

**Impact of oral midodrine on duration of intravenous vasopressor therapy**

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**Background:** Persistent hypotension poses a significant barrier to intensive care unit (ICU) discharge. Management often includes intravenous (IV) vasopressor therapy which necessitates the use of a central line, along with administration within the ICU. Use of IV vasopressors may increase the risk of hypertension, bradycardia, and ischemia.<sup>1</sup> Midodrine, an  $\alpha_1$ -adrenergic receptor agonist, may be used as an oral alternative to IV vasopressors to minimize adverse events associated with IV administration and promote ICU discharge. It is approved for use in orthostatic hypotension. However, it is used off-label for several indications, including prevention of dialysis-induced hypotension, hepatorenal syndrome, and vasovagal syncope.<sup>2</sup> Currently, few studies have been done to determine its effect on patients with shock.<sup>3-4</sup> The goal of this study is to evaluate the effect of midodrine on duration of IV vasopressor use.

**Objectives:** The purpose of this study is to compare the duration of IV vasopressor administration in patients who did or did not receive oral midodrine. The secondary objectives are to compare duration of IV vasopressor administration in patients who did or did not receive oral midodrine stratified according to a baseline predisposition to hypotension; incidence of IV vasopressor re-initiation during ICU stay; rate of ICU readmission; differences in ICU and hospital lengths of stay; and adverse events.

**Methodology:** A non-interventional medical chart review will be conducted from September 1, 2013 to September 1, 2016. Patients 18 years of age and older admitted to the medical ICU or surgical ICU with a diagnosis of shock requiring a total duration of at least 24 hours of IV vasopressors will be included. Patients will be excluded if midodrine was used for an indication other than IV vasopressor weaning or if patients were on chronic midodrine therapy prior to hospital admission. Patients with a predisposition to hypotension will include those with diagnosed heart failure, chronic kidney disease, and/or end stage liver disease as identified by ICD-9 and ICD-10 codes. Patients will be propensity matched according to the likelihood of midodrine receipt. Data collected will include patient demographics, vasopressor agents used, dosages of vasopressor agents, ICU readmission, ICU length of stay, hospital length of stay, and adverse events (heart rate and serum lactate). The starting dose, maximum dose, and duration of midodrine therapy will be collected for the midodrine cohort. Nominal data will be analyzed with the Chi-square test or Fisher's exact test, as appropriate. Continuous data will be analyzed with the Student's t-test or Mann Whitney U test, as appropriate.

**Results and conclusions:** To be determined.

**References:**

1. Poveromo LB, Michaellets EL, Sutherland SE. Midodrine for the weaning of vasopressor infusions. *J Clin Pharm Ther.* 2016; 41(3):260-5.
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4. Levine AR, Meyer MJ, Bittner EA, et al. Oral midodrine treatment accelerates the liberation of intensive care unit patients from intravenous vasopressor infusions. *J Crit Care.* 2013;28(5):756-62.

## Impact of $\beta$ -lactam Allergies on the Treatment of Methicillin-Susceptible *Staphylococcus aureus* Infections

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**Background:** Approximately three million people in the United States report a penicillin drug allergy and less than 5% of these patients mount a type I hypersensitivity or “immediate” reaction mediated by IgE antibodies (i.e. anaphylaxis, angioedema, bronchospasm, etc.). However, almost 80% of patients with IgE-mediated reactions lose their hypersensitivity over 10 years<sup>1,2</sup>. The identification of penicillin allergies becomes especially essential in the treatment of methicillin-susceptible *Staphylococcus aureus* (MSSA) infections, in which  $\beta$ -lactam therapy has shown superiority over vancomycin, specifically in the treatment of MSSA bacteremia<sup>3-4</sup>. Thus, patients with unverified penicillin allergies may receive treatment with suboptimal therapy, which could potentially lead to decreased clinical cure, increased mortality, and selection of resistant bacteria.<sup>5</sup>

The aim of this study is to determine the impact of documented  $\beta$ -lactam allergies on antimicrobial selection for MSSA infections.

**Objectives:** The objective of this study is to determine the frequency at which treating providers elicit a clinical history in  $\beta$ -lactam-allergic patients with MSSA infections. The primary endpoint is the percentage of patients with documentation of a  $\beta$ -lactam allergy history as identified by CPRS documentation in the patients’ allergy tab and/or progress note upon initiation or discontinuation of therapy for MSSA infections. Secondary endpoints include antibiotic treatment failure, rate of alternative therapy, length of hospital stay, cost, and adverse drug events.

**Methodology:** This is a retrospective chart review of patients from June 2006 to June 2016 with a  $\beta$ -lactam allergy who received treatment for an MSSA infection, regardless of treatment setting. The MSSA isolates will be identified via microbiological culture results from any bodily source with susceptibilities to oxacillin. The documentation of an appropriate allergy history will be identified from the allergy tab or progress note within the VA’s Computerized Patient Record System (CRPS<sup>®</sup>) at the initial episode of MSSA infection. An appropriate allergy history will be satisfied if information including, but not limited to, timing, type of allergic reaction, and subsequent exposure to  $\beta$ -lactam antibiotics are present in the electronic medical record. Two hundred patients that meet the aforementioned criteria will be included in this study, as long as antibiotics were not administered prior to drawn cultures. The authors hypothesize that less than 50% of the included patients will have a documented history of the patients’  $\beta$ -lactam allergy.

**Results and Conclusions:** Pending IRB-approval; results to be presented at the Spring OCCP meeting

### References:

1. Macy E. Penicillin and beta-lactam allergy: epidemiology and diagnosis. *Curr Allergy Asthma Rep.* 2014;14(11):476.
2. Salkind AR, Cuddy PG, Foxworth JW. The rational clinical examination. Is this patient allergic to penicillin? An evidence-based analysis of the likelihood of penicillin allergy. *JAMA.* 2001;285(19):2498-505.
3. Blumenthal KG, Parker RA, Shenoy ES, Walensky RP. Improving Clinical Outcomes in Patients With Methicillin-Sensitive *Staphylococcus aureus* Bacteremia and Reported Penicillin Allergy. *Clin Infect Dis.* 2015;61(5):741-9.
4. McDanel JS, Perencevich EN, Diekema DJ, Herwaldt LA, Smith TC, Chrischilles EA, et al. Comparative effectiveness of beta-lactams versus vancomycin for treatment of methicillin-susceptible *Staphylococcus aureus* bloodstream infections among 122 hospitals. *Clin Infect Dis.* 2015 Aug 1;61(3):361-7.
5. Macy E. Penicillin allergy: optimizing diagnostic protocols, public health implications, and future research needs. *Curr Opin Allergy Clin Immunol.* 2015;15(4):308-13.

## Impact of pharmacist-led medication history overnight in a community hospital

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### Background:

Incorrect medication histories are the most frequent cause of medication errors during hospitalization<sup>1</sup>. Up to 60% of patients admitted to the hospital will have at least one error in their medication history, and of those patients, 6% will experience a serious adverse event. These errors can cause an interruption in therapy or inappropriate administration of medications during hospitalization, creating a substantial safety risk for patients.<sup>2,3</sup> Currently at Southwest General Health Center, we employ an emergency department pharmacist from 11am-11pm, and a pharmacy technician from 7am-12am. When pharmacy staff is not available to complete medication histories, the task typically falls to nursing. Discharge pharmacists have been finding medication errors most commonly in patients that were admitted between 12am to 7am. Current literature demonstrates the positive impact that pharmacists can have on reducing discrepancies in medication histories.<sup>3</sup> However, there is significant research lacking in the benefit of twenty-four hour coverage in the emergency department.

### Objectives:

The objective of this study is to quantify medication history errors occurring overnight, and validate the need for twenty-four hour pharmacist coverage in the emergency department.

### Methodology:

This prospective quality improvement study was submitted to the Institutional Review Board for approval. A pharmacist will identify patients that have been admitted between the hours of 12am and 7am via the electronic medical record. A new medication history will be obtained within forty-eight hours of admission. Medication histories will be acquired from the patient, family members, available medications lists, and external prescription records. Information that would not be available at the original time of the medication history will not be included. All data will be recorded without patient identifiers to maintain confidentiality. Discrepancies in the medication history will be documented on a daily monitoring form. Errors identified will include incorrect dosage, incorrect frequency, inactive medications listed, and missing medications. Potential adverse drug events, defined as harmful or potentially harmful medication discrepancies, will also be reviewed.

**Results and conclusions:** Research in Progress

### References:

- 1) Bobb A, Gleason K, Husch M, et al. The epidemiology of prescribing errors. *Arch Intern Med* 2004;164:785–92
- 2) Todd AR et al. Pharmacist-versus physician-obtained medication histories. *Am J Health-Syst Pharm*. 2008; 65:857-60
- 3) Becerra-Camargo et al.: A multicenter, double-blind, randomized, controlled, parallel-group study of the effectiveness of a pharmacist-acquired medication history in an emergency department. *BMC Health Services Research* 2013 13:337

## Effect of a Sedation Protocol Revision on Sedative Use in the Medical Intensive Care Unit (MICU) in an Academic Medical Center

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**Background:** Critically ill patients requiring mechanical ventilation often receive sedatives to treat their agitation, anxiety, and pain, as well as improve ventilator synchrony.<sup>1</sup> However, sedatives have been identified as a predictor of prolonged mechanical ventilation durations, intensive care unit length of stays (ICU LOS) and hospitalizations. Continuous or deep sedation may limit physical exam interpretation, leading to difficulty distinguishing mental status changes due to sedative use or neurologic injury, and is associated with increased incidences of delirium and ventilator-associated events (VAEs).<sup>2-3</sup> In patients who are mechanically ventilated, daily interruptions of sedatives have been shown to decrease the duration of mechanical ventilation and ICU LOS.<sup>2</sup> The Society of Critical Care Medicine (SCCM) 2013 guidelines for pain, agitation, and delirium (PAD) recommend either daily sedation interruption (DSI) or a light target level of sedation be routinely used in mechanically ventilated adult ICU patients (grade +1B).<sup>4</sup>

**Objectives:** To evaluate the impact of an automatic daily sedation interruption (DSI) protocol and healthcare team education on sedative use in the MICU.

**Methodology:** There was a sedation protocol for mechanically intubated patients in the medical ICU (MICU) at the University of Toledo Medical Center (UTMC); however, this protocol did not include a required DSI. In 2015, the protocol was revised to include an automatic order for a DSI, unless contraindicated, to better reflect the 2013 SCCM guidelines on PAD with the intent of decreasing sedative use and improving patient outcomes. With this protocol change, the MICU clinical pharmacist provided education on the importance of DSI to both physicians and nurses. A retrospective chart review will be conducted pre- and post-sedation protocol implementation. All patients over 18 years of age, admitted to the UTMC MICU, and mechanically ventilated during August 1, 2013 to November 30, 2014 (pre-implementation) and December 1, 2015 to May 31, 2016 (post-implementation) will be included. Exclusion criteria include: pregnant patients, those whom life-sustaining support was withdrawn or expired within 48 hours of admission, those patients using sedatives for purposes other than sedation, and those remaining in the MICU after the study's stop date. Data to be collected will include: ICU admission date, ICU discharge date, reason for ICU admission, duration on mechanical ventilation, Acute Physiology and Chronic Health Evaluation (APACHE II) score, Riker Sedation-Agitation Scale (SAS) scores, pain scores, agitation scores, all sedatives and opioids administered, neurologic diagnostic studies, VAEs [e.g., ventilator-associated pneumonia (VAP), self-extubations, re-intubation, and survival to discharge. All data will be collected using the patient's electronic medical record.

**Results and conclusions:** To be determined

### References:

1. Hughes CG, Girard TD, Pandharipande PP. Daily sedation interruption versus targeted light sedation strategies in ICU patients. *Crit Care Med.* 2013;41(9 Suppl 1):S39-45
2. Robinson BR, Mueller EW, Henson K, Branson RD, Barsoum S, Tsuei BJ. An analgesia-delirium-sedation protocol for critically ill trauma patients reduces ventilator days and hospital length of stay. *J Trauma.* 2008;65(3):517-26.
3. Kress JP, Pohlman AS, O'connor MF, Hall JB. Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. *N Engl J Med.* 2000;342(20):1471-7.
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**Process Evaluation of a Pharmacist-Led Post-Discharge Transitional Care Clinic**

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**Background:** Transitioning between care settings is overwhelming to patients, especially regarding medication changes, putting the patient at increased risk of medication-related problems (MRPs).<sup>1-2</sup> Pharmacists are trained to identify medication-related problems; studies have shown that pharmacist involvement reduces adverse outcomes from MRPs.<sup>2-5</sup> In fall 2015, Cleveland VA outpatient clinics began seeing recently discharged patients in a pharmacist-driven Post-Discharge Transitions-of-Care Clinic. No standardized process for this pharmacy service currently exists.

**Objective:** The purpose of this project is to describe the current state of the Post-Discharge Transitions-of-Care Clinic, implement a standardized process to guide clinicians' consulting pharmacy, and to evaluate if standardization improves patient capture rate.

**Methodology:** This quality improvement project will be conducted through utilization of the electronic medical record and survey results. The targeted patient population includes all patients seen by a pharmacist and/or a provider in the outpatient clinics for a follow-up appointment after discharge from an inpatient facility. An electronic chart review of patients seen by the pharmacist and/or provider will be completed, and a survey will be administered to nurses and providers to determine factors leading to pharmacist consultation. Following review, a checklist, process map, and note template will be developed and implemented in the Akron, Mansfield, and Parma community based outpatient clinics (CBOCs). After implementation, prospective chart review will be completed on patients seen for post-discharge follow-up by a pharmacist and/or a provider through early spring 2017. The primary objectives include determination and characterization of the decision process for clinicians' consulting pharmacy, implementation of a standardized process for consultation to pharmacy service, and to evaluate the feasibility and impact of long-term implementation of a standardized process on clinicians utilizing the RE-AIM (Reach, Efficacy, Adopt, Implement, Maintenance) Framework. Secondary objectives will be to describe the clinic in terms of interventions, patient population seen, and clinician-patient interactions, as well as re-admissions within 30 days of the visit. Data collected will be analyzed using descriptive statistics.

**Results and conclusions:** To be determined

**References:**

1. Haynes KT, Oberne A, Cawthon C, Kripalani S. Pharmacists' recommendations to improve care transitions. *Ann Pharmacother.* 2012; 46: 1152-9
2. Ploenzke C, Kemp T, Naidl T, Marraffa R, Bolduc J. Design and implementation of a targeted approach for pharmacist-mediated medication management at care transitions. *J Am Pharm Assoc.* 2016; 56: 303-9
3. Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization. *Ann Intern Med.* 2009; 150: 178-87
4. Mekonnen AB, McLachlan AJ, Brien JE. Effectiveness of pharmacist-led medications reconciliation programmes on clinical outcomes at hospital transitions: a systematic review and meta-analysis. *BMJ Open.* 2016; 6: 1-14
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**Assessment of Select Components of CMS Core Measure Compliance in Patients with Malignancy and Neutropenic Sepsis**

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**Background:** Oncology patients are a fragile population that require special care. They are at an increased risk for infection due to reduced immune system functioning. Oncology patients often receive cytotoxic therapies as the mainstay of treatment which produces harmful effects to our body's cells. Bone marrow suppression is a limitation of cytotoxic drugs leading to neutropenia which predisposes patients to life-threatening infections.<sup>1</sup> Neutropenia is defined as an abnormally reduced number of neutrophils in the blood. Patients can be further described as having febrile neutropenia when they have a single temperature of  $> 38.3^{\circ}\text{C}$  or  $< 36^{\circ}\text{C}$ .

Many important variables impact the mortality rate, length of stay, and cost of healthcare for patients with febrile neutropenia. Mortality rates associated with febrile neutropenia have been reported as high as 20% and would likely be higher in patients with the complications associated with sepsis.<sup>2</sup> Patients with sepsis are often burdened by systemic inflammation, a procoagulant state, and hypotension.<sup>3</sup> It is important for all hospitals to follow best practices in order to help treat patients with sepsis in a timely and efficient manner.

The Centers for Medicare and Medicaid Services (CMS) has outlined core measures or best practices for patients that are diagnosed with severe sepsis and septic shock.<sup>4</sup> Identifying potential barriers to best practices will ultimately improve outcomes in oncology patients with neutropenic sepsis and severe sepsis or septic shock. Measuring compliance of select components of the core measure set forth by CMS will enable Cleveland Clinic Akron General to assess their current status and better serve patients in their community.

**Objectives:** The primary objective is to report the proportion of oncology patients with febrile neutropenia receiving empiric antibiotics within the CMS defined timeframe for treatment of severe sepsis and septic shock. The secondary objective is to identify predictors of CMS compliant empiric antibiotic treatment in oncology patients with severe sepsis and septic shock. Compliance or non-compliance will also be assessed for select components of the CMS core measure for severe sepsis or septic shock.

**Methodology:** This is a retrospective single center cohort study that will measure compliance of empiric antibiotic administration in oncology patients with febrile neutropenia and severe sepsis or septic shock.

**Results and conclusions:** The expected study results are to report the compliance of select components of the CMS core measure for severe sepsis and septic shock. Additionally, predictors of CMS compliant empiric antibiotic administration will be identified.

**References:**

1. Friefeld A, Bow E, Sepkowitz K, Boeckh M, Mullen C, Raad I, et al. Clinical Practice Guideline for the use of antimicrobial agents in neutropenic patients with cancer; 2010 Update by the Infectious Disease Society of American. *Clin Infect Dis* 2011, 52(4):e56.
2. Kuderer N, Dale D, Crawford J, Cosler L, Lyman G: Mortality, morbidity, and cost associated with febrile neutropenia in adult cancer patients. *Cancer* 2006. 106:2258-66.
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**Valproic acid induced hyperammonemia:  
Incidence, clinical significance, and treatment management**

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**Background:** Valproic acid induced hyperammonemia poses several clinical challenges in psychiatric medicine. The reported incidence of this adverse effect varies widely across the literature. Furthermore, many practitioners order ammonia levels and treat hyperammonemia in asymptomatic patients although studies suggest this practice is unnecessary and can lead to diagnostic confusion. Various treatment modalities, such as discontinuing valproic acid, reducing the dose, or beginning lactulose have been employed; however, researchers have attempted to determine if levocarnitine may be a better option for these patients as one risk factor that may contribute to elevated ammonia levels is carnitine deficiency.

**Objectives:** The purpose of this study is to evaluate the clinical implications of monitoring ammonia levels in potentially asymptomatic patients. This project's primary objective is to determine the incidence of hyperammonemia in psychiatric patients on valproic acid that had at least one ammonia level drawn during admission. The secondary objectives are to evaluate the incidence of symptomatic hyperammonemia and to evaluate the incidence and efficacy of various treatments for hyperammonemia.

**Methodology:** This study will be submitted to the Institutional Review Board for approval. Patients will be retrospectively identified through a database query from June 2011 to June 2016. Patients will be included if they were admitted to a psychiatric unit, received at least one dose of valproic acid, and had at least one ammonia level drawn during admission. Exclusion criteria include a diagnosis of cirrhosis at admission. Data will be extracted from a shared electronic medical record and uploaded into a secured collection database. Collected data points will include demographic information, diagnosis, symptoms of hyperammonemia, ammonia levels drawn during admission, and treatment modality chosen. Hyperammonemia will be defined as greater than 47 micromoles per liter. Symptomatic hyperammonemia will be defined based on symptoms, such as lethargy and altered mental status. Only patients with multiple ammonia levels drawn will be used to assess efficacy of treatment modalities. The ammonia levels will be trended during admission, and the treatment modality will be deemed successful if the ammonia level was within normal range (17 to 47 micromoles per liter) at discharge.

**Results and conclusions:** *In progress*

**References:**

1. Gugler R, von Unruh GE. Clinical pharmacokinetics of valproic acid. *Clin Pharmacokinet* 1980; 5:67.
2. Coulter DL, Allen RJ. Hyperammonemia with valproic acid therapy. *J Pediatr* 1981; 99:317.
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## **A Comparison of Customized Antimicrobial Stewardship Alerts between an External Clinical Decision Support System and a Large Electronic Health Record**

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### **Background:**

Antimicrobial resistance is increasing globally, with two million Americans acquiring a serious infection with resistant bacteria annually-23,000 of which lead to death<sup>1</sup>. Antimicrobial Stewardship (AMS) is a key method for curtailing resistance<sup>2</sup>. AMS may be performed passively (e.g. through formulary restrictions), but there are also opportunities for active AMS, commonly referred to as prospective audit and feedback, which is a cornerstone of AMS. An example of a powerful tool in facilitating active AMS is the use of Clinical Decision Support Systems (CDSS), which have been shown to improve adherence to guidelines, improve appropriateness of prescribing, may decrease costs and length of stay, and increase the efficiency of data review compared with passive strategies<sup>3-8</sup>. Clinical pharmacists throughout the Cleveland Clinic Health System utilize an external AMS CDSS tool separate from the electronic health record (EHR). Nineteen rules are currently in use, including opportunities for de-escalation or escalation, drug interaction monitoring, and adverse drug reaction prevention. Through an upgrade to the EHR, the same AMS CDSS rules utilized in the external CDSS can now be built into the EHR. The goal of the present study is to validate and implement AMS alerts within an EHR and compare their sensitivity, specificity, and usability to alerts generated from an external CDSS.

### **Objectives:**

The primary objective will determine the sensitivity and specificity of alerts by comparing the number of alerts generated in the external and internal systems by alert type. Secondary objectives measure usability of both systems by measuring the number of clicks necessary to address alerts in either system, number of redundant alerts, and user satisfaction as measured via Likert survey.

### **Methodology:**

This study is a pre-post observational study comparing the number and types of alerts generated within our EHR and the external CDSS throughout the Cleveland Clinic Health System between November 1<sup>st</sup> 2016 and March 31<sup>st</sup> 2017. All alerts will be included for the 4 month study period. Alerts in the EHR will first be validated in a test environment by assigning conditions which trigger or suppress alerts to ensure proper functionality. After validation, all triggered and suppressed alerts in both systems will be counted and categorized by type. Discrepancies in the number of alerts generated in the EHR will then be examined for cause. To evaluate usability, five infectious disease clinical pharmacy specialists will review AMS alerts in the EHR on a weekly rotating basis. The primary outcome will be evaluated using a paired t-test. The secondary outcomes of number of redundant alerts and number of clicks will be evaluated using the student t-test and user satisfaction will be measured using the Mann-Whitney U test.

### **Results and conclusions:**

Pending data collection

### **References:**

1. Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States. Atlanta; 2013
2. Society for Healthcare Epidemiology of America, Infectious Diseases Society of America, Pediatric Infectious Diseases Society. Policy statement on antimicrobial stewardship by the society for healthcare epidemiology of america (SHEA), the infectious diseases society of america (IDSA), and the pediatric infectious diseases society (PIDS). *Infect Control Hosp Epidemiol*. 2012 Apr;33(4):322-7.
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## Evaluation of PlasmaLyte on intraoperative acidosis in patients who undergo cardiopulmonary bypass

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**Background:** Fluid management plays an important role in intraoperative and postoperative care for patients who undergo cardiopulmonary bypass. There are many different fluids used for maintenance of intravascular volume, with normal saline (NS) being one of the most common. Although NS is commonly used, current literature shows that NS can cause hyperchloremia in acidotic patients, lengthening the duration of acidosis<sup>1-3</sup>. Literature also states that normal saline, also known as physiological saline, is neither “normal” or “physiological” due to its low pH of 5.4 and unbalanced electrolyte profile (Na<sup>+</sup> 154 mEq/L and Cl<sup>-</sup> 154 mEq/L) compared with human serum<sup>4</sup>. PlasmaLyte is calcium-free crystalloid solution that contains electrolyte concentrations (Na<sup>+</sup> 140 mEq/L, Cl<sup>-</sup> 98 mEq/L, acetate 27 mEq/L, gluconate 23 mEq/L, K<sup>+</sup> 5.0 mEq/L, Mg<sup>2+</sup> 3.0 mEq/L, and 294 mOsm/L) similar to plasma and has a more physiologic pH of 7.4<sup>5</sup>. In a study performed in 2014 by Young et al<sup>1</sup>, PlasmaLyte and NS were compared in a randomized control trial of 46 adult trauma patients. The primary outcome was changes in base excess from 0 to 24 hours. Mean change in base excess was significantly greater with PlasmaLyte compared to normal saline {7.5±4.7 vs 4.4±3.9 mmol/L; difference = 3.1 mmol/L [95% CI 0.5-5.6]}. This study aims to determine if patients that use PlasmaLyte as their primary intraoperative fluid have a lower rate of intraoperative acidosis compared to NS.

**Objective:** To evaluate the difference between PlasmaLyte and NS in incidence of acidosis on the last intraoperative arterial blood gas during cardiothoracic surgery requiring cardiopulmonary bypass.

**Methodology:** This study is a non-interventional retrospective chart review that will be submitted for IRB approval. The Society of Thoracic Surgeons database will identify patients who have undergone cardiothoracic surgery requiring cardiopulmonary bypass. The following data will be collected: baseline characteristics, intraoperative fluid balance, 24-hour fluid balance, arterial blood gas, systolic blood pressure, central venous pressure, amount of bicarbonate administered, albumin administration, basic metabolic panel, lactate, serum osmolality, intubation duration, vasopressor duration, mortality, new-onset atrial fibrillation, and acute renal failure. The primary endpoint will be difference in rate of acidosis, defined as base excess of less than -2, on the last intraoperative ABG, between groups. Secondary endpoints include differences in postoperative length of stay, duration of vasopressors, time to extubation, in-hospital mortality, 30-day mortality, incidence of new-onset atrial fibrillation, and acute renal failure between groups.

**Results and conclusions:** To be determined.

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**Impact of a continuous local anesthetic pain ball on post-operative pain in kidney transplant recipients**

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**Background:**

A multimodal approach for the management of post-operative pain utilizing local anesthetic wound infiltrations, such as the ON-Q pain ball, has gained momentum over the last decade. This multimodal approach has proven to be efficacious for reducing post-operative opioid consumption and opioid related complications in procedures involving the abdominal wall. However, data are controversial in regards to this multimodal approach for renal transplant (RT) recipients. The objective of this study is to determine the effectiveness of a continuous wound infusion of local anesthetic in the reduction of post-operative opioid consumption compared to traditional post-operative pain management in RT recipients.

**Objectives:**

Determine the effectiveness of a continuous wound infusion of local anesthetic compared to traditional post-operative pain management in renal transplant recipients.

**Methodology:**

This retrospective cohort study was approved by the Institutional Review Board at The University of Toledo Medical Center (UTMC). Patients 18 years and older admitted to UTMC from July 1, 2006 through July 30, 2016 with an ICD 9 or 10 code correlating to end stage renal disease or kidney transplantation will be screened for inclusion into the study. Eligible patient will have undergone kidney transplantation during the specified time period. The following data will be collected: age, gender, type of post-operative pain management regimen, type of transplant, post-operative pain scores, and post-operative opioid requirements. The primary endpoint will be the cumulative opioid consumption in intravenous morphine equivalents at 24, 48, and 72 hours following transplantation. Secondary outcomes will include the difference in post-operative pain scores (24, 48, and 72 hours), hospital length of stay, surgical wound infections, and a sub-group analysis of recipients of living donor versus deceased donor transplants.

**Results and conclusions:**

Data Collection in progress. Result to be determined.

**References:**

- 1) Williams M, Milner QJ. Postoperative analgesia following renal transplantation current practice in the UK. *Anaesthesia*. 2003 Jul;58(7):712-3.
- 2) Jankovic ZB, Pollard SG, Nachiappan MM. Continuous transversus abdominis plane block for renal transplant recipients. *Anesth Analg*. 2009 Nov;109(5):1710-1.
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## Evaluation of a pharmacist-driven darbepoetin optimization protocol

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**Background:** Anemia is a common disorder in patients who suffer from chronic diseases such as chronic kidney disease, chronic inflammatory conditions, and those patients receiving chemotherapy or zidovudine for human immunodeficiency virus infection.<sup>1</sup> Darbepoetin alpha (Aranesp®) is an erythropoietin-stimulating agent (ESA) FDA approved for the management of anemia of chronic disease. Based on the onset and duration of effect, darbepoetin use in the inpatient setting is unlikely to have an impact on hemoglobin values during an acute inpatient admission. Darbepoetin has been associated with increased risk of serious cardiovascular events and stroke, for which it bears a black box warning.<sup>2</sup> Moreover, darbepoetin has been identified as one of the top medications in our pharmacy drug budget. In view of this, the appropriate use of this medication in the inpatient setting must be ensured. A study by Clapp et al. on the therapeutic and cost-saving impact of a pharmacist-managed clinic for patients receiving ESAs, showed a yearly cost savings of about \$116,540.98, and an increase in mean serum hemoglobin concentration from 11.1 ± 0.9 g/dL at baseline to 11.8 ± 0.8 g/dL (p=0.015).<sup>3</sup> In a similar study, the implementation of an institutional epoetin-utilization management protocol led to a 25% reduction in inappropriate prescribing after protocol implementation, resulting in a 23.8% reduction in drug costs (p < 0.001).<sup>4</sup> The goal of this study is to evaluate the impact of a newly implemented darbepoetin pharmacy protocol.

**Objectives:** The primary objective is to compare cost and usage between pre- and post-implementation phases of a pharmacist-driven darbepoetin protocol. Secondary objectives include evaluation of adherence to the protocol, safety, efficacy and all-cause 30-day readmission rates post protocol implementation.

**Methodology:** This study has been approved by the institutional review board. This will be a pre- and post-analysis of darbepoetin use following the implementation of the pharmacist-driven darbepoetin protocol at Cleveland Clinic Marymount Hospital. The pre-phase of the study will include a retrospective evaluation of darbepoetin use that was completed between October 7, 2014 and January 17, 2015. The post-phase of the study will be a prospective evaluation of darbepoetin use from October 1, 2016 through February 28, 2017. All inpatients ≥ 18 years old with darbepoetin orders within the study period will be included. All orders for darbepoetin in the outpatient setting will be excluded. Data collection will include patient demographics, indication and dose of darbepoetin, hemoglobin level at therapy initiation, iron, folate and vitamin B<sub>12</sub> levels, as well as prescribing service. Safety data will include number of packed red blood cell transfusions prior to therapy initiation and during therapy, potential etiologies of persistent anemia, and all-cause 30-day readmission. Data will be analyzed using descriptive statistics. Student t-test will be used to evaluate the primary outcome. Cost analysis will be performed using the hospital's darbepoetin acquisition cost data.

**Results and conclusions:** To be determined.

### References:

1. Means RTJr, Krantz SB. Progress in understanding the pathogenesis of the anemia of chronic disease. *Blood*. 1992;80:1639–47.
2. Food and Drug Administration. Safety alert on erythropoiesis-stimulating agents. (Available at <http://www.fda.gov/Medwatch/safety/2006/safety06.htm#ESA2>. (Accessed August 13, 2016).
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## **Interventions and Cost Savings Associated with Pharmacy Resident Rounding on Weekends in a Medical Intensive Care Unit**

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**Background:** The American College of Critical Care Medicine has stated that pharmacists are an integral part of the intensive care team and recommend that a dedicated pharmacist participate in daily multidisciplinary rounds to reduce errors and improve quality of care.<sup>1</sup> Furthermore, a 1999 study by Leape, et al. used a historical control to show that by participating in rounds with the medical intensive care team, a pharmacist was able to decrease the number of preventable adverse drug events due to prescribing errors by 66% from 10.4 to 3.5 per 1,000 patient-days ( $p < 0.001$ ).<sup>2</sup> Despite the stated importance of critical care pharmacists, PROTECTED-UK by Shulman, et al. observed that only two out of twenty-one United Kingdom critical care units studied had pharmacist coverage on weekends. Overall there was a statistically significant increase in interventions on Mondays (24.1%) as compared to any other weekday (17.0-21.0%) ( $p = .01$ ) which may be attributed to lack of pharmacist presence on weekends.<sup>3</sup> At Cleveland Clinic Akron General (CCAG), two PGY-2 Critical Care Pharmacy residents have recently been added who rotate rounding with the medical intensive care unit (MICU) team on the weekends. The pharmacy residents also respond to code blue, stroke and trauma alerts, and chart review patients in other critical care units as time permits.

**Objectives:** The objective of this study is to describe the number and type of interventions made by pharmacy residents rounding in the MICU on weekends and associated medication, laboratory, and imaging cost savings.

**Methodology:** This study is a single-center, prospective, quality improvement project approved by the CCAG Institutional Review Board. Interventions made on weekends by the PGY-2 Critical Care Pharmacy residents from September 17, 2016 to December 31, 2016 will be categorized by type and analyzed for associated cost savings. A description of each intervention made per patient and physician acceptance rate will be recorded by the pharmacy residents. Types of interventions will include changing routes of administration, dosing adjustments, de-escalation or discontinuation of antibiotics, discontinuation of inappropriate medications, initiation of medications, medication reconciliation forms, non-medication interventions, participation in medical emergencies, renal dosing, and pharmacokinetics. Daily drug cost savings will be calculated by procurement price multiplied by frequency of drug administration. Total drug cost savings will equal the daily drug cost savings multiplied by 2 if the intervention was made on Saturday or 1 if made on Sunday, assuming the pharmacotherapy specialist would make this intervention on Monday when they return.

**Results and conclusions:** Research is currently in progress.

### **References:**

1. Brill R, Spevetz A, Branson RD, et al. Critical care delivery in the intensive care unit: Defining clinical roles and the best practice model. *Crit Care Med*. 2001; 29(10): 2007-19.
2. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA*. 1999; 282: 267-70.
3. Shulman R, McKenzie CA, Landa J, et al. Pharmacist's review and outcomes: Treatment-enhancing contributions tallied, evaluated, and documented (PROTECTED-UK). *J Crit Care*. 2015; 30: 808-13.

**Tolerability of aerosolized versus intravenous pentamidine for Pneumocystis Jirovecii Pneumonia prophylaxis in immunosuppressed pediatric patients**

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**Background:** At a pediatric academic children's hospital, pentamidine is a commonly used alternative for Pneumocystis Jirovecii Pneumonia (PJP) prophylaxis when the drug of choice, sulfamethoxazole-trimethoprim, is not tolerated due to adverse reactions. Pentamidine is an antifungal medication that is administered, aerosolized or intravenously, every 2 to 4 weeks. Current evidence has shown safety and efficacy of aerosolized and intravenous formulations as PJP prophylaxis in young children, but there is a lack of literature comparing tolerability between the two administration routes.

**Objective:** The primary objective of this study is to determine the tolerability of aerosolized versus intravenous pentamidine for PJP prophylaxis in immunosuppressed pediatric patients.

**Methodology:** This retrospective study will be submitted to the local Institutional Review Board for approval. The study will assess the incidence and types of adverse reactions associated with pentamidine prophylaxis in immunosuppressed pediatric patients over the past 3 years, from January 1, 2014 to January 1, 2017. Study variables will be retrieved from the electronic medical record (EMR). The following data will be collected: patient gender, ethnicity, age, patient weight, allergy history, location of administration, primary diagnosis, concurrent medications (if applicable), cycle of chemotherapy (if applicable), days from transplant (if applicable), pentamidine dose, dosage form, frequency, infusion duration, pre-medications, immunosuppressive therapy, type of reaction, history of sulfamethoxazole-trimethoprim use, number of pentamidine doses before reaction, absolute neutrophil count (ANC), and Immunoglobulin E serum concentrations. The information for each reaction will be categorized for both administration routes and compared relative to the collected variables focusing on dosage, route, use of concurrent immunosuppression, and the reaction(s). Non-parametric statistics and frequency analysis will be used to assess differences between the two routes of administration. Linear regression will be used to evaluate the variable(s) to determine if there is any association with a greater likelihood of route-induced reaction.

**Results and conclusions:** Results and conclusions are to be determined, thus will be presented at a later date.

**References:**

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3. Levy ER, Musick L, Zinter MS, et al. "Safe and Effective Prophylaxis with Bimonthly Intravenous Pentamidine in the Pediatric Hematopoietic Stem Cell Transplant Population". *Pediatr Infect Dis J.* 2016 Feb; 35(2):135-41.

**Evaluation of a Heparin Anti-Xa Monitoring Protocol**

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**Background:** Intravenous (IV) heparin is an anticoagulant of choice for thromboembolic conditions such as acute coronary syndromes, deep vein thrombosis, and pulmonary embolism.<sup>1</sup> Due to heparin's narrow therapeutic window, timely monitoring and adjustment of doses is necessary. The anticoagulant effect of heparin is usually monitored by the activated partial thromboplastin time (aPTT), with a therapeutic range of 1.5 to 2.5 times the control. The aPTT is a test that is sensitive to the inhibitory effects of heparin on thrombin, factor Xa, and factor IXa.<sup>2</sup> The aPTT must be calibrated to an antifactor Xa assay before use, and the correlation of aPTT to the antifactor Xa is variable. Due to this variability of the aPTT test, recent literature indicates superiority of clinical outcomes with anti-Xa assays than with aPTT.<sup>3</sup> On July 12, 2016, the Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC) implemented an anti-Xa heparin monitoring protocol in place of a prior aPTT monitoring protocol.<sup>4</sup> The anti-Xa monitoring protocol is a nurse driven protocol that is divided into low intensity and high intensity. The provider may order a nurse managed protocol if the patient meets criteria based on indication and treatment goals. The anti-Xa nurse driven protocol is divided into low and high intensity ordering options. This quality assurance (QA) project will evaluate the nurse driven heparin anti-Xa protocol initiated by the LSCVAMC.

**Objectives:** The primary endpoint is the time to first therapeutic anti-Xa level. Secondary endpoints include the number of patients who reached a therapeutic level within 24 hours, average initial bolus, average initial infusion rate, average therapeutic infusion rate, compliance to the anti-Xa protocol, and correlation between therapeutic anti-Xa levels and PTT drawn at the same time for patients being bridged to warfarin. Safety endpoints include major bleeding (drop in hemoglobin of greater than 2 g/dL, need for a transfusion of 2 or more units of blood, or a bleed of the retroperitoneum, cranium, or prosthetic joint), minor bleeding (all documented bleeding not meeting major bleed criteria), HIT (greater than a 50% drop in platelet count), and critical anti-Xa values.

**Methodology:** A retrospective chart review will be performed on 100 patients who have been on the heparin anti-Xa protocol for at least 24 hours, up to 4 days or until heparin is stopped or interrupted. Patients who were already included in the study during a prior admission, patients on the anti-Xa protocol for less than 24 hours, patients with a ventricular assist device (VAD), and patients on a physician-managed heparin protocol will be excluded. Data points to be collected include patient admission date, age, weight, baseline platelet count, location in the hospital at the time of heparin initiation, lab collect or ward collect, diagnosis, high or low intensity protocol, heparin start date and time, initial bolus dose (mL), initial infusion rate (mL/hr), therapeutic infusion rate (mL/hr), therapeutic anti-Xa level, therapeutic anti-Xa level date and time, time to therapeutic anti-Xa (hours), estimated percentage of time spent in therapeutic range (hours), number of anti-Xa labs per day, % of anti-Xa labs that were subtherapeutic, therapeutic, supratherapeutic, or critical, and PT/INR if bridging to warfarin. To determine compliance to the anti-Xa protocol, the following will be evaluated: appropriate choice of high or low intensity protocol, correct initial dose, correct adjustment of doses based on level, time of lab draw, and parameters for holding heparin in the instance of a critical anti-Xa value. The data will be analyzed using descriptive statistics.

**Results and conclusions:** To be determined.

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2. Rosborough TK and Shepherd MF. Achieving Target Antifactor Xa Activity with a Heparin Protocol Based on Sex, Age, Height, and Weight. *Pharmacotherapy*. 2004;24(6):713-19.
3. Rosenberg AF, Zumberg M, Taylor L, et al. The Use of Anti-Xa Assay to Monitor Intravenous Unfractionated Heparin Therapy. *Journal of Pharmacy Practice*. 2010;23(3):210-16.
4. Williams TD, Sullivan K, Lacey C, et al. Nurse-Driven Intravenous Heparin Protocol. *AACN Advanced Critical Care*. 2010;21(2):152-161.

**Prevalence and predictors of antipsychotic prescribing in adults with Parkinson's disease. A national cross-sectional study.****Richard Chan, Pharm. D.,** Mate Soric, Pharm. D., BCPS

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**Background:** Parkinson's disease is a complex neurological disorder that has been estimated to affect up to 7.5 million people worldwide.<sup>1</sup> A cross sectional study from 2010 concluded that psychosis occurs in as much as 60% of patients with Parkinson's disease.<sup>2</sup> Antipsychotics are the drug of choice for psychosis, though the efficacy of antipsychotics in patients with Parkinson's disease psychosis has been conflicting. A recent review evaluated the evidence for the treatment of Parkinson's disease psychosis and found that clozapine was effective at lower doses to treat psychosis without a significant change in motor functions in two placebo-controlled trials. Quetiapine was shown to be effective in multiple open label studies but failed to show efficacy in three double blind trials, though it did not show a worsening of motor functions. Other antipsychotics have not had any compelling evidence supporting their efficacy in treating Parkinson's disease psychosis.<sup>3</sup> The prescribing of antipsychotics in patients that have Parkinson's disease, with or without psychosis, has been associated with a marked increase in mortality.<sup>4,5</sup> A recent cohort study of the Veterans Health Administration reported that antipsychotic use was associated with more than a two-fold risk of mortality compared to nonuse in patients with Parkinson's disease.<sup>5</sup> This finding stresses the importance of the need to be cautious with the prescribing of antipsychotics in patients that have Parkinson's disease. With psychosis developing in over half of all Parkinson's disease patients, the decision to treat with antipsychotics to reduce the strain on both patient and caregiver quality of life versus the potential increased risk of death must be considered. The goal of this study will be to describe the prevalence, predictors and quantity of the specific antipsychotics utilized in adults with Parkinson's disease.

**Purpose:** The objective of this study is to evaluate the prevalence of and factors that are associated with prescribing antipsychotic medications in patients with Parkinson's disease in an outpatient population.

**Methods:** This national cross-sectional study will use data from the National Ambulatory Medical Care Survey (NAMCS) from 2008 through 2013. This study will be submitted to the Institutional Review Board for approval. Upon IRB approval, data sets for the years 2008 through 2013 of the NAMCS will be obtained through the Centers for Disease Control and Prevention website. The de-identified data sets will be combined and evaluated to include patients that are at least 65 years old with diagnosis of Parkinson's disease. Patients who have a diagnosis of bipolar disorder, schizophrenia, Lewy body dementia or secondary Parkinsonism will be excluded from the study. The primary outcome will be the rate of antipsychotic prescribing, as well as the classification of the antipsychotic prescribed, in patients who have Parkinson's disease. Multivariate logistic regression will be used to identify variables that may be associated with prescribing antipsychotics in this patient population, including: patient demographics, payer type, co-morbid conditions and prescriber characteristics.

**Results and conclusions:** Results and conclusions are pending data collection and will be presented at the Ohio Pharmacy Residency Conference.

**References:**

- (1) Pringsheim T, Jette N, Frolkis A, Steeves TD. The prevalence of Parkinson's disease: a systematic review and meta-analysis. *Mov Disord.* 2014;29(13):1583-1590.
- (2) Fénelon G, Soulas T, Zenasni F, Cleret de Langavant L. The changing face of Parkinson's disease-associated psychosis: a cross-sectional study based on the new NINDS-NIMH criteria. *Mov Disord.* 2010;25(6):763-766.
- (3) Friedman, J.H. Parkinson disease psychosis: Update. *Behav Neurol.* 2013 Jan 1;27(4):469-77.
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**A novel outpatient service for diabetic vaccination provided by an inpatient pharmacy**

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PGY1 General Pharmacy Practice Residency  
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**Background:**

Roughly 10,000 – 30,000 diabetic patients in the U.S. die annually from complications associated with influenza and pneumonia. Only one half of adult diabetics receive an annual influenza vaccination and only one third are adequately immunized against pneumococcal disease.<sup>1</sup> According to the American Society of Health-System Pharmacists (ASHP), trends in inpatient pharmacy practice over the next five years will focus on outpatient services and preventative care with the intent of reducing hospital admissions and other costs associated with acute illness.<sup>2</sup> The purpose of this project is to establish a novel outpatient vaccination service through an inpatient pharmacy within a local community hospital. Diabetic patients from the community were recruited to receive influenza and pneumococcal vaccinations at an on-site health fair.

**Objectives:**

To develop a protocol for administration of outpatient vaccinations under an authorizing physician, establish a method of patient registration for the provision of billable services, administer vaccinations under protocol to diabetic patients at an on-site community health fair, and determine the feasibility of providing this community service on a larger scale.

**Methodology:**

An immunization protocol specific to a diabetes health fair was developed and agreed upon between the inpatient pharmacy and authorizing physician. The protocol was tailored to meet federal and state of Ohio laws, rules, and regulations. The inpatient pharmacy offering the service, lacking outpatient software, consulted Patient Access/Registration personnel to create a method of outpatient billing within the pre-existing inpatient electronic medical record (EMR). Patients who displayed interest at a health education seminar three weeks prior were pre-registered and screened for insurance coverage by Patient Access/Registration. Courtesy reminder calls were provided to patients eligible for full coverage of vaccination prior to the health fair. Additional diabetic patients were recruited through flyers distributed by physician's offices, marketing calls, and newspaper advertisements encouraging walk-ins for immunization.

**Results and conclusions:**

Of the 15 patients who pre-registered for the health fair, nine received vaccinations. There were two additional walk-in patients on the day of the event, for a total of 11 patients immunized. One pneumococcal and 10 influenza immunizations were administered. Additional results will be discussed at the time of the conference.

**References:**

1. U.S. Centers for Disease Control and Prevention (CDC). Flu and Pneumonia Vaccinations Decrease Relative Morbidity Risk for People with Diabetes. [Accessed: October 2, 2016.] [Available at: <http://www.cdc.gov/diabetes/projects/pdfs/hpnewsletter.pdf>].
2. Zellmer WA, ed. Pharmacy forecast 2016-2020: strategic planning advice for pharmacy departments in hospitals and health systems, December 2015. Bethesda, MD: ASHP Research and Education Foundation. [Accessed: September 10, 2016]. [Available from: [www.ashpfoundation.org/pharmacyforecast/](http://www.ashpfoundation.org/pharmacyforecast/)].

**Utilization of clotting factor concentrates at a tertiary medical center**

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**Background:** Hemostasis is a mechanism initiated in the circulatory system to arrest blood flow. This process is achieved through recruitment of platelets to the site of bleeding and blood coagulation initiated by tissue factors. Deficiency or absence of clotting factors is associated with deficits in the pathway responsible for thrombus formation leading to bleeding complications. The standard of care for management of clotting factor deficient conditions, such as hemophilia and von Willebrand's disease, is prevention and/or treatment of bleeding through replacement of deficient clotting factors.<sup>1,2,3</sup> Due to the high cost of clotting factor concentrate products, institutions have implemented factor stewardship programs to balance efficacy, safety, and fiscal responsibility.<sup>4,5</sup> Current practice at our institution restricts clotting factor usage to hematology approval for formulary approved agents. The purpose of this project is to characterize a current usage state in an effort to identify other areas of opportunity for formulary optimization.

**Objectives:** The objective of the study is to characterize the current usage of clotting factor concentrate products among those utilized at a tertiary medical center. Secondary objectives include evaluation of efficacy, safety, and financial analysis for clotting factor concentrate products.

**Methodology:** This study has been submitted to the Institutional Review Board for approval. The design of this research is a single-center, retrospective cohort study of patients who received at least one dose of a clotting factor concentrate product during an inpatient hospitalization from August 1<sup>st</sup>, 2015 through July 31<sup>st</sup>, 2016. Patients will be identified through the electronic medical record. Patients  $\geq$  18 years old with a factor deficient condition who received factor VIIa, factor VIII, factor IX, factor X, factor XIII, anti-inhibitor coagulant complex, or fibrinogen concentrate will be included in the study. Patients < 18 years old, receiving clotting factor concentrates for anticoagulation induced bleeding or thromboelastography monitoring will be excluded from this study. Data to be collected includes: patient demographics, type of factor deficient condition, admitting diagnosis, current factor product used outpatient and dosing regimen, factor(s) used inpatient and dosing regimen, pertinent lab values prior to and following factor use (CBC, fibrinogen, PT/INR, factor levels, inhibitor levels), length of hospital stay including days spent in the intensive care unit, transfusions required, thrombotic events, use of alternative or adjuvant treatments, discharge status, and readmission within 30 days. Additionally pharmacy analytic and wholesaler reports will be utilized for financial information related to site factor usage.

**Results and conclusions:** Research is currently in progress.

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**Comparison of the use of aripiprazole and quetiapine for the adjunctive treatment of Major Depression (MDD)**

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**Background:** According to the World Health Organization, major depressive disorder (MDD) is associated with the greatest degree of disability among mental and behavioral disorders<sup>1</sup>. MDD is a mood disorder characterized by persistent low mood or irritability that often leads to changes in weight, appetite, sleep, energy, and concentration. Despite many treatment options, approximately 70% of patients experience non-response to initial monotherapy with a first-line antidepressant and often require switching to a different antidepressant or augmentation with other agents.<sup>2</sup> Since aripiprazole gained FDA approval in 2007 as adjunctive treatment of MDD in adults, second generation antipsychotics (SGAs) aripiprazole and now quetiapine have become a mainstay in treatment. Currently, limited data exist comparing these two adjunctive agents.<sup>3</sup> The purpose of this study is to compare aripiprazole and quetiapine in the augmentation of selective serotonin uptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs) to determine their effects on inpatient psychiatric admission rates and time to discontinuation. In addition we will compare the two medications and assess the reason for discontinuation (lack of efficacy, adverse drug event, lost to follow-up, or patient non-adherence).

**Objectives:** The primary objectives are to compare antidepressant augmentation with oral aripiprazole and quetiapine and their effects on inpatient psychiatric admissions and discontinuation rates. Secondary objectives will compare antidepressant augmentation with oral aripiprazole and quetiapine and their influence on reasons for discontinuation.

**Methodology:**

Patients will be identified for inclusion in the study through a pharmacy generated patient list including all patients with diagnosis of major depressive disorder and bipolar disorder based on ICD 9 and 10 codes who received prescriptions aripiprazole and quetiapine plus a SSRI or SNRI from January 1, 2007 to September 1, 2015. Patient charts will be reviewed retrospectively to identify patients that meet inclusion criteria via electronic medical record. This study aims to enroll 200 patients with a diagnosis of major depressive disorder or bipolar disorder who were initiated on oral aripiprazole or quetiapine as adjunctive agents to antidepressants. We will include adult patients who have current diagnosis of major depressive disorder or bipolar disorder on a SSRI or SNRI with aripiprazole or quetiapine augmentation. Patients with current diagnosis of delirium, dementia, amnesic or other cognitive disorders, schizophrenia, and patients on concomitant psychiatric medications (mood stabilizers, antipsychotics other than aripiprazole or quetiapine, antidepressants other than SSRIs and SNRIs, thyroid hormone used as augmentation, stimulants, mirtazapine >15mg, trazodone >300mg, and buspirone) will be excluded.

**Results and conclusions:** Research In Progress

**References:**

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**Dosing of Enoxaparin in Morbidly Obese Individuals: A Retrospective Cohort****Michael Czupryn, PharmD**; Cristal Exline, PharmD, BCPSEmail address: [czuprym@ccf.org](mailto:czuprym@ccf.org) PGY-1 Clinical Pharmacy Resident

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**Background:** The prevalence of morbid obesity in the U.S. has been trending upwards since 2005.<sup>1</sup> Obesity significantly affects the pharmacokinetics of low molecular weight heparins like enoxaparin. Enoxaparin is dosed on total body weight; however, the appropriateness of this strategy in morbidly obese patients is still undetermined. Studies investigating the effect of non-standard doses on Factor Xa levels in this population have shown mixed results with the majority indicating higher incidence of supratherapeutic levels.<sup>2-4</sup> Additionally, there is a paucity of evidence analyzing thrombosis and bleeding risk in this population. Existing trials have had small sample sizes or focused only on a single indication making it difficult to observe a significant difference.<sup>2-5</sup>

**Objective:** The primary objective of this study is to evaluate incidence and risk of major bleeding between different enoxaparin dosage strategies in patients weighing greater than or equal to 120 kg receiving treatment doses of enoxaparin.

**Methodology:** This study will be completed using patient medical records stored in Epic®, the shared medical record system for all Cleveland Clinic Hospitals. Patient data will be extracted for three community hospitals from the past five years. Patients will be included in the primary analysis if they received enoxaparin with the intent of full anticoagulation for more than 24 hours, weighed greater than or equal to 120 kg at the time of treatment, and had outcomes data documented throughout the course of therapy. Data will be collected for patients with a creatinine clearance less than 30 mL/min (including dialysis patients) and pregnant patients for the purposes of an ad-hoc subgroup analysis, but this data will be excluded from the primary analysis. Patients less than 18 years old, patients with no creatinine or weight data, and patients with documented heparin induced thrombocytopenia will be excluded. The incidence of primary outcomes occurring within seven days of therapy will be compared between patients receiving an enoxaparin dose less than 0.9 mg/kg twice daily and greater than or equal to 0.9 mg/kg twice daily and also between patients weighing greater than or equal to 150 kg and less than 150 kg.

**Results and conclusions:** N/A

**References:**

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3. Lalama JT, Feeney ME, Vandiver JW, Beavers KD, Walter LN, McClintic JR. Assessing an enoxaparin dosing protocol in morbidly obese patients. *J Thromb Thrombolysis*. 2015 May;39(4):516-21.
4. Deal EN, Hollands JM, Riney JN, Skrupky LP, Smith JR, Reichley RM. Evaluation of therapeutic anticoagulation with enoxaparin and associated anti-Xa monitoring in patients with morbid obesity: a case series. *J Thromb Thrombolysis*. 2011 Aug;32(2):188-94.
5. Spinler SA, Ou FS, Roe MT, Gibler WB, Ohman EM, Pollack CV, et al. Weight-based dosing of enoxaparin in obese patients with non-ST-segment elevation acute coronary syndromes: results from the CRUSADE initiative. *Pharmacotherapy*. 2009 Jun;29(6):631-8.

**Automated dispensing cabinet optimization to reduce incidence of medication stock outs****Matthew D. Delisle, PharmD**

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PGY-1

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6780 Mayfield Road, Mayfield Heights, OH 44124**Background:**

The proper use of automated dispensing medication cabinets can enhance patient safety, reduce medication error rates and lead to greater efficiency in pharmacy processes and procedures.<sup>1</sup> Hillcrest hospital utilizes Pyxis™ medication cabinet technology, which is capable of assigning maximum and minimum drug levels. Automated dispensing cabinets can be refilled with a scheduled fill or a percentage trigger threshold. The use of scheduled fills at Hillcrest Hospital resulted in an average stock out incidence of 12.7%.

**Objectives:**

The primary objective is to determine the percentage decrease of a stock out incidence with the implementation of percentage trigger threshold compared to scheduled fills. The secondary objective is to determine the work flow impact in central pharmacy with the implementation of percentage trigger thresholds measured by: hourly volume based on capacity to fill, technician time to complete a delivery round, productivity in other technician tasks (ex. packaging) and allocation of technician FTEs.

**Methodology:**

The study will be conducted in a 510-bed acute and tertiary care hospital. The percentage trigger thresholds will be activated and monitored by a report of the following criteria: drug name, location of drug, time of day order when was processed, time of day order placed in carousel queue, and order type (new order, stat, cart fill, stock out, Pyxis™ replenishment). Test groups will be created to determine when the CBL is used at different percentages, 25%, 50% and 75%. Statistical tests include chi square tests for the primary objective and descriptive statistics for secondary objectives. A stock out rate calculation (incidence of stock outs divided by the incidence of stock out plus the incidence of Pyxis™ replenishments) will be performed to determine the average incidence of stock outs for each group.

**Results and conclusions:**

The anticipated start date of the study is 4<sup>th</sup> quarter 2016. Study results and conclusions will be reported upon final completion of the study.

**References:**

1. Temple J, Ludwig B. Implementation and evaluation of carousel dispensing technology in a university medical center pharmacy. *Am J Health Syst Pharm.* 2010; 67: 821-9.
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## **The impact of offering a urinalysis with reflex to culture on antibiotic usage and utilization of urine studies for patients admitted to an internal medicine service**

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### **Background:**

The overuse of antibiotics has led to complications such as greater antibiotic resistance and rising health care costs. One disease syndrome that has been evaluated is antibiotic use in urinary tract infections (UTI's). In an effort to reduce healthcare costs many hospitals have instituted reflex testing of urine specimens based on predetermined micro- and macroscopic findings of a urinalysis. One study utilized a modified reporting of urine cultures and found a 20% reduction in the treatment of asymptomatic bacteriuria.<sup>1</sup> Other studies have evaluated the use of urine studies, but there are inconsistencies in the literature whether a urinalysis with reflex to culture leads to an increase or decrease in the number of urine cultures performed.<sup>2,3</sup>

In February 2016 Cleveland Clinic Akron General made a urinalysis with reflex to culture order available for patients admitted to the hospital. Although current literature supports that by utilizing urinalysis criteria to determine when to perform a culture results in a decrease in the number of urine cultures performed and a trend toward a decrease in antibiotic use, the impact of simply offering a urinalysis to reflex culture has not been evaluated.<sup>1-3</sup> This practice would allow clinicians to reevaluate the need for a culture based on a clinical suspicion of UTI, hopefully reducing the number of cultures done on asymptomatic patients. It may also impact the use of antibiotics since clinicians are able to have a culture performed reflexively on a urine sample taken before antibiotics are given without ordering a urine culture on every patient.

### **Objectives:**

The overall study objective is to determine the impact of offering a urinalysis to reflex culture on antibiotic usage and the utilization of urine studies among patients admitted to Cleveland Clinic Akron General. The impact will be studied at an institutional level (urine studies) and in a subgroup of patients who had a urinalysis performed upon admission to an internal medicine teaching service (urine studies and antibiotic usage).

### **Methodology:**

This is a retrospective, single center, pre-post study to assess the impact of offering a urinalysis to reflex culture on the usage of antibiotics and urine studies for adult patients on an internal medicine teaching service. The impact on urine studies will also be assessed across the entire institution.

### **Results and conclusions:**

The expected study results are to present the rate of treatment with antibiotics, proportion of urinalysis to urine cultures performed, how urine cultures were ordered (reflex or not), and proportion of positive cultures. Additional secondary outcomes from a subgroup of patients will be compared by the ordering method in which the urine culture was obtained and will determine the proportion of patients who receive antibiotic therapy prior to urine culture.

### **References:**

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3. Dietz J, Lo TS, Hammer K, et al. Impact of eliminating reflex urine cultures on performed urine cultures and antibiotic use. *Am J Infect Control* 2016:1-2.

**Use of dexamethasone vs. prednisolone eye drops for prevention of high-dose cytarabine-induced conjunctivitis**

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**Background:**

Conjunctivitis is an established adverse event with high-dose cytarabine ( $\geq 1000$  mg/m<sup>2</sup>). Cytarabine has the ability to penetrate body fluids including the blood-brain barrier and aqueous humor in tears. Corneal toxicity is related to the concentration and duration of exposure to cytarabine in the aqueous humor.<sup>1</sup> Approximately 40-65% of patients receiving high-dose cytarabine experience this adverse effect. Common ocular symptoms experienced by the patient include: blurred vision, severe discomfort or burning pain, photophobia, decreased visual acuity, tearing, and foreign body sensation. Topical prophylaxis with corticosteroid eye drops has been effectively used to prevent this toxicity,<sup>2</sup> however, there is limited literature on the use of these agents for this indication. Without corticosteroid therapy, the incidence of conjunctivitis is reported to be 85-92%.<sup>3</sup> One study found that 13/29 (45%) of patients who received dexamethasone (dex), experienced conjunctivitis, with 12/13 having grade 2-3 ocular toxicity.<sup>2</sup> Another study with 9 patients that received prednisolone (pred) eye drops, 5/9 (55%) patients experienced conjunctivitis.<sup>4</sup> Since no head-to-head study has been conducted to date that directly compares the efficacy of dex vs. pred eye drops, this project will determine whether rates of cytarabine-induced conjunctivitis will differ between the two treatments.

**Objective:**

To compare the incidence of conjunctivitis with prophylactic dexamethasone versus prednisolone eye drops in patients receiving high-dose cytarabine.

**Methodology:**

Data will be retrospectively collected through a non-interventional medical chart review. The calculated sample size needed for 80% power with one-sided  $\alpha = 0.025$  and 20% non-inferiority margin is 237 cycles of high-dose cytarabine. Approximately 100 to 150 patients will be included if they are  $\geq 18$  years old and received high-dose cytarabine ( $> 1000$  mg/m<sup>2</sup>) as a component of the acute myeloid leukemia post-remission regimen. Patients will be excluded if they received eye drops other than prophylactic dex 0.1% or pred eye drops 1% (administered as 2 drops in each eye every 6 hours starting prior to first cytarabine dose and continued until at least 48 hours after the last cytarabine dose), and if they received additional eye drops concomitantly with dex or pred eye drops. Patients with pre-existing eye conditions (infection, glaucoma, etc) or patients who received concomitant chemotherapy in addition to cytarabine will be excluded. Screening data will include: age, gender, weight, body mass index, disease type and baseline serum creatinine (SCr). For each chemotherapy cycle, cytarabine dose, SCr, and administrations of total body irradiation, pred vs. dex eye drops, and intravenous dexamethasone will be collected. The primary endpoint is the incidence of conjunctivitis. Documented symptoms may include blurred vision, discomfort, photophobia, tearing, and foreign body sensation. The primary endpoint will be analyzed using Fisher's Exact test. Secondary endpoints include the incidence of conjunctivitis following first cycle of high-dose cytarabine, duration and severity (per National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03) of conjunctivitis in patients receiving pred eye drops vs. dex eye drops for prophylaxis.

**Results and conclusions:** To be determined.

**References:**

1. Bubalo, J., Prevention and Treatment of Cytarabine-Induced Keratoconjunctivitis. *Journal of Hematology Oncology Pharmacy*, 2015. 5(1): p. 13-15.
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## **Potential impact of a clinical pharmacist on treatment of urinary tract infections among older adults diagnosed at the emergency department**

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**Background:** Urinary tract infections (UTIs) are one of the most common infections in patients over 65 years old. Despite the frequency, research has shown many instances where UTIs are over-diagnosed and over-treated. The over-diagnosis is well documented in long-term care, hospitalized, and community-dwelling older adults with new research now focusing on the emergency department.<sup>1-2</sup> This is especially harmful in the older adult population as it leads to bacterial resistance and potential adverse drug events.<sup>4</sup>

Pharmacists can provide beneficial services in the emergency department which impact overall optimization of antimicrobial stewardship. This can be completed through chart review, analyzing resulting cultures, and contacting the patient for follow up. While this impact is generally identified, few studies have analyzed the impact solely on UTI.<sup>5</sup> The potential impact of pharmacy on the management and follow up care in older adults diagnosed with a UTI in this environment is unknown

**Objectives:** The primary objective of this study is to evaluate the potential for pharmacy to intervene based on urinary culture results in patients  $\geq 65$  years without a chronic catheter presenting to the emergency department who received a diagnosis of UTI within a nine month time frame. Interventions will include number of antibiotics that could have been discontinued based on negative cultures, number of mismatches between microbiological culture and patient-directed therapy, and number of antibiotics that could have been narrowed based on culture results. Secondary outcomes will include presentation of symptoms in the older adult population based on the Loeb criteria<sup>5</sup>, specific use of antibiotics, number of unnecessary days of antibiotic therapy remaining with negative cultures, and incidence of negative urine cultures and negative urinalyses.

**Methodology:** This evaluation will be a retrospective cohort study of patients discharged from the emergency department with a primary or secondary diagnosis of urinary tract infection. A list of patients will be identified based on urinary cultures collected between January 2015 and September 2015. Patients will be included if they are  $\geq 65$  years old, were diagnosed with a UTI, and were prescribed antibiotics on discharge. Exclusion criteria include patients admitted to the hospital, presence of a chronic indwelling urinary catheter or temporary foley catheter, identification of polymicrobial urinary culture, co-infection with bacteremia, or lack of a provider note with data concerning the patient's diagnosis. Additional data collected will include patient demographics and medical co-morbidities, sensitivity and resistance patterns, incidence of adverse drug events, and method of urine collection. All data will be presented using descriptive statistics.

**Results and Conclusions:** Pending

### References

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2. Gordon LB, Waxman MJ, Ragsdale L, Mermel LA. Overtreatment of presumed urinary tract infection in older women presenting to the emergency department. *JAGS*. 2013;61(7):788-792.
3. Nicolle LE, Mayhew WJ, Bryan L. Prospective randomized comparison of therapy and no therapy for asymptomatic bacteriuria in institutionalized elderly women. *Am J Med*. 1987;83(1):27-33.
4. Lingenfelter E, Drapkin Z, Fritz K, et al. ED pharmacist monitoring of provider antibiotic selection aids appropriate treatment for outpatient UTI. *Am J Emerg Med*. 2016;34(8):1600-3.
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## Implementation of Matrix-Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) and BD Phoenix™ Automated Microbiology System at an Academic Medical Center

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**Background:** Blood stream infections (BSIs) are associated with increased morbidity and mortality in hospitalized patients.<sup>1</sup> Prompt organism identification is vital for optimizing antimicrobial therapy in patients with BSI and decreasing morbidity and mortality as well as antimicrobial resistance. To help improve treatment of BSIs, several rapid diagnostic tests (RDT), such as the Matrix-Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF), have been developed. MALDI-TOF identifies a wide range of microorganisms and decreases time to organism identification by 1.2 to 1.5 days compared to conventional methods.<sup>2,3</sup> Studies have shown that RDTs along with antimicrobial stewardship programs help improve time to effective therapy and have a positive impact on patient outcomes including mortality in patients with BSI.<sup>3,4</sup> The objective of this study is to assess the impact of this combined approach on the management of BSIs at the University of Toledo Medical Center (UTMC).

**Objective:** The goal of this study is to determine whether the implementation of this technology combined with ASP intervention will decrease time to effective antimicrobial therapy in patients with blood stream infections.

**Methodology:** This study is an IRB-approved single-center pre-post quasi-experiment. Patients treated for a documented BSI at UTMC between January 1, 2015 and December 31, 2016 will be included. Patients will be excluded if they were transferred from an outside hospital with a documented BSI or had blood cultures that grew *Mycobacterium* species, *Nocardia* species, anaerobic organisms, or filamentous fungi. Outcomes will be compared between pre- and post-MALDI-TOF implementation groups. Primary endpoint of time to effective antimicrobial therapy is defined as time from blood culture draw to administration of the first antimicrobial with known susceptibility per microbiology report. Secondary endpoints include time to optimal antimicrobial therapy, 30-day readmission and all-cause mortality, hospital and intensive care unit (ICU) length of stay following blood culture positivity, and recurrent bacteremia within 30 days of discontinuation of antimicrobial therapy. All statistical analyses will be performed using SPSS software.

**Results and conclusions:** To be determined.

### References:

1. Al-Rawajfah OM, Stetzer F, Hewitt JB. Incidence of and risk factors for nosocomial bloodstream infections in adults in the United States, 2003. *Infect Control Hosp Epidemiol* 2009;30(11):1036-44.
2. Vlek AL, Bonten MJ, Boel CE. Direct matrix-assisted laser desorption ionization time-of-flight mass spectrometry improves appropriateness of antibiotic treatment of bacteremia. *PLoS one*. 2012;7(3):e32589.
3. Huang AM, Newton D, Kunapuli A, et al. Impact of rapid organism identification via matrix-assisted laser desorption/ionization time-of-flight combined with antimicrobial stewardship team intervention in adult patients with bacteremia and candidemia. *Clin infect dis*. 2013:cit498.
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**Implementation of pharmacist led medication reconciliation and education in the emergency department; a pilot project at a small, Planetree community hospital**

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**Background:** In 2013, there were approximately 135 million emergency department visits. Eight five percent (115.6 million) were discharged after their visit and not admitted to the hospital<sup>1</sup>. The Centers for Medicaid and Medicare Services began penalizing hospitals for high readmission rates; this is due to avoidable hospital readmission costing CMS approximately \$17 billion annually<sup>2</sup>. For this reason, health care systems are attempting to reduce readmission rates and improve patient outcomes. One area in which pharmacists can assist in reducing medication errors and improve patient outcomes is by performing comprehensive medication reviews (CMRs), prescription counseling, and disease state counseling in the Emergency Department (ED). Previous studies have examined the effectiveness of pharmacist-involved medication reconciliation programs and transitions of care programs from the ED resulting in decreased ED visits, improved patient safety, and increased patient follow up with primary care physicians<sup>3,4</sup>. In addition, a follow-up telephone call by a pharmacist can reduce 30-day readmission rates and reduce the incidence of unplanned hospital utilization<sup>5</sup>. Current studies have only examined readmission rates with pharmacist-led medication reconciliation in the ED- they did not include patient counseling upon discharge with a follow-up phone call from a pharmacist.

**Objective:** The primary objective of this study is to examine the impact of pharmacist-directed medication reconciliation and patient education within the Emergency Department by examining readmission rates at 30 and 90 days following discharge from ED.

**Methodology:** This study has been submitted to the Institutional Review Board for approval. Upon patient admission to the Emergency Department from November 1-30, 2016, the pharmacist will complete a medication reconciliation with the patient and provide medication counseling. Upon conclusion of the visit, patients that are being discharged with a new prescription or diagnosis of a chronic disease will be counseled by the pharmacist. In addition, the pharmacist will provide a follow up phone call for patients within 48-72 business hours after the initial visit to review changes, answer questions, and reinforce education topics. Daily ED activity reports will be collected via the hospital's electronic medical record system (EMR), Meditech, to track patients the pharmacist counseled, patients that were missed, or patients that were admitted to the ED when the pharmacist was not available. In February 2017, readmission rates at 30 and 90 days post initial presentation to ED will be examined to determine if the patients that received counseling by the pharmacist had lower readmission rates compared to those patients that did not receive counseling. Other information that will be collected include the number of pharmacist interventions, number of patients that left the ED without being seen, number of Outcomes MTM™ opportunities for patients, age, number of medications on admission, number of medications at discharge, and number of medications that are scheduled compared to as needed.

**Results:** Research in progress.

**References**

- 1) CDC/National Center for Health Statistics. Emergency Department Visits. [Internet]. [Atlanta, (GA)]. c2016. [2016 Jul 6; cited 2016 Aug 28]. Available from: <http://www.cdc.gov/nchs/fastats/emergency-department.htm>.
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**Use of dalbavancin as an alternative to traditional agents for the treatment of acute bacterial skin and skin structure infections (ABSSSI)**

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PGY-1

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**Background:**

Dalbavancin is a lipoglycopeptide antimicrobial given as a one-time intravenous (IV) dose for the treatment of ABSSSI. The advantages of dalbavancin are one time dosing, no therapeutic drug monitoring and potential avoidance of hospital admission. The disadvantages of dalbavancin are high cost and potential overuse in settings where less expensive options exist or antimicrobial therapy is not warranted.

**Objectives:**

The primary objective of this study is to determine the number (%) of patients with an ABSSSI diagnosis admitted to a level 1 trauma center who would have qualified for dalbavancin treatment using predefined use criteria. Secondary objectives are days of hospitalization, adverse events, number of lab tests ordered, and 30 day readmission rates among those patients who qualified for dalbavancin use.

**Methodology:**

The study will be submitted to the Institutional Review Board for approval. This is a prospective chart review of adult patients admitted to a level 1 trauma center with a primary diagnosis of cellulitis (ICD10 L03) and/or local skin and soft tissue infections (ICD10 L08.9). Inclusion criteria are presence of greater than or equal to 2 local signs/symptoms of complicated ABSSSI and greater than or equal to 1 systemic sign or complicating factor requiring IV therapy. The following data will be collected from the electronic medical record: patient age, gender, ethnicity, hospital unit and service, antibiotic allergies, length of stay, local symptoms and signs of infection, temperature, laboratory results (including white blood cell count, vancomycin levels, microbiology results), antibiotic therapy, adverse effects related to antibiotic therapy, peripherally inserted central catheter placement, need for surgical intervention, development of deep seated infection during hospitalization related to ABSSSI, intravenous drug use, contraindication to linezolid oral therapy and 30 day readmission. Patients will be classified as qualifying for dalbavancin if they meet all of the following criteria: requirement of IV therapy for at least 3 days but less than 14, no gram negative or anaerobes isolated, no need for operative interventions, linezolid therapy contraindicated, and no need for hospital management of other comorbidities. All data will be de-identified and maintained confidentially. Descriptive statistics will be utilized to analyze results.

**Results and conclusion:**

To be presented at OCCP spring meeting 2016.

**References:**

1. Dalbavancin (Dalvance®). Durata Therapeutics. Parsippany, New Jersey: January 2016.
2. Leuthner KD, Buechler KA, Kogan D, et al. Clinical efficacy of dalbavancin for the treatment of acute bacterial skin and skin structure infections (ABSSSI). *Ther Clin Risk Manag* 2016;12:931-40.
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**Evaluation of the safety and economic impact of an antibiotic allergy protocol in a tertiary medical center**

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PGY-1

Research Site: Summa Health- Akron Main Campus

**Background:**

Beta-lactam antibiotics are the first line agent for the treatment of many common bacterial infections within the hospital setting. Approximately 8% of the population is reported to have a penicillin allergy in the United State<sup>1</sup>. Inconsistency in antibiotics allergy documentation can promote antibiotics resistance by increasing the use of broad-spectrum antibiotics<sup>2</sup>. Antibiotic allergy protocols maybe a helpful tool to determine if patients have a life-threatening reaction (IgE mediated) to the previous antibiotic exposure. Among patients who reported antibiotic allergy, only 10% have a true IgE-mediated hypersensitivity reaction<sup>3</sup>. Using a step-wise approach protocol to assess patients with a history of penicillin allergy and performing penicillin skin testing when necessary, can prevent the misuse of antibiotics, reduce resistance and lower overall antibiotic cost. The goal of this project is to develop and implement a safe and valid assessment tool to determine patient's antibiotics allergy status and to reduce the cost of antimicrobials in the hospital.

**Objectives:****Primary outcome:**

- Number of patients with listed beta-lactam antibiotics allergy that tolerated Beta-lactam antibiotics after evaluations and the percentage change in antibiotics prescribed after pharmacist's recommendations

**Secondary outcome:**

- Cost reduction per day, length of antibiotic treatment, mortality, hospital length of stay, incidence of *C. difficile* infection, acute kidney injury, gastrointestinal upset, and infusion related reactions

**Methodology:**

Patients will be screened for Beta-lactam antibiotic allergies in the electronic medical record. Once patients are identified, pharmacists will perform a face-to-face or telephone interview with either patients or family members. Pharmacists will be using a standardized medication allergy assessment form, which is developed by the Summa Health Department of Pharmacy to determine the patient's allergy status. Pharmacists will not change patient's allergy record in the electronic medical record without the confirmation of penicillin skin test or physician consultation. Pharmacists will then make recommendations to prescriber based on clinical guidelines, protocols and local antibiotic resistance patterns. The primary investigator of the study will create the allergy assessment form and will be heavily involved in patient interviews and making recommendations. Patient encounters will be documented and located in a security hardware drive (G: drive) which make assessable for project team members only. The patient will be followed for clinical outcomes and adverse reactions up to seven days beginning on first day transitioning to B-lactam antibiotics.

**Results and conclusions:**

To be determined

**References:**

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**Background:** Epilepsy is a debilitating disorder with the ability to affect the developmental, physical, and mental health of a patient. It affects approximately 450,000 children nationwide and results in a significantly decreased quality of life.<sup>1</sup> Safe and effective pharmacotherapy is important in the management of this disorder. Therapeutic drug monitoring (TDM) of anti-epileptic drugs (AEDs) is challenging in pediatric patients due to limited correlation between drug concentration and effective seizure management, concern for side effects and toxicities, and wide inter- and intravariability in pharmacokinetic and pharmacodynamics profiles.<sup>2</sup>

There are currently no widely accepted guidelines defining “appropriate” TDM for pediatric epilepsy. Some practices have developed their own criteria defining when it is acceptable to order and collect AED serum levels. In a study by Salih and colleagues at another large hospital institution, it was concluded only 27% of the TDM levels were appropriately ordered according to predefined criteria, leading to over \$300,000 worth of unnecessary spending<sup>3</sup>. Other institutions have analyzed AED TDM orders as well and report similar numbers of levels ordered for inappropriate indications.<sup>3,4</sup> These numbers may suggest a shift in practice that overemphasizes the value of TDM.

Currently, the practice of obtaining AED serum levels at Cleveland Clinic Children’s Hospital is unknown. The aim of this study is to evaluate TDM practice for AEDs over the past year with the end goal of implementing pharmacy services to optimize TDM utilization in order to improve the lives of patients.

**Objectives:** The primary objective of this study is to define the current practice of therapeutic drug monitoring of antiepileptic medications in pediatric patients diagnosed with epilepsy. The secondary objectives are to assess the usefulness of anti-epileptic medication serum level orders and to evaluate potential cost-savings if drug monitoring practices were improved.

**Methodology:** A non-interventional, retrospective medical chart review will be performed for inpatient epileptic children (<18 years) admitted to Cleveland Clinic Children’s Hospital between February 1, 2016 and May 31, 2016. Patients prescribed at least one AED and ordered a minimum of one serum level laboratory result will be included. Patients admitted as part of an antiepileptic clinical study or who are pregnant will be excluded. Each patient will be evaluated for number of anti-epileptic medications prescribed, number of laboratory requests for AED levels, and appropriateness of each level ordered based on pre-defined criteria. The data will be analyzed using descriptive statistics.

**Results and conclusions:** To be determined

#### References:

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**Evaluation of Perioperative Medication Regimens in Bariatric Surgery Patients**

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**Background:** Bariatric surgeries present a unique challenge with regard to the effects these procedures have on medication efficacy and safety. While medication-specific data is limited, certain issues concerning pharmacokinetics in patients who have undergone bariatric surgery can be anticipated.<sup>1</sup> With the possibility of altered pharmacokinetics, it is important to evaluate medication regimens in these patients. According to the 2013 update to the Clinical Practice Guidelines for the Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient, there are specific medication recommendations for these patients. These recommendations include medications and supplements that should be incorporated and medications that should be avoided.<sup>2</sup> Additionally, the safety and efficacy of many medications will need continuous monitoring as weight loss occurs, which presents a unique opportunity for pharmacist intervention.

There is currently a lack of literature evaluating the role of the pharmacist in the care of bariatric surgery patients. This proposed study would aid in providing research to fill this gap. Pharmacists may have an opportunity to intervene in the management of bariatric patients' medication therapy by utilizing their knowledge and expertise of pharmacokinetics and dosage forms to impact patient care and outcomes.<sup>3</sup>

**Objectives:** The primary objective is to describe the medication-related issues that exist in the period of time surrounding bariatric surgery.

The secondary objectives are to identify the time points where medication interventions are currently addressed, and to identify opportunities for pharmacist intervention.

**Methodology:** This is a retrospective, single-center cohort study evaluating the potential for pharmacist involvement in the medication management of patients undergoing bariatric surgery at Cleveland Clinic Akron General. Medication lists will be evaluated at the following time points: pre-surgery, hospital admission, hospital discharge, first post-surgery follow-up visit, and the six-month post-surgery follow-up visit. The primary outcome will be the total number of possible medication related issues identified at each of the time points as well as the total number of possible medication related issues in each of the following categories at each time point: recommended medications that are absent, medications that are not recommended but are present, and narrow therapeutic medications that are present. The secondary outcome will be predictors of having  $\geq$  median number of medication related issues at each time point.

**Results and conclusions:**

To be determined.

**References:**

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## Characterizing dexmedetomidine use for sedation in neonates during therapeutic hypothermia; a single cohort observational study

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**Background:** Hypoxic ischemic encephalopathy (HIE) can result from perinatal asphyxia and if left untreated can result in brain injury. Therapeutic hypothermia (TH) is a strategy employed that attempts to minimize brain injury in neonates who suffer from HIE. TH is a first-line treatment for HIE and has been shown to reduce the risk of death or severe disability<sup>1,2</sup>. Infants must undergo sedation while receiving TH, and traditionally benzodiazepine, barbiturate, and opioid infusions have been used as sedative agents. Several animal studies have indicated that commonly used sedative agents, such as diazepam, midazolam, phenobarbital, and chloral hydrate cause neuronal injury or accelerated neuronal apoptosis and subsequent learning deficits in neonatal rodents<sup>3,4</sup>. Currently there are no trials evaluating dexmedetomidine use in this specific patient population. Dexmedetomidine has become an attractive option for sedative use in neonates due to ease of titration and limited adverse effect profile. The aim of our study is to evaluate the safety and efficacy of dexmedetomidine for TH sedation in neonates with HIE.

**Objective:** Investigate the safety and efficacy of dexmedetomidine use for sedation in neonates receiving therapeutic hypothermia for hypoxic ischemic encephalopathy in the neonatal intensive care unit (NICU).

**Methodology:** A retrospective, single cohort chart review will be performed for all patients who meet the inclusion and exclusion criteria. All neonates undergoing TH with a diagnosis of HIE in the Cleveland Clinic Children's NICU between January 1, 2012 and September 1, 2016 and who received dexmedetomidine will be included. Patients will be excluded for the following indications: transferred into the NICU already on dexmedetomidine, no documentation of N-PASS scores in the electronic medical record or any patients with a diagnosis of neonatal abstinence syndrome. Each subject meeting criteria will be evaluated at the initiation of dexmedetomidine for the following baseline characteristics: gender, birth weight, mode of delivery, APGAR at 1, 5 and 10 minutes, and gestational age. Postnatal age and weight will be collected at the initiation of dexmedetomidine. Liver function panels, including aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase (ALP), total bilirubin, conjugated bilirubin, and albumin will be collected at the following time points: baseline, once during TH, once during the re-warming phase, and once post-TH treatment. Renal function will be evaluated based on serum creatinine and blood urea nitrogen (BUN) and will be collected at the following time points: baseline, once during TH, once during the re-warming phase, and once post-TH treatment. To evaluate the primary outcome, mean arterial pressure and heart rate will be recorded at the following time points: initiation of dexmedetomidine, initiation of TH, and at each N-PASS score charted up through three days after the end of the re-warming phase. To continue monitoring the safety of dexmedetomidine mean arterial pressure and heart rate data will also be recorded during any hypotensive or bradycardic event up to day 28 of life. To evaluate the secondary outcome, N-PASS scores will be recorded at initiation of dexmedetomidine, initiation of TH, and through three days after the end of the re-warming phase. Other clinically relevant data including, dexmedetomidine duration and dose, incidence of seizures, concomitant narcotic, sedative, and antiepileptic drug use, incidence of shivering, and mechanical ventilation status will also be collected for evaluating trends and potential confounding variables and will be collected at the following time points: baseline, once during TH, once during re-warming phase, and once post-TH treatment. Descriptive statistics will be used to analyze baseline characteristics and the primary and secondary endpoints using mean, median, mode and standard deviation.

**Results and Conclusions:** N/A

### References:

1. Edwards AD, Brocklehurst P, Gunn AJ, et al. Neurological outcomes at 18 months of age after moderate hypothermia for perinatal hypoxic ischemic encephalopathy: Synthesis and meta-analysis of trial data. *BMJ*. 2010; 340-363. doi: 10.1136/bmj.c363.
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**Pharmacist management of vancomycin dosing in the critical care unit of an acute care urban hospital****Rachel Gresko, PharmD**; Matthew Reale, PharmD, BCCCP; Kyle Sobecki PharmD, BCPS

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PGY1 Pharmacy Resident

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**Background:**

Vancomycin is a glycopeptide antibiotic with effective coverage against Gram-positive bacteria, and is the primary antibiotic in the treatment of methicillin resistant *Staphylococcus aureus* (MRSA).<sup>1</sup> Vancomycin dosing is typically 10-20mg/kg which is based off of a patient's actual body weight.<sup>1,2</sup> When given intravenously, there is a potential for harmful adverse events including nephrotoxicity and ototoxicity.<sup>1</sup> Monitoring trough concentrations allows clinicians to minimize adverse effects, while ensuring efficacy. If left unmonitored, a patient is at a risk for developing nephrotoxicity, which could potentially become irreversible. Vancomycin nephrotoxicity is associated with elevated trough values (> 15mg/mL)<sup>1</sup>, doses greater than 4 grams per day, and prolonged therapy (greater than 7 days). Pharmacist management of vancomycin therapy in a hospital setting can provide an increased frequency of therapeutic troughs, in addition to safety decrease in adverse events.

Studies have been conducted that shows benefits when pharmacists dose vancomycin in a healthcare setting. In a study conducted by Marquis et al., it was shown that pharmacist-guided vancomycin improved optimal dosing regimens, during a pilot program at a hospital. It was found that patients were dosed correctly 96.8% of the time post-implementation of pharmacy dosing compared to 40.4% of the time pre-implementation (P<0.001).<sup>3</sup> In another study conducted by Masuda et al., it was shown that pharmacist intervention might impact care by balancing higher trough targets with the risk of nephrotoxicity. It was shown that there was a 45% decrease in the rates of nephrotoxicity when comparing pre and post-implementation of a pharmacist intervention protocol; however the results were not significant. Additionally, it was noted that there was a significant improvement in therapeutic trough levels once pharmacy was dosing vancomycin compared to the pre-implementation data (p<0.001).

**Objectives:**

The primary objective of this study is to assess the number of therapeutic first troughs obtained from pharmacist managed vancomycin compared to non-pharmacist vancomycin management. The ultimate goal of this research is to implement a hospital-wide pharmacy-to-dose vancomycin protocol.

**Methodology:**

Pharmacy will manage all vancomycin dosing and monitoring for patients admitted to the intensive care unit (ICU) during the month of November 2016. Management includes ordering appropriate initial vancomycin doses, measuring and assessing troughs, making dosing adjustments, monitoring cultures, and providing recommendations for changes in therapy when necessary. Data collected from current patients will be retrospectively compared with patients who were prescribed vancomycin in the ICU in November 2015. The primary outcome of the study is the percentage of troughs therapeutic at first draw. Secondary outcomes of this study will include percentage of subtherapeutic troughs (<10 mcg/mL) and percentage of suprathreshold troughs (>20 mcg/mL). Inclusion criteria will be patients with an initial vancomycin consult while in the ICU and patients admitted to the ICU from the emergency department with no more than 1 dose of vancomycin administered. Exclusion criteria include patients started on vancomycin outside of the ICU, hemodialysis patients, pregnant patients, and patients with orders for oral vancomycin therapy.

**Results and conclusions:**

TBD

**References:**

1. Rybak M, LoMaestro B, Rotschafer J, et al. Therapeutic Monitoring of vancomycin in adult patients: A consensus review of the American Society of Health-System Pharmacists, The Infectious Disease Society of America, and The Society of Infectious Disease Pharmacists. *Am J Health-Syst Pharm* 2009; 66: 82-98.
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**Evaluation of a pain, agitation, and delirium order-set protocol**

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PGY-1

Research Site: Louis Stokes Cleveland VA Medical Center

**Background:**

Pain, agitation, and delirium are serious issues for patients in the intensive care unit (ICU), leading to increased morbidity and mortality. More than 50% of patients report some pain during their ICU stay,<sup>1</sup> while the prevalence of delirium in ICU patients is as high as 32%.<sup>2</sup> The pain, agitation, and delirium guidelines, updated in 2013, focused on preventing and treating these complications in the ICU. Their recommendations detailed a step-wise approach beginning with treating pain, which left untreated increases the risk of agitation and delirium. The evaluation of pain, agitation, and delirium are scored on the Critical Care Pain Observation Tool (CPOT), the Richmond Agitation and Sedation Scale (RASS), and the Confusion Assessment Method (CAM), respectively, which are three of the most widely used and validated assessments in the ICU.<sup>3</sup> Since the publication of the guidelines, institutions have been implementing protocols to reflect the updated recommendations. In June 2016, The Louis Stokes Cleveland Veteran Affairs Medical Center (VAMC) implemented a medical intensive care unit (MICU) order-set to facilitate the optimal selection of medications and increase the documentation of patients' assessments; ultimately reducing patient's pain, agitation, and risk of delirium in the ICU.

**Objectives:**

The purpose of this study is to evaluate the Louis Stokes Cleveland VAMC ICU protocol. The primary objective is to assess whether patients' pain, agitation, and delirium scores are at goal (CPOT, RASS, CAM). The primary endpoint is the percentage of documented CPOT, RASS, and CAM scores that are at goal for the first 72 hours of intubation or until extubation. Secondary objectives include the frequency that the protocol is followed, the time it takes to get a patient to goal, as well as the medication and average dose used.

**Methodology:**

This is a retrospective chart review of mechanically ventilated patients intubated greater than 24 hours in the MICU. Patients charts will be reviewed from July 1<sup>st</sup> 2016 forward until target sample of 100 patients is achieved. Patients will be excluded if they are intubated for seizures or alcoholic withdrawal. Patients will be identified by the "Respiratory Airway Management Note" in the Computer Personal Records System (CPRS) and filtered by patients with a location of "WMICU". Definition of pain, delirium, and sedation goals are as followed: CPOT scores of 0 to  $\leq 2$ , RASS scores of -2 to 0, and CAM scores of negative. The frequency that the protocol is followed measured by the adjustments (within 10% of protocol) of medications when pain and agitations scores are not at goal: dexmedetomidine (mcg/kg/hr), fentanyl (mg/hr), midazolam (mg/hr), morphine (mg/hr), propofol (mcg/kg/hr). The initial dosing of the medications and average dose(previous 12 hours) when CPOT and RASS are at goal will be collected. The time of intubation ("Respiratory Airway Management Note") to first documented assessment (CPOT, RASS, CAM) at goal will also be obtained.

**Results and conclusions:** Pending; results will be present at OCCP spring meeting.

**References:**

1. Chanques G, Sebbane M, Barbotte E, et al: A prospective study of pain at rest: Incidence and characteristics of an unrecognized symptom in surgical and trauma versus medical intensive care unit patients. *Anesthesiology* 2007; 107:858–860.
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## Implementation of two follow-up interactions between a pharmacist and patient after hospital discharge to reduce 30-day readmission rate

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**Background:** In 2010, The Patient Protection and Affordable Care Act was passed which allowed the Centers for Medicare and Medicaid Services to implement a hospital readmission reduction program to reduce hospital readmission.<sup>1</sup> In 2011, there were approximately 3.3 million adult 30-day hospital readmissions, resulting in \$41.3 billion in hospital costs.<sup>2</sup> Of all 30-day readmissions, the majority occurs within 15 days of hospital discharge.<sup>3</sup> It is estimated that 20% of discharged patients experience adverse events, and nearly two-thirds of them are medication-related.<sup>1</sup> Pharmacist involvement in patient care decreases 30-day readmissions up to 30%.<sup>4</sup> Bellone et al. (2012) compared post discharge pharmacist visit to no visit and showed a statistically significant difference in readmission rates, 18% versus 43.1% ( $p=0.002$ ).<sup>5</sup> Pharmacists are integral in providing medication education, improving adherence, preventing medication errors, and identifying adverse events that may contribute to readmissions.

**Objectives:** The primary objective of this study is to evaluate the impact of pharmacist involvement in the hospital follow-up appointment and subsequent phone call on 30-day readmission rate. Secondary objectives include adherence score, number of accepted and total pharmacist interventions, time spent with patient, patient satisfaction, and physician satisfaction.

**Methodology:** The Institutional Review Board approved this study. This is a descriptive study that will be conducted from October-December 2016 in the Mercy Ambulatory Care Clinic (ACC). Patients discharged from the Medical Teaching Service are scheduled for a hospital follow-up appointment within ten days in the ACC. The pharmacist will contact the patient prior to their scheduled appointment to serve as a reminder call and inform the patient to bring in all of their medications. At the hospital follow-up appointment, the patient will meet with the pharmacist prior to meeting with the physician. During this interaction, the pharmacist will complete a medication history/reconciliation. Additionally, the pharmacist will assess adherence via the 4-item Morisky Medication-Taking Adherence Scale (MMAS), provide adherence/medication counseling, and identify pharmacist interventions. Patients will also be given an optional, anonymous survey to assess satisfaction with the pharmacist. The interaction will be documented in the patient's electronic medical record and the findings will be reiterated to the patient within seven days after the appointment via telephone. The physicians will be given an optional, anonymous survey to assess satisfaction with the pharmacist. The following data will be collected; age, gender, ethnicity, admitting diagnosis, discharge date, emergency department visits, co-morbidities, number of medications, adherence score, pharmacist interventions, patient and physician satisfaction via survey, and the time spent with patient during the appointment.

### Results and Conclusions:

Results and conclusions in progress

### References:

1. Centers for Medicare and Medicaid Services. Readmissions reduction program overview. April 26, 2013. Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/ReadmissionsReduction-Program.html>.
2. Hines Anika L, Barrett Marguerite L, Jiang Joanna, et al. Conditions with the largest number of adult hospital readmissions by payer, 2011. *HCUP*. 2014
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**Effectiveness, safety, and economic comparison of inhaled Flolan and inhaled Veletri in cardiothoracic surgery patients**

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**Background:** Epoprostenol is a chemical analogue of the naturally occurring substance prostacyclin.<sup>1</sup> It contains antithrombotic, antiproliferative, and anti-inflammatory properties which makes it an ideal pulmonary vasodilator.<sup>1</sup> When epoprostenol is administered intravenously, patients may experience significant hypotension, tachycardia, and facial flushing.<sup>2</sup> Inhaled epoprostenol, an off-label route of administration, has reduced systemic effects due to its local action in well-ventilated areas of the lungs in comparison to the intravenous route.<sup>2,3</sup> Inhaled administration has been studied for acute respiratory distress syndrome, pulmonary hypertension, acute right ventricular failure, and perioperatively.<sup>2</sup> Due to differences in the available epoprostenol formulations, there are some clinically relevant concerns when converting from Flolan to Veletri. Veletri has an extended duration of stability at ambient temperatures compared to Flolan making Veletri favorable in terms of dispensing and administration. Flolan and Veletri both contain mannitol, but Flolan uses glycine to maintain its pH, while Veletri uses arginine.<sup>2</sup> The concern in formulation is in relation to the arginine component of Veletri. It has been theorized that repeated daily exposure of inhaled arginine may result in increased bronchospasm, severe deterioration of the patient's general condition, and inflammation visualized on direct fiberoptic visualization.<sup>4</sup> There is limited published data comparing inhaled Flolan and inhaled Veletri in mechanically ventilated patients. A previously published study showed no difference in the PaO<sub>2</sub>/FiO<sub>2</sub> ratio one hour after initiation between Flolan or Veletri (P = 0.54). Differences noted in their secondary outcomes of duration of mechanical ventilation and intensive care unit (ICU) length of stay (LOS), and hospital mortality were likely due to differences in this study's baseline characteristics.<sup>2</sup> Given the lack of published literature comparing inhaled Flolan and inhaled Veletri, the goal of this project is to evaluate a formulary conversion from Flolan to Veletri to determine if there is a difference in the effectiveness, safety, or cost when used in mechanically ventilated cardiothoracic surgery patients. By focusing on cardiothoracic surgery patients, we hope to isolate the true difference in effects of the inhaled epoprostenol formulations.

**Objectives:** The primary objective is to evaluate the change in the PaO<sub>2</sub>/FiO<sub>2</sub> ratio after one hour of inhaled Flolan in comparison to inhaled Veletri administration. The secondary objectives are to evaluate differences in ventilatory support and hemodynamic variables, ICU and hospital LOS, in-hospital mortality, adverse effects, and medication average wholesale costs per patient between inhaled Flolan and inhaled Veletri.

**Methodology:** This is a retrospective, noninferiority study performed at a single, large academic medical center comparing inhaled Flolan and inhaled Veletri in cardiothoracic surgery patients. This study has been approved by the Institutional Review Board. Included subjects will be ≥18 years old, who were admitted to the cardiothoracic ICU at Cleveland Clinic and received inhaled Flolan or inhaled Veletri therapy for ≥1 hour while mechanically ventilated. The study period will include subjects who received inhaled epoprostenol between January 1, 2015 – December 1, 2016. The study is powered using a 1-sided test of noninferiority and α of 0.025, assuming a difference in the change in the PaO<sub>2</sub>/FiO<sub>2</sub> ratio after 1 hour of therapy of 20, 116 patients are needed in each group (232 total patients) to achieve 80% power to detect the noninferiority margin.<sup>5</sup> Categorical data will be analyzed with Chi-Square test or Fisher exact test, while continuous variables will be analyzed with Student's t-test or Mann-Whitney U test. A subgroup analyses will be performed as appropriate.

**Results and Conclusions:** To be determined.

**References:**

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**Implementation of an Antimicrobial Restriction Policy: Is the “Paper” More Persuasive?**

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**Background:** Antibiotic resistance is becoming an issue of bigger prevalence due to the increasing mortality associated with resistant organisms<sup>1</sup>. Central to the idea of antibiotic resistance is the increased use of antimicrobials and the inappropriate use of antimicrobials; a recent study provided evidence that over a third of antibiotic prescriptions are not consistent with evidence-based guidelines<sup>2</sup>. The most recent IDSA guidelines on the use of an Antibiotic Stewardship Program published in 2016 recommend the use of pre-authorization and/or prospective audit and feedback over the absence of such interventions<sup>3</sup>. Prior to December of 2015, the University of Toledo Medical Center (UTMC) utilized only a prospective audit and feedback (PAF) method where the antibiotic steward pharmacist would review the use of certain medications as well as culture reports in order to make interventions in order to optimize therapy. In December 2015, UTMC implemented a protected antimicrobial policy which restricted the use of linezolid, micafungin, and meropenem. A Cochrane review published in 2013 analyzed the impact of prospective audit and feedback versus restrictive measures<sup>1</sup>. In the meta-analysis, restrictive measures over prospective audit and feedback alone was able to affect prescribing outcomes significantly at 1 month while the significance was lost at the 6 or 12 month post intervention month mark<sup>1</sup>. For microbial outcomes, the intervention was statistically significant at 6 months but not at 12 months. Another study performed by Mehta et al looked at the removal of a prior authorization policy in an academic medical center<sup>4</sup>. The removal of a prior authorization procedure increased the duration of broad spectrum antimicrobials by 9.65 days<sup>4</sup>. This study seeks to determine the impact of a restrictive antibiotic policy in addition to the use of PAF at an academic medical center.

**Objectives:** The objective is to determine the impact of a restrictive antibiotic policy implemented at the University of Toledo Medical Center (UTMC) in December 2015.

**Methodology:** This study is a pre-post quasi experimental retrospective study currently awaiting IRB approval. Adult patients who received at least 1 dose of linezolid, meropenem, or micafungin during the study period (January 1, 2015 to December 31, 2016) will be included in the study. Patients will be excluded if they are pregnant, a prisoner, under 18 years old, or have been previously enrolled in the study and are identified during a readmission. Data describing the baseline characteristics will be collected to assess for differences in the two groups. The primary endpoint will be incidence of appropriate prescribing based on currently approved hospital criteria at 24h, 48h, and 72h or later to assess the effects of implementation of a restrictive antibiotic policy. Secondary endpoints will be percentage of patients meeting clinical criteria for use, incidence of *Clostridium difficile* associated diarrhea, length of stay, duration of antibiotic therapy, cost associated with antibiotic therapy adjusted for cost differences, 30 day all-cause mortality, and in hospital mortality.

**Results and conclusions:** To be determined.

**References:**

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**Evaluation of customization from standard total parenteral nutrition (TPN) for patients admitted to a level IV neonatal intensive care unit (NICU)**

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**Background:**

TPN is an intervention used to support the nutritional needs of patients that are unable to receive adequate enteral nutrition. Currently, five standard TPN formulations are utilized by the NICU. Patients' age and weight dictate which standard formulation is used to provide nutrition. A need has been identified to assess the rate of customization from standard formulations. Deviation from standard formulations are driven by patient specific electrolyte laboratory values.

**Objectives:**

The objective of this study is to describe the frequency at which the calcium and phosphorous concentrations are customized in standard TPN formulations for patients located in the NICU.

**Methodology:**

This descriptive study will be a single site, retrospective evaluation of all patients receiving TPN in the NICU from January 1, 2015 until August 31, 2016. Patients will be included from the first day of TPN therapy until discontinuation. A subgroup analysis for patients weighing less than 1500 grams will be completed. Data will be collected from the electronic medical record (EMR), TPN compounding machine, and pharmacist documented errors upon order and product verification. Data collection will include patient age, weight, standard TPN duration, custom TPN duration, dose of calcium and phosphorous administered from the TPN each day, composition of the daily TPN, and pertinent laboratory values. Descriptive statistics will be utilized to analyze data. Additionally, this study will assess secondary outcomes impacting patient safety such as error rates associated with customization of TPNs.

**Results and conclusions:**

The results of this retrospective descriptive study are yet to be determined. After completing the analysis, reconsideration of standard formulations may occur to ensure 80% of TPN formulations prescribed are standard with 20% or less customized.

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**COPD Homegoing Program: Pharmacist intervention in reducing hospital readmissions**

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PGY-1

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**Background:** Chronic Obstructive Pulmonary Disease (COPD) is a major health and economic burden in both the United States and around the world.<sup>1</sup> Resources aimed at smoking cessation, COPD education and early detection, and improved treatment options will be of utmost importance in reducing morbidity and mortality.<sup>1</sup> Previous studies have evaluated effectiveness of pharmacist led discharge programs and found favorable results. One randomized controlled trial concluded that the rate of hospital utilization within 30 days after discharge in patients who received discharge counseling was significantly lower (0.314 vs 0.451 p=0.009) compared to those not receiving discharge counseling.<sup>2</sup> Another study in which pharmacists provided medication and disease state education reviewed 30 day readmission rates as well as medication compliance and patient satisfaction.<sup>3</sup> Authors concluded that rates of primary medication adherence were 58.5% and 75.7% in the control and intervention groups, respectively, which was found to be clinically and statistically significant (P=0.05).<sup>3</sup>

**Objectives:** This study is a retrospective chart review aimed at evaluating the impact of pharmacist-led COPD disease state and inhaler education along with providing patients with a supply of medication upon discharge. Net clinical benefit will also be used to improve clinical practice at our site and determine the benefit of a pharmacist-led counseling and discharge medication program.

The primary outcome of this study is the 30 day COPD readmission rate in patients admitted for COPD exacerbation who received pharmacist counseling at discharge versus those who received standard of care (no pharmacist counseling at discharge). Secondary outcomes include 30 day readmission for reasons other than COPD, presence of respiratory therapist inhaler education, emergency department visits for COPD within 30 days of discharge, patient satisfaction, adherence, and side effects.

**Methodology:** A pharmacist-led COPD discharge consult service was started at UHRMC in October 2016. Hospital personnel with consult-placing credentials had the ability to place a consult on patients admitted for COPD exacerbation. Pharmacists provided education on COPD and inhaler counseling on indication, directions, side effects, special considerations, and correct usage for all discharge inhalers. If patients went home on formulary agents Advair, Spiriva, or albuterol, they received a short supply of the medication from the inpatient pharmacy. Two weeks post-discharge, a pharmacist called patients to deliver a 7-question phone-based survey to assess their satisfaction with the service provided, side effects, and compliance. An electronic medical record query spanning October through December of 2010 through 2015 will be used to find all patients meeting inclusion and exclusion criteria at UHRMC with a discharge diagnosis of COPD prior to service implementation. These patients will serve as the control group. An electronic medical record query spanning October 2016 through February 2017 will be used to find all patients who received completed pharmacist consults with or without respiratory therapist inhaler education. These patients will serve as the intervention group. This chart review will aim to analyze at least 150 patients. Secondary outcomes including respiratory therapist inhaler education and emergency department visits for COPD within 30 days of discharge will be collected through chart review.

**Results and conclusions:**

N/A

**References:**

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**Impact of FilmArray Technology on Patient Outcomes in Intensive Care Unit Bacteremias**

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**Background:** Bacteremias in the intensive care unit (ICU) are associated with increased mortality and length of stay in the ICU.<sup>1</sup> Effective therapy requires targeting antibiotics to the specific causative pathogen. However, there is often a delay of approximately 24 to 72 hours for blood cultures to yield a positive or negative result.<sup>2</sup> Summa Health System recently implemented the FilmArray Multiplex Polymerase Chain Reaction (PCR) rapid diagnostic tool on September 2015. This tool provides accurate test results in about one hour for 24 different blood pathogens and 3 genes known to confer antibiotic resistance.<sup>3</sup> Two retrospective studies evaluated the time to organism identification, to de-escalation of therapy, and to effective therapy in patients with *Staphylococcus aureus* and vancomycin resistant *Enterococcus* bacteremias using the FilmArray PCR.<sup>4, 5</sup> Data from these studies showed a significant reduction in time to organism identification, to de-escalation of therapy, and to effective therapy.<sup>4, 5</sup>

**Objectives:** The primary objective is to determine the effect of FilmArray technology implementation on time to optimal therapy, specifically in the ICU. Secondary objectives include: length of ICU stay, inpatient mortality, time to effective therapy, time to identification of the organism, time to clinical stability, cost of hospital stay, hospital length of stay, 30-day readmission, 30-day all-cause mortality, 60-day all-cause mortality, whether or not infectious disease was consulted, whether or not the antimicrobial stewardship pharmacist (ASP) intervened, and whether or not the ASP recommendations were accepted.

**Methodology:** The design of this study is a retrospective chart review of patients in the ICU with confirmed bacteremias. The study encompasses data one year pre- and post-implementation of the FilmArray PCR technology at Summa Health Akron City Campus. Both parametric and non-parametric tests will be used where appropriate

**Results and conclusions:** To be determined

**References:**

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**Assessment of Glycemic Control in Diabetic Patients While Unable to Eat**

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**Background:** Hypoglycemia in the general medicine ward is associated with increased in-hospital mortality, length of stay, and 1-year mortality.<sup>1</sup> Previous evidence demonstrated half of identified hypoglycemic events were associated with decreased caloric intake without a medication change.<sup>2</sup> There is insufficient evidence specific for the glycemic management of diabetic patients that are unable to eat (NPO). The 2016 American Diabetes Association treatment guidelines recommend a basal plus correction regimen for diabetic patients that are NPO in the noncritical care setting.<sup>3</sup> In the perioperative period, the guidelines recommend full doses of long-acting insulin and half doses of morning insulin NPH. Two randomized clinical trials demonstrated that a lack of basal insulin adjustment may be associated with an increased frequency of hypoglycemia. A prospective observational study, found that 50% of hypoglycemic events were related to decreased oral intake, without a subsequent medication change.<sup>2</sup> The number of events evaluated was small; however, it indicates an area for improvement. The randomized RABBIT 2 Surgery trial, was designed to compare the safety and efficacy of a basal-bolus regimen to a sliding scale insulin (SSI) regimen in surgical patients with diabetes.<sup>4</sup> The study protocol required full basal insulin administration when a patient was NPO. RABBIT 2 Surgery demonstrated significantly more hypoglycemic events in the basal-bolus group than the SSI group. The authors associated the hypoglycemic events to decreased oral intake in the patient population. This further indicates the need to assess the glycemic management of NPO patient with diabetes.

**Objective:** To assess glycemic control of NPO patients with type 2 diabetes.

**Methodology:** This is an Institutional Review Board-approved retrospective cohort study. Adult patients admitted to a noncritical care setting with type II diabetes, prescribed outpatient basal insulin, received at least one basal insulin injection while inpatient, and were NPO during their admission will be included. Patients will be excluded if they have diabetic ketoacidosis, hyperosmolar hyperglycemic state, hypoglycemia on admission, received corticosteroid therapy, received total parenteral nutrition, cardiovascular surgery, type I diabetes, or are pregnant. Data describing baseline characteristics, diabetic therapy and blood glucose control will be collected. The primary outcome is the difference in hypoglycemic events, defined as a blood glucose less than 70 milligrams per deciliter, between patients with a greater than or equal to fifty percent or less than fifty percent reduction in home basal insulin dose while NPO. Secondary outcomes include comparing glycemic control, defined as a blood glucose between 70 and 180 milligrams per deciliter, severe hypoglycemic events, hyperglycemic events, administration of glucose or dextrose, hospital length of stay, hospital complications and inpatient total daily dose of insulin between both groups.

**Results and conclusions:** To be determined

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**Effects of acid suppressive therapy on clinical outcomes in patients treated with tigecycline for bloodstream infections**

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**Background:** Tigecycline is a glycylicycline antibiotic with activity against Gram-positive and Gram-negative aerobic and anaerobic bacteria. Due to its broad-spectrum activity and ability to evade tetracycline efflux pumps, tigecycline is regarded as a last resort to treat multidrug-resistant pathogens including carbapenem-resistant Enterobacteriaceae, *Acinetobacter* spp., vancomycin-resistant enterococci, and methicillin-resistant *Staphylococcus aureus*.<sup>1-3</sup> Due to increasing bacterial resistance, tigecycline is often used off-label to treat blood stream infection (BSI). However, due to a large volume of distribution and tigecycline's bacteriostatic activity, the low serum concentrations achieved with standard dosing may not overcome typical organism minimum inhibitory concentrations (MICs).<sup>2</sup> Given the frequency of proton-pump inhibitor (PPI) use observed in hospital settings, an *in vitro* study investigated the effect of PPIs on tigecycline activity. When cultures were supplemented with human-simulated concentrations of pantoprazole, a two-fold increase in tigecycline MIC was reported for several organisms.<sup>4,5</sup> It is unknown whether this *in vitro* effect on tigecycline activity translates to worse clinical outcomes *in vivo*.<sup>1</sup> Therefore, our study aims to investigate whether the concomitant use of PPIs plus tigecycline affects clinical outcomes in human BSI, and to determine the potential need to evaluate alternative treatments.

**Objectives:** To compare clinical outcomes in patients with BSI receiving tigecycline with or without pantoprazole (PPI).

**Methodology:** This non-interventional, retrospective cohort study will be conducted to evaluate clinical outcomes in patients who received tigecycline for at least 48 hours and had a minimum of one positive culture documenting BSI. Those with bacterial isolates resistant to tigecycline (MIC  $\geq 4$  mg/L) will be excluded. Patients will be divided into two groups, those receiving tigecycline plus PPI and those receiving tigecycline without PPI. The primary outcome will compare 28-day all-cause mortality. Secondary outcomes: favorable clinical response, microbiologic cure, and incidence of breakthrough infection between groups. Favorable clinical response will be defined as resolution of fever (temperature  $\geq 38.3$  °C), leukocytosis (WBC  $\geq 11 \times 10^9$  /L), and hypotension (MAP  $\leq 65$  mm Hg) without requiring vasoactive agents. Microbiologic cure will be defined as documentation of microbiologic eradication within 7 days of the first positive blood culture after at least 48 hours of susceptible antimicrobial therapy. Patients will be matched 1:1 based on organism (Gram-negative vs. Gram-positive) and receipt of combination definitive antimicrobial therapy. Variables collected will encompass severity of illness at baseline, acid suppressive therapy, and infection-related data. Multivariable logistic regression will be utilized to assess for independent predictors of 28-day mortality.

**Results and conclusions:** To be determined

**References:**

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**Evaluating the impact of a pharmacist on guideline directed medical therapy in patients with reduced ejection fraction heart failure****Adam Ingram, PharmD**

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**Background:** Heart failure continues to be one of the world's foremost health problems with its prevalence estimated to reach more than 8 million Americans by the year 2030.<sup>1</sup> It is the most frequent principal diagnosis of patients discharged from a hospital and the most common diagnosis for hospital readmission.<sup>2</sup> One possible reason for this may be the underutilization of medications that have been shown to reduce the morbidity and mortality associated with heart failure patients with reduced ejection fraction. The current heart failure guidelines emphasize the use of guideline directed medical therapy (GDMT), which includes recommendations to titrate specific medications shown to reduce morbidity and mortality to target doses reflected in published literature.<sup>3</sup> This pilot study aims to investigate the impact of a pharmacist-run, outpatient heart failure management clinic on patients' heart failure outcomes and healthcare related costs.

**Objectives:** The primary objective is to evaluate the time (number of weeks and number of clinic visits) to achieve individualized target doses of GDMT. Beta-blocker titration will be evaluated within the secondary endpoints: percentage of patients titrated to target doses, reasons for inability to fully titrate, and the percentage of patients with a left ventricular ejection fraction of 35 percent or greater after maximal beta-blocker titration. Additional secondary endpoints include the total and per-visit revenue generated as well as the change in average number of all cause and heart failure-specific hospital admissions and emergency department visits.

**Methodology:** This is a retrospective electronic chart review pending approval from the Institutional Review Board. Patients who were referred to the pharmacist-run, outpatient heart failure management clinic will be considered for inclusion. Data will be stratified into two patient groups; those whose medications were partially titrated and those whose medications were not titrated at the time of enrollment into the clinic. Data reviewed will include demographic characteristics, New York Heart Association functional class, baseline and post-titration ejection fraction, dates and number of visits, reasons for inability to titrate beta-blockers, as well as number and type of hospital admissions and emergency department visits. Analysis of continuous variables will be completed using a Wilcoxon signed rank test. All other endpoints will be reported using descriptive statistics.

**Results and conclusions:** N/A**References:**

1. Go AS, Mozaffarian D, Roger VL, et al. Heart disease and stroke statistics: 2014 update. *Circulation*. 2014; 129:e28-e292.
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## **Incidence of potassium abnormalities during cooling, maintenance, and rewarming phases of therapeutic hypothermia in patients after return of spontaneous circulation**

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**Background:** The Advanced Life Support Task Force of the International Liaison Committee on Resuscitation recommends that comatose (lack of meaningful response to verbal commands) patients with return of spontaneous circulation (ROSC) after cardiac arrest have targeted temperature management<sup>1</sup>. Targeted temperature management or therapeutic hypothermia (TH), is defined as a constant temperature between 32-36° C for at least 24 hours after achieving target temperature. The benefit of TH has been demonstrated in numerous studies<sup>2,3,4</sup>. Therapeutic hypothermia has been shown to increase favorable neurological outcomes (able to live independently and work at least part-time) at 6 months (NNT =6) and decrease death at 6 months (NNT=7)<sup>2</sup>. Several studies have noted electrolyte abnormalities as a side effect of TH, but the prevalence varies<sup>4,5,6,7,8</sup>. Cleveland Clinic Akron General has a standardized electrolyte replacement protocol, but the incidence and type of electrolyte abnormalities have not been established at this institution or in the literature. Knowing the type, prevalence, and predictors of electrolyte abnormalities will help guide treatment before and during therapeutic hypothermia.

**Objectives:** The primary objective of this study is to report the incidence of potassium abnormalities during the cooling, maintenance, and rewarming phases of TH in patients with ROSC after cardiac arrest. Secondary objectives will report the incidence of magnesium, glucose, phosphorus, and ionized calcium abnormalities during each phase of TH; report the treatment of hyperkalemia; quantify the amount of electrolyte replacement required during TH; and report predictors of potassium abnormalities in patients undergoing TH.

**Methodology:** This study will be submitted to the Institutional Review Board for approval. The electronic medical record system will identify patients who were charged for the Arctic Sun Hypothermia Pads and received at least 12 hours of TH after cardiac arrest. The following patient data will be collected: age, gender, race, comorbidities present on admission (diabetes mellitus, congestive heart failure, renal insufficiency, end stage renal disease on hemodialysis), presenting temperature, presenting and subsequent electrolyte values (glucose, magnesium, ionized calcium, potassium, phosphorus), lowest cooled temperature, presence of insulin infusion, time to rewarming in hours, first reported rhythm of arrest (ventricular tachycardia, ventricular fibrillation, pulseless electrical activity, asystole), and cerebral performance category score on discharge. The potassium levels for all patients will be compared based on which TH phase (cooling, maintenance, rewarming) the level was obtained. Data collected will be used to determine predictors of potassium abnormalities during TH. All data will be recorded without patient identifiers to maintain confidentiality. A statistician will aid in the evaluation of data.

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## Comparison of Narrow versus Broad Spectrum Antibiotics in Elderly Patients with Acute Exacerbations of Chronic Obstructive Pulmonary Disease

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**Background:** Acute exacerbations of chronic obstructive pulmonary disease (AECOPD) are associated with significantly increased morbidity, mortality, and health-care cost.(1) The 2016 GOLD guidelines recommend the use of antibiotics in patients with AECOPD that have at least two of the three cardinal symptoms, increase in dyspnea, sputum volume, and sputum purulence, if one of these symptoms is increased purulence. (2) However, little guidance is provided regarding the selection of antibiotic therapy. Clinical opinion, epidemiological studies, and post hoc analyses of major clinical trials has supported utilizing a risk stratification approach in selecting antimicrobial therapy suggesting broader spectrum antibiotics in four groups of patients at higher risk for poorer outcomes, including the elderly (age >65 years). (3-4) The prevalence of chronic obstructive pulmonary disease (COPD) is 3 times higher in patients 65 years and older than those 40 to 64 years of age. (5) The elderly are a large, clinically important subgroup of patient with COPD. To date, no study has specifically targeted broad versus narrow spectrum antibiotics in elderly patients hospitalized with AECOPD.

**Purpose:** The purpose of this study is to compare outcomes of elderly patients receiving broad versus narrow spectrum antibiotics during a hospitalization for AECOPD.

**Methods:** A retrospective observational study will be performed using electronic medical records of patients >65 years old admitted with a primary diagnosis of AECOPD or a primary diagnosis of acute respiratory failure and a secondary diagnosis of AECOPD. The planned primary outcome of the study is a composite of mechanical ventilation within 48 hours of admission, transfer to intensive care status after 48 hours of admission, readmission within 30 days for COPD exacerbation, oxygen saturation less than 90% on room air and increased oxygen requirements from baseline after 48 hours. Secondary outcomes include individual components of the primary outcome, hospital length of stay, 10-day and 90-day readmission for AECOPD, all-cause 30-day and 90-day readmission, and clinical decompensation after 48 hours based on systolic blood pressure, respiratory rate, heart rate, oxygen saturation, and increased supplementary oxygen needs. Safety outcomes to be analyzed include *Clostridium difficile* associated diarrhea and reported adverse reaction to study medications. Data to be collected and analyzed will include patients baseline demographics, risk factors for multidrug resistant bacteria, home medications, concomitant hospital treatments, and antibiotics used.

**Results and conclusions:** Results and conclusions are pending data collection and will be presented at the Ohio Pharmacy Residency Conference.

### **References:**

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(4) Wilson R, Jones P, Schaberg T, et al. Antibiotic treatment and factors influencing short and long term outcomes of acute exacerbations of chronic bronchitis. *Thorax* 2006; 61:337.

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## Prescribing Patterns, Patient Characteristics, and Outcomes for Oncology Patients with Venous Thromboembolism at Akron City Hospital

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**Background:** Venous thromboembolism (VTE) represents a major cause of morbidity and mortality for cancer patients. Studies have shown that cancer patients have a seven fold higher risk of developing VTE than patients without cancer<sup>1</sup>. Although the association between VTE and cancer is clear, the best choice for anticoagulation is not. According to the 2016 American College of Chest Physicians CHEST Guideline and Expert Panel Report on Antithrombotic Therapy for venous thromboembolism (VTE), a low molecular weight heparin (LMWH) is preferred over vitamin K antagonists (VKA), or direct oral anticoagulants (DOACs)<sup>2</sup>.

The lack of a head to head trial comparing DOACs with LMWH has prevented these drugs from becoming recommended agents within oncology and hematology guidelines. However, this has not precluded their use<sup>3</sup>. DOACs represent an attractive alternative to both LMWH and VKA. DOACs require no routine monitoring and are taken orally. DOACs have proven to be non-inferior to warfarin without an increased risk of bleeding<sup>4</sup>.

A 2016 randomized, double-blind trial examined the safety and efficacy of the edoxaban versus warfarin. The sample size included 771 patients with cancer, representing a larger sample size than in previous anticoagulant trials<sup>3</sup>. Results showed that edoxaban has non-inferior effectiveness compared to warfarin for preventing recurrent VTE but with less clinically relevant bleeding. This trial showed that a DOAC may be useful in patients with active cancer.

Given the above information, there is a need to identify prescribing patterns at Akron City Hospital for oncology patients diagnosed with VTE. While guidelines list LMWH as first line treatment, this is not always the agent chosen for these patients. This analysis will identify what impact these prescribing patterns have on patients at Akron City Hospital.

**Objectives:** The primary objective of this study is to determine prescribing patterns for oncology patients diagnosed with VTE at Akron City Hospital. Secondary objectives include analyzing rates of recurrence and adverse effects among oncology patients diagnosed with VTE and determine cost of anticoagulation therapy including management of adverse effects and monitoring.

**Methodology:** A retrospective chart review will examine all patients with a cancer diagnosis who arrived at the Emergency Department and were diagnosed with VTE. From these patients, an evaluation of anticoagulation therapy will be conducted. Further chart review will be conducted to examine any recurrences of VTE or side effects attributable to anticoagulation therapy. Subsequent costs related to therapy including drug monitoring, drug acquisition, and hospital stays will be assessed.

**Results and conclusions:** To be determined.

### References:

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## Adherence to vaccination guidelines in patients awaiting kidney or kidney-pancreas transplant

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### Background:

Vaccines are a critical component of preventative medicine that provides immunity for multiple infections. Vaccine schedules are recommended by the Advisory Committee on Immunization Practice (ACIP) in order to prevent diseases and to avoid potential future complications.<sup>1</sup> The low vaccination rates in the general population are concerning; though, more concerning are low vaccination rates in the immunocompromised population due to an increased risk of morbidity caused by common, preventable infections.<sup>2,3</sup> In a recent study conducted by Lee, et al., the vaccination rate in listed kidney transplant patients for pneumococcal vaccination was reported to be 35.9% ; influenza vaccination, 55%; and zoster vaccination, 6.9%.<sup>3</sup> Vaccinations are generally less effective when they are administered during concomitant immunosuppression, thus is it recommended that vaccines are administered prior to transplantation to ensure the immune response has fully developed.<sup>4</sup> Transplant recipients are exposed to the healthcare system both prior to transplant, often waiting an extended period of time until receiving a donor organ, and after transplant. For these reasons, it is important that efforts focus to improve vaccination adherence in transplant candidates.

### Objectives:

Primary:

- To describe pre-transplant vaccination rates for pneumococcal and influenza vaccines among adult kidney or kidney-pancreas transplant recipients

Secondary:

- To describe pre-transplant vaccination rates (or associated immunity) for other vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) among adult kidney or kidney-pancreas transplant recipients
- To compare patient demographics and vaccination rates of those evaluated by Infectious Disease prior to transplant versus those who were not
- To compare vaccination rates between transplant recipients requiring dialysis versus those receiving a preemptive transplant

### Methodology:

A retrospective chart review will include all adult transplant recipients receiving kidney or kidney-pancreas allografts at the Cleveland Clinic from October 12, 2013 to October 12, 2016. Pre-transplant vaccination history, laboratory markers of immunity for selected vaccine-preventable diseases, baseline demographics, and transplant-related data will be collected from the electronic medical record (EMR) and an internal transplant database. Access to the Ohio Department of Health (ODH) immunization database will be pursued; with ODH institutional review board (IRB) approval, this database will supplement study subjects' vaccination information when applicable. Vaccination will be recognized if administration or history of administration is documented in the EMR or ODH database. Descriptive statistics will be reported for the primary objective; a univariate analysis will be performed for secondary objectives in addition to reporting descriptive statistics. A multivariable analysis will also be completed to identify factors correlated to receiving evaluation by infectious disease.

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1. Savoy M. ACIP Releases 2016 Adult Immunization Recommendations. *Am Fam Physician*. 2016;93(4):323-326.
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## Identifying perceptions of adherence in Human Immunodeficiency Virus (HIV)-positive patients through individual elicitation interviews

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**Background:** Medication adherence is defined as “the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen.”<sup>1</sup> Near-perfect adherence with antiretroviral therapy (ART), or taking at least 95% of scheduled medication doses, is associated with improved virological suppression and immunological recovery in HIV-infected patients.<sup>2</sup> Poor virologic and immune response is not only linked with progression to acquired immunodeficiency syndrome (AIDS) and mortality, it is also correlated with development of ART resistance, inability to use select treatment options in the future, and increased risk of HIV transmission.<sup>3,4</sup> For an individual to maintain this level of adherence, they cannot miss more than one dose per month of a single-tablet regimen or three doses per month of a twice daily regimen. It was estimated in a meta-analysis that adequate adherence rates are achieved in only 55% of the HIV population in North America.<sup>4</sup> This low adherence rate likely accounts for the roughly 76% of ART-prescribed individuals in the United States whom have attained suppressed viral loads. Factors influencing adherence range from behavioral to psychosocial to structural. Some notable barriers to adherence include mental illness, decreased social support, substance abuse, poverty, nondisclosure of HIV-positive status, denial, and stigma.<sup>4</sup> Many studies have assessed adherence as it relates to individuals already prescribed ART. However, little is known about the ability to predict adherence in HIV individuals newly-diagnosed and newly-treated. Therefore, this study aims to identify themes and predictors of adherence by evaluating perceptions of HIV-positive patients. The themes and predictors identified will be used to develop a brief survey that can prospectively predict adherence in treatment-naïve HIV-infected individuals.

**Objective:** To identify perceptions that impact adherence to antiretroviral medications in human immunodeficiency virus (HIV)-positive patients receiving care at an outpatient clinic.

**Methodology:** The study will be submitted to the Institutional Review Board at the University of Toledo Medical Center (UTMC) for approval. HIV-positive patients, 18 years and older receiving care at UTMC’s HIV outpatient clinic will be identified by a third party through review of the electronic medical record system and clinic-based software. Patients will be selected based on “expected” adherence (based on previously identified risk factors for adherence) and actual adherence (based on current viral loads) with four groups being identified – expected/adherent, expected/non-adherent, not expected/adherent, and not expected/non-adherent. Five to ten subjects will be selected for each group. Adherence will be defined as patients with an undetectable HIV ribonucleic acid (RNA) level. Data collected will include the following: age, gender, race, education, income, and most recent viral load. Individuals meeting inclusion into the study will be invited to participate in an individual elicitation interview conducted by a trained interviewer. Following consent, the sessions will follow a structured interview format using predetermined questions related to the Health Belief Model and patient perceptions of disease state, social support, and medication management. Subjects’ responses will be noted, audio recorded, and subsequently transcribed. The data derived from these sessions will be de-identified and remain confidential. Themes will then be extracted and summarized from the transcribed recordings. Responses will be compared between adherent and non-adherent participants. From this, factors that influence the likelihood to be adherent to antiretroviral therapy will be determined.

**Results and conclusions:** To be determined.

### References:

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## **Comparative evaluation of pharmacist managed vancomycin dosing in a community hospital following implementation of a system-wide vancomycin dosing guideline**

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### **Background:**

Vancomycin is one of the most commonly-used antimicrobials in the treatment of gram positive infections, including those colonized with methicillin-resistant *Staphylococcus aureus* (MRSA). Dosing vancomycin in the elderly, young, and obese has proven difficult due to the complex pharmacokinetic and pharmacodynamic properties of vancomycin. Previous studies have shown that pharmacist-directed vancomycin dosing and monitoring results in an increased number of patients optimally dosed and a shorter length of vancomycin therapy. Even with pharmacist managed vancomycin dosing, the actual practices for dosing and monitoring vancomycin are not universal between hospitals. At St. John Medical Center (SJMC), pharmacists are consulted to dose and monitor vancomycin. Over the years, pharmacists have realized that the elderly and renally impaired tend to be overdosed, whereas the young and obese are under dosed with vancomycin therapy following the hospital protocol. Upon incorporation into University Hospitals (UH) system, a new vancomycin dosing guideline was developed and implemented at SJMC. The purpose of this study is to evaluate the implementation of a large hospital system vancomycin dosing guideline in a community hospital with pharmacist-led vancomycin management.

### **Objectives:**

The primary objectives of this study are to evaluate the time to goal serum trough concentration and the total days of vancomycin therapy pre and post-implementation of the new vancomycin dosing guideline. Additional data to be collected includes the following: patient's weight (kg), white blood cell count (WBC), temperature (T), age divided into categories (young: < 40 years, middle-age: 40-64 years, and elderly:  $\geq$  65 years), serum creatinine (sCr), creatinine clearance (CrCl) divided into categories based on the new vancomycin protocol (normal > 50 mL/min, mild impairment 30-50 mL/min, and severe impairment < 30 mL/min), and vancomycin indication.

### **Methodology:**

A retrospective chart review was conducted from November 2015 to March 2016 for patients on vancomycin dosed by pharmacists (pre-implementation of UH vancomycin dosing guideline). This data was compared to electronic medical records (EMR) of patients on vancomycin dosed by pharmacists between November 2016 to March 2017 (post-implementation of UH vancomycin dosing guideline). A sample size of 84 people per study group was required to achieve a power of 90%, with alpha at 0.05 and beta at 0.1 with an effect size of 0.5. Patient's age, weight (kg), sCr, CrCl, vancomycin indication, dosing, frequency, WBC, T, time to goal trough concentration, and days of vancomycin therapy were documented and analyzed. Patients were excluded if they were currently receiving dialysis at the time of vancomycin dosing or less than 18 years of age. Data was analyzed using descriptive and inferential statistics and interval data for the primary objective was analyzed using a student t-test.

**Results and conclusions:** Results and conclusions to be presented after completion of the study.

### **References:**

1. Rybak M, Lomaestro B, Rotschafer J, et al. Therapeutic drug monitoring of vancomycin in adult patients: a consensus review of the American Society of Health-System Pharmacists, the Infectious Diseases Society of America, and the Society of Infectious Diseases Pharmacists. *Am J Health-Syst Pharm.* 2009;66:82-98.
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## The clinical and economic impact of extended-infusion versus intermittent-infusion piperacillin-tazobactam for selected gram-negative infections at a community medical center

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**Background:** Piperacillin-tazobactam is a time-dependent penicillin antibiotic that is used empirically for many suspected gram-negative infections.<sup>1</sup> Antimicrobial stewardship is an essential resource institutions utilize to enhance activity of antimicrobial agents and to decrease resistance rates of pathogenic organisms.<sup>2</sup> Pharmacokinetic and pharmacodynamic studies show that penicillin-derived drugs achieve maximal bactericidal effect when the free drug concentration is above the minimum inhibitory concentration (MIC) greater than 50% of the time (50%  $fT > MIC$ ).<sup>3</sup> Utilizing an extended-infusion dosing strategy for piperacillin-tazobactam (4 hour infusion) offers enhancements in the pharmacokinetics of the antibiotic by increasing the time that the free drug concentration exceeds the bacterial MIC.<sup>3</sup> Retrospective cohort studies have shown mixed results regarding clinical outcomes in patients treated with extended-infusion piperacillin-tazobactam and have studied various populations.<sup>4</sup> This study seeks to add to the current literature and assess gaps such as safety and convenience of extended-infusion dosing for piperacillin-tazobactam.

**Objectives:** The purpose of this study is to compare clinical outcomes, economic data, safety, resistance patterns, and intravenous line accessibility of intermittent-infusion versus extended-infusion piperacillin-tazobactam in patients with selected gram-negative infections.

**Methodology:** This study will be submitted to the Institutional Research Review Board (IRRB) for approval. Hospital billing records and microbiology reports will be used to identify patients with *Escherichia coli*, *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Pseudomonas aeruginosa*, and *Serratia* spp. infections who received piperacillin-tazobactam for at least 48 hours. Patients over the age of 18 that received piperacillin-tazobactam before August 1, 2012 will be placed in the intermittent-infusion group and patients receiving the drug after August 1, 2012 will be placed in the extended-infusion group. Patients that were pregnant, discharged to hospice care, or had organisms that were intermediate or resistant to piperacillin-tazobactam will be excluded from the study. The primary outcome is the difference in mortality (in-hospital) between the intermittent-infusion and extended-infusion groups. Secondary outcomes to be compared in these groups include length of stay, length of piperacillin-tazobactam therapy, number of peripheral and central lines inserted after initiation of piperacillin-tazobactam, incidence of *Clostridium difficile* infection, and incidence of acute kidney injury. Additionally, cost of drug acquisition per admission and susceptibility patterns of selected gram-negative infections over the study period will be analyzed as secondary outcomes. All data will be recorded without patient identifiers to maintain confidentiality. Confounding variables to be assessed include Intensive Care Unit (ICU) stay, source of infection, renal impairment, Body Mass Index (BMI), and concomitant antibiotic use. A statistician will aid in the evaluation of data.

**Results and conclusions:** The study results will be reported upon approval from the IRRB and completion of data collection.

### References:

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2. Fishman N. Antimicrobial stewardship. *American Journal of Infection Control*. 2006;34(5):S55-63.
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4. Yang H, Cui X, Zhou M, Liu L. Evaluation outcomes associated with alternative dosing strategies for piperacillin/tazobactam: A systematic review and meta-analysis. *J Pharm Pharm Sci*. 2016;19(2):274-89.

## Time to hepatitis C treatment start when managed by Cleveland Clinic Specialty Pharmacy

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### Background:

The treatment for hepatitis C virus (HCV) has considerably evolved since the introduction of HCV protease inhibitor therapies in 2011, with success rates surpassing 95%. However, dramatic time lapses are known to occur between diagnosis and starting anti-HCV therapy for various reasons. Referral to an appropriate hepatitis specialist can take several months to a year. Once anti-HCV therapy is prescribed, completion of pre-treatment paperwork, insurance coverage, and medical eligibility need to be assessed as a patient is referred to a specialty pharmacy. If any elements are missing, time to treatment start is delayed. These times may vary, ranging from several days to a few months. Turnaround time for prescriptions is one of the five mandatory measures assessed by the Utilization Review Accreditation Commission (URAC) and is becoming increasingly important to improve the quality of patient care, avoiding further costs in the future.

### Objective:

The purpose of this study is to evaluate the time to treatment start of anti-HCV therapy at Cleveland Clinic Specialty Pharmacy.

### Methodology:

The primary objective will be to determine the time to hepatitis C therapy treatment start by assessing time from receipt of prescription through the electronic medical record to time of treatment start when managed by the Cleveland Clinic Specialty Pharmacy. Secondary objectives will include assessing medication adherence, SVR12 rates, difference in time to treatment start based on insurance carrier and therapy prescribed, and assessing the time from receipt of prescription to time of prior authorization approval or denial status. If the prior authorization is denied, the time from denial to appeal approval will also be assessed. Patients will be included if they have at least one claim for one or more hepatitis C treatment medications during the study period (January 6, 2015 - July 29, 2016) and must have detectable HCV RNA. Patients will be excluded if they have an undetectable HCV RNA at the study start time. Baseline characteristics and primary and secondary endpoints will be analyzed using descriptive statistics.

### Results and conclusions:

To be determined

### References:

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## **The Impact of Using a Mini-Cog Screening Tool with a Caregiver Intervention on 30-day and 90-day Readmission Rates and Recurrent ED Visitations in Congestive Heart Failure Patients**

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**Background:** Cognitive impairment within the congestive heart failure (CHF) population is considered to be a major predictor of unplanned 30-day readmissions and emergency department visits.<sup>1</sup> Intervening on this high risk population has been met with variable approaches.<sup>2,3</sup> Most interventions targeting the cognitively-impaired CHF population have involved self-management education, comprehensive medication review, a follow-up telephone call, and/or creation of a liaison between a the patient and primary care provider, with mixed results.<sup>2,3</sup> To our knowledge, none of these have involved direct caregiver education as a part of the discharge process, with the intent of improving the patient's medication adherence.

**Objectives:** To determine the impact of screening patients with CHF using the Mini-Cog screening tool, and implementing a caregiver intervention during discharge counseling for those who are identified to have cognitive impairment, on the composite outcome of 30-day and 90-day unplanned readmissions and emergency department (ED) visitations.

**Methodology:** A prospective, randomized, interventional study will be performed at Cleveland Clinic Akron General from August 1<sup>st</sup>, 2016 to February 28<sup>th</sup>, 2017. Patients with a diagnosis of CHF who are at least 65 years old and have at least 6 scheduled medications on admission will be randomized in a 1:1 fashion to be screened for cognitive impairment with the Mini-Cog assessment tool or to receive standard of care. In both groups, patients will receive discharge medication review and counseling by a pharmacist at discharge as part of the standard of care. Patients who are identified to have cognitive impairment will have their caregiver educated about their medications either at discharge or as a follow-up phone call within 5 days of discharge. Those patients who do not have a caregiver will be suggested for a referral for home health care. The primary outcome will be the number of 30-day and 90-day unplanned readmissions and ED visits in the intervention group, as compared with the control group. Statistical significance of the composite primary outcome will be measured using the Fisher's exact or Chi-square test, as appropriate.

**Results and conclusions:** To be determined.

### **References:**

1. Patel P, Parikh R, Howell EH, et al. Mini-cog performance: novel marker of post discharge risk among patients hospitalized for heart failure. *Circ Heart Fail.* 2015;8:8-16.
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3. Davis KK, Mintzer M, Himmelfarb CRD, et al. Targeted intervention improves knowledge but not self care or readmissions in heart failure patients with mild cognitive impairment. *Eur J Heart Fail.* 2012 Sep;14(9): 1041-9.

## Evaluation of hypertonic sodium solution guideline compliance at a large academic medical center

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PGY-2 Critical Care

### Background:

Hypertonic sodium solution (HSS) induces an osmotic gradient to draw water from the interstitial space to the intravascular space reducing intracranial volume and intracranial pressure (ICP) without the risk of rebound cerebral edema. HSS has been compared to mannitol for the reduction of ICP, demonstrating HSS had improved ICP control.<sup>1,2</sup> The use of buffered HSS (50:50 sodium chloride: sodium acetate) has been used to reduce the risk of hyperchloremic acidosis while demonstrating reduction in ICP.<sup>1,3</sup> HSS is typically administered as repeated bolus doses of up to 23.4% sodium chloride<sup>2,4</sup> or as a continuous infusion.<sup>1,2,3</sup> The majority of evidence is with the bolus administration of HSS compared to the continuous infusions.<sup>1,2</sup> The current procedure for HSS at University Hospitals Cleveland Medical Center (UHCMC) is either bolus administration, continuous infusion or a combination of bolus with a continuous infusion.

### Objectives:

The objective of the study is to evaluate the compliance rate among patients prescribed hypertonic sodium solutions within the intensive care units at UHCMC. Secondary objectives of this study are to evaluate use of HSS in accordance with institution guidelines, use of HSS for ICP management, and mortality stratified by initial therapy (mannitol vs. HSS).

### Methodology:

This retrospective cohort study will take place from January 1<sup>st</sup>, 2015 to December 31<sup>st</sup>, 2015. Patients receiving HSS ordered from the HSS order set will be eligible for inclusion into the study. Patients will be stratified based on the administration technique of HSS. Adult patients will be included if they are receiving HSS for ICP management. Patients receiving HSS for management of hyponatremia will be excluded. The study will take place in the intensive care units at UHCMC. The primary endpoint is compliance with the UHCMC HSS guideline defined as: neurocritical care team as primary or consult service, HSS IV bolus volume and rate within guideline recommendations, HSS IV continuous infusion volume and rate within guideline recommendations, and electronic orders for repeat bolus administration placed in electronic medical record. Secondary endpoints include usage without neurocritical care involvement, when ICP is monitored: measuring device, median number of excursions of ICP > 20 mm Hg per day, and median ICP measurement during HSS therapy. Other secondary endpoints include utilization of alternative therapies to reduce ICP within 24 hours prior and 72 hours post initiation of HSS, hospital mortality stratified by initial therapy with mannitol or HSS, Modified Rankin Scale at discharge and 6-12 month follow-up, adverse events (central pontine myelinolysis), and discharge status.

### Results and conclusions:

Pending IRB approval; results will be presented in the spring of 2017.

### References:

1. Forsyth LL, Liu-DeRyke X, Parker D, et al. Role of hypertonic saline for the management of intracranial hypertension after stroke and traumatic brain injury. *Pharmacotherapy*. 2008;28(4):469-484.
2. Forsyth LL, Liu-DeRyke X, Parker D, et al. Role of hypertonic saline for the management of intracranial hypertension after stroke and traumatic brain injury. *Pharmacotherapy*. 2008;28(4):469-484.
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**Optimal norepinephrine equivalent dose to initiate epinephrine in patients with septic shock**

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**Background:** Septic shock is one of the leading causes of infection-related death with an estimated in-hospital mortality rate of 30%.<sup>1</sup> The 2012 Surviving Sepsis Campaign recommends the use of norepinephrine as the first-line vasopressor for septic shock with epinephrine, vasopressin, or, in the appropriate patient, phenylephrine as potential second agents.<sup>2</sup> The specific norepinephrine dose at which a second agent should be added has not yet been identified. Consequently, the addition of a second vasopressor has occurred at a broad range of doses in literature, and it is driven mainly by clinician preference.<sup>3-5</sup> Given the varied approaches, it is likely that improvement in patient outcomes can be achieved by better understanding the appropriate vasopressor dosing to ensure maximum benefit with minimum risk. The aim of this study is to determine the optimal norepinephrine-equivalent dose at which epinephrine should be initiated in patients with septic shock.

**Objectives:** The primary objective of this study is to determine the optimal norepinephrine-equivalent dose at epinephrine initiation that is associated with hemodynamic stability in patients with septic shock. Hemodynamic stability will be defined as two subsequent decreases in norepinephrine-equivalent dose without an increase within eight hours.<sup>6</sup> Secondly, two cohorts of patients will be identified: those who received the optimal norepinephrine equivalent-dose and those that did not. Differences between the two cohorts in the time to achieve mean arterial pressure goal, shock-free survival, ICU-free days, hospital length of stay, and the 48 hours change in sequential organ failure assessment score from baseline will be determined. For safety, the incidence of significant arrhythmias, lactic acidosis, and hyperglycemia will be assessed.

**Methodology:** This study will be a non-interventional, retrospective cohort study. Adults admitted to the medical, surgical, or neurological ICU at the Cleveland Clinic Main Campus between August 1, 2010 and August 31, 2016 will be included if they had a diagnosis of septic shock, received norepinephrine prior to initiation of epinephrine, and received epinephrine for at least one hour. Patients will be excluded if norepinephrine and epinephrine were started concomitantly or if epinephrine was started prior to admission. Approximately 1700 patients will be screened for study inclusion. Classification and regression tree analysis will be conducted to determine the optimal norepinephrine-equivalent dose based on hemodynamic stability. Secondary outcomes will be compared between the optimal norepinephrine-equivalent dose cohort and the non-optimal norepinephrine-equivalent dose cohort. Categorical data will be analyzed with  $\chi^2$  test or Fisher exact test, and Student's t-test or Mann-Whitney U test will be used for continuous variables, as appropriate.

**Results and conclusions:** To be determined.

**References:**

1. Angus DC, van der Poll T. Severe sepsis and septic shock. *N Engl J Med.* 2013;369(9):840-51.
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## The Impact of Achieving Virologic Response from Hepatitis C Direct-Acting Antivirals on Diabetes Control

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PGY-2 Ambulatory Care

Louis Stokes Veterans Affairs Medical Center

**Background:** Approximately 2.7-3.9 million people in the United States are infected with hepatitis C virus (HCV). The prevalence of patients infected with HCV and suffer from type 2 diabetes has been noted to be as high as 50%.<sup>1</sup> A relationship has been described between HCV infection and impaired insulin sensitivity, with improved glycemic control upon virologic response from peginterferon and ribavirin.<sup>2</sup> A new era of hepatitis C treatment emerged in 2013 with the FDA approval of short course direct acting antivirals (DAAs). These medications have demonstrated dramatically higher cure rates of greater than 90%, resulting in a large uptake of their utilization.<sup>3</sup> Manifestations of successful HCV treatment beyond the liver have yet to be explored, including the impact of successful HCV treatment on glucose control.

**Objectives:** This study will expand on a previous study completed at the Louis Stokes Veterans Affairs Medical Center which found that 27% of Veterans with type 2 diabetes successfully treated with DAAs had de-escalation of their diabetes medications. Additionally, a statistically significant decrease in A1C of 0.63% was found. Given uncertainty of the impact of close pharmacist medication management potentially motivating patients to maintain higher adherence to diabetes medications, this current study will assess initial and sustained A1C change in patients who have completed treatment with short course DAAs. The primary objective of this study is to assess the change in A1C from baseline to 4 months post HCV treatment among patients who achieve a cure defined as, sustained virologic response 12 weeks post-treatment (SVR12). Secondary objectives include assessing the sustained change in A1C, assessing change in antihyperglycemic therapy, and comparing these changes in those who achieve SVR12 to those who relapse.

**Methodology:** This study was submitted to the local Institutional Review Board for approval. Medication dispense history will be utilized to identify patients prescribed sofosbuvir, simeprevir, ledipasvir/sofosbuvir, ombitasvir/paritaprevir/ritonavir +/- dasabuvir, elbasvir/grazoprevir, and sofosbuvir/velpatasvir between February 1, 2014 and September 27, 2016 who also have a diagnosis of diabetes per ICD9 and ICD10 codes. Patients will be excluded if they did not complete a full hepatitis C treatment course or are not taking any diabetic medications prior to the start of hepatitis C treatment. The primary endpoint is the change in A1C from baseline to 4 months post HCV treatment. Secondary endpoints include sustained change in A1C up to 18 months post treatment and changes in diabetes medications at the end of treatment defined as escalation, de-escalation, and no change. Additionally, the changes in A1c and diabetes medications will be compared among those who achieve SVR12 and those who relapse. A paired t test will be used to analyze changes in A1C, while descriptive statistics will be used for other secondary endpoints. The anticipated sample size after inclusion and exclusion will be 160.

**Results and Conclusions:** To be determined

### References:

1. Centers for Disease Control and Prevention. Surveillance for Viral Hepatitis – United States, 2014. MMWR 2009;58(SS-3).
2. Jacobson I, Cacoub P, Dal Maso L, et al. Manifestations of chronic hepatitis C virus infection beyond the liver. *Clinical Gastroenterology and Hepatology*. 2010; 8;1017-1029.
3. American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), "Recommendations for Testing, Managing, and Treating Hepatitis C," found at <http://www.hcvguidelines.org/full-report-view>.

## **A targeted multimodal antimicrobial stewardship protocol in patient with or at high risk for developing *Pseudomonas aeruginosa* pneumonia**

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PGY-1

St. Elizabeth Youngstown Hospital

### **Background:**

The 2016 IDSA guidelines for implementation of antimicrobial stewardship along with newly published Hospital and Ventilator-associated Pneumonia guidelines recommend alternative dosing strategies for broad-spectrum beta lactams and proper identification of patients at high risk for multi-drug resistant (MDR) gram negative organisms. The objective of this study is to determine if length of IV anti-pseudomonal therapy can be decreased by implementing a pharmacist-driven antimicrobial stewardship program aimed at providing institution-specific appropriate double coverage to high risk patients, optimizing beta-lactam dosing to improve pharmacodynamics, and providing recommendations for appropriate duration of antibiotics in patients with *Pseudomonas aeruginosa* pneumonia.

### **Objectives:**

To reduce the duration of IV anti-pseudomonal therapy in patients with *Pseudomonas* pneumonia by quickly and effectively identifying at risk patients and initiating appropriate treatment

### **Methodology:**

This study is Institutional Review Board approved. It is a before after study to investigate the impact of a clinical pharmacist facilitated antimicrobial stewardship program on duration of IV anti-pseudomonal antibiotics in hospitalized patients with *Pseudomonas* pneumonia. The electronic medical record will be utilized to identify patients with respiratory cultures having been drawn within the previous 24 hours. Patients will be screened for the necessity of double anti-pseudomonas coverage by assessing antibiotic use within the previous 90 days. Other patients that will receive a recommendation for double coverage include those with septic shock and those with increased risk of mortality. Patients will be followed until culture results are obtained, and therapy narrowed if appropriate. Patients will be included in the study if they have a positive *Pseudomonas* respiratory culture. Beta-lactam administration will be optimized by providing extended infusion cefepime and piperacillin/tazobactam at doses recommended by the HAP and VAP guidelines if indicated. A Monte Carlo simulation may be run to ensure probability of target attainment of 90% on select patients. Patients will be followed daily by a clinical pharmacist. When patients meet clinical criteria for resolution, and after at least 7 full days of treatment, a call will be made to the physician recommending discontinuation of anti-pseudomonal therapy. If the recommendation is not accepted, an additional call will be made on days 10 and 14. Length of IV anti-pseudomonal duration will be compared retrospectively to culture positive *Pseudomonas* pneumonia patients.

### **Results and conclusions:**

This project is currently ongoing. Results will be presented at a later time.

### **References:**

1. Kalil AC, Metersky ML, Klompas M, et al. Management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clin Infect Dis*. 2016.
2. Dellit TH, Owens RC, McGowan JE Jr., et al. Infectious Diseases Society of America and the Society for Health-care Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. *Clin Infect Dis*. 2007;44:159–177.
3. Bauer K, West J, O'Brien J, et al. Extended-infusion cefepime reduces mortality in patients with *Pseudomonas aeruginosa* infections. *Antimicrob Agents and Chemoth*. 2013;57(7):2907-12.

**Impact of pharmacist-driven post-discharge medication reconciliation on 30-day readmission rates: a retrospective chart review.**

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PGY-1 Pharmacy Resident

Research Site: Cleveland Clinic - Medina Hospital

**Background:** Medication discrepancies have the potential to prolong hospital length of stay and lead to increased utilization of other healthcare resources, including increased emergency department visits and hospital readmissions. Medicare readmissions within thirty days of discharge have been estimated to cost approximately \$17.4 billion a year, which represents substantial implications for both patients and the entire health care system.<sup>1</sup> As part of the Protecting Access to Medicare Act of 2014, Congress enacted a skilled nursing facility (SNF) readmission policy, where facilities will begin publicly reporting in October 2017. This also requires development of an all-condition, risk-adjusted, potentially preventable readmission measure by October 2016.<sup>2</sup> Previous studies have shown that medication reconciliation led by pharmacists post-discharge can decrease readmissions and provide cost savings.<sup>3,4</sup> These studies typically only included patients being discharged to the community and not to nursing facilities. At Cleveland Clinic Medina Hospital, a large percentage of inpatients are admitted from nursing facilities and/or discharged to nursing facilities. This study will focus specifically on patients discharged to nursing facilities.

**Objectives:** The primary outcome is readmission to a Cleveland Clinic inpatient facility within thirty days of discharge. Secondary outcomes include number and type of medication discrepancies, drug interactions, interventions requiring physician contact, and average time of phone call.

**Methodology:** This study is a randomized, retrospective chart review of patients discharged from Cleveland Clinic Medina Hospital to SNFs and long term acute care facilities (LTACs). Daily discharge reports will be evaluated to identify patients discharged to SNFs and LTACs. All patients discharged to a SNF or LTAC will be randomized equally into two groups: patients who will receive post-discharge medication reconciliation and patients who will not. The nursing facility will be contacted to conduct a medication reconciliation within three days of discharge for those patients randomized into the intervention group. The following baseline data will be collected from the electronic medical record: patient age, gender, number of scheduled medications, length of stay, and primary discharge diagnosis. The number of medication discrepancies, drug interactions, interventions requiring physician contact, and length of the phone call will be documented. A medical record review will be completed to determine readmission rate to a Cleveland Clinic inpatient facility within thirty days of discharge. All data will be recorded in a secure database to maintain patient confidentiality. This study will be submitted to the Institutional Review Board for approval.

**Results and conclusions:** Research in progress.

**References:**

1. Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in Medicare fee-for-service program. *N Engl J Med*. 2009;360:1418–1428
2. Medicare Payment Advisory Commission (MEDPAC). Skilled nursing facility services. In: Report to the Congress: Medicare Payment Policy. Washington, DC; 2016. p. 175-205.
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4. Reducing Readmission at an Academic Medical Center: Results of a Pharmacy-Facilitated Discharge Counseling and Medication Reconciliation Program. *Hosp Pharm*. 2016 Jun;51(6):468-73. doi: 10.1310/hpj5106-468.

**Clinical and humanistic outcomes of face-to-face and telehealth warfarin management: A retrospective, repeated measures study.**

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PGY-1 Hospital

Research Site: MetroHealth Medical Center

**Background/Purpose:** Health systems are rapidly expanding to offer ambulatory services, including warfarin-management, throughout surrounding communities. This can lead to various warfarin-management approaches with lack of standardization from site to site. This study will evaluate clinical and humanistic outcomes of warfarin management via face-to-face and telephone encounters to determine how well patients are clinically managed in each setting; as well as how satisfied patients are with telehealth care. This information may help guide health-systems to decide which services to offer and which patients may benefit from telehealth or face-to-face encounters.

**Methodology:**

This study will be approved by the institutional review board prior to commencement. The population includes about 165 patients transitioning from two satellite anticoagulation clinics to the Medication Management Clinic (MMC) for warfarin management. Patients must be 18 years or older, taking warfarin, and managed by one of the two satellite clinics at least six months prior to transitioning to MMC. Patients will be excluded if warfarin is discontinued during the study period, patient is home INR testing, or if the patient uses the face-to-face clinic instead of telehealth more than 25% of the time. Excel software will be used for retrospective data collection including; demographics, indication, goal INR range, use of chronic NSAIDs or antiplatelet medications, use of vitamin K, encounter type, INRs, number of procedural interruptions, and hospitalizations/emergency room visits stratified by primary diagnosis and bleed type per BARC score (Bleeding Academic Research Consortium). Data will be collected from six months prior to transitioning to MMC through six months following the transition. Design: Non-inferiority, retrospective, repeated measures. Primary outcome: time in therapeutic range (TTR) calculated via the Rosendaal method. Secondary outcomes include extreme INR level ( $\text{INR} \geq 4.5$  or  $\text{INR} \leq 1.5$ ), noncompliance to follow-up, and hospitalizations/ER visits stratified by primary outcome and BARC bleeding score. Humanistic outcomes will be assessed via mailed patient satisfaction surveys. 70 patients must complete this study to meet 99% power.

**Results and conclusions:** Pending institutional review board approval prior to study commencement.

**References:**

1. Erkens P, ten Cate H, Büller H, Prins M. Benchmark for Time in Therapeutic Range in Venous Thromboembolism: A Systematic Review and Meta-Analysis. *Plos ONE*. September 25, 2012;7(9):1-11.
2. Singer D.E., Hellkamp A.S., Piccini J.P., et al; Impact of global geographic region on time in therapeutic range on warfarin anticoagulant therapy: data from the ROCKET AF clinical trial. *J Am Heart Assoc*. 2013; 2(1):1-15.
3. Mehran R, Rao S, White H, et al. Standardized Bleeding Definitions for Cardiovascular Clinical Trials A Consensus Report From the Bleeding Academic Research Consortium. *Circulation*. 2011;123:2736-2747.
4. Schulman S, Parpia S, Stewart C, Rudd-Scott L, Julian JA, Levine M. Warfarin dose assessment every 4 weeks versus every 12 weeks in patients with stable international normalized ratios: a randomized trial. *Ann Intern Med*. 2011;155(653-659):W201–W653.

## Impact of a Pharmacy-led Tobacco Cessation Medication Protocol at Discharge in a Community Hospital

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**Background:** Tobacco use has been well established as a contributor to preventable disease and death. According to the latest data from the Centers for Disease Control and Prevention (CDC), nearly 1 in every 6 adults smoke cigarettes in the United States. The number of adults who use other forms of tobacco such as cigars, smokeless, and E-cigarettes only add to this number. It is estimated that 1 in every 5 deaths can be attributed to smoking and over 16 million Americans are currently living with a smoking-related disease. In addition, health care costs related to tobacco use accumulate to an estimated 96 billion dollars per year.<sup>1</sup> Despite a decrease in smoking rates in recent years, there remains a need to educate current tobacco users on the detriment it is causing to their health and the health of those around them. Providing resources and support through healthcare interventions has been proven to help tobacco users quit more effectively than on their own. A study by Puschel et al. revealed that a minimal intervention lasting less than 3 minutes in primary care clinics decreased the overall prevalence of tobacco users.<sup>2</sup> Pharmacists have the specific skill set required to share information about nicotine replacement therapies (NRTs) and other medication management options for quitting. The Joint Commission, in combination with the Partnership for Prevention and the Substance Abuse and Mental Health Services Administration (SAMHSA), has created a standardized performance measure to address tobacco screening and cessation counseling for all hospitalized inpatients. The Centers for Medicare and Medicaid Services (CMS) Tobacco Treatment (TOB) measure set contains four measures and is available to hospitals to meet their six core measure set accreditation requirement. Of the four measures, TOB-3 (Tobacco Use Treatment Provided or Offered at Discharge) and TOB-3a (Tobacco Use Treatment at Discharge) provide the most opportunity for pharmacy intervention. University Hospitals St. John Medical Center (UHSJMC) is currently meeting the TOB-3/3a measure in 0% of patients, with a goal of 50%. A pharmacy driven tobacco cessation medication pilot program at discharge was implemented to reach this goal and to provide an intervention encouraging tobacco users to quit.

**Objectives:** The primary objective is to determine the number of tobacco cessation medication and education interventions made before discharge. The secondary objectives are to determine the percentage of tobacco users given an over the counter (OTC) nicotine replacement therapy (NRT) recommendation upon discharge and the percentage referred to the tobacco cessation Quitline.

**Methodology:** The study will be submitted to the Institutional Review Board for approval before initiation. A retrospective review of this pilot program will be completed from November 2016 through April 2017. A daily list is compiled identifying all current tobacco users with an inpatient status and their response to initial assessment questions regarding their willingness to accept tobacco cessation and/or medications. Based on this convenience sample, patients are identified and seen by a pharmacy representative to discuss tobacco use history, benefits of quitting, and resources available to help patients quit. Per the approved pharmacy protocol, patients are given an education sheet reviewing the different OTC NRT options to determine which one is best for them. The pharmacist places an order for the chosen OTC NRT on the discharge medication list as a new medication. A prescription is not given, rather, the patient is instructed to purchase the selected NRT as an OTC medication at their local pharmacy. Each intervention is documented electronically by the pharmacist in the patient's medical record. Patients meeting the TOB-3/3a quality measure are also documented. The total number of prior interventions and patients meeting the TOB-3/3a measure from November 2015 through April 2016 will be analyzed against the study group using descriptive statistics.

**Results and conclusions:** Results and conclusions to be presented after completion of the study.

### References:

1. Centers for Disease Control and Prevention. Current Cigarette Smoking Among Adults in the United States. Fact Sheet 2014.
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3. Fiore, M. C., Jaen, C. R., & Baker, T. B. (2008). A clinical practice guideline for treating tobacco use and dependence: 2008 update a U.S. public health service report. *American Journal of Preventive Medicine*, 35(2), 158-176.

## Evaluating intubation success after establishment of a rapid sequence intubation guideline

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**Background:** The first task that clinicians are often faced with when an unstable, acutely ill patient experiences respiratory compromise, is to secure the patient's airway via intubation to maintain adequate oxygenation. Rapid sequence intubation (RSI) is a technique that is often utilized in these situations to provide optimal intubating conditions. RSI incorporates a rapidly acting sedative, known as the process of induction, with a neuromuscular blocking agent for paralysis. After these agents are administered, the physician will utilize a laryngoscope to visualize the airway and guide the tube into the appropriate position<sup>1</sup>. There have been several previous trials that have shown the positive impact an RSI protocol can have on intubation success rates, time to intubation, and reduced rates of medication readministration<sup>2, 3, 4</sup>. Currently, the procedure for intubation at University Hospitals- Cleveland Medical Center is practitioner specific with no standardized guideline for practitioners to utilize. Therefore, the primary aim of this study is to implement an RSI guideline that has been developed by several specialties (pulmonary/critical care, pharmacy, anesthesiology, trauma, emergency medicine) and evaluate intubation outcomes after it has been established.

**Objectives:** The primary objective of the study is to evaluate intubation success rates after an RSI guideline has been established and implemented at University Hospitals- Cleveland Medical Center. The secondary objective is to assess overall guideline adherence rates to correlate the rate at which the guideline is being followed.

**Methodology:** This study will be a single-center, prospective, non-interventional chart review analyzing intubation outcomes after a rapid sequence intubation guideline is implemented at the institution. Data will be collected from all patients aged 18 and older undergoing rapid sequence intubation in the emergency department or intensive care units from January 1, 2017 through March 1, 2017 at University Hospitals- Cleveland Medical Center. Exclusion criteria includes patients less than 18 years old, and patients intubated without rapid sequence intubation. Patients will be identified via intubation notes entered in the electronic medical record, ICD-10 codes, and by the RSI guideline that is to be filled out during or immediately after each intubation is completed. In brief, the guideline includes required equipment, medications with dosing information, medication precautions, airway assessment and passing the tube instructions, and post-intubation plans. Adherence to the guideline is defined as utilizing the medications on the guideline at the appropriate dose indicated and filling out all parts of the guideline sheet. Data collection points include patient demographics, significant past medical history of paraplegia or quadriplegia, skeletal muscle myopathies, or a personal or family history of malignant hyperthermia, Glasgow coma score, injury severity score, mechanism of injury, pre- and post-intubation vital signs, laboratory results, induction and neuromuscular blocking agents used with dose, indication for RSI, number of intubation attempts, and if intubation was effectively achieved. All data will be recorded and maintained confidentially via the REDCap™ database system. The primary endpoint will be assessed by determining the proportion of patients that are intubated successfully, and secondary endpoints will be evaluated by determining the proportion of patients that adhere to all aspects of the protocol. Statistical analysis will be conducted as appropriate.

**Results and conclusions:** Research is ongoing.

### References:

1. Hampton JP. Rapid-sequence intubation and the role of the emergency department pharmacist. *Am J Health-Syst Pharm.* 2011; 68:1320-30.
2. Pearson S. Comparison of intubation attempts and completion times before and after the initiation of a rapid sequence intubation protocol in an air medical transport program. *Air Med J.* 2003; 22(6): 28-33.
3. Ballow SL, Kaups KL, Anderson S, Chang M. A standardized rapid sequence intubation protocol facilitates airway management in critically injured patients. *J Trauma Acute Care Surg.* 2012; 73(6): 1401-5.
4. Jones JH, Weaver CS, Rusyniak DE, Brizendine EJ, McGrath RB. Impact of emergency medicine faculty and an airway protocol on airway management. *Acad Emerg Med.* 2002; 9(12): 1452-6.

## **Evaluation of antibiotic use and the impact of pharmacist and provider education in the treatment of asymptomatic bacteriuria in a community teaching hospital**

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PGY-1 Pharmacy Practice

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### **Background:**

The Infectious Diseases Society of America (IDSA) defines asymptomatic bacteriuria (ASB) as the isolation of a bacterial pathogen without signs or symptoms of a urinary tract infection. Antibiotics are not recommended in these patients with the exception of pregnant patients and those undergoing urologic procedures.<sup>1</sup> One randomized trial showed that treatment of ASB in premenopausal women did not have a benefit in frequency of symptomatic infections.<sup>2</sup> In a variety of institutional settings, treatment with antibiotics may occur in as many as 68% of patients with ASB.<sup>3</sup> Inappropriate use of antibiotics can lead to complications such as the development of multi-drug resistant organisms, *Clostridium difficile* infections, and subsequent symptomatic urinary tract infections.<sup>3</sup>

### **Objectives:**

The objective of the study is to assess the impact of education on antibiotic prescribing practices for ASB patients. The primary endpoint is the number of patients with ASB who were treated in accordance with IDSA guidelines. The secondary endpoints include duration of antibiotic therapy and number of patients discharged on oral antibiotics.

### **Methodology:**

This retrospective before and after study will compare the number of ASB patients treated in accordance with the IDSA guidelines before and after medical staff education led by pharmacy. The control (before) group will be obtained through a hospital medical record search for adult patients diagnosed with a urinary tract infection or ASB admitted between October 19, 2015 and January 20, 2016. The study (after) group will be obtained through the same process using the dates from October 20, 2016 to January 20, 2017. The study will include three internal medicine services with the same attending physician for both study periods. Education will consist of dissemination of hospital treatment guideline for urinary tract infections and ASB, formal presentations for medical and pharmacy staff, and continued pharmacy intervention throughout the post-study period on medical floors with decentralized pharmacists. Inpatients greater than 18 years of age with a hospital discharge diagnosis of urinary tract infection or ASB will be included. Patients will be excluded if pregnant, history of renal transplant, or undergoing a urological procedure during admission.

### **Results and conclusions:**

This study is ongoing. Results will be presented.

### **References:**

1. Nicolle et al. Infectious diseases society of America guidelines for the diagnosis and treatment of asymptomatic bacteriuria in adults. *Clinical Infectious Diseases*. 2005; 40:643-54
2. Nicolle LE. A paradigm shift to non-treatment of asymptomatic bacteriuria. *Pathogens* 2016; 5(2):38
3. Dull R. Friedman S. Risoldi Z. et al. Antimicrobial treatment of asymptomatic bacteriuria in noncatheterized adults: a systematic review. *Pharmacotherapy* 2014; 34: 941-960.

## Impact of an individualized education approach on readmission rates in heart failure patients

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**Background:** Heart failure is the leading cause of hospitalization among adults 65 years of age and older in the United States. More than one million patients are hospitalized with a primary diagnosis of heart failure annually, accounting for a total Medicare expenditure surpassing \$17 billion. The Hospital Readmissions Reduction Program, established by the Affordable Care Act, requires the Center for Medicare and Medicaid Services (CMS) to reduce payments to hospitals with the highest heart failure readmission rates during the first 30 days of discharge. The program offers incentives for hospitals to decrease readmission rates for patients with heart failure and improve continuity of care.<sup>1</sup> The 2013 ACCF/AHA Guideline for the Management of Heart Failure stresses the importance of education before hospital discharge, at the first post-discharge visit, and in subsequent follow-up visits.<sup>2</sup> A study examining the effect of a transition of care pharmacy resident on heart failure 30-day readmissions found a statistically significant reduction in rehospitalizations in the intervention group compared to the control group (12.3% vs. 23.8%).<sup>3</sup> Furthermore, TMF Health Quality Institute, the Medicare quality improvement (QI) organization in Texas, performed a CMS-funded QI project focused on transitions of care in heart failure patients and discovered poor communication and inadequate education to be two major causes of high readmission rates.<sup>4</sup> Therefore, this study seeks to determine if pharmacist-provided bedside education will lead to a significant reduction in heart failure readmissions.

**Objectives:** The primary objective of this study is to determine if an individualized approach to patient education reduces 30-day hospital readmission rates of heart failure patients at Cleveland Clinic Main Campus. The secondary objective is to compare the proportion of patients who successfully fill new heart failure prescriptions post-discharge in the individualized education group versus the standard of care education group.

**Methodology:** Patients in the individualized education group will receive one-on-one bedside medication education provided by the PGY-2 cardiology pharmacy resident within three days prior to discharge. The education session will involve a comprehensive review of the patient's medications, including their mechanism of action, associated benefits, side effects, dosing, and monitoring, as well as pertinent discharge instructions. Pill boxes and pill splitters will be supplied to help increase adherence. The resident will also educate the patient on the proper use of the pill organizer and pill splitter and ensure the patient is able to open prescription bottles. The teach-back method will be utilized to verify understanding and identify opportunities to address education deficits. Both groups will continue to receive the current standard of practice education on the heart failure service, which includes a heart failure class taught by a nurse, pharmacist, and nutritionist, or bedside education from these caregivers if the patient is unable to attend the class. In addition, as is currently the standard of practice, a subset of patients in both groups will receive follow-up phone calls from a care coordinator if a care coordination consult is ordered. A follow-up medical visit post-discharge will be scheduled for all patients.

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**Impact of a pharmacist-driven sliding-scale insulin dosing protocol on glycemic control in medical inpatients at a community teaching hospital**

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Pharmacy Residency: PGY-1 Pharmacy Practice

Research Site: Cleveland Clinic South Pointe Hospital, Warrensville Heights, OH

**Background:**

Hyperglycemia in hospitalized patients is a common and serious concern that is associated with increased risk of infection, impaired wound healing, multi-organ failure, prolonged hospital stay, and death (1). Sliding scale insulin is intended to retroactively manage elevated glucose levels and supplement scheduled prandial and basal insulin (2). The use of sliding scale insulin is still widespread in this country likely due to the potential advantages of convenience, simplicity, and promptness of treatment. This therapy is easy to implement and does not require a physician order for each individual administration (3). The purpose of this study is to assess the impact of a pharmacist-driven sliding scale insulin dosing protocol on improving glycemic control in hospitalized non-ICU patients in a community teaching hospital. Our current protocol states that nurses should contact the provider to increase sliding scale insulin when there are two consecutive blood glucose readings  $\geq 250$  mg/dL and no increase in basal insulin within 24 hours. Through anecdotal experience, this protocol is not being utilized to its full capacity and glycemic control can be further optimized. It is hypothesized that a pharmacist-driven protocol for sliding scale insulin dosage adjustment will improve glycemic control in the study population.

**Objective:**

The primary safety endpoint will be the number of hypoglycemic events. The primary efficacy endpoint will be the change in random blood glucose on days 2 and 3 following pharmacist intervention. Secondary endpoints will be the percentage of patients continued on oral hypoglycemic agents upon admission and glycemic control for patients on high-dose corticosteroids.

**Methodology:**

This retrospective study will compare mean blood glucose values before and after implementation of a pilot pharmacist intervention program on sliding scale insulin therapy. We will evaluate a 3 month time period in each study group. Eligible patients will be those admitted to our institution to a regular nursing floor with clinical pharmacist coverage and those with two consecutive blood glucose readings  $\geq 250$  mg/dL within 24 hours. Patients will be excluded if they are admitted to the ICU, receiving intravenous insulin, admitted for diabetic ketoacidosis or hyperosmolar hyperglycemic state, have an endocrinology consult, on dialysis, eating < 50% of their meals, or have a blood glucose reading <70 mg/dL in the last 24 hours.

**Results and Conclusions:** To be determined

**References:**

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2. Magaji, V, Johnson, JM. Inpatient Management of Hyperglycemia and Diabetes. *Clinical Diabetes.* 2011;29(1):3.
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## Evaluation of diabetic ketoacidosis and hyperosmolar hyperglycemic syndrome management in the medical intensive care unit

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**Background:** Diabetic ketoacidosis (DKA) and hyperglycemic hyperosmolar syndrome (HHS) are serious hyperglycemic crises that require accurate and timely management. The Centers for Disease Control and Prevention estimated that 170,000 emergency department visits for hyperglycemic crises in 2009 and costing \$2.4 billion to the health care system.<sup>1,2</sup> The American Diabetes Association (ADA) consensus statement outline recommendations for the management of DKA/HHS, which include a combination of fluid and electrolyte management along with insulin therapy.<sup>2</sup>

A retrospective study by Beik et al. demonstrates the impact of utilizing a standardized nomogram based on the ADA guidelines.<sup>3</sup> Investigators compared patient outcomes PRE and POST implementation of the nomogram. Length of medical intensive care unit (MICU) stay and time to anion gap closure were significantly shorter in the POST group. A significant decrease in mean episodes of hypokalemia was seen in the POST group. At Cleveland Clinic Marymount, the DKA/HHS nomogram is not consistently utilized, which results in dosing and pharmacotherapy variability. The large number of patients admitted for DKA/HHS at our institution provides an opportunity to assess current practices. The purpose of this study is to evaluate whether the management of DKA/HHS in the MICU is consistent with the ADA guidelines.

**Objectives:** The primary objective is to evaluate the current management of DKA and HHS in the MICU at Cleveland Clinic Marymount Hospital. Secondary objectives include time to DKA/HHS resolution, MICU length of stay, incidence of hypoglycemia and hypokalemia, assessment of appropriate transition from insulin infusion to basal insulin and occurrence of recurrent hyperglycemic crises.

**Methodology:** A retrospective chart review will be conducted for patients admitted to the MICU and on insulin infusion between January 1, 2016 and June 30, 2016. Patients will be included in the analysis if they are 18 years or older and diagnosed with DKA or HHS. Data collection will include patient demographics, MICU length of stay, blood glucose levels, presence of urine ketones or serum  $\beta$ -hydroxybutyrate, serum osmolality and pH levels, timing and dosage of intravenous insulin infusion, duration of insulin infusion, time of subcutaneous insulin initiation, occurrence(s) of hypoglycemia or hypokalemia, presence of endocrinology consult, and type of insulin order utilized. Data will be analyzed using descriptive statistics.

**Results and conclusions:** To be determined.

### References:

1. Centers for Disease Control and Prevention. Diabetes public health resource. <http://www.diabetes/stastics/data/national.html>. Updated April 27, 2015. Reviewed October 24, 2014. Accessed September 16, 2016.
2. Kitabchi AE, Umpierrez GE, Miles JM, *et al.* Hyperglycemic crises in adult patients with diabetes. *Diabetes Care* 2009; 32(7):1335-1343.
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**Comparison of standard vs extended durations of antimicrobial therapy for hospital-acquired pneumonia**

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**Background:** Hospital-acquired pneumonia is one of the most common nosocomial infections, accounting for up to 13% of healthcare-associated infections.<sup>1</sup> The Infectious Diseases Society of America (IDSA) recommends a 7 day duration of antimicrobial therapy for hospital-acquired pneumonia.<sup>2</sup> However, this recommendation is based on low quality evidence with the majority of literature supporting this recommendation from ventilator-associated pneumonia clinical trials.<sup>3-5</sup> Nonetheless, the evidence from these studies suggest that short courses of antimicrobial therapy (7-8 days) results in no differences in mortality, recurrent pneumonia, treatment failure, hospital length of stay, or duration of mechanical ventilation.<sup>2</sup> These study results caused the IDSA guideline panel to recommend shorter courses of antimicrobial therapy due to potential reductions in antimicrobial related side effects, *Clostridium difficile* colitis, the acquisition of antibiotic resistance, and costs. This study aims to provide further evidence for these recommendations in hospital-acquired pneumonia.

**Objective:** To determine the difference in clinical cure rate for patients with hospital-acquired pneumonia treated with less than or equal to 8 days versus those treated with greater than 8 days of antimicrobial therapy.

**Methodology:** This retrospective cohort study has been approved by the University of Toledo Medical Center Institutional Review Board and data are currently being collected. Patients will be included if they are 18 years or older, have a diagnosis of hospital-acquired pneumonia with 1 sign or symptom of pneumonia and received at least 72 hours of antimicrobial therapy. Patients will be excluded if they have community-acquired pneumonia on admission, are pregnant, have cystic fibrosis, are immunocompromised, or received effective antimicrobial therapy for greater than 24 hours during the 72 hours prior to diagnosis of hospital-acquired pneumonia. Data describing baseline characteristics, antimicrobial therapy, and clinical cure and failure will be collected. The primary outcome will be the clinical cure rate at day 28 in patients treated with less than or equal to 8 days (standard duration) versus patients treated with greater than 8 days of antimicrobial therapy (extended duration). Secondary outcomes will include 30-day hospital readmission rates, mortality rates, hospital length of stay and rate of *Clostridium difficile* infection in patients treated with standard versus extended duration of antimicrobial therapy.

**Results and Conclusions:** To be determined.

**References:**

1. Magill SS, Edwards JR, Fridkin SK; Emerging Infections Program Healthcare-Associated Infections Antimicrobial Use Prevalence Survey Team. Survey of health care-associated infections. *N Engl J Med* 2014; 370:2542-3.
2. Kalil AC, Metersky ML, Klompas M, et al. Management of Adults With Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clin Infect Dis* 2016;63(5):e61-e111.
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## **Analysis of potentially inappropriate medication (PIM) use in the older adult population at an academic medical center**

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### **Background:**

The risk of adverse effects from prescription drug use is high in the older adult population due to polypharmacy and multiple comorbidities. The use of potentially inappropriate medications (PIMs) in the older adult population has the potential for negative effects on mental status, fall prevalence, and mortality. The Beers Criteria provide a list of medications associated with poor outcomes in the older adult population due to their adverse effects.

The American Geriatrics Society 2015 Updated Beers Criteria introduce two new major changes compared to the previous 2012 criteria. The new criteria include the following two categories: 1) potentially clinically important non-anti-infective drug-drug interactions that should be avoided in the older adult population, and 2) non-anti-infective medications that require dose adjustments in the older adult population with varying degrees of kidney impairment.

### **Objectives:**

This study aims to further evaluate the use of PIMs and the presence of subsequent adverse events associated with their use in an inpatient setting according to the most recently Updated 2015 Beers Criteria. The objectives of this study are to 1) determine the prevalence of and types of PIMs used in the older adult population at an academic medical center from January 1, 2016 through June 30, 2016, and 2) assess the prevalence of and categorize the adverse events due to PIMs.

### **Methodology:**

The health-system's Institutional Review Board approved this study. The electronic medical record system will identify patients 65 years of age and older admitted to the non-intensive care unit inpatient setting. The two new categories added to the 2015 Beers criteria will be used to identify PIMs. Data will be collected on clinically relevant baseline characteristics to evaluate this study's objectives. Adverse events will be defined as medication side effects that may be associated with patients' hospital admission or an adverse event during hospitalization. Any documentation in the medical record of an adverse event to a medication will also be considered in this definition. Medical records of patients who are identified to have a drug interaction will be evaluated using the Drug Interaction Probability Scale. The Naranjo scale will be used for evaluating the probability of adverse drug reactions. The Wilcoxon rank-sum test and the independent student's t-test will be used for statistical analysis. Results will be considered statistically significant when  $p < 0.05$ .

**Results and conclusions:** This study is currently in progress. Results and conclusions are pending.

### **References:**

1. Marcum Z, Hanlon J. Commentary on the new American geriatric society beers criteria for potentially inappropriate medication use in older adults. *Am J Geriatr Pharmacother.* 2012 April;10(2):151-9.
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**Impact of pharmacist lead disease state management in a primary care clinic****Benjamin Alan Pontefract, PharmD**

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The MetroHealth System

**Background:** In 2013, the prevalence of diabetes in the United States of America was 10.9%, increased from 9.3% in 2012.<sup>1,2</sup> Previous studies have shown that pharmacist disease state management of patients with diabetes will lower hemoglobin A1c (HbA1c) by a greater degree when compared to usual care.<sup>3,4</sup> Medication adherence is a vital aspect of disease state management, and a pharmacist's positive effect on adherence in a primary care clinic has been demonstrated.<sup>3</sup> Reimbursement based on patient satisfaction is likely to be included in the future for health systems reimbursed by Centers for Medicare and Medicaid Services (CMS). The ability of a pharmacist to impact patient satisfaction has been explored, but no effect has been proven.<sup>5</sup> Another area with little exploration is the financial viability of an ambulatory care pharmacist in a primary care clinic. While previous studies have looked at a subset of these endpoints, there has not been a study that has investigated all of these outcomes together. This study will be conducted in the MetroHealth system, where clinical pharmacy has been involved with outpatient clinics starting May 2016. In these clinics, patients will be diagnosed with diabetes by a primary care physician who can then refer for collaborative management of this disease state to an ambulatory care pharmacy specialist.

**Objectives:** To assess the impact of disease state management by a clinical pharmacist practicing under a collaborative practice agreement in a primary care clinic compared to usual care. Primary endpoint will be change in HbA1c over six months from the index visit. Secondary objectives include number of patients with HbA1c less than seven percent and less than nine percent, patient satisfaction based on responses to the CG-CAHPS survey, patient adherence to prescribed medications, percentage of patients on statin therapy, and the financial implications of clinical pharmacy services in a primary care office.

**Methodology:** This is a two part study. The first part is a prospective chart review of patients referred to the clinical pharmacist versus usual care. The second part of the study will be a patient satisfaction survey assessed using an abbreviated version of the CG-CAHPS survey administered directly following the patient's office visit with the clinical pharmacist. Continuous data will be analyzed using the student t-test and nominal data will be analyzed using the Chi-squared test. All other data will be assessed using descriptive statistics. Financial viability will be determined by comparing the total revenue brought in by the service and subtracting out the cost of providing that service.

**Results and conclusions:** Based on the proposed timeline for this study, data collection should be completed in March of 2017. The final results of this study will be presented at the OCCP Spring Meeting and the Ohio Pharmacy Residency Conference in May 2017.

**References:**

1. Guariguata L, Whiting D, Hambleton I, Beagley J, Linnenkamp U. Global estimates of diabetes prevalence for 2013 and projections for 2035. *Diabetes Res Clin Pract.* 2014;103(2):137-49.
2. Centers for Disease Control and Preventions. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services; 2014.
3. Butt M, Adliah A, Mohd B, and Norlaila M. Impact of a pharmacist lead diabetes mellitus intervention on HbA1c, medication adherence and quality of life: a randomised controlled study. *Saudi Pharm J.* 2016;24(1):40-48.
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5. Correr C, Pontarolo R, Souza R, Venson R, Melchioris A, et al. Effect of a pharmaceutical care program on quality of life and satisfaction with pharmacy services in patients with type 2 diabetes mellitus. *Braz J Pharm.* 2009;45(4):809-17.

**Implementation and evaluation of pharmacist-managed vancomycin per hospital protocol**

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**Background:** Vancomycin is an intravenous antimicrobial agent that is routinely prescribed in the hospital for gram-positive infections, particularly methicillin-resistant *Staphylococcus aureus* (MRSA).<sup>1</sup> Vancomycin has a number of potential adverse effects including nephrotoxicity, ototoxicity, and infusion-related reactions. Data has shown that when vancomycin is used at conventional dosages the risk of adverse effects is significantly decreased. Other studies have demonstrated that appropriate dosing and monitoring of vancomycin leads to not only decreased rates of adverse events, but also improved outcomes and decreased antimicrobial resistance.<sup>1</sup> The role of a pharmacist in infection prevention and control has been well established through published literature. A pharmacist-managed vancomycin dosing program implemented at an academic medical center resulted in 50% more patients being optimally dosed.<sup>2</sup> Another study showed a statistically significant difference in reaching therapeutic troughs when vancomycin dosing was managed by pharmacists.<sup>3</sup> Pharmacist-managed vancomycin therapy optimizes both dosing and safety. Currently at Parma Medical Center, pharmacist involvement in vancomycin dosing is limited to ordering a timed trough on behalf of the physicians, if one is not already ordered. In 2015, a vancomycin dosing guideline was approved system-wide. While used as a guide, full ownership of vancomycin dosing and monitoring by pharmacy has not yet been implemented. Approval for this service is slated for October 2016.

**Objectives:** The primary objective of this quality improvement project is to implement a pharmacy vancomycin consult service, and then to compare the outcomes of pharmacist-managed vancomycin to physician-managed vancomycin. Outcomes studied for comparison will be percentage of therapeutic vancomycin troughs and adherence to the system-wide vancomycin dosing guideline. Secondary outcomes include correct timing of troughs, appropriateness of dose adjustments, and occurrence of side effects due to vancomycin (nephrotoxicity, rash, thrombocytopenia, red man syndrome).

**Methodology:** This quality improvement project is pending review by the institutional review board. A system-wide vancomycin dosing guideline will be used to guide initial dosing, monitoring of levels, and dosing adjustments. A competency assessment will be developed for pharmacists to dose vancomycin prior to implementation of the consult service. A retrospective chart review will be performed to compare data results from pre-implementation and post-implementation of the vancomycin consult service. Pre-implementation charts will be reviewed from January 1, 2016 to February 29, 2016, while post-implementation charts will be reviewed from January 1, 2017 to February 28, 2017. Data to be collected includes: date of admission, date of discharge, reason for admission, age, gender, initial temperature, height, weight, past medical history, baseline kidney function, WBC, indication, prescriber, culture results, dosing information, other nephrotoxic medications, appropriate first dose, trough, dose regimen changes, time to therapeutic trough, kidney function, and other side-effects.

**Results and Conclusions:** To be determined

**References:**

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## Association Between Tacrolimus Levels and Graft Loss in Renal Transplant Patients

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**Background:** Renal transplant is often preferred for patients with end stage renal disease (ESRD) as it improves quality of life and delays or prevents the need for dialysis.<sup>1</sup> Success associated with kidney transplants is attributable to calcineurin inhibitors (CNIs), specifically tacrolimus, and their ability to reduce acute rejection rates and improve overall graft survival.<sup>2</sup> Trough levels are closely monitored, to remain in the recommended reference range, in order to minimize adverse effects. Specific CNIs trough values that minimize patients risk of acute or chronic rejection, have not been specifically identified.<sup>3</sup> Therefore, the objective of this study is to evaluate the effect of tacrolimus trough concentrations following kidney transplant on long term graft loss.

**Objective:** To evaluate the effect of tacrolimus levels following kidney transplant on long term graft loss.

**Methodology:** This is an IRB-approved retrospective cohort study at the University of Toledo. Patients 18 years and older who underwent a renal transplant between Oct 1, 2006 to July 31, 2016, received alemtuzumab induction therapy and tacrolimus and mycophenolate maintenance therapy at University of Toledo Medical Center are eligible for inclusion. Patients will be excluded if they were treated with agents other than tacrolimus, mycophenolate and prednisone for long term immunosuppression, those pregnant or breast-feeding, with documented allergy to any agent in the post-transplant protocol, patients without at least 50% available outpatient labs and those without a one year tacrolimus level. A mean tacrolimus trough level will be calculated based on trough values at 3, 6 and 12 months. Average tacrolimus concentrations at 12 months will then be stratified into quartiles and compared to the overall mean tacrolimus trough. Kaplan-Meier curves will be used to analyze the probability of graft loss over time. The primary endpoint is to compare the incidence of death-censored graft failure based on tacrolimus trough concentrations. Secondary endpoints include the incidence of acute rejection episodes, and adverse outcomes including new onset of diabetes mellitus, hyperlipidemia, and opportunistic and surgical site infections over the first twelve months post-operatively. A planned sub-group analysis of deceased versus live donor transplant will be done on all outcomes.

**Results and Conclusion:** To be determined.

### References

1. Goldberg R, Weng F, Kandula P. Acute and Chronic Allograft Dysfunction in Kidney Transplant Recipients. *Medical Clinics of North America*. 2016;100(3):487-503.
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3. Shuker N, Shuker L, van Rosmalen J et al. A high inpatient variability in tacrolimus exposure is associated with poor long-term outcome of kidney transplantation. *Transplant International*. 2016;

## Outcomes Resulting from Three-Day Tramadol Taper for Acute Opioid Withdrawal at Summa Health System

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### Background:

Rates of opioid dependence and abuse are currently at record highs, nationally as well as locally in northeast Ohio. Treatments for medication assisted withdrawal include tapers of buprenorphine, methadone and tramadol. Several studies have been published comparing tramadol to buprenorphine, methadone or clonidine for the treatment of acute opioid withdrawal. These studies utilized 4-day, 5-day, 6-day and 14-day tapers and all concluded that tramadol is a safe and effective option for treating acute opioid withdrawal. The treatment of choice for medically assisted withdrawal of opioids at Summa Health System has traditionally been a 6-day tramadol taper. On August 8, 2014, tramadol became a Schedule IV medication. Therefore, legally only 72-hours of scheduled narcotic can be provide to opioid dependent patients for the purposes of relieving acute withdrawal symptoms. Summa Health System's St. Thomas detoxification unit is not a DEA regulated opioid treatment program. As a result, the traditional tramadol taper was truncated to a 3-day taper.

### Objectives:

To determine patient outcomes associated with tramadol as a 3-day taper for medication assisted withdrawal at Summa Health System given its change of status to a scheduled drug. The primary endpoint will be the difference in the change in Clinical Institute Narcotic Assessment (CINA) score from baseline until discharge. Secondary endpoints will include length of stay, use of adjuvant medications for symptom relief, detoxification completion rates, highest CINA score, adverse events and 30-day readmission rates.

### Methodology:

A retrospective, chart review, quality improvement study describing outcomes of opioid dependent patients in acute withdrawal admitted on the detoxification unit at St. Thomas hospital between September 2014 and September 2016 receiving the 3-day taper. Inclusion criteria includes: patients  $\geq 18$  years old and admitted for opioid dependence. Patients were excluded if they were pregnant. Patients were identified using the computerized physician order entry system by identifying orders for the tramadol taper order set for patients, restricted to the detoxification unit. Data to be collected will be patient demographics, treatment dates, tramadol doses, drugs of abuse, CINA scores, use of adjuvant medications, adverse events, 30-day readmission and 30-day emergency department visit rates.

### Results and conclusions:

To be determined.

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**Characterization of the use of post-operative pulmonary hypertension therapy in patients in the surgical intensive care unit: Part I**

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**Background:** Increased pulmonary arterial pressure is commonly observed following cardiothoracic surgery. This increase in pressure can be due to insults induced by cardiac surgery such as the use of cardiopulmonary bypass, which can lead to vascular and ischemic injury. Post-operative increases in mean pulmonary arterial pressure (mPAP) can worsen patient outcomes. One therapy for increased post-operative mPAP is inhaled nitric oxide (iNO). Major risks associated with iNO therapy are development of methemoglobinemia and buildup of nitrogen dioxide. Additionally, the price of iNO can be cost prohibitive to its use. More recently, clinical research has examined use of inhaled epoprostenol for pulmonary hypertension. Mechanistically inhaled epoprostenol has the potential to increase bleeding, but this has not been demonstrated in clinical trials thus far. When compared to placebo or iNO, inhaled epoprostenol has demonstrated efficacy in reducing mPAP and pulmonary vascular resistance (PVR) without significantly affecting systemic mean arterial pressure (MAP). Both agents have short half-lives and potential for rebound pulmonary hypertension if abruptly discontinued. Several tertiary care institutions have developed protocols for use of inhaled epoprostenol due similar therapeutic outcomes between agents and decreased cost with inhaled epoprostenol. Currently University Hospitals Cleveland Medical Center (UHCMC) uses iNO for post-operative pulmonary hypertension and does not have a protocol for use of inhaled epoprostenol in these patients.

**Objectives:** The objective of this research is to characterize the use of post-operative pulmonary hypertension therapy in patients in the surgical intensive care unit (SICU). A protocol for the use of inhaled epoprostenol is under development at UHCMC with implementation planned for January 2017. Research will be completed in two parts. Part one of this study will retrospectively examine current use of iNO. Part two will occur post protocol implementation and will retrospectively assess use of inhaled epoprostenol. After part two, part one and part two data will be examined using comparative statistics.

**Methodology:** Part one of this study will be a retrospective chart review examining use of iNO in patients with post-operative pulmonary hypertension treated with iNO in the SICU at UHCMC from October 1, 2015 to March 31, 2016. Patients with pulmonary hypertension following heart transplant will be excluded from the research. The number of subjects will be capped at 50. The primary outcome is a decrease in mPAP to less than 30 mmHg within 6 hours of SICU admission. Secondary outcomes include characterizing costs associated with iNO therapy, assessing patients duration of mechanical ventilation, intensive care unit length of stay, mean daily milrinone requirement, and adverse events such as bronchospasm which will be measured by albuterol usage and device malfunction. Data to collect includes patient age, gender, race, hospital length of stay, mPAP, PVR, MAP, time on mechanical ventilation, SICU length of stay, median daily milrinone requirement, bronchospasm occurrence, albuterol usage, and occurrence of device malfunction. Data from part one will be analyzed using descriptive statistics.

**Results and conclusions:** N/A

**References:**

1. Bernhard R. The pathophysiology and management of perioperative pulmonary hypertension with specific emphasis on the period following cardiac surgery. *Int Anesthesiol Clin.* 1999;37(2):55-80.
2. Hache M, Denault A, Belisle S, Robitaille D, Couture P, Sheridan P, et al. Inhaled epoprostenol (prostacyclin) and pulmonary hypertension before cardiac surgery. *J Thorac Cardiovasc Sur.* 2003;125:642-9.
3. Buckley MS, Feldman JP. Inhaled epoprostenol for the treatment of pulmonary arterial hypertension in critically ill adults. *Pharmacotherapy.* 2010;30(7):728-40.
4. McGinn K, Reichart M. A comparison of inhaled nitric oxide versus inhaled epoprostenol for acute pulmonary hypertension following cardiac surgery. *Ann Pharmacother.* 2016;50(1):22-6.
5. Torbic H, Szumita PM, Anger KE, Nuccio P, Lagambina S, Weinhouse G. Clinical and economic impact of formulary conversion from inhaled flolan to inhaled veletri for refractory hypoxemia in critically ill patients. *Ann Pharmacother.* 2016;50(2):106-12.

## Evaluation of Albumin 25% Use in Critically Ill Patients

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### Background:

Albumin is a plasma protein that maintains colloid osmotic pressure (COP), which is a major determinant of fluid movement between the interstitium and vasculature spaces. Albumin levels account for approximately 75-80% of total COP and is therefore frequently used for volume expansion in resuscitation and maintenance of oncotic pressure.<sup>1</sup> While serum albumin levels are increased with albumin administration, there has been no difference in intensive care unit (ICU) and hospital lengths of stay, mortality, or ventilator dependence when compared to crystalloid for general volume resuscitation or albumin supplementation.<sup>2-4</sup> Clinical indications in which albumin 25% has been studied include large volume paracentesis, acute respiratory distress syndrome, vasospasm post subarachnoid hemorrhage (SAH), hepatorenal syndrome (HRS), and spontaneous bacterial peritonitis (SBP). The American Association for the Study of Liver Diseases support the use of albumin for the following indications; HRS, SBP, and large volume paracentesis. The American Heart Association/American Stroke Association support the use of albumin for volume expansion during vasospasm post-SAH. At this time, albumin is relatively expensive compared to crystalloid fluid options. Given the increased cost associated with 25% albumin and limited patient populations where it may provide benefit, this study seeks to evaluate the prescribing practices of 25% albumin at a large tertiary academic medical center.

### Objectives:

The primary objective of the study is to describe the prescribing patterns and indications for use of albumin 25% within the intensive care units at the Cleveland Clinic main campus. The secondary objectives are to compare the albumin 25% patterns of use with the indications and dosing regimens that are supported by primary literature or treatment guidelines, evaluate the costs associated with albumin 25% therapy, and evaluate 25% albumin pharmacy turn-around time.

### Methodology:

The study being conducted is a retrospective, non-interventional, descriptive study of albumin 25% use between June 1<sup>st</sup>, 2015 and June 30<sup>th</sup>, 2016. Inclusion criteria consists of patients with an age  $\geq$  18 years old and who have received at least one dose of albumin 25% while admitted to the Cleveland Clinic main campus intensive care units. Exclusion criteria were any study subjects who had an albumin 25% order but did not have administration documented in the electronic medical record, or if patients were not in an intensive care unit at the time of administration. The study will analyze approximately 500 patient encounters. Descriptive statistics will be used for the primary and secondary objectives along with Chi-square, Mann-Whitney U, and Student's t-test as appropriate. This study has been approved by the Institutional Review Board at Cleveland Clinic.

**Results and conclusions:** To be determined at a later date.

### References:

1. Michelis R, Sela S, Zeitun T, Geron R, Kristal B. Unexpected Normal Colloid Osmotic Pressure in Clinical States with Low Serum Albumin. *PLoS one*. 2016;11(7):e0159839.
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3. Roberts I, Blackhall K, Alderson P, Bunn F, Schierhout G. Human albumin solution for resuscitation and volume expansion in critically ill patients. *Cochrane Database Syst Rev*. 2011(11):CD001208.
4. The SAFE Study Investigators. A Comparison of Albumin and Saline for Fluid Resuscitation in the Intensive Care Unit. *N Engl J Med*. 2004;350(22):2247-2256.

## Evaluation of the outcomes of the use of lurasidone for the treatment of bipolar depression at the Louis Stokes Cleveland VAMC

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PGY-2 Psychiatric Pharmacy Resident

Research site: Louis Stokes Cleveland Veterans Affairs Medical Center

**Background:** Bipolar I disorder has a prevalence of approximately 1% of the population.<sup>1</sup> While symptomatic, patients experience depressive symptoms approximately threefold longer than manic symptoms<sup>2</sup> and contribute significantly to health care costs.<sup>3</sup> Current practice includes treatment with mood stabilizers as monotherapy or in adjunct to antidepressants, with questionable antidepressant efficacy in bipolar disorder. Quetiapine and lurasidone are atypical antipsychotics both indicated for bipolar depression. Lurasidone was FDA approved for bipolar depression in 2013<sup>4</sup> and due to recent use at Louis Stokes VAMC, it is unknown whether patients experience similar benefit as shown in previous clinical trials as compared to quetiapine.<sup>5</sup>

**Objectives:** The primary objective of this study is to assess the time to medication discontinuation over a one year period in veteran patients prescribed lurasidone versus quetiapine for the treatment of ICD 9 and 10 diagnosis of bipolar depression from January 1, 2014 to January 1, 2016. Time to medication discontinuation will be assessed over a one year period starting with the first lurasidone or quetiapine prescription up to January 1, 2017.

**Methodology:** A retrospective chart review will be conducted in patients prescribed lurasidone versus quetiapine for the treatment of ICD 9 and 10 diagnosis of bipolar depression from January 1, 2014 to January 1, 2016. Medication discontinuation will be defined as not receiving a subsequent prescription for lurasidone or quetiapine within thirty days of exhausting the medication day supply for the prior prescription. The reason for medication discontinuation and additional secondary outcomes will be determined by an electronic chart review. Secondary outcomes will assess the average length of medication treatment, the average dose of lurasidone and quetiapine prescribed, the use of adjunctive treatment by medication class for bipolar depression, the percentage and time to psychiatric hospitalizations, and the percentage of accurate medication directions of "take with food" for lurasidone.

**Results:** N/A

**Conclusions:** N/A

### References:

1. Merikangas, Kathleen R. et al. "Prevalence and Correlates of Bipolar Spectrum Disorder in the World Mental Health Survey Initiative." *Archives of general psychiatry* 68.3 (2011): 241–251.
2. Calabrese, Joseph R., et al. "A randomized, double-blind, placebo-controlled trial of quetiapine in the treatment of bipolar I or II depression." *American Journal of Psychiatry* 162.7 (2005): 1351-1360.
3. Parker, Gordon, et al. "Costs of the principal mood disorders: a study of comparative direct and indirect costs incurred by those with bipolar I, bipolar II and unipolar disorders." *Journal of affective disorders* 149.1 (2013): 46-55.3.
4. Latuda (lurasidone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc.; July 2013.
5. Loebel A, Cucchiaro J, Silva R, et al. Lurasidone monotherapy in the treatment of bipolar I depression: a randomized, double-blind, placebo-controlled study. *American Journal of Psychiatry*. 2014;171(2):160–168.

**Incidence of falls in hospitalized elderly patients prescribed potentially inappropriate medications****Leah Schomburg, PharmD**, Heather Carey, PharmD, BCPP

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**Background:** The rate of falls in the inpatient setting varies based on medical unit type but overall occurs in approximately 2% of hospitalized patients.<sup>1</sup> About 25% of falls in these patients result in injury, which may substantially increase hospital length of stay and cost.<sup>1</sup> There are many risk factors related to the cause of a fall including both non-medication and medication related elements. Some non-medication risk factors are intrinsic and include age-related decline in sensory and musculoskeletal function as well as many acute and chronic illnesses. The extrinsic risk factors related falls include environmental concerns such as an unfamiliar hospital setting, inappropriate footwear, and improper lighting. Medication use is also considered an extrinsic risk factor and many medication classes have been identified that can increase fall risk through various pharmacologic mechanisms.<sup>2</sup> Major categories implicated in fall risk include benzodiazepines, opioids, sedative hypnotics, tricyclic antidepressants, and antipsychotics.<sup>3</sup> These medications have been identified and compiled in resources such as the Beers criteria and the STOPP/START criteria which have recommendations on the avoidance of high-risk medications that increase fall risk and other health risks in elderly patients.<sup>4,5</sup>

**Objective:** The primary outcome of this study is to assess the number of patients who were prescribed and received one or more doses of high fall risk medication(s) and experienced a fall during inpatient hospitalization, compared to the number of patients who were prescribed and received one or more doses of these medications who did not experience a fall. Secondary outcomes include the number of high-risk medications patients with a fall were prescribed, assessment of accuracy of fall risk category assigned upon admission, the presence or absence of post-fall medication changes, and the presence or absence of a pharmacy clinical intervention note in the electronic medical record addressing potential medication changes in the fall patient.

**Methodology:** This study is a retrospective chart review. Patients who experienced a fall during their hospital stay between June 2015 and May 2016 will be identified using the PASS event reporting system. Inclusion criteria include patients at least 65 years of age or older. Exclusion criteria include palliative care or hospice patients, post-orthopedic surgery patients, and patients with conditions significantly compromising stability including post-stroke hemiparesis, Parkinson's disease, multiple sclerosis, and post lower limb amputation.

A chart review will be performed to identify the high-risk medications prescribed to the patients who experienced a fall. The medications in the Beers criteria listed as agents to be avoided in patients with a history of falls or fractures will be utilized as the initial guide for medications to be evaluated. Once the medications utilized in the fall patient group are identified from the chart review, the use of those medications in patients meeting the study criteria who did not have a fall will be evaluated. The incidence of falls with the use of the specified high-risk medications in the institution will be assessed using the data from the two groups.

**Results and Conclusions:** In progress**References:**

1. Bouldin, et al. Falls among adult patients hospitalized in the United States: Prevalence and trends. *Patient Saf.* 2013 March; 9(1): 13–17.
2. Guideline for the prevention of falls in older persons. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. *J Am Geriatr Soc.* 2001;49(5):664-72.
3. Tinetti, M.E. Preventing falls in elderly persons. *N Engl J Med.* 2003;341(1):42-49.
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## Evaluation of suspected gonorrhea and chlamydia incidence and the utilization of empiric antibiotics within a large, academic emergency department setting

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### Background:

In the Emergency Department (ED) patients are typically treated empirically for gonorrhea and chlamydia prior to confirmation of test results because of the extended time period it takes to receive these results. Recently, concern has been raised around antibiotic resistance patterns of *Neisseria gonorrhoeae*. Gonorrhea now has increasing resistance to multiple drug classes.<sup>1</sup> Previous research has been conducted to address the concerns of overtreatment, undertreatment, and follow-up treatment success of management of chlamydia and gonorrhea.<sup>2</sup> Also, there have been multiple studies to help determine predictor variables of sexually transmitted diseases (STDs).<sup>3,4</sup> However, to date, there have been limited studies evaluating the treatment of STDs in correlation with specific predictor variables in a clinical setting. This study will fill the gaps in literature regarding correlation of antibiotic treatment and predictor variables. The significance of this information would allow for future studies on the implementation of a protocol for health care providers to better treat STDs with the goal to decrease antibiotic resistance.

### Objectives:

The primary objective is to determine the incidence of positive cultures in patients that receive chlamydia and gonorrhea screening in the ED. The secondary objective is to determine the proportion of patients treated empirically with antibiotics. Additionally, the study aims to identify predictors of positive cultures. Subgroup analyses will include; patients who are pregnant, entire population excluding patients with low positive MOTA score, entire population excluding outlying EDs, patients positive for gonorrhea only, patients positive for chlamydia only, and patients positive for both gonorrhea and chlamydia.

### Methodology:

The study is a retrospective cohort chart review evaluating the number of patients who resulted in a positive or negative gonorrheal or chlamydial test and assess the utilization of antibiotics in patients who received treatment in the ED.

### Results and conclusions:

The expected study results are to present the incidence of positive gonorrheal or chlamydial test results and the proportion of patients treated with empiric antibiotics. Additional secondary objectives are to identify any predictors which can be used to assist in predicting positive cultures to allow for empiric treatment.

### References:

1. Kirkcaldy RD, Harvey A, Papp JR, et al. *Neisseria gonorrhoeae* antimicrobial susceptibility surveillance — The gonococcal isolate surveillance project, 27 sites, United States, 2014. *Surveillance Summaries*. July 15, 2016. 65(7);1–19.
2. Levitt MA, Johnson S, Engelstad L, Montana R, Stewart S. Clinical management of chlamydia and gonorrhea infection in a county teaching emergency department--concerns in overtreatment, undertreatment, and follow-up treatment success. *J Emerg Med*. 2003 Jul;25(1):7-11.
3. LeFevre ML. USPSTF: screening for chlamydia and gonorrhea. *Ann Intern Med*. 2014;161:902–10.
4. Upchurch DM, Brady WE, Reichart CA, Hook EW 3rd. Behavioral contributions to acquisition of gonorrhea in patients attending an inner city sexually transmitted disease clinic. *J Infect Dis*. 1990 May;161(5):938-41.

**Evaluation of an electrolyte replacement protocol in critically ill patients at a community hospital****Melody Smith, Pharm.D.**

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**Background:**

Electrolyte imbalances in critically ill patients have been positively correlated with increased morbidity and mortality.<sup>1,2</sup> Although the use of electrolyte correction protocols has become more common in critical care settings, minimal data exists pertaining to the safety and efficacy of these protocols.<sup>3</sup> Cleveland Clinic Medina Hospital implemented a nursing-driven electrolyte replacement protocol for patients in the intensive care unit (ICU), which targets hypokalemia, hypomagnesaemia, and hypophosphatemia. This study will evaluate the safety and efficacy of the new protocol.

**Objectives:**

The primary efficacy outcome will compare the proportion of measured values of serum potassium concentration within the desired range (3.5 to 5.0 milliequivalents per liter) the morning after potassium replacement during the pre-protocol period versus the post-protocol period. Secondary outcomes will include assessment of magnesium and phosphate concentrations the morning after replacement, the average time from low electrolyte level to administration of electrolyte replacement, the incidence of cardiac arrhythmias during ICU admission, in-hospital mortality, as well as nurse and physician satisfaction measured with an anonymous survey.

**Methodology:**

This retrospective chart review will include adult (18 years and older) inpatients at Cleveland Clinic Medina Hospital admitted to the ICU who received electrolyte replacement between April 1, 2015 through October 31, 2015 (pre-protocol period) and who received protocol-driven electrolyte replacement between April 1, 2016 through October 31, 2016 (post-protocol period). Per protocol, patients who experienced the following during ICU stay will be excluded: serum creatinine greater than 2 milligrams per deciliter, dialysis, rhabdomyolysis, diabetic ketoacidosis, anuria, or weight less than 40 kilograms. Chi-squared and Student t-test will be utilized in the statistical analysis, as appropriate.

**Results and conclusions:**

N/A: research-in-progress

**References:**

1. Kraft M, Btaiche I, Sacks G, Kudsk K. Treatment of electrolyte disorders in adult patients in the intensive care unit. *Am J Health Syst Pharm.* 2005 Aug 15;62(16):1663-82.
2. Todd S, Sucher J, Moore L, Turner K, Hall J, Moore F. A multidisciplinary protocol improves electrolyte replacement and its effectiveness. *Am J Surg.* 2009 Dec;198(6):911-5.
3. Couture J, Létourneau A, Dubuc A, Williamson D. Evaluation of an electrolyte repletion protocol for cardiac surgery intensive care patients. *Can J Hosp Pharm.* 2013 Mar;66(2):96-103.

## **Comparison of adherence to manufacturer dosing recommendations with apixaban, dabigatran, and rivaroxaban therapy**

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**Background:** Among the non-warfarin oral anticoagulants, differences in manufacturer recommended dosing strategies may lead to inconsistencies in adherence to dosing guidelines between agents. Dosing reductions are required for apixaban in patients meeting two of the following criteria: age  $\geq 80$  years, weight  $\leq 60$  kg, or serum creatinine  $\geq 1.5$  mg/dL. Conversely, rivaroxaban and dabigatran require reduced doses based solely upon creatinine clearance. Previous research shows a higher incidence of reduced dosing for apixaban in U.S. cardiology practices when compared to registration trials. In contrast, the frequency of reduced-dose prescribing for rivaroxaban was observed to be similar in registration trials compared to U.S. cardiology practices.<sup>1</sup> Concern for a higher risk of bleeding may drive prescribers to choose the lower dose of apixaban if a patient meets only one dosing reduction criteria. However, prior analysis of standard dosing of apixaban in patients with a single dose reduction factor displayed superior safety and similar efficacy when compared to warfarin.<sup>2</sup> An additional study investigated the use of reduced-dose apixaban, rivaroxaban, and dabigatran. Frequent non-adherence to manufacturer recommendations was observed.<sup>3</sup> Further research is required to determine the incidence of adherence to manufacturer recommendations for both standard and reduced dosing of apixaban, rivaroxaban and dabigatran dosing.

**Objective:** This study will compare the relative incidence of adherence to manufacturer recommended dosing strategies for apixaban, dabigatran, and rivaroxaban in the treatment of non-valvular atrial fibrillation. It is hypothesized that a higher incidence of non-adherence to manufacturer recommended dosing guidelines will be observed with apixaban when compared to dabigatran and rivaroxaban due to its unique reduced-dosing criteria.

**Methodology:** A retrospective chart review spanning the dates of 1/1/2013-9/30/15 will be performed. This study will use records from a large integrated health system and will include patients at least 18 years of age receiving apixaban, rivaroxaban, or dabigatran with a diagnosis of non-valvular atrial fibrillation and admitted as inpatient or observation status for at least 24 hours. Exclusion criteria include treatment for deep vein thrombosis (DVT), pulmonary embolism (PE), secondary prevention of recurrent DVT or PE, or postoperative thromboprophylaxis. The primary outcome is the incidence of inappropriate dosing for apixaban, rivaroxaban and dabigatran therapy. Additional data to be collected include age, sex, cardiology consult, history of thrombotic events, concomitant use of p-glycoprotein and CYP3A4 inhibitors, race, serum creatinine, age group (18-50, 51-79, or 80 years of age and older), and HAS-BLED score (hypertension, abnormal renal and liver function, history of stroke or bleeding, labile INRs, elderly, history of drug or alcohol abuse). A logistic regression model will be developed to identify predictors of prescribing patterns that are inconsistent with manufacturer recommendations. A total study population of 200 will be required to meet power.

**Results and Conclusion:** To be determined.

### **References:**

- 1) Nguyen E et al. Doses of apixaban and rivaroxaban prescribed in real-world United States cardiology practices compared to registration trials. *Curr Med Res Opin.* 2016 Jul;32(7):1277-9.
- 2) Alexander JH et al. Apixaban 5 mg Twice Daily and Clinical Outcomes in Patients With Atrial Fibrillation and Advanced Age, Low Body Weight, or High Creatinine: A Secondary Analysis of a Randomized Clinical Trial. Apixaban for Reduction of Stroke and Other Thromboembolic Complications in Atrial Fibrillation (ARISTOTLE) Investigators. *JAMA Cardiol.* 2016 Jul 27.
- 3) Barra et al. Evaluation of Dose-Reduced Direct Oral Anticoagulant Therapy. *The American Journal of Medicine.* Jun 2016.

## Evaluation of a Heart Failure Clinic Pilot within an Internal Medicine Residency Clinic

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**Background:** In 2012, it was estimated that approximately 5.7 million Americans had heart failure (HF).<sup>1</sup> Following a diagnosis of HF, the absolute mortality rate is 50% within 5 years.<sup>2</sup> As a result, the associated financial burden is approximately \$30.7 billion per year, including both direct and indirect costs. The majority of these costs are attributable to HF-related hospitalizations.<sup>1</sup> The Center for Medicare and Medicaid Services (CMS) has shown that one in four patients initially admitted with HF are readmitted within 30 days of discharge.<sup>3</sup> These numbers are only expected to grow, as the prevalence of HF is estimated to increase 46% by 2030 with a projected total cost of \$69.8 billion.<sup>4</sup>

Therefore, it is crucial that patients with HF receive optimal care in the ambulatory setting. In an analysis of hospitals that participated in the Get With the Guidelines-Heart Failure quality improvement registry, it was found that those with a post-discharge HF disease management program had significantly lower readmission rates.<sup>5</sup> The aim of this project is to implement an interdisciplinary clinic that will improve the quality of care for HF patients. The focus will be to prevent hospital readmissions and disease progression through use of evidence-based therapy and patient education.

**Objectives:** The primary objective of this study is to evaluate hospital readmission rates for HF patients seen at the Internal Medicine Center (IMC). Secondary objectives include adherence to American College of Cardiology Foundation and American Heart Association (ACC/AHA) outpatient performance measures, patient satisfaction, and adverse events.

**Methodology:** This pilot will include all English-speaking IMC patients 18 years of age or older with a diagnosis of HF. Patients will be excluded if they are hospice patients or are active patients of the Northeast Ohio Cardiovascular Specialists group. Patients will be recruited to the HF clinic on an ongoing basis from a registry of HF patients and also through referrals from IMC primary care physicians. Following the pilot phase, a retrospective chart review will be conducted. Data collected will include baseline demographics, comorbidities, HF medications, vital signs, left ventricular ejection fraction, New York Heart Association functional classification, history of cardiac catheterization, and hospital admission dates and diagnoses. Descriptive statistics will be used to summarize data. Nominal data will be analyzed via the Chi-Square or Fisher's Exact Test, as appropriate, while continuous data will be analyzed with the Mann-Whitney U or Student's t-test, as indicated.

**Results and conclusions:** To be determined.

### References:

1. Mozzafarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, et al on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2016 update: a report from the American Heart Association. *Circulation*. 2016;133(4):e38-e360.
2. Yancy CW, Jessup M, Bozkurt B, Butler J, Casey DE Jr, Drazner MH, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation*. 2013;128(16):e240-327.
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**Impact of tighter blood glucose control for inpatients on a routine medical floor**

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**Background:**

Appropriate blood glucose control has consistently proved to be a controversial topic amongst health care providers in the hospital setting. While there have been many controversial trials that have demonstrated the benefits of tight blood glucose control and the risks involved with even tighter control, the goal stated by the 2016 American Diabetes Association Standards for inpatient blood glucose is less than 180 mg/dL<sup>1</sup>. This inpatient blood glucose goal has been decided upon based on the findings that improved glucose control leads to better outcomes in many patient populations with specific comorbidities, such as infectious processes, cardiovascular events, and cerebrovascular events. Although this goal has proven to be the ideal target for hospitalized patients, it has not consistently been the standard of care for diabetic patients on general medical floors, including patients seen at Southwest General.

To tackle this problem, a wide variety of methods have been implemented at other institutions and clinics involving multiple health care providers. Johns Hopkins Hospital is one location that completed a study involving an interdisciplinary Glucose Steering Committee that developed hospital-wide glucose control policies along with education<sup>2</sup>. The implementation of this led to an increased number of blood glucose readings at the goal of less than 180 mg/dL and a reduction in the number of hypoglycemic events. Another study conducted in an academic medical center in which structured insulin orders and an insulin management algorithm were implemented also resulted in an increased amount of blood glucose readings at goal and a reduction in hypoglycemia<sup>3</sup>. While various trials have proven that there are multiple ways to improve inpatient blood glucose control, pharmacist involvement in these efforts is consistent and critical.

**Objectives:**

To determine the impact of pharmacist led blood glucose monitoring and subsequent clinical interventions for inpatients on general medical floors. To develop a process that can be carried on by pharmacists to improve blood glucose control for inpatients on general medical floors.

**Methodology:**

This study has been approved by the institutional review board and is ready for implementation. Data collection will begin with daily blood glucose reports that will be generated in the laboratory department for patients on general medical floors, which represents a total of four patient units at Southwest General. These reports will identify patients with at least two blood glucose readings at or above 250 mg/dL from the previous day. Once these patients are identified, interventions will be made based on a blood sugar control algorithm. This algorithm will include how insulin is to be titrated based on the previous day's blood sugar readings, along with guidance on the appropriate addition of oral antidiabetic agents. These recommendations will be communicated to the attending physician and documented in the electronic medical record. Blood glucose readings will be collected to assess the primary outcome of percentage of blood glucose readings at the goal of less than 180 mg/dL before pharmacist intervention(s) compared to percentage at goal after the intervention(s). As a safety endpoint, the amount of blood glucose readings below 70 mg/dL will also be monitored.

**Results and conclusions:** To be determined.

**References:**

1. American Diabetes Association. Diabetes Care in the Hospital. *Diabetes Care*. 2016;39:S99-S104.
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3. Maynard G, et al. Improved Inpatient use of Basal Insulin, Reduced Hypoglycemia, and Improved Glycemic Control: Effect of Structured Subcutaneous Insulin Orders and an Insulin Management Algorithm. *J Hosp Med*. 2009 Jan; 4(1):3-15.

## Evaluating the Impact of Alvimopan (Entereg) in Radical Cystectomy Care Path Outcomes

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**Background:** Radical cystectomy (RC) is among the most complex urological surgeries and is predominately used to treat muscle invasive bladder cancer.<sup>1</sup> This procedure is associated with considerable complications including post-operative ileus (POI) which results in prolonged hospital length of stay and an increased cost. There are many interventions used to help reduce these complications including enhanced recovery after surgery (ERAS) protocols that include bowel regimens, chewing gum, and multi-modal analgesia targeted at reducing POI. Alvimopan, a peripherally acting mu-opioid receptor antagonist, has been shown to significantly decrease gastrointestinal (GI) recovery time and reduce hospital length of stay when incorporated into ERAS protocols.<sup>2</sup> Although only Food and Drug Administration approved to accelerate the time to upper and lower GI recovery following certain surgeries, several studies including a randomized controlled trial, demonstrated that alvimopan significantly decreased GI recovery time and reduced hospital length of stay in patients undergoing RC.<sup>3,4</sup> At Cleveland Clinic, alvimopan was incorporated into the ERAS protocol within the Bladder Cancer Care Path following RC in September of 2016.

**Objective:** The primary objective of this study is to determine the impact of alvimopan on clinical outcomes in patients undergoing RC.

**Methodology:** This retrospective cohort study will be conducted at Cleveland Clinic Main Campus from February 2016 to February 2017. Patients will be divided into groups based on pre and post implementation of alvimopan into the care path. All patients that have undergone a RC will be included. Those that underwent additional unplanned surgical interventions during the RC will be excluded. The primary objective is to evaluate hospital length of stay and secondary objectives include time to upper and lower GI recovery. Lower GI recovery will be determined based on time to first bowel movement and upper GI recovery will be determined by time to tolerating  $\geq 50\%$  of solid diet. In addition, the total number of alvimopan doses, concomitant laxative use, and analgesia regimen will be assessed. The primary objective will be analyzed using a student's t-test and secondary objectives will be analyzed using survival analysis with reported hazard ratios.

**Results and Conclusions:** To be determined.

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**Impact of early pharmacist-driven diabetes education on patient knowledge of diabetes management****Kailey Stough, PharmD**; Dave Ferris, PharmD, CGP; Amy Murray, PharmD[KStough@swgeneral.com](mailto:KStough@swgeneral.com)

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**Background:** Diabetes is a major chronic health problem in the United States, affecting more than 29 million patients nationally and accounting for more than 20% of health care spending<sup>1</sup>. Patients who are unaware of how to manage their chronic condition are at higher risk for experiencing complications and further contributing to the growing problem in the US. The serious lack of attention and education given to diabetic patients in the US, however, opens a wide range of opportunities for pharmacists to be involved in diabetes care depending on their needs and understanding of their diagnosis. It has been discussed in previous literature that pharmacists can help to identify patients currently undiagnosed with diabetes, assess the health status of diabetic patients and develop a plan of care, provide in-depth patient education about the disease state and medication therapy, refer patients to other members of the health care team, and monitor the course of a patient's diabetes care<sup>2</sup>. Education regarding the diagnosis, management, goals, and outcomes of diabetes are all keys to improving self-management of diabetes, all of which a pharmacist can provide to patients at a level they can comprehend. Studies have also demonstrated the significant impact of pharmacist-run diabetes clinics on clinical results, such as HbA1c, blood pressure and cholesterol panels, in addition to better self-management<sup>3</sup>. At Southwest General Health Center there has been a lack of diabetes education for all patients admitted with either new onset or uncontrolled diabetes. Currently pharmacists are asked to provide intense education to diabetic patients just prior to discharge, as well as figure out cost-assistance for these patients who cannot afford meters, strips, or insulin. The lack of time right before discharge and inability to prepare for an education session leaves the patients feeling unprepared and unable to care for themselves appropriately at home.

**Objectives:** (1) To provide diabetes education from a pharmacist early in the patients' hospital admission to improve patient knowledge of diabetes and ability to self-manage after discharge home. (2) To increase the number of referrals to the outpatient diabetes educator, as well as attendance at outpatient diabetes education classes.

**Methodology:** Patients to be included in the study population will be referred to the pharmacist by the consulted endocrinologist, attending physician, case manager on the floor, and/or nursing staff caring for the patient. Referral is to happen by the second day of their hospital admission. If agreeable, the patient will complete a diabetes knowledge questionnaire, obtained from the University of Michigan Diabetes Research Center, to assess their current level of knowledge about their disease state and treatment regimen. The pharmacist will educate the patient on the diagnosis of diabetes, treatment goals, their specific insulin regimen and insulin technique, and the importance of diet, exercise and physician follow-up visits to monitor diabetes management. The pharmacist will utilize educational videos available at the study site, known as TIGR Patient Education Guide, and pre-printed educational patient handouts from the National Institute of Diabetes and Digestive and Kidney Diseases, a branch of the National Institute of Health. At the completion of the diabetes education, the patient will again complete the same diabetes knowledge questionnaire to assess their knowledge level after receiving education early in the hospital stay. The change in score on the diabetes knowledge questionnaire will serve as the primary endpoint for the study. It is hypothesized that by providing education to patients early in the hospital admission and throughout their stay, their scores on the diabetes knowledge questionnaire will improve. At the completion of the service and prior to discharge, the patient will be encouraged to follow-up with an outpatient diabetes educator.

**Results and Conclusions:** To be determined.

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**Establishing a long-acting injectable antipsychotic clinic at a community hospital**

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**Background:** Long-acting injectable (LAI) antipsychotics have demonstrated clinical benefits in the treatment of psychiatric patients, including reducing risk of relapse and re-hospitalization. These clinical benefits are especially important for schizophrenic patients because of their low medication adherence and high rate of re-hospitalization. One current challenge to providing these benefits is that there are few pharmacist-led LAI clinics even though pharmacists are among the most accessible healthcare providers. In Ohio, pharmacists are recently permitted to administer LAIs to patients. This project aims to establish an outpatient LAI clinic under a collaborative practice agreement between pharmacists and psychiatrists at a community hospital.

**Objectives:** The outpatient LAI clinic will be established to provide LAIs for behavioral health patients with the needs for these medications with the goals of optimizing patient adherence, minimizing hospital readmission rates, and reducing associated costs.

**Methodology:** In this clinic, psychiatric clinical pharmacists will provide the injections, laboratory monitoring, medication counseling, and therapy adjustments. The PGY2 resident will develop a collaborative drug therapy management (CDTM) agreement, which will define the pharmacists' scope of practice and include detailed protocols for drug administration, laboratory ordering and monitoring, therapy adjustments, and patient follow-up services. The protocols will specify pharmacist training requirements, pharmacist peer review process, and periodic quality assessment of the services provided. The practice agreement will adhere to all the laws and rules established by the Ohio State Board of Pharmacy to allow clinically trained pharmacists to provide LAIs to patients. The practice agreement and protocols will be presented to the Pharmacy and Therapeutics (P&T) Committee for approval after the psychiatrists have the opportunity to make suggestions and modifications. Once the P&T committee approves the practice agreement and relevant protocols, they can be implemented provided that the other components of the LAI clinic, such as space, pharmacist training, and drug acquisition process are ready.

**Results and conclusions:** *In progress*

**References:**

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## Evaluation of Sepsis-3 recommendations in a large community teaching hospital

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**Background:** The SEPSIS-3 consortium introduced the quick sequential organ failure assessment (qSOFA) in February of 2016, and recommended that it be utilized to identify patients at an increased risk for mortality in the non-ICU setting.<sup>1</sup> Within the SEPSIS-3 study, qSOFA demonstrated a sensitivity to identify patients at risk for death in the non-ICU setting of 55%, while the Systemic Inflammatory Response Syndrome (SIRS) score had 64% sensitivity. Conversely, qSOFA had an 84% specificity vs. 65% for SIRS in the same population. The study states that qSOFA has a predictive validity, defined as the area under the receiver operating curve (AUROC), of 0.81 vs. SIRS at 0.76; however, the value of *predictive validity* in the clinical setting has yet to be determined. SIRS is known to be specific for sepsis albeit lacking in specificity.<sup>2</sup> Preliminary analyses of qSOFA and SIRS in our own institution has not produced significant clinical findings indicating that qSOFA should be utilized to identify patients at risk for death from sepsis in the inpatient setting. The need for a tool that is both sensitive and specific for mortality in sepsis remains.<sup>3</sup>

**Objectives:** To identify criteria that are predictive for an increased risk of mortality due to sepsis, are readily assessable at the bedside, and can be formulated into an assessment tool that is sensitive and specific for sepsis.

To evaluate qSOFA vs. SIRS among patients with suspected sepsis in a large community teaching hospital by comparing:

1. Sensitivity and specificity
2. Positive predictive value and negative predictive value
3. Additional criteria, including lactate, for predictive value
4. AUROC

**Methodology:** All encounters including patients 18 years and older with suspected or confirmed sepsis between January 1, 2015 and December 31, 2015 were evaluated. Patients who received empiric antibiotic treatment and had cultures drawn within 24 hours of presentation to our hospital met the criteria for suspected sepsis. Variables used to evaluate both SIRS and qSOFA scores were obtained for all patients, with a score of zero assigned for missing values. The SIRS and qSOFA scores were evaluated for each patient, and descriptive statistics were utilized to determine the sensitivity and specificity of both assessment tools in our institution. The AUROC for qSOFA and SIRS was also determined. Further analysis will be utilized to determine the sensitivity, specificity, and AUROC of other variables, particularly lactate, in combination with qSOFA and SIRS in an effort to identify the optimal tool to assess inpatient risk of mortality due to sepsis. Information was obtained by query of the EPIC<sup>®</sup> electronic record management system. The study was approved by Cleveland Clinic IRB.

**Results & Conclusions:** Preliminary analysis of qSOFA and SIRS scores in our population failed to yield the sensitivity and specificity reported in SEPSIS-3. The finding has led to further investigation into the clinical utility of predictive validity and use of the qSOFA score in practice to identify at-risk patients.

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## **An Outpatient Antimicrobial Stewardship Intervention Targeting Cytomegalovirus (CMV) Viremia in Solid Organ Transplant (SOT) Recipients**

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**Background:** CMV is an opportunistic herpesvirus that is associated with significant complications in SOT recipients. CMV infection may lead to tissue-invasive disease, other opportunistic infections, graft rejection, and an overall increased morbidity and mortality. Given the rapid rate of CMV replication, close monitoring and prompt treatment (if indicated) are essential to prevent the development and progression of CMV disease. However, these efforts become more logistically challenging once patients transition out of the inpatient setting. There are few studies describing the impact of outpatient stewardship interventions on patient outcomes, and even fewer data describing stewardship in an immunocompromised population. This study seeks to determine the effect of real-time notification of CMV results paired with pharmacist intervention on virologic and clinical outcomes in outpatient SOT recipients with CMV viremia.

**Objectives:** The primary objective is to evaluate the impact of notification and pharmacist intervention on viremia eradication at 21 days from therapy initiation. Secondary objectives are to compare time-to-viremia eradication, time-to-antiviral initiation, rate of discontinuation due to adverse drug events while on antiviral therapy, and hospital days in the pre-intervention and intervention phase, as well as to describe the number and type of recommendations made in the intervention phase.

**Methodology:** This is an IRB-approved quasi-experimental study. This study will include patients who are SOT recipients with whole-blood or plasma specimen with quantifiable CMV viral load detected in the outpatient setting, and will exclude patients with a history of bone marrow transplant or AIDS/HIV. The pre-intervention phase consists of a 6-month period (10/2015 – 3/2016) during which pharmacists were not notified of positive CMV results in real-time. Pharmacists were not regularly involved in reviewing or optimizing management of outpatients with CMV viremia. The intervention phase consists of a 6-month period (6/2016 – 11/2016) during which all new positive CMV results were automatically emailed to an infectious diseases pharmacist in real-time, prompting a patient profile review and recommendations for optimizing management, as appropriate. Recommendations were individualized to the patient and may have included repeating a CMV test, initiating or discontinuing therapy, adjusting an antiviral dose, reducing immunosuppression, obtaining a CMV resistance panel, or considering hospital admission for intravenous ganciclovir. Data collection will include patient demographics, transplant characteristics, antiviral and immunosuppressive therapy, virologic outcomes, adverse drug events, and pharmacist intervention. Parametric and non-parametric tests will be used to evaluate differences in patient characteristics between the two groups. Multivariate regression and survival analysis will be used to determine the impact of outpatient stewardship intervention on primary and secondary endpoints.

**Results and conclusions:** To be presented at the OCCP Spring meeting.

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## **Enhanced medication awareness in hospice patients through a medication perception survey and individualized patient and caregiver education: a pharmacist-led initiative**

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**Background:** Medicare is a large provider of the hospice service and requires that patients receive care by an interdisciplinary team and employ a licensed pharmacist or have an agreement for available pharmaceutical consultation. Recent surveys on the involvement of pharmacists in the hospice environment have suggested that typically the pharmacist is an actual member of the interdisciplinary team. Pharmacists in these roles can promote cost-effective medication use, monitor symptom relief, monitor therapeutic outcomes, minimize duplication, streamline therapy and provide education to families and healthcare professionals alike. Education provided can lead to effective symptom management, while minimizing adverse effects. Research has begun on the methods by which pharmacists can provide or contribute to the care and symptom management a patient receives as he or she nears the end of their life. However, up until this point, the assessment of the pharmacists' value has mostly been described solely through physician-based surveys and broader notes on the general subjective contribution of the pharmacist to the clinic.

**Objectives:** Pharmacists are trained to provide effective symptom management through optimization of therapy while minimizing adverse effects to patients in all care settings. The objective of this study is to survey hospice patients and caregivers to provide individualized education for appropriate symptom control as symptoms progress during their hospice tenure. Education will focus on patient centered care strategies to enhance symptom control by empowering appropriate medication administration.

**Methodology:** All patients enrolled in Alliance Community Hospice between November 1<sup>st</sup> and November 30<sup>th</sup> will be included in the survey regardless of terminal diagnosis, comorbid conditions, and location of hospice care. Information will be obtained through the electronic medical record, including but not limited to hospice care location, hospice diagnosis, time enrolled in the benefit, medications and comorbid medical conditions. Specialized hospice nurses will be utilized to obtain consent as well as initial and follow-up medication related survey responses from patients and their caregivers. All data will be de-identified and contained within a secure location with the locked pharmacy department. The initial survey will ask the responders to evaluate their confidence in medication knowledge, their current symptom control and topics of concern regarding their care through Likert scales. A patient/caregiver meeting will be arranged by the pharmacist during which education will be given on all medications with an emphasis on patient or caregiver identified areas of concern and as needed medications. Any additional concerns identified by the pharmacist will be communicated to the hospice care team. Follow-up surveys will be sent at two and ten weeks following education to assess how perceptions and symptom control were impacted. Descriptive statistics will be used to evaluate changes in patient and caregiver medication perception. The primary goal is to observe changes in Likert scale points that correspond with a decrease in symptoms and an increase in medication confidence. Secondary results will include a comparison of surveys in different hospice locations, between caregivers and patients, as well as between initial administration and 10 week follow-up. All interventions made will be recorded

**Results:** N/A

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## **A comparison of total cumulative doses of intranasal versus intravenous naloxone in patients with opioid overdose**

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**Background:** The United States is facing a major health crisis involving an epidemic of deaths from drug overdose. In 2014, there were approximately one and a half times more drug overdose deaths in the United States than deaths from motor vehicle crashes. Furthermore, since 2000, the rate of overdose deaths in the United States involving opioids increased by 200 percent.<sup>1</sup>

Naloxone hydrochloride is a short-acting opioid antagonist used to reverse opioid overdose. Naloxone is effective against all opioid agonists, and multiple doses of naloxone may be necessary depending on the amount, type, and route of administration of the opioid being antagonized.<sup>2,3</sup>

There is a perception that the intranasal administration of naloxone correlates with an increase in total amount of naloxone required in patients with opioid overdose when compared to naloxone intravenously (IV) administered. Previous literature found prehospital intranasal naloxone administered by emergency medical services (EMS) was associated with increased subsequent naloxone doses when compared to IV administration. Additionally, intranasal naloxone administration was associated with a longer time to clinical response compared to IV administration, although the overall time from patient contact to clinical response was not found to be statistically different.<sup>4</sup> Although previous studies have assessed naloxone use in the field, a comparison of total cumulative doses of intranasal naloxone versus IV has yet to be evaluated in patients also treated with naloxone in the emergency department (ED).

**Objectives:** The primary objective of this study is to determine if patients who received intranasal naloxone for initial resuscitation required a greater cumulative dose to have a clinical response compared to patients who received IV naloxone. The secondary objectives of this study are to determine if the administration of the first dose of naloxone intranasally corresponds to worse patient outcomes when compared to IV administration and to identify predictors of increased cumulative dose requirements.

**Methodology:** This is a single center, retrospective cohort study to determine if patients who were initially administered intranasal naloxone for opioid overdose required a greater cumulative dose (in milligrams) to have a clinical response when compared to patients who initially received IV naloxone. Additionally, time to clinical response after initial naloxone administration will be recorded and assessed. In order to evaluate secondary outcomes, the following data will be collected: Emergency Severity Index (ESI) score, discharge disposition from the emergency department, length of stay in the ED, rate of readmission, acuity of inpatient admission, discharge disposition after inpatient admission, length of inpatient admission, and resuscitative measures.

**Results and conclusions:** The primary outcome will be expressed as the total cumulative naloxone dose administered to each patient. This data will be presented and further assessed to determine if any of the pre-defined predictors are more likely to be associated with the primary outcome. The secondary outcome will be expressed as patient experienced outcomes in the intranasal versus IV groups.

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**Impact of obesity shared medical appointments on weight loss and other cardiometabolic risk factors****Stephanie Yager, PharmD, Marcie Parker, PharmD, BCACP, Jennifer Luxenburg, PharmD, BCACP**

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PGY-2 Ambulatory Care Pharmacy

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**Background:**

More than one-third of US adults are obese<sup>1</sup> and weight loss in obese individuals reduces risk factors for diabetes and cardiovascular disease<sup>2</sup>. The Cleveland Clinic Beachwood Family Health Center has an obesity shared medical appointment (SMA) program designed to promote weight loss for patients enrolled. Few studies have been published evaluating obesity SMAs. One study found patients who attended at least one obesity SMA lost more weight than patients who had at least one office visit after a mean duration of 4 months<sup>3</sup>. The total number of SMA visits was associated with weight loss and body mass index (BMI) reduction. This study will evaluate the effectiveness of the obesity SMA at Beachwood Family Health Center.

**Objectives:**

- 1) Evaluate the change in weight over 3 months and percent change in weight at 3 months for patients attending the shared medical appointment
- 2) Evaluate the change in glycated hemoglobin (A1c), lipids, blood pressure (BP), body mass index (BMI) at 3 months and at the end of the study period
- 3) Evaluate the change in number of hypertension and diabetes medications at 3 months and at the end of the study period
- 4) Determine the proportion of patients that achieved 5% weight loss at the end of the study period
- 5) Evaluate the change in A1c, lipids, BP, BMI in relation to weight loss medication
- 6) Determine if there is a correlation between number of appointments attended and change in weight and BMI

**Methodology:**

This retrospective observational study will evaluate weight loss in patients who attended at least 1 obesity SMA at Beachwood Family Health Center between 12/10/2015 and 8/30/2016. Weight loss and other cardiometabolic risk factors will be compared compared from the time of the patients' first SMA, 3 months after the first SMA, and at the end of the study period. The change in weight, BMI, BP, A1c, and lipids will be compared using a paired t-test. The correlation between appointments attended and weight loss will be evaluated using linear regression.

**Results and conclusions:**

This study will provide insight into the effectiveness of the obesity SMA at Beachwood Family Health Center and obesity SMAs in general. It will provide further information on the role a pharmacist can play in an SMA and the weight loss achieved on different weight loss medications. It will also provide information on the change in cardiometabolic risk factors.

**References:**

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## Vasopressin plasma concentrations in responders and non-responders to exogenous vasopressin infusion in patients with septic shock

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**Background:** Vasopressin is an endogenous hormone that increases blood pressure through agonism of the vascular vasopressin V1 receptor.<sup>1</sup> A “relative deficiency” of vasopressin is theorized to exist in patients with septic shock, as endogenous vasopressin levels are initially elevated but quickly fall to levels at or below those of normal physiology because of the depletion of endogenous stores.<sup>1,2</sup> This has led to the addition of exogenous arginine vasopressin (AVP) to exogenous catecholamines to increase mean arterial pressure (MAP) and to decrease catecholamine requirements in patients with vasodilatory shock, with the assumption that increasing doses (and therefore, increasing plasma concentrations) will lead to increasing MAP. In a retrospective study, hemodynamic response to AVP was associated with decreased odds of mortality.<sup>3</sup> However, lower body weight and concomitant use of corticosteroids (factors that have previously been associated with increased plasma vasopressin concentration) were not associated with hemodynamic response, suggesting that a dose-response relationship between plasma vasopressin concentration and hemodynamic response may not exist.<sup>3</sup> This study seeks to evaluate the relationship between plasma vasopressin concentration and hemodynamic response to better inform AVP dosing.

**Objectives:** Primarily, to compare plasma vasopressin concentrations in hemodynamic responders and non-responders to fixed-dose AVP in patients with septic shock. Secondarily, to identify factors that are predictive of plasma vasopressin concentration, and determine an optimal plasma vasopressin concentration that is associated with hemodynamic response (if one exists).

**Methodology:** A prospective observational study of 100 patients will be conducted to compare plasma vasopressin concentrations in hemodynamic responders and non-responders to AVP in the setting of septic shock. Hemodynamic response will be defined as a MAP  $\geq 65$  mmHg with a decrease in total catecholamine dose from the time of AVP initiation until the time of the vasopressin blood sampling. Blood samples will be collected 3-6 hours after initiation of fixed-dose AVP and centrifuged. The resultant plasma will be frozen until all samples are collected, and then will be analyzed in batch using the Enzo Life Sciences Arg<sup>8</sup>-Vasopressin ELISA kit. Adult patients will be included if they are treated in a medical, surgical, or neurosciences ICU with fixed-dose AVP as an adjunct to catecholamines for at least 3 hours. Patients will be excluded if AVP is the sole vasoactive therapy, is used for an indication other than septic shock, or is titrated prior to 3 hours or before a blood sample is obtained. Data describing patient demographics, baseline characteristics, severity of illness and organ dysfunction, and concomitant medication administrations will be collected. Secondary objectives include determination of a plasma vasopressin concentration that is associated with hemodynamic response, determination of factors associated with hemodynamic response to AVP, and the comparison of plasma vasopressin concentrations in patients receiving different AVP doses. Hemodynamic responders and non-responders will also be compared in regards to ICU mortality, in-hospital mortality, and presence of acute kidney injury according to the risk, injury, failure, loss, and end-stage kidney disease criteria.

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