Pharmacy Newsletter

St Mary's Hospital

November 2010

Unprecedented Drug Shortages are Impacting Therapy

The year 2010 has seen an unprecedented number of drug shortages with approximately 140 medications currently on the American Society of Health-System Pharmacists' drug shortage list. Of particular concern is how many of the medications affected by the shortage are critically important medications. Everything from antibiotics to chemotherapy medications are in short supply and in some areas of the country routine procedures are being cancelled and regimens are being altered because necessary medications are unavailable.

When it is not possible to get a certain medication, alternatives must be used forcing healthcare providers to work with medications they are less familiar with. Healthcare providers are also forced to prioritize patients in terms of who has the most need for medications in short supply. There are many reasons a drug can become in short supply. A few of the more common reasons include: shortages in raw materials, company mergers that result in narrowing the focus of the medication line, voluntary recall, and FDA enforcement actions that halt medication manufacturing.

Many of these drug shortages come with little or no warning leaving healthcare providers scrambling to find acceptable alternatives. Manufacturers are only required to disclose the underlying cause of a shortage or notify the FDA regarding decisions to stop medication manufacturing if they are the sole provider of a medication and it is a medically necessary medication. Few manufacturers supply letters to healthcare providers regarding the reason for the shortage and also the anticipated duration. Generally, St. Mary's Pharmacy staff discovers there is a shortage only when the medication is not delivered. Once the shortage has been discovered several steps are taken including:

- Order the contracted medication direct from the company or other source
- Order a different dosage form of the contracted medication, i.e. vial, ampule, etc.
- Order the medication off-contract from another manufacturer
- Work with providers to determine a therapeutic equivalent
- Work with providers to prioritize the utilization of the medication
- Communication to all practitioners affected by the shortage

A considerable amount of time is spent by pharmacy staff continuously checking vendors for medications that are in short supply to try to maintain a sufficient amount. Often pharmacies are forced to purchase the medications from alternative vendors that can increase the cost of the medications five to ten times the original cost.

Unfortunately, there is little relief in site and since the FDA currently has no regulatory authority to proactively manage medication shortages it is an issue that will continue in the future. A current listing of drug shortages can be found on both the FDA website and the website for American Society of Health-Systems Pharmacists (ASHP). Any concerns regarding negative impacts on patient care as a result of a drug shortage, including near-misses, should be reported to the pharmacy department.

FDA website: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

ASHP website: http://www.ashp.org/shortages

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Pharmacy and Therapeutics Committee Actions

The Pharmacy and Therapeutics (P&T) Committee took action on the following items at the July and September 2010 meetings:

A Basal Bolus Insulin Protocol Development and Implementation Task Force was commissioned by the P&T Committee to institute a change in practice managing inpatient diabetics. The task force membership includes practitioners from Endocrinology, Hospitalists, Diabetic Nurse Educators, Nursing and Pharmacy. Progress will be reported at future P&T Committee meetings.

Approved the 2010 updates to the Antimicrobial Susceptibilities and Formulary Antibiotic Considerations documents which can be found on St. Mary's intranet under Clinical Resources. Annually, the microbiology lab reviews the antimicrobial susceptibilities of major pathogens ("antibiogram") at the Infectious Disease Working Group meeting. Complementing this review and any recently published infectious disease guidelines, pharmacy highlights changes in antibiotic prescribing in "Formulary Antibiotic Considerations".

- Cefoxitin is useful in surgical prophylaxis ; monotherapy treatment of intra-abdominal infection is discouraged due to increasing B. fragilis resistance
- B. fragilis and Prevotella sp are usually penicillin resistant. Clindamycin is demonstrating resistance; metronidazole, ertapenem, meropenem, and piperacilllin -tazobactam are drugs-of-choice.
- Quinolones (eg. moxifloxacin) as a class have potential for increased risk for QTc prolongation and infrequent cases of arrhythmias. Hypo- and hyper-glycemia are also side-effects.
- Increasing E. Coli resistance (~30 %) limits Unasyn's (ampicillin-sulbactam) usefulness. Ertapenem is better choice per IDSA guidelines for empiric therapy in intra-abdominal infections.
- Vancomycin isolates with an MIC ≥ 2 are currently considered susceptible but have an increased risk of clinical failure. An ID consult is strongly encouraged.

Drug Shortages

Furosemide (Lasix ®) IV has recently become part of a national shortage. An alternative alert in the electronic health record (EHR) has been activated to convert to IV bumetanide (Bumex ®).

The **Adult amino acids (Clinisol ®)** that are used to prepare 3 in 1 TPN solution are part of a recent shortage. The TPN Pharmacists in conjunction with the Clinical Dieticians are using a premixed Clinimix ® formulation in addition to the custom 3 in 1 TPN formulation to manage the shortage. The shortage is expected to last until the 1st quarter of 2011.

Succinylcholine is now part of a shortage. The pharmacy is working with the OR to limit the use to those cases where it is essential.

Clevidipine (Cleviprex ®) continues to be unavailable from the manufacturer. There has not been a confirmed release date.

Propofol (Diprivan®) continues to be in nationwide shortage. Manufacturers continue to work with the FDA, but cannot confirm a date when the shortage will be resolved. At this time, the pharmacy has been able to maintain a supply of propofol.

Please consult with your pharmacist if you have any questions related to drug shortages.

Advair® Therapeutic interchange

At the July 2010 Pharmacy & Therapeutics Committee meeting the therapeutic interchange of Advair HFA ® to Advair ® Diskus ® was approved. This interchange will be achieved by an alternate alert in EHR .

Product	*Total Daily Dosing Regimen*	*Current TOTAL daily dose*	*Formulary ITEM-ADVAIR DISKUS®*
Advair HFA® 45 mcg, 115 mcg, 230 mcg	Low	45mcg 1-2 puffs BID	100mcg 1 puff BID
	Medium	115 mcg 1-2 puffs BID	250 mcg 1 puff BID
	High	230 mcg 1-2 puffs BID	500 mcg 1 puff BID

Daptomycin Medication Use Evaluation

Daptomycin is an invaluable antibiotic used in the treatment of complicated skin / soft tissue infections, right-sided endocarditis, and bacteremia. In contrast to vancomycin, daptomycin is generally more rapidly bactericidal, dosed once daily, requires no drug level monitoring, and reduces the need for dosage adjustment in renal dysfunction. The primary concerns for daptomycin selection over vancomycin are the risk of bacterial resistance and increased patient cost of therapy (approximately $100 daily for vancomycin versus $1,000 for daptomycin).

Results and recommendations of medication use evaluation:

- Cellulitis (recurrent or rapidly progressive) is the primary indication in more than half of the patients
- Daptomycin can be ordered for moderate-severe cellulitis. Within 24 hours, an Infectious Disease consult is required.
- Infectious Disease involvement results in at least one day earlier transition to oral therapy.
- Seriously ill patients (eg. bacteremias, endocarditis) were transitioned to the ID Infusion Clinic to complete therapy. Length of stay was reduced (average 4 inpatient versus 16 outpatient days of treatment) with ID involvement.
- Potential levels / effects of daptomycin may be increased with concurrentstatin therapy. Alternatives to holding statin: monitor baseline CK; CK weekly levels; patient education on symptom monitoring.

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