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University of Medicine & Dentistry of New Jersey

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Special Points of Interest:

- P&T Update
- Policy and Procedures Update
- Counterfeit Drugs
- Clostridium difficile – Impact on the Economics of Healthcare at the University Hospital
- 2011 NJSHP The Pharmacy Technician Award
- 1st Quarter 2011 Employee of the Quarter

P&T Update

Formulary Addition/Deletion

- The following ophthalmic anti-infectives were removed from the formulary.
- Neomycin/bacitracin/polymyxin (Neosporin®) ophthalmic Ointment
- Neomycin/polymyxin/dexamethasone (Maxitrol®) ophthalmic drops and ointment
- Neomycin/polymyxin/gramicidin (Neosporin®) ophthalmic Drops
- Neomycin/polymyxin/hydrocortisone (Cortisporin®) ophthalmic drops
- Sulfacetamide sodium (Bleph® - 10) ophthalmic drops
- Sulfacetamide/prednisolone (Blephamide®) ophthalmic drops and ointment
- Formulary deletion of the 6 ophthalmic products approved.
- Update on the automatic therapeutic exchange policy presented for approval to include the following additional automatic substitutions:

Beclomethsone, budesonide, ciclesonide, flunisolide, fluticasone 27.5mcg (Veramyst®), mometasone, triamcinolone nasal sprays to generic fluticasone nasal 50mcg/spray at the doses outlined in the table attached to the policy.

Coagulation factors VIII, IX, vwF:Rco, Prothromin Complex Concentrate – automatic dose rounding by pharmacist within 10% of the prescribed dose Immune globulin 10% - automatic dose rounding by RPh to utilize full vial.

Update on automatic therapeutic exchange policy (ATEP) approved. (http://uhpolicies.umdnj.edu/live/)

- Moxifloxacin ophthalmic soln 0.5% (Vigamox®)-approved to add on formulary.
- A recommendation to delete levofloxacin (Quixin®) ophthalmic solution from UH Formulary – Levofloxacin (Quixin®) Formulary deletion.
- Fluticasone nasal spray - Fluticasone propionate nasal spray.

  (Flonase®) is a synthetic corticosteroid product used for the management of seasonal and perennial allergic rhinitis and non-allergic rhinitis. – Formulary addition of fluticasone nasal spray approved.
- Beclomethasone nasal spray – a class review of all nasal Corticosteroid products was presented and reviewed. Formulary deletion of beclomethasone nasal spray approved.
- Glucose 4mg tablets – line extension Glucose 5mg chewable tablets are no longer available. Formulary addition of glucose 4mg tablets approved. Formulary deletion of glucose 5mg tablets.
- Levothyroxine 200mcg tablets – formulary deletion. Motion made to remove levothyroxine 200mcg tablets from formulary due to low usage. – Formulary deletion of levothyroxine 200mcg tablets approved.

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P&T Update *(Continued from page 1)*

- 706-100-340 Pharmaceutical and radio-pharmaceutical management Policy on pharmaceutical and radiopharmaceutical management was presented for approval. – Approved
- Emergency burn cache supply: New policy describing procedures to maintain and distribute emergency burn cache items in event of a "Burn Disaster Event" was presented for approval. – Approved
- IV drug administration guideline for adults revision to the IV drug administration guideline were presented for approval. The following revisions were discussed:
- Inclusion of telemetry units along with step down units as monitored beds.
- Set maximum diltiazem infusion rate to 20mg/hr in stepdown/telemetry units.
- Change dobutamine maximum infusion rate to 50mcg/kg/min in the ECHO lab and 7.5mcg/kg/min in step down/telemetry units.
- Increase recommended maximum infusion rate of nitroglycerin to 60mcg/min in step down/telemetry units.
- Policy and procedure manual for prescribing of Erythropoietic Therapy and Iron Supplementation, ESA APPRISE oncology program patient and healthcare provider acknowledgment form, Erythropoietic therapy/iron supplementation order form were presented. Approved

Counterfeit Drugs

Everyday consumers of medications take their daily drugs trusting that it contains what is written on the label. Depending on where they acquired the medication, the drug could be subtherapeutic or may not even contain the active ingredient at all. Some estimates 10-25% of drugs sold globally are counterfeit, 50-90% of drugs sold over the internet are counterfeit. These fake medications are not limited to a specific therapeutic category and include but are not limited to hormones, antibiotics, antivirals, analgesics, antihistamines, and the most popular; weight loss supplements.

The sales of counterfeit medications exceed heroin and the legal penalties for committing the crime are nearly non-existent in developing countries, making it extremely lucrative with little risk, this is why counterfeits are very attractive to criminals. Nearly 1,700 incidents were reported last year to the WHO, this is triple the amount reported in 2004. 1,693 known incidents of counterfeit medicines last year according to Geneva-based International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). India, one of the leading nations in producing generic drugs also has a big problem with counterfeits and subtherapeutic medicines. This hurts the image and the exports of India's pharmaceutical industry, which is estimated to be $8.5 billion a year. The problem is also a growing concern in many other Asian countries especially China. It's hard to pinpoint the impact that counterfeits have monetarily and the patients they have affected, but experts say the counterfeit industry is worth about $90 billion and causes 1 million deaths a year as well as drug resistance to antibiotics.

The FDA warns consumers about counterfeit Alli (over the counter weight loss product) sold over the internet. Apparently the counterfeit version did not contain the active ingredient orlistat but contained sibutramine, which should only be taken with physician oversight. Reports began to emerge at the end of 2009 by consumers buying the counterfeits over the internet. FDA also warned consumers in June of 2010 about "Generic Tamiflu" which contained cloxacillin instead of the active ingredient oseltamivir.

Many companies are making efforts to stop counterfeit medications. Lilly for example has initiated a broad range of actions against criminal counterfeiters, including enhanced Anti-Counterfeiting technologies for their products and packaging and changes in their distribution system. MSN labs, uses technology from PharmaSecure that allows consumers to check authenticity by sending a text message of the code written on the products. These companies and many others from the private sector are actively partnering with government organizations to strengthen and enforce Anti-Counterfeiting laws. The FDA and CDER has released guidance for the industry for incorporating physical-chemical identifiers into solid oral dosage form drug products for

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Counterfeit Drugs

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anticounterfeiting. Manufacturers also include colors, dyes in their products that are harder to replicate as well as holograms on the bottles, but sophisticated counterfeiters can replicate those products in a matter of months. So the best measure that can be taken is education of patients. Pharmacists should warn patients about the hazards of buying drugs on the internet. If patients insist then they can be more confident buying from online pharmacies with the National Association of Boards of Pharmacy Verified Internet Pharmacy Site seal, also known as VIPPS seal. Online pharmacies carrying the seal are listed at www.vipps.info. Counterfeits are a real and growing problem that takes collaboration and patient education to tackle.

Contributed by:
Ivan Quan, Pharm. D Candidate 2011

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New Jersey Society of Health-System Pharmacists (NJSHP) 2011 The Pharmacy Technician Award – Jovilyn C. Ballesteros, CtPhT, Pharmacy Procurement Supervisor

Jovilyn Ballesteros has been nominated for the NJSHP "2011 The Pharmacy Technician Award" The award is presented to a technician who performs above and beyond their normal responsibilities in a health system setting. The exceptional performance must involve some area of leadership, strategic planning, patient focused pharmaceutical care, pharmacy process/ performance improvement, or positive outcomes in pharmacy practice.

Jovi is also instrumental in coordinating the New Jersey Pharmacy Leadership Group (NJPLG) agendas and action items. The NJPLG is also comprised of many NJSHP members and this meeting has fostered numerous discussions about pharmacy practice and regulatory issues.

Jovi has exemplified leadership at UMDNJ– University Hospital with her involvement in her role as the Pharmacy Buyer. She has made numerous recommendations with respect to inventory control, contract negotiation, formulary management and cost analysis. She is also responsible for training new pharmacy technicians, creating the schedule, and providing daily supervision of technical staff.

Jovi consistently works with pharmacy leadership, pharmacists and pharmacy technicians to ensure safe and effective inventory controls, drug delivery, medication storage and appropriate formulary selection. She consistently follows up with the pharmacy technician's practices of delivery, restocking and handling of medication inventory as it relates to patient care and safety.

Contributed by: Pharmacy Management Team

Clostridium difficile – Impact on the Economics of Healthcare at The University Hospital

Clostridium difficile, more commonly known as C. diff., has been recognized as a major complication of antibiotic use since the 1970s and is the leading cause of infectious diarrhea in the hospital setting. When a patient is being treated with antibiotics, the effects of the medication can also kill off the ~40,000 different bacteria residing in the gastrointestinal tract as normal flora. This creates imbalances which can cause certain bacteria, specifically *Clostridium difficile,* to overgrow and colonize a greater portion of the gut, leading to an increase in toxin production.[1,2]

Patients in the hospital setting have multiple different risk factors for acquiring a primary *Clostridium difficile* infection (CDI), of which the most important to consider are antibiotic use, advanced age, and residence in acute care or long term care facilities.[1] The most common antibiotics linked with the greatest incidence of a CDI are clindamycin, ampicillin, parenteral cephalosporins (cefotaxime, ceftriaxone), and fluoroquinolones.

Another concern related to antibiotic use and its effect on the normal gut flora is the possibility of selecting for resistant strains. Improper selection or use of antibiotics can create selective pressures for bacteria to acquire resistance via spontaneous gene mutations, and in a Darwinian sense create an environment where 'survival of the fittest' bacteria will overgrow. In the past decade, there has been a resurgence of CDI most likely due to a new strain of *C. difficile* known as the North American pulse-field gel electrophoresis type 1 (NAP1). This strain is completely resistant to all fluoroquinolones.[3]

The graph below shows the incidence and trends of CDI rates at The University Hospital in 2010 (courtesy of Infection Control Department):

STATISTICS FOR DETECTION OF C DIFFICILE - 2010

Month	# Patient Specimens	# Positive Specimens	% Positive Patients
Jan - 10	101	10	9.90%
Feb - 10	80	9	11.25%
Mar - 10	98	11	11.22%
Apr - 10	99	11	11.11%
May - 10	107	17	15.89%
Jun - 10	113	13	11.50%
Jul - 10	94	21	22.34% ←
Aug - 10	102	13	12.75%
Sep - 10	97	14	14.43%
Oct - 10	101	13	12.87%
Nov - 10	78	7	8.97%

Approximately 80-85% of patients tested for suspected CDI came back with a negative result. Patients who should be tested include those with signs and symptoms of infectious diarrhea and/or colitis, such as fever, cramps, and presence of fecal leucocytes. Also, patients with CDI can have a very distinct stool odor due to the production of volatile short chain fatty acids and aromatic amines by the bacteria.

Clostridium difficile infections can not only increase patients' risk for mortality, but can also increase the incremental costs of overall healthcare for patients. Meta-analyses of hundreds of studies in the past 30 years have shown that patients contracting a primary CDI can increase healthcare cost anywhere between $2,871 - $4,846 per episode. Recurrent infections can further increase costs in the range of $13,655 - $18,067 per episode. Other studies in special populations including patients with irritable bowel disease, surgical inpatients, and intensive care unit patients can have dramatically greater incremental cost increases ranging between $6,242 - $90,664 per episode.[4]

The current mainstays of antibiotics used for the treatment of *C. difficile* are oral vancomycin and metronidazole. Metronidazole has been shown to be non-inferior to vancomycin in clinical trials and is generally used in mild to moderate cases. Oral vancomycin is used in severe cases due to its ability to concentrate in the GI tract. The combination of both medications has been used in persistent or recurrent CDIs, although there is limited data to support combination therapy. In case reports, intravenous tigecycline has also shown to be effective in severe cases of CDI. Fidaxomicin is a new, investigational antibiotic in phase 3 clinical trials and has been granted fast track status by the FDA. It has been

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Clostridium difficile

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shown to be comparable to vancomycin in treating primary CDIs with a significantly lower rate of recurrence in non-NAP1 strains of C. difficile.[5,6,7]

The best way to reduce the occurrence of CDIs and avoid the associated additional healthcare costs is by using preventative strategies. Antimicrobial stewardship programs, adherence to contact precautions, and use of disposable thermometers have proven very effective in helping to reduce the incidence of CDIs. There have been many studies that have evaluated the effectiveness of antimicrobial stewardship programs in the hospital setting. Data shows that the use of the programs can drop the rate of CDI anywhere from one half to one quarter of the rate prior to the start of the programs. Glove use and overall hand hygiene have been

considered the oldest methods of prevention. As simple as it sounds, reaching 50% compliance rates with appropriate hand hygiene have been surprisingly difficult to achieve. It is recommended to vigorously wash your hands with soap and water to wash off any spores which may be on the hands, especially in situations where the hands become visibly soiled. Studies have shown a reduction close to one fifth the rate (7.7/1000 cases to 1.5/1000 cases) when proper hand hygiene was used. Disposable thermometers have also been shown to reduce infection rates by close to half the rate prior to initiation. Studies on environmental disinfection have demonstrated efficacy in helping with the prevention of infection. It has been shown that using bleach or hydrogen peroxide to clean the rooms of high risk patients may help reduce infection rates by one third. Probiotics have also been used; however, there is not enough evidence in clinical trials to officially recommend these agents as standard of care.[8, 9]

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Contributed by: Chirag Paghdal, Pharm. D.

New Lead Pharmacy Technician Harry Cuartas, CPhT

It is a pleasure to welcome Harry Cuartas to the position of Lead Pharmacy Technician on the first shift. Harry has been a pharmacy technician since 2005 in various different settings. He has been a rotational technician at UMDNJ since 2008 and has worked on all three shifts. With this experience and his enthusiasm for the new role I am certain Harry will be a great asset to our team. CONGRATULATIONS Harry!

Contributed By: Mary Wilson, CPhT
Lead Pharmacy Technician

Employee of the 1st Quarter

Merlin Punnoose, Pharm. D.

Compassionate, exuberant, and idealistic are a few of the endless attributes that Merlin Punnoose emanates daily, which allows her to stand out when she serves the patients here at University Hospital. It is with pride and pleasure that the Pharmacy Department honors Merlin this time around with the Employee of the Quarter Award for the first quarter of 2011. Her proficient, proactive, and overall positive attitude, are qualities which depict the *Essential Piece Award,* and Merlin clearly deserves such merit as she exhibits such qualities naturally. As a pharmacist her diligence and dedication set her apart as an exceptional employee. Among the nominations submitted, it is agreed that Merlin in fact is an amazing pharmacist who diligently works from the heart, which is clearly evident by her overall impeccable performance. Merlin joined the Pharmacy Department in January of 2010 and since then while growing in her career has reached many breakthroughs on the mid-night shift as she progresses as a Pharmacist. Her pleasant and easy-going personality works well along with her dedication, in contributing to the overall progression here at University Hospital.

Merlin is a very cordial team player who has formed a special bond with individuals inside and outside of the pharmacy department. These remarkable traits also transcend into her personal life, as Merlin works on making a huge difference worldwide by fulfilling her philanthropic goals, serving other less fortunate countries in need. An article published recently last year, described her altruistic efforts and accomplishments on her Medical Mission trip to Tanzania. She has recently returned from another Medical Mission trip, this time to Peru in South America. She joined a crew of 60 health care professionals, to serve a population of 50,000 in need of immediate medical treatment, by far her biggest missionary trip yet. Such a noble attitude is truly admired and cherished in the Pharmacy Department. We are very fortunate to have Merlin on our staff, and continue to promote her development as she works diligently on improving patient medical treatment outcomes here at University Hospital. Join us all in Congratulating Merlin as she receives Pharmacy's most distinguished honor. Thank you for touching our lives and the lives of so many who seek your compassion!

Contributed by
Harry Cuartas, Lead Pharmacy Technician