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NYS-ACCP Insider

D'Youville College School of Pharmacy

DYCSoP-ACCP Chapter Synopsis

Special points of Interest:

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- Diabetes Guideline Review
- Mail Order Pharmacy
- Pharmacists as Immunizers
- New Drug
- Clinical Spotlight: Dr. Aubrey Gawron

DYC-ACCP Chapter members 2015/2016

D'Youville College (DYC) School of Pharmacy's Chapter of the American College of Clinical Pharmacy (ACCP) was first introduced in the spring of 2015 by Dr. Tristan Thomas (class of 2016). The main goal of our organization is to promote core values of ACCP which includes providing information to students about careers and opportunities within the field of clinical pharmacy, promoting dedication to excellence in patient care, research and education, encouraging skill development necessary to function within an interdisciplinary team, and advocating for the role of clinical pharmacists within healthcare. We incorporate these principles by educating and promoting clinical pharmacy practice within our student population. During the academic year, we organize various events to help achieve these goals including a clinical pharmacist speaker series, field trip visits to pharmacy relevant industries, community outreach and service events, research symposia, and pharmacy advocacy in collaboration with other organizations.

Our clinical pharmacist speaker series is held each month in the fall semester. At these seminars students learn about the professional careers in clinical pharmacy, the specialties in clinical pharmacy, the requirements of becoming a clinical pharmacist and opportunities available to new and up-coming clinical pharmacists. We have so far invited speakers from Niagara Hospice and Roswell Cancer Institute both located in Buffalo, NY and the Rochester Poison Prevention Center located in Rochester, NY. We also organized a tour of the facilities at Cleveland Clinic, in Cleveland Ohio at the Cleveland Clinic, students were taken on a tour of the pharmacy department and the new genomic research center. Our organization has also hosted several professional development workshops including curriculum vitae writing, mock interviews and residency preparedness seminars which have all helped to reduce anxiety amongst potential residency applicants. During the spring semester, our ACCP chapter, in collaboration with the Student Pharmaceutical Research Association (SPRA) at DYC, organizes an annual student research symposium, where students give a brief platform presentation of their research endeavors to faculty and students of the college.

In addition to professional development efforts, we also embark in community outreach. We visited the Belle Center located in Buffalo, NY which provides after school programs for children between the ages of 10-14, where we educated the kids on the harmful effects of misusing prescription medications. Also, in collaboration with Phi Delta Chi we started an initiative to collect used prescription vials and donated them to Matthew Ministries. Matthew Ministries is a Church based organization located in Cincinnati, Ohio. One their mission endeavors involves, collecting donations of basic medical supplies such as empty pill bottles and sending them overseas to help improve health care quality in developing nations.

Although our chapter is relatively new, we are encouraged by our accomplishments thus far. It is our goal to continue to pursue opportunities for expanding the clinical knowledge of our student body and to encourage more of our members to be involved in clinical research and publication.

-Jamie Lukasiewicz Pharm D. Candidate DYC 2018

Standards of Medical Care in Diabetes:

A Review of Selected Sections of the 2017 ADA Updates

The American Diabetes Association (ADA) updates its *Standards of Medical Care in Diabetes* yearly to provide the most up to date clinical recommendations.[1] These updates are made for all practitioners involved in the management of diabetes patients based on both the most recent scientific and medical evidence. This year, updates were made to 14 sections of the ADA guidelines, but in this review, we will be highlighting just a few of the changes made.

Classification and Diagnosis of Diabetes

Terminology has been revised as well as clarification on new screening techniques for patients at higher risk for prediabetes and type 2 diabetes that has gone undiagnosed. Type 1 Diabetes classification has been updated into three stages for patients with different diagnostic criteria (Table 1). The new focus is on beta-cell functioning and disease progression through monitoring of glucose status. The update also included a type 2 diabetes screening tool which allows patients to assess their risk for type 2 diabetes and to guide the provider in determining whether a diagnostic test is appropriate. Discovery of genes now related to monogenic diabetes have been included in an updated table along with the clinical features related to those specific genes. Regarding women with gestational diabetes, it is recommended that they are tested for persistent diabetes 4-12 weeks postpartum. Also, delivering a baby weighing 9-lbs or more is no longer a risk factor for the development of prediabetes and type 2 diabetes.

Table 1: Staging of type 1 diabetes (adapted from *Table 2.1* in ADA 2017 standards[1])			
	Stage 1	***Stage 2***	***Stage 3***
Stage	Autoimmunity	Autoimmunity	New-onset hyperglycemia
	Normoglycemia	Dysglycemia	Symptomatic
	Presymptomatic	Presymptomatic	
Diagnostic criteria	Multiple autoantibodies	Multiple autoantibodies	Clinical symptoms
	No IGT or IFG	Dysglycemia: IFG and/or IGT	Diabetes by Standard Criteria
		FPG 100-125 mg/dL (5.6-6.9 mmol/L)	
		2-h PG 140-199 mg/dL (7.8-11.0 mmol/L)	
		A1C 5.7-6.4% (39-47 mmol/mol) or ≥ 10% increase in A1C	

IGT: impaired glucose tolerance; IFG: impaired fasting glucose; FPG: fasting plasma glucose

Glycemic Targets

There were also changes in the definition of hypoglycemic states. "Clinically significant hypoglycemia" is now defined as a glucose concentration less *than* 54 mg/dL (3.0 mmol/L), the glucose alert value is defined as *less than or equal to* 70mg/dL (3.9 mmol/L), with *no specific glucose threshold* for "severe hypoglycemia" but in the presence of severe cognitive impairment requiring assistance for recovery.

Pharmacologic Approaches to Glycemic Treatment

The name of this section was updated to emphasize the pharmacologic treatment for glycemic control. Recent evidence has shown a connection between the long-term use of metformin and vitamin B12 deficiency. It is now recommended to consider periodic management of B12 levels and supplementation if necessary. A recommendation to consider the addition of empagliflozin or liraglutide in patients with type 2 diabetes and established cardiovascular disease was also included in the update. Two clinical trials, the EMPA-REG OUTCOME trial and the LEADER trial, provided results that empagliflozin and liraglutide reduced the risk of mortality when added to standard of care in this patient population.[2,3] In the 2017 update there is now a section that includes the role of biosimilar insulins in diabetes care due to concerns about affordability of insulin and other antihyperglycemic agents. Lastly, recent studies reflect the changes that were made to the algorithm for the use of combination injectable therapy. The algorithm reflects the non-inferiority of *basal insulin plus GLP-1 receptor agonist* versus *basal insulin plus rapid acting insulin* versus *two daily injections of premixed insulin*.[1]

Management of Diabetes in Pregnancy

Insulin remains the treatment of choice and is emphasized in pregnant women with diabetes, due to concerns of metformin and glyburide concentrations for the fetus. In managing diabetes during pregnancy, pre-prandial self-monitoring of blood glucose was deemphasized. Recommendations now suggest that self-monitoring of fasting and post-prandial blood glucose is sufficient for controlling glucose levels in pregnant women with gestational diabetes or preexisting diabetes.[1]

Standards of Medical Care in Diabetes (cont'd)

A Review of Selected Sections of the 2017 ADA Updates

Diabetes Care in the Hospital

This section was updated to clarify the recommendation that in non-critically ill patients, basal-bolus insulin may be used to improve glycemic control and reduce hospital complications in general surgery patients with T2DM. Sliding scale insulin alone is strongly discouraged. This is supported by the RABBIT 2 surgery trial which showed that non-critically ill patients with type 2 diabetes, treated with insulin glargine or glulisine, had greater improvement in glycemic control than those treated with sliding scale insulin therapy ($P<0.01$).[5] Greater detail and recommendations were expanded on parenteral feedings regarding insulin type, timing, dosing, nutritional and correctional considerations.

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—Chelsea Weselak and Laura Wilkinson, PharmD Candidates, DYCSOP Class of 2019

The Pros and Cons of Mail-Order Pharmacy

Mail order pharmacy services have become a common pharmaceutical service offered to patients. However, mail-order pharmacies are criticized by some health professionals and patients, while others see mail order pharmacy as a beneficial service. The service may allow for patients in rural areas to have better access to medication, increase adherence, and reduce costs for the pharmaceutical insurance plans.[1] Nevertheless, mail order pharmacies lack the pharmacist-patient interaction that retail pharmacies provide. Pharmacists feel that this relationship is crucial to positive patient outcomes. Patients may feel that the insurance companies are forcing them to use this service, leading to legislation within New York State that outlines a procedure for handling various scenarios related to mail order pharmacies. Pharmacists may in turn feel as though their jobs are being replaced by such a service. However, a review of the positives and/or negatives of this service need to be assessed to determine its usefulness.

The use of mail order pharmacy service has shown to be beneficial for patient adherence and cost reduction. Patients in rural areas may not have access to a pharmacy near their home and are required to drive long distances to obtain pharmaceutical care.[1] Mail-order pharmacy services have been able to reach them by delivering medication through regular mail services such as the United States Postal Service. This service being especially beneficial for medication adherence in chronic disease states such as diabetes mellitus. Diabetic patients who used a mail order pharmacy service had a 6.2% reduction in emergency room (ER) visits when compared to diabetic patients who used a retail pharmacy. In patients with asthma, a 22.73% increase in medication adherence resulted due to the use of mail-order pharmacies.[2] Patients with hypertension were 2.24 times more adherent, patients with dyslipidemia had lower LDL levels, and diabetic patients were also more adherent than patients with the same disease states using retail pharmacies.

Mail order pharmacy services have reduced patient and insurer costs, resulting in the governmental insurance, Tricare, requiring a switch to mail order for brand named maintenance prescription medications.[3] The use of retail or community pharmacies had higher medication prices and higher dispensing fees compared to mail order causing more insurers to require or give incentive to members who switch to mail order pharmaceuticals.[4] The use of mail order pharmacies has also been shown to have negative outcomes. Mail order pharmacies cost more for third party insurers and Medicare Part D due to higher patient cost sharing at retail pharmacies.[5] In a recent study the cost per prescription for third party payers using retail pharmacies was $0.59 compared to $0.72 for mail order pharmacies.[5] Patients who use retail pharmacies are 22% less likely to have a gap in therapy within 30 days in comparison to similar patients using mail order.[6] It was theorized that pharmacist-patient interaction can be the factor that impacts adherence rather than the quantity of medications dispensed. Studies also indicate that patients who use retail pharmacies had adherence rates 3.68% higher than patients who receive prescriptions from mail-order pharmacies.[6] Retail pharmacist led medication reviews have been shown to have significant impact on patient outcomes related to diabetes, blood pressure, and cholesterol.[7] With face-to-face interactions at retail pharmacies, consultations with patients have shown in recent studies to increase patient adherence and help resolve medication related problem.[8] This interaction with pharmacists appears to be a beneficial part of the process based on these studies.

All the current evidence shows that there are advantages and disadvantages to using mail order pharmacies services. Third party payers and patients must consider these augments as they weigh the option of using these services. Future research needs to be conducted to ensure patients are not negatively affected by the requirement of mail order pharmacy by some insurance carriers. Currently the NYS Anti-Mandatory Mail Order (AMMO) insurance law was passed to allow patients to receive “specialty drugs” either through the mail or at their local pharmacy. This bill removes some of the terms and conditions imposed on pharmacies for patients who have mail order pharmacy from their insurer allowing patients to decide on how they would like to receive their medication. Additional legislation is being presented to the New York State Senate that clarifies the concerns of patients and health care professionals, addressing concerns about medication delays and costs, privacy and limited pharmacist’s oversight when using mail-order pharmacies.

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—Kenneth Dill and Yousef Kasem, PharmD Candidates, DYCSOP Class of 2019

Pharmacists as Immunizers:

Continuing to Expand Our Role

Pharmacists have been playing a huge role in the efforts to immunize for over 20 years. Currently all fifty states allow certified Pharmacists to immunize, but only 46 states allow for the complete list of Centers for Disease Control and Prevention (CDC) recommended vaccines to be administered by Pharmacists.[1] Many states still have restrictions on the age of patients that can be vaccinated, with only 27 allowing for all ages to be vaccinated by Pharmacists.[1] As Pharmacists and Student Pharmacists, we are in an ideal position to immunize, as we are highly trusted and easily accessible.

Pharmacy Lobby Day 2017 - Elizabeth Riegle with Assemblyman John T. McDonald III (NYS Assembly District 108), a Pharmacist himself and a strong advocate for the profession

In New York State, licensed Pharmacists are currently allowed to administer the following five vaccines: influenza, Tdap, pneumococcal, herpes zoster, and meningococcal. This current piece of legislation contains a sunset clause, meaning after an assigned number of years the law will cease to exist.[2] Every two years we find ourselves back in Albany lobbying to keep the legislation and expand upon it. This April 2017, Pharmacists and Student Pharmacists from across the state have met in Albany to once again lobby for this important pharmacy issue. When speaking with Legislators we stressed the importance of removing the sunset clauses in order to make these statutes permanent. Like the other 46 states across the country, residents of New York State would greatly benefit from Pharmacists being able to administer all CDC recommended adult immunizations. Pharmacists would be able to provide immunization services in the current 153 medically underserved areas that currently exist in New York, and assist in state declared medical emergencies, like the H1N1 outbreak of 2009.[2] Removing the patient age restrictions from the immunizations that New York licensed Pharmacists can administer is not currently part of the proposed legislation, but it is important to get the conversation started. New York is one of the seven remaining states that only allows Pharmacists to vaccinate adults 18 years and older.[1]Studies performed in states like Oregon, showed that between the years 2011 and 2014, influenza immunization rates increased 37.4% in adolescents (ages 11-17) when allowing Pharmacists to immunize this age group.[3] Lowering the age restrictions applied to adolescent or pediatric populations will only improve public health.

In New York State, Student Pharmacists are unable to immunize until they are licensed Pharmacists. Currently, forty-three states allow pharmacy interns to immunize when under the supervision of a licensed Pharmacist.[4] Pharmacy students in New York are trained through APhA's certification program usually during the third professional year of school. After that training, many of them do not immunize in practice until after becoming a licensed Pharmacist. Students immunizing would further expand access to immunizations in the community setting, as well as allow students to perfect this clinical skill.

Expanding the number of immunizations that a licensed Pharmacist can administer, and authorizing student pharmacists to assist will benefit the health and wellness of people of New York State. Since 2008, more than 12,000 pharmacists have been working hard to improve adult immunization rates, and with further lobbying and support, immunization rates can only improve.[2]

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—Elizabeth Riegle, PharmD Candidate, DYCSOP Class of 2018

Xultophy® 100/3.6

Xultophy®, otherwise known as IDegLira, is a combination therapy of insulin degludec and liraglutide (100 units/ 3.6 mg). This combination, anti-diabetic agent was recently approved in November of 2016, and is indicated as an adjunct to diet and exercise in type 2 diabetic patients whose disease state is not adequately controlled by either basal insulin or a glucagon-like-peptide 1 (GLP-1) receptor agonist alone. It should be noted that IDegLira is not currently a recommended first line agent and should not be used in combination with any additional products containing a GLP-1 receptor agonist. Thus far, IDegLira has not been studied in combination with rapid acting, bolus insulin products or in patients with pancreatitis.[1]

What are insulin degludec and liraglutide?

Insulin degludec is a subcutaneous form of long acting insulin used in both type 1 and type 2 diabetes. The sites of action of insulin include the liver, skeletal muscles, and adipose tissue in order to increase glycogen, fatty acid, and protein synthesis, allowing for storage of glucose.[2] Liraglutide is a subcutaneously injected GLP-1 agonist used in patients with type 2 diabetes.[1,2] This GLP-1 receptor agonist acts by increasing insulin secretion as glucose is increased, as well as decreasing glucagon secretion, with an additional indirect effect of decreased gastric emptying time and increased satiety in the brain. Slowed gastric emptying can result in a loss of appetite, allowing it to be used as a potential aid for weight loss in diabetes. These two anti-glycemic agents have been formulated into a combined drug: Xultophy® (IDegLira) which is indicated for use in type-2 diabetes.[1,2] Combination products such as IDegLira are beneficial as they are able to provide a supply of basal insulin throughout the day, as well as control postprandial increases in glucose levels.[1] Insulin degludec works to lower fasting plasma glucose and liraglutide works through glucose-dependent effects; therefore, the two drug therapies, in combination, work to control a patient's blood glucose levels.[3]

How does the efficacy of IDegLira combination therapy compare to insulin degludec or liraglutide monotherapy?

Two randomized trials were formulated to compare efficacy of treatment between IDegLira, insulin degludec (IDeg) and liraglutide monotherapy in type II diabetics.[3,4,5] The first trial, DUAL I, was a non-inferiority trial which had a primary efficacy endpoint of change in HbA1c after 26 weeks of treatment.[3,5] The second trial, DUAL II, was a superiority trial which had a primary efficacy endpoint of change in HbA1c from baseline.[4,5] DUAL I compared the intervention group, IDegLira, to the monotherapies of insulin degludec and liraglutide.[3,5] DUAL II compared the intervention group, IDegLira, to insulin degludec.[4,5] After 26 weeks of treatment, the results of DUAL I indicated that mean HbA1c had decreased by 1.9% (HbA1c of 6.4%) with IDegLira, decreased 1.4% (HbA1c of 6.9%) with insulin degludec, and decreased 1.3% (HbA1c of 7%) with liraglutide. The results indicated that IDegLira was non-inferior to insulin degludec ($p<0.0001$) and superior to liraglutide ($p<0.0001$).[3,7] Likewise, the results of DUAL II demonstrated that after 26 weeks of treatment, mean HbA1c decreased by 1.9% with IDegLira and by 0.9% with insulin degludec. Ultimately, IDegLira was found to be superior to insulin degludec in achievement of glycemic control ($p<0.0001$).[4,5] In conclusion, the use of IDegLira was more efficacious in the reduction of mean HbA1c from baseline than either treatment with insulin degludec or liraglutide alone.[3,4,5]

What is the safety profile of IDegLira in the treatment of Type 2 Diabetes?

The safety of IDegLira was also investigated in the DUAL clinical trials. Common side effects of liraglutide include gastrointestinal effects, weight gain and hypoglycemia. IDegLira has been shown to have an equivalent and possibly favorable side effect profile when compared to liraglutide.[3,4,6] In these DUAL trials, nausea was experienced in 8.8% of patients treated with IDegLira, while liraglutide treatment resulted in 19.7% of patients experiencing nausea.[3] In regards to weight gain, insulin degludec shows no significantly resulting weight change, whereas IDegLira therapy resulted in a mean weight reduction of 2.7 kg ($p<0.0001$).[4] The risk of hypoglycemic events per patient year was limited to 1.8 with use of IDegLira, and 2.6 with use of insulin degludec.[3] The number of patients who developed hypoglycemia was consistently lower in patients being treated with IDegLira versus other comparators such as metformin, pioglitazone, sulfonylureas, and glinides, regardless of dosing time. Overall IDegLira has shown a better safety profile when compared to the traditional monotherapies. Results from these trials have also indicated that with the help of its insulin sparing mechanism, IDegLira provides better glycemic control while limiting adverse effects that are seen with monotherapies.[3,4,6] Additionally, based on the results of the LIRA-RENAL trial, IDegLira was shown to be safe and efficacious for the treatment of type 2 diabetes in patients with moderate renal impairment (estimated glomerular filtration rate [eGFR] 30–59 mL/min/1.73 m^2).[7] In conclusion, IDegLira has been deemed to be beneficial, which has stemmed from its clinical advantages over other therapies and limited side effects.[3,4,6] However, it should be noted that IDegLira has a black box warning: risk of thyroid C-cell tumors. The liraglutide component has been linked with medullary thyroid carcinoma (MTC) from animal trials. IDegLira is contraindicated in patients with a personal or family history of MTC or multiple endocrine neoplasia syndrome type 2 (MEN 2).[1]

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—Sarah Hopseker, Michaela Coventry, Alayna Kehr, PharmD Candidates, DYCSOP Class of 2019

Clinical Faculty Spotlight: Aubrey A. Gawron, PharmD, BCCCP

Clinical Assistant Professor, D'Youville College School of Pharmacy
Critical Care Pharmacist, Buffalo General Medical Center

Tell us about your career as a pharmacist so far.
I obtained my Doctor of Pharmacy degree from the University at Buffalo in 2014. After graduation I moved to Columbia, SC where I completed my first-year general pharmacy practice residency at Palmetto Health Richland. I'm originally from the Western New York region and was able to move back home to complete my second-year critical care residency at the Buffalo General Medical Center. I had always planned to pursue post-graduate training after pharmacy school, but I never thought I would find myself specializing in critical care. After being thrown into the medical intensive care unit during the second month of my PGY-1 residency, I quickly fell in love with critical care pharmacy. I enjoy the challenge of caring for these highly dynamic patients and optimizing their complex medication regimens.

What is your current practice/role?
I am a clinical assistant professor at D'Youville College School of Pharmacy. My practice site is in the medical intensive care unit at Buffalo General Medical Center in Buffalo, NY. I precept IPPE and APPE students as well as first and second year pharmacy residents. I also work with students and pharmacy residents who are interested in completing research projects in the critically ill patient population.

"Embrace each moment, learn as much as you can, do not accept the status quo, and always be innovative, creative, and progressive in ways to better improve patient outcomes and the clinical pharmacy services for your department"

What organizations were you involved with in pharmacy school and which organizations did you maintain involvement in after graduating pharmacy school?
During pharmacy school I was a member of the American Society of Health-System Pharmacists (ASHP), Student National Pharmaceutical Association (SNPhA), and Western New York Society of Health-System Pharmacists (WNYSHP). After graduating pharmacy school and throughout completion of my residencies I became actively involved in WNYSHP, the American College of Clinical Pharmacy (ACCP), and the Society of Critical Care Medicine (SCCM).

Why did you initially get involved with American College of Clinical Pharmacy (ACCP) in your career and how did it help you achieve your goals?
I initially joined ACCP in the beginning of my first-year pharmacy residency when I decided to pursue a second-year residency in critical care. My mentor recommended that I join this organization and subscribe the critical care practice and research network (PRN). Last year, I joined the critical care PRN communications committee where I work with other critical care pharmacists to provide literature updates and education via social media outlets. Being a part of ACCP has helped me to achieve my goals by providing me with the opportunity to become involved at a national level and collaborate with critical care pharmacist from different areas of the country. I wish I was a part of this national organization as a student. There are many different PRNs and I recommend you go find one that complements your interests!

Spotlight (cont'd)

How do you keep up with the latest findings and advancements in clinical pharmacy?
A few of the many ways I keep up with the advancement in clinical pharmacy include attending local continuing education events, participating in the SCCM – CPP journal club programs, reviewing the monthly SCCM CCP critical care pharmacotherapy literature update, and receiving daily emails with late breaking news and medical research from a variety of societies and journals. I also enjoy listening to the iCritical Care and EMCrit Podcasts.

Finally, what advice would you give to a student pursuing a career in clinical pharmacy?
I will provide students who are pursuing a career in clinical pharmacy with a piece of advice I received from one of my preceptors on match day during my post graduate year 1 residency. "Embrace each moment, learn as much as you can, do not accept the status quo, and always be innovative, creative, and progressive in ways to better improve patient outcomes and the clinical pharmacy services for your department."

—Elizabeth Riegle, PharmD Candidate, DYCSOP Class of 2018

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