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Rx Focus

Antibiotic Abuse in the ER

Source: *Archives of Internal Medicine* 2003; 163: 601-605.

Roughly 80% of patients who are given fluoroquinolone antibiotics (Cipro®, Levaquin™) in emergency departments of academic medical centers are being treated improperly.

Researchers studied 100 patients at a tertiary-care hospital and at an urban community hospital. Of the 100 patients, 81 received a fluoroquinolone for an inappropriate indication. In more than half of these instances (43 patients, 53%), another agent had been considered firstline treatment (usually sulfamethoxazole-trimethoprim for urinary tract infection); in another third (27 patients, 33%), there was no evidence of infection based on the clinical evaluation or diagnostic studies; and in the rest (11 patients, 14%), evaluation was insufficient.

Even when the right drug was given, the dose and duration were often wrong. Of 19 instances in which the fluoroquinolone was given appropriately, only one patient received the right dose for the right duration. In general, when the dose and duration were incorrect, the dose was higher and the duration was longer than recommended by institutional guidelines. The most common example was an uncomplicated urinary tract infection that was treated for more than seven days or treated with levofloxacin injection (Levaquin™, Ortho-McNeil) 500 mg/day instead of 250 mg/day.

The researchers suggest that emergency department prescribers might be taking their patients' habits into account more than they should. For instance, knowing that many emergency-room patients don't have access to routine health care, some practitioners might be using broader-spectrum agents than necessary because of concerns that such patients will not follow up with their physicians for treatment. However, such assumptions can lead to other problems.

Multiple courses of fluoroquinolone antibiotics, for example, have been associated with resistance to these drugs. In addition, patients might be less likely to fill a prescription for the more expensive fluoroquinolone, increasing the chance that an infection will remain un-

treated. Finally, higher doses and longer durations of fluoroquinolone therapy have been associated with a greater risk of adverse events.



Industry Report

Lipitor Recall: On May 23rd the FDA announced a voluntary recall of 3 lots of popular cholesterol lowering medication Lipitor, repackaged by Med-Pro, Inc. The recall was issued due to evidence that suggest that the product in these lots might be counterfeit. On June, 9th an additional announcement was made to include all lots of Lipitor that were purchased by Albers and repackaged by Med-Pro. The patient's are advised to contact their pharmacies if they have received the recalled product.

Serevent: As part of phasing out all products that contain CFC (chlorofluorocarbons), GlaxoSmithKline has now ceased production and distribution of Serevent Inhalation Aerosol. Starting June 2003 the Aerosol may no longer be available and patients will be transitioning to the still available Serevent Diskus formulation or other equivalent products.



State & Federal Updates

On June 12th, 2003, the Food and Drug Administration (FDA) announced new regulations and review procedures to streamline the process for making safe, effective generic drugs available to consumers. The new rule will limit a drug company to only one 30-month "stay" of a generic drug's entry into the market for resolution of a patent challenge. The FDA is also implementing changes in its review procedures intended to help improve the speed and reduce the cost of determining that a new generic drug is safe and effective, and therefore can be made available to patients.

The changes in the regulations alone will save consumers an estimated \$35 billion over 10 years by making generic alternatives to certain more costly brand-name drugs available more quickly, by avoiding time-consuming legal delays. The improvements in the efficiency of review procedures, which will require changes by both FDA and

generic manufacturers to improve the review process, are expected to save consumers billions more by generally reducing the time for approving new generic drugs.



New Drug Approvals

InnoPran® XL Approved 3/12/03

Chemical Name: Propranolol HCL
Manufacturer: Reliant Pharmaceuticals
Therapeutic Class: Beta-Blocker - Cardiovascular
Approved Indications: Hypertension, Angina, Tremors, and Migraines
Other Drugs in Class: atenolol, propranolol, metoprolol.
Average Wholesale Price: \$1.18750 per unit

Oxytrol™ Approved 2/26/03

Chemical Name: Oxybutynin
Manufacturer: Watson Pharmaceuticals
Therapeutic Class: Urinary Incontinence Drugs
Approved Indications: Treatment of overactive bladder
Other Drugs in Class: Ditropan XL, Detrol, oxybutynin tablets.
Average Wholesale Price: \$10.235 per unit
Special Notes: Only transdermal in the market. Quantity limited to 8 patches every 30 days.

Vigamox™ Approved 4/15/03

Chemical Name: Moxifloxacin HCl 0.5%
Manufacturer: Alcon, Inc.
Therapeutic Class: Ophthalmic Antibiotic
Approved Indications: Bacterial Conjunctivitis
Other Drugs in Class: tobramycin, erythromycin
Average Wholesale Price: \$48.75 for a 3ml bottle

Fuzeon™ Approved 03/13/03

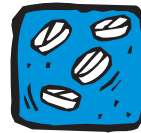
Chemical Name: Enfuvirtide
Manufacturer: Roche Pharmaceuticals
Therapeutic Class: Fusion Inhibitors
Approved Indications: Treatment of HIV in combination with other antiretroviral agents
Other Drugs in Class: None
Average Wholesale Price: \$2,082.29 per unit
Special Notes: CBCA Rx has implemented a prior authorization for all plans that cover HIV treatment. Please review the Rx Tidbits on Fuzeon released in May 2003.

Zymar™ Approved 03/28/03

Chemical Name: Gatifloxacin 0.3%
Manufacturer: Allergan
Therapeutic Class: Ophthalmic Antibiotic
Approved Indications: Bacterial Conjunctivitis
Other drugs in class: tobramycin, erythromycin
Average Wholesale Price: \$49.30 for a 5ml bottle

Femring™ Approved 03/20/03

Chemical Name: Estradiol Acetate
Manufacturer: Galen Ltd.
Therapeutic Class: Vaginal Estrogen Preparations
Approved Indications: Treatment of hot flashes and vaginal symptoms associated with menopause
Other drugs in class: Several estrogen tablets, patches and creams
Average Wholesale Price: \$95.63 per unit



New Generic Approvals

Hydrocodone Bitartrate / Ibuprofen: (4/11/03)

Brand name equivalent: Vicoprofen® Tablets
Manufacturer: Mylan

Taztia: (4/10/03)

Brand name Equivalent: Tiazac® Capsules
Manufacturer: Andrx

Brimonidine tartrate ophthalmic solution: (5/28/03)

Brand Name Equivalent: Alphagan Ophthalmic Solution
Manufacturer: Bausch & Lomb

Quinapril Hydrochloride: (5/30/03)

Brand Name Equivalent: Accupril Tablets
Manufacturer: Teva Pharmaceuticals



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