December / January 2012

Winter Issue

Gulf Coast Society of Health-System Pharmacists

Has your contact information changed?

Please send all changes to

gcshp.membership@gmail.com

Inside this issue:

President's Report
Monica Green, PharmD, BCPS

Happy New Year, GCSHP Members!

I am excited to report that it has been a great year for our organization due to the overwhelming support of the Board of Directors and the involvement of the membership.

This year we added a New Practitioner Liaison position to the Board of Directors, provided alternatives for communication via Facebook and Twitter, and maintained CE programs for members. It is not over yet! We will be hosting the **GCSHP Annual Seminar** at University of Houston, **Saturday, February 4, 2012!** This important event will focus on resources required to deal with challenges in the hospital and health-system settings and new endeavors that will advance the pharmacy profession. I invite ***you*** and encourage you to invite at least one of your colleagues.

It is also time for 2012-2013 Elections. You should have received a nomination ballot via email this week. As a member, you are encouraged to be involved in the election process. The available positions include: President-Elect, Director, Treasurer, and Recording Secretary. The position responsibilities are included in this edition's newsletter. Nominations for outstanding pharmacist, outstanding student, outstanding technician, and outstanding industry representative will also be included on this ballot. The deadline for nominations is Tuesday, January 31, 2012. Once the nomination process is completed, the election ballot will follow.

If you have any ideas you would like to share to continue the efforts of improving our organization, please feel free to email me at Monica_Green@hchd.tmc.edu. I look forward to hearing from you.

Although this will be my last newsletter, I will continue to work toward the mission and vision of GCSHP!

Monica Green

42nd GCSHP Annual Seminar

February 4, 2012

See Page 3 for more details!

December 2011

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Schedule of Events

- December 5-9, 2011
  ASHP Midyear Clinical Meeting
- December 25, 2011
  Christmas
- December 31, 2011
  New Year's Eve
- January 1, 2012
  New Year's Day
- January 19, 2012
  UH/TSU Residency Mentoring Social
- February 4, 2012
  GCSHP Annual Seminar

January 2012

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4	5	6	7
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Gulf Coast Society of Health-System Pharmacists Annual Seminar
Saturday, February 4, 2012

Texas Legislative Update
Brad Shields

Drug Shortages
Stacey Lavsa, PharmD, BCPS

Drug Shortages Panel
TMC Clinical Staff

Pharmacy Practice Model Initiative
Catina Brimmer, PharmD, MBA

Accountable Care Organizations
Lourdes Cuéllar, MS, RPh, FASHP

Pharmacy Benefit Manager
Ryan Roux, PharmD, MS
Tam Nguyen, RPh, MBA
Shahana Quadri, PharmD, MS

Program Goal

To provide pharmacists, technicians, and students with an overview of the resources required to deal with challenges in hospital and health-system settings, embark upon new endeavors and overall enhance the profession of pharmacy.

Target Audience

Registered pharmacists, technicians, and students practicing pharmacy in hospital and health-system pharmacies.

Continuing Education Credit

This program provides 5.0 hours (0.5 CEUs) of continuing pharmaceutical education. Pharmacists and Technicians will receive an ACPE certificate by mail within 30-45 days of the end of the program.

Registration Information

Click the link: GCSHP Registration
Credit Cards accepted online

****Breakfast & Lunch will be provided****

Registration Fees

Pharmacists/GCSHP Member: $50	Pharmacists/Non-GCSHP Member: $65
Technician/GCSHP Member: $20	Technician Non-GCSHP Member: $35
Student/GCSHP Member: $20	Student/Non-GCSHP Member: $35

ONLINE REGISTRATION DEADLINE:

FRIDAY, JANUARY 27, 2012

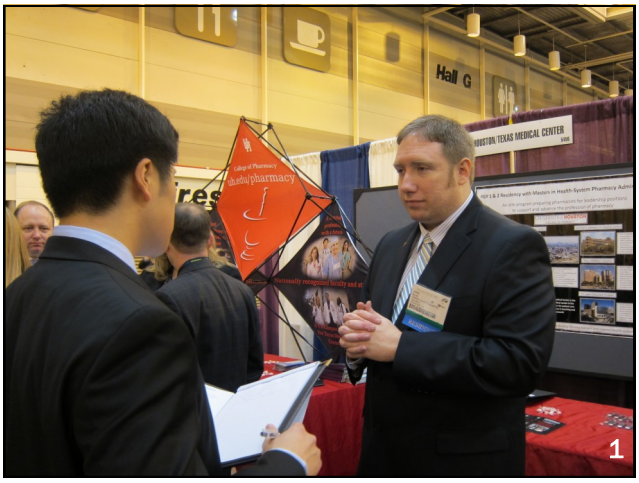
To join GCSHP, log on to www.TSHP.org and click on the membership link to obtain joint membership. For questions regarding membership, please contact the membership secretary at gcshp.membership@gmail.com

Gulf Coast Society of GCSHP Health-System Pharmacists

University of Houston
University Center
4800 Calhoun RD
Houston, TX 77004

Register Today!

ASHP MidYear Clinical Meeting
December 5-9, 2011 New Orleans, LA



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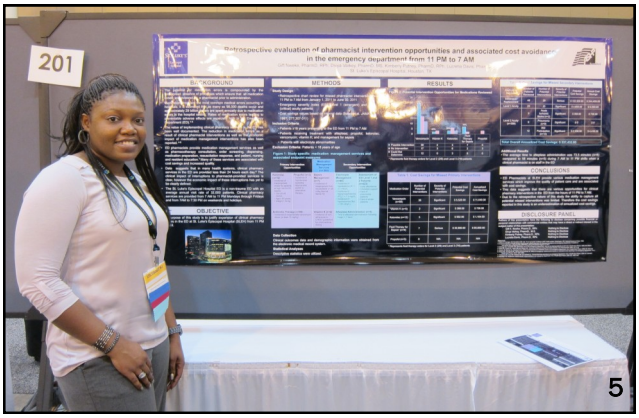

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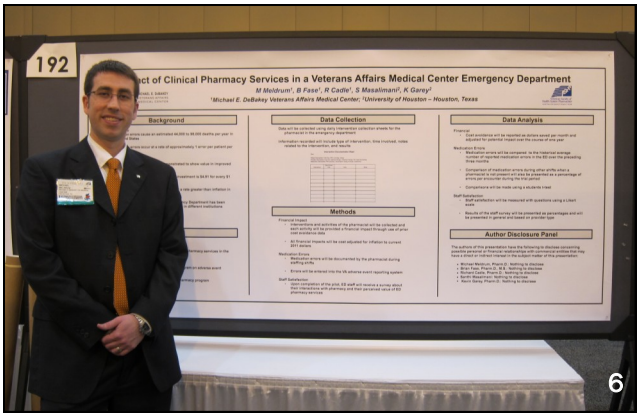

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This page:
1.) John Blee promotes residency programs at the Residency Showcase 2.) Rodney Cox and Perry Flowers network at the Residency Showcase. 3.) Aily Liem, 4.) Daniel Ortiz, 5.) Gift Nweke, and 6.) Mike Meldrum present their posters during the Resident Poster Session. 7.) Ogechi Eshleman and Joyce Tipton catch up at the Residency Showcase.

Next Page:
8.) Brian Cohen and Monica Morgan chat during the resident poster session. 9.) Monica Green and Alex Winans prepare for the Residency Showcase.

A Day in the Life: Anticoagulation Clinic

Name / Credentials: Allison Torregrossa, BS Pharm, PharmD

Title: Clinical Pharmacist II

Institution / Work Location: Harris County Hospital District, Quentin Mease Hospital Anticoagulation Clinic

Area of Focus: Ambulatory Care / Anticoagulation

Biography / Path to Career:

I had always planned to be a veterinarian from the time I was very young. My father is a veterinarian and I witnessed many interesting things as a child. There were times we had baby tigers and lions at our house so my father could keep a close watch on them overnight. I realized as I got older, however, that performing euthanasia was not something I could handle emotionally. It was then I started thinking of alternative careers.

While in high school, my mother suggested pharmacy as a good career choice for a woman. At the time I was working at Kmart and I occasionally filled in for the pharmacy cashier. The pharmacist there inspired me. He always provided excellent patient care and remembered every patient's name, no matter how long it had been since the last visit. I made the decision that I was going to be a retail pharmacist. I entered the University of Wisconsin as a pre-pharmacy student and after 2 years was accepted to pharmacy school.

At the time I entered, most students were receiving a Bachelor's of science in Pharmacy. During my second year of pharmacy school, I realized my path might take a different turn from what I had originally anticipated. Therapeutics class and all the interesting disease-state discussions motivated me to broaden my horizons and apply to the PharmD program. I was accepted and along with 21 other students was able to complete my Bachelor's degree and doctorate degree at the same time. Because our PharmD class was so small, we received a lot of personal attention from our professors. They encouraged me to apply to a residency program.

My route to Houston was slightly unconventional. I had a significant other living in Houston at the time, so I was determined to move here. I applied to all the residency programs in Houston and matched to the PGY1 program at The Methodist Hospital. That year of residency was one of the best of my life. I loved being able to experience so many different things in one single year. Being from Wisconsin (lots of small towns) coming to the Texas Medical Center was both intimi-

Continued on page 17

STUDENT SECTION

University of Houston SSHP
Sunaina Rao, President

P2 students talk to elementary school children about the difference between Candy and Medicine.

SSHP at the University of Houston College of Pharmacy welcomes you to 2012! This chapter update covers a few events from the past semester as well as highlights our plans for the spring.

In October, at our 2nd Annual Residency Workshop, over 85 students acquired an early insight on Residencies and the Match Process, Health-System Pharmacy Conventions and Conferences, and Research in Residency. The topics were presented by Dr. Matthew Wanat, Dr. Ryan Roux and Dr. Ali-Reza Shah-Mohammadi, and Dr. Lauren Biehle, respectively.

SSHP promoted National Health System Pharmacy Week at a retirement facility during a Brown Bag Medication Review session. This served as an eye opening experience for the elderly residents and students alike, highlighting the importance of medication adherence, therapy assessment and preventative care. We would especially like to thank our two preceptors, Dr. Kimberly Birtcher and Dr. Jessica Cottreau, for dedicating their afternoon to verifying interventions and assisting with counseling. Also in honor of Pharmacy Week, UH SSHP presented the TSHP Educator Excellence Award to Dr. Jeffrey Sherer for his support and dedication to the pharmacy profession, and passion for helping students.

Prior to Halloween festivities, our chapter visited a local elementary school to educate over 100 Kindergarten through 2nd Grade students about the difference between Candy and Medicine through interactive presentations and games.

On November 4th, UH SSHP organized the Texas Medical Center (TMC) Residency Showcase, which hosted 29 Texas-area residency programs and brought together 200 students from 9 schools of pharmacy. With this event being majorly funded by GCSHP, we would like to thank them for their yearly financial and professional support to pharmacy students in the Houston-Galveston Area!

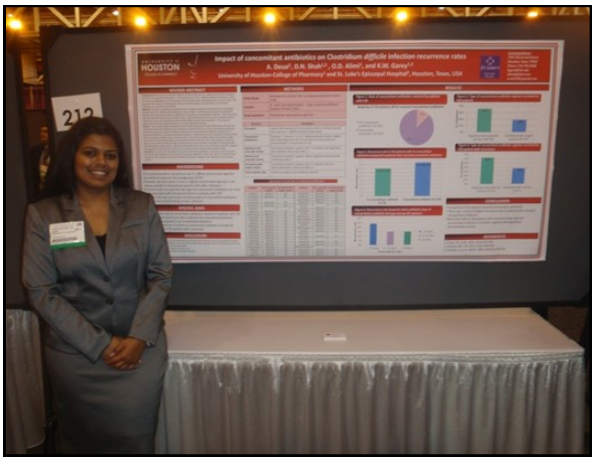
With 51 students attending ASHP Midyear Clinical Meeting 2011, University of Houston College of Pharmacy held a strong presence. Nineteen students presented posters and our local Clinical Skills Competition Winners, Ghazaleh Ranjbar and Natalie Lee, P4s, participated in the national level com-

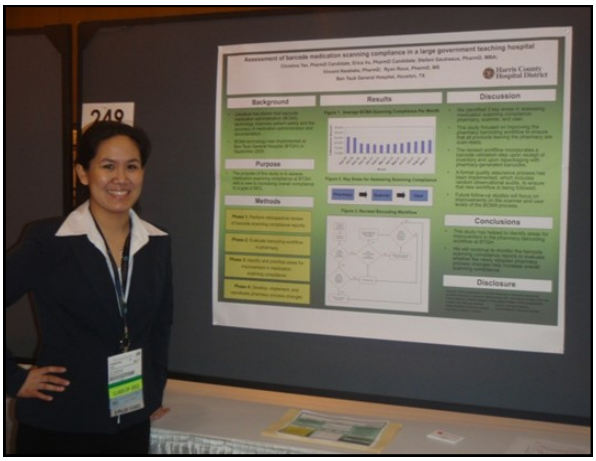

Students mingle with Houston-area residency programs at the TMC Residency Showcase on Nov. 4th, 2011

petition. Our students thoroughly enjoyed visiting with out-of-state programs as well as our local area residencies, in addition to participating in PPS and the variety of student programming offered. The attendees also provided great feedback and tips to the students who couldn't make it to Midyear!

To start off the Spring Semester with a bang, UH - SSHP in coalition with TSU – SSHP will hosted the 7th Annual Residency Mentoring Social (RMS) on January 19th 2012. The event features our keynote speaker, Ms. Joyce A. Tipton, followed by a "round-robin style" interactive social with TMC area residency programs for the students from both schools.

Post- RMS, our chapter has planned 6 Main Campus and 5 TMC Campus meetings. Our focus this semester will be on service as well as the state-wide initiatives of Antibiotics Awareness and Medication Safety.





From Top left to right :

Top: UH SSHP past officers Avani Desai (Immediate Past President), Tara Thompson (Immediate Past VP of Communications), and Christina Tan (Immediate Past VP of Programming) present their posters at ASHP midyear .

Middle Right: P4 students mingle at the Showcase.

Bottom: Local Clinical Skills Competition Winners Natalie Lee and Ghazaleh Ranjbar.

STUDENT SECTION

Texas Southern University SSHP
Kinyatta Weatherspoon, President

Greeting from Texas Southern University Student Society of Health System Pharmacists (TSU-SSHP)!

We would like to start by thanking GCSHP for its generous support of our chapter. The Fall 2011 semester was a very busy and exciting one.

TSU SSHP Past President Celia Fenceroy and Current Officers Muhammad Qudoos (Webmaster), Kinyatta Weatherspoon (Chapter President), Helen Muoneke (Vice President), Ndidi Uwadia (Historian), and Osita Okafor (President- Elect).

We began our semester with P1 Orientation in August. We provided our incoming class with information about our organization and all the benefits that come with membership.
We kicked off the semester with our first general meeting on September 19th. Over fifty students came to find out about joining TSU SSHP!

The month of October was a busy one for our chapter. We started the month with our annual Antibiotics Awareness Program. The antibiotic awareness, handwashing workshop took place at Cooney Homes YMCA. There were about thirty students ranging from grades 1-5 in attendance. TSU SSHP used a very hands-on approach to educate the students on antibiotics and how to properly wash their hands.
The event started with a skit on the importance of hand washing, followed by an elementary-friendly presentation on how to properly wash hands, and antibiotic awareness.

TSU SSHP Officers pose with students from Cuney Homes YMCA After School Program. Precious Anwanyu (Community Service Chair) helps the children get ready for snack time. Kinyatta Weatherspoon, Helen Muoneke, and Quyen Ho (Secretary) say goodbye to the children.

After the presentation each student was taken to the bathroom and demonstrated how to

properly wash their hands. When the students finished washing their hands, a jeopardy game was played with antibiotic awareness as the main topic. Each student left the event with a good understanding on how to wash their hands and a goody bag filled with treats, hand sanitizer, and a antibiotic awareness coloring book. The event was a huge success, and we can't wait to do it again next year.

Following the Antibiotics Awareness Program, we had our second general meeting with guest speaker Dr. Pamela Price, from the Texas Society of Health System Pharmacists New Practitioner Section. Our students really enjoyed her presentation on the importance of being involved in professional organizations and the benefits of becoming a member of SSHP.

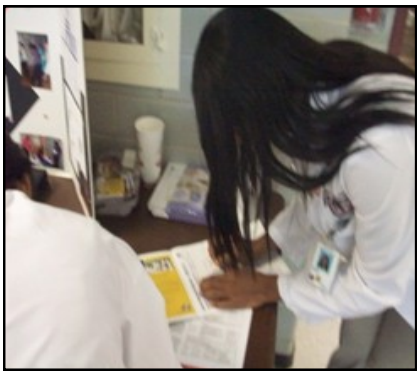
Next was our Clinical Skills Competition. This year's winners were Oanh Ngo and Huenvy Van.

Following the Clinical Skills Competition, we closed out the month of October with a CV Writing workshop with Dr. Todd Canada. Dr. Canada gave the students a presentation on how to prepare a CV that gets noticed and answered questions about what items to include on a CV. Following his presentation, he shared with us resources to help students navigate the residency process.

In November, we held our third general meeting. Mr. Lance Henderson and Dr. Adlia Ebeid spoke to our third year students about selecting APPE rotations. The speakers gave wonderful advice on the types of rotations that residency bound students should select and the types of resources that can be used while on rotations.

We closed out the Fall semester with Midyear in New Orleans. Midyear was attended by more than fifty third- and fourth-year students, and twenty-three students from TSU presented posters. We would like to wish all students that attended the best of luck in their future endeavors.

We opened the Spring 2012 semester with the 7th Annual TSU-UH Residency Mentoring Social. The event was attended by several program directors and residents from the Texas Medical Center. Students from both universities came to find out more about residencies, and how to improve their chances of matching with residency programs. The event was a huge success and it would not have been possible without the generous support of the Gulf Coast Society of Health System Pharmacists! We can not thank you enough.



From left to right: Clinical Skills Competition winners Oanh Ngo and Huenvy Van. TSU SSHP Posterboard outlining chapter activities and the benefits of membership. Students becoming members of TSU SSHP

STUDENT SECTION

The Use of Factor Xa Inhibitors in DVT Prophylaxis and Treatment

Sarah Ortega, Pharm. D. Candidate
University of Houston College of Pharmacy

Venous thromboembolic disease has the potential to affect hundreds of thousands of individuals every year, particularly those who are undergoing major orthopedic surgery. According to the CHEST guidelines for venous thromboembolism prevention, these patients have a 40-60% chance of developing a DVT while they are hospitalized without thromboprophylaxis, and the risk doesn't go away once they leave the hospital. Post-operative venous thromboembolism is the 2nd most common medical complication up to 3 months after hospital discharge.

The current standard of care for these patients includes low molecular weight heparins, fondaparinux, or warfarin and although the aforementioned medications are considered safe and effective, they are also difficult to continue outside the hospital[1]. A new class of drugs, direct factor Xa inhibitors, may be able to provide effective thromboprophylaxis and treatment without the drawbacks of current therapy.

Factor Xa inhibitors prevent the conversion of Factor X to Factor Xa, thereby preventing a burst of thrombin generation and subsequent clot formation. While inhibiting any clotting factor can decrease clot formation, factor Xa plays a role in both the intrinsic and the extrinsic pathway, which could mean that its inhibition could lead to even more effective anticoagulation[2]. Factor Xa inhibitors also have predictable pharmacokinetics and pharmacodynamics, eliminating the need for frequent blood tests and dose adjustment. There is also no need to worry about vitamin K intake or numerous drug interactions. On July 1, 2011, after several promising phase 3 trials, rivaroxaban became the first oral direct factor Xa inhibitor FDA approved for thromboprophylaxis in patients undergoing hip and knee arthroplasty[3].

The RECORD1 trial investigators compared rivaroxaban to enoxaparin for extended thromboprophylaxis after hip arthroplasty. They used a randomized double-blind study design to assign 4541 patients to receive either a once daily dose of rivaroxaban 10 mg or enoxaparin 40 mg for 35 days after surgery. The primary efficacy outcome, which was the composite of DVT, nonfatal PE, or death from any cause at day 36 occurred in 1.1% of patients in the rivaroxaban group and 3.7% in the enoxaparin group (CI 1.5-3.7; $p<0.001$). They also found the two drugs to have similar safety profiles[4]. The RECORD2 trial also looked at hip arthroplasty, but the investigator's objective was to compare extended duration rivaroxaban (10 mg once daily for 31-39 days) with short duration enoxaparin (40 mg once daily for 10-14 days). The trial had similar results with 3% of patients in the rivaroxaban group and 9.3% in the enoxaparin group experiencing the primary outcome without a statistically significant difference in safety profiles[5].

The RECORD3 and RECORD4 trials both compared rivaroxaban to enoxaparin for thromboprophylaxis after knee arthroplasty, but RECORD3 used a once daily dose of enoxaparin 40 mg while the other trial looked at enoxaparin 30 mg every 12 hours. Both trials found rivaroxaban to be superior to enoxaparin with a similar safety profile[6,7]. All 4 RECORD trials looked at the same primary efficacy and safety outcomes and had consistent results. Although the RECORD trials showed slightly more bleeding events with rivaroxaban, the numbers never reached statistical significance.

Although rivaroxaban's only FDA approved indication is for DVT prophylaxis in orthopedic patients, the EINSTEIN investigators conducted an open-label, randomized event-driven study comparing standard therapy for symptomatic venous thromboembolism with rivaroxaban and found rivaroxaban to be noninferior with a similar safety profile[8]. Rivaroxaban and other factor Xa inhibitors could play a very important role in prevention and treatment of venous thromboembolism in patients who are unable or unwilling to utilize the current standard of care.

References:

1. Geerts WH, Bergqvist D, Pineo GF, Heit JA, Samama CM, Lassen MR, Colwell CW. Prevention of thromboembolism: American College of Chest Physicians evidence-based clinical practice guidelines. CHEST. 2008; 133: 381S-453S.
2. Turpie AGG. Oral, direct factor Xa inhibitors in development for the prevention and treatment of thromboembolic diseases. Arterioscler Thromb Vasc Biol. 2007; 27: 1238-1247.
3. Rivaroxaban package insert. 07/2011
4. Eriksson BI, et al. for the RECORD1 investigators. Rivaroxaban versus enoxaparin for thromboprophylaxis after hip arthroplasty. N Engl J Med. 2008; 358: 2765-2775.
5. Kakkar AK et al. for the RECORD2 investigators. Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double blind randomized controlled trial. Lancet. 2008; 372: 31-39.
6. Lassen MR et al. for the RECORD3 investigators. Rivaroxaban versus enoxaparin for thromboprophylaxis after total knee arthroplasty. N Engl J Med. 2008; 358: 2776-2786.
7. Turpie AGG et al. for the RECORD4 investigators. Rivaroxaban versus enoxaparin for thromboprophylaxis after total knee arthroplasty (RECORD4): a randomized trial. Lancet. 2009; 373: 1673-1680.
8. The EINSTEIN investigators. Oral rivaroxaban for symptomatic venous thromboembolism. N Engl J Med. 2010; 363: 2499-2510.

Novel Anticoagulants in the Treatment of Nonvalvular Atrial Fibrillation

Eleanor Hobaugh, Pharm.D. Candidate
University of Houston College of Pharmacy

Atrial fibrillation (AF), the most common arrhythmia in clinical practice, is a supraventricular tachyarrhythmia characterized by uncoordinated atrial activation and contraction leading to decline of mechanical function and can be readily identified on an electrocardiogram by an absence of consistent P waves, which are replaced with rapid oscillations.[1] Nonvalvular AF refers to those cases uncomplicated by rheumatic mitral valve disease, prosthetic heart valve, or valve repair.[2]

AF is associated with a four- to five-fold increase in the risk of ischemic stroke and estimated to account for 15% of all strokes.[3,4] Although the pathogenesis of thromboembolism is complex and often multifactorial, stasis in the left atrial appendage as a result of irregular and uncoordinated atrial contractions is generally associated as the main source of ischemic stroke and systemic arterial occlusion in AF.[5] Several clinical schemes have been developed to stratify risk of ischemic stroke in patients with AF, with one of the most commonly utilized being the CHADS2 score.[6] The CHADS2 score is based on a point system in which 2 points are assigned for a history of stroke or TIA and 1 point each is assigned for age over 75 years and a history or hypertension, diabetes, or heart failure. Additional risk factors to consider include a history of vascular disease (i.e. peripheral artery disease, myocardial infarction, aortic plaque), age 65-74 years, and female gender.[7] The threshold for use of anticoagulation remains somewhat controversial, however recent guidelines suggest that oral anticoagulation is recommended or preferred for patients with one or more risk factors.[2,7]

Those determined to be at low or intermediate risk may require no antithrombotic therapy or only low-dose aspirin. For intermediate to high-risk nonvalvular AF patients, warfarin has been the anticoagulant of choice to reduce the risk of thromboembolic events for the past 50 years. Though warfarin has proven clinical efficacy it requires regular laboratory monitoring and constant dose adjustments to maintain goal international normalized ratio (INR) proves both inconveniencing and expensive, as well as the multiple drug and food interactions to be considered that complicate its therapy. A surge of novel anticoagulants including the direct thrombin antagonist dabigatran and factor Xa inhibitors apixaban and rivaroxaban seek to revolutionize standard of care for prevention of thromboembolism in AF and promise more predictable and convenient anticoagulation with better bleeding profiles as compared to warfarin.[8,9,10]

Both dabigatran (110 mg and 150 mg twice daily) and rivaroxaban (20 mg once daily) were proven noninferior to warfarin in the Randomized Evaluation of Long-Term Anticoagulation Therapy (RE-LY) trial and Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation (ROCKET AF) trial, respectively.[8,10] In Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation (ARISTOTLE), a randomized, double-blind clinical trial including a total of 18,201 subjects, apixaban (5 mg twice daily) was proven superior to warfarin, reducing the risk of stroke or systemic embolism by 21% and the risk of major bleeding by 31%.[9] Apixaban, dabigatran, and rivaroxaban, as compared with warfarin, all reduce the risk of serious bleed and significantly reduce the risk of hemorrhagic stroke.[8,9,10] While apixaban is the first of these novel anticoagulants to illustrate a significant reduction in the risk of death from any cause (p=0.047)[9], similar trends in decreased mortality were noted with dabigatran and rivaroxaban.[8,10] Differences in study design, subject population, and mean percentage of time INR was in therapeutic range introduce challenges for direct cross-trial comparisons.

While apixaban, rivaroxaban, and dabigatran eliminate the need for routine blood monitoring and their rapid onset of action remove the need for bridge therapy as required with warfarin, these novel anticoagulants are not without limitations. Currently specific antidotes to reverse the effect of these anticoagulants are still under development and are not routinely available. Additionally, high medication cost may serve as a deterrent for some patients. However, it is important that total cost of therapy (i.e. laboratory and professional fees) be considered rather than medication cost alone.

References:

1. Prystowsky EN, Katz AM. Atrial Fibrillation in Textbook of Cardiovascular Medicine. Philadelphia: Lippincott-Raven, 1998:1661.
2. Fuster V, Ryden LE, Cannom DS, et al. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation – executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients with Atrial Fibrillation). Circulation. 2006; 114:700-752.
3. Wolf PA, Abbot RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. Stroke 1991; 22:983-988.
4. Idem. Atrial fibrillation: a major contributor to stroke in the elderly: the Framingham Study. Arch Intern Med 1987; 147:1561-1564.
5. Bogousslavsky J, Van Melle G, Regli F, et al. Pathogenesis of anterior circulation stroke in patients with nonvalvular atrial fibrillation: the Lausanne Stroke Registry. Neurology 1990; 40:1046 -1050.
6. Gage BF, Waterman AD, Shannon W, et al. Validation of clinical classification schemes for predicting stroke: results from the National Registry of Atrial Fibrillation. JAMA 2001; 285: 2864–2870.
7. European Heart Rhythm Associa-

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RESIDENT SECTION

The Last Xigris®?

Matthew A. Wanat, PharmD, BCPS
PGY2 Critical Care Resident
The Methodist Hospital

By now the news has spread throughout the medical community that drotrecogin alfa, Xigris®, has been removed from the market and is no longer available. Xigris came onto the scene in 2001 amid much hope for our critically-ill septic shock patients after the PROWESS trial showed a 6.1 % absolute reduction in mortality and a number needed to treat of 16 to prevent one death with Xigris[1]. Word of this new "miracle drug" for patients with septic shock spread and Eli Lilly promoted the drug heavily. However therapy with Xigris was not without risks, most notably the increased risk of bleeding when the drug was given. The PROWESS trial had a strict set on inclusion and exclusion criteria in determining which patients received the drug. For this reason many hospitals created pharmacist-driven protocols or consults to help evaluate which patients were appropriate candidates for Xigris, and our large, 900 bed academic hospital was no different. Any time Xigris was ordered a pharmacy consult was created and a clinical specialist evaluated the patient and provided a recommendation to the intensivist regarding the appropriateness of therapy. This next paragraph describes the last patient to receive Xigris at our institution.

The patient was a 74 year old female with symptomatic cholelithiasis who received a laparoscopic cholecystectomy. It was noted that the patient tolerated the procedure without any complications and was transferred to the surgical ICU for high-risk monitoring because she had received a lung transplant several years prior. Less than 12 hours post surgery the patient developed a septic picture with decreased responsiveness, hypotension and altered mental requiring intubation for airway protection.

The intensivist asked clinical pharmacist to evaluate this patient for Xigris treatment. According to our Xigris evaluation, the patient met the criteria for treatment. Her suspected source of infection was from the intra-abdominal area considering the surgery she just had undergone. She met systemic inflammatory response syndrome (SIRS) criteria as her heart rate (91 bpm) and respiratory rate (35 bpm) were elevated and her core temperature was low (96.2 ^{0}F). The next step in the evaluation was presence of acute organ dysfunction. She met the criteria due to a severe metabolic acidosis with a lactic acid level that increased to 20.3, and her urine output decreased several hours after surgery from 30 mL/hr to 0 mL/hr despite fluid resuscitation and normally functioning kidneys prior to surgery. With suspected infection, SIRS criteria and multi-organ dysfunction our patient met the criteria for Xigris administration. We next evaluated the patient for any exclusion criteria and none was present so the recommendation was provided to the intensivist. After it was determined that the patient would not be going back to the OR for surgery and bleeding was ruled out with imaging and labs, Xigris was started. It was stopped 24 hours into the treatment course due to bleeding. Fortunately, she recovered from the septic shock and was discharged from the hospital 9 days later.

The events surrounding our patient receiving Xigris seemed to foreshadow the future of the medication. Just as Xigris was stopped less than 24 hours into treatment for bleeding in our patient, two days later Eli Lilly pulled Xigris from the market after preliminary results from the PROWESS-SHOCK trial failed to show a reduction in mortality with Xigris and found the drug still had an increased risk of bleeding events. As pharmacists, whether we believed in the mortality benefit of Xigris to its relative bleeding risk in our patients or not, we definitely will remember Xigris as a polarizing drug in our field of practice. Sepsis remains a troubling disease in critical care medicine and our treatment options are still very limited. I know I will definitely remember my last patient that received Xigris as I am sure many other pharmacists will as well. The question I will always wonder though: Was this the last patient ever to receive Xigris?

References:

1. Bernard GR, Vincent JL, Laterre PF, et al. Efficacy and Safety of Recombinant Human Activated Protein C For Severe Sepsis. N Engl J Med 2001;344:699-709.

The 42nd GCSHP Annual Seminar is Saturday, February 4, 2012

Register Now! See Page 3 for more details!

Pegloticase (Krystexxa®) Drug Monograph

Rosemary Akachukwu
PGY1 Pharmacy Resident
Harris County Hospital District

Gout, defined as hyperuricemia with symptoms or signs of urate crystal deposition, typically afflicts men more often than women. Gout affects 1 in 1,000 men ages 40 to 44 years and 1.8 in 1,000 men ages 55 to 64 years annually.[1] Although, there are currently multiple agents available for gout prophylaxis many patients continue to experience symptomatic hyperuricemia despite use of these agents due to issues such as hypersensitivity, intolerance, and refractoriness. In an effort to minimize the number of patients with suboptimal gout management, the urate-lowering agent pegloticase (Krystexxa®) was FDA approved in September 2010 for the treatment of chronic gout in adult patients refractory to conventional therapy.

Mechanism of Action

Pegloticase is a pegylated recombinant form of mammalian uricase, an enzyme that is not found in humans. Pegloticase reduces urate levels by catalyzing the oxidation of uric acid to allantoin, a water-soluble purine metabolite that is renally eliminated. The conjugated inert polymer, monomethoxypolyethylene glycol (m-PEG), prolongs the half-life of uricase and aids in the reduction of immunogenic reactions.

Clinical Efficacy

Sundy, JS, et al (2008)

In a phase II randomized, open-label, multicenter, parallel-group study to assess the efficacy and safety of multiple doses of pegloticase, forty-one patients were enrolled for a duration of 12-14 weeks. Participants received either pegloticase 4 mg every two weeks for 6 doses (n=7), 8 mg every two weeks for 6 doses (n=8), 8 mg every four weeks for 3 doses (n=13), or 12 mg every four weeks for 3 doses (n=13). Fifteen patients withdrew from the study due to adverse events with the exception of one participant. Participants that received pegloticase 8 mg every two weeks had the greatest reduction in plasma urate levels. At the conclusion of the trial, the mean ± standard deviation plasma urate level was 4.12 ± 2.02 mg/dl in the 4 mg every two weeks group, 1.42 ± 2.06 mg/dl in the 8 mg every two weeks group, 3.21 ± 2.26 mg/dl in the 8 mg every four weeks group, and 3.09 ± 2.46 mg/dl in the 12 mg every four weeks group. Participants receiving pegloticase 8 mg every two weeks also had the greatest response rate (87.5% of the intent to treat (ITT) patients and 87.5% of the patients who completed the study), while the 4 mg every two weeks group had the lowest percentage of responders (57.1% and 50% of the ITT and completer populations respectively). Infusion related events were significant accounting for 12.7% of all adverse events. Eighty-eight percent of patients reported ≥ 1 flares during the study (86% in the 4 mg every two weeks group, 63% in the 8 mg every two weeks group, 92% in the 8 mg every four weeks group, and 100% in the 12 mg every four weeks group). Lastly, 86% of patients in the 4 mg every two weeks, 63% in the 8 mg every two weeks, 69% in the 8 mg every four weeks, and 85% in the 12 mg every four weeks regimen exhibited seroconversion during the study which was associated with shortened circulating pegloticase half-life and lower response rates.

Sundy, JS, et al (2011)

In two replicate, randomized, 6-month, double-blind, placebo-controlled trials (Trial 1 and Trial 2), a total of 225 patients (109 in Trial 1 and 116 in Trial 2) were randomized to receive twelve biweekly intravenous infusions of either pegloticase 8 mg at each infusion (biweekly pegloticase group; n=85), pegloticase alternating with placebo at successive infusions (monthly pegloticase group; n=84) or placebo (n=43). All groups were initiated on colchicine 0.6 mg daily or twice daily one week prior to infusions and during infusions as gout flare prophylaxis. In trial 1, a statistically significant proportion of participants in the biweekly (20 of 43 patients; p<0.001) and monthly groups (8 of 41 patients; p<0.04) experienced a plasma uric acid level <6.0 mg/dL for ≥ 80% of the study period in comparison to placebo (0 of 20 patients). In trial 2, a statistically significant proportion of participants in the biweekly (16 of 42 patients; p=0.001) and monthly groups (21 of 43 patients; p<0.001) experienced a plasma uric acid level <6.0 mg/dL for ≥ 80% of the study period in comparison to placebo (0 of 23 patients). In total (trials 1 and 2), a statistically significant proportion of participants in the biweekly (36 of 85 patients; p<0.001) and monthly groups (29 of 84 patients; p<0.001) experienced a plasma uric acid level <6.0 mg/dL for ≥ 80% of the study period in comparison to placebo (0 of 43 patients).

Dosing and Administration

Pegloticase 8 mg is administered as a slow intravenous infusion over a minimum of 120 minutes every two weeks. The optimal duration of treatment has not been established.[2] In pegloticase studies, however, the duration of treatment ranged from 3-6 months. Due to the high risk for infusion related reactions, patients should be premedicated with corticosteroids and antihistamines prior to each infusion. Furthermore, gout prophylaxis should be initiated one week prior to the first infusion and continued for six months.[2] Serum uric acid levels should be measured prior to infusions and discontinuation of treatment should be considered if levels increase to above 6 mg/dL. Pegloticase does not require any renal, hepatic, age-specific or gender-related dose adjustments.

Precautions, Adverse Effects, and Contraindications

Pegloticase has black box warnings for infusion reactions and anaphylaxis. Pegloticase must be administered in a healthcare setting by healthcare providers prepared to manage infusion reactions and anaphylaxis. Patients must be pre-treated with antihistamines and corticosteroids. Pegloticase should be infused slowly over no less than 120 minutes. In the event of an infusion reaction, the infusion should be slowed, or stopped and restarted at a

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slower rate. The risk of infusion reaction is higher in patients whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed. Furthermore, an increase in gout flares is frequently observed upon initiation of urate-lowering therapy. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug or colchicine is recommended at least one week before initiation of pegloticase and lasting at least 6 months, unless medically contraindicated or not tolerated. Pegloticase does not need to be discontinued due to a gout flare.

Common side effects of pegloticase are as follows: antibody formation (antipegloticase antibodies: 92%; anti-PEG antibodies: 42%), gout flare (74% within the first 3 months), infusion reactions (26%), bruising (11%), urticaria (11%), nausea (12%).

Pegloticase is contraindicated in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency due to the risk for hemolysis and methemoglobinemia. Patients at a higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) should be screened for G6PD deficiency prior to starting pegloticase.

Lastly, pegloticase has risk evaluation and mitigation strategy (REMS) requirements which include a communication plan and a medication guide.

Overall, clinical trials have shown that pegloticase is an effective agent in rapidly reducing tophus size and urate levels in patients that are refractory to conventional treatment options. However, concerns regarding infusion reactions, the lack of formal studies in special populations (i.e. renal and hepatic impairment), and no long-term safety and efficacy data are limiting factors for usage.

References

1. Choi HK, Atkinson K, Karlson EW, et al. Purine-rich foods, dairy and protein intake, and the risk of gout in men. NEJM 2004;350:1093–1103.
2. Krystexxa (pegloticase) Injection, for intravenous infusion package insert. East Brunswick, NJ: Savient Pharmaceuticals, Inc., 2010 Sep.
3. Sundy JS, Ganson NJ, Kelly SJ, et al. Pharmacokinetics and pharmacodynamics of intravenous PEGylated recombinant mammalian urate oxidase in patients with refractory gout. Arthritis and Rheumatism 2007; 56:1021-8.
4. Sundy JS, Becker MA, Baraf HS, et al. Reduction of plasma urate Levels following treatment with multiple doses of pegloticase (polyethylene glycol-conjugated uricase) in patients with treatment-failure gout: results of a phase II randomized study. Arthritis and Rheumatitis 2008; 58(9):2882-91.
5. Yue CS, Huang W, Alton M, et al. Population pharmacokinetic and pharmacodynamic analysis of pegloticase in subjects with hyperuricemia and treatment-failure gout. Journal of Clinical Pharmacology 2008; 48(6):708-18.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2011. Available at: http://www.clinicalpharmacology-ip.com. Updated October 2010. Accessed on December 12, 2011.
7. Lexi-Comp Online™, Hudson, Ohio: Lexi-Comp, Inc. Accessed on December 12, 2011.
8. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. JAMA 2011;306(7):711-20.

Drug Information Q&A: Thalidomide

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Question: Could thalidomide be responsible for the new onset confusion seen in this patient, and if so how would it present?

Clinical Indication: Thalidomide has been used for the treatment of multiple myeloma as both monotherapy, and in combination with numerous other chemotherapeutic agents. It has been granted orphan drug status by the FDA for its use in advanced and refractory patients.

Evaluation of Literature: According to the package insert thalidomide is commonly associated with confusion, ranging from mild to severe. Up to 30% patients may experience this to some degree. The other major neurologic side effect is neuropathy which has been reported in 27-54% of patients receiving thalidomide. Additional side effects may include headache (10-20%), insomnia (20%), and lightheadedness (4-20%). Several studies comment specifically on confusion and altered mental status, which are the symptoms present in our patient.

Rajkumar and colleagues conducted a randomized, double blind, placebo controlled trial evaluating dexamethasone plus thalidomide in newly diagnosed multiple myeloma patients. A total of 104 patients received dexamethasone alone, and 103 patients received dexamethasone plus thalidomide. Patients in the thalidomide group received 200 mg of thalidomide daily (our patient currently receiving 50 mg daily). Confusion from grades 1-4 was noted to occur in 28.4% of patients receiving combination therapy, and only 11.8% of patients receiving dexamethasone alone. Combination therapy was associated with rates of 5.9% and 2.9% for grades 3 and 4 confusion, compared to 2% and 2.9% for dexamethasone. Onset of confusion was highly variable with some patients

reporting within the first week of therapy, and others after several months of therapy.

Plasmati and colleagues conducted a prospective study that assessed the development of neuropathy on thalidomide monotherapy. Thirty-one patients were followed with baseline workups and assessment at 4 months. The authors found that 66% of patients exhibited some peripheral neuropathy and movement disorders within 4 months of therapy. These patients had not been previously exposed to known neurotoxic medications, unlike other case series data published. As our patient has difficulties with the physical act of feeding herself, there may be some correlation. Neurotoxicity has also been reported in other studies that have been published recently, however thalidomide is frequently part of a larger chemotherapy regimen, so isolation of neurotoxicity to thalidomide is challenging. Additional reports of thalidomide toxicity date back to literature supporting initial utilization in the 1950's and 60's before being withdrawn. At this time, it is unclear the exact mechanism of action, and it is likely multi-factorial.

Recommendations: Based on literature review, altered mental status and confusion within the first week of thalidomide initiation is plausible. Although not as common as peripheral neurotoxicity, there is some evidence in the literature supporting new onset confusion with variable time course. Recommend consultation with medical oncology group regarding possibility of alternative chemotherapeutic agents, and discontinuation of all other non-essential neuroactive medications and continued monitoring.

References:

1. Rajkumar et al. J Clin Oncol 24:431-436.
2. Plasmati et al. Neurology 2007;69:573–581.
3. Sioka et al. Cancer Chemother Pharmacol 2009;63:761-67.
4. Zara et al. J Neurol Neurosurg Psychiatry 2008;79:1258-61.
5. Clinical Pharmacology online database.
6. Micromedex online database.

(Hobaugh—continued from page 11)

tion, et al. Guidelines for the management of atrial fibrillation: the Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC). Eur Heart J. 2010 Oct; 31(19):2369-2429.

8. Connolly SJ, Ezekowitz MD, Yusuf S, et al. Dabigatran versus warfarin in patients with atrial fibrillation. N Engl J Med 2009; 361:1139-1151.
9. Connolly SJ, Eikelboom J, Joyner C, et al. Apixaban versus warfarin in patients with atrial fibrillation. N Engl J Med 2011; 365:981-992.
10. Patel MR, Mahaffey KW, Garg J, et al. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. N Engl J Med 2011; 365:883-891.

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2012-2013 GCSHP Elections

Nominate a colleague or yourself for a GCSHP Board position or award! Review the criteria below and submit your nominations to Monica Green via email at monica_green@hchd.tmc.edu by **January 31, 2012.** Please include supporting comments for each award nomination.

*** Award nominees must be members of TSHP/GCSHP ***

GCSHP Leadership Position Duties and Award Criteria

Leadership Positions

President-Elect
- Act as the principal elected official of the Society.
- Appoint, with the approval of the Board of Directors, the Chair and approve members of all councils and committees, and be an ex-officio member of each council.
- Be a member of the Board of Directors and serve as its Chair.
- Be a member of TSHP and represent GCSHP through service as a member of the TSHP Board of Directors.
- Support the activities of TSHP and ASHP.
- Includes one year term as President and one year term as Immediate Past President.

Director
- Represent the general membership on the Board of Directors.
- First-year director shall serve as the vice-chair.
- Second-year director shall serve as the Society's Annual Seminar Chair.
- Chairs committee to solicit nominations for awards and election of new officers.
- Two year term.

Treasurer
- Serve as custodian of Society funds and shall invest and distribute them at the direction of the Board of Directors. The Treasurer shall serve as Chair of the Committee on Finance and shall obtain validation of Societal expenses by the Finance Committee every three months.
- The outgoing Treasurer shall be responsible for verification of Society assets within 30 days of vacating the office.
- Two year term

Recording Secretary
- Records, prepares and distributes agenda and minutes of GCSHP business meetings.
- Forwards a copy of the approved minutes of each business meeting to the Secretary of TSHP.
- Two year term.

Organizational & Professional Affairs Council Chair
- Review the organizational structure of the Society
- Analyze its effectiveness, and making recommendations for improvements
- Draft proposed amendments to the Constitution and Bylaws

Awards

Outstanding Pharmacist Award
- Recognition of outstanding contributions as a hospital pharmacist.
- Active participation in the growth of GCSHP and exemplary dedication to improving the delivery of quality health care.

Outstanding Student Award
- Demonstration of active participation in GCSHP and interest in institutional pharmacy practice through research or other activities.

Industry Service Award
- Outstanding service, demonstration of the highest standard of professionalism and constructive interest in the formation, growth, and programs of GCSHP.
- Advancement of improved, rational, safe, effective, and economic drug therapy and health care of the people.

Outstanding Technician Award
- Recognition of outstanding contributions to professional and community service as a hospital pharmacy technician.

dating and impressive. Residency did help me focus on what type of practice I wanted to pursue. I enjoyed most the rotations in internal medicine, geriatrics and transplant –all of which had direct patient care aspects. I found that critical care was not my forte.

Before graduation, two of my fellow residents and I learned that Harris County Hospital District was hiring clinical pharmacists. We all applied and all three of us were hired. I was put into the anticoagulation clinic which had been run by a volunteer pharmacist from St. Luke's for several years. The physicians had requested a full-time pharmacist for the clinic. The first year I held this position I did a lot of continuing education to enhance my knowledge base in this area including the ASHP traineeship and a 40-hr CE program from the University of Southern Indiana. Providing direct patient care has been very rewarding and I have now been an ambulatory clinical pharmacist at Harris County Hospital District for eleven and a-half years.

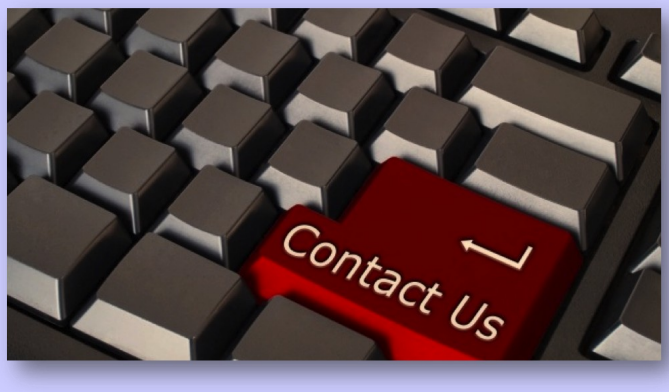
Challenges:
My biggest daily challenge is finding time for both work and family. I have two small children and I often feel that I am not able to spend as much time with them as I would like. Another challenge I face is maintaining the professional distance from my patients. The patients we serve often have had very difficult lives. Additionally, they have very advanced disease states. This makes my job interesting, but it is tough to see the hardships our patients face. It is especially hard to keep a distance at times. When I was a new practitioner, I actually gave my pager number to all of my patients. Over the years (and after many, many inappropriate late-night pages), I learned this was not a good idea. I am better at keeping a distance now, but it is still very sad when a favorite patient dies.

Advice to students / residents:
For the students – I always advise considering residency. I know not every student can pursue residency (for a variety of reasons), but I really appreciated having an extra year with preceptors before being on my own.
Another piece of advice would be to always be self-motivated in your learning. I still research at least one thing every day I am at work. If there is something you don't know about a patient, or a disease-state you are not familiar with, look it up. You will be able to speak more knowledgably to physicians and it will help you understand what the patient is going through. Try to learn everything you can, not just about medications, but about diseases in general. As pharmacists, we have a unique perspective on the medical team. If you are rounding and hear of a patient complaint, always consider if a medication could be causing the problem and communicate that to the physicians.

For residents – when you start your first post-residency job, don't volunteer for lots of projects right away. Give it a little time and settle in or you could easily be overwhelmed. Remember that this is a job and you need to have a balance with your personal and family life. No matter where you are practicing you will be serving patients. Always be honest with them. If you don't know something, tell the patient you don't know but you will try to find out. They will respect you more and listen to what you have to say.

Finally, enjoy your career. If you dread going to work every day, start looking for a new position.

Pharmacy is unique in that you could work in many different practice settings. And always remember the patient. They are why we have careers!



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