FALL 2023

ADULT MEDICINE PRN NEWSLETTER

The biannual newsletter of the ACCP Adult Medicine PRN

Message from the Chair

By: Rachel Khan, PharmD, BCPS

Hopefully I'm not alone when I say that I can get caught up in everyday life and miss big movements happening around, but not directly to, me. The majority of my focus definitely falls on my immediate family and workplace, but as I reflect back on the year in pharmacy I can't help but notice a major theme - advocacy. That word has been in practically every newsletter and message sent by ACCP this year as well as many other pharmacy organizations. For years now, our profession has been practicing at the top of our degree and credentials, yet we lack recognition of our services from other professions and the government. Pharmacists have been fighting for this recognition all along, and this year brings some light in the tunnel.

ACCP recently launched a new advocacy platform, outlining the College's priorities and strategies to advance the profession. You can access it using the QR code below. They identify four priorities: improve patient health outcomes, increase patient access to pharmacy services, support the pharmacy workforce, and advance health equity. Keywords include team-based care, payment and policy reform, diversity and inclusion, and health equity - all terms that our PRN members know well and hold dear. Efforts have been made to change policy at the state and national level and they've partnered with companies, institutes, and organizations to effect these changes. As just one example, ACCP and others have been working to secure reimbursement for comprehensive medication management services. Its precursor, medication therapy management, has been around for 20 years, and many pharmacists provide some form of these services to patients. The states of Maryland, Missouri, North Dakota, Virginia, and Wyoming all passed legislation in 2023 for pharmacists to receive reimbursement for

WHAT'S INSIDE THIS ISSUE?

Message from the Chair Continued...

services provided under Medicaid or other insurances. We now have what feels like a small army of people lobbying for our profession in Washington, D.C.. In another example, ACCP's DC chapter is revved up and ready to spark reform, reviving their Capitol Hill Lobby Day Event in March. ("new phone who dis" anyone?). Brilliantly, they've even reached out to neighboring SCCP chapters to involve our student pharmacists. As a member of ACCP for over 10 years, I've never seen such a force dedicated to pharmacy advocacy.

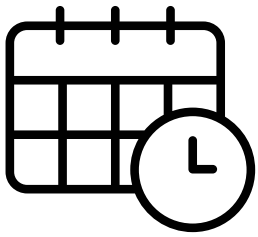
It's a proud moment to see our profession demanding to be seen and implementing change that will benefit current and future pharmacists. I encourage PRN members to take a moment to read more about these efforts and create your own action plan. If you need a starting point, ACCP's platform has a list of what members can do to help. No act is too small. This is a bandwagon we should all be jumping on.

On a final note, I want to take a moment to say how much I've enjoyed being a PRN officer for the past 3 years. The support offered by previous officers was huge (Carmen, Jon, Nicole!), and the number of people I now consider my pharmacy friends continues to grow. I could not have made it through this year without Haley, Kristina, and the committee chairs/vice chairs. THANK YOU!

Access the Advocacy Platform from ACCP:

Achieving medication optimization by advancing comprehensive clinical pharmacy services

UPCOMING DATES



Poster Review Sessions

October 23, 25, & 30
November 1

SNPhA x ACCP Virtual Residency and Fellowship Showcase

October 24 & 26
5 - 8 pm CDT

ACCP Annual Meeting

November 11 - 14

Check out "A Closer Look at the Adult Medicine PRN" with another Current Clinical Issue in the October National Resident Advisory Committee Newsletter

AMED PRN Committee Updates

Walk Rounds Committee

VOLUNTEER TO BE A POSTER REVIEWER

The AMED PRN Walk Rounds Committee will coordinate reviews for any poster with AMED members listed as authors at the 2023 ACCP Annual Meeting held November 11-14th.

There are five scheduled poster sessions. If you are available to serve as a reviewer, please note your availability through the survey below by October 28th.

Assigned posters, instructions, and evaluation rubrics will be provided by the Walk Rounds Committee prior to the Symposium. Thank you for your service!

Nominations Committee

Since the last newsletter, we held a successful PRN officer election for the 2023-2024 year. We also decided on the PRN Award Winners. Please find those sections in the newsletter to meet the new officers and award winners!

Be on the lookout for a call to the PRN to solicit applications for 2025 ACCP elected offices and for the Robert C. Elenbaas Service, C. Edwin Webb Professional Advocacy, Russell R. Miller, Clinical Practice, and Education Awards with a due date of November 2023.

External Affairs Committee

Don't forget to follow the AMED PRN on the following platforms:

ACCP Adult Medicine PRN
facebook.com/accpamedprn

ACCP Adult Med PRN
twitter.com/accpamedprn

Committee Updates Continued

Internal Affairs Committee

Thank you!

Thank you to the committee for their hard work in putting this newsletter together.

Research Committee

The Research Committee has been working to address barriers to productivity and engagement in research or scholarship based on what was expressed by ACCP members in survey responses earlier this year. We have held 2 networking events for finding research collaborators/mentors and continue to encourage project ideas and collaboration via the link on the AMED PRN webpage (use the QR code below).

Also, be on the lookout for resources which we are compiling for how to use SPSS and interpret output from SPSS!

PRN AWARD WINNERS

Three outstanding members of the Adult Medicine PRN will be recognized during the 2023 ACCP Annual Meeting in Dallas, TX. Congratulations to the AMED PRN award winners!

Emerging Member Award

Kathleen K. Adams, PharmD, BCPS

Intent: To recognize excellence in adult medicine pharmacy clinical practice, research, and service to the PRN by an active member of the ACCP Adult Medicine PRN in the early stages of their pharmacy career

Mentoring Award

Ashley E. Woodruff, PharmD, BCPS

Intent: To recognize an ACCP Adult Medicine PRN member whose outstanding teaching and guidance inspires students, residents, fellows, and others in the profession of pharmacy in a way that significantly impacts the careers of the mentees

Clinical Practice Award

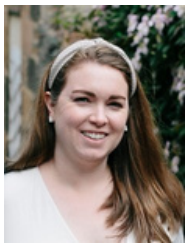
Kajal Patel, PharmD, BCPS

Intent: To recognize excellence in adult medicine pharmacy clinical practice by an active member of the ACCP Adult Medicine PRN

Congrats!

Welcome 2023-2024 AMED PRN Officers

Chair
Haley Johnson



Chair-Elect
Kristina Evans

Secretary/Treasurer
Emmeline Tran

Thank You

Outgoing Officers

Chair
Rachel Khan

Chair-Elect
Haley Johnson

Secretary/Treasurer
Kristina Evans

Stock Photo from Canva

Training and Travel Award Winners

The Training and Travel Awards committee selected three winners for 2023. The student and resident/fellow winners will be presenting posters before the start of the AMED PRN Business and Networking Meeting. Please come by to learn about their work.

Student Travel and Registration Research Award

Katrina Lepro

Resident Travel and Registration Research Award

Tara Parnacott, PharmD

Practitioner Registration Award

Emily Hanners Dunn, PharmD

Image from https://www.accp.com/meetings/am23/index.aspx

AMED PRN Programming

Building Immunity: A Guide to Managing Immune-Mediated Medications for the General Practitioner

Date: Tuesday, November 14, 2023
Time: 1:15 PM to 2:45 PM CST
Location: Lone Star Ballroom A4

Moderator:
Haley N. Johnson, PharmD, BCPS

Session 1: "Initiating and Monitoring Biologic Agents"
Speaker: Sheila M. Wilhelm, PharmD, FCCP, BCPS

Session 2: "Management of Biologic Agents in Perioperative Settings and Acute Infection"
Speaker: David E. Nix, PharmD, FCCP, BCIDP, BCPS

Session 3: Administering and Monitoring Intravenous Immunoglobulin
Speaker: Nikitha R. Patel, PharmD, BCPS

You are invited to the

AMED PRN Business Meeting

Free for AMED PRN Members
Food and beverage provided

Date: Monday, November 13, 2023
Time: 6:30 PM to 8:30 PM CST
Location: Dallas Ballroom D2

Pre-Meeting (6-6:30PM): Training and Travel Award winners presenting posters outside of the room

Meeting Agenda:

- Board of Regents report
- Treasurer's report
- 2023 AMED PRN award winners
- AMED PRN Committee reports
- AMED PRN Group Activity

Please check the ACCP website for further details as they are released.

We look forward to seeing everyone in Dallas!

TRAINEE POSTER REVIEW SERVICE

Coming soon!

Receive feedback from Adult Medicine PRN Pharmacist members on verbal presentation skills ahead of the 2023 ACCP Annual Meeting!

Register at:

http://bitly.ws/SHHc

by October 16, 2023

Zoom
20 minute time slots

Oct. 23, 25, 30 & Nov. 1
6-7 pm Central Standard Time

Student, Resident, & Fellow Members

accp
American College of Clinical Pharmacy

Resident eJournal Club Summary

Trainee Engagement Committee

On the third Wednesday of the month, the Trainee Engagement committee hosts an eJournal club. The journal club pairs a pharmacy resident (PGY2 Internal Medicine or PGY1/2 Pharmacotherapy resident) with a volunteer mentor. We will include summaries from recent eJournal club presentations.

Comparative Effectiveness of Apixaban and Rivaroxaban Lead-in Dosing in VTE Treatment: Observational Multicenter Real-World Study

Resident: Kaylee Worsham, PharmD, MBA
PGY2: Internal Medicine, University of Kentucky Healthcare *(completed June 2023)*

Citation: Alshaya OA, Korayem GB, Al Yami MS, Qudayr AH, Althewaibi S, Fetyani L, Alshehri S, Alnashmi F, Albasseet M, Alshehri L, Alhushan LM, Almohammed OA. Comparative Effectiveness of Apixaban and Rivaroxaban Lead-in Dosing in VTE Treatment: Observational Multicenter Real-World Study. J Clin Med. 2022 Dec 27;12(1):199. doi: 10.3390/jcm12010199. PMID: 36615002; PMCID: PMC9821121.

Introduction: The FDA approval of standard lead-in dosing of rivaroxaban and apixaban (21 days and 7 days, respectively) for acute venous thromboembolism (VTE) were established in the EINSTEIN and AMPLIFY trials.Nearly all patients in these trials received < 2 days of parenteral anticoagulants prior to direct oral anticoagulant (DOAC) randomization. In clinical practice, patients often remain on parenteral anticoagulation for longer durations and some clinicians shorten the oral lead-in time accordingly. The primary aim of this study was to assess the safety and efficacy of mixed (oral and parenteral) lead-in strategies for apixaban and rivaroxaban for acute VTE.

Methods: This was a retrospective, multicenter, cohort study that included patients 18 years or older with newly diagnosed VTE treated with either apixaban or rivaroxaban. This study compared patients in the recommended lead-in group to those in the mixed lead-in group. The recommended group received the FDA recommended duration of lead-in therapy and not more than two days of parenteral anticoagulation. The mixed lead-in group allowed for longer durations of parenteral therapy prior to DOAC initiation and a combined (parenteral plus DOAC) lead-in therapy duration of at least 6 days for apixaban or at least 19 days for rivaroxaban.Patients were excluded if they received combined lead-in therapy for greater than 9 days for apixaban or greater than 23 days for rivaroxaban. The outcomes of this trial included recurrent VTE (rVTE), major bleeding (MB), clinically relevant non-major bleeding (CRNMB), rehospitalization, and all-cause death.

Results: The recommended lead-in group had 296 patients and the mixed lead-in group had 72 patients. There were no differences in rates of rVTE (1.4% vs. 1.4%, p=1.00), MB (9.7% vs. 4.7%, p=0.150), CRNMB (9.7% vs. 9.8%, p=0.984), or rehospitalization (2.8% vs. 4.4%, p=0.745) between the mixed and recommended lead-in strategies and there were no deaths in either group.

Impact to Patient Care: This study provides initial data that lead-in therapy with either parenteral or oral agents may be safe and efficacious for adult patients with acute VTE. Pharmacists can aid in the decision to use either oral or parenteral agents for lead-in therapy by considering patient specific factors such as risks for bleeding, risks for clotting, patient's clinical status, and practicality of therapy.

Current Clinical Issues

We have re-vamped our clinical review section. Moving forward, we will have cowritten articles between pharmacy trainees and mentors on current clinical issues or pearls.

Current Clinical Issue: SGLT2 inhibitor initiation as part of GDMT for patients with acute decompensated heart failure

Authors: Rachel Massey, PharmD 2025 Candidate; Nathanael Smith, PharmD, BCPS

The ACC recently recommended certain sodium-glucose cotransporter-2 (SGLT2) inhibitors be added to guideline-directed medication therapy (GDMT) for patients with HFrEF; however, when to initiate and titrate GDMT, specifically SGLT2 inhibitors, remains controversial and inconsistent among practitioners.(1) The 2021 ACC decision pathway recommends SGLT2 inhibitors be initiated when patients are clinically stable, between 24 hours and 5 days of hospital admission in patients with NYHA class II-IV, HFrEF (EF ≤ 40%), and appropriate eGFR (Class I, level of evidence: A). Considerations for initiating SGLT2 inhibitors prior to hospital discharge include risks of volume reduction, acute kidney injury, and changes in blood pressure (BP). Communication across transitions of care to inpatient and outpatient practitioners is important to improve medication titration and adverse effect management for appropriate GDMT outcomes.

The initiation of SGLT2 inhibitors after hemodynamic stabilization has shown significant clinical benefit for patients hospitalized for acute decompensated heart failure with reduced ejection fraction (HFrEF); however, concerns for proper guideline-directed medical therapy of SGLT2 inhibitors are still being reviewed. In 2021, updated information on titration and initiation of HF medications with SGLT2 inhibitors based on the EMPULSE trial were provided for patients who were clinically stable between 24 hours and 5 days of hospital admission.(1,2) The current EMPA-AHF trial is designed to determine whether empagliflozin administered in the early acute phase of HF admission before clinical stabilization will provide similar decreases in cardiovascular mortality and morbidity as after clinical stabilization.(3) This will be within 12 hours of hospital admission compared to after stabilization.

Dapagliflozin, empagliflozin, and now sotagliflozin are FDA approved to reduce the risk of cardiovascular death and hospitalization for adults with HF (preserved and reduced).(4,5,6) These SGLT2 inhibitors may be started even if beta blockers, ARNI/ACEi/ARBs, or MRAs are not titrated to the maximally tolerated doses.(1) For dapagliflozin and empagliflozin, the eGFR must be >30 mL/min/1.73m and >20 mL/min/1.73m, respectively.(2,4,5) For sotagliflozin, it has not been studied in patients with eGFR less than 25 mL/min/1.73m.(2,6) It is recommended for clinicians to achieve optimal GDMT within 3 to 6 months of an initial diagnosis of HF and obtain maximally tolerated doses within 6 months of hospital discharge.(1)

Clinicians should monitor for BP, volume depletion, kidney function and acute kidney injuries (AKIs), ketoacidosis, urinary tract infections (UTIs), pyelonephritis, and Fournier's gangrene in patients with Type 2 Diabetes.(4,5) The EMPULSE trial, which assessed empagliflozin use in patients with acutely decompensated HF, showed no ketoacidosis events for both empagliflozin and placebo groups; however, the FDA has reported ketoacidosis, Fournier's gangrene, and genital infections postmarketing.(2,5) Table 1 lists the reported adverse events from the EMPULSE trial.

The EMPULSE trial showed that empagliflozin had little effect on BP in patients with HF but slightly higher volume depletion as compared to placebo (Table 1). This shows that empagliflozin may have diuretic effects without lowering BP and could be beneficial for patients with low BP at baseline who still need diuresis. This may reduce the need for loop diuretics as SGLT2 inhibitors have diuretic effects and renal protection.(1) In Yeoh et al, dapagliflozin was not superior to metolazone in reducing congestion in HF patients based on weight (dapagliflozin 3.0 kg, metolazone 3.6 kg, 95% CI -0.12,1.41 kg; p=0.11).(7) However, since weight reduction was similar between groups, SGLT2 inhibitors may be useful in patients experiencing diuretic resistance while also reducing the need for another diuretic. Hypovolemia after adding an SGLT2 inhibitor and diuretic has been exhibited in patients. Typically, this has been seen in patients 65 and older, an eGFR <60 mL/min/1.73 m2, and chronic use of SGLT2 inhibitors.(8)

An ongoing study, DICTATE-AHF, is evaluating diuretic benefits of dapagliflozin within 24 hours of hospital admission for patients in acute decompensation.(9) This study, in addition to existing data, may impact how early providers can administer SGLT2 inhibitors in patients hospitalized for ADHF and potentially reduce loop diuretic requirements to maintain euvolemia.

Current Clinical Issues

Current Clinical Issue: SGLT2 inhibitor initiation as part of GDMT for patients with acute decompensated heart failure *(Continued)*

	Empagliflozin	Placebo
Acute renal failure	7.7%	12.1%
UTIs	4.2%	6.4%
Volume depletion	12.7%	10.2%
Systemic hypotension	1.2%	1.5%
Systolic blood pressure*	0.1 mm Hg (95% CI: −2.5 to 2.7)	1.0 mm Hg (95% CI: −1.6 to 3.6)
Diastolic blood pressure*	−0.3 mm Hg (95% CI: −1.8 to 1.3)	−0.7 mm Hg (95% CI: −2.3 to 0.8)

Table 1. Adverse effects reported during the EMPULSE trial.
*the adjusted mean change from baseline to 90 days

SGLT2 inhibitors have proven morbidity and mortality benefits for HF patients when given prior to discharge and may reduce the number of diuretics needed. However, more trials may be needed to further demonstrate their diuretic efficacy and use prior to clinical stabilization. Additionally, the cost of these medications for patients could prevent more clinicians from following the 2021 ACC GDMT initiation pathway. Early hospital initiation of SGLT2 inhibitors decrease rehospitalizations which may offset the upfront cost while also reducing long-term mortality.

Current Clinical Issue: Hospital Interchange for Concentrated Insulin Products

Authors: Brittany Glowacki, PharmD candidate 2024; Janci Addison, PharmD, BCPS; Denise Kelley, PharmD, BCPS; Kristin Janzen, PharmD, BCPS; Steven Wulfe, PharmD

Basal insulin remains a mainstay of therapy in glucose management for diabetes mellitus.(1,2) Increased insulin resistance caused by disease progression leads to usage of high doses of basal insulin to maintain glycemic control. These larger doses are costly, painful to administer, and put individuals at an increased risk for injection site reactions. (3,4) Novel concentrated insulin formulations (U-200 and U-300) have been developed to account for higher insulin units needed, allowing individuals to administer smaller volumes, offsetting cost and injection side effects. However, these new formulations pose a new challenge for inpatient pharmacists in their role of glycemic management within the setting of formulary interchanges upon admission.

Safety and efficacy have been proven for concentrated insulins when compared to U-100 glargine through several Phase III trials conducted in the outpatient setting. The EDITION trials evaluated U-300 glargine, the DEVOTE trials assessed U-200 degludec, and the ONWARDS trials studied U-700 icodec.(5-10) Although noninferiority has been demonstrated, differences in pharmacokinetics and pharmacodynamics exist.(5-10) Concentrated insulins have shown to have more constant pharmacological effects over a prolonged period of time when compared to their U-100 counterparts.(5,11,12) Therefore, converting between formulations of concentrated insulin and non-concentrated insulin may not be a direct 1:1 unit interchange. However, many hospitals only use glargine or detemir U-100 basal insulin per their formulary, leading to a need for appropriate conversion plans between insulin formulations.

Inpatient conversions between concentrated insulins and the U-100 basal insulins commonly on hospital formularies have not been well-studied. There is no clear consensus on the recommended interchange for the different formulations of concentrated insulins in the hospital setting. While attempting to prove noninferiority of concentrated U-300 glargine, the EDITION trials discovered higher doses of U-300 glargine were needed when compared to U-100 glargine to achieve similar glucose lowering effects.(5-10) This suggests a difference in the pharmacokinetic profiles and potency of each formulation despite both having the same active ingredient. As a result, the manufacturers recommended a 20% dose reduction when transitioning from U-300 glargine to U-100 glargine.(13) While the EDITION trials have compared U-100 glargine to U-300 glargine, there have not been any prospective studies or guideline recommendations for converting between U-300 glargine to U-100 detemir. We conducted a retrospective cohort study

Current Clinical Issues

Current Clinical Issue: Hospital Interchange for Concentrated Insulin Products *(Continued)*

at our institution that found a 1:1 unit conversion between U-300 insulin glargine to formulary U-100 insulin detemir led to an increased rate of inpatient hypoglycemic events.(14) Given this data, an interchange protocol was developed that would reduce the dose of inpatient U-100 insulin detemir by at least 20% if it was confirmed that the patient used U-300 insulin glargine outpatient.(14)

Similar to U-300 insulin glargine, there is limited literature and recommendations on how to convert U-200 degludec to inpatient non-concentrated insulins.(15) Currently available recommendations are summarized in Figure 1 below. Practitioners must remember these dose transitions are recommendations and clinical discretion should always be applied. Questions remain regarding the ways in which different clinical scenarios may alter these recommended interchanges. With increased outpatient use of concentrated insulins, additional research is needed to explore factors affecting insulin dose conversions for hospitalized patients. Appropriate dose conversions are the best strategy to successfully handle such scenarios within the hospital formulary setting.

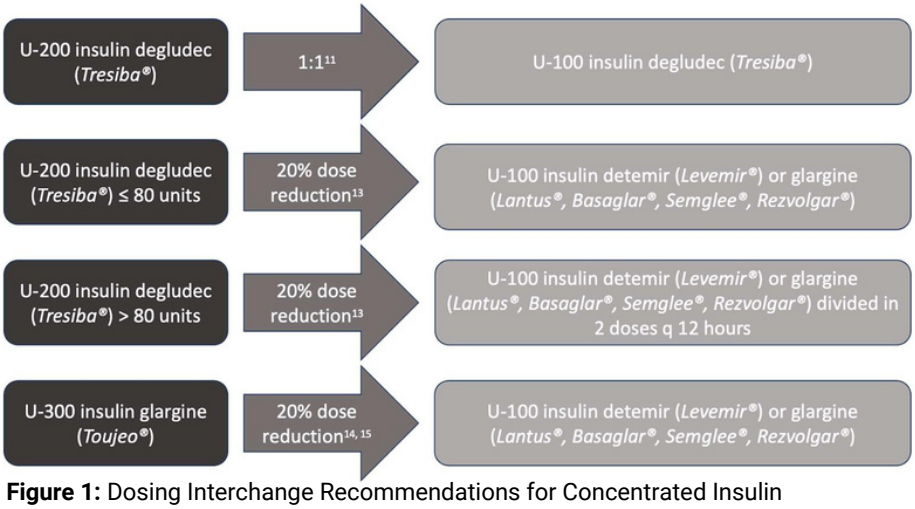


Figure 1: Dosing Interchange Recommendations for Concentrated Insulin

Current Clinical Issue: Utilization of Biosimilars in Diabetes Treatment

Authors: Jordan Childress, PharmD Candidate 2024, Wilkes University; Molly Walbrown, PharmD, BCPS, CACP, CDE

Biologics are complex products created from microorganisms or other living systems through biogenetic technology.(1) Some of these products include vaccines, blood products, gene therapies, and insulins. In clinical trials, biologics are often utilized as reference products for the Food and Drug Administration (FDA) approval of a biosimilar. The FDA is a federal agency that is tasked with drug regulation and approval in order to protect the health of the general public. For a biosimilar to become FDA approved, manufacturers must be able to establish that the biosimilar has similar safety and efficacy compared to the reference biologic.(2) Although generic medications can be substituted within the community or hospital pharmacy for brand name medications, biosimilars are not considered generics due to lack of precise replication of the biologic. Biosimilar products may undergo additional studies to become an interchangeable biosimilar, resulting in the ability for pharmacists to substitute these products without contacting a provider for approval beforehand.(3) Overall, biosimilars can be advantageous for patients with limited prescription coverage since these medications are often much cheaper than their reference products, thus offering patients cost-effective treatment alternatives for diabetes management. For example, the wholesale price of insulin glargine (Lantus) is estimated to be about $90 for a single insulin pen, while Semglee is about $30 for the same quantity.(2)

Semglee (insulin glargine-yfgn) is the first FDA-approved interchangeable biosimilar for U-100 insulin glargine (Lantus). In July of 2021, Semglee was approved for interchangeability with U-100 insulin glargine (Lantus) since both medications provided the same A1c and glycemic control for patients when studied.(4) These medications are considered bioequivalent products with the same purity, efficacy, and safety for patients. The INSTRIDE 1 trial was the

Current Clinical Issues

Current Clinical Issue: Utilization of Biosimilars in Diabetes Treatment *(Continued)*

first clinical trial to compare Semglee to U-100 insulin glargine (Lantus). The data showed that Semglee was non-inferior to insulin glargine (Lantus) and had similar cases of adverse events such as hypoglycemia.(4) In December 2021, Rezvoglar (insulin glargine-aglr) became the second FDA-approved biosimilar to U-100 insulin glargine (Lantus). Rezvoglar has an increased risk of heart failure diagnosis and heart failure exacerbations.(4) As a result, the medication is currently undergoing clinical trials to assess its safety and use with other diabetes medications.

More patients with diabetes who are using biosimilar products could potentially present to the hospital as a result of the FDA approval of these medications. Pharmacists can aid in transitioning of therapies by being aware of the dosage conversions listed in Table 1 for biosimilars and other available insulin products. Utilization of the provided dosage conversion is crucial as more insulin biosimilar products are currently in the process of approval by the FDA with launch dates as early as 2024.(4) The information in this article is meant to be utilized by all healthcare providers who encounter a patient on insulin therapy and wish to transition the patient to or from Semglee and Rezvoglar.

Table 1. Insulin Conversions Table (5)

Insulin Products for Conversion	Conversion and Product Considerations
Semglee to insulin degludec U-100 (Tresiba)	1 unit to 1 unit conversion; Give once daily; In patients with type one diabetes, reduce the TDD by 20% and give insulin degludec once daily
Semglee or Rezvoglar to insulin glargine U-100 (Lantus)	1 unit to 1 unit conversion
Semglee or Rezvoglar to insulin detemir U-100 (Levemir)	1 unit to 1 unit conversion; Insulin detemir should be given once or twice daily
NPH to insulin glargine U-100 (Lantus), Semglee, or Rezvoglar	NPH once daily - 1 unit to 1 unit conversion; NPH twice daily - reduce total daily dose by 20% and give insulin glargine U-100 twice once daily
Insulin glargine U-100 (Lantus), Semglee, or Rezvoglar to NPH	1 unit to 1 unit conversion or reduce dose by 20%; Give ⅔ of TDD of NPH in the morning and ⅓ of TDD of NPH at dinner time

TDD - Total daily dose, NPH - Neutral Protamine Hagedorn
Adapted from: Clinical Resource, How to Switch Insulin Products. Pharmacist's Letter/Pharmacy Technician's Letter/Prescriber's Letter. May 2023.

Current Clinical Issue: Clinical Pearls of Biosimilar Insulin Therapy

Authors: Nicole Borkosh, PharmD Candidate 2025, Wayne State University; Melissa Lipari, PharmD, BCACP

The American Diabetes Association (ADA) has estimated that the cost of managing diabetes in 2017, to be $327 billion dollars, which includes $237 billion in direct medical costs and the remaining $90 billion in reduced productivity.(1) The high cost of insulin products contributes to the overall direct medical costs and can pose a barrier to patient access. Biosimilar and interchangeable insulin products provide a lower cost alternative to the branded insulin products available on the market, however due to patents and market exclusivity, the growth process is gradual.

Since biologic therapies are derived from living organisms, the approval process for biosimilars requires a more thorough check system than generic drugs. These standards include similarity in physiochemical and biologic pharmacokinetic and pharmacodynamic profiles, and safety with a priority on immunogenicity.(2) This differs from generic drug approval where drug companies must simply demonstrate bioequivalence. The FDA defines a biosimilar product as highly similar to the reference product despite minor differences in clinically active components as well as having no clinically meaningful differences in terms of potency, purity, and safety.(3) Using a biosimilar instead of a brand name product provides greater access of medications which would decrease costs for patients. Moreover,

Current Clinical Issues

Current Clinical Issue: Clinical Pearls of Biosimilar Insulin Therapy *(Continued)*

follow-on products are defined as “copies of the original innovator biologics.” Because of the inability to copy the structure exactly, this leads to possible differences in safety and efficacy.(3) In addition to the biosimilar and follow-on product regulatory processes, the FDA has an additional designation for interchangeability. An interchangeable product can be switched for the reference product as phase 3 trials comparing it to the reference product prove safety and efficacy.(4) While other generic medications can be automatically substituted by pharmacists, biosimilars can only be substituted if they have interchangeable designation from the FDA.

As of August 2023, 41 biosimilars and 4 interchangeable products have been FDA approved. Of the FDA approved interchangeable products, two are interchangeable with Lantus® (insulin glargine), Rezvoglar® (insulin glargine-aglr) and Semglee® (insulin glargine-yfgn). Rezvoglar® was first approved in December 2021 as a biosimilar, but was granted interchangeability by the FDA in November of 2022. It has officially launched on the US market in April of this year.(5) Semglee® was granted interchangeability in July 2021 and is currently available for patient use.(6,7) Basaglar® is a biosimilar in reference to Lantus® and was approved in 2016 as a “follow-on” product, but has since been named a biosimilar.(8) In terms of short-acting insulin, Admelog® is currently the only insulin product that has been approved as a follow-on product in the U.S. in reference to Humalog® (insulin lispro).(9) Currently, there are no biosimilar or interchangeable medications in reference to this product.

While biosimilars are considered a more affordable option, the top three producers of insulin, Eli Lilly, Novo Nordisk, and Sanofi, continue to establish high costs. In response to the Inflation Reduction Act of 2022, which cut the out-of-pocket monthly costs for of insulin to $35 for those covered by Medicare Part D, all three companies agreed to reduce out of pocket costs of insulin to $35 for adults. These new changes are planned to take place in late 2023 and early 2024.10 Unfortunately, this does not include patients who have commercial insurance or are uninsured. Medicaid has also begun to introduce coverage for biosimilar and interchangeable insulin products recently.(11) With many changes pending, there are hopes to see a decline in cost for DM patients.

As exclusivity for biologic patents begins to expire, the growth of biosimilars and interchangeable products begins to rise in the United States. Pharmacists must continue to advocate for the availability and utility of insulin biosimilars and interchangeable products, as well as continue to educate prescribers on the key points and differences between products.

Thank you to all of our authors!

Please use the QR code to access all references from the Clinical Issues

AMED PRN Member Accomplishments

March 2023 - August 2023

Promotions

- **Rachel Khan**: Associate Professor, Virginia Commonwealth University School of Pharmacy
- **Jon P. Wietholter**: Adjunct Professor, West Virginia University School of Medicine
- **Tianrui Yang**: Clinical Associate Professor, University of Texas at Tyler Fisch College of Pharmacy

Awards

- **Cait Gibson:** Excellence in Interprofessionalism Award, Virginia Commonwealth University Center of Interprofessional & Collaborative Care
- **Scott Mosley:**
  - 2022-2023 Professor of the Year, USC Mann School of Pharmacy and Pharmaceutical Sciences Class of 2025
  - 2023 Teaching Faculty of the Year, USC Mann Residency Programs
- **Heather Savage:** Foundation Award for Excellence in Teaching, University of Louisiana Monroe Foundation
- **Hailey Soni:** Preceptor of the Year, University of Illinois Chicago College of Pharmacy
- **Taylor Steuber:**
  - Pharmacy Practice Section Best Paper Award, American Association of Colleges of Pharmacy
  - Excellence in Scholarship of Experiential Education, American Association of Colleges of Pharmacy Education Section
  - 2022-2023 Rufus A. Lyman Award Nomination, American Association of Colleges of Pharmacy
- **Erik Wasowski:** Preceptor of the Year (Ohio Region), Cleveland Clinic Residency Program

Grants

- **Carly Steuber:** Designing a Health IT Prototype to Improve Clinician Communication Across Care Settings. Kauffman Foundation Funded UMKC Entrepreneurship Innovation Grants (EIG) Program. Principal Investigator ($58000).

Publications

- **Kathleen Adams**
  - **Adams KK**, Shah S. Health system evaluation of fluoroquinolone hypersensitivity: an assessment of cross-reactivity. J Antimicrob Chemother. Published online May 10, 2023.
  - Sobieraj DM, **Adams KK,** Doyno CR, Nigro SC, Waters K. A systematic review of interventions implemented by pharmacy programs to improve postgraduate residency placement. Am J of Pharm Edu. 2023;87(5):100019. Published online May 22, 2023.
- **Sarah L Anderson**
  - **Anderson SL**, Marrs JC. Tirzepatide for type 2 diabetes. Drugs Context. 2023;12:2023-6-1.
- **Joshua Gaborcik**
  - Booth JP, Aycock AC, Elefritz JL, **Gaborcik JW**, Wardlow LC and Loborec JD. A resident preceptor collaboration to encourage wellness and reduce burnout amongst pharmacy residents. Am J of Pharm Edu. 2023, 100139.

AMED PRN Member Accomplishments

March 2023 - August 2023

Publications Continued

- **Cait Gibson**
  - Hulsizer AL, Davis S, **Gibson CM**. Does emergency medical services blood collection shorten time to tissue plasminogen activator in ischemic stroke? J Pharm Tech. 2023; 39(4):195-198.
  - **Gibson CM**, Larson S, Behnen EM, Dugan SE, Moody AE, Wagner JL. Feeding the soul: The impact of community circles on the AACP Women Faculty SIG. Am J Pharm Educ. 2023;8 7(1):Article 8927.
- **Lisa Hong**
  - **Hong LT**, Downes KJ, FakhriRavari A, et al. International consensus recommendations for the use of prolonged-infusion beta-lactam antibiotics: Endorsed by the American College of Clinical Pharmacy, British Society for Antimicrobial Chemotherapy, Cystic Fibrosis Foundation, European Society of Clinical Microbiology and Infectious Diseases, Infectious Diseases Society of America, Society of Critical Care Medicine, and Society of Infectious Diseases Pharmacists. Pharmacother. 2023;43(8):740-777.
- **Rachel (Flurie) Khan**
  - Maisch AM, Omecene NE, Lai J, Ong R, Hylton Gravatt LA, **Khan RW.** Pharmacokinetic-pharmacodynamic and clinical considerations for extended- and continuous-infusion antibiotics. Clin Microbiol Newsl. 2023 July;45(14):115-123. [Epub ahead of print]
  - Zbyrak V, Alhomoud IS, **Flurie RW**, Bucheit JD. Understanding the role of finerenone among current treatment options for diabetic kidney disease. ADCES in Practice. 2023. [Epub ahead of print]
- **Scott Mosley**
  - Chu M, Bchakjian T, Ding L, **Mosley S**. A1c Trends in Patients with Type 2 Diabetes receiving continuous Diabetes care during the COVID-19 Lockdown. J of Pharmacol & Clin Res. 2023; 9(3): 555762.
- **Julie Murphy**
  - Fornwald C, Tuttle N, **Murphy JA**. NPH insulin versus insulin glargine versus NPH insulin plus insulin glargine for the treatment of dexamethasone-induced hyperglycemia in patients with COVID-19: a retrospective cohort study. J Pharm Technol. 2023 Mar.
- **Carmen Smith, Erin Hennessey, Andrew Crannage**
  - **Smith CB**, **Hennessey EK**, Crossey C, **Crannage AJ**. Impact of vitamin K administration for elevated international normalized ratio in chronic liver disease. Clin Appl Thromb Hemost. 2023;29:10760296231164642.
- **Hailey Soni**
  - Mercer KJ, Craddock KE, Patel SV, Knoebel RW, **Soni HP**, Lourenço LM, Bastow SS, Szwak JA. Implementation of Debriefing Services for Pharmacy Residents in a 24-Hour, In-House Clinical Pharmacy On-Call Program: A Pilot Study. J Pharm Pract. [Epub ahead of print]
- **Taylor Steuber**
  - **Steuber TD**, Rosandich T, Cadwallader T, et al. Dosing and administration strategies of tocilizumab in patients with COVID-19: a retrospective cohort analysis. Ann Pharmacother. 2023; [Epub ahead of print]
  - Eiland LS, **Steuber TD**. A few small steps or giant leap? De-densify the curriculum in one move. Curr Pharm Teach Learn. 2023; [Epub ahead of print]
  - Belk M, Hammond O, Seales C, Edwards J, **Steuber TD**. Effect of microbiology comment nudging on antibiotic use in asymptomatic bacteriuria: a pre-post quasi-experimental study. Infect Control Hosp Epidemiol. 2023; [Epub ahead of print]

AMED PRN Member Accomplishments

March 2023 - August 2023

Publications Continued

- **Taylor Steuber (continued)**
  - Belk M, Hammond O, Seales C, Edwards J, Steuber TD. Effect of microbiology comment nudging on antibiotic use in asymptomatic bacteriuria: a pre-post quasi-experimental study. Infect Control Hosp Epidemiol. 2023; [Epub ahead of print]
- **Andrew Stone**
  - Sheredy SA**, Stone AC,** Mostafavifar AM, Mostafavifar LG, Smith RM, Doepker BA. Risk Stratification for Supratherapeutic Peak Anti-Xa Levels in Adult Patients on Therapeutic Enoxaparin. Ann Pharmacother. 2023; [Epub ahead of print]

Presentations

- **Sarah Anderson**
  - Let's Get Social! Social Media Networking For Continuous Professional Development. Presented at: Joint Accreditation Leadership Summit; May 16, 2023; Chicago, IL.
  - Hands-on Approach to CVD Risk Management in the Psychiatric Population. Presented at: College of Psychiatric and Neurologic Pharmacists webinar; March 1, 2023; virtual.
- **Nicole Campbell**
  - Using anticoagulation in special populations: considerations for patients with obesity, chronic kidney disease and during pregnancy. Presented at: NJSHP North Central Chapter Meeting; May 2023; virtual.
- **Cait Gibson**
  - Quality is a Habit: Improving Quality Assurance in Experiential Education. Presented at: American Association of Colleges of Pharmacy Annual Meeting; July 2023; Aurora, CO.
  - Chronic Care in Cardiology. Presented at: American College of Clinical Pharmacy Annual Updates in Therapeutics; April 2023; virtual.
- **Scott Mosley**
  - Precision Health and Comprehensive Medication Management. Presented at: California Right Meds Collaborative (CRMC) Spring 2023 Learning Session; April 2023; Las Vegas, NV.
- **Julie Murphy**
  - Blending Early Warning and Remediation Processes to Facilitate Student Success. Presented at: American Association of Colleges of Pharmacy Annual Meeting; July 2023; Aurora, CO.
- **Heather Savage**
  - To Infinity and Beyond Up-to-Date (R): Helping Learners Improve Evidence Based Practice Skills. Presented at: American Association of Colleges of Pharmacy Annual Meeting; July 2023; Aurora, CO.
- **Carmen Smith**
  - Stop the Clot – Managing VTE. Presented at: CEImpact Education; February 2023 – present; Webinar and Clinical Cases.
- **Mate Soric**
  - Is Tenure Included in the Contemporary Prescription for Pharmacy Practice Faculty? Presented at: American Association of Colleges of Pharmacy Annual Meeting; July 2023; Aurora, CO.
  - Clinical Trial Designs. Presented at: American College of Clinical Pharmacy Fundamentals of Biostatistics and Clinical Trial Design Workshop; April 2023; virtual.

AMED PRN Member Accomplishments

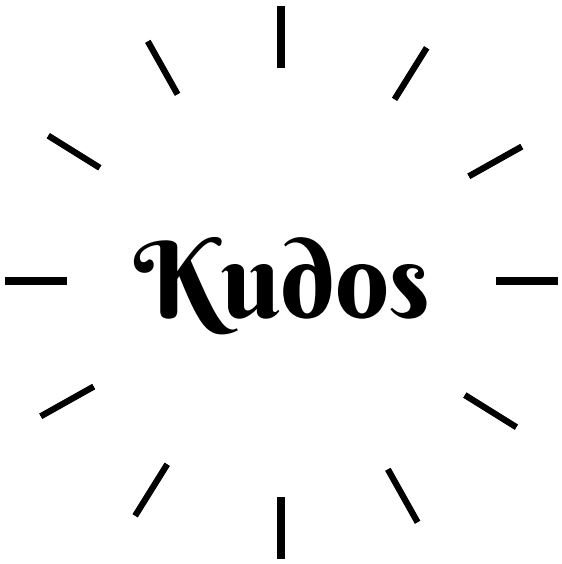
March 2023 - August 2023

Presentations Continued

- **Taylor Steuber**
  - Research Productivity Hacks: Doing More with Less. Presented at: Alabama Infectious Disease Society Third Annual Meeting; Aug 2023; Birmingham, AL.
  - Next Steps: Getting the most "Bang for your Buck" when Publishing Your Findings. Presented at: University of North Texas Health Science Center College of Pharmacy SoTL Workshop; July 2023; Zoom Session.
  - Leveraging Learners to Preserve Scholarship Productivity – a Win-Win. Presented at: American Association of Colleges of Pharmacy Practice Section; May 2023; virtual.

Other Notable Achievements

- **Julie A. Murphy:** 2023-2024 Academic Leadership Fellow with the American Association of Colleges of Pharmacy
- **Mate Soric:** Fellow of American Society of Health-System Pharmacists
- **Carmen Smith:** 2023-2024 ACCP Professional Leadership Development (APLD) program



Thanks to the Internal Affairs Committee for editing the following sections of the newsletter!
Editors: Kristina Evans (chair), Alex Ebied (co-chair)
Committee Highlights: Heidi Berman
PRN Awards: Karissa Chow
Resident eJournal Clubs: Ben Pullinger (Trainee Engagement Committee)
Clinical Issue/Pearl Editors: Jen Adema, Alex Ebied, Kristina Evans, Beth Ford, Amber Hutchison, Nicole Metzger, Susan Smith