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The Society further encourages high standards of conduct and character and fosters fellowship among its members.

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RHO Rx CHI post

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RHO CHI POST: TEAM MEMBERS

@ Davidta Brown

6th Year, STJ; Editor-in-Chief

My two great loves are innovative science and quality writing; the Rho Chi Post is an insightful combination of both. As an editor, I look forward to bringing relevant information and fresh perspectives to the student and faculty of St. John's University, as well as to making the Rho Chi Post a newsletter that offers something new to every reader.

@ Bharat Kirthivasan, PhD

Graduate Copy Editor [Content-Focused]

I received my doctorate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.

@ Tamara Yunusova

6th Year, STJ; Copy Editor [Content-Focused]

I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.

@ Jack (Hongkai) Bao

5th Year, STJ; Staff Editor

In my 3rd year of pharmacy school, I was introduced to the Rho Chi Post, an award-winning newsletter run by students. My involvement began by simply reading monthly articles, but as time passed, my passion for writing grew. Coupled with my interest in pharmacy, I made the initiative to apply for a position. Now, as a team member, I believe that the Post is a great way for students and faculty to stay up to date concerning pharmacy news.

@ Sang Hyo Kim

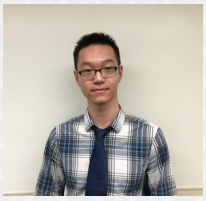
5th Year, STJ; Section Editor: Puzzles

Advancing technology and medicine, as well as prolonging the lifespan and improving quality of life, have increased the geriatric population. Pharmaceutical industries and healthcare systems persistently work to find solutions to changing demands and new problems of the society. I wish to learn, educate, and prepare myself and others for the future.

@ Nicollette Pacheco

6th Year, STJ; Staff Editor [Graphics-Focused]

As a new member of the Rho Chi Post team, I have a vast appreciation of what it means to be a future pharmacist in the rapidly evolving world of healthcare. I am looking forward to being on the team as a graphics-focused staff editor, and I hope to bring my passion for science and creativity to the Rho Chi Post.



@ Alex Chu

4th Year, STJ; Staff Writer

With a constantly evolving healthcare field, it is imperative that we keep ourselves up to date with the latest news. This is what led me to join the Rho Chi Post, which constantly comes out with interesting and informative topics. It is an honor to write for the Rho Chi Post, and I wish to contribute innovative and intriguing articles to this newsletter.

We are always looking for creative and motivated students to join our team!

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TABLE OF CONTENTS

QUOTE OF THE MONTH

By: Nicollette Pacheco, Staff Editor

Carfentanil Poses New Threat of Epidemic in Local Communities

By: Gabrielle Flavoni, PharmD Candidate c/o 2018

Drug diversion has always been a golden target for our nation's law enforcement agents, and a new level of overdose epidemic is taking center stage. Last month, the U.S. Drug Enforcement Agency (DEA) issued a public health warning regarding a synthetic opioid known as carfentanil. Carfentanil is a schedule I drug that has primarily been used in mammals, and has not been approved for human use.[1] As a general tranquilizing agent in veterinary medicine for large animals, it has a dangerous potential to cause fatal overdoses or severe detrimental effects to any human ingesting it for any reason. Human research has not been conducted, and there is no current evidence indicating the safe dosage, use, or ingestion of it. In fact, this potent analog of fentanyl, a widely used opioid, has a potency 10,000 times stronger than morphine.[2] When used properly and in safe doses, the drug poses no threat. However, when abused, carfentanil has the potential to be lethal.[3]

Abuse of fentanyl-based opioids stems back from as early as the 1970's and has only grown since then. Currently, there are over 12 different analogs of fentanyl on the market. Many of these are abused on a regular basis, both by patients being treated with them for analgesia as well as for recreational use.[2] Fentanyl-based drugs have a similar biologic effect to Heroin when they are abused. However, the only overwhelming difference is how drugs like carfentanil are marginally more potent. According to the National Institute of Drug Abuse, fentanyl analogs bind to opioid receptors in the brain, which affects pain levels and emotions.[4] When the drug is ingested, a euphoric effect takes place and the patient gets a "high" to relieve them of pain. This class of drugs has proven to be troublesome in terms of addictive behavior, and has become a source of recreational drug use. Carfentanil has recently taken the spotlight in this issue.

The drug has become increasingly popular in many communities throughout the U.S. At the end of September, the DEA raised a red flag to authorities regarding the use of the drug and the rising trend of overdose-related-deaths due to the mishandling and improper use of the drug.[3] Chuck Rosenberg, a DEA administrator, even commented that in some areas of the country, carfentanil has been sold in communities disguised as heroin. It has been found within the community as powders, blotter papers, tablets, and sprays, which sometimes makes it difficult to identify.[1] With such a wide range of dosage forms, people must stay vigilant and knowledgeable when handling foreign substances.

Further study of the drug has also shown that dermal exposure to the drug or inhalation of any powders may lead to absorption into the body.[1] The DEA has issued heavy warnings to first responders to practice extreme caution while handling any unknown substances. The risk of absorbing unknown amounts of carfentanil can lead to toxicities and overdosing without even orally ingesting the opioid. They have also been advised that if they suspect that they have been exposed to it at all, that they shall be immediately transported to an emergency medical facility for treatment.

What will come of this upcoming threat is still unclear, but health care professionals and federal law enforcement alike will remain vigilant in limiting the abuse from spreading further.

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FDA Approves Obiltoxaximab (Anthim®) Injection for Inhalational Anthrax

By: Alex Chu, Staff Writer

On March 21 2016, the Food and Drug Administration (FDA) approved obiltoxaximab (Anthim®), an intravenous injection, for the treatment and prevention of inhalational anthrax toxicity for adult and pediatric patients. Developed by Elusys Therapeutics, obiltoxaximab is a monoclonal antibody that binds to the protective antigen of anthrax, which is a cell binding protein component of anthrax toxin.[1,4,5] The cell binding protein components of obiltoxaximab are composed of edema factor and lethal anthrax factor, which are thought to be the enzymatic toxins responsible for its pathology. Obiltoxaximab inhibits the entry of lethal anthrax and edema factors into cells.[1,4,5]

Although cases of anthrax are rare in the U.S., it is a life-threatening, infectious disease with a fatality rate of 45% if left untreated.[2] Due to its lethality and ease of intentional transmission through the air, the CDC (Centers for Disease Control) notes that anthrax is regarded as a biological warfare and bioterrorism threat listed under Category A, and therefore poses the highest risk to national security and health.[2] Because treatment for anthrax is critical in maintaining health and combating bioterrorism, obiltoxaximab was approved under the FDA Animal Rule. Under this rule, findings from adequate and well-controlled animal studies that demonstrate drug efficacy may be used in obtaining drug approval in situations where it is normally unfeasible, such as conducting clinical trials in humans with anthrax due to its high fatality rate.[1,4,5]

The efficacy of obiltoxaximab was demonstrated in four double-blinded clinical studies involving NZW rabbits and cynomolgus macaques. In the trial, the animals were given aerosolized *B. anthracis* spores at doses much higher than lethal doses in order to achieve a mortality rate of 100% , if left untreated.[1] Treatments of either obiltoxaximab or placebo were administered after positive serum electrochemiluminescence assay levels which indicate infection, were detected in the blood.[1] The animals were observed for survival 28 days after initial administration of the spores.[1] In studies 1 and 2 that involved NZW rabbits, none of the rabbits that were administered placebo (n=9, n=13) survived in comparison to the 93% and 62% that survived after obiltoxaximab was administered (n=14/p=0.0010, n=13/p= 0.0013).[1] In studies 3 and 4, 6% and 0% of cynomolgus macaques survived after administration of placebo (n=16, n=17) as compared with 47% and 67% with obiltoxaximab (n=15/p=0.068, n=33/ p=0.0055).[1]

The safety of obiltoxaximab was studied in 320 healthy subjects over the course of three clinical trials.[1,3] Study 1 was a placebo-controlled study evaluating adverse reactions between a single dose of 16mg/kg IV obiltoxaximab vs placebo (n=210, n=70).[1] Study 2 was a repeat dose study in which 70 subjects received one dose, and then 34 and 31 subjects received a second dose 2 weeks and 4 months apart, respectively.[1] Study 3 was a drug interaction analysis of 40 subjects in which half of the subjects received a single dose of obiltoxaximab while the other half received obiltoxaximab plus ciprofloxacin for 9 days.[1] The combined results from studies 1 and 2 demonstrate that the most common adverse reactions resulting from administration of single dose obiltoxaximab vs placebo (n=300, n=70) were headaches (8% vs 6%), itching (4% vs 1%), and upper respiratory tract infections (5% vs 3%)[1] Overall, patients who were pre-medicated with diphenhydramine were found to be less likely to experience adverse reactions compared to those who were not (42% vs 58%).[1] Findings of the drug interaction analysis indicate that co-administration of ciprofloxacin orally or intravenously, did not alter pharmacokinetic properties of obiltoxaximab and resulted in higher survival outcomes than antibacterial therapy alone.[1,4]

Because of how rare and deadly anthrax is, obiltoxaximab is mainly used by militaries and federal agencies such as the CDC (Centers for Disease Control) and the National Institute of Health for emergency preparation and public health. The recent approval of obiltoxaximab adds an additional treatment and prevention option for anthrax toxicity as opposed to treatment with antibiotics.

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Results of Largest Pharmacotherapy Smoking Cessation Trial Prompts Debate over Varenicline's Black Box Warning

By: Nicollette Pacheco, PharmD Candidate c/o 2017

It is an easy decision to include a black box warning on a drug label in response to clinically significant drug safety information. The decision to *remove* such a warning, on the other hand, has recently proven to be a more difficult decision.

Varenicline (Chantix®) was approved in 2006 for use as an aid to smoking cessation treatment. Mechanistically, the drug competitively binds to nicotinic acetylcholine receptors with a higher affinity and selectivity than nicotine, stimulating receptor-mediated activity at a lower level than nicotine itself.[1] Because of its significant potential benefit to public health as a smoking cessation agent, the FDA placed a priority on its review for approval in order to expedite the drug approval process. After its approval, Pfizer began reporting neuropsychiatric events such as suicidality and behavior/mood changes in patients using varenicline. In response to these reports, the Food and Drug Administration required the manufacturers of both varenicline and bupropion (Zyban®), another smoking cessation agent, to include a black box warning that highlights the risk of serious mental health events while taking these drugs.[2]

In addition to the boxed warning, the FDA also required the development of a sufficiently large randomized controlled trial to collect data on smoking cessation treatments and their correlation to neuropsychiatric events. While this large study was underway in 2011, several smaller retrospective observational studies were published that suggested no significant association between varenicline use and neuropsychiatric events. The Psychopharmacology Drugs and Risk Management Advisory Committee of the FDA met in review of this retrospective data and its impact on the label in 2014 and ruled to keep the boxed warning in the label. While the smaller trials were sufficiently impactful to raise questions about the validity of the boxed warning, they were ultimately not reliable enough to determine causality and remove the warning altogether.[3]

The neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES) trial was completed in 2016 and was the first trial to provide definitive evidence on the relative safety and effectiveness of smoking cessation treatments in smokers with psychiatric disorders compared to those without psychiatric disorders. The study did not show a significant increase in the rates of moderate-to-severe neuropsychiatric events with either varenicline or bupropion relative to nicotine patches or placebo in those with or without psychiatric disorders. The Psychopharmacology Drugs and Risk Management Advisory Committee met once more in September 2016 to discuss varenicline's boxed warning, this time with results from the largest trial of smoking cessation pharmacotherapy to date.[4] Of the 19 panel members, 10 voted to remove the boxed warning completely, 4 voted to rephrase it, and 5 voted to keep the warning as is. As an ongoing process, the FDA will make its official decision based on the results of this vote and the opinions of the panel.[5] Since there is considerable indecision among the committee members, the FDA is likely to carefully weigh each option.

The FDA's intrinsic role as a public health agency often means that their requirements err on the side of caution; at times, boxed warnings can be issued expeditiously before all the data is collected. While this conservative stance effectively mitigates potential patient harm, it may also create a false warning that can only be disproven by subsequent data.[3]This boxed warning is a major consideration when prescribers compare the risks of smoking cessation medications with the benefits of smoking cessation itself. The EAGLES study provides new data that will help prescribers weigh the risks of smoking-related illness and death with the risks of smoking cessation medication.

Patients with psychiatric disorders smoke at a rate two- to three-times higher than the general population and are more prone to smoking-related illness. The presence of a boxed warning regarding neuropsychiatric events has drastically affected the use of efficacious smoking cessation medications in these patients and may have prevented their access to beneficial treatment.[4] Data from the EAGLES trial depicts the risk of neuropsychiatric events more reliably than the data that initially prompted the inclusion of the boxed warning and should therefore be included in the product's label. The majority of the committee felt that the data from the EAGLES trial was sufficient to promote safe use of these medications in patients with and without psychiatric disorders in prac-

tice.[6] Revisions to the varenicline label to accurately reflect the risk of developing suicidal ideations and mood changes will allow both prescribers and patients to make well-informed decisions about smoking cessation.

Although the slight majority of 10 panel members voted to remove the boxed warning completely, 9 members still voted to keep the warning or to make revisions to the warning.[5] Upon completion of the EAGLES trial, the FDA conducted its own sensitivity analysis with the study's results to determine the validity of the trial. The main area of criticism of the trial stems from adverse event severity coding, which was found to be inconsistent among investigators involved in the study. The FDA determined that this variability may have lowered the number of primary outcome events in the studies, creating a bias towards its null finding. Committee members that ruled to keep the boxed warning felt that removing the warning would send the wrong message, while leaving it in the label would certainly not cause any harm.[7]

When post-marketing reports of a drug show adverse events that were previously unknown, the FDA utilizes several tools to minimize patient harm. Recommending additional safety trials, REMS programs, label amendments, and marketing authorization restrictions all serve to mitigate patient harm. The FDA must also act when the validity of these tools is called into question in response to emerging data.[3]

UPDATE: The FDA has reached a verdict on varenicline labeling since the time that this article was written in October 2016. Upon review of the EAGLES trial, the FDA ruled that the risk of serious side effects on mood, behavior, or thinking with varenicline and bupropion is lower than previously suspected, and removed this Boxed Warning from both drugs' labels. The Warnings and Precautions section of the labels will also be updated to include the results reported from this clinical trial. This decision was reached on December 16, 2016.[8]

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A Step in the Right Direction

By: Sal Monaco, PharmD Candidate c/o 2018

In recent years, the state of California has remained at the forefront of innovative pharmacy practice by recognizing of the importance of pharmacists in healthcare. The state recently took action which puts them another step ahead and strengthens the support pharmacists in the state receive. On September 25, 2016 the state of California passed an important piece of legislation which could bring pharmacists one step closer to gaining nationwide healthcare provider status. This legislation, entitled Assembly Bill No. 1114 (AB-1114), extends reimbursement for pharmacist services.

AB-1114 allows for reimbursements for pharmacy services under the Med-Cali program, which is the state's program for Medicare and Medicaid. A total of five services were approved for reimbursement: dispensing travel medications, Naloxone, and self-administered hormonal contraceptives, administering vaccinations, and providing tobacco cessation counseling and nicotine replacement therapy.1 The amount that pharmacists will get reimbursed for these services is set at 85% of what physicians receive for similar services.1 The legislation also states, "This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect."1 This one excerpt greatly emphasizes the importance that California places on the role of pharmacists in today's healthcare system.

While AB-1114 allows for pharmacists to be reimbursed for the above mentioned services, it is not the bill which gave pharmacists permission to provide these services. The power to perform these services actually came in 2014 with Senate Bill No. 493 (SB-493). SB-493 is also the piece of legislature that granted pharmacists in California the much sought-after provider status.2

As student pharmacists and pharmacists, it is our responsibility to be proud of our profession and to prove to others the importance and value of pharmacists in healthcare. One of the best ways to support our profession is to attend PSSNY's Pharmacy Lobby Day. By attending the lobby day, we are able to help push the legislative agenda of PSSNY to advance the field of pharmacy by bringing the importance of our role to the attention of state legislators. Without our advocacy efforts, it is likely the legislators will view pharmacists solely as people who stand behind a counter and dispense medications. I believe it is our obligation to teach others about our capabilities and the value we can provide to the healthcare system.

The recent actions taken by the government of California, as well as the actions taken by many other states, are truly a step in the right direction towards nationwide recognition of pharmacists as healthcare providers and proper reimbursement for their services. Currently, the federal government has proposed The Pharmacy and Medically Underserved Areas Enhancement Act, which would grant pharmacists nationwide provider status and reimburse pharmacy services in medically underserved areas.3 The bill currently has strong bipartisan support; however, an official vote has yet to take place. It is hopeful that the proposed federal bill along with the varied state legislatures will continue to grow the field of pharmacy and expand its current scope of practice.

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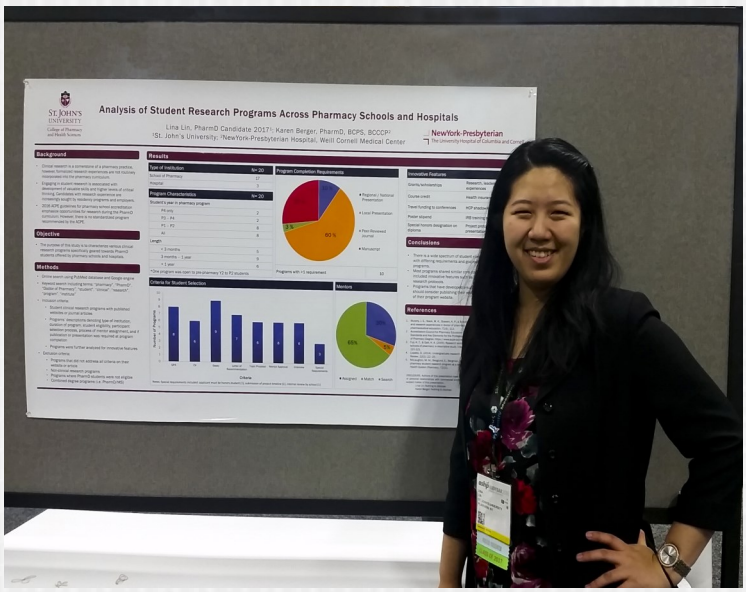
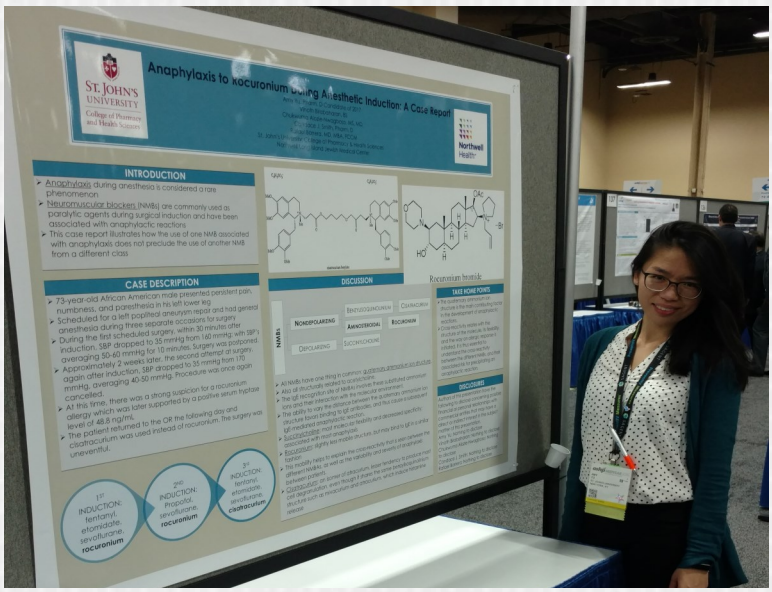
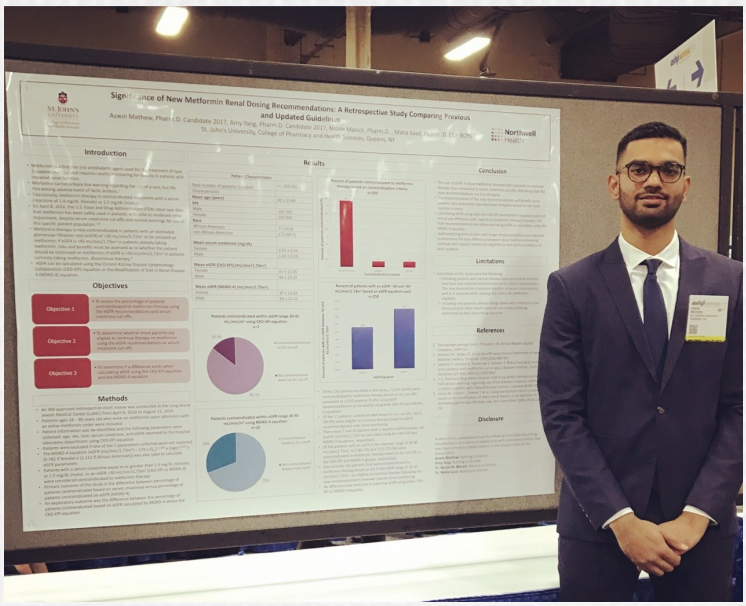


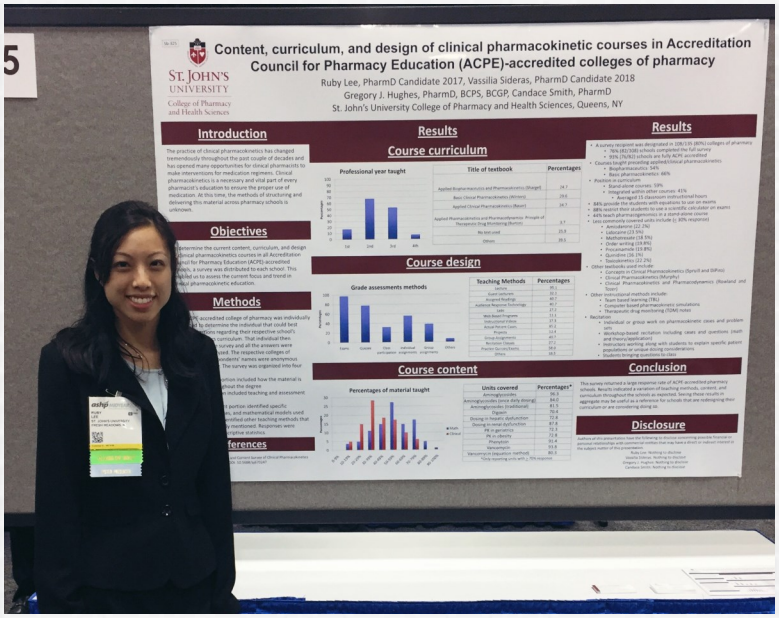
***Lina Lin:** Analysis of Student Research Programs Across Pharmacy Schools and Hospitals*



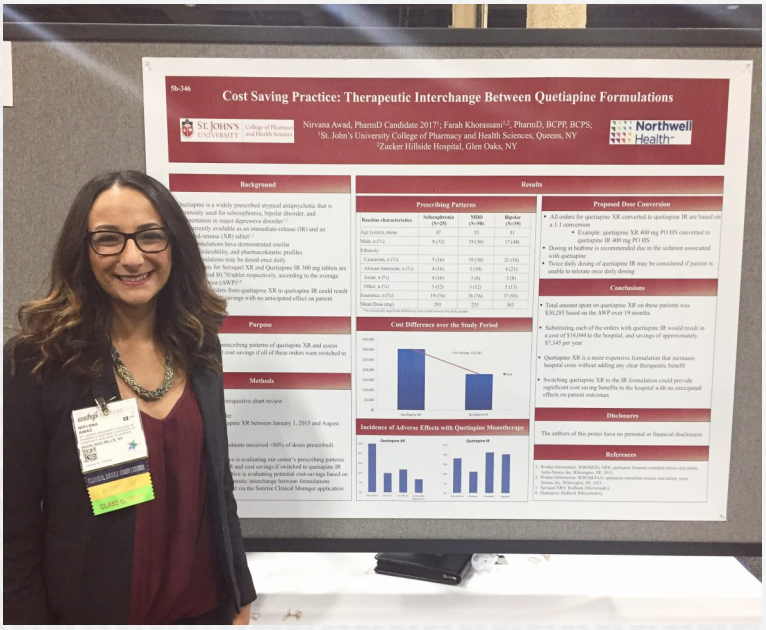
***Amy Yu:** Anaphylaxis to Rocuronium During Anesthetic Induction—A Case Report*



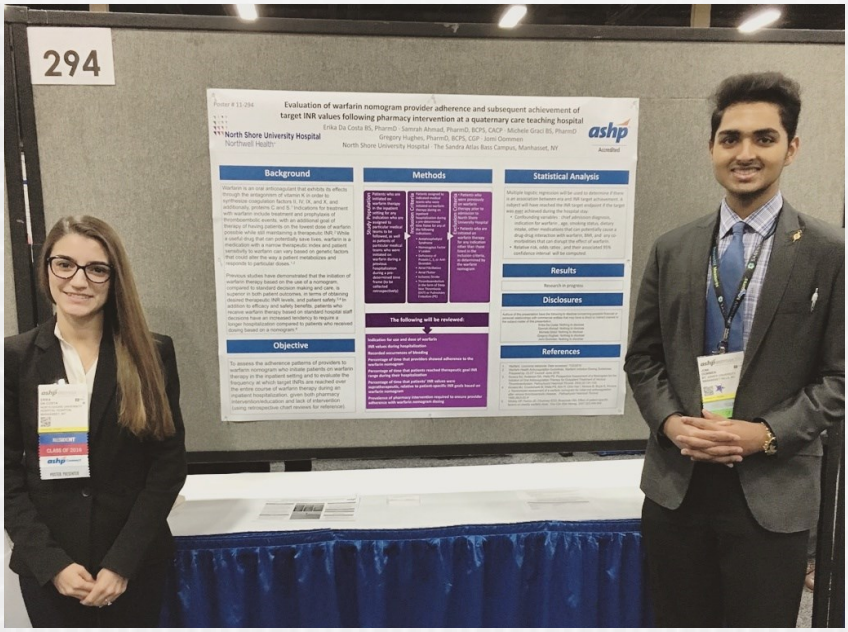
***Aswin Mathew:** Significance of New Metformin Renal Dosing Recommendations: A Retrospective Study Comparing Previous and Updated Guidelines*



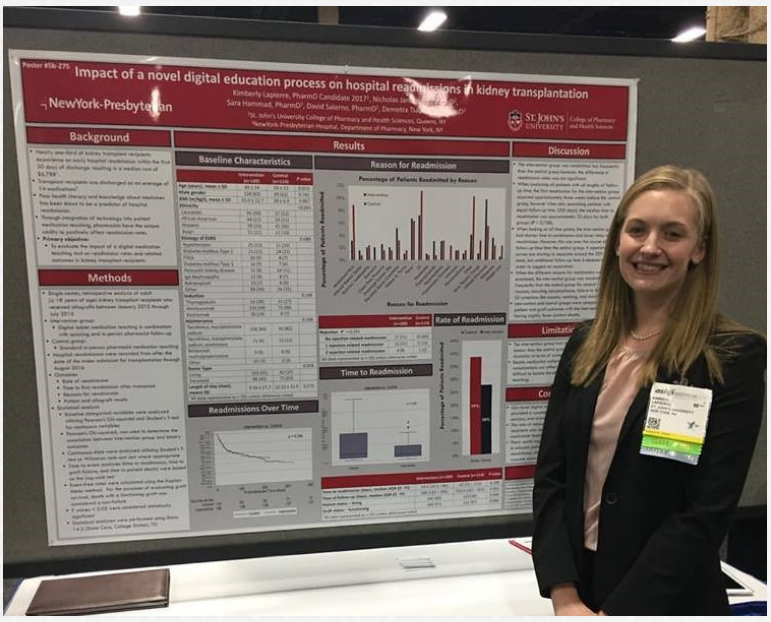
***Ruby Lee:** Content, curriculum, and design of clinical pharmacokinetic ocurses in Accreditation Council for Pharmacy Education (ACPE)-accredited colleges of pharmacy*



Nirvana Awad: Cost Saving Practice: Therapeutic Interchange Between Quetiapine Formulations

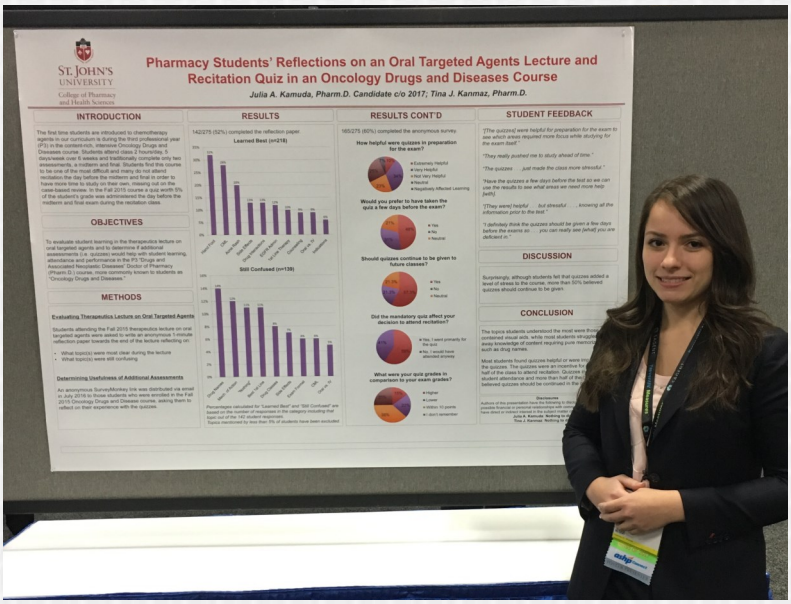


Erika Da Costa and Jomi Oommen: Evaluation of warfarin nomogram provider adherence and subsequent achievement of target INR values following pharmacy intervention at a quaternary care teaching hospital

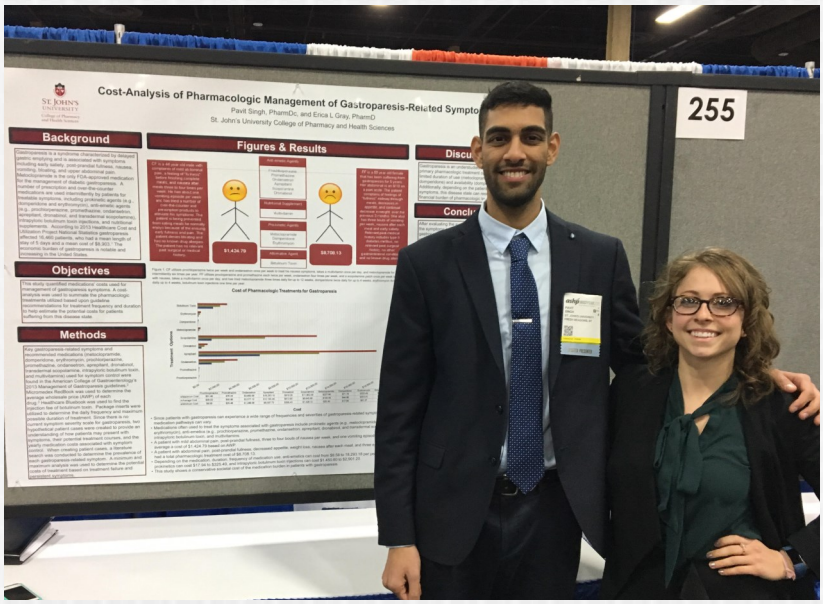


Kimberly Lapierre: Impact of a novel digital education process on hospital readmissions in kidney transplantation

Matthew Li: Pharmacy Speed Networking



Julia A. Kamuda: Pharmacy Students' Reflections on an Oral Targeted Agents Lecture and Recitation Quiz in an Oncology Drugs and Diseases Course



Pavit Singh and Erica L. Gray: Cost-Analysis of Pharmacologic Management of Gastroparesis-Related Symptoms

Went to an event on campus?

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Diabetes Clinical Corner

By: Sang Hyo Kim, Section Editor

Do you know the difference between Type 1 Diabetes and Type 2 Diabetes?

Type 1 is referred to as insulin-dependent diabetes mellitus (IDDM). It usually presents in children from the autoimmune destruction of the B-cells of the pancreas. Patients who are type I need insulin injections; no oral medication is taken. Type 2 is referred to as noninsulin-dependent diabetes mellitus (NIDDM). There is insulin resistance of the beta cells, leading to loss of insulin production. For type 2, patients start off with oral medications. If patients however cannot be managed by oral therapy, insulin is considered.

Oral pharmacologic options for Diabetes Mellitus II:

Biguanides:
Metformin (Glucophage®)

Sulfonylureas:
Glyburide (Diabeta®)
Glipizide (Glucotrol®
Glimepiride (Amaryl®)

DPP-4 Inhibitors:
Alogliptin (Nesina®)
Saxagliptin (Onglyza®)
Sitagliptin (Januvia®)
Linagliptin (Tradjenta®)

Thiazoladinediones:
Pioglitazone (Actos®)
Rosiglitazone (Avandia®)

SGLT-2 Inhibitors:
Canagliflozin (Invokana®)
Empagliflozin (Jariance®)
Dapagliflozin (Farxiga®)

Meglitinides:
Repaglinide (Prandin®)
Nateglinide (Starlix®)

Alpha Glucosidase Inhibitors:
Acarbose (Precose®)
Miglitol (Glyset®)

There are four types of insulin: rapid acting insulin, regular or short acting insulin, intermediate acting insulin, and long acting insulin.

Rapid acting insulin:
Insulin glulisine (Apidra®
Insulin lispro (Humalog®)
Insulin aspart (Novolog®
Inhaled (Afrezza®

Short Acting Insulin:
Humulin R
Novolin R

Intermediate Acting Insulin:
NPH (Humulin N, Novolin N)

Long Acting Insulin:
Insulin detemir (Levemir®)
Insulin glargine (Lantus®)

Five symptoms of HYPOglycemia:
Shaking
Sweating
Anxious
Dizziness
Hunger

Five symptoms of HYPERglycemia:
Polyuria
Polyphagia
Polydipsia
Blurred vision
Headaches

MISSION

The Rho Chi Post is an award-winning, monthly, electronic, student-operated, faculty-approved publication that aims to promote the pharmacy profession through creativity and effective communication. Our publication is a profound platform for integrating ideas, opinions, and innovations from students, faculty, and administrators.

VISION

The Rho Chi Post aims to become the most exciting and creative student-operated newsletter within St. John's University College of Pharmacy and Health Sciences

Our newsletter continues to be known for its relatable and useful content

Our editorial team continues to be known for its excellence and professionalism

The Rho Chi Post essentially sets the stage for the future of student-operated publications in pharmacy

VALUES

Opportunity

Teamwork

Respect

Excellence

GOALS

To provide the highest quality student-operated newsletter with accurate information

To maintain a healthy, respectful, challenging, and rewarding environment for student editors

To cultivate sound relationships with other organizations and individuals who are like-minded and involved in like pursuits

To have a strong, positive impact on fellow students, faculty, and administrators

To contribute ideas and innovations to the Pharmacy profession