P&T Update

Formulary Addition/Deletion

Oncology Subcommittee
Attending physicians authorized to write chemotherapy orders at UH- lists of physicians from various Departments/Divisions (Ophthalmology, Liver Transplant, OB/GYN and EENT) with privileges to write oncology medication orders were presented for member review and approval. – Approved

Gadoxetate disodium is an intravenous contrast agent FDA approved for use in T1-weighted MRI of the liver. Formulary addition of gadoxetate disodium – Approved

Thrombin (Thrombin-JMI®) formulary addition
Thrombin is a coagulation protein used topically as an aid to hemostasis whenever bleeding from capillaries and small venules is accessible. Thrombin products have been used during orthopedic, neurosurgical, and hepatobiliary surgical procedures. The hospital currently has recombinant thrombin (Recothrom®) as the formulary thrombin product. – Formulary addition of thrombin not deemed necessary at this time.

Daptomycin (Cubicin®) formulary addition
Daptomycin is a lipopeptide antibiotic that is FDA approved for the treatment of S. aureus bloodstream infections and complicated skin and skin structure infections. It is also used off-label in the management of other invasive infections (osteomyelitis, left sided endocarditis, etc.) due to S. aureus or Enterococcus species. The medication is currently used in the inpatient and outpatient settings as a non-formulary item. – Formulary addition of daptomycin approved as restricted medication requiring approval by an Infectious Diseases physician

Automatic therapeutic exchange policy revision
The automatic therapeutic exchange policy was updated to allow automatic substitution of dexlansoprazole (Dexilant®) to the formulary proton pump inhibitor of pantoprazole. – Approved

Multiple vitamin renal formulation (Nephrovite-Rx®) – formulary addition of renal MVI (Nephrovite-Rx®) – Approved. Auto-sub of all renal MVI to Nephrovite-Rx® – Approved. Deletion of Strovite® tabled

Insulin Detemir (Levemir®) formulary addition - Formulary addition of Insulin Detemir NOT approved at this time.

Policies & Procedures/Floorstocks
Automatic therapeutic exchange policy – revision. The automatic therapeutic exchange policy was updated to allow:

a. ALL adult renal vitamin auto-sub to Nephrovite-Rx® approved
b. Insulin glargine auto-sub to Insulin Detemir not approved

c. When IM/IV/subcutaneous narcotics pain meds ordered in conjunction with oral narcotics for pain to allow automatic additional comment to specify IM/IV/subcutaneous pain narcotic meds to be used “when pt is NPO, vomiting or experiencing refractory pain while on oral narcotic pain meds” not approved
Illicit prescription opioid use has become more prevalent than the use of methamphetamine, cocaine, and heroin combined. According to the 2008 National Survey on Drug Use and Health (NSDUH), 4.7 million individuals over the age of 12 reported using prescription opioids for recreational purposes.1 Most of the prescription opioids are formulated for oral use, but when they are abused, they are used intravenously or intranasally. While opioids are certainly abused by ingesting large amounts of the drug, a recent study has suggested that up to 40% of illicit opioid users have experimented with intravenous use.2 Current immediate-release formulations of oxycodone (Roxicodone®, OxyIR®, OxyFast®) can be crushed and snorted or crushed and dissolved to be injected. OxyContin®, a long-acting form of oxycodone, recently changed to a tamper-resistant formulation under the same name. Combination products containing oxycodone (Percocet®, Endocet®, etc.) are not as desirable because of the large amount of the other product in the formulation.

Oxecta® is a new formulation of oxycodone in an immediate-release tablet. It is considered to be tamper-resistant to discourage potential abusers. Oxecta® breaks into chunks instead of a powder if it is crushed and it turns into a gel when dissolved. To prevent intranasal use, it contains sodium laurel sulfate, which irritates the nose when snorted.3 There is still the potential for abuse with large doses of oxycodone ingested, however, niacin was added which will cause unpleasant skin flushing with higher doses.

Oxecta® is supplied as a 5 mg and 7.5 mg tablet and is indicated for the treatment of acute and chronic moderate to severe pain. Opioid-naïve patients should be started on a dose of 5 to 15 mg every 4 to 6 hours as needed for pain.4 Dose titration should be based upon patient response. Due to the formulation, Oxecta® should not be used in nasogastric, gastric or other feeding tubes. Oxecta® is contraindicated in patients with respiratory depression where resuscitation equipment is not available, paralytic ileus, known hypersensitivity, or severe bronchial asthma.4

Oxecta® provides a potential solution to the growing problem of opioid abuse. It was FDA approved in June 2011 and is set to be released in early 2012 for sale.

Author: Tyler McCamish, PharmD

Welcome Two New Pharmacists

Priscilla Phan, Pharm. D. is excited to join UMDNJ as a staff pharmacist. She graduated from Rutgers University in 2010 and was previously working in a community pharmacy. In her spare time, she enjoys cooking and outdoor activities.

Tyler McCamish, Pharm. D. started as a staff pharmacist at UMDNJ in September 2011. He obtained his Doctor of Pharmacy degree from Purdue University College of Pharmacy in West Lafayette, IN and moved to New Jersey shortly after graduation. Outside of work, he enjoys reading and doing mission work. He has been to Uganda, Africa and plans on going back in the near future.
Board Certified Pharmacotherapy Specialist Pharmacist
Mary Soliman, RPh, Pharm. D, BCPS

"Hello. This is Mary Soliman from Pharmacy. How can I help you?" is the response that is heard every time the former Five-Star and Employee of the Quarter picks up the phone. Many nurses may describe the sense of relief felt when they hear the voice of one of the kindest, sweetest, most professional and benevolent individuals in the pharmacy department. She goes above and beyond her abilities for each patient only to ensure the best patient care possible, always placing the lives of each patient before hers when on duty. This is not the first time Mary Soliman is featured in the Pharmacy Newsletter, for her accomplishments have granted her the spotlight many times. Thus on behalf of the Pharmacy Department, it is with great pleasure to commend Mary for her professional advancement and many amazing accomplishments that must not go unnoticed.

From the time when Mary first joined The University Hospital in 2008, she has always been a great asset to the Pharmacy Department. While exceeding all expectations at work, Mary has also focused on working toward reaching her biggest dreams of becoming a Clinical Pharmacist, and with such passion for the profession she has proven that nothing will stop her. For the past couple of years, the entire department has witnessed Mary working tirelessly beyond her abilities to obtain her Pharm. D while working full-time on the night shift. This past September, all of her dedication and efforts paid off when she was awarded her well deserved Doctorate in Pharmacy degree (Pharm. D) from the University of Massachusetts. But of course the Mary Soliman we all know and love sets her goals quite high and decided that the journey should not end just there. In October, she went a step further and obtained her certification to become a Board Certified Pharmacotherapy Specialist. This certification is usually essential for many Clinical Pharmacists as they are more clinically involved and responsible in direct patient care, often function as members of a multidisciplinary team, and are frequently the primary source of drug information for other healthcare professionals.

On behalf of the Pharmacy Department, it is more than an honor to congratulate Mary Soliman on these amazing professional milestones. We are truly grateful for such determination in continuing to pursue excellent advancement opportunities in her profession. She has accomplished a great deal while serving her patients with the utmost compassion and diligence. In addition, she has completed many clinical projects that have not only eased the workload on her colleagues in the Pharmacy Department but also alleviated many financial burdens. The successful outcomes on these projects only allow us a preview of what we can expect from Mary in the years to come when she once again successfully reaches her next goal. The journey will never end for Mary; she has a profound passion for the profession and will continue to work extra hard to become that amazing professional only she can envision. It is the combination of her numerous accomplishments, drive to persistently improve and such humility all which is so inspiring and which makes her a great mentor to many in the Pharmacy Department. Mary, it has been a motivational experience to witness such endless dedication and determination in reaching your own dreams, while at the same time working above and beyond expectation to reach the goals of the department. Congratulations on these amazing professional milestones; perseverance does pay well at the end.

Contributed by,
Merlin Punnoose, Pharm. D
Drug Shortages -
A Growing Concern For Patient Care

The job of a doctor can be divided into 2 parts, diagnosing the condition and providing appropriate treatment once diagnosed. The most difficult part of this process tends to be diagnosis since there are many guidelines available to advise a physician on treatment choices. In most cases the doctor can choose a medicine, write a prescription for it, and then move on; confident the pharmacy will fill the order and reliably deliver it to the patient or nurse for administration, as appropriate. However, in cases of a drug shortage, this process breaks down because the pharmacy either doesn't have the drug at all or has to ration it to ensure enough remains for patients who need it most. This then forces the doctor to write for another, often less desirable, medication, or to accept that the patient will not receive this treatment or will receive it with a delay. The consequences resulting from this can be anything from simply switching to a more expensive medicine in a class, to being forced to use a chemotherapy regimen that offers lower rates of survival than the preferred one.

While the potential harm of drug shortages is easy to understand, the reason for their existence is less so. After all, it is not the single-producer brand medications that most often go on shortage, but the generic medications produced in a competitive market. On the surface, this seems to be the same kind of market structure as is responsible for providing us with eggs, milk, cars, and many of the other things we use every day that never seem to end up on shortage. The reason shortages rarely occur in competitive markets is the balance of supply and demand. If demand for a product rises, for instance more people want to buy a Mac, prices would start to go up and the company would increase production to satisfy demand. If the supply for a product drops, say from a poor orange harvest, this would raise prices and decrease the demand. In this way, changes in either demand or supply will follow each other using price changes as a mediator, and anyone wanting to buy a product at market price will be able to. Unfortunately this auto-regulation by price is not effective in preventing shortages of sterile injectable medications. This is because neither suppliers nor consumers are sensitive to price changes in the short term. Consumers do not respond to price changes because most purchase through insurance companies that have fixed payment schedules, and thus do not feel any change in price set by the manufacturer. Moreover, when a shortage occurs of a medically necessary drug, the physician will generally not change his order regardless of the price. Unfortunately suppliers cannot rapidly respond to price changes either. The creation of sterile injectable medications is a complex, closely regulated process that requires expensive equipment and can often take years to bring about any changes in capacity. This means that while companies can adjust to gradual or predictable changes in supply and demand, it takes a long time to increase production during an acute shortage.

The existence of drug shortages is nothing new; what is gathering attention is the rapid increase in the number of shortages reported. In 2010, the FDA received reports of 178 drug shortages, triple the 61 seen in 2005 and double the 90 reported in 2007. An explanation for this increase seems to be the large number of injectable drugs that went generic from 2008 to 2010. This has not only increased the number of sterile injectables made by generic companies, the drug class most vulnerable to shortages, but also pushed these companies close to their production capacities, leaving them less capable to respond to market changes. Several of these companies are
Drug Shortage *(Continued from page 4)*

building new facilities to expand capacity, but it will still take time for the new facilities to open and these facilities are only intended to alleviate the current imbalance in supply and demand, not prevent a new one from emerging. So the next question becomes what can or should be done to prevent new shortages from happening.

Many of the shortages are caused when one of the manufacturers has a problem with production and excess demand is placed on other manufacturers. A simple solution is to make the production lines in such a way that they could quickly increase capacity. However the flaw in this plan is that having manufacturing capacity that is not in use is a poor financial decision in a highly competitive market and any company doing so would be inefficient compared to its competitors. This is especially the case since the manufacturer suffers relatively few consequences when a shortage occurs; they are not liable for damages caused by patients unable to receive their medications and “failure to provide” clauses in their contracts are only binding if product is available elsewhere. Maintaining increased drug inventories will similarly price a company out of competition. Naturally, this becomes less of an issue with brand medications for which the manufacturer maintains higher margins and is less willing to lose sales due to a shortage and is more worried about the associated bad publicity, resulting in far fewer shortages of brand medications. If we cannot rely on generic manufacturers to work to prevent shortages, the next option is the FDA.

Drug manufacturers are required to let the FDA know if they will discontinue producing a drug they are the only supplier of, as well as encouraged to inform the FDA on any anticipated shortages of medications they produce. The FDA then uses this information in an attempt to prevent or minimize drug shortages by asking other companies making a medication to ramp up production and expediting review of new manufacturers, manufacturing changes, production facilities, or suppliers that will assist in bringing the shortage under control. These actions prevented 137 drug shortages since 2010, however they were not enough to stop the other 178 shortages that did occur. President Obama issued an executive order directing the FDA to take further action to prevent shortages and price gouging. At the present time the only change this brings to FDA policies is to increase funding to hire more staff to work on drugs on shortage. The actual steps taken by the FDA to resolve these shortages will be the same as they have been in the past. The other parts of this executive order included a letter reminding manufacturers of the requirement to report discontinuation of certain drugs and encouraging them to report all others and the release of a report from the director of Health and Human Resources of the economic causes of drugs shortages as well as an FDA report of the steps they are taking to mitigate shortages and the success these steps are having. There is also legislation pending that will require all drug shortages to be reported to the FDA, however at this time the reporting is still optional.

The emergence of drug shortages in sterile injectable preparations is the natural consequence of short term fluctuations in supply (manufacturing defects) or demand (changes in guidelines) in a market in which producers cannot rapidly increase production and consumers are unable or unwilling to change products. As long as manufacturers have more to lose from building the facilities and stocking inventory to prevent a shortage than from the shortage itself, these temporary but sometimes highly damaging drug shortages will continue to plague the generic sterile injectable drug market.

**References:**


Contributed by,

Oleg Fisakov, 2012 Pharm. D. candidate
Congratulations on Your Retirement Margaret!

After countless tears were shed and hugs and kisses exchanged, the journey at The University Hospital came to an end. It is with mixed emotions that we all extended our best wishes to Margaret Newkirk on her retirement at the end of November. We all shared the same feeling of sorrow to know she would depart, however we’re very glad to congratulate her now that she would retire. A couple of months shy of two long decades of service, Margaret finished off one chapter to embark on the next chapter in her life. It was back in January of 1992 that the department gladly welcomed Margaret when she first joined The University Hospital and now at the near end of 2011, heartbroken, we must all say farewell. To many of her colleagues at The University Hospital, Margaret was more than just a co-worker; she was more like a mother to most and a genuine friend to others. Her personality was extremely remarkable; she will always be remembered for her pleasant, warm, and charming demeanor which generated off to all so instantly. The majority if not all in the Pharmacy Department can easily express how a great team player Margaret had been; there are many fond memories of the many times Margaret went out of her way to meet the goals of the department. On behalf of the Pharmacy Department, we would like to thank you for your continuous hard work and dedication over the years, and your loyalty to The University Hospital. Margaret, you will be deeply missed; it is such great void that you have left behind. Overall, we would just love to thank you for being so remarkable, and for the fabulous working relationship we all have had; have a happy and healthy retirement!

Contributed by,
Harry Cuartas, CPhT
Lead Pharmacy Technician

New Lead Pharmacy Technician
Norma Innamorato, CPhT

It is a pleasure to welcome Norma Innamorato to the position of Lead Pharmacy Technician on the first shift. Norma has been a pharmacy technician at The University Hospital since 1999. Her outstanding dedication and impeccable performance in the past gained her the Essential Piece Award for being selected as the Employee of the Quarter. Norma has always been an exceptional team player, leader, and mentor to her fellow colleagues in the department. She is widely known for being very passionate about the job, and for her amazing ability to work so well with others. Norma always strives for excellence; her enthusiasm motivates many, and it is that great vibe she generates which is comforting to many. With such great qualities and drive to succeed in the new role, I am certain Norma will be a great asset to our team.

CONGRATULATIONS Norma!!
Contributed by,
Harry Cuartas, CPhT
Lead Pharmacy Technician
Compassionate, dynamic, intelligent, and delightful are qualities easily found in many of our Pharmacy Staff, but Ahmed depicts such qualities so profoundly. We are proud to announce that our Employee of the Quarter for the fourth quarter of 2011 is Ahmed El-Kority. Ahmed has been on staff at The University Hospital since 2007, and ever since has graced us with his presence. Ahmed is a true asset to the Pharmacy Department. Ahmed works the second shift, and those who work closely with him find him to be an amazing resource. Ahmed has a great working relationship with his colleagues here in the Pharmacy Department, who are pleased to know that he has been awarded with such a distinguished honor. Those that work closely with him agree that he is a great team player, very helpful, efficient, and always in a great mood. His work ethic is exceptional, for he is very efficient and works to full potential. When on duty, he is one of the first to take on the leadership role to resolve any issue. Ahmed is very intelligent and knowledgeable; he is very detailed and thorough in explaining and teaching. He willingly helps anyone in need of assistance, and does so very eagerly. Ahmed’s true admiration for the profession can be easily seen in his performance at work; the great vibe he generates to everyone at The University Hospital is admirable, if not contagious. He is one health care professional who embodies perfection in the field. It is mainly his intelligence and infinite knowledge intertwined with his true compassion and amazing personality which makes him “simply-fabulous” as some would call him. Ahmed, on behalf of the Pharmacy Department, we’d like to congratulate you for your outstanding dedication and exceptional performance because at the end of the day what truly matters to you is improving the lives of those who highly depend on you!

Contributed by,
Harry Cuartas, CPhT
Lead Pharmacy Technician