Fluoroquinolones are a class of antibiotics that have a broad spectrum of activity and can be utilized to treat a variety of different infections. Several fluoroquinolones have been withdrawn from the market after approval due to severe adverse effects. In 2008, the Food and Drug Administration (FDA) released safety warnings about tendon rupture and tendinitis and again in 2013 for peripheral neuropathy, prompting the inclusion of a black box warning. Despite these warnings, fluoroquinolones are still commonly prescribed antibiotics in the community. Fluoroquinolones are also associated with causing exacerbations of myasthenia gravis, hallucinations, photosensitivity, QTc prolongation, and hypo/hyperglycemia. As a result, this class of antibiotics has been closely monitored for toxicity.

On May 12, 2016, the FDA released a safety announcement, “...the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with acute sinusitis, acute bronchitis, and uncomplicated urinary tract infections who have other treatment options.” The serious side effects prompting the FDA warning involve the tendons, muscles, joints, nerves, and central nervous system. The proposed mechanism for tendon rupture is a direct (Continued on page 2)
New Drug Primer: Active Leptospermum Honey (Medihoney®)

by Eric Ocheretyaner, Pharmacy Practice Resident

Active leptospermum honey (ALH) is a medical grade honey for the management of wounds and burns. Utilizing its high osmotic potential, it increases outflow of fluid to the wound surface, thus helping the body promote debridement of necrotic tissue. The low pH of ALH helps to lower the pH at the wound site, which has been shown to have wound healing benefits.

Indications:
- Diabetic foot ulcers
- Leg ulcers (venous stasis, arterial, and leg ulcers of mixed etiology)
- Pressure ulcers / sores (partial and full thickness)
- First- and second-degree partial thickness burns
- Donor sites, and traumatic and surgical wounds

Contraindications:
- Third-degree burns
- Known sensitivity to honey or any component of the product, including algae or seaweed
- To control heavy bleeding

Adverse Reactions:
- Allergic site reactions, pain, stinging

Hospital Formulary Restrictions:
- None

Fluoroquinolones - More Harm than Good?

Drug Shortage Updates

Fluoroquinolones - More Harm than Good?

(Continued from page 1)

effect of the fluoroquinolones on the quantity and quality of collagen fibrils due to up-regulation of matrix metalloproteinases, which may then lead to tendon rupture and possibly aortic dissection and aneurysm, as well as retinal detachment.

Furthermore, from an antimicrobial stewardship perspective, fluoroquinolones cause a significant amount of “collateral damage.” Collateral damage refers to ecologic adverse effects of antibiotics, especially the selection of drug-resistant organisms. Fluoroquinolones have been linked to an increased risk of methicillin-resistant S. aureus (MRSA), C. difficile, and drug-resistant gram-negative infections. Less noticeably, resistance to fluoroquinolones has increased for most bacteria due to overuse.

References:
Pharmacy Focus: Biosimilars – The New “Generics”  
by Eric Ocheretyaner, Pharmacy Practice Resident

“Biosimilars” is a new terminology that has recently entered the pharmaceutical world to describe products that may be used interchangeably with current biological products on the market. The pathway to create biosimilars was outlined in the Affordable Care Act (signed in March 2010) under the subtitle of the Biologics Price Competition and Innovation Act (BPCI Act) of 2009. Despite the availability of biosimilars in the European Union market since 2006,1 the first biosimilar launched in the United States, filgrastim-sndz (brand name Zarxio®), was not approved until 2015.2

“Biologics” are complex molecules derived from living organisms or cells of living organisms (such as yeast, bacteria, or animals) that are far more complex than standard chemical drug moieties. Examples include erythropoietin (Epogen®, Procrit®) and rituximab (Rituxan®). The complexity and size of biologics creates difficulty in creating a traditional “generic” that would be structurally identical to the reference product. The FDA defines a biosimilar as a biological product that has “data [to] show that, among other things, the product is ‘highly similar’ to an already-approved biological product and has no clinically meaningful differences in terms of safety and effectiveness.”3 FDA approval of a biosimilar to be interchangeable with the reference biologic product requires the manufacturer to demonstrate that the biosimilar produces the same clinical effect and that risks associated with switching between biologic and biosimilar are no greater than potential risks of continued use of the biologic alone.3 Similar to generics, once approved as interchangeable to brand and legend drugs, biosimilars inherit the same FDA-approved indications as the reference product.4

References:

Nurses Want To Know …
Q: Why does the pharmacy send vials of medication to the floors? Doesn’t the pharmacy mix IVs?
A: In general, the Pharmacy Department dispenses intravenous compounds (or IV admixtures) in ready-to-use form as premixed or compounded IV bags. However, a number of medications must be used within a very short period of time, if not immediately, due to limited stability in solution. At University Hospital of Brooklyn, short stability is defined as medications that are stable for 4 hours or less from the time the medication is mixed with an IV diluent. Common short stability drugs include ampicillin and sulfamethoxazole-trimethoprim (Bactrim®). When mixing these drugs, practice aseptic technique in clean areas and wipe rubber stoppers and IV bag ports with an alcohol pad prior to puncture with a needle.

Spotlight on Safety: Taking Medications “As Directed”  
by LilyAnn Jeu, Medication Safety/Internal Medicine Clinical Pharmacist

When 76-year old RG was discharged from University Hospital in January 2016, he probably did not expect to return to the hospital one day after a nearly month-long stay at a skilled nursing facility. Upon discharge from the nursing facility, RG was prescribed insulin aspart (NovoLog®). Without a clear dose on the label, RG’s son administered 100 units of the rapid-acting insulin as the patient’s very first dose of insulin. Within 4 - 5 hours, RG became very jittery and was sweating profusely. EMS brought RG to the Emergency Department, where multiple fingerstick blood glucose readings were less than 20 mg/dL. RG was treated with Dextrose 50% boluses and recovered from severe hypoglycemia with no permanent harm.

Further assessment by the admitting team found RG’s hemoglobin A1c to be 6.2%, and thus the insulin was discontinued. Interview of the patient and son also revealed that the family had never been counseled about the appropriate dose or the need for insulin. At least for this family, “As Directed” actually meant “Never said it.” Electronically submitted prescriptions today will mandate the dose field to be completed on the prescription; however, communication and patient education are still essential component for the safe use of medications.
Clinical Pearls: Enoxaparin Treatment Doses in Obesity

By Ishtiaq Chowdhury, PharmD Candidate

For most patients, weight-based treatment doses of enoxaparin (Lovenox®) generally achieve target anti-factor Xa levels without the need for laboratory monitoring. However, although some studies have shown that capping doses in obese patients to avoid over-anticoagulation may result in failure to achieve targeted levels, few studies have included patients with total body weights above 140 kg.

To examine the impact of enoxaparin doses on bleeding risk in larger patients, Lee et al. assessed anti-Xa levels among adults with a body-mass index (BMI) > 40 mg/kg² or body weight > 150 kg following a course of enoxaparin 1 mg/kg twice daily. Targeting 0.5 - 1.1 units/mL, 50.5% of 99 patients (weighing 99-249 kg) had a therapeutic level, 14.1% (weighing 78-244 kg) subtherapeutic, and 35.4% (weighing 103 – 249 kg) supratherapeutic up to 2.0 units/mL. No bleeding events were recorded, and no differences in major bleeding or transfusion were observed.

Similarly, among patients with BMIs > 30 mg/kg², Bazinet and colleagues observed that 60% of patients treated with enoxaparin 1.5 mg/kg once daily (n= 30/60; weighing 66 -136 kg) achieved target anti-Xa levels (1.0 - 2.0 units/mL), while 45% of patients treated with enoxaparin 1 mg/kg twice daily (n = 23/51; weighing 63-159 kg) achieved target levels (0.5-1.1 units/mL). Meanwhile, the once-daily regimen tended to result in subtherapeutic levels (37% of patients), while the twice-daily regimen tended to result in supratherapeutic levels (53% of patients).

These studies suggest weight-based enoxaparin dosing using total body weight does not consistently result in supratherapeutic anti-Xa levels, even among (morbidly) obese patients or patients weighing more than 240 kg. Instead, adjustment of enoxaparin dose based on anti-Xa levels is still recommended, and a once-daily regimen of enoxaparin should be used cautiously in obese patients due to greater potential for initially subtherapeutic anti-factor Xa levels prior to adjustments.

References:

Team Tip of the Day
Discharge Counseling Pharmacist

If you would like to request a consult for medication counseling, please page the Discharge Counseling Pharmacist at (917) 219–9855.