

April / May 2012

Spring Issue

# Gulf Coast Society of Health-System Pharmacists



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## President's Report Rodney Cox, PharmD, MS

These are very interesting times for health system pharmacy.

With one hand, we welcome the promise and opportunity provided to our profession in the form of The Affordable Care Act. We embrace our burgeoning role in direct patient care and celebrate our proven track record of improving outcomes in the acute care setting. We look forward

to the future and new opportunities on the horizon to extend our reach within the ambulatory setting effectively closing the loop on management of patients throughout the continuum of care. We continue to develop and find innovative ways to empower all professionals in our reach, clinicians to technicians, to practice at the very highest level of their abilities.

And yet we must remain on guard and vigilant, ready to confront the challenging questions that threaten to compromise our future. How do we turn our vision advocated by ASHP's Practice Model Initiative into reality while justifying our clinical services? If the rumblings of pharmacist and technician saturation are true, what then is the impact on our profession? How do we assure a seat at the table of decision-makers drafting the final rules for healthcare reform? What are the roadblocks to provider status and how do we overcome them? How do we continue to maintain and expand our roles in areas where other allied healthcare professionals are beginning to stake claim?

The challenges and opportunities that face our profession impact us all, new graduates and veterans alike. We don't have all the answers, but we are ready to join the fight! Over the next year, our leadership team will work hard to keep you engaged and informed, and hopefully stimulate dialogue that leads our profession down the road of change and progress.

We can't do it alone. We will need your help and your insight. Your voice makes a difference. Get active, get involved. Become a member today. Follow us on twitter at @GCSHP, on Facebook (search GCSHP or use this [link](#)), and by email at [gcsHP.membership@gmail.com](mailto:gcsHP.membership@gmail.com).

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

[Rodney.Cox@memorialhermann.org](mailto:Rodney.Cox@memorialhermann.org).

I look forward to hearing from you.



*Rodney*

## April 2012

Sun	Mon	Tue	Wed	Thu	Fri	Sat
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>
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<b>29</b>	<b>30</b>					

### *Schedule of Events*

- March 17, 2012  
St. Patrick's Day
- April 1, 2012  
April Fools' Day
- April 11-15, 2012  
Alcalde & TSHP Annual Seminar
- April 22, 2012  
Earth Day
- May 5, 2012  
Cinco de Mayo
- May 13, 2012  
Mother's Day
- June 17, 2012  
Father's Day

## May 2012

Sun	Mon	Tue	Wed	Thu	Fri	Sat
		<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>6</i>	<i>7</i>	<i>8</i>	<i>9</i>	<i>10</i>	<i>11</i>	<i>12</i>
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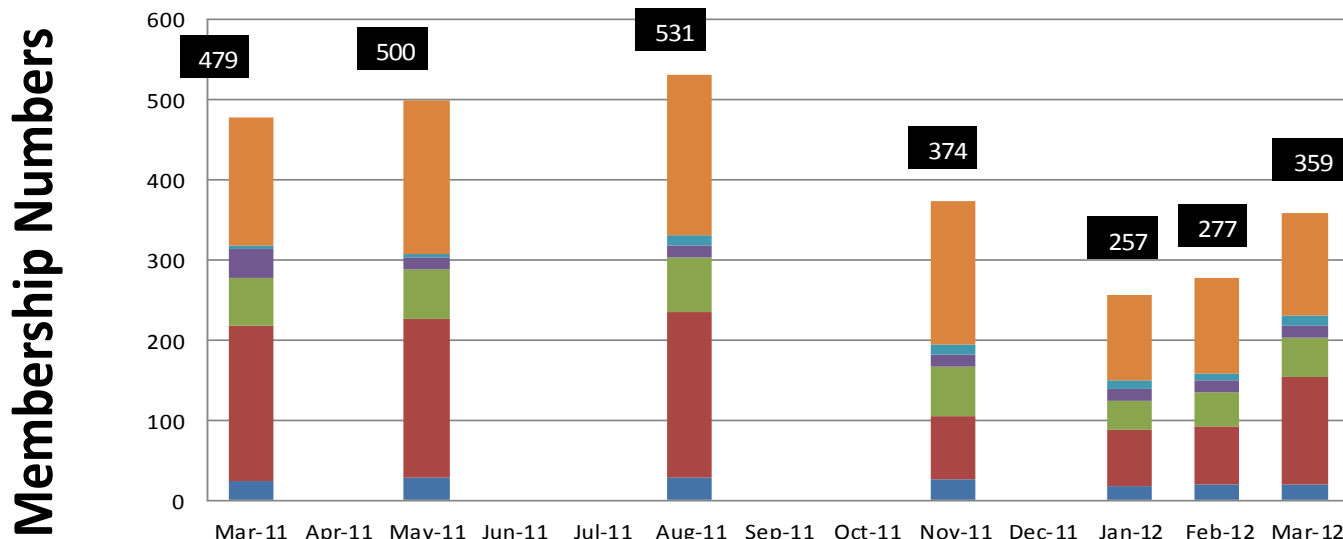
## GCSHP Membership Secretary – Membership Report

Linda Haines, PharmD, MS

Please help contribute to our growth by spreading the word about GCSHP to your friends and colleagues. Non-members can easily become members via the TSHP/GCSHP application process found on TSHP's website (<http://www.tshp.org>).

Any additional questions regarding membership can be sent to [GCSHP.membership@gmail.com](mailto:GCSHP.membership@gmail.com).

### GCSHP Membership Trends 2011-2012



	Mar-11	May-11	Aug-11	Nov-11	Jan-12	Feb-12	Mar-12
Pharmacists	160	192	200	180	107	118	128
Associates	6	4	12	12	10	10	12
Honorary	36	16	16	16	16	15	15
New Practitioners	58	61	67	61	37	42	49
Students	196	199	207	78	70	73	136
Technicians	23	28	29	27	17	19	19

## GCSHP Communications Chair – 2012-2013 Election Report

Ogechi Eshleman, PharmD, BCPS



Congratulations to the GCSHP 2012-2013 election and award winners.

#### Leadership Positions

**President-Elect:** Brian Fase, PharmD, MS.

**Director:** Todd W. Canada, PharmD, BCNSP, FASHP

**Recording Secretary:** Malar Narayanan PharmD, BCPS

**Treasurer:** Jennifer D. Nguyen, PharmD, BCPS.

#### Awards

**Outstanding Pharmacist:** Katy Toale

**Outstanding Student Award:** Sunaina Rao

# GCSHP Annual Meeting - February 4, 2012 - Houston, TX



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This year's seminar provided an excellent opportunity to enjoy a full day's worth of CE programming, all while taking in timely presentations on topics that directly impact and advance the profession of pharmacy. With over sixty attendees, and morning and afternoon refreshments as well as lunch provided, it also served as a great platform to network with colleagues.

We extend our thanks to those who directed their time and talent to making the seminar successful. We also thank our speakers for their contributions to our profession!



## GCSHP Annual Seminar — 2012 Speakers

Catina Brimmer	Kim Putney
Lourdes Cuéllar	Shahana Quadri
Mallory Gessner-Wharton	Curt William Quap
Stacey Lavsa	Ryan Roux
Amy Moss	Vidya Saldivar
Jennifer Nguyen	Brad Shields
Tam Nguyen	Dominic Vu



Previous page:

1.) Brad Shields discusses the latest legislative updates. 2.) Pharmacy students gain valuable insight from Jennifer D. Nguyen. 3.) Pharmacy Program Residents Mallory Gessner-Wharton, Dominic Vu, and Amy Moss give helpful advice to pharmacy students.

This Page:

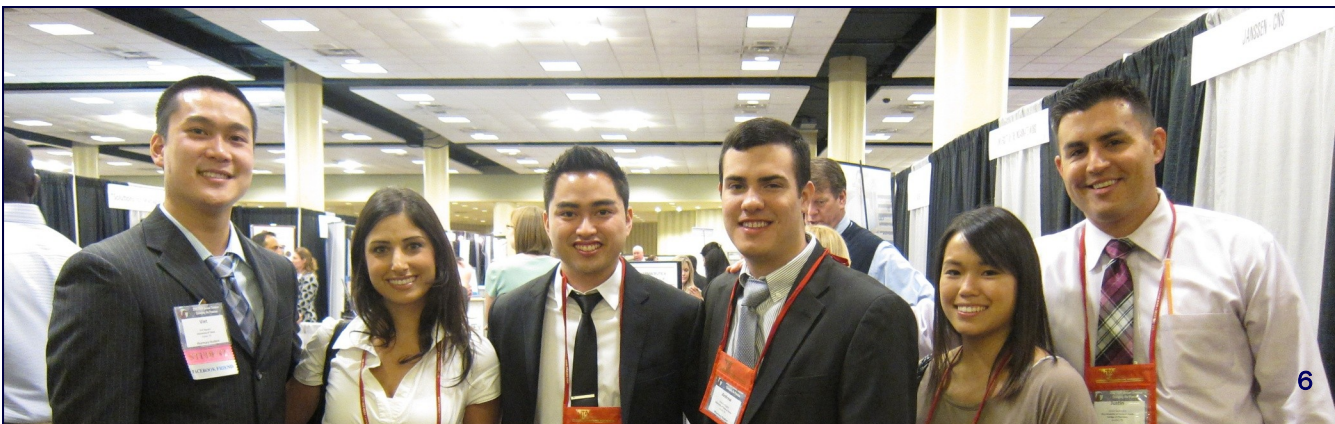
4.) Monica Green and Rodney Cox show their appreciation to Brad Shields, our TSHP Lobbyist. 5.) Monica Green and Doug Rasmussen (session moderator) offer a token of appreciation to Catina Brimmer. 6.) Drug Shortages Panelists Curt William Quap, Stacey Lavsa, Kim Putney, Lourdes Cuéllar and Vidya Saldivar pose with Ogechi Eshleman (session moderator). 7.) Christopher Loucks (session moderator), offers thanks to Pharmacy Benefit Manager Presenters Tam Nguyen, Shahana Quadri, and Ryan Roux with Monica Green. 8.) Jennifer Nguyen and Sunaina Rao man the registration table.



# Elevating The Practice

Alcalde and TSHP Annual Meeting  
April 11-15, 2012 Dallas, TX





Previous Page:

- 1.) The Dallas skyline, including the TSHP host hotel, The Hyatt Regency.
- 2.) Monica Green and Paul Davis at the TSHP Mentor Social
- 3.) View of the waterfall at the host hotel.
- 4.) Andy Laegeler meets and greets his mentee, Hellen.
- 5.) Tammy Cohen of Metroplex Society fame and Sunaina Rao mingle at the Mentor Social.

Next Page:

- 6.) Viet Nguyen and friends visit during the Exhibitor Session.
- 7.) David Wallace, Monica Green, Rodney Cox and Nancy Myers at the Exhibitor Session.
- 8.) Steve Pass, TSHP Education Council Chair, mingles at the Mentor session.
- 9.) Ogechi Eshleman and Ogechi Iwuorie at the Student Poster session



In recognition of her contributions to our professional society, we offer thanks to our outgoing GCSHP President,

*Monica Green*



# STUDENT SECTION

## University of Houston SSHP Sunaina Rao, President

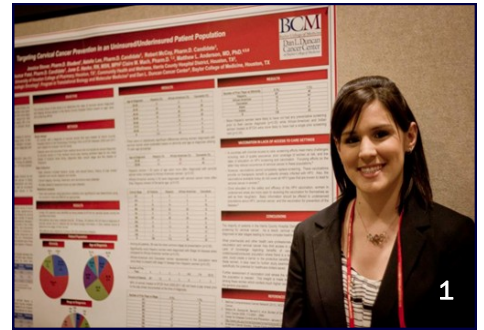
It is so hard to imagine that we have almost reached the end of Spring semester! For UH-SSHP, the focus of this semester was on the expansion of state wide initiatives of Medication Safety and Antibiotic Awareness as well as preparation for TSHP Annual Seminar.

As part of the Medication Safety Initiative this year, we established the development of a formal educational program targeting elementary school children, emphasizing the importance of distinguishing between candy and medicine. Our four interactive visual and oral presentations this semester, have been overwhelmingly received by the elementary school children, teachers and parents alike and, by the end of this year, over 500 students will have been impacted! Congratulations to Nancy Mai for leading this initiative, along with her co-chair, Amanda Martin!

For Antibiotic Awareness, our P1 co-chair, Tara Molina organized an information table to educate students about vaccinations and hygiene while distributing antibacterial wipes and other goodies to UH Main Campus faculty, students and staff. Ngozi Ahaiwe, P3 co-chair, along with member Otsanya Ochogbu gave a presentation to approximately 20 retirement home residents on common infections, antibiotics, and optimal use of antibiotics. We successfully dissipated information on common illnesses caused by bacteria vs. viruses, discussed common therapies and stressed the importance of adherence and completion of antibiotic/antiviral medication. Also at this facility, P1 and P2 students had the opportunity to counsel patients on their medication as part of our semesterly Brown Bag Medication review

TSHP Annual Seminar participation from UH students has exceptionally increased in the past year. This year, among the 40 students in attendance, 16 UH students presented posters (of a total of 31 posters from the 6 Pharmacy schools), 32 participated in the Clinical Skills Competition (CSC), and 12 participated in the Disease State Management Competition (DSM)! Our strength, however, showed not just in numbers but also in results. P3, Jessica Stover, won the award for "Best Student Poster". Two P3 teams, Heather Schoeneberg with Lea Garcia and Saroosh Lodhi with Shiva Zanganeh, received Honorable Mention for the CSC, and Heather Schoeneberg once again, who received Honorable Mention for her performance on the DSM competition! I also want to congratulate Gregg Morgan and Jessica Preston, SSHP Convention chairs, for organizing faculty and resident-led CSC and DSM training sessions for first-time participants as well as actively promoting TSHP Seminar attendance this semester.

Also, I would like to wholeheartedly thank our service chairs, Holly Murray and Carly Mason, for collecting 115 teddy bears for the annual collection drive, a friendly competition between the six colleges of Pharmacy at TSHP! We received great feedback from all, including first-time attendees, with especially rave reviews of the student programming planned by TSHP's Student Section Executive Committee



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- 1.) Jessica Stover, P3, was awarded "Best Student Poster" at TSHP Annual Seminar
- 2.) Shiva Zanganeh and Saroosh Lodhi received Honorable Mentions for the Clinical Skills Competition.
- 3.) Lea Garcia and Heather Schoeneberg received Honorable Mentions for the Clinical Skills Competition.



and the mentor-mentee reception, where we enjoyed seeing so many familiar Houston-Galveston area practitioners. We invite you to visit our [facebook page](#) for more pictures from TSHP Annual Seminar!

The successes of this past year has been a direct result of the passion and dedication of our outgoing officers and truly feel blessed to have had the opportunity to have worked with this amazing team! That said, I have no doubt that, under the able leadership of UH-SSHP President, Amy Lehnert and the guidance of our advisors, Dr. Jessica Cottreau and Dr. Paige Pitman, the incoming officer board will take the chapter to new heights in the 2012-2013 school year!

Please join me in congratulating our newly elected officers:

President: Amy Lehnert  
 President Elect: Zachary Kirk  
 VP of Programming: Omik Patel  
 VP of Communications: Melanie Laine  
 Secretary: Tara Molina  
 Treasurer: Lynsey Smith  
 Historian: Morgan Payne

Orientation Chairs: Elizabeth Franco and Amanda Martin  
 Service Chairs: Lilian Ooi and Ashley Smart  
 Convention Chairs: Catherine Carey and Alex Whiddon  
 Fundraising Chairs: Victor Faniyi and Anh Nguyen  
 Social Chairs: Quang Nguyen and Laura Stokes  
 ACCP Committee Chair: Jennifer Parma

Thank you and on behalf of UH SSHP, I wish all students an amazing end to the school year and a happy summer!

## Texas Southern University SSHP Kinyatta Weatherspoon, President

Greetings from Texas Southern University Student Society of Health System Pharmacists!

This semester has been very exciting for our chapter. We started off with the 7<sup>th</sup> Annual TSU-UH Residency Mentoring Social that brought students together with residency programs from the Texas Medical Center. The event was a huge success, and we look forward to working with our colleagues from the University of Houston again next year.

During the month of February, we held a general meeting that highlighted all the scholarship opportunities available to our student members. At the TSHP Annual Seminar, we had several students attend the seminar and compete in the Clinical Skills Competition and present posters. In April, we conducted our elections for next year's officers. Congratulations to Osita Okafor, who is the incoming president, and the newly elected officers. Lastly, we are looking forward to closing out the semester with a health fair later this month.

TSU-SSHP wishes all students good luck during finals, and congratulates all upcoming graduates, especially our students that matched with residency programs (Nddi Alino, Dawn Bey, Brandy Ceril, Mohammed Fahimuddin, Mohamed Hersi, Daniel Laine, Diana Luong, Christopher Njigha, and Uchenna Obianagu).

- 1.) Student members Celia Fenceroy and Gwendolyn Burgess at the Poster Session.
- 2.) Interim Dean, Dr. Shirlette Milton, with TSU SSHP Chapter President, Kinyatta Weatherspoon at the poster session.
- 3.) Student members Oanh Ngo and Huyenvy Van prepare for competition.



# RESIDENT SECTION

## Treatment of Ocular Toxoplasmosis

**Wai-Ying M. Lam, PharmD**  
**PGY-1 Pharmacy Resident**  
University of Texas Medical Branch

**Case:** A 26 year old Hispanic male presents to the emergency department with the chief complaint of left eye pain, diplopia, floaters, blurry vision, and redness that developed 2 weeks before presentation. The patient was born in Mexico and has been residing in Texas for over 15 years, currently living in Galveston. The patient denies having any cats at home and states that he eats well cooked meats. The patient tested positive for *Toxoplasma* IgG, but was IgM negative. An ophthalmologist diagnosed the patient with ocular toxoplasmosis. The infectious diseases service was consulted for antibiotic management.

Ocular toxoplasmosis is caused by the intracellular protozoan parasite, *Toxoplasma gondii*. Although infection by *T. gondii* is usually asymptomatic, manifestations in the eye can occur. Approximately 28-55% of posterior uveitis is caused by *T. gondii*. Causes of infection include congenital transmission, contact with cat excrement, and eating contaminated vegetables or uncooked meat. The majority of cases present as congenital infection, reactivation of congenital infection in young adults, or infection in immunocompromised patients.<sup>1</sup>

Symptoms of ocular toxoplasmosis include blurry or hazy vision, vitreous floaters, and mild ocular pain. Upon examination, ocular toxoplasmosis can manifest as retinal lesions, a grey-white area of focal necrotizing retinitis, vitreous inflammation, vasculitis, granulomatous iridocyclitis, and optic nerve swelling. In more severe cases involving larger lesions, complications include exudative retinal detachment, macular ede-

ma, epiretinal membranes, retinal vessel occlusion, and blindness.<sup>2</sup>

The diagnosis of ocular toxoplasmosis is based on clinical findings since diagnostic tests are currently unavailable. The presence of anti-*T. gondii* IgG antibodies cannot be utilized to diagnose acute infection since anti-*T. gondii* IgG antibodies can persist for years after the initial infection. However, the absence of anti-*T. gondii* IgG antibodies can be used to rule out ocular toxoplasmosis. Utilization of polymerase chain reaction (PCR) for pathological diagnosis has also been investigated, but is not widely used.<sup>2</sup>

The goals of treatment are to cease *T. gondii* replication and to reduce scarring of the retina and optic disc. The decision to treat patients is controversial because ocular toxoplasmosis is a typically self-limiting disease. However, treatment of active lesions may be indicated due to the possibility of permanent loss of visual acuity and retinal detachment.<sup>3</sup> Treatment options and dosage regimens have been widely variable, although therapy usually includes the use of antimicrobial agents with or without corticosteroids. Agents such as pyrimethamine, sulfadiazine, trimethoprim-sulfamethoxazole, azithromycin, and clindamycin have been utilized. The classical treatment regimen includes pyrimethamine 100 mg PO daily for 2 days followed by 25 mg PO daily plus sulfadiazine 2 g PO daily for 2 days followed by 500 mg PO every 6 hours for 4-6 weeks. To protect against bone marrow suppression caused by pyrimethamine, which is typically thrombocytopenia and leukopenia, leucovorin 5 mg PO daily is added to the regimen, and blood cell and platelet count monitoring is necessary.<sup>3</sup> Starting on the third day of therapy, oral prednisone 1 mg/kg daily may be administered and tapered over 2-6 weeks. Use of cortico-

steroids is a debated topic, which requires further evaluation to investigate their anti-inflammatory role in ocular toxoplasmosis.<sup>2</sup>

Soheilian and colleagues conducted a study comparing the efficacy of 2 tablets of trimethoprim-sulfamethoxazole (80/400 mg) every 12 hours with prednisolone versus the classical treatment regimen consisting of pyrimethamine and sulfadiazine for 6 weeks. There was no significant difference in reduction of retinochoroidal lesion size ( $P = 0.75$ ) or visual acuity ( $P = 0.56$ ), suggesting that trimethoprim-sulfamethoxazole was as efficacious as the classical regimen.<sup>4</sup> In a study conducted by Yazici and colleagues, the investigators evaluated the efficacy and safety of azithromycin 1000 mg PO on day 1 and then 500 mg daily in combination with trimethoprim-sulfamethoxazole (160/800 mg) PO twice daily for 6-8 weeks. Of the 19 patients included in the study, 15 patients (78.9%) had better visual acuity after treatment; the improvement in visual acuity from presentation was statistically significant ( $P < 0.01$ ). The combination of azithromycin and trimethoprim-sulfamethoxazole was tolerated well by all the patients and was determined to be a safe and effective treatment regimen.<sup>5</sup> Intravitreal injections of clindamycin and dexamethasone are being investigated and appear to be a viable treatment approach.<sup>3</sup>

**Case conclusion:** The patient was started on azithromycin 1000 mg on day 1 and then 500 mg daily in combination with trimethoprim-sulfamethoxazole (160/800 mg) twice daily for 6 weeks. Timolol ophthalmic drops were also started to decrease intraocular pressure. The patient was scheduled for follow-up in the internal medicine clinic and ophthalmology clinic to monitor

therapy and disease progression, but did not keep his appointments.

#### References

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2. Commodaro AG, Belfort RN, Rizzo LV, et al. Ocular toxoplasmosis – an update and review of literature. *Mem Inst Oswaldo Cruz* 2009;104(2):345-350.
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4. Soheilian M, Sadoughi M, Ghajarnia M, et al. Prospective randomized trial of trimethoprim/sulfamethoxazole versus pyrimethamine and sulfadiazine in the treatment of ocular toxoplasmosis. *Ophthalmology* 2005;112(11):1882-4.
5. Yazici A, Ozdal PC, Taskintuna I, et al. Trimethoprim/sulfamethoxazole and azithromycin combination therapy for ocular toxoplasmosis. *Ocul Immunol Inflamm* 2009;17(4):289-91.

#### The Difficulty in Dosing Prothrombin Complex Concentrates

Daniel Ortiz, Pharm.D.

PGY-1 Pharmacy Resident

University of Texas Medical Branch

Warfarin therapy has demonstrated its effectiveness in patients with atrial fibrillation, cardiac valve replacements, and other disease states in which patients are at an increased risk for thromboembolic events. One of the major adverse effects of warfarin therapy is warfarin-associated hemorrhage, and the risk for bleeding increases as the INR increases. When patients develop warfarin-related bleeding, healthcare providers may need to reverse the effects of warfarin using prothrombin complex concentrates (PCCs) among other agents.<sup>1</sup> However, appropriate dosing of PCCs is an area of current research and multiple strategies have been studied.

Warfarin exerts its action by inhibiting the synthesis of vitamin K-dependent clotting factors (II, VII, IX, and X). Due to this mechanism of action, warfarin has limitations regarding onset of action and duration of anticoagulation after a dose. A single warfarin dose may not achieve a peak effect for 24-72 hours; furthermore, the duration of anticoagulation can last 2-5 days after a dose. Therefore, when patients experience a warfarin-related hemorrhage, patients may require rapid reversal of the effects of warfarin in addition to withholding subsequent warfarin doses. Among these hemorrhagic events, the most concerning to healthcare providers are major or life-threatening bleeding. These hemorrhages often originate intracranially or within the gastrointestinal tract.<sup>1</sup> Warfarin-related hemorrhages occur in 15-20% of patients on warfarin therapy and, considering that over 3 million people are taking warfarin, there is little surprise that managing warfarin-associated hemorrhages is of major interest to healthcare providers.<sup>2</sup> Guidelines for the management of a major or life-threatening bleed have been devel-

oped by the American College of Chest Physicians (ACCP) which recommend the use of fresh frozen plasma, vitamin K, PCCs, and/or recombinant factor VII.<sup>1</sup> Each of these agents has demonstrated their utility in managing a hemorrhagic event but not without disadvantages. For example, administration of fresh frozen plasma can lead to volume overload while the administration of vitamin K may take up to 8-24 hours to produce an effect.<sup>3,4</sup>

Prothrombin complex concentrates contain vitamin K-dependent clotting factors and produce rapid correction of INR within minutes but may put the patient at an increased risk for thrombotic events. Another disadvantage of using PCCs is the difficulty in dosing these agents since there has not been a consensus on whether fixed dosing regimens or weight-based dosing should be used. The dosing range for three-factor PCCs commonly employed in recent studies is 25-50 units/kg given once intravenously, and the calculated dose is usually rounded to the nearest vial size for convenience and economic considerations. In the United States (US), three-factor products are available which contain factors II, IX, and X in varying amounts with very little factor VII. Outside the US, four-factor products are commonly used which contain more factor VII.<sup>3</sup> In a recent study using three-factor PCCs, a dose of approximately 25 units/kg was shown to be less effective in correcting the INR when patients presented with a median INR of 3.5 compared to patients presenting with a median INR of 2.5.<sup>5</sup> Although these results might suggest that the use of 25 units/kg dosing is less effective than higher weight-based dosing such as 50 units/kg, a consensus on the matter has not been reached. Furthermore, the most recent guidelines developed by the ACCP failed to elaborate on the use of PCCs in warfarin-associated hemorrhage.<sup>6</sup>

Although PCCs produce a more rapid

*Continued on page 13*

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**Rilpivirine (Edurant™) Drug Monograph**

**Amy C. Moss, PharmD**  
**PGY-1 Pharmacy Resident**  
**Harris County Hospital District**

Rilpivirine (Edurant™) is manufactured by Tibotec Therapeutics, Inc, and is a novel antiretroviral (ARV) agent, more specifically, a non-nucleoside reverse transcriptase inhibitor (NNRTI), comparable to efavirenz. Rilpivirine is indicated for the treatment of HIV-1 infection in combination with other ARV agents and is administered orally 25 mg once daily with food. It is not appropriate for use in treatment-experienced patients.

There are three first-generation NNRTIs (efavirenz, nevirapine, and delavirdine) and two second-generation, diarylpyrimidine (DAPY) NNRTIs (etravirine and rilpivirine) currently available for use. There are no dosing adjustments necessary for renal or hepatic impairment, and significant removal is unlikely during hemodialysis/ peritoneal dialysis due to the extensive protein binding. Administration with a normal to high-calorie meal is necessary because rilpivirine is pH-dependent.<sup>5</sup>

**Pharmacology**<sup>1</sup>

As a NNRTI, rilpivirine binds to reverse transcriptase, then blocks the RNA-dependent and DNA-dependent DNA polymerase activities, including HIV-1 replication. It does not require intracellular phosphorylation for antiviral activity.

**Pharmacokinetics**<sup>1, 2</sup>

See Table 1.

**Adverse Events / Reactions**<sup>1</sup>

The most common adverse events impact CNS, hepatic, and endocrine/metabolic systems. Depressive disorders occurred in 4% to 8% of patients. Cholesterol increased to 200-300 mg/dL in 19% and levels >300 mg/dL occurred in <1% of patients. LDL levels increased to 130-190 mg/dL in 17% of patients, but levels >191 mg/dL occurred in <1% of patients. Triglyceride levels increased to 500-750 mg/dL in 2% of patients, but rarely increased to >750 mg/dL (<1%). Hepatic transaminases increased in patients as well, but rarely above five times the upper limit of normal. Alanine aminotransferase (ALT) levels increased in 19% of patients, AST levels increased in 15%, with 2% greater than five times the upper limit of normal (ULN), and bilirubin increased in about 7% of patients taking rilpivirine.

**Contraindications**<sup>1</sup>

Concurrent use of carbamazepine, dexamethasone (>1 dose), oxcarbazepine, phenobarbital, phenytoin, proton pump inhibitors (PPIs), rifabutin, rifampin, rifapentine, or St John's wort is contraindicated with rilpivirine.

**Warnings and Precautions**<sup>1</sup>

Rilpivirine may cause depressive disorders (depressed mood, dysphoria, mood changes, negative thoughts, suicide attempts, or suicidal ideation), fat redistribution (buffalo hump, peripheral wasting with increased abdominal

girth, and cushingoid appearance), and immune reconstitution syndrome.

**Comparative Clinical Efficacy**<sup>3, 4</sup>

Comparative clinical efficacy is shown in Table 2. In the randomized, double-blind, phase III trials [ECHO (TMC278-C209) and THRIVE (TMC278-C215)], rilpivirine plus NRTIs demonstrated non-inferiority to efavirenz plus NRTIs with regard to HIV-1 RNA < 50 copies/mL at week 48 in treatment-naive HIV-infected patients. It was also noted that:

- Virologic failure was more frequent with rilpivirine than efavirenz.
- Failure due to toxicity was more common with efavirenz than rilpivirine.
- Cross-resistance to etravirine was commonly observed among patients failing rilpivirine.
- Grade 2-4 drug-related events were significantly less common with rilpivirine compared to efavirenz.
- Neurologic, psychiatric events, rash, and lipid increases were significantly less frequent with rilpivirine compared to efavirenz.

**Summary**

Rilpivirine is a novel NNRTI that may be used in combination with other ARV agents in treatment-naive patients with a viral load of less than 100,000 copies/mL. While rilpivirine demonstrated more frequent virologic failure than efavirenz, treatment failure due to toxicity was more common in efavirenz.

**References**

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Table 1.	Rilpivirine	Efavirenz
Absorption	Increased 40% with a meal (normal-to-high calorie)	Increased absorption with high fat or reduced fat meals
pH Dependent	Yes	No
Time to peak, plasma	4-5 hours	3 to 5 hours
Protein	99.7% (primarily albumin)	99.5% to 99.75%
Metabolism	Hepatic, primarily by CYP3A4	Hepatic: via CYP3A4 and CYP2B6 pathways
Half-life	~50 hr	40 to 55 hr
Excretion	Fecal: 85%, ~25% as unchanged drug Urine: ~6%; <1% as unchanged drug	Fecal: 16-61%, primarily unchanged Renal: 14-34%, as inactive metabolites

Moss, continued from page 12

double-blind, randomised, phase III trials comparing TMC278 versus efavirenz in treatment-naïve, HIV-1-infected patients. Program and abstracts of the XVIII International AIDS Conference; July 18-23, 2010; Vienna, Austria. Abstract THLB206.

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Ortiz, continued from page 11


decrease in INR compared to conventional therapies, they have failed to show a significant benefit in neurological outcomes or mortality in intracranial hemorrhages. Furthermore, with a variety of dosing strategies available, selecting the appropriate dose of prothrombin complex concentrates may be difficult. Additional research in the management of warfarin-associated hemorrhage should be conducted so that both outcomes and the effect of different dosing strategies of PCCs can be better determined.

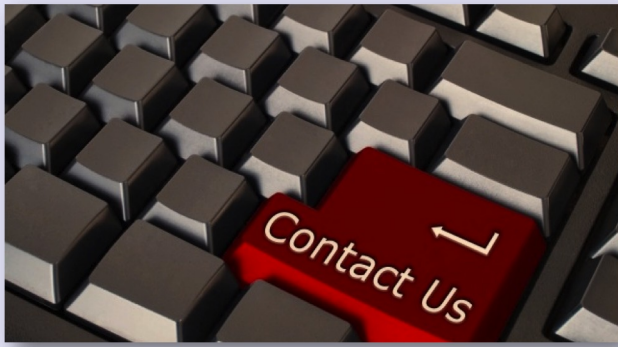
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Table 2	Rilpivirine	Efavirenz
Product Availability	25 mg tablet	50, 200 mg capsule, 600 mg tablet
Regimen	Daily, with food	Daily, without food, preferably at bedtime
Monitoring	Cholesterol, triglycerides, hepatic transaminases; signs of skin rash, and signs and symptoms of infection	Serum transaminases (consider discontinuation of treatment for persistent elevations > 5 x ULN), cholesterol, triglycerides, signs and symptoms of infection
Adverse Events	<p><b>Dermatologic:</b> Rash (grade 2 or higher, 3%)</p> <p><b>Endocrine metabolic:</b> Raised low density lipoprotein cholesterol (grade 1, 12%; grade 2, 5%; grade 3, less than 1%), Serum cholesterol raised (grade 1, 14%; grade 2, 5%; grade 3, less than 1%)</p> <p><b>Hepatic:</b> ALT/SGPT level raised (grade 1, 15%; grade 2, 4%; grade 3, less than 1%; grade 4, less than 1%), AST/SGOT level raised (grade 1, 12%; grade 2, 3%; grade 3, 2%; grade 4, less than 1%)</p> <p><b>Neurologic:</b> Headache (grade 2 or higher, 3%), Insomnia (grade 2 or higher, 3%)</p> <p><b>Psychiatric:</b> Depression (all grades, 8%)</p>	<p><b>Dermatologic:</b> Pruritus (up to 9%), Rash (5% to 45.6%), Rash, grade 2 (14.7% to 31.6%)</p> <p><b>Endocrine metabolic:</b> Serum cholesterol raised (9% to 54%), Serum triglycerides raised, grades 3 to 4 (6% to 11%)</p> <p><b>Hepatic:</b> ALT/SGPT level raised, grades 3 to 4 (2% to 8%), AST/SGOT level raised, grades 3 to 4 (5% to 8%), Gamma-glutamyl transferase raised, grades 3 to 4 (2% to 8%)</p> <p><b>Neurologic:</b> Dizziness (2% to 9%), Headache (2% to 11%), Insomnia (up to 7%)</p> <p><b>Psychiatric:</b> At risk for suicide (0.5%), Depression (Severe), Psychotic disorder, Suicidal thoughts (0.7%)</p>
Pregnancy Category	B	D
AWP Cost	\$ 756.00 / 30 tablets	\$ 679.58/ 30 tablets

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