Pharmacy Department Network Quality Council Annual Report
Fiscal Year 2025 – Executive Summary

As health care continues to undergo a nationwide transformation, we remain driven to do more in support of our organizational mission of improving lives. To succeed, we continue to be guided by Quadruple Aim. Pharmacy Services continues to innovate, providing the highest level of pharmacy services to our patients through outstanding clinical services, and a distribution model that provides safety and efficiencies like no other.

Better Health (pg. 3)

- Pharmacy supports all reductions in harmful errors through the safety systems that are built into medication management. The FY25 harmful medication error rate was 0.34 per 100,000 doses.
- Pharmacists are members of LVHN's emergency response teams and have attended 1,004 emergency events.
- The Emergency Department (ED) Direct Oral Anticoagulant (DOAC) discharge starter pack program expanded in FY25 to include newly diagnosed artrial fibrillation (Afib) patients. In FY25 the program dispensed 821 packs to ED patients with low-risk deep vein thrombosis (DVT), pulmonary embolism (PE) and Afib.

Better Care (pg. 5)

- The department has 51 pharmacists that maintain Board Certifications. This represents 2.7% of all Board-Certified Pharmacotherapy Specialists in the state.
- Pharmacists published two articles and presented 42 times in FY25.
- A common, overarching Pharmacy & Therapeutics Committee exists for LVHN comprised of the following licensed entities: 1) Lehigh Valley Hospital (LVH) that includes LVH-Cedar Crest, LVH-17th Street, LVH-Tilghman, LVH-Muhlenberg, LVH-Hecktown Oaks, LVH-N Cedar Crest/Highland, and LVH-Carbon; 2) LVH-Dickson City; 3) LVH-Hazleton; 4) LVH-Schuylkill; 5) LVH-Pocono; and 6) LVH-Macungie and Gilbertsville. The Pharmacy & Therapeutics Committee has reviewed 75 drugs and/or drug classes, drug practices and three Medication Use Evaluations in FY25.
- To support better care, LVHN Pharmacy Department is rolling out workflow technology across the network that includes barcoding and picture capture during sterile and non-sterile compounding. In FY25, 230,380 doses were prepared with this technology. In FY26, we will continue to rollout this workflow technology to additional sites.

Better Cost (pg. 14)

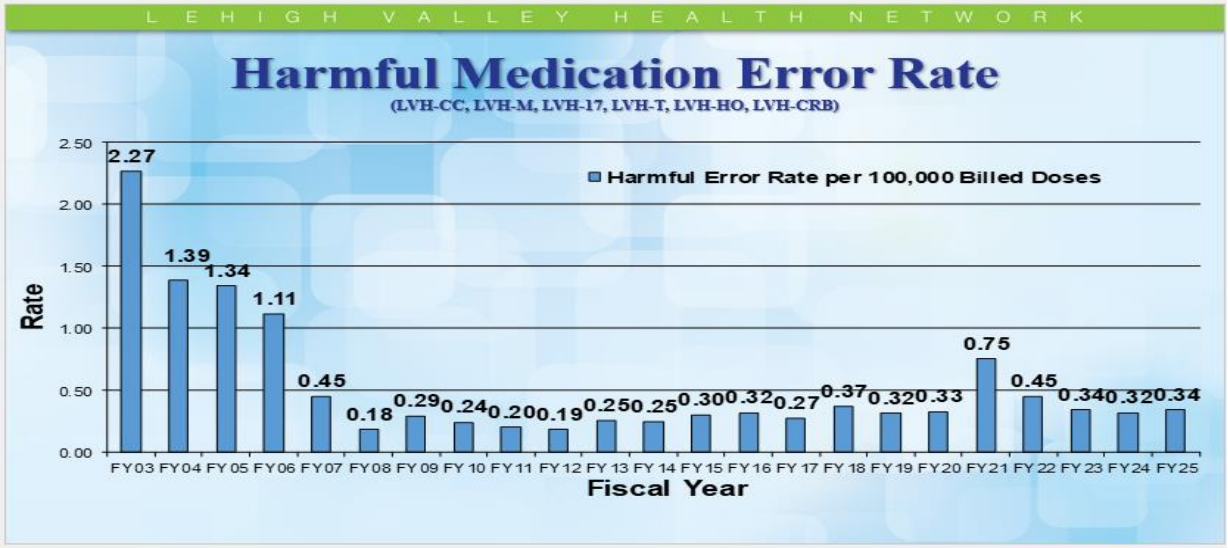
- Supported cost savings initiatives that contributed over $2,000,000 toward medication related expense reduction for both our inpatient and retail pharmacies.
- Significant cost containment initiatives include conversions from brand medications to biosimilars. Conversions of potassium chloride riders have projected annual savings of $70k-$120k/year.

Pharmacy Services Mission and Strategy

- Pharmacy Services is committed to supporting our organizational mission of improving lives. We are guided by the strategic pillars of vertical optimization and horizontal integration, while staying grounded in our values: putting people first, doing what's right, and pursuing excellence. Our efforts are guided by the Quadruple Aim: delivering better health outcomes, better care experiences, improved cost efficiency, and a better colleague experience.
- Efforts to ensure health equity
    - Transition of Care/Meds to Beds provides access to medications and decrease readmission regardless of the patient's personal characteristics.
    - Cancer/Infusion center and financial counselor work to ensure quality and safe treatment options regardless of the patient's personal characteristics.
    - LVPS – Specialty and Home infusion works to find financial coverage, educate, and provide quality and safe personalized treatment options regardless of the patient's personal characteristics.
- Commitment to Sustaining an Inclusive Environment: Daily Huddles, Anonymous Surveys, and Electronic Suggestion Forms promote and enhance the exchange of communication between colleagues and leadership. The anonymous surveys have identified numerous improvement ideas from frontline staff. The electronic suggestion process has generated 123 suggestions with 45 implemented in FY25. Celebration of holidays and other activities to reinforce our commitment to diversity, equity, inclusion and belonging.

BETTER HEALTH

1. Harmful Medication Error Rate:

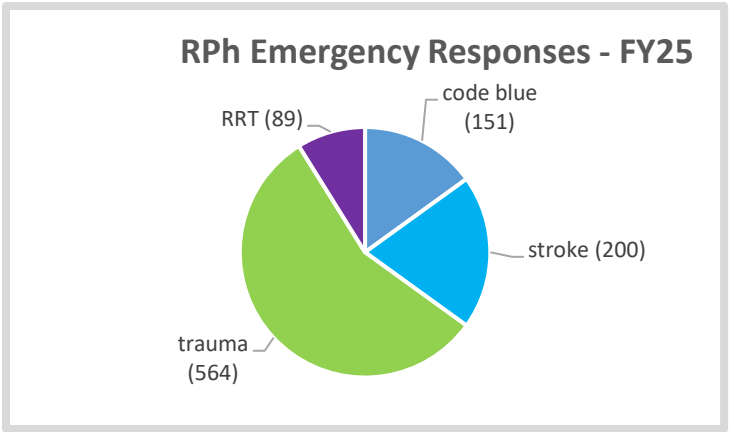


2. Pharmacists Emergency Response

Pharmacists at the Cedar Crest site continue to play a critical and often underrecognized role as members of the Rapid Response Team. Their expertise can significantly enhance the response team's efficiency as they provide quick medication preparation, ensure proper dosage and administration (including pediatric calculations), provide compatibility information, and review current medication lists for drug interactions, especially with thrombolytics. Studies have demonstrated better patient outcomes with pharmacist involvement in code blue. Pharmacists can anticipate which medications will be needed and can quickly obtain any medication not stocked in code carts or emergency boxes. All participating pharmacists maintain proper training, including BLS, ACLS, and/or PALS as required for their position, as well as attend hands-on training provided by our team. We respond to emergencies in the ED, trauma bay, pediatric hospital, and all inpatient and outpatient areas of the hospital.

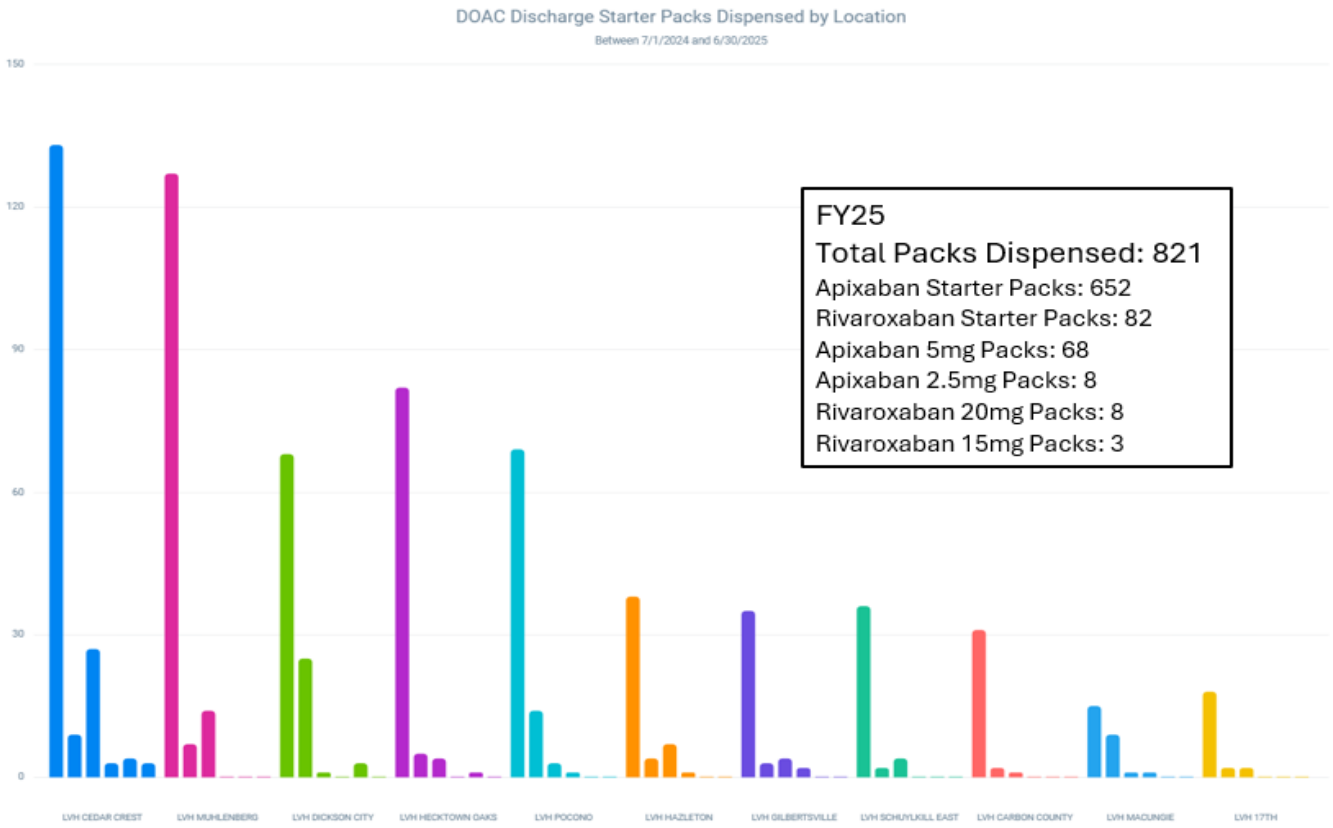
In FY25, at least 42 pharmacists responded to and documented involvement in 1004 emergencies, including 564 Trauma Alerts, 200 Stroke Alerts, 151 Code Blues, and 89 rapid responses/intubations. We assisted in the bedside preparation of 35 doses of Tenecteplase since it became the network preferred thrombolytic for stroke last year.

Pharmacists are an integral part of the emergency response team and are often sought out for assistance. We will continue to enhance our presence and contributions in the coming years.



3. <u>Emergency Department Direct Oral Anticoagulant Pack</u>

The network began the Emergency Department (ED) Direct Oral Anticoagulant (DOAC) discharge starter pack program in 2022 with the intention of reducing hospital admissions for low-risk deep vein thrombosis (DVT) and pulmonary embolism (PE). Given the success of this program, we expanded to include DOAC discharge starter packs for newly diagnosed atrial fibrillation (Afib) in FY25. This program provides ED patients with an initial supply of oral anticoagulation and a referral to Access Afib with the goal of improving continuity of care and reducing hospital admissions for low-risk atrial fibrillation. Patients prescribed a starter pack for Afib, DVT or PE receive their initial dose in the ED and take the remaining supply home to continue treatment after discharge. The DOAC discharge starter pack program improves patient care by ensuring continuity of anticoagulation therapy, reducing hospital admissions, reducing readmission risk, and improving safety during the patient's transition of care from the ED to home. Since the program's inception we have dispensed over 1,800 DOAC starter packs to patients in the EDs across the network.



BETTER CARE

- LVHN ASHP Accredited PGY1 Pharmacy Residency Program graduated four pharmacists in FY25:
  - Ashley Brown, PharmD
  - Carissa Kern, PharmD
  - Madeline Stauffer, PharmD
- Awards:
  - Friends of Nursing Award, Excellence as a Pharmacist – Arun Mancheril, LVH-CC
  - Being Exceptional Everyday (BEE) Award, April 2025 – Christopher Hayes, LVH-Pocono (Award from the Carbon Infusion Center, a recognition for non-nursing team members)
  - Pennsylvania Society of Health-System Pharmacists (PSHP)'s The Joe E. Smith Award for Excellence in Practice and Service to Institution, Community, and Profession of Pharmacy – Rhonda Thomas, LVH-MHC
- Great Catch Awards –
  - Total 40 = Tier 1 - 27; Tier 2 – 13; Tier 3 – 0
- Certified Pharmacy Technicians (CPhT): 105 (includes southern and northern tier sites)
- Certified Compounded Sterile Preparation Technicians (CSPT): 12
- Advanced Certified Pharmacy Technician (CPhT-Adv): 2
- Board Certified Hazardous Drug Management (BCHCPT): 1

Laura Curatola, CPhT, CSPT	Ammira Jones, CPhT, CSPT
Donald Durant, CPhT-Adv, CSPT	Jill Los, CPhT, CSPT, BCHCPT
Nesrine Eladly, CPhT, CSPT	Mick Nicholas, CPhT, CSPT
Ashley Hein, CPhT, CSPT	Rebecca Pounds, CPhT, CSPT
Erin Hoffman, CPhT, CSPT	David Saravia, CPhT-Adv, CSPT
Kathleen Holden, CPhT, CSPT	Alison Schoenherr, CPhT, CSPT

- Pharmacists Certified to Administer Immunization: 114 (includes southern and northern tiers)
- LVHN has 51 Pharmacists holding Board Certification through the Board of Pharmaceutical Specialists, with nine of those pharmacists holding two board certifications. This represents 2.7% (51/1887) of all certified pharmacists in Pennsylvania.

Janine Barnaby, BCOP	Nick Hastain, BCPS	David Moll, BCCCP	Patti Simms, BCPS
Chandni Bhagat, BCPS	Laura Hayn, BCPS	Abigail Nemeth, BCCCP	Adrienne Snik, BCPS
Kristin Bishop, BCPS	Michelle Jones, BCPS	Katie Nesbitt, BCPS	Caryn Stapinski, BCPS
Brooke Broczkowski, BCIDP	Jarrod Kile, BCPS, BCIDP	Babatunde Ogun, BCPS	Megan Taylor, BCCCP
Attia Chaudhry, BCPS, BCCCP	Katelin Kimler, BCPPS	Frank Pacana, BCPS	Taylor Teshon, BCCP
Darlene Chaykosky, BCPS, BCCCP	Ann Kirka, BCGP	Jessica Price, BCPS	Rhonda Thomas, BCPS, BCSCP
Kristen Cosentino, BCPS	Beth Lally, BCPS	Sarah Reightler, BCPS	Jasica Vo, BCPS
Meredith Eschbach, BCPS, BCOP	Jason Laskosky, BCPS	Jonna Reynolds, BCPS	Nisha Vyas, BCPS
Matthew Fair, BCPS, BCGP	Amber Linkhorst, BCPS, BCEMP	Maria Rosenthal, BCPS	Kathryn Walker, BCPS
Kristy Fegley, BCPPS	David Lorchak, BCPS	Jane Russek, BCPS	Kristin Held Wheatley, BCOP
Anthony Gabriel, BCPS	Kristina Mazzie, BCPS	Milisha Shah, BCPS, BCTXP	Nicholas Yackanicz, BCCCP
Michelle Gronski, BCPPS	Melissa Mennen, BCPS	Jared Shayka, BCPS	Peter Yakoub, BCPS
Shalu Gupta, BCPS, BCOP	Stacy Mesics, BCPS	Elizabeth Shober, BCPPS	

- Pharmacy Services IV Room Metrics: Sterile Compounding utilizing Epic's Dispense Prep workflow
  - FY25:
    - Total number of manufacturing batches compounded was 13,894, which included 325,427 preparations.
    - Total number of patient specific doses compounded in IV room using Dispense Prep was 172,376 with an average accuracy rate of 99.75%.

Pharmacy & Therapeutics

A common, overarching Pharmacy & Therapeutics Committee exists for Lehigh Valley Health Network comprised of the following licensed entities: 1) Lehigh Valley Hospital (LVH) that includes LVH-Cedar Crest, LVH-17th Street, LVH-Tilghman, LVH-Muhlenberg, LVH-Hecktown Oaks, LVH-1503 N. Cedar Crest/Highland Avenue, and LVH-Carbon; 2) LVH-Dickson City; 3) LVH-Hazleton; 4) LVH-Schuylkill; 5) LVH-Pocono; 6) LVH-Macungie; and 7) LVH-Gilbertsville. The committee minutes shall be deemed to reflect the considerations and decisions of the seven hospitals. Considering the commonality of the hospitals and overlapping Formulary/Medical Staff/Allied Health Professional Staff, all decisions related to Therapeutics Committee actions are identical for all hospitals and no decisions, unless specifically noted, are site-specific.

1. Formulary Review – A comprehensive review of efficacy, safety, and cost for use within LVH was conducted.
   a. Additions:

• Imetelstat (Rytelo) – outpatient infusion centers • Tarlatamab (Imdeltra) – patients who failed platinum therapy • Tocilizumab-aazg (Tyenee) – inpatient and outpatient use • Brilliant Blue G Ophthalmic Solution (TissueBlue) • DaxibotulinumtoxinA (Daxxify) – outpatient neurology practices • Donanemab (Kisunla) – outpatient infusion centers • Cefiderocol (Fetroja©) – restricted to Infectious Diseases • Sulbactam-Durlobactam (Xacduro©) – restricted to Infectious Diseases • Purathick • Hepatitis B Immune Globulin (Human) (HBIG) (HepaGam®) – restricted to transplant surgery, infectious diseases, and hepatology • Levonorgestrel (Kyleena®) – outpatient OB/GYN sites • Romiplostim (Nplate®) – restricted to HemOnc providers • Hyaluronate Sodium, Cross-linked, 30mg/3mL syringe – outpatient use only • Hyaluronate Sodium, Stabilized, 60mg/3mL syringe – outpatient use • Hylan G-F 20, 16mg/2mL syringe – outpatient use only • Hylan G-F 20, 48mg/6mL syringe – outpatient use only • Sodium Hyaluronate 10mg/mL syringe – outpatient only • Sodium Hyaluronate 16.8mg/2mL syringe – outpatient only • Retifanlimab (Zynyz®) – outpatient formulary only • Zolbetuximab (Vyloy®) – outpatient formulary only • Disopyramide (Norpace®) • Nafcillin IV	• Atezolizumab/Hyaluronidase (Tecentriq Hybreza), SubQ formulation – outpatient formulary only • Eravacycline (Xerava®) – restricted to Infectious Diseases • Entecavir oral solution (0.05mg/mL) • Pneumococcal Conjugate 21 valent PCV21 (Capvaxive®) • Guselkumab (Tremfya®) • Nivolumab and Hyaluronidase-nvhy (Opdivo Qvantiq™) – restricted to outpatient infusion centers • Zenocutuzumab (Bizengri®) – restricted to outpatient infusion centers • Zanidatamab-hrii (Ziihera®) – restricted to outpatient infusion centers • Datopotamab deruxtecan-dlnk (Datroway®) – restricted to outpatient infusion centers • Mirikizumab (Omvoh®) – restricted to the outpatient setting • Enfamil AR RTF • Enfamil AR powder • Glucerna 1.2 • Glucerna • PolyCal • Juven Unflavored and Pineapple Coconut • Prosource TF20 Enfit Compatible • Banatrol Liquid • Ocrelizumab/hyaluronidase (Ocrevus Zunovo™) SubQ – restricted to outpatient use • Silver Nitrate 0.5% Topical Solution • Lansoprazole ODT

   b. Removals:

• Olsalazine 250mg Capsules • Givosiran 189mg/mL Solution • Lanolin • Vivitrol • Neomycin/polymyxin/HC OTIC Solution – suspension formulation remains on formulary • Miconazole 100mg vaginal suppository • Metaproterenol • Ofloxacin • Mafenide 5% Solution	• Cefprozil • Oxacillin • Demeclocycline • Tigecycline • Artesunate • Quinine • Trimethoprim • Molnupiravir • Doravirine • Darunavir/Cob/Emtri/Tenof alaf (Symtuza) • Capecitabine (Xeloda) • Clofarabine (Clolar)	• Erlotinib (Tarceva) • Isatuximab-IRFC (Sarclisa) • Aprepitant Emend-oral • Anagrelide capsules • Palivizumab (Synagis) • Sarilumab • Similac • Promote with Fiber • Ensure HP • Moxetumomab (Lumoxiti) • MCT Oil

c. Reviewed – Not Added:
   - Docusate Sodium (Enemeez)
   - Metronidazole Oral Suspension (Libmez®)
   - Gilteritinib (Xospata®)

d. Therapeutic Modifications:
   - Digoxin Level Ordering – created an initiate digoxin level order and placed it within digoxin loading and maintenance (IV/PO) order panel

2. Medication Use Evaluation
   a. Evaluation of Phenobarbital Utilization in Management of Alcohol Withdrawal Syndrome
   b. Daptomycin
   c. Pediatric Urinary Tract Infection Prophylaxis Using Trimethoprim-Sulfamethoxazole (TMP-SMX): Dosing, Breakthrough Infections, and Drug Resistance

3. Other
   a. Andexanet (Andexxa®) – restrictions remain in place
   b. Naming Changes for NaCl Shortage DKA Bags
   c. Vaccine Equivalence – LVHN will follow the guidance of the CDC ACIP committee regarding vaccine equivalence. Vaccines deemed to be therapeutically equivalent by ACIP are also therapeutically equivalent within LVHN.
   d. Potassium Chloride (KCl) Repletion Orders - transition from potassium chloride 10mEq/100mL riders to potassium chloride 20mEq/100mL rider as the standard product for both peripheral and central administration
   e. Lacosamide - administering lacosamide doses ≤400mg as a slow intravenous push over five minutes (max rate of 80mg/minute) for adult patients
   f. Antithrombotic Agent Reversal Guide – revised to replace KCentra with Balfaxar®
   g. Gentamicin for Chorioamnionitis-Pharmacy Dosing Weight – a verifying pharmacist can adjust the dosing weight from actual body weight to adjusted body weight if the actual body weight exceeds 1.2 times ideal body weight (IBW) on gentamicin orders for chorioamnionitis without contacting the provider.
   h. Enoxaparin – Neighborhood hospitals can use Enoxaparin as the standard in parenteral therapeutic anticoagulation management
   i. Eculizumab – removed from restriction list
   j. IV Push Medications – approved pharmacy substitution of specific infusion methods as long as they are FDA approved modalities and the appropriate supporting documentation is updated and nursing is properly educated when changes are made. This primarily relates to the administration of medications via IV Push.
   k. Preferred Vaccines – reviewed and approved
   l. Contrast Media – FDA approved products in one of the following classes is accepted as therapeutically equivalent: 1) Iodinated intravascular contrast agents; 2) Non-barium oral contrast agents; 3) Barium oral contrast agents; 4) Ionic genitourinary agents; and 5) Gadolinium based intravascular contrast agents.
   m. Pharmacy & Therapeutic Charter Reviews:
      - LVH-Dickson City
      - Pharmacy & Therapeutic Committee
   n. Policy review and approval:
      - Medication Times of Administration-Pharmacy
      - Management of Therapeutic Medication Duplication-Pharmacy
      - Adult MRSA Nasal Screening Pharmacy Driven Protocol-Antimicrobial Stewardship

- IV to PO Conversion-Pharmacy
- Vancomycin Pharmacy to Dose – changes for northern tier sites

o. Review and approval of Nutritional Services items:
- Trauma Nutrition Order
- Bariatric nutrition protocol
- Registered Dietician privilege to order a metabolic study
- Adding lab values to TPN and Lipid orders for neonates, pediatrics, and adults

p. Adverse Drug Reaction Reports - Annual FY24 Report, and FY25 Qtr. 1 and Qtr. 2
q. Formulary Safety Evaluation
r. Providers of Outsourced Pharmacy Products
s. Annual Formulary Review
t. Medication Education Cards – 16 cards covering: anticoagulants, asthma, Afib, cardiothoracic surgery, COPD, diabetes (oral medications), MI, heart failure, hypertension, pancreatitis, infused medications, insulin, joint restoration, seizure, stroke, and vascular surgery

4. Nutrition Sub Committee Report-Sodexo Clinical Nutrition Services
   a. Clinical Nutrition-Network Wide:
      - Performance Improvement Studies:
        - Pediatric Malnutrition Tracker. A tool to track pediatric patients identified with malnutrition during hospitalization and referred to the outpatient pediatric malnutrition team for follow-up. The goal is to ensure timely resolution of malnutrition. Data collection is ongoing, with forty referrals made to outpatient pediatric registered dietitians at discharge. An outpatient RD sees patients 23 days post-discharge, on average.
        - Fast Track to RD Program/Peds Specialty Center-Gastroenterology. Patients referred directly to the dietitian (RD) facilitating the physicians to see higher acuity cases. 180 cases documented.

      - Posters/Publications/National Presentations:
        - Food and Nutrition Expo & Conference 2024 posters:
          - *Thinking Outside the Site: Implementing a Network Staffing Approach*. Results: Enhanced staffing model supported the increase in nutrition consults to achieve charting compliance goal. Achieved budget neutral staffing model. Facilitated dietitians to practice at the top of their skillset.
        - American Congress of Rehabilitation Medicine Annual Conference 2024 Poster in collaboration with LVHN Rehab Services:
          - *Get a Grip! Grip Strength and Post Hospital Discharge Weight Within an Oncology Service Line.* Focused data set of 59 patients, 74.6% received rehab services while hospitalized and 28.8% had readmissions within 30 days.
        - Clinical Nutrition Manager Symposium 2025 Poster
          - *Validation of Nutrition Focus Physical Assessment via Telehealth.* The presence of malnutrition (moderate or severe) versus no malnutrition exceeded the hypothesized goal with 76.6% agreement. The severity level (none vs. moderate vs. severe) was 64.8%, slightly lower than the hypothesized goal.
        - Sodexo National Engagement Series:
          - *Registered Dietitians Gifting Patients the Key That Opens the Door to Improve Wound Healing - 300 participants.* Estimated cost savings from 2023-2024: $3,623,098.

      - Awards:
        - 2,322 total downloads of 19 Clinical Nutrition papers via LVHN Scholarly Works.

- Community Outreach:
  - Easton Public Market Cooking Demo: Cancer Prevention Healthy Cooking Demonstration in collaboration with LVHN: 16 participants.
  - Bridging Generational Gaps through Food Cooking Demonstration. Purpose: Bringing community members together from different ages and backgrounds to combat loneliness and obesity through a healthy cooking demonstration and nutrition discussion - 5 attendees with 100% reporting satisfaction with the activity; 100% likely to attend another event; 100% likely to recommend an event to friends or family
  - Virtual Food Pantry through LVHN Topper Oncology Center. Total donations: $1867.00.
  - October 24: Hospital and Community Breast Cancer Events reaching >2000 participants.
  - November 24: Pancreatic Cancer event - 112 attendees.
  - Breast Cancer Support Group presentation - 15 attendees
  - Sodexo partnership with Allentown/Bethlehem/Easton Blue Zones Project.
  - STEM Career Fair at DaVinci Center targeted middle school students to learn more about careers in healthcare.

- Patient Experience & Value Delivery:
  - Therapeutic Diet Tray Cards provided to patients when a new diet is prescribed to help educate patients, aid in understanding of the diet benefits, and direct the patient on how to connect to a dietitian.
  - National Nutrition Month promotion March 2025 with weekly sampling of Mindful features over 4 weeks and opportunity for dietitian Q&A.
  - Malnutrition Awareness table September 2024. A dietitian offered information re: the prevention and treatment of malnutrition. Tastings of the nutrition supplements were offered.

b. <u>Inpatient Nutrition: Cedar Crest:</u>
- Key Performance Indicators:
  - Average nutrition charting times met for Cedar Crest, Muhlenberg, Schuylkill, Dickson City, Carbon, and Hecktown Oaks. Key Performance Indicator = 99.5% (goal 98%)
  - Average Daily Productivity- Interventions per productive hour for Cedar Crest, Muhlenberg, Schuylkill, Dickson City, Carbon, and Hecktown Oaks. Key Performance Indicator = 1.6 (goal 1.5)

- Interdisciplinary Presentations:
  - Parkinson's support group nutrition education - 12 participants.
  - Parkinson's patient and caregiver symposium - 212 participants.
  - Annual Burn Survivor support group nutrition education - 15 participants.
  - Parenteral Nutrition (PN) Presentation for Surgery Residents - 30 surgery resident participants. Outcomes: 90% of participants stated an increase in their understanding of PN management.
  - Quarterly Presentations:
    - PCP Academy- 158 participants
    - New Hire RN Wound Orientation- 279 participants
    - RN Skin Education Days- 1400 participants
    - New Hire Pediatric RN Orientation- 50 participants

- Media
  - Social media platforms, Facebook, and LinkedIn, utilized by Sodexo Food & Nutrition to disseminate colleague engagement events and specials.

- Shortform video developed to highlight the accomplishments of the “Tube Team” utilizing ENvue technology.
- Interview and Blog for Nutrition during the Superbowl and March Madness: How to Regulate Heart Health, Make Nutritious Choices, While Enjoying Big Games.
- LVHN The Healthiest You Podcast - Exploring the Mediterranean Diet- Featuring Alexa Roseberry, RDN.

- Clinical Excellence
  - Food & Nutrition Conference and Expo (FNCE) 2024 Poster Presentations
    - *Provider Support of Parenteral Nutrition Order Writing by Registered Dietitians.* Pre-countermeasure: providers spent 38.6 hours/week on PN management. Post countermeasure: providers spent 19.6 hours/week.
    - *Parenteral Nutrition Order Writing by Registered Dietitians Reduces Bottlenecking of PN Orders to Pharmacy Staff*. Granting RDs TPN order writing privileges reduced pended order accumulation and last-minute verifications thus improving patient safety.

  - Research/Publications
    - *Protocol-Driven Insulin Regimen Improves Parenteral Nutrition-Induced Hyperglycemia and Provides Trend Toward Meeting Dextrose Calorie Goals While Posing a Low Hypoglycemic Risk* published in *Journal of Topics in Clinical Nutritio*n on January 9, 2025.

- Clinical Initiatives
  - Dietitian-led placement of small-bore feeding tubes by Certified Nutrition Support Clinicians (CNSC) using visual tube tracing via ENvue. Successfully placed 70 feedings tubes and reduced consult to placement time by 31%.
  - Pathway developed to identify patients at risk for Refeeding Syndrome. Pathway is comprised of guidelines for nutritional management and monitoring of lab parameters. Pathway education offered to LVHN Hospital Medicine providers - 77 participants.
  - Established a nutrition department journal club where dietitians can present new research/articles to fellow colleagues for continuing education credits.
  - Acquired and established competency for Q-NRG+ Metabolic Monitor for improved accuracy of providing nutrition support via indirect calorimetry.
  - In the process of implementing a “catch-up protocol” within the LVH- CC Regional Burn Unit to meet severely burn patients’ estimated nutrition needs despite frequent enteral nutrition holds for surgical procedures. – 14 patients since January 2025.
  - Developed a peer-to-peer chart audit system to increase consistency with regulatory compliance and RDN collaboration in ensuring appropriate patient documentation through automating chart audits across the network.
  - Wound healing protocol: Patients experiencing wounds receive a script to purchase an at cost wound healing nutrition supplement at the LV Pharmacy. (LV Pharmacy Sales: 179 cases of wound healing supplement sold in 2023 versus 373 cases in 2024.)
  - ICU intervention tracking to assess timeliness of enteral initiation and advancement to goal. Within the recommended 48-hour time limit per ASPEN guidelines.

- Patient Experience/Satisfaction:
  - Discharge supplement handout developed to encourage patient compliance with nutrition supplements post discharge.
  - Trauma After Nutrition handout developed for patients to provide nutrition tips promoting healing.

- Clinical Nutrition Manager collaborated with Food Services and created a low sodium condiment packet. The goal of the condiment packet was to enhance the flavor profile of the entrée meal. Result: uptick in patient satisfaction scores for patients ordered cardiac/low sodium diets.
- Annual formulary review held in April 2025. New adult and pediatric product additions/changes outlined in the following:
    - Gel-mix- added as a new product for babies that need thickened breast milk or formula.
    - PolyCal- added to fortify current tube feeds on formulary to meet the proper evidenced- based macronutrient distribution for burn patients.
    - Glucerna 1.2- Replacement for Promote with Fiber discontinuation. This product is frequently requested by providers and caretakers for admitted patients with diabetes.
    - Prosource TF20- Enfit tube compatible which will ease use for nursing to connect and administer through tubing via pouch which is more efficient than the current process of mixing separately with water in a med cup and giving via syringe.
    - Banatrol TF- also added for Enfit compatibility and less fluid required than the powder formulation.
    - Enfamil AR- added to replace Similac for Spit Up to facilitate continuity of care after discharge with more community accessible formula.

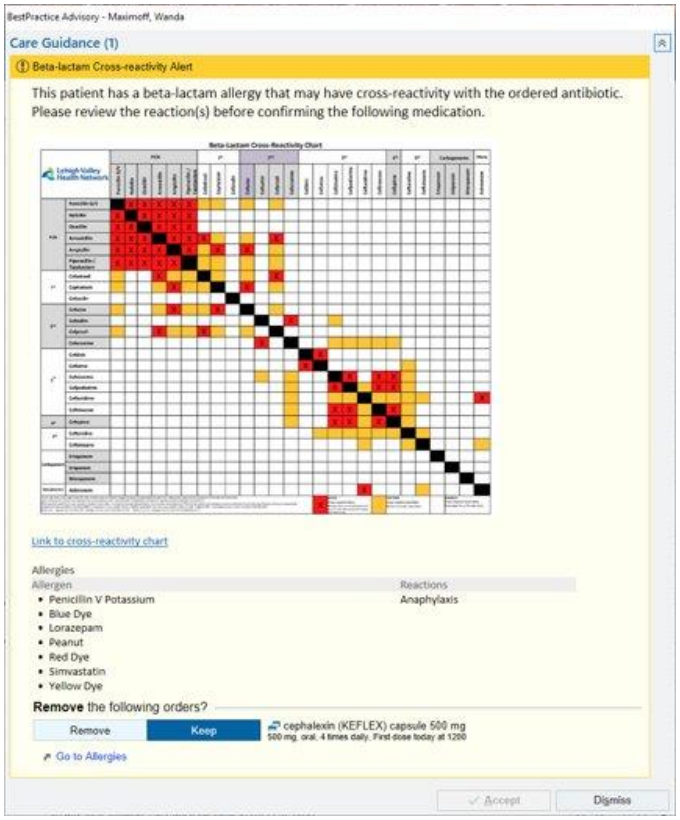
- Goals for the Future:
    - Pursue reimbursement opportunities for diagnosis of obesity.
    - Improve transitions of care by implementing discharge tube-fed patient standard operating procedure and enhance the referral process from inpatient to outpatient.
    - Utilize the Global Malnutrition Composite Score.
    - Implement Enhanced Recovery After Surgery (ERAS) program.
    - Have a dietitian in the outpatient Gastrointestinal clinic space.
    - Pursue order writing privileges in the Neonatal ICU (NICU).
    - Expand the clinicians trained to place small- bore feeding tubes.
    - Finish Sodexo National Micronutrient Task Force project.

5. <u>Antimicrobial Stewardship Sub-Committee Report</u>

The inpatient and outpatient antimicrobial stewardship committees are co-led by Eric Young, MD, FIDSA and Jarrod W. Kile RPh., BCPS, BCIDP.

Inpatient Antibiotic Stewardship - The inpatient antimicrobial stewardship finalized three major initiatives, in concert, related to updating beta-lactam allergies, surgical prophylaxis and the Anesthesia preference lists in Epic.

Recently literature has proven that type 1 allergic reactions are related to the side chain components of beta-lactam antibiotics. Epic was updated to disconnect beta-lactam allergies, and a BPA was utilized to inform providers of a possible beta-lactam allergy. (Note screenshot below).



Considering the first major initiative, the second major initiative was to update the Adult pre-operative antibiotic prophylaxis guidelines to:

a. Thoroughly review published national guidelines for inclusion in local recommendations.
b. Educate that cefazolin has NO similar side chains to other beta-lactam allergies and is safe to give in patients with beta-lactam allergies.
    - For patients allergic specifically to cefazolin, the alternative antibiotic being recommended will be cefTRIAXone.
c. Narrow the definition for MRSA coverage to “history of infection or colonization of MRSA” to decrease IV vancomycin utilization pre-operatively.
d. Removal of prophylactic antibiotics from the majority of post-operative order sets.

The updated Adult pre-operative antibiotic recommendations can be found in the Sanford Guide.

The third initiative was a full review of the Anesthesia preference lists in Epic with appropriate category and antibiotic builds to match the pre-operative antibiotic updates for both pediatric and adult patients.

Fourth, to further decrease the empiric use of IV vancomycin, a pharmacist-driven MRSA nasal screen policy/procedure was initiated. If not ordered upon admission and if meeting criteria defined in the policy/procedure, pharmacists can enter a MRSA nasal screen per Therapeutics. If the result is negative, it provides valuable information to discontinue empiric IV vancomycin.

Finally, a multi-disciplinary team has converted the Emergency Department paper “blue packets” for blood and body fluid exposure, which includes HIV exposure, to an Epic order set and workflow. This new process links-up patients with appropriate follow-up with our HIV colleagues at Comprehensive Health Services when appropriate.

The LVHN antimicrobial stewardship program promotes and guides the use of appropriate antimicrobials in the inpatient setting through multiple strategies including antimicrobial preauthorization, audit and feedback on prescribing habits, adherence to evidence-based antimicrobial guidelines and order sets, targeted interventions, and data analysis. This committee is also tasked with updating LVHN's inpatient and outpatient antibiograms yearly.

6. Transfusion Sub Committee Report

The interdisciplinary Transfusion Committee (TC) focuses on blood and compatibility test utilization, transfusion statistics, blood management, decreasing blood wastage, review of newly available blood components and services, transfusion safety, safe and best transfusion practices, policies, and education.

Highlights from FY 2025 include:

a. Blood is a valuable resource donated by volunteers. Our committee reviews blood utilization along with Patient Blood Management, and blood product wastage. The details and circumstances surrounding each unit wasted are investigated, reported as a PSR, and findings are presented at TC. This allows causes, trends, and potential process issues to be identified, shared, discussed, and addressed, as needed, in a collaborative manner. Blood (RBCs, plasma as requested) sent to the OR in Blood Bank (BB) validated coolers to be readily available, e.g., cardiac surgery, was identified as a cause of wastage and/or potential wastage, as surgical cases may be complicated and long. Coolers for transport of these blood components were therefore validated to hold proper temperature conditions for up to 12 hours as opposed to the prior eight hours, decreasing the likelihood of unused products being returned to the BB out of the proper conditions and wasted.
b. Transfusion audits are conducted by BB leadership and reviewed with the participants at the time of transfusion and results presented at TC to promote best practice, improve patient safety and readiness for facility and laboratory inspection by accrediting agencies (TJC, AABB, CAP). Issues identified on audits are shared and discussed with nursing leadership at TC, facilitating follow-up and education.
c. With the change in primary blood supplier in July 2024, and consequent introduction and/or increase of pathogen reduced platelets (PRP) into BB inventory at multiple sites, the need for additional education about PRP was recognized. Re-education about PRP was discussed and approved at TC and implemented.
d. Regarding enhancements in the provision of blood components and transfusion practice, TC facilitated changes to nursing documentation in EPIC prior to transfusion; several questions were reorganized and/or eliminated thus streamlining the process.
e. The rapid provision of blood and blood components for patients in need of emergent transfusion and provision of services to innovative programs, TC shared:
    - MedEvac – Group O whole blood or red cell units became available on ambulances and helicopters for emergent pre-hospital transfusion or during interhospital transfer; emergent blood was transfused to patients in need in multiple instances.
    - Liver transplant program updates.
    - Cellular therapy program updates.

BETTER COST

1. Cost Containment
    - Pharmacy Procurement Standardization: Pharmacy services utilizes the SpendMend Trulla procurement software to standardize our purchasing across the network. This allows us to identify and capture any cost savings opportunities at every pharmacy location. Fiscal Year 2025 savings for both our inpatient and retail pharmacies were $2,668,547.
    - Significant cost containment initiatives included:
        - Conversions from brand medications to biosimilars:
            - Actemra to Tyenne
            - Procrit to Retacrit
        - Conversion of potassium chloride riders in the second half of the year which is projected to have an annual savings of $70k-$120k/year for the network.

APPENDIX A

Accreditation Council for Pharmacy Education

- Lehigh Valley Hospital Pharmacy Department sponsored 13 ACPE activities accounting for 324 certificates of completion and 32.575 CEU or 325.75 continuing education credit hours for pharmacy staff.
- Lehigh Valley Hospital Pharmacy Department sponsored 15 ACPE activities in cooperation with the Department of Education accounting for 43 certificates of completion and 11.6 CEU or 116 continuing education credit hours for pharmacy staff.

Publications

Kristin Wheatley

- Stewart A, **Wheatley K**, Kunvarjee B, Kuhn A, Pauley JL, Bowman S. Hematology/Oncology Pharmacy Association Oncology Pharmacy Pediatric Toolkit (2024).

Madeline Stauffer

- M. Stauffer Medication Matters volume V issue II: 2024-2025 COVID-19 Vaccine Recommendations, December 2024

Presentations

Janine Barnaby

- Oncology Core Course – presented to oncology nurses and ancillary staff, October 2024 and April 2025, CE presentation

Janine Barnaby and Arun Mancheril

- Hematology/Oncology Fellow lecture series: General Oncology Overview, August 2024; Antineoplastic Agents, August 2024; Biologic Therapy, August 2024.
- Transplant Course-Preparative Regimens – Oncology nursing and ancillary staff, January 2025 and March 2025, CE presentation.

Rhonda Thomas

- Experience with supporting a Certified Pharmacy Technician Program, presented at Pennsylvania Society of Health-System Pharmacists (PSHP)'s Annual Meeting, April 2025

Ashley Brown

- Case Presentation: Bullous Impetigo, presented to clinical pharmacists and pharmacy residents
- Case Presentation: Statin Intolerance and Non-Statin Lipid-Lowering Therapies, presented to clinical pharmacists, pharmacy residents, and pharmacy students
- Case Presentation: Prophylaxis of Invasive Candidiasis in the Neonatal Intensive Care Unit, presented to clinical pharmacists and pharmacy residents
- Case Presentation: Evaluating Use of Dietary Supplements in Ambulatory Care Patients, presented to ambulatory care clinical pharmacists and pharmacy residents
- Family Medicine Learning Lab: Antibiotics, presented to family medicine residents
- ACPE Preceptor Pearl: Integrating Artificial Intelligence (AI) in Precepting, presented to clinical preceptors
- ACPE Presentation: Addressing Antibiotic Dilemmas in Pediatric Infectious Disease, presented to clinical pharmacists and pharmacy residents
- Medication Use Evaluation of Daptomycin, presented to Infectious Disease providers and at Vizient and ASHP Midyear conferences

- Comparison of Tenecteplase and Alteplase Door-to-Needle Time at a Comprehensive Stroke Center, presented at MEPSHP Night of the Residents and Eastern States Residency Conference

Matthew Fair

- "Opioid Prescribing in the Hospital Setting" - presented to incoming medical residents (July 2024)
- "What's the best way to treat iron deficiency anemia? Ironically, of course!" " CE presentation to LVHN Pharmacists (April 2025)

Carissa Kern

- Case Presentation: Impactful Interaction: Carbapenems + Valproate – presented to clinical and staff pharmacists
- Case Presentation: BPH Breakdown: Best Practices in Pharmacotherapy Management – presented to clinical and staff pharmacists
- Case Presentation: Lemierre's Syndrome: The Management of a Rare Disease – presented to clinical and staff pharmacists
- Case Presentation: Diabetes Strikes a Nerve – presented to population health pharmacists
- Family Medicine Presentation: Antibiotic Management – presented to family medicine residents
- ACPE Presentation: Precepting Pearls – presented to clinical and staff pharmacists
- ACPE Presentation: Beta Lactam Dose Optimization: Navigating Prolonged Infusions, Obesity, and Therapeutic Drug Monitoring – presented to clinical and staff pharmacists

Jarrod Kile

- Motivational Interviewing for the Vaccine Hesitant Patient, LVHN Project ECHO® videocast: ANCC/CE/CME credits, Jarrod W. Kile, Dr. Mark Knouse, Dr. Monica Lancellotti, July 19th, 2024
- Hot Topics in Infectious Diseases, PSHP Annual Meeting, Philadelphia, PA, April 11th, 2025

Madeline Stauffer

- Case Presentation: Doxorubicin Induced Heart Failure, presented to clinical pharmacists, and pharmacy residents
- Case Presentation: Necrotizing Pneumonia, presented to clinical pharmacists, pharmacy residents, and pharmacy students
- Case Presentation: Diabetic Retinopathy, presented to clinical pharmacists, and pharmacy residents
- ACPE Preceptor Pearl: Engaging and Motivating Learners, presented to clinical preceptors
- ACPE Presentation: A Pharmacist's Guide to CAR-T, presented to clinical pharmacists, and pharmacy residents
- Medication Use Evaluation of Pediatric Urinary Tract Infection Prophylaxis Using Trimethoprim-Sulfamethoxazole: Dosing, Breakthrough Infections, and Drug Resistance, presented to pharmacists at Vizient and ASHP Midyear conference
- Evaluation of Intravenous Sotalol Loading Protocol on Length of Stay, presented at MEPSHP Night of the Residents and Eastern States Residency Conference
- Inpatient Hyperglycemia Management, presented to family medicine residents

Kristin Wheatley

- Talking Toxicities: Management Across the Continuum. Toxicities in the Pediatric Patient Population. Hematology/Oncology Pharmacy Association Annual Conference, Portland, Oregon, April 2025.
- Blina Breakthroughs and More: ALL, DVL, and Pharmacy Updates from the Fall 2024 COG Meeting. Children's Oncology Group Pharmacy Members (virtual), October 2024.
- Upfront Immunotherapy in Pediatric Hodgkin Lymphoma: A Clinical Debate. The Betsy Poon Pharmacy Education Series, Children's Oncology Group Meeting, New Orleans, Louisiana, September 2024.
- Everything BUT Beta-Lactam Antibiotics, presented to pediatric medical residents, PediaPred Lecture Series, August 2024.

- Beta-Lactam Antibiotics, presented to pediatric medical residents, PediaPred Lecture Series, July 2024.

Ann Kirka
- *Collaborating with Pharmacy to Avoid Falls*, Nurse Residency Research Day, September 2024
- *Side Effects That Increase Fall Risk*, Annual Fall Prevention Retreat, November 2024

Jessica Price
- Pharmacokinetics of Psychotropics. Lecture to Psychiatry Residents. LVHN-Muhlenberg; 10-16-24
- Pharmacotherapy in Treatment of Anxiety. Psychiatry Grand Rounds. LVHN (Virtual); 11-20-24
- Psychiatric Pharmacy Pearls - Pharmacokinetics: Pediatrics vs Adults, Dosage Formulations, Therapeutic Drug Monitoring. Lecture to Psychiatry Fellows. LVPG Adult & Pediatric Psychiatry; 5-14-25

Kush Sheth and Sidney Fries
- Prescription for a Better Discharge: Incorporating a Transition of Care Pharmacist into the Discharge Process. American College of Surgeons, TQIP24 Annual Conference, November 12-14, 2024

Posters

Ashley Brown
- Medication Use Evaluation of Daptomycin, Vizient and ASHP Midyear poster presentation

Matthew Fair
- "Description of Pharmacist Activities in a Post Intensive Care Unit Recovery Clinic" at ASHP Midyear conference (December 2024)

Sidney Fries
- Prescription for a Better Discharge, ASHP Midyear 2024

Carissa Kern
- Medication Use Evaluation of Phenobarbital Utilization in the Management of Alcohol Withdrawal Syndrome – presented at Vizient and ASHP Midyear conferences
- Evaluation of Transition From aPTT to Anti-Xa Heparin Monitoring Protocols – presented at MEPSHP Night of the Residents and Eastern States Residency Conference

Jarrod Kile
- Adherence to Guideline-Based Treatment of Recurrent C. difficile within LVHN Hospitals, Zoe Tarun; Kathryn Zaffiri, MPH; Eric Young, MD; Jarrod W. Kile, RPh., BCPS, BCIDP; LVHN Research Summer Scholar Program; Allentown, PA, August 2024.

Madeline Stauffer
- Medication Use Evaluation of Pediatric Urinary Tract Infection Prophylaxis Using Trimethoprim-Sulfamethoxazole: Dosing, Breakthrough Infections, and Drug Resistance, Vizient and ASHP Midyear poster presentation

Journal Club

Ashley Brown
- Teplizumab and β-cell Function in Newly Diagnosed Type 1 Diabetes (PROTECT)
- Insulin Efsitora versus Degludec in Type 2 Diabetes without Previous Insulin Treatment (QWINT-2)
- Safety of Switching from a Vitamin K Antagonist to a Non-Vitamin K Antagonist Oral Anticoagulant in Frail Older Patients with Atrial Fibrillation (FRAIL-AF)
- Azithromycin therapy for prevention of chronic lung disease of prematurity (AZTEC)

Carissa Kern

- Finerenone in Heart Failure with Mildly Reduced or Preserved Ejection Fraction (FINEARTS-HF) – presented to population health pharmacists
- Effects of Semaglutide on Chronic Kidney Disease in Patients with Type II Diabetes – presented to clinical and staff pharmacists
- Trial of Selective Early Treatment of Patent Ductus Arteriosus with Ibuprofen (Baby-Oscar Trial) – presented to clinical and staff pharmacists
- Intubation rates in Patients receiving Parenteral Olanzapine ± a Parenteral Benzodiazepine in the Emergency Department – presented to clinical and staff pharmacists

Madeline Stauffer

- Beta-Blockers after Myocardial Infarction and Preserved Ejection Fraction
- Nivolumab-AVD in Advanced Stage Classic Hodgkin Lymphoma
- Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity
- Comparison of Two-bag and Three-bag Acetylcysteine Regimens in the Treatment of Paracetamol Poisoning

Clinical Pearls

Ashley Brown

- Carbamazepine-Associated Pancytopenia
- Anticoagulation for Patients with Cirrhosis and Atrial Fibrillation
- VTE Prophylaxis in the Neurocritical Care Unit

Carissa Kern

- Memantine for Migraine Prophylaxis – presented to clinical and staff pharmacists
- Extended Infusion Beta-Lactams: Patient Selection and Tolerability – presented to clinical and staff pharmacists
- Mass Ingestion Acetaminophen Management – presented to clinical and staff pharmacists

Jessica Price

- Commonly Prescribed Sleep Agents. Presented to Behavioral Health Nurses. LVHN-Muhlenberg; 1-8-25
- Achieving Glucose Control with SQ Insulin. Presented to Pharmacists. Muhlenberg Hospital; 12-5-24, 6-25-25

Madeline Stauffer

- Drugs to Avoid in G6PD
- Candidemia
- Carbapenem-Resistant Enterobacterales

Emily Touma

- Carbidopa-Levodopa (Sinemet) for Pediatric Idiopathic Dystonia, June 2025

APPENDIX B
PROVIDERS OF OUTSOURCED PHARMACEUTICAL PRODUCTS
September 2025

This is a review of the companies the inpatient pharmacy contracts with to obtain products which are compounded in a ready-to-use fashion. This review is based on a recommendation from The Joint Commission to periodically inform the medical staff of these services. All quality metrics are met per the contract agreement.

Company Name: *AIS Healthcare*
Website: www.aiscaregroup.com
Location(s): 2 Locations. Dallas, Texas and Ridgeland, Mississippi
Background Information: AIS is a leader in targeted drug delivery and infusion care. In the targeted drug delivery division, AIS has two state-of-the-art 503A specialty compounding pharmacies. They prepare and ship more than 145,000 patient specific prescriptions annually. They use a process that combines aseptic processing with terminal sterilization on patient-specific prescriptions to achieve higher sterility assurance and extended beyond use dating.
Quality Assurance: AIS uses sterile cleaning agents throughout the entire cleanroom suite. All stock solutions and patient-specific compounding are done only by a licensed pharmacist. Perform gloved fingertip sampling every 3 months for technicians and monthly for pharmacists. They utilize multiple 0.22-micron sterilizing-grade filtration steps, including filter integrity testing to ensure medication sterility.
Products Obtained: Pain management syringes and cartridges
Reason for use: Extended expiration dating, decrease waste, unique pain management compounds.

Company Name: *Central Admixture Pharmacy Services (CAPS)*
Website: www.capspharmacy.com
Location(s): 24 locations located throughout the United States. The locations in Lehigh Valley, and Philadelphia service LVHN.
Background Information: CAPS is the nation's largest network of outsourcing admixture pharmacies. Founded in 1991, it specializes in the outsourcing of compounded sterile preparations such as parenteral nutrition solutions, cardioplegia solutions, controlled substances, and pre-filled anesthesia syringes. The company offers CAPSlink, a web-based ordering software that manages complex and patient-specific prescriptions, such as parenteral nutrition. Making over 300,000 local deliveries annually, CAPS pharmacies operate 365 days a year to service all of their health system customers. Central Admixture Pharmacy Services, Inc. operates as a subsidiary of B. Braun Medical Inc.
Quality Assurance: Clean down and line clearance are performed every day between every drug. Particulate and bioburden air tests, along with employee fingertip tests, are performed on a weekly basis. Media-fill validation of compounding processes is performed semi-annually. Our customers receive QA reports on a quarterly basis. Every batch is quality tested and not released for sale until all testing is complete and a Certificate of Analysis is generated. All sterility testing is quarantined for a minimum of 14 days. Each manufactured lot goes through endotoxin, particulate matter, and potency testing. A separate Quality Assurance department approves all batches for release.
Products Obtained: Parenteral Nutrition (patient specific TPNs), Oxytocin Bags, Cardioplegia bags, DelNido bags
Reason for use: Daily delivery of patient specific TPNs. Decreased costs by allowing us to balance FTE resources, avoid purchasing TPN compounding equipment, and storing multiple additives required for TPN admixture. Extended dating on Cardioplegia and Oxytocin bags.

Company Name: *Fagron Sterile Services*
Website: www.fagronsterile.com/
Location(s): Wichita, KS 67205
Background Information: Fagron Sterile Services is a DEA and FDA registered 503B facility that opened in 2005 and has over 14,000 ft² of cGMP compliant cleanroom space. They are owned by Fagron, Inc. based out of Rotterdam in the Netherlands. They are licensed to service in all 50 states, and mainly provide high risk sterile products to hospitals, surgery centers, specialty clinics, and physician offices. Their main areas of focus are renal, pain, ophthalmic and OR syringes with over 50 products available. They employ over 100 people, and have built a second facility in Wichita that measures 50,000 square feet.
Quality Assurance: Every product is quality tested and not released for sale until all testing is complete and a Certificate of Analysis is generated. All sterility testing is quarantined for a minimum of 14 days. Each manufactured lot goes through endotoxin, particulate matter, and potency testing. A separate Quality Assurance department approves all batches for release. Online access allows us to see release testing information per batch.
Products Obtained: Eye drop- tropicamide 1% /cyclopentolate 1%/phenylephrine 2.5%, AminoProtect 25gm/1000ml, Bevacizumab 1.25mg/0.05ml, Fentanyl infusions, Fentanyl epidurals, hydromorphone 50mg/50ml, ketamine 50mg/5ml, norepinephrine 4mg/250ml, oxytocin 30 units/500ml , Phenylephrine bags and syringes, Ephedrine 50mg/5mL syringes, Phenol 6% injection, LET gel, rocuronium 10mg/ml-5ml, succinylcholine 100mg/5ml, vancomycin infusions.
Reason for use: Ophthalmologic surgery. Properly labeled OR syringes. Beyond use dating. Combination product reduces waste and costs.

Company Name: *Hikma*
Website: www.hima503b.com
Location(s): Cherry Hill & Dayton, New Jersey
Background Information: Hikma Pharmaceuticals PLC is a multinational pharmaceutical company that was founded in 1978. They launched their 503B division in 2022 a new outsourced sterile compounding business focused on providing high quality, ready-to-administer injectable medications. They operate out of a 65,00 square foot state of the art sterile outsourced compounding and distributing facility.
Quality Assurance: As an FDA-registered 503B outsourcing facility, Hikma is required to meet current Good Manufacturing Practice (CGMP) standards, which include rigorous quality control and testing for every batch of product. Provide batch specific COA, testing each batch for sterility, potency, and endotoxins.
Products Obtained: Diltiazem 125 mg/125 mL, Ketamine 50 mg/5 mL, Rocuronium PF 50 mg/5mL
Reason for use: Properly labeled OR syringes. Extended beyond use dating. Drug shortages, Reduces waste and costs.

Company Name: *Leiters*
Website: **www.leiters.com**
Location(s): Englewood, CO
Background Information: Leiters Health, founded in 1926, is an FDA-registered 503B outsourcing provider of high-quality hospital and ophthalmic compounded sterile preparations.
Quality Assurance: Leiters meets all USP797 standards
Products Obtained: dexmedetomidine 20mcg/5ml syringes, neostigmine PF 5mg/5ml, ropivacaine 600ml, succinylcholine 200mg/10ml
Reason for use: extended use dating, drug shortages

Company Name: *Nephron Pharmaceuticals*
Website: **www.nephronpharm.com/**
Location(s): West Columbia, South Carolina
Background Information: Nephron is an outsourcing facility for a wide variety of compounded sterile preparations including Operating Room syringes and luer lock vials, and respiratory products. Nephron has over 27 years of sterile automated manufacturing experience to hospitals and ambulatory care centers in all 50 states. Nephron is the world's largest blow-fill-seal (BFS) manufacturing company by total capacity. At our 408,000 square-foot facility, Nephron can efficiently produce a range of products using BFS technology.
Quality Assurance: Every batch is quality tested and not released for sale until all testing is complete and a Certificate of Analysis is generated. All sterility testing is quarantined for a minimum of 14 days. Each manufactured lot goes through endotoxin, particulate matter, and potency testing. A separate Quality Assurance department approves all batches for release. Online access allows us to see release testing information per batch.
Products Obtained: Del Nido Cardio 1000ml bags
Reason for use: Extended BUD

Company Name: *OurPharma*
Website: **www.ourpharma.net**
Location(s): Fayetteville, Arkansas
Background Information: Our Pharma is an FDA-registered 503B outsourcing facility created to address the need for compounded medications that are in short supply regionally and nationally. The initial focus is on sterile-to-sterile and API-to sterile compounding of ready to administer pain management finished drug products in a variety of container types, including cassettes, syringes, PCA vials and IV bags.
Quality Assurance: Each batch undergoes environmental and personnel monitoring as part of the QA batch release process. The quality unit qualifies third-party FDA-regulated labs for batch release testing including but not limited to, sterility, assay, endotoxin, appearance, pH, and particulate matter.
Products Obtained: fentanyl epidurals, fentanyl infusion
Reason for use: Drug shortages, extended use dating

Company Name: *SCA*
Website: **www.scausa.net**
Location(s): two manufacturing facilities. Little Rock, Arkansas; Windsor, CT.
Background Information: SCA is an outsourcing facility for compounded sterile preparations such as epidurals, antibiotics and narcotic drips. They provide sterile admixtures to hospitals and ambulatory care centers in all 50 states.
Quality Assurance: Every batch is quality tested and not released for sale until all testing is complete and a Certificate of Analysis is generated. All sterility testing is quarantined for a minimum of 14 days. Each manufactured lot goes through endotoxin, particulate matter, and potency testing. A separate Quality Assurance department approves all batches for release.
Products Obtained: Methadone IV syringes, rocuronium PF syringes
Reason for use: Extended expiration dating. Ability to stock epidurals at room temperature. Decrease waste.

Company Name: *Wells Pharma*
Website: **www.wellspharmatx.com**
Location(s): Houston, Tx
Background Information: Wells Pharma is an FDA-registered 503B Outsourcing Facility, providing Ready-To-Use (RTU) medications to hospitals and surgical centers. They have a state-of-the-art, fully automated facility.
Quality Assurance: Wells Pharma utilizes a rigorous quality assurance program that meets all USP797 standards.
Products Obtained: indomethacin suppositories, dextrose syringes, cefazolin syringes
Reason for use: drug shortages, ready-to-use products

A Summary (Table 1) of vendors and key characteristics that reflect compliance with FDA current good manufacturing practice (cGMP) regulations is below. This includes compliance with sterility, stability, and endotoxin testing by batch. Additionally, environmental monitoring is performed by all vendors, and includes but is not limited to, IV room particle counts, surface sampling, cleaning logs, equipment calibration, and controlled room environment monitoring. Detailed reports are available online, via the therapeutics link, for hospital staff, and medical staff to review at any time.

Vendor	AIS	CAPS	Fagron	Hikma	Leiters	Nephron	OurPharma	SCA	WellsPharma
Type of Product	Pain Management syringes and cartridges	Parenteral Nutrition, Oxytocin bags, Cardioplegia bags	Combination eye drops, Ephedrine syringes, phenylephrine infusions and syringes, Fentanyl infusions, oxytocin infusions, rocuronium syringes, succinylcholine syringes, vancomycin infusions	Diltiazem infusions. Ketamine syringes, rocuronium syringes	dexmedetomidine 20mcg/5ml syringes, neostigmine PF 5mg/5ml, ropivacaine 600ml, succinylcholine 200mg/10ml	DelNIdo cardio bags	fentanyl epidurals and infusions	Fentanyl epidurals	indomethacin suppositories, dextrose syringes, cefazolin syringes
FDA 503B	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Quality Assurance	Utilize third party testing of all stock solutions, utilize multiple filtration steps	Certificate of Analysis (sterility, potency and endotoxin testing performed)	Certificate of Analysis (sterility, potency and endotoxin testing performed)	Certificate of Analysis (sterility, potency and endotoxin testing performed)	Certificate of Analysis (sterility, potency and endotoxin testing performed)	Certificate of Analysis (sterility, potency and endotoxin testing performed)	Certificate of Analysis (sterility, potency and endotoxin testing performed)	Certificate of Analysis (sterility, potency, and endotoxin testing performed)	Certificate of Analysis (sterility, potency and endotoxin testing performed)
Environmental Monitoring	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sterility Testing	Not required for Patient Specific doses	All batches pass USP 71-compliant sterility testing as part of release testing	All batches pass USP 71-compliant sterility testing as part of release testing	All batches pass USP 71-compliant sterility testing as part of release testing	All batches pass USP 71-compliant sterility testing as part of release testing	All batches pass USP 71-compliant sterility testing as part of release testing	All batches pass USP 71-compliant sterility testing as part of release testing	All batches pass USP 71-compliant sterility testing as part of release testing	All batches pass USP 71-compliant sterility testing as part of release testing
Potency Testing	Not required for Patient Specific doses	All batches compliant with USP drug monograph specs	All batches compliant with USP drug monograph specs	All batches compliant with USP drug monograph specs	All batches compliant with USP drug monograph specs	All batches compliant with USP drug monograph specs	All batches compliant with USP drug monograph specs	All batches compliant with USP drug monograph specs	All batches compliant with USP drug monograph specs
Endotoxin Testing	Not required for Patient Specific doses	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications	All batches pass USP 85 compliant Endotoxin testing per USP drug monograph specifications

Table 1. Summary Table

APPENDIX C
Central Admixture Pharmacy Services (CAPS)

Executive Summary for Qtr. 3 CY2024-Qtr. 2 CY2025

Summary of Company:

CAPS, a BBraun company, was founded in 1991 and is the nation's largest network of outsourcing admixture pharmacies. There are 24 locations throughout the United States. It is a pioneer in the outsourcing of compounded sterile preparations. CAPS delivers high-quality admixture services and solutions to hospitals and outpatient facilities across the nation. They are State-licensed and FDA-registered. The company goal is to provide the most comprehensive and continuous quality assurance program in the industry. They perform environmental monitoring and regular process validations as part of their routine Continuous Quality Assessment and Improvement Program. The company offers CAPSlink, a web-based ordering software that manages complex and patient-specific prescriptions, such as parenteral nutrition. Making over 300,000 local deliveries annually, CAPS pharmacies operate 365 days a year to service all of their health system customers. Central Admixture Pharmacy Services, Inc. operates as a subsidiary of B. Braun Medical Inc.

Warehouse locations servicing LVHN:

Primary:
Lehigh Valley, PA (503B batch orders)
Philadelphia, PA (503A-patient specific orders)

Secondary due to shortages:
Phoenix, AZ (503B)

Products obtained:

Patient Specific Total Parenteral Nutrition (TPN) bags
Neonatal TPN starter bag
Oxytocin bags
Cardioplegia solutions

Quality Analysis Customer Report Highlights:

- Reports are received quarterly from each facility
- Data collection includes:
    - Environmental Testing
    - Personnel and Process Validations using Media Fill technique
    - End product testing for sterility
    - Customer complaints and inquiries
    - Licensing
    - Employee Training
- All CAPS 503B Outsourcing facility products remain quarantined until CAPS Quality Assurance reviews all release criteria for each batch including final readings and analysis of environmental samples. All Out of Specifications (OOS) results are investigated and addressed appropriately as part of the release process. Quarantined batches are only released after it can be determined that any OOS test results had no adverse effect on the product.

Annual Results Summary:

- See attached chart
- Corrective actions were taken on any area that was OOS. As applicable, any ISO5 hood that showed positive results was taken out of service and cleaned. Resampling was completed on involved areas for three consecutive days.

Enclosures/Attachments:

- CAPS 503B Pharmacy Quarterly Customer Service reports from Lehigh Valley
    - Qtr 3, 2024
    - Qtr 4, 2024
    - Qtr 1, 2025
    - Qtr 2, 2025
- CAPS 503A Pharmacy Quarterly Customer Service reports from Philadelphia
    - Qtr 3, 2024
    - Qtr 4, 2024
    - Qtr 1, 2025
    - Qtr 2, 2025
- CAPS 503B Pharmacy Quarterly Customer Service reports from Phoenix
    - Qtr 3, 2024
    - Qtr 4, 2024
    - Qtr 1, 2025
    - Qtr 2, 2025

CAPS QA Reports - Summary of Findings - Qtr. 3 CY2024 - Qtr. 2 CY2025

Facility	*Measurement*	*Findings*
Lehigh Valley (503B)	Environmental Controls Goal: 0 findings	***2024:***
		Q3: 0.1% workstations; 0.1% surfaces; 0.2% gloved fingertips; 0.1% sleeves; 0.3% air bioburden
		Q4: 0.1% workstations; 0.2% surfaces; 0.1% gloved fingertips; 0.1% air bioburden
		2025:
		Q1: 0.1% workstations; 0.1% surfaces; 0.2% gloved fingertips; 0.1% air bioburden
		Q2: 0.1% surfaces; 0.1% gloved fingertips;
	Media Fill Goal: 0 findings	***2024:***
		Q3: 1/21
		Q4: no findings
		2025:
		Q1: 1/28
		Q2: no findings
	End Product Testing Goal: 0 findings	***2024:***
		Q3: no findings
		Q4: no findings
		2025:
		Q1: no findings
		Q2: no findings
	Customer complaints/ inquiries	***2024:***
		Q3: 0 complaints; 11 inquiries
		Q4: 0 complaints; 2 inquiries
		2025:
		Q1: 0 complaints; 7 inquiries
		Q2: 0 complaints; 10 inquiries
	Employee Training Goal: >/=95% compliance	***2024:***
		Q3: 99.5%
		Q4: 99.3%
		2025:
		Q1: 100%
		Q2: 98.4%

Facility	*Measurement*	*Findings*
Philadelphia (503A)	Environmental Controls Goal: 0 findings	***2024:***
		Q3: 0.66%-sleeve covers
		Q4: 1.27%-gloved fingertips
		2025:
		Q1: 0.63%-gloved fingertip
		Q2: no findings
	Media Fill Goal: 0 findings	***2024:***
		Q3: no findings
		Q4: no findings
		2025:
		Q1: N/A
		Q2: no findings
	End Product Testing (Not done on 503A products)	***2024:***
		Q3: N/A
		Q4: N/A
		2025:
		Q1: N/A
		Q2: N/A
	Customer complaints inquiries	***2024:***
		Q3: 2 complaints; 0 inquires
		Q4: 1 complaint; 1 inquiry
		2025:
		Q1: 1 complaint; 2 inquiries
		Q2: 1 complaint; 2 inquiries
	Employee Training Goal: >/=95% compliance	***2024:***
		Q3: 99.9%
		Q4: 100%
		2025:
		Q1: 100%
		Q2: 100%