, thus protected from legal discovery under WA State Code



### Question...

Who has seen a toxic side effect of fluoroquinolones?

A. YepB. NopeC. I'm not sure...

Paul Pottinger MD

## **Heightened FQ Concern: Neuropathy**

Certain Antibiotics Spur Widening Reports of Severe Side Effects

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### HURT BY LEVAQUIN

#### BRAIN/BODY TOXIC DRUG

HOME	BLOG	PURPOSE OF BLOG	SIDE EFFECTS	MEDIA/NEWS	REFERENCES	LINKS	ADVOCACY	JOHNSON	& JOHNSON	
	I	HUR	Г	9		1	Welco After suffer through approximat three years daily pain fi antibiotic co	ing rely of rom an	Viy Web	osite
	E	BY	IINI				Levaquin, I decided to b	egin g my life in	LIFE BEFO LEVAQUI an effort to h	

If I can save just one person from having their life ruined as a result of Levaquin toxicity, then this blog will have served its

### www.levaquinadversesideeffect.com

purpose.

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## **Heightened FQ Concern: Neuropathy**

Certain Antibiotics Sour Widening Reports of Severe Side Effects

Blog

Alexander Shunnarah PERSONAL INJURY ATTORNEYS Over \$100 Million Recovered For Clients!

Attorneys

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rved Contact Us

Settlements

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#### Cipro

Home

**Cipro**, also known as Ciprofloxacin, is used to treat a number of infections which include the following: respiratory tract infections, urinary tract infections, gastroenteritis, bone and joint infections, among others. It is marketed by Bayer A.G. As a result of such adverse reactions, additional warnings, together with "dear doctor letters," and black box labels have been added. The FDA requested warning labels be added identifying peripheral neuropathy (irreversible nerve damage), and heart problems contributing to the severity of these reactions. Ciprofloxacin has generated billions of dollars in revenue. Bayer's gross sales of Cipro were approximately \$1.04 in 1999. A lawsuit was filed in 2003 involving postal workers against Bayer during the Anthrax scare in which the workers suffered serious side effects after being given Cipro. If you or a loved one took Cipro and need more information, **please call Alexander Shunnarah Personal Injury Attorneys today at 800-808-9083.** 

**Drugs Recalls** 



**Nursing Homes** 



"no 'common thread' of negative evidence that would lead the agency to remove quinolones from the market"

## FDA Black Box Warnings

- 2008: Tendonitis
- 2011: Myasthenia Gravis exacerbation
- 2013: Peripheral Neuropathy



Home > Drugs > Drug Safety and Availability



F

Musculoskeletal and Pe	Central Nervous System
Tendinitis	s Risk: 2.4 / 10,000 Anxiety
Tendon rupture	Depression
Numbness or tingling or ATR Ris	k: 1.2 / 10,000
Muscle weakness	Tendon Injury Risk
Muscle pain	Factors
Joint pain	✓ Advanced Age
Joint swelling	✓ Male Gender
Other Body Systems	✓ Low GFR
Worsening of myasthenia gravis	✓ Rheumatologic Dz
Skin rash	✓ Corticosteroid use
Sunburn	<ul> <li>✓ Hyperlipidemia</li> </ul>
Abnormal, rapid or strong heart beat	
Severe diarrhea	<ul> <li>✓ Hyperparathyroidism</li> </ul>
http://ww	w.fda.gov/Drugs 🗸 Physical Activity

"We have determined that fluoroguinolones" should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis, (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risk of these serious side effects generally outweighs the benefits in these patients. For some serious bacterial infections the benefits of fluoroquinolones outweigh the risks, and it is appropriate for them to remain available as a therapeutic option." – FDA, 5/12/16

Severe diarrhea

http://www.fda.gov/Drugs/DrugSafety/ucm511530.htm

# **Cystitis Recommendations**

- Nitrofurantoin (*Macrobid*) 100mg PO BID x 5 days (caution in pyelo, age > 65) OR
- TMP/SMX (*Bactrim*) resistance <20%: 1 DS PO BID x 3 days OR
- Fosfomycin (*Monurol*) 3gm PO x 1 dose (caution in pyelo!)
- TMP/SMX resistance >20%:
  - $\checkmark$  Cipro 500mg PO QD x 3 days *OR*
  - ✓ Cefpodoxime 100mg PO BID x 7 days

# Cystitis Recommendations

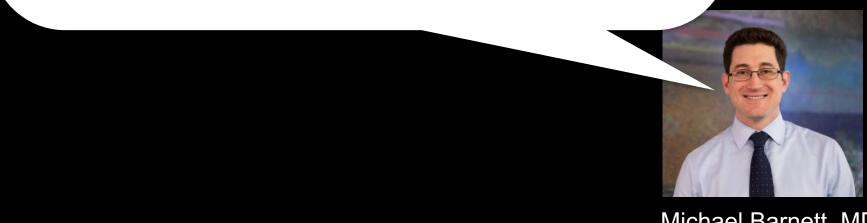
- Nitrofurantoi
   5 days (cau
   Puget Sound: ~20%
   Resistance
- TMP/S Modified IDSA recommendations soon?

O x 1 dose

stance <20%: 1

✓ Cipro 500mg PO QD x 3 days OR
 ✓ Cefpodoxime 100mg PO BID x 7 days

"Despite clear evidence, guidelines, quality measures and more than 15 years of educational efforts stating the antibiotic prescribing rate should be zero, the antibiotic prescribing rate for acute bronchitis is around 70%"



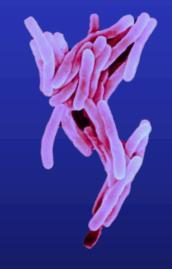
Michael Barnett, MD JAMA 2014



Your Suggestions for Provider Resources are Welcome!

# **BACTERIAL PATHOGENS IN ADULT RHINOSINUSITIS**

Pathogen	Incidence (%)
S.pneumoniae	41
H.influenzae	35
Anaerobes	7
Streptococci	7
M.catharralis	4
S.aureus	3
Other	4





# Abx Update 2017: Rhinosinusitis

- First-Line Empiric Abx
- Amox/clav 875-2,000 BID x 5-7 days

# Second-Line Empiric Abx

- Doxycycline 100 BID or
  - Levofloxacin 500 QD or Moxifloxacin 400 QD

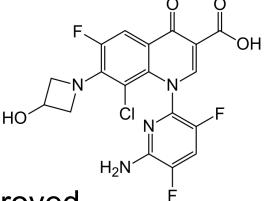
# No Longer Recommended

Azithromycin or TMP/SMX

**IDSA Gudielines April 2012** 

# Delafloxacin: New FQ

- Similar structure to Levofloxacin
- IV and PO formulations. Dose BID
- Approved for ABSSSI



- CAP and UTI indications not yet FDA approved
- Superior MRSA activity vs levo or moxi
- Not yet available... pricing unknown
- Carries **SAME black box warning** as other FQ's



### Conclusions

FQ Toxicity is Real Valuable class of abx... use them when you need to! ✓ Balancing toxicity with efficacy more important than ever ✓ Medicolegal burden now on us if we use for UTI or URI



Paul Pottinger MD