August/September 2014 Fall Issue

Gulf Coast Society of Health-System Pharmacists (GCSHP)



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President's Report Katy Toale, PharmD, BCPS



Welcome to another exciting year at GCSHP!!!

Thank you to everyone who came out to the 2nd Annual GCSHP Casino Night at St, Arnolds Brewery on July 17th. We had a great time meeting our members and gambling the night away.

Some of the upcoming events we have planning for the 2014-2015 year include a law continuing education event, volunteer activities, and preceptor continuing education events. Please keep an eye on your email or check our website at http://www.gcshptx.org/ for up to date information. In addition to local events, joint membership with the Texas Society of Health-Systems Pharmacists (TSHP) offers many benefits as well including: 1)TSHP journal, 2)annual meeting, 3)mentor programs, 4)drug information alerts, and 5) lobby and regulatory agency representation.

I would like to congratulate our new officers and winners of the outstanding achievement awards for 2013-2014. Our new officers include:

President elect – Thani Gossai Treasurer – Stephen Davis Director – Katie Morneau Communications Council – Abimbola Farinde Professional and Legal Affiars – Rick Burnett

The Board of Directors is working hard to ensure that your membership is worthwide. We would be happy to hear from our members so please send any comments/suggestions/feedback to gcshp.membership@gmail.com.

Katy Toale, PharmD, BCPS





GCSHP 2^{ml} Annual Casino Night

Back by popular demand, The GCSHP hosted the **2nd Annual Casino Night at Saint Arnold Brewing Company** on **Thursday July 17, 2014 from 6-9pm!!!** There was free dinner, drinks and casino games galore! There was also the opportunity to network with other pharmacists and technicians in the Houston/Galveston region. Attendees learned more about what GCSHP is doing along with our state organization Texas Society of Health System Pharmacists (TSHP) to advance the pharmacy profession. Awards were presented to the 2013-2014 outstanding student and pharmacist.

















































Save the Date

- Educational dinner on Multifocal Motor Neuropathy (MMN), a branded (Gammagard Liquid Immune Globulin) presentation on early diagnosis and appropriate treatment sponsored by Baxter. Date: Sept 11th 6pm. Location: Fleming's Prime Steakhouse, 2405 West Alabama Street, Houston, TX 77098
- Preceptor CE conference. Date: October 25th 8am-12pm.
 Location: TSU TMC Campus.
- Law continuing education event. Speaker Brad Shields. Date:
 Feb 18th at 6pm. Location: MD Anderson Cancer Center, Hickey Auditorium.
- TSHP Annual Seminar. Date: **April 24-26**. Location: The Henry B. Gonzalez Convention Center, San Antonio, TX.

GCSHP Supported Activities

UH and TSU Membership drive/start-up support, 9/3/2013

4th Annual Residency Workshop, 10/7/2013

Annual Residency Showcase, 11/1/2013

9th Annual UH/TSU SSHP Residency Mentoring Social, 1/21/2014 GCSHP also provided support to send pharmacy students to national meetings. You can see a report of their experiences on the following pages.

















2014 ASHP Summer Meeting Post Conference Reflection

By Hongmei Wang, Texas Southern University SSHP

I really appreciated that GCSHP gave me this great opportunity to attend the 2014 ASHP Summer Meeting in Las Vegas. Through this 4-day meeting, I learned so much about leadership, pharmacy practice and policy, and medical safety. The meeting was large and there were so many activities for us to attend that it's hard for me to put all of the activities and my thoughts in this reflection.

My first day May 31st, started with meeting with my mentor Dr. Amy Kwak who was coming from Houston Methodist Hospital. She shared with me her residency experiences and also introduced her residency program director to me later. I discussed with her my short-term and long-term career goals. In the poster session held on June 2nd, she presented her poster and shared with me her research experiences as well.

Leadership activities on the 2nd day, June 1st were very interesting. The top practice leaders in the panel discussion discussed their career experiences including the chances and challenges and how they encounter them. They talked about their professional responsibilities, network, influence, and vision. The leadership development workshop had a presentation session and a game session. I learned the practical ways to build leadership skills and to gain influential skills. The two empowering sessions on the 3rd and 4th day from Dr. Paul Aldo were "Creating and Delivering Great Messages" and "Creating a Powerful Executive Presence". He mentioned nine-expressive dimensions related to leadership which are passion, poise, self-confidence, candor, clarity, openness, sincerity, thoughtfulness and warmth¹. At the end of the session, I had the opportunity to set my improvement plan around how the dimensions affected me and problem behaviors. I planned to improve my candor and clarity dimensions first by being ready to accept bad news, staying positive, and practice to create a clear message.

The most inspirational session I attended has to be the inaugural address "The constant in the patient care equation" presented by Dr. Christene Jolowsky, president of ASHP. After the meeting, I always think about the patient-care equation "Pharmacist involvement in "X" times passion = Better patient care and more recognition of pharmacists² and she solved the equation. I, as a pharmacy student and a student leader, have the responsibility to contribute to better involvement in daily practice. In the coming year, I will work with my TSU SSHP board team to get more involved in the community patient-care events in interdisciplinary and multi-organization collaboration way.

The 2014 ASHP Summer Meeting has ended but it is not the end. It's time for me to move on to plan a successful TSU-SSHP 2014-15 calendar year!

References:

- 1. Aldo, Paul. "Creating a Powerful Executive Presence." 2014 ASHP Summer Meeting. Mirage Hotel, Las Vegas, NV. 2 June 2014.
- 2. Jolowsky, Christene. "The Constant in the Patient Care Equation" 2014 ASHP Summer Meeting. Mirage Hotel, Las Vegas, NV. 3 June 2014.

http://www.ashpintersections.org/2014/06/the-constant-in-the-equation/#sthash.iwmctfGt.dpuf







2014 ASHP Summer Meeting & Exhibition, Las Vegas, NV | May 31 – June 4, 2014 Meghann Davis, University of Houston SSHP



As a student representative for UHCOP, I was privileged to attend the 2014 ASHP Summer meeting this year. One of the highlights of the Summer Meeting for students was the Meet & Greet with Pharmacy Leaders. Sara White, Director of Pharmacy at Stanford Hospital in California, facilitated a session in which we discussed topics in small groups with experienced practitioners and leaders within pharmacy. Many of the conversations focused on practical advice from practitioners on how students can direct their own professional growth, while also participating in advancing the growth of the pharmacy profession. The level of dedication to student advancement was humbling and enlightening and their willingness to share their wisdom was remarkable.

Students also took part in an interactive Leadership Workshop facilitated by Jeffrey Little, PharmD and Lindsay Massey, PharmD, the Director of Pharmacy and Pharmacy Operations Supervisor, respectively, of Saint Luke's Hospital in Kansas City, MO. The workshop gave an overview of current pharmacy practice as well as current factors that are re-shaping the pharmacy profession. The presentation particularly focused on comparing and contrasting management and leadership. Teams of students were given various health-system based scenarios and challenged with resolving a complex problem. The teams then presented their solutions to a panel of student judges and a panel of practitioners for feedback. This opportunity was incredibly valuable and has inspired me to carry some visionary ideas back to my UH SSHP chapter.

Thanks to the generous financial support of the GCSHP, I took part in some excellent programming at the ASHP Summer Meeting. The opportunity to experience speakers and seminars from the three main boutiques – Informatics Institute, Medication Safety Collaborative, and Pharmacy, Practice, and Policy – was a tremendous learning experience. The quality and format of this meeting truly fulfilled its tagline of "What happens in Vegas... improves patient care!"



2013 ASHP Summer Meeting & Exhibition Minneapolis, MN | June 1st – 3rd, 2013 Zachary Kirk, University of Houston SSHP



Peter Diamandis, keynote speaker at the ASHP Summer Meeting said, "I have the general philosophy of creating the future you want to see." Diamandis is certainly a controversial visionary; he runs the X Prize Foundation, which offers large cash incentive prizes to inventors who can solve grand challenges like space flight and low-cost mobile medical diagnostics. Heard of private space exploration? This market didn't exist before, but now the general public, for the right price, can travel to space primarily due to the outcomes of the X-Prize. In medicine, the Tricorder X Prize is offering \$10 million to the first team that creates a mobile device capable of "diagnosing patients better than or equal to a panel of board certified physicians". Star Trek- style healthcare seems ridiculously lofty, but is becoming more plausible considering the advancements in mobile computing, artificial intelligence, and sensor technology. Can you imagine an iPad-like device with the ability to read glucose, lipids, LFT's, and, best (or worst?) of all, interpret the results, prescribe the medication and counsel the patient? What are pharmacists left to do?

One of the highlights of the Summer Meeting for students was the Meet & Greet with Pharmacy Leaders. Sarah White, Director of Pharmacy at Stanford Hospital in California, facilitated a session in which we discussed topics in small groups with experienced practitioners and leaders within pharmacy. In light of the keynote speaker's message, several discussions wound up focusing on how technology will alter our future practice. The common, reassuring thread that came from each seasoned leader centered on pharmacists owning the very thing that might change the field: technology doesn't innovate by itself, people do. And who better to guide the innovation and changes in pharmacy than pharmacists themselves? I've heard this message before, but it never felt so immediate or personal. The level of dedication to student advancement was humbling and enlightening and their willingness to share their wisdom was remarkable.

Students also took part in a marvelous Leadership Workshop facilitated by Meghan Swarthout, PharmD, Director, Ambulatory and Care Transitions, The Johns Hopkins Hospital. The workshop gave an overview of current pharmacy practice and the changes expected by initiatives like PPMI. The presentation particularly focused on comparing and contrasting management and leadership. Teams of students were given various health-systems based scenarios and challenged with resolving a complex problem. The teams then presented their solutions to a panel of student judges and a panel of practitioners for feedback. This opportunity was incredibly valuable and has inspired me to carry some visionary ideas back to my UH SSHP chapter.

Thanks to the generous financial support of the GCSHP, I took part in some excellent programming at the ASHP Summer Meeting. As a third-year student, the potential changes technology will bring to healthcare during my future career seem overwhelming. Diamandis and others out there are pushing healthcare into a future that looks drastically different than the one today. When I consider "What are pharmacists left to do?" — I think the answer may simply be doing what all the pharmacy leaders have done before — lead pharmacy forward by boldly owning our drug expertise.



The ASHP Summer Meeting was held at the Minneapolis Convention Center in downtown

UH SSHP Summer 2014 Chapter Report

Meghann Davis, Chapter President & P3 Student

Greetings from UH SSHP! In May, members of the 2014-15 UH SSHP officer team were inducted into their positions by Dr. Katy Toale, GCSHP President, at our annual New Officer Retreat. These officers are excited to begin another successful year and are sure to contribute great things through their

leadership and passion for health-system pharmacy. With classes quickly approaching, plans for fall events are well underway. Our chapter is joining with the UH APhA-ASP chapter to host a Casino Night Social on August 25 as a P1 membership drive. We hope to attract many P1 students to join our chapter by showcasing member benefits such as our residency preparation information, networking events, and leadership opportunities. As we look forward to the various



programming our chapter will be providing this year, we would like to extend our sincere appreciation to the GCSHP for sponsoring many of our major events such as the fall Residency Workshop and the spring UH/TSU Residency Mentoring Social. Events such as these provide tremendous experiences for student members as they are able to interact and learn from many different pharmacy professionals in the TMC. We wish everyone a wonderful end to your summer and hope to see many of you throughout the year.



TSU-SSHP Summer 2014 Chapter Report

Hongmei Wang, Chapter President

We hope everyone is having a great summer.

TSU-SSHP will have two interactive events with the P1 pharmacy students in summer academy. The first one, SSHP officers will present in the P1 summer academy for about 15 minutes to help them gain more information about SSHP organization and residency programs. The second one will be TSU Annual P1 Organization Day which will help gain much interest from many potential members.

Our chapter will have the first officers' meeting in August discussing the planning of the upcoming year including guest speakers for this year, health care events, midyear attendance, TSHP Annual Seminar attendance, clinical competition, membership drive, merchandise sales, fundraising and much more. Then we will have the first general meeting in the beginning of September discussing more details of the planning of upcoming year. Our chapter is planning to have its best year ever this current term and we are looking forward to contributing our effort to the Gulf Coast community. All the best to everyone for the remainder of the summer!

Carmine Colavecchia, PGY2 Health-System Pharmacy Administration Resident, Houston Methodist Hospital, University of Houston College of Pharmacy Laura Stokes, Pharm.D. Candidate 2015, University of Houston College of Pharmacy

Afrezza® (inhaled technosphere insulin)



Overview and Indications¹

Approved by the FDA on June 27, 2014, Afrezza® (technosphere insulin (TI)) is a new inhaled insulin indicated for improving glycemic control in type 1 and type 2 diabetes mellitus (DM) patients. MannKind™ Corporation developed the inhaled formulation and device, however, the company is currently not manufacturing the agent. The company is seeking a partnership with another pharmaceutical corporation to manufacturer the agent, and the drug will not be available until a partnership is made.

Another inhaled insulin product was on the market until 2007, Exubra®, and subsequently discontinued by Pfizer due to poor sales. The main difference between TI and Exubra® is the delivery device, which Exubra®'s delivery system consisted of a large inhalation system. TI's delivery device is as small as a whistle and easy to carry and transport for patients. MannKind™ predicts the novel delivery device will make TI more marketable and feasible for patient use.

Efficacy^{2,3}

For the purposes of this article, only 3 clinical trials are summarized in detail. All of the clinical trials included can be found in MannKind $^{\text{\tiny TM}}$ Corporation's new drug application.

In a multicenter, randomized, open-label, parallel-group study, patients with type 2 DM and poor glycemic control despite insulin treatment were enrolled in a 1:1 ratio to receive TI plus Lantus ® (glargine) or Novolog® (NPH and aspart) 70/30 twice daily. The primary endpoint assessed the change of glycosylated hemoglobin (Hgb A1c) with a non-inferiority margin of 0.4%. The change in Hgb A1c with inhaled insulin plus insulin glargine was -0.68% (SE 0.077, 95% CI -0.83 to -0.53) and non-inferior to the NPH and aspart cohort, -0.76% (SE 0.071, 95% CI -0.90 to -0.62). The between-group difference was 0.07% and less than the non-inferiority margin 0.4%. The inhaled insulin plus glargine group had significantly lower weight gain and fewer mild-to-moderate and severe hypoglycemic events. However, the inhaled insulin group had an increase in the occurrence of cough and change in pulmonary function.

In 24-week multicenter, randomized, double-blind, place-controlled trial, type 2 DM patients were randomized to receive TI plus an oral antidiabetic drug (OAD) or placebo (inhaled powder) plus an OAD. Again, the primary endpoint was change in Hgb A1c. TI plus OAD reduced Hgb A1c by 0.82% and placebo plus OAD baseline reduced Hgb A1c by 0.42%. The author's concluded TI was superior in reducing Hgb A1c when compared to placebo as add-on to OADs in insulin naïve subjects.

Finally, type 1 DM patients were randomized to either continue their basal and prandial insulin or switch to TI for prandial glucose control and continue their home basal insulin. The primary endpoint was a 24-week Hgb A1c with a non-inferiority margin set a 0.4%. The TI plus basal insulin group was determined non-inferior to the group that continued their home basal and prandial insulin regimen, with mean decreases in Hgb A1c of 0.21% and 0.4%, respectively.

Pharmacokinetics^{2,3}

Similar to short acting and ultra-short acting insulins, TI should be used to control post-prandial blood glucose and should be inhaled 10-15 minutes prior to mealtime. Based on the pharmacokinetics of the agent, TI reaches a maximum serum insulin concentration 12-15 minutes after inhalation and serum insulin concentrations decline to patients' baselines after 180 minutes. See Table 1 for a comparison short acting insulin pharmacokinetics.

Short Acting Insulin Pharmacokinetic Comparison³⁻⁶

Insulin Type	Onset	Peak	Duration of action (hr)
TI (Inhaled insulin)	12-15 minutes	54 minutes	2.7
Novolog® (aspart)	10-15 minutes	40-50 minutes	3-5
Humalog® (lispro)	10-15 minutes	40-50 minutes	3-5
Regular insulin	30-60 minutes	2.5-5 hours	5-7

Contraindications and Warnings^{2,3}

TI is contraindicated in patients with chronic lung disease such as asthma and chronic obstructive pulmonary disease as well as in patients allergic to insulin. Similar to other insulins, TI should be used during episodes of hyperglycemia or if the patient is allergic to the medication. The newly approved agent carries a black box warning for causing bronchospasms in patients with lung disease, so a detailed medical history, physical examination, and pulmonary functions tests should be performed prior to initiating therapy.

Adverse Reactions^{2,3}

Like other insulin agents, TI can cause hypoglycemia. The new drug's most common adverse reactions include cough and throat pain or irritation.

Two new cases of lung cancer have been reported in patients using TI during clinical trials. One in controlled trials and one in uncontrolled trials (2 cases in 2750 patient-years of exposure), while no cases of lung cancer were observed in the control groups (0 cases in 2169 patient-years of exposure). In both cases of lung cancer, a prior history of heavy tobacco use was discovered as a risk factor for lung cancer. Two additional cases of lung cancer (squamous cell) occurred in non-smokers exposed to inhaled insulin and were reported by investigators after clinical trial completion. At this point in time, the clinical evidence is insufficient to determine whether inhaled insulin has an effect on lung or respiratory tract tumors.

The risk evaluation and mitigation strategy (REMS) for TI includes a communication plan to inform healthcare providers to screen patients for baseline lung function and be aware of patients' FEV1 declining over time.

Pregnancy³⁻⁶

TI is pregnancy category C, since the medication has not been studied in humans. All other insulins are pregnancy category B.

Table 2: Storage Requirements and Stability³⁻⁶

Product	Unopened	Opened	Opened	Open Strips
Product	Refrigerated	Refrigerated	Room Temp	Room Temp
	Until	10 days	10 days	
TI*	expiration	(unopened	(unopened	3 days
	date	blister cards)	blister cards)	
Novolog® (aspart)	Until			
vial or pen	expiration	28 days	28 days	n/a
	date			
Humalog® (lienro)	Until			
Humalog® (lispro) vial	expiration	28 days	14 days	n/a
	date			
Humulin R®	Until			
	expiration	28 days	14 days	n/a
(regular insulin) vial	date			

^{*}Storage of Inhaler: may be stored at 2-25 C, but when it use, should be stored at room temperature. The inhaler may be used for 15 days from the date of first use and must be discarded and replaced with new inhaler after 15 days.

Exubra Delivery System ⁷



TI Delivery System⁸





Table 3: TI's Benefits and Pitfalls

Advantages	Diaglanda and
Advantages	Disadvantages
No injections	Black box warning of bronchospasms
Superior to oral anti-diabetic agents for	Not recommended in patients with lung
glucose lowering effects	disorders
Potentially more convenient for patients	REMS program
Potential for less weight gain compared to	May decrease lung function over time
insulin	
Patients less likely to administer incorrect	Short stability after opening drug (however,
amount of agent compared to injectable	normally will be used immediately after
insulin	opening)
No lipodystrophy adverse effects	Not approved for use if < 18 years of age
Potential for less waste in hospital if insulin is	Less flexibility in exact dose that is
being dispensed as a bulk product	administered (supplied in 4 unit and 8 units
	cartridges)
	Potential for erratic absorption based on
	inhalation technique

Afrezza Dose Conversion³

Injected Mealtime Insulin Dose	AFREZZA® Dose	# of 4 unit (blue) cartridges needed	# of 8 unit (green) cartridges needed
up to 4 units	4 units		
5-8 units	8 units		
9-12 units	12 units	+	
13-16 units	16 units		
17-20 units	20 units	+	
21-24 units	24 units		



Resources

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- 2. Rosenstock J, Lorber DL, Gnudi L, et al. Prandial inhaled insulin plus basal insulin glargine versus twice daily biaspart insulin for type 2 diabetes: a multicenter randomized trial. *Lancet*. 2010;375(9733):2244.
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 - http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/endocrinologicandmetabolicdrugsadvisorycommittee/ucm390865.pdf. Accessed July 28, 2014.
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- 5. Humalog® (insulin lispro [rDNA origin] injection) [package insert]. Indianapolis, IN: Lilly USA, LLC; 2011 Oct.
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- 8. Holding our breath for Afrezza inhaled insulin. Diabetes Mine. http://www.diabetesmine.com/2014/04/holding-our-breath-for-inhaled-insulin-afrezza.html. Accessed July 28, 2014.



MEMBERSHIP REPORT

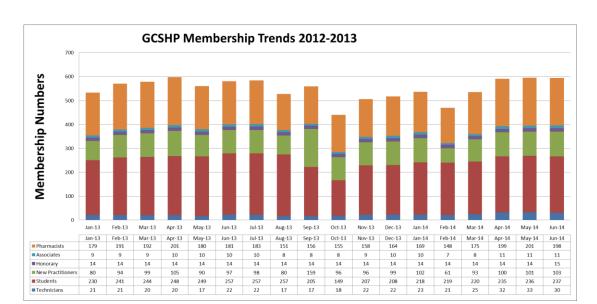
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