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Special Points of Interest:

- P&T Update-Formulary Addition/Deletion
- Policy and Procedures/ Floorstock Update
- Pharmaceutical Research: Turning an Idea into a Medication on the Market
- Welcome New Pharmacist

P&T Update

Formulary Addition/Deletion

1. Rilpivirine/Emtricitabine/Tenofovir (Complera®) – formulary addition approved.
   Complera® is a combination product containing two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs-Emtricitabine/Tenofovir) and one non-nucleoside reverse transcriptase inhibitor (NNRTI- Rilpivirine). – Formulary addition approved.

2. Mesalamine (Asacol HD®) 800mg delayed release tablets – Line of extension approved.

3. Mesalamine (Asacol®) 400mg delayed release tablets have been discontinued by the manufacturer. – Formulary deletion approved.

4. Mesalamine (Pentasa®) – Formulary deletion approved.
   Based on limited usage and UH Gastroenterology Dept. recommendation, this product was voted upon by the P&T members to be deleted from the UH formulary.

5. Hydroxyethyl starch (Voluven®) – Formulary deletion approved.
   In light of the FDA advisory that warned the healthcare professionals of increased mortality/renal injury in critically ill patients, and excess bleeding in open heart surgery patients, Anesthesia Dept. chair requested to remove this product from the formulary.

6. Paclitaxel protein bound particles for injectable suspension (Abraxane®) – formulary addition approved.
   Abraxane® is microtubule inhibitor that prevents reorganization of microtubule network essential for cellular functions. It is indicated as second line therapy for metastatic breast cancer (MBC) and non-small cell lung cancer (NSCLC).

7. Radium 223 dichloride (Xofigo®) – formulary addition approved.
   Xofigo® is a targeted alpha-emitter that selectively binds to areas of increased bone turnover in bone metastases and emits high-energy alpha particles of short range (<100 µm). The product is indicated for castrate-resistant carcinoma of prostate metastatic to the bone, given at 50 kBq/kg body weight at 4-6 week intervals for 6 injections.

8. Dental Clinic medications – formulary additions/line extension – approved.
   A proposal to grandfather in all the dental clinical medications was proposed to the members.

   1. Bupivacaine HC1 (Marcaine®)/epinephrine 0.5%-1:200,000
   2. LidocaineHC1 (Xylocaine®)/epinephrine 1:100,000
   3. Articaine HC1 (Septocaine®)/epinephrine 4%-1:100,000
   4. Mepivacaine HC1 (Carbocaine®) 3% 1.7mL
   5. Benzocaine (Topex®) 20% oromucosal spray

   Members voted in favor of formulary addition/line extension with one member abstained. – approved.

9. Ranitidine (Zantac®) IVPB 50mg/50mL – manufacturer discontinued.
   Formulary deletion approved.

Policies and Procedures/Floorstock Update

1. **707-600-129 Pharmacy Systems Downtime**
   Specific guidelines have been created to establish proper distribution and control of medications in the event that the following Pharmacy information systems are inaccessible: order entry, shadow server, medication order scanning system, and automated dispensing machines. – Approved
2. **707-400-103 Medications Samples Policy Revision**
   Sample medications shall be labeled and dispensed in a standardized manner according to hospital policy, applicable law and regulations and standards of practice. – Approved
3. **707-600-154 Decontamination and Air Flow Testing – New Policy**
   This policy clarifies that cleaning and air flow testing will ensure that laminar hoods and glove boxes are free from any detectable contamination. – Approved
4. **Blood Borne Pathogen Exposure Control Plan Policy**
   The Exposure Control Plan for University Hospital was updated to relfect changes in the guidelines for Management of Occupational Exposures to Human Immunodeficiency Virus. – Approved
5. **707-800-104 Needlestick Medication Starter Kits for HIV Post Exposure**
   Revised policy outlines the regimens for PEP (Post Exposure Prophylaxis) at UH. The preferred regimen consists of Truvada® (tenofovir 300mg and emtricitabine 200mg) one tablet daily along with Isentress® (raltegravir 400mg) one tablet twice daily for 4 weeks. – Approved
6. **707-600-127 Refrigeration Units and Temperature Monitoring Policy Revision**
   Revised policy includes the updated temperature log form. Vaccines are to be placed in the top center shelf of the refrigerator to the best efforts possible as the space permits. – Approved
7. **707-400-102 Drug Recalls or Discontinued Medications Policy Revision**
   Revised policy to include notification of a recalled/ discontinued medication to the patient for class I and II recalls. The Pharmacy shall determine if the drug being recalled is in stock in the hospital; if not, document, save and keep record. – Approved
8. **707-800-103 Multidose Vial Policy Update**
   The policy indicates to discard any MDV once opened and used in the ORs, ER and PACU. Any MDV used in immediate patient care areas will be discarded after single use or when MDV is brought out of the medication rooms on any patient care unit. – Approved
9. **Alaris Pump Library Revision**
   The IVIG guardrail for all profiles (adult ICU,PCU-step down, med-surg, PICU, peds) was revised for the Alaris Pump Drug Library. – Approved

Bar Code Medication Administration

Medication safety has been a global concern for many years.[1,2] A medication error, defined as "any preventable event that may cause or lead to inappropriate medication use or harm to a patient," is unfortunately a common phenomenon.[3] The Institute of Medicine (IOM) approximates that on average a hospitalized patient is prone to have one medication error per day.[4] The cost associated with medication errors is also significant. Preventable adverse drug events generate an estimated two billion dollars in direct hospital costs each year, which contributes to increased hospital length of stay and patient morbidity and mortality.[5] The use of healthcare information technology is a big step in reducing medication errors. Because of this, the American Society of Health-System Pharmacists (ASHP) encourages health systems to adopt bar code medication administration, or BCMA.[6]

BCMA is a system designed to ensure that the right medication is administered at the right dose to the right patient at the right time. Ideally, the patient is to wear a wristband with a barcode, which serves as a unique patient identifier, upon admission. This barcode is to be scanned before administering any medication. In this system, there are bedside scanners that are linked to the admission, discharge, and transfer database, the pharmacy information system, the laboratory information system, the personnel system, and software to supply active decision support. The barcode on the unit-dosed medication, which either represents the National Drug Code (NDC) number or another identifier, is also to be scanned.

The process for medication administration with BCMA is the following; pharmacy dispenses individually packaged bar coded medication doses to a patient's location, the nurse scans his/her barcoded employee identifier, then the patient's wristband, and finally each package of medications that will be administered. The system then checks the nurse and patient information with the medication profile in the pharmacy information system, provides any necessary alerts, electronically records the administration in an on-line medication administration record, and stores data for future analysis.

BCMA helps to verify the five rights: right patient, medication, dose, route, and time. BCMA also assists in producing a more accurate medication administration record than the traditional ones that are generated manually. Bar coding has the capacity to encode data such as lot number, expiration date, and unique serial numbers of the medications administered. BCMA will also improve inventory control, billing accuracy, and reduction of rework. Certain BCMA systems have additional features that will assist the nurse by providing drug reference information and various alerts and reminders. BCMA also gathers data for retrospective analysis to monitor trends.[7]

Several studies have been conducted to assess the effectiveness and the improvement in safety using BCMA, effect of Bar-Code Technology on the Safety of Medication Administration, evaluated the error rates in order transcription and medication administration before and after the BCMA system was implemented at an academic medical center. This study found a 41% reduction in administration errors that were not associated with timing of medication administration and 51% reduction in potential adverse drug events from these errors. However, errors were not entirely eliminated. The study suggests that this can be due to two reasons; non-compliance and the fact that earlier software was used, which has since been improved. This study encourages the use of BCMA as a method to improve patient safety.[8]

Along with the many advantages of adopting a BCMA system, there are several disadvantages. Although BCMA greatly helps to reduce errors, it does not eliminate them. BCMA also requires a significant investment in technology, infrastructure, and training. Pharmacies must have equipment to dispense barcoded doses,

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Bar Code Medication Administration

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patient care areas need to be equipped with mobile barcode readers, and the information system must integrate the technology. Moreover, the bar codes must appear on the patients' wristbands and on every dose of medication in unit dose packaging. This can be a challenge because not all manufacturers' medications contain barcodes and not all medications are available in a unit dose form.[5]

There is no standard for in-house relabeling of medications; therefore the hospital will have to follow the commercial standards. In-house repackaging of medication is not a reimbursed cost, especially when done manually, which will also introduce a new source of error. BCMA requires training of pharmacy staff and nurses. When there is a nursing staff shortage, floating nurses may not be familiar with the system, which will require additional training. The pharmacy will also need to make bar coding for products that are patient specific medications, such as multi-additive intravenous solutions, pediatric dosage forms, and pharmacy compounded products.[5,7]

Bar code medication administration is a powerful technological advance that can improve medication safety. The key to a successful implementation of BCMA is compliance of all the steps in the medication administration process. Pharmacists and nurses must develop and maintain the infrastructure that is needed for BCMA to be effective. BCMA is costly and does require adequate training and preparation. However, the reduction in the amount of medication errors is significant and worth the effort.

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Contributed by:

Sejal Chaudhari, Pharm. D. Candidate 2014, Rutgers University
Danna Hamdan, Pharm. D. Candidate 2014, Rutgers University

Acetaminophen-Associated Fatal Skin Reactions

Acetaminophen has been around for decades. It is an excellent analgesic and antipyretic. Up until recently, it was also considered the safest over-the-counter pain killer with minimal side effects that can be administered to children. However, FDA recently issued a warning regarding the use of acetaminophen.[7] Upon reviewing the literature and FDA Adverse Event Reporting System, FDA investigators found 107 case reports documenting the link between acetaminophen and potential fatal skin reactions. These reports all identified acetaminophen as the probable culprit.[3,4,5,6,8,10] These hypersensitivity reactions range from mild to life-threatening. Patients may present with acute generalized exanthematous pustulosis, Stevens-Johnson Syndrome or toxic epidermal necrolysis.

All three skin diseases' symptoms can include rash, blisters and widespread damage to the surface skin with acute generalized exanthematous pustulosis being the least severe and toxic epidermal necrolysis being the most severe. Clinicians are advised to not rechallenge the patient who has a history of acetaminophen associated skin reactions as this may lead to

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UH Hospital Formulary Additions/Deletions – Jan 2012- Nov 2013

Generic Name	Brand Name	Initial P&T Date	Approved (Date)	Denied (Date)	Deleted	Reason / Comments / Criteria
Rabies vaccine	Imovax®	Jan-12	X			Preparation is preferrable to RabAvert, more cost effective
Rabies vaccine	RabAvert®	Jan-12			X	Imovax costs less/ easier preparation
Diphtheria, tetanus toxoid	DT®	Jan-12			X	Low and inappropriate usage
Tetanus toxoid		Jan-12			X	Inappropriate usage, recommended use of Td vaccine
Hyaluronidase Human Injection 150 units/ml	Hylenex®	Feb-12	X			Amphadase 150units/ml no longer on market
Hyaluronidase bovine injection	Amphadase®	Feb-12			X	Amphadase 150units/ml no longer on market
Acyclovir ointment	Zovirax®	Feb-12			X	High cost, oral therapy available
Ganciclovir capsules		Feb-12			X	Oral valganciclovir preferred
Tramadol	Ultram®	Apr-12	X (Apr 12)			lower incidence of respiratory depression, constipation, and abuse
Ticagrelor	Brilinta®	Apr-12	X (Apr 12)			Restricted to Cardiology approval, one-time dose in ED, and patients taking medication from home
Fludeoxyglucose F18 diagnostic for IV adm.		May-12	X			
Sodium Fluoride F18 diagnostic for IV adm.		May-12	X			
Imipenem/cilastatin IV	Primaxin®	May-12			X	Comparable efficacy to meropenem but more expensive
Cytomegalovirus Immune Globulin IV Human	Cytogam®	May-12			X	Discontinued by manufacturer
Sodium citrate 4% for IV line lock		Jun-12	X (Jun 12)			
Ioflupane I123	DatScan®	Jun-12		X (Nov 12)		Requestor unable to attend P&T meeting, await hire of movement disorder specialist
Clopidogrel 300mg tablet	Plavix®	Jun-12			X	Generic 75 mg tablets available
Mecamylamine	Inversine®	Jun-12			X	Discontinued by manufacturer
Dimethicone 5% external cream		Jun-12			X	Discontinued by manufacturer
Sodium octoxynol-2 ethane	Phisoderm®	Jun-12			X	New formulation available
Metopirone		Jun-12			X	Discontinued by manufacturer
Protirelin	Thyrel®	Jun-12			X	Discontinued by manufacturer
Alcohol 5% in dextrose 5% IV solution		Jun-12			X	Discontinued by manufacturer
Fulvestrant	Faslodex®	Jul-12	X (Jul 12)			
Chloral hydrate 500 mg/5 mL oral syrup		Jul-12			X	Discontinued by manufacturer
Tigecycline	Tygacil®	Sep-12	X (Sep 12)			Restricted to ID approval
Clevidipine	Cleviprex®	Sep-12	X (Oct 12)			
Rosiglitazine	Avandia®	Sep-12			X	Discontinued by manufacturer
Mebendazole	Vermox®	Sep-12			X	Discontinued by manufacturer
Ranibizumab 0.3 mg/0.05 mL injection	Lucentis®	Oct-12	X			
Acetaminophen intravenous	Ofirmev®	Nov-12	X (Nov 12)			Restricted to Anesthesiology Service in the Doctors Office Center Same Day Surgery suites for maximum of 2 doses
Aflibercept	Eylea®	Jan-13	X (Jan 13)			
Cromolyn sodium MDI and nebulization solution	Intal®	Jan-13			X	
Didanosine 10 mg/mL oral solution	Videx®	Jan-13			X	Nov 2012 Anti-Infective Subcommittee
Stavudine 20 mg capsule	Zerit®	Jan-13			X	Nov 2012 Anti-Infective Subcommittee
Stavudine 1 mg/mL oral solution	Zerit®	Jan-13			X	Nov 2012 Anti-Infective Subcommittee
Etravirine 100 mg tablet	Intelence®	Jan-13			X	Nov 2012 Anti-Infective Subcommittee
Atazanavir 150 mg capsule	Reyataz®	Jan-13			X	Nov 2012 Anti-Infective Subcommittee
Saquinavir 200 mg capsule	Invirase®	Jan-13			X	Nov 2012 Anti-Infective Subcommittee
Tipranavir 250 mg capsule	Aptivus®	Jan-13			X	Nov 2012 Anti-Infective Subcommittee
Zidovudine 300 mg tablet	Retrovir®	Jan-13	X			Nov 2012 Anti-Infective Subcommittee

UH Hospital Formulary Additions/Deletions – Jan 2012- Nov 2013

Generic Name	Brand Name	Initial P&T Date	Approved (Date)	Denied (Date)	Deleted	Reason / Comments / Criteria
Saquinavir 500 mg tablet	Invirase®	Jan-13	X			Nov 2012 Anti-Infective Subcommittee
Mitomycin ophthalmic kit	Mitosol®	Feb-13		X (Apr 13)		
6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection	Voluven®	Feb-13	X (Mar 13)			Restricted to Anesthesiology Service in OR/PACU setting
Ciprofloxacin 50 mg/mL oral suspension	Cipro®	Feb-13			X	Jan 2013 Anti-Infective Subcommittee
Erythromycin stearate 250 mg tablets	Erythrocin®	Feb-13			X	Jan 2013 Anti-Infective Subcommittee
Anti-thymocyte globumin (rabbit)	Thymoglobulin®	Mar-13	X (Mar 13)			
Erythromycin 200 mg/5 mL oral suspension	Erythrocin®	Mar-13			X	Feb 2013 Anti-Infective Subcommittee
Indomethacin rectal suppository	Indocin®	Apr-13	X (Apr 13)			
Epinephrine 0.3 mg/0.3 mL injection	EpiPen®	Apr-13	X			
Reteplase recombinant	Retavase®	Apr-13			X	
Muromonab-CD3	OKT3®	Apr-13			X	
Lepirudin	Refludan®	Apr-13			X	
Lidocaine HCl ophthalmic gel 3.5%	Akten®	May-13		X (June 13)		
Darunavir 400 mg tablets	Prezista®	Jun-13			X	Discontinued by manufacturer
Darunavir 800 mg tablets	Prezista®	Jun-13	X			
Rilpivirine/emtricitabine/tenofovir	Complera®	Jul-13	X (July 13)			
Mesalamine 800 mg delayed release tablets	Asacol HD®	Jul-13	X			Replacement for mesalamine 400 mg tablets - manufacturer D/C
Mesalamine 400 mg delayed release tablets	Asacol®	Jul-13			X	Discontinued by manufacturer
Mesalamine	Pentases®	Jul-13			X	Low usage, discussed with GI Division
6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride injection	Voluven®	Jul-13			X	FDA Safety Alert on increase risk of mortality, renal injury, and bleeding
Paclitaxel protein-bound particles for injectable suspension	Abraxane®	Sep-13	X (Sept 13)			
Radium 223 dichloride	Xofigo®	Sep-13	X (Sept 13)			
Bupivacaine hydrochloride/epinephrine 0.5%-1:200,000 solution for injection	Marcaine/ epinephrine®	Sep-13	X			
Lidocaine hydrochloride/epinephrine 1:100,000 solution for injection	Xylocaine/ epinephrine®	Sep-13	X			
Articaine hydrochloride/epinephrine 4%-1:100,000 solution for injection	Septocaine®	Sep-13	X			
Mepivacaine hydrochloride 3% solution for injection	Carbocaine®	Sep-13	X			
Benzocaine 20% oromucosal spray	Topex Handicaine Stix®	Sep-13	X			
Ranitidine IVPB 50 mg/50 mL	Zantac®	Sep-13			X	
Argatroban 250mg/250mL		Oct-13	X (Oct 13)			
Dinoprostone 0.5 mg gel	Prepidil®	Oct-13			X	Low usage
Hydroxocobalamin	Cyanokit®	Nov-13	X (Nov 13)			
Sodium Thiosulfate+sodium Nitrite+ Amyl Nitrite	Cyanide antidote kit®	Nov-13			X	Manufacturer Discontinued

Acetaminophen-Associated Fatal Skin Reactions *(Continued from page 4)*

hospitalization and/or possibly death. Patch testing has been used to confirm this diagnosis. In practice, however, not all patients will have positive results. This phenomena is not limited to just acetaminophen tablets. Acetaminophen comes in various different dosage forms such as tablet, capsule, oral solution, suppository, and most recently intravenous injection. It is also part of many combination products, prescription and non-prescription alike, such as Percocet® for pain and Excedrin® for headaches. Patients are to exercise caution when selecting these products and health care professionals are to be mindful of these potential adverse effects when counseling patients.

Despite this newly identified adverse effect, FDA reassures consumers that acetaminophen is still a safe medication to use as long as it is used for the right indication in the right amounts (i.e. do not exceed 3 grams in 24 hours).[7] Some alternatives for people with these skin reactions include salicylates such as aspirin, ibuprofen and naproxen.[1,2,9] A thing to watch out for with the class of salicylate pain relievers is that they can cause gastrointestinal irritation so patients need to take them with food to minimize the side effect. Aspirin itself has a number of unique side effects on of its own. It can cause Reye's syndrome so it is contraindicated in children less than 12 years old. It is also a potent platelet inhibitor so it might cause excessive bleeds in certain patients. No medication is completely safe so educating patients about the medications they are taking is crucial to maximize positive outcomes.

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Contributed by:
Min Gong, Pharm.D. Candidate 2015, Rutgers University

The Use of Intravenous Fat Emulsion (IFE) Therapy in Acute Overdose Toxicities Involving Lipophilic Drugs: Place in Therapy and Concerns

Intravenous fat emulsion (IFE) therapy has been used as a successful novel treatment in reversing acute toxicity of certain drugs. IFE therapy has been used to treat toxicities caused by highly lipophilic drugs such as bupivacaine, bupropion, diltiazem, verapamil, propranolol, quetiapine, and venlafaxine. Medical toxicologists are recommending the use of IFE as a treatment strategy for acute overdose toxicities.[1] The first case report of IFE being utilized described a patient that was successfully resuscitated after bupivacaine related cardiac arrest in 2006.[2] In a verapamil overdose case, *Young et al.* reported the rapid stabilization of a 32 year old male who had ingested 13.44 g verapamil with other co-ingestions after IFE therapy.[3] Verapamil is a very potent calcium channel blocker which can cause significant cardiac toxicity. Most US Poison Control Centers (PCCs) have incorporated the use of IFE therapy for treating acute overdoses. Some Poison Control Centers participated in a survey that asked whether the medical directors often recommended the use of IFE or not. 45 of the 57 PCCs that participated have a protocol for IFE therapy for highly lipophilic drugs.

Amongst the 45 PCC directors, the percentage of directors that recommended IFE therapy for patients with cardiac arrest induced by a single drug were the following: bupivacaine (43/45; 96%), amitriptyline

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The Use of Intravenous Fat Emulsion (IFE)

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(31/45; 69%), and verapamil (36/45; 80%). IFE therapy is often recommended by PCC medical directors for lipophilic drug toxicities. Despite numerous recommendations, the fact that IFE therapy is weakly backed up by mostly case reports is reflected in the following statement by The American College of Medical Toxicology (AMCT): "Given the uncertainty of its beneficial effect in human poisonings, it is the opinion of the American College of Medical Toxicology that there are no standards of care requirements to use, or to choose not to use, lipid resuscitation therapy (LRT). However in circumstances where there is serious hemodynamic, or other, instability from a xenobiotic with a high degree of lipid solubility, LRT is viewed as reasonable consideration for therapy, even if the patient is not in cardiac arrest."[1]

Regarding safety involving IFE, there are some general items to point out. It is shown in previous studies that large volumes of lipid emulsion administered with parenteral nutrition resulted in pulmonary complications.[4] The Association of Anaesthetists of Great Britain and Ireland (AAGBI) recommends the monitoring of patients for biochemical markers representative of developing pancreatitis post treatment.[5] The maximum dose that can be administered is unknown and the recommended upper limit for humans for 20% intravenous lipid is 10 mg/kg.[6] It is also important to keep in mind that IFE can also cause disturbances and report falsely elevated hemoglobin and platelet counts; therefore, samples should be taken prior to IV lipid therapy.[7]

Despite some of the adverse effects reported and one event of asymptomatic hyperamylasemia post IFE use, most authors have not reported adverse events.[4] Although most of the clinical studies involving IFE use in acute overdose toxicities are based on case reports, IFE therapy is still recommended by most of the PCC medical directors with implementation of IFE protocols to accompany. IFE has been successful in the use of acute overdoses of certain drugs despite its unknown mechanism of action with suggestions of the Lipid Sink and Lipid Flux theory.[5]

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Contributed By:

Lloyd Alcala, Pharm.D. Candidate 2015, Rutgers University

Pharmaceutical Research: Turning an Idea into a Medication on the Market

8 years - this is the approximate time is takes to bring a new drug to the market in the United States. This may seem too long, especially when these new drugs can help treat disease states that we do not have many options for treatment. However, the process is long to help ensure safety and efficacy when the medication is used on a large scale in a lot of people. This article is a brief overview of the process from when a new drug is discovered to when it is in your local pharmacy or hospital for use.

After the drug is discovered, the pharmaceutical company submits an **Investigational New Drug Application (IND)** to the FDA, which has 30 days to complete the review. This application needs to be approved before the company can begin sending the medication across state lines for clinical trials. Once received by the FDA, the drug is evaluated for safety and to assure there are not any unreasonable risks to the subjects in the clinical trials. This data is usually obtained from animal studies.

After the 30 day IND approval process, clinical trials can begin. There are three phases of trials before the drug is able to go to the market. Each of these phases is approximately 18 months in length.

Phase I: This phase is usually completed in a small number (20-80) of healthy volunteers. The primary goal of this phase is to develop a safety profile for the drug in humans. A secondary goal is to show a relationship between dosing and the subject's systemic drug exposure. In other words, a safe dosing range is being determined.

Phase II: During this phase, the drug is given to a larger number (100-300) of subjects who have the disease that is being treated. Researchers are looking to show that the drug is effective in the targeted patient population. They are also trying to show a relationship between the dose of drug given and response to the drug. During this phase, safety of the drug is continuing to be monitored.

Phase III: This is the final phase before the drug is approved for marketing and involves a large number of subjects (1000-3000). During this phase, effectiveness is still being evaluated as well as duration of effect, effect in different populations, and varying doses. Potential drug-drug interactions are also evaluated at this time.

Following the three phases of clinical trials, a **New Drug Application (NDA)** is submitted to the FDA. This application contains all of the information about the drug and what was found during the clinical trials. It also contains how the drug is going to be manufactured, processed, and packaged. After submission, the FDA has 60 days for preliminary review. Following preliminary review, the FDA either determines that the application is insufficient and denies the application or whether it can go to substantive review. They also determine whether the review is a standard review (10 months to complete) or priority review (6 months). After the NDA is fully approved, the drug can be placed on the market.

Even after the drug is approved for marketing, many drugs still require **Phase IV** or post-marketing studies to continue to monitor the safety and efficacy of the drug. These studies may last up to 18 months.

Tyler McCamish, PharmD
Clinical Pharmacy Specialist
Investigational Drug Services

Welcome New Pharmacist

Chris Yong, Pharm. D. graduated from Rutgers Ernest Mario School of Pharmacy in May 2013 and is excited to be a staff pharmacist with University Hospital. His previous experience was largely in retail. Outside of work, his main interests include cars and rock climbing.

Fluoroquinolone Antibiotics Associated with Peripheral Neuropathy

The US Food and Drug Administration (FDA) released a Drug Safety Communication in August 2013 regarding fluoroquinolones and the risk of peripheral neuropathy. All drug labels and medication guides required an update to provide additional information about this serious side effect. Peripheral neuropathy has been listed as an adverse effect in the labeling of all systemic (oral and injectable) fluoroquinolones since 2004. However, the rapid onset and risk of permanence were not previously described. Peripheral neuropathy can develop in patients soon after administration of the medication, often within a few days of starting fluoroquinolone therapy. Furthermore, patients may experience prolonged, or potentially permanent, symptoms after discontinuation of the offending drug. Only systemic formulations (oral and injectable) were shown to be associated with peripheral neuropathy. Peripheral neuropathy has not been observed with topical fluoroquinolones, such as ophthalmic and otic drops.

Fluoroquinolones antibiotics include ciprofloxacin (Cipro®), gemifloxacin (Factive®), levofloxacin (Levaquin®), moxifloxacin (Avelox®), norfloxacin (Noroxin®), and ofloxacin (Floxin®). This class of antibiotics has been increasingly used due to its popularity in treating a variety of infections, such as urinary tract infections and pneumonia. Fluoroquinolones have a broad spectrum of activity with coverage against many gram-positive, gram-negative, and atypical bacteria. However, fluoroquinolones do come with drawbacks, including the significant side effects of peripheral neuropathy, QT prolongation, and tendon rupture.

As a healthcare professional, it is important to educate patients on the use of fluoroquinolones and their risks, including peripheral neuropathy. Symptoms include pain in the arms or legs, tingling or burning sensation, numbness, or weakness. Onset of neuropathy from fluoroquinolones can occur at any time during therapy and may last for weeks to months or even lead to permanent damage. Patients should receive medication guides and be informed to contact a physician immediately if symptoms of peripheral neuropathy occur. Incidences of peripheral neuropathy should be reported the FDA for continuous monitoring of this significant adverse effect.

References:

1. US Food and Drug Administration. FDA Drug Safety Communication: FDA requires label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection. [Updated: 22 August 2013, Accessed: 27 October 2013]. Available from: http://www.fda.gov/Drugs/DrugSafety/ucm365050.htm.
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3. National Institute of Neurological Disorders and Stroke. Peripheral Neuropathy. [Updated: 22 September 2012; Accessed: 30 October 2013]. Available from: http://www.ninds.nih.gov/disorders/peripheralneuropathy/detail_peripheralneuropathy.htm.

Contributed By:

Tracy Ngo, Pharm.D. Candidate 2014, Rutgers University
Polly Jen, Pharm.D., BCPS, AAHIVP, Clinical Pharmacy Specialist