UNIVERSITY OF GEORGIA
College of Pharmacy

The Transition

4th Year Pharmacy Students Entering the Real World of Pharmacy

VOLUME V, ISSUE II FEBRUARY 2017

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Rotation Spotlight: Grady Health System

"Atlanta can't live without Grady," was what all the students, volunteers, and new staff were told at orientation. I had the privilege of spending an emergency medicine rotation in Atlanta's only ACS-verified Level I trauma center, and it truly lived up to its reputation. During my time there, I saw so many gunshot wounds, motor vehicle accidents, drug overdoses, and stroke alerts. I ran eight flights of stairs to codes with the PGY2 emergency medicine resident. With pharmacist supervision, I was able to prime IV lines, push medications, and do chest compressions. I helped roll trauma patients as the medical residents triaged them, and I always kept a few normal saline pushes on me for the nurses. Needless to say, I was a very busy student on this rotation.

"These are learning experiences that will stay with me forever."

As a safety net hospital, the patients had the most complicated medical and social situations I have ever encountered. If we were lucky, patients came in conscious or with a medical history, but many times, this was not the case. There were many occasions where these patients did not make it, but the moments that made the greatest impression on me were when the whole healthcare team, amidst all the chaos, still took the time to treat the deceased patient with respect by stopping everything and giving the patient a moment of silence.

At Grady, the pharmacist had an integral role on the interdisciplinary team. Each person of the team was assigned a designated area to stand in the trauma rooms, and the pharmacist's spot was next to the Pyxis® to pull and dose medications. The medical residents and attendings readily accepted the pharmacist's recommendations, and the nurses appreciated it when the pharmacist would help them document. However, the pharmacist's role was not limited to just the emergency situations. As patients awaited their admission to the floor or to be discharged, the pharmacists constantly reviewed their medications and were sought out by the team for recommendations. Throughout the day, the pharmacist walked through the emergency department just to assist or answer any questions.

Did I have an incredible time in those five weeks? Yes, it was exciting to see the toxicology team simultaneously deal with an anti-freeze overdose and a diphenhydramine overdose. Yes, it was amazing to see a patient transition from having extreme respiratory depression to having a normal conversation with the nurses just ten minutes after being given naloxone. These are learning experiences that will stay with me forever. However, I think what will stay with me most is seeing how quickly and calmly the pharmacists worked and seeing their commitment to taking care of their patients regardless of long hours or dangerous conditions. So I agree that Atlanta can't live without Grady, but I also think Grady can't live without its pharmacists.

Michelle Vu (Atlanta, GA)

Handling Nonsterile Compounded Preparations

The United States Pharmacopeia (USP) is a non-profit organization that establishes standards regulating the development and maintenance of healthcare quality. USP Chapter <795> discusses the compounding principles for nonsterile preparations, such as oral, topical, and rectal dosage forms.[1] USP Chapter <800> is a new section that will become federally enforceable in July 2018, addressing hazardous drugs.[2,3] In summary, the standards set by USP minimize exposure of these hazardous medications to personnel and also minimize contamination in order to deliver safe and high-quality medications.

USP <795>[1]	USP <800>[2,3]
Three types of nonsterile compounding:[1] • Simple preparations have directions in USP/manufacturer monograph or in peer-reviewed journal articles (i.e., Amoxicillin suspensions reconstitution). • Moderate preparations require special calculations or procedures or one without stability data, i.e. diphenhydramine troches. • Complex preparations require special training/facilities/ equipment/procedures (i.e., hazardous drugs).	Focuses on:[2,3] • Hazardous drugs, including antineoplastics (i.e.. cyclophosphamide) • Non-antineoplastics (i.e., tacrolimus) • Drugs that have reproductive risk only (i.e., bosentan) • Others listed on the National Institute for Occupational Safety and Health (NIOSH) list
General compounding rules:[1] • Wear personal protective equipment. • Assign appropriate beyond-use dates. • Document master formulation records and compounding records.	Compounding hazardous drugs requires:[2,3] • Gowns • Hair and shoe covers • Two pairs of chemotherapy gloves
Facility requirements:[1] • Adequate space specified for compounding • Clean, orderly, sanitary, and in good state of repair • Designed, arranged, and used to prevent cross-contamination • Well lighted • Appropriate heating, ventilating, and air conditioning • Hand/equipment-washing facilities and plumbing system	Facility requirements:[2,3] • Well- ventilated hood placed in a physically separate control room that is under negative pressure, externally ventilated, and has at least 12 air changes per hour.[4] • The walls, floors, shelving, counters, cabinets, and cabinets must be smooth, impervious, and non-shedding. • Except when handling final dosage forms that do not produce particles, aerosols, or gasses.

Written by: Lynn Doan (Columbus, GA)

Reviewed by: Jennifer Sterner-Allison, PharmD

Lifestyle Corner: Loaded Potato Soup

Ingredients:

- ◊ 1 pound of bacon (may use olive or vegetable oil--see directions below for non-bacon option)
- ◊ 5 pounds of potatoes, peeled and diced
- ◊ 1-2 large white or yellow onion(s), diced
- ◊ 1 large carton of heavy cream (to lighten recipe, use half the amount of half & half in place of heavy cream)
- ◊ Salt and pepper to taste
- ◊ 1 pound of freshly shredded cheddar cheese (sharpness of your choice)
- ◊ 1 bunch of green onions, sliced
- ◊ Water to cover potatoes (~3 to 5 cups)

Directions:

1) In a large pot, cook bacon on medium to medium-high heat until crispy.
2) Remove from pot and set aside for later.
3) Add onions and potatoes to bacon grease (may substitute ~1/4 cup of olive oil or vegetable oil instead).
   Stir frequently for approximately 10-15 minutes or until onions become translucent.
   A) FYI, you will need a sturdy spoon. I like a wooden spoon.
   B) Be careful not to scorch! Burnt potatoes = burnt tasting soup
4) Add enough water to cover potatoes and bring to a boil.
5) Cover and continue to boil until potatoes are very tender.
6) Add heavy cream and stir well.
7) Add salt and pepper to taste.
8) Continue to cook for an additional 10-15 minutes.
9) While soup is cooking, crumble bacon from step 1 to use as soup topping
10) Serve hot and top with cheese, green onions, and crumbled bacon.

Written by: Cindy Dyer (Athens, GA)

Delafloxacin (Baxdela®): The New Fluoroquinolone on the Block

In this world of rampant antimicrobial resistance, the U.S. Food and Drug Administration's approval of delafloxacin (Baxdela®), a drug manufactured by Melinta Therapeutics, is a notable achievement that should excite the healthcare industry. Delafloxacin, a new fluoroquinolone antibiotic, was approved on June 17, 2017 for the treatment of acute skin and skin structure infections (ABSSSI) in adults after proving its non-inferiority to vancomycin and aztreonam combination treatment.[1] With *in vitro* activity against Methicillin-resistant *Staphylococcus aureus (*MRSA*)* and availability in both oral and IV formulations, delafloxacin shows promising potential as a possible weapon against growing antimicrobial resistance, particularly in the hospital setting.

Delafloxacin has a mechanism of action similar to that of other fluoroquinolones. It inhibits both bacterial topoisomerase IV and DNA gyrase (topoisomerase II), thereby halting bacterial DNA replication, transcription, repair, and recombination.[2] It demonstrates concentration-dependent bactericidal activity against numerous gram-positive bacteria (i.e., including MRSA), as well as gram-negative bacteria.[2] Delafloxacin also shares a similar safety profile compared to the other fluoroquinolones, with common side-effects including nausea, diarrhea, headache, elevations in transaminase, and vomiting. The serious side-effects include tendinitis and tendon rupture, peripheral neuropathy, CNS effects, exacerbation of myasthenia gravis, hypersensitivity reactions, and *Clostridium difficile*-associated diarrhea.[2]

The recommended doses of delafloxacin for treatment of ABSSSI in adults are 300 mg intravenously (IV) or 450 mg orally every 12 hours for 5-14 days.[2] For patients with an estimated glomerular filtration rate (GFR) between 15-29 mL/min/1.73m^2, the intravenous dose must be adjusted to 200 mg every 12 hours, while no dosage adjustment is necessary for the oral formulation. Delafloxacin is not recommended in patients with end stage renal disease (i.e., eGFR less than 15 mL/min/1.73m^2), including those on hemodialysis. No dosage adjustments are necessary for patients with hepatic impairment. At this time, there is no data establishing safety and efficacy in pediatric patients below the age of 18 years. Additionally, caution is warranted when administering delafloxacin to elderly patients, as they are at an increased risk for developing tendon disorders like tendonitis or tendon rupture.

For an economical perspective, the average wholesale price for a standard 10-day IV course is $3,180 and for a standard 10-day oral course is $1.620.[3]

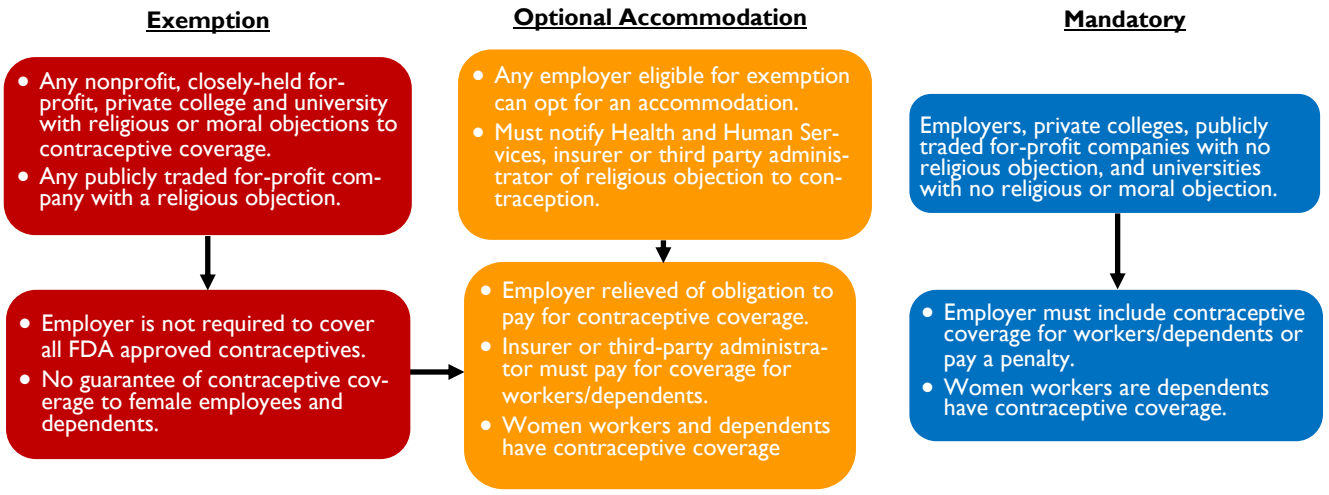
While a phase 3 clinical trial evaluating delafloxacin monotherapy in patients with uncomplicated urogenital gonorrhea was terminated for insufficient efficacy, another study for its use in adults with community-acquired bacterial pneumonia is currently ongoing. As more research is completed and analyzed, the role of delafloxacin in this world of antimicrobial resistance will become more apparent. Stay tuned!

Written by: Joanna Lee (Augusta, GA)
Reviewed by: Stephanie Lively, Pharm.D. BCPS

https://jamanetwork.com/data/Journals/JAMA/936400/jfd170040fa.png

From the Hill: Rollback on Contraceptive Coverage

Exemptions and Accommodations Under the Trump Administration Regulations



https://www.kff.org/womens-health-policy/issue-brief/new-regulations-broadening-employer-exemptions-to-contraceptive-coverage-impact-on-women/

The "Birth Control Mandate" has been a controversial topic since its addition to the Affordable Care Act under President Obama's Administration in 2012. This mandate requires preventative care, such as FDA-approved female contraception and screening, to be covered by all health insurance plans.[1] This presented a positive investment in women's health, and was applauded by women's rights advocates nationwide. Approximately 55 million women have benefited from full contraceptive coverage since the mandate's enactment.[2,3] Although it was considered a step forward for women's rights, several religious affiliates felt discriminated against, stating that the requirement forces them to violate their religious beliefs; thus, the mandate has been a topic of debate.

The Obama Administration attempted to address the disparity by exempting religious employers from the requirement in order to "protect sincerely held religious beliefs".[2] However, the U.S. government has historically provided protection for moral convictions in addition to religious beliefs when concerning access to healthcare.[3] For this reason, many lawsuits and challenges were brought forth by non-religious organizations with moral convictions in regard to required contraceptive coverage. The efforts made by the Obama Administration were insufficient to diffuse the opposition by religious and nonreligious organizations, so the disparity continues to this day.

In early October 2017, President Trump's Administration announced that they would be rolling back the contraceptive coverage mandate, expanding exemptions for entities citing moral or religious objection.[1,2,3] These rules became effective on October 6, 2017 after being displayed in the Federal Register. Although many individuals are likely to understand religious objection to the contraceptive coverage mandate, the term "moral conviction" is used very loosely in the mandate and no specific requirements are listed stating who is eligible for an exemption under this rule. Pro-life advocacy groups, for instance, who oppose contraceptive use remain the symbol for groups with moral conviction to the mandate. An ongoing concern is the fear that some employers may take advantage of the new rules and claim moral conviction just to pinch pennies. This is no longer strictly a religious or moral battle, but also a financial one. The cash price of birth control can range from $5 to $100+ in numerous pharmacies for a 28-day supply. That is a significant increase in patient cost when the guarantee of $0-copay contraception has been taken away.

As healthcare professionals and individuals affected, we can expect to see this topic in the news more and more as it starts to unfold in daily practice. The voluntary exemptions will inevitably retract the progress that has been made in women's health to this day. Dealing with expensive contraceptives, refusal to pay for birth control, and noncompliance may become the norm in the retail setting. Unplanned pregnancies are likely to rise, as well as abortions, without the guarantee of contraceptive coverage. However, religious freedom will remain intact and morals will not be compromised. But, where does that leave us in regard to women's rights and access to healthcare? How will the government ensure that moral or religious objections are sincere? As healthcare providers it is important to stay educated with the new legislation impacting our profession. Where will you stand on this issue?

Written by: Shelby Bridges (Columbus, GA)

Off-Block Adventures

This year's fourth year students showed us that it's possible to work hard and still have a bit of fun during a hectic year of rotations. Here are a few of the incredible places the P4s have visited this year:

(Left) Ashni Patel and Ebonne Ugbo watched this breathtaking sunset in Florence, Italy. What a view!

(Right) Trinh Nguyen visited Zurich, Switzerland in September and snapped this awesome photo. Can you spot the friendly swan?

(Left) Alia Reid enjoyed an elephant ride around the Bayon Temple in Angkor Wat, Cambodia!

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UPCOMING EVENTS

Mar. 20th - Residency Phase I Match

Apr. 24th to 27th - Pharmacy Review

Apr. 27th 6:30 PM - Senior Banquet

Apr. 28th 2:00 PM- Graduation

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3. Kienle, P.C. (2015). Chapter 48: compounding nonsterile preparations. Competence Assessment Tools for Health-System Pharmacies (ASHP): 671-80.
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Delafloxacin article:

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2. BAXDELA (delafloxacin) [prescribing information]. Lincolnshire, IL: Melinta Therapeutics, Inc.; June 2017
3. Delafloxacin. Lexicomp Online® , Hudson, Ohio: Lexi-Comp, Inc.

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