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.1 Midodrine, an α1-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.2 Currently, few studies have been done to determine its effect on patients with shock.3-4

Objectives: The primary objective of this study was to compare the duration of IV vasopressor administration in patients who did or did not receive oral midodrine. The secondary objectives were 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; rate of ICU readmission; differences in ICU and hospital lengths of stay; and adverse events.

Methodology: A non-interventional medical chart review was 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 were included. Patients were 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 included those with diagnosed heart failure, chronic kidney disease, and/or end stage liver disease as identified by ICD-9 and ICD-10 codes. Patients were propensity matched according to the likelihood of midodrine receipt. Data was collected on patient demographics, vasopressor agents used, dosages of vasopressor agents, ICU readmission, ICU length of stay, hospital length of stay, Acute Physiology and Chronic Health Evaluation (APACHE) III score, and adverse events (bradycardia and ischemia). The starting dose, maximum dose, and duration of midodrine therapy was collected for the midodrine cohort. Nominal data were analyzed with the Chi-square test. Continuous data were analyzed with the Wilcoxon signed-rank test.

Results and conclusions: Of the 2070 patients included, 1861 patients received IV vasopressors only and 209 patients received IV vasopressors with concomitant midodrine. Patients in the midodrine cohort had a higher APACHE III score at ICU admission (84 vs. 77; P<0.01), as well as a greater number of patients with diagnosed septic shock (70.8% vs. 57.8%; P<0.01); diagnosed CKD (44.5% vs. 22.7%; P<0.01); and diagnosed ESLD (19.1% vs. 7.9%; P<0.01). Patients received midodrine for a median of 9.2 days with a starting daily dose of 15 mg (IQR 15-30) and maximum daily dose of 30 mg (IQR 15-30). The median vasopressor duration prior to midodrine initiation was 3.6 days (IQR 0.8-6.9). Patients in the midodrine cohort had a longer vasopressor duration (13.4 days vs. 3.5 days; P<0.01); hospital length of stay (24.4 days vs. 15.9 days; P<0.01), and ICU length of stay (13.4 vs. 7.8 days; P<0.01). There were no differences in hospital mortality or ICU mortality. A higher ICU readmission rate occurred in the midodrine cohort (27.8% vs. 19.4%; P<0.01). There were no significant differences in adverse events between the two cohorts. When propensity matched to account for confounding factors, midodrine patients had a longer vasopressor duration (13.5 vs. 7.7 days; P<0.01); hospital length of stay (24.4 vs. 20.7 days; P<0.01); and ICU length of stay (13.4 vs. 9.7 days; P<0.01). The minimal overlap of vasopressor duration between the two cohorts, as evidenced by the confidence intervals, may have limited the accuracy of propensity matching and subsequent analyses. Further analyses controlling for vasopressor duration differences prior to midodrine initiation are needed to elucidate the true impact of midodrine on IV vasopressor duration.

References:

Impact of β-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 years1,2. The identification of penicillin allergies becomes especially essential in the treatment of methicillin-susceptible *Staphylococcus aureus* (MSSA) infections, in which β-lactam therapy has shown superiority over vancomycin, specifically in the treatment of MSSA bacteremia3,4. 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.5

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

**Objectives:** The objective of this study was to determine the frequency at which treating providers elicit a clinical history in β-lactam-allergic patients with MSSA infections. The primary endpoint was the percentage of patients with documentation of a β-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 included antibiotic treatment failure, rate of alternative therapy, length of hospital stay, and adverse drug events.

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

**Results and Conclusions:** Results to be formally presented at OCCP Spring Meeting

**References:**

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).1-2 Pharmacists are trained to identify medication-related problems; studies have shown that pharmacist involvement reduces adverse outcomes from MRPs.2-5 In fall 2015, Cleveland VA outpatient clinics began seeing recently discharged patients in a pharmacist-driven Post-Discharge Transitional 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 Transitional 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 was conducted through utilization of the electronic medical record and survey results. The targeted patient population included all patients seen by a pharmacist 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 or provider was completed and pre-implementation surveys were administered to nurses, pharmacists, and providers to determine factors leading to pharmacist consultation. Following review, an algorithm and note template were developed and implemented in the Akron, Mansfield, Lorain, Parma, and Youngstown community based outpatient clinics (CBOCs). After implementation, prospective chart review was completed on patients seen for post-discharge follow-up by a pharmacist or a provider through early spring 2017. Additionally, following the prospective implementation period, post-implementation surveys were distributed to nurses, pharmacists, and providers at the participating clinics to assess convenience and implementation of the standardized process as well as any suggestions for future improvements. 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 evaluation of 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 are 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 analysis is completed using descriptive statistics.

Results and conclusions: To be presented at the OCCP Spring Conference May 26, 2017.

References:

Assessment of injection technique by pharmacists

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Background:
Injection related errors occur across multiple health settings. Improper administration of an injection could lead to serious illness and possibly death. According to the Center for Disease Control and Prevention (CDC), the US has had four large outbreaks of HBV and HCV in ambulatory care facilities. Safe injection practices, as defined by WHO, do not harm the patient, do not expose the providers to any avoidable risk, and do not result in waste dangerous to the community. While some events cannot be avoided, safe injection technique and practices should occur every time. Injection technique should be evaluated on an ongoing basis. Since community pharmacists provide many injections, it is important to analyze how vaccines are delivered in a pharmacy based setting to ensure optimal injection safety.

Objective:
The objective of this study is to determine if safe injection practices are followed by pharmacists in various settings.

Methodology:
This pilot study will evaluate adherence to current CDC standards in injection administration, as well as whether years of experience affect injection technique. Participants will include pharmacists. Participants must be able to administer injectables. Recruitment will be conducted in person and via email. Additionally, to recruit participants, emails will be sent via the American Society of Health-System Pharmacists Connect Community, the American College of Clinical Pharmacy electronic mailing list servers, and other pharmacy contacts. The survey instrument is based upon the CDC Injection Safety Checklist and the CDC Skills Checklist, consisting of yes or no style questions. Data will be assessed using descriptive statistics evaluating for trends.

Results and conclusions:
There were 17 total participants in this study. Participants were from a variety of pharmacy settings (retail, n=9; hospital, n=3; ambulatory care, n=3; managed care, n=1; other, n=1). Of these participants, 41.2% (n=7) met the entire criteria of the evaluation survey. However, 58.8% (n=10) of participants were evaluated missing one or more of the criterion in the survey. Areas that were not met include: patient/parent education, vaccine handling, vaccine administration, administering immunizations, and recording procedures. While the sample size of this study is limited, core areas of this skills evaluation were omitted. Each of the areas that were not met, create an opportunity for an accident to occur. Continuing to strive towards safety standards is the upmost importance.

References:
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. 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. 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°C or < 36°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. Patients with sepsis are often burdened by systemic inflammation, a procoagulant state, and hypotension. 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. 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: Antibiotics administered within the CMS time frame occurred in 72% of patients pre-implementation and in 80% of the patients post-implementation of the CMS core measures (p = 0.39). Lactate levels were more compliant from pre to post-implementation (p = 0.01). When data was analyzed for antibiotic administration and select components from the CMS core measures in combination, statistical significance demonstrated (p = 0.01). Antibiotic administration is an important measure in patients with severe sepsis and septic shock. Assessing compliance with CMS measures will help guide institutions to best practices.

References:
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. 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 prevalence and efficacy of various treatments for hyperammonemia.

Methodology: This study was completed at Cleveland Clinic Lutheran Hospital and has been approved by the Institutional Review Board. Patients were retrospectively identified through a database query from June 2011 to June 2016. Patients were 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 included a diagnosis of cirrhosis at admission. Hyperammonemia was defined as greater than 47 micromoles per liter. Symptomatic hyperammonemia was defined based on symptoms present per documentation in the electronic medical record, such as lethargy and altered mental status. Only patients with multiple ammonia levels drawn were used to assess efficacy of treatment modalities. The ammonia levels were trended during the admission, and the treatment modality was deemed successful if the ammonia level was within normal range (17 to 47 micromoles per liter) at discharge.

Results and Conclusions: Of the 357 patients screened, 347 patients were included for analysis. Patients included had a median age of 47 years and 66.9% were male. The most common admitting diagnoses were schizophrenia (32%) and schizoaffective disorder (30.6%). The reported incidence of hyperammonemia was found to be 36%, with 43.2% of these patients presenting with symptoms. Initiation of lactulose was the most common treatment modality chosen (48.7%). Discontinuation of valproic acid was the most effective treatment (56.3% success rate). Initiation of levocarnitine had a success rate of 50%, and initiation of lactulose had a success rate of 41.8%.

The results demonstrate that many patients with elevated ammonia levels are asymptomatic, and, therefore, do not require treatment. Although lactulose was found to be the most common treatment initiated, the most effective treatment was discontinuation of valproic acid.

References:
Comparison of Antimicrobial Stewardship Advisories between an External Clinical Decision Support System and an Electronic Health Record

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Background: Antimicrobial Stewardship (AMS) is a key method for curtailing antibiotic resistance\(^1\). Prospective audit and feedback (PAF) is a cornerstone of AMS. A powerful tool for facilitating PAF is the use of Clinical Decision Support Systems (CDSS), which can improve guideline adherence, decrease costs, and increase efficiency of data review\(^3\)\(^-\)\(^5\). Clinical pharmacists at Cleveland Clinic Health System utilize an external CDSS separate from the electronic health record (EHR). Thirty advisories are currently in use, including advisories for identifying patients who may qualify or be at risk for: de-escalation or escalation opportunities, drug interactions, adverse drug reactions, and therapeutic drug monitoring. During a recent technical upgrade to our EHR, it was found that these external CDSS advisories can be built into the EHR. The present study aims to validate and implement AMS advisories within an EHR to compare their accuracy and usability to advisories in the external CDSS.

Objective: The primary objective determined accuracy of advisories by comparing number of advisories generated in the external CDSS and in the EHR by advisory type. Secondary objectives measured usability of both systems by measuring the number of clicks necessary to access and address advisories in either system, the number of redundant advisories, and user satisfaction as measured via Likert survey.

Methodology: This was an implementation and validation study comparing the number and types of advisories generated within the EHR and the external CDSS between February 6\(^{th}\) 2017 and May 31\(^{st}\) 2017. Advisories in the EHR were tested to ensure proper functionality, then advisories in both systems were counted and categorized by type. Discrepancies in number of advisories were examined for cause. To evaluate usability, nine infectious disease pharmacists reviewed advisories in the EHR on a rotating basis. The primary outcome was analyzed using descriptive statistics. The secondary outcomes of pharmacist satisfaction and clicks was evaluated using the Wilcoxon rank-sum test and the number of redundant advisories was evaluated using descriptive statistics.

Results and conclusions: Implementation of AMS advisories within the EHR was found to be feasible. There was, however, a large increase in the number of specific advisory types detected in the EHR and extensive build corrections were necessary to address this issue. The integration of a robust patient summary report within advisories and the removal of a login step was found to decrease the number of clicks necessary to use the EHR advisories vs in the external CDSS. Overall, AMS advisories within our EHR allow for more extensive customizability and superior reporting capabilities, but require heavy initial investment with specialized staff in order to implement. Furthermore, extensive testing and optimization are crucial to success.

References:
Evaluation of a pharmacist-driven darbepoetin optimization protocol

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Background: Anemia is a common disorder in patients with chronic kidney disease, chronic inflammatory conditions, as well as in patients receiving chemotherapy for malignancy. Darbepoetin alfa (Aranesp®), an erythropoietin-stimulating agent (ESA), is 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. Moreover, darbepoetin has been associated with increased risk of serious cardiovascular events and stroke. Due to the cost and safety concerns, appropriateness of use of ESAs in the inpatient setting must be ensured. The clinical and economic impact of a pharmacist-managed ESA optimization protocol has been previously evaluated in literature.

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

Methodology: This study was approved by the institutional review board. This was 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 was a retrospective evaluation of darbepoetin use that was completed between October 7, 2014 and January 17, 2015. The post-phase of the study was 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 were included. All orders for darbepoetin in the outpatient setting were excluded. Data collection included patient demographics, indication and dose of darbepoetin, hemoglobin level at therapy initiation, as well as prescribing service. Safety data included number of packed red blood cell transfusions prior to therapy initiation and during therapy and all-cause 30-day readmission. Data was analyzed using descriptive statistics and student t-test. Cost analysis was performed using the hospital's darbepoetin acquisition cost.

Results and conclusions: Total number of inpatients ordered darbepoetin decreased by 54.4% (90 vs. 41, p< 0.001) post-protocol implementation. Difference in cost of usage between pre- and post-implementation phase was $40,367.58 ($p = 0.0048). Mean change in hemoglobin from baseline was not clinically significant (0.48 ± 0.36 g/dL) during post-protocol phase. Implementation of the darbepoetin optimization protocol led to a significant reduction in darbepoetin usage, with no impact on transfusion requirement and no clinically significant adverse effects.

References:
Interventions and Cost Savings Associated with Pharmacy Resident Rounding on Weekends in a Medical Intensive Care Unit

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Background: A 1999 study by Leape, et al. used a historical control to show that by participating in rounds with the medical ICU 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). In 2001, the American College of Critical Care Medicine stated that pharmacists are an integral part of the ICU team and recommended that a dedicated pharmacist participate in daily rounds with the team to reduce errors and improve quality of care. 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.

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 was designated to be a quality improvement project by the Cleveland Clinic Akron General Institutional Review Board and took place at a 532 bed, acute care, teaching hospital located in northeast Ohio that did not previously have clinical pharmacist coverage on weekends in the critical care units. Two post graduate year 2 (PGY-2) critical care pharmacy residents rotate rounding with the medical intensive care unit team on 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. A description of each intervention made per patient was recorded by the pharmacy residents and whether this intervention was accepted by a physician. Interventions made on weekends from September 17, 2016 to December 31, 2016 were categorized by type and analyzed for associated cost savings based on Truven Health Analytics monetary values. Types of interventions included changing routes of administration, dosing adjustments, de-escalation or discontinuation of antibiotics, addition of stop dates, discontinuation of inappropriate medications, initiation of medications, medication reconciliation completion, non-medication interventions, participation in medical emergencies, renal dosing and pharmacokinetics, and an other category for interventions not classified in the aforementioned groups.

Results and conclusions: Over 27 weekend days, the pharmacy residents were able to make 905 interventions on 264 patients with a 98% physician acceptance rate. Of the patients who required pharmacist intervention, there was an average of 3.4 interventions made per patient per weekend. The most common types of interventions included discontinuation of inappropriate medications and non-pharmacologic interventions which included laboratory monitoring and nutrition recommendations. More than $80,000 of interventions were made by the pharmacy residents on weekends during the study period. PGY-2 pharmacy residents were able to fill a void in the pharmaceutical care of critically ill patients at Cleveland Clinic Akron General and demonstrate cost savings from therapeutic interventions. This staffing model may be effective at other institutions that do not have clinical pharmacist coverage on weekends.

References:

Tolerability of aerosolized versus intravenous pentamidine for *Pneumocystis jirovecii* pneumonia prophylaxis in immunosuppressed pediatric patients

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**Background:** *Pneumocystis jirovecii* pneumonia (PJP) is a fungal infection caused by an ascomycetes fungus (*Pneumocystis jirovecii*) and effects those who are severely immunosuppressed. In the malnourished and immunocompromised populations, PJP has been shown to have high rates of transmission and increased mortality, thus requiring prophylaxis. In the pediatric population, the development of PJP is most commonly observed in lymphoid malignancies, hematopoietic stem cell transplant (HSCT) patients, chronic corticosteroid use, and severe lymphocytopenia. Sulfamethoxazole-trimethoprim is the drug of choice for prophylaxis, however due to adverse effects alternative therapies may be utilized, including pentamidine. Pentamidine is an antifungal medication that interferes with the synthesis of RNA, DNA, and proteins ultimately leading to cellular death. Current evidence has demonstrated that both aerosolized and intravenous formulations of pentamidine are effective in preventing PJP disease. However, there is a lack of literature comparing tolerability between the two administration routes.

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

**Methodology:** This study is a retrospective, observational chart review looking at the pediatric immunosuppressed population at Rainbow Babies and Children’s Hospital. Inclusion criteria included patients with a cancer diagnosis, HSCT recipients, renal transplant recipients, and those who received pentamidine for PJP prophylaxis. Exclusion criteria included patients who received pentamidine for treatment of PJP. The study data will be obtained from the electronic medical record and will include: gender, ethnicity, age, patient weight, allergy history, days from transplant, pentamidine dose and dosage form, pentamidine dosing frequency, pentamidine infusion duration, pre-medications, type of reaction to pentamidine, number of pentamidine doses prior to reaction, cycle of chemotherapy, other immunosuppressive therapy, history of sulfamethoxazole-trimethoprim use, and absolute neutrophil count. The data will be assessed using non-parametric statistics and frequency analysis in order to detect differences between the two routes of administration.

**Results and Conclusions:** A total of 96 patients met inclusion criteria and were included in the retrospective chart review. Ten of the 96 patients were identified as having reacted to either the aerosolized or intravenous pentamidine formulation (p=0.134). Nine of 10 patients that reacted received intravenous pentamidine compared to one patient who received the aerosolized formulation (p=0.132). Those patients that were diagnosed with a blood cancer had an increased incidence of reaction compared to solid tumor and non-oncologic diagnoses (p=0.042). The tolerability of aerosolized versus intravenous pentamidine is not statistically significant, but does warrant further evaluation in a larger patient population.

**References:**

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. 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. 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 with anti-Xa assays than with aPTT. 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. The anti-Xa monitoring protocol is a nurse driven protocol that is divided into low intensity and high intensity. This quality assurance (QA) project evaluated the nurse driven heparin anti-Xa protocol initiated by the LSCVAMC.

Objectives: The primary objective was to determine the time to first therapeutic anti-Xa level. Secondary objectives evaluated the compliance to the protocol, correlation between anti-Xa and aPTT drawn at the same time, and safety.

Methodology: A retrospective chart review was 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 was 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 were excluded. Data points collected included 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 anti-Xa (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 was 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 was analyzed using descriptive statistics.

Results and conclusions: In the total population (n = 100), the average time to first therapeutic anti-Xa level was 10.82 hr (median 9.47 hr). Seventy-five patients (75%) achieved two consecutive therapeutic anti-Xa levels within 24 hrs. Thirty patients (30%) were on the low intensity protocol and 70 patients (70%) were on the high intensity protocol. Overall, 94% of patients were on the correct intensity protocol, 96% of patients received the correct initial dose, and 92% of patients received correct dose adjustments. In the total population, there were 12 critical anti-Xa levels (12%). There were no major bleeds or incidences of HIT. There was 1 documented minor bleed. Overall, the implementation of the nursing-driven anti-Xa heparin monitoring protocol was successful at the LSCVAMC. Compared to prior studies of heparin protocols at the LSCVAMC, therapeutic heparin levels were attained quicker, with few subtherapeutic, supratherapeutic, and critical levels. The next steps will be to conduct a cost-analysis and nursing satisfaction survey.

References
Prevalence and predictors of antipsychotic prescribing in adults with Parkinson's disease. A national cross-sectional study

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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. A cross-sectional study from 2010 concluded that psychosis occurs in as much as 60% of patients with Parkinson's disease. 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 and quetiapine were potentially effective. Other antipsychotics have not had any compelling evidence supporting their efficacy in treating Parkinson’s disease psychosis. The prescribing of antipsychotics in patients that have Parkinson's disease, with or without psychosis, has been associated with a marked increase in mortality. 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. This finding stresses the importance of the need to be cautious with the prescribing of antipsychotics in patients that have Parkinson’s disease.

Objective: 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.

Methodology: This national cross-sectional study will use data from the National Ambulatory Medical Care Survey (NAMCS) from 2005 through 2014, which was obtained through the Centers for Disease Control and Prevention website. The de-identified data sets were 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 are excluded from the study. The primary outcome will be the rate of antipsychotic prescribing 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: A total of 845 patients met the inclusion and exclusion criteria for this study. These 845 patients represent a weighted total of 11,901,800 patients. Between 2005 and 2104, antipsychotics were started, reordered, or continued in 5.7% of office visits for Parkinson’s disease. A majority of patients were male (57.7%), Caucasian (80.8%), ≥ 75 years old (64.8%), used 0 or 1 dopaminergic agent (65.7%), and paid with Medicare (76.2%). In the multivariate analysis, females had higher rate of antipsychotic prescribing compared to males (OR: 3.096, CI: 1.166-8.220), established patients had a higher rate of prescribing compared to new patients (OR: 4.831, CI: 1.353-17.391), neurologist were more likely to prescribe antipsychotics compared to primary care and internal medicine (OR: 12.437, CI: 7.298-21.196), other specialists, not including primary care, internal medicine and primary care, were also more likely to prescribe compared to primary care and internal medicine (OR: 50.212, CI: 19.444-129.665), and patients that were from the South were at higher risk compared to the Northeast (OR: 4.946, CI: 1.386-17.652).

References:

**Code stroke alert: a streamlined process for IV t-PA**

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**Background:** Treatment of acute ischemic stroke (AIS) with IV tissue plasminogen activator (t-PA) within 3 hours (up to 4.5 in eligible patients) of symptoms has been shown to drastically improve recovery symptoms.1,2 The American Heart Association/American Stroke Association (AHA/ASA) recommend a goal IV t-PA door-to-needle (DTN) time for a patient admitted with stroke-like symptoms of ≤60 min.2 Our stroke committee determined our institutional DTN time was suboptimal (83 min on average, 26% time within 60 min from April – October 2016) and attributed delays to pharmacy. However, DTN time is multifactorial and metrics collected by the stroke committee did not adequately capture all potential gaps in the process. Currently, pharmacy mixes and delivers t-PA to the bedside and we are committed to continuing this service and quality improvement. Therefore, we developed a new Stroke Alert procedure to assure t-PA ordering, delivery and administration is uniform across all pharmacist shifts. The purpose of this study was to evaluate the new Stroke Alert process.

**Objectives:** (1) reduce institutional DTN time to ≤60 min (2) assure t-PA order to infusion time to ≤15 min, and (3) identify institution-specific barriers to timely administration of t-PA.

**Methodology:** The new process started Dec 1st, 2016 and data was collected for four months. Pharmacists were engaged in documentation of discrete time-points during code Stroke Alert not previously captured by the institutional stroke response committee. Variables analyzed were either pharmacy-dependent or pharmacy-independent, as some aspects of the t-PA process can be influenced by pharmacy and others cannot. Data points included time of stroke alert announcement over the hospital public address system, ED patient registration (official time upon which DTN is calculated), order entry, reconstitution, delivery, and administration. We analyzed the difference between these data points to identify the average time necessary to complete each step in the process. We identified barriers on a case-by-case basis where t-PA administration did not meet goal metric of ≤60 min.

**Results and Conclusions:** During the four month period, 120/189 Stroke Alerts were captured by pharmacy, including 11 t-PA administrations (10 in ED, 1 in-house). Average DTN time was 69 min based upon ED registration times, 36% of the cases met DTN time ≤60 min. Of those that did not meet goal, two met metric exclusion criteria (HTN and no history) and five were attributed to other delayed decision making and delayed administration. Challenges involved delays due to on-site physicians consulting with neurology at the comprehensive stroke center (Cleveland Medical Center) and delays from equipment readiness. Order to administration time was 14 min on average, which demonstrates opportunity for improvement considering that order entry to delivery time was 6 min on average. Future directions will address improved time to t-PA decision, more extensive staff education on stroke urgency and equipment readiness, and to work with the stroke committee to develop more aggressive goals in preparation for new target DTN time ≤45 min.

**References**


Utilization of clotting factor concentrates for bleeding disorders at a tertiary medical center

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Background: Hemostasis is a mechanism to arrest blood flow initiated at a site of vascular injury. 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 disease, is prevention and/or treatment of bleeding through replacement of deficient clotting factors. Institutions have implemented factor stewardship programs in order to balance efficacy, safety, and fiscal responsibility of factor products. Current practice at our institution restricts clotting factor concentrate usage to hematology for approval of formulary approved agents.

Objectives: The primary objective of this study was to characterize the current usage of clotting factor concentrate products at a tertiary medical center in order to identify areas of opportunity for formulary optimization. Secondary objectives included evaluation of efficacy, safety, and pharmacoeconomic analysis of clotting factor concentrate products.

Methodology: This was a single-center, retrospective study of patients who received at least one dose of a clotting factor concentrate product during an inpatient hospitalization from August 1, 2015 to July 31, 2016. Patients were identified through the electronic medical record. Patients with a factor deficient condition who received factor VIIa, VIII, IX, X, or XIII, anti-inhibitor coagulant complex, or fibrinogen concentrate were included in the study. Patients <18 years old, receiving clotting factor concentrates for anticoagulation-induced bleeding or thromboelastography monitoring, and use of prothrombin complex concentrate were excluded from this study. Data points collected include: patient demographics, bleeding disorder history, admitting diagnosis, inpatient factor regimen, pertinent lab values prior to and following factor use, length of hospital stay, transfusions required, thrombotic events, use of alternative or adjuvant treatments, discharge status, and 30-day readmission. Additionally, pharmacy analytic and wholesaler reports were utilized for financial information related to site factor usage.

Results and conclusions: Final results and conclusions will be presented at Ohio College of Clinical Pharmacy’s Spring Meeting.

References:
Comparison of the use of aripiprazole and quetiapine for the adjunctive treatment of Major Depressive Disorder (MDD)

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Background: According to the World Health Organization, major depressive disorder (MDD) carries the heaviest burden of disability among mental and behavioral disorders. 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. Since gaining FDA approval in 2007 as adjunctive treatment of MDD in adults, second generation antipsychotics (SGAs) aripiprazole and quetiapine have become a mainstay in treatment. While beneficial for many patients, SGAs can cause serious side effects such as weight gain, diabetes, and dyslipidemia, and extrapyramidal symptoms. These side effects can be a burden to patients and are often a leading cause of discontinuation. The purpose of our study is to compare antidepressant augmentation with aripiprazole and quetiapine and determine their effects on admission rates. In addition we will also look at time to discontinuation, tolerability, and incidence of various side effects. Our Hypothesis is that augmentation with oral aripiprazole vs quetiapine will lead to significantly different time to discontinuation of augmenting agent and time to inpatient psychiatric admission

Objective: The primary objective was to compare antidepressant augmentation with oral aripiprazole and quetiapine and their effects on inpatient psychiatric admissions and discontinuation rates. The secondary objective is to compare antidepressant augmentation with oral aripiprazole and quetiapine and their influence on reasons for discontinuation.

Methodology: This study was a retrospective chart review targeting 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. All adult patients who have current diagnosis of major depressive disorder or bipolar disorder on an SSRI or SNRI with aripiprazole or quetiapine augmentation will be included. We will exclude patients with current diagnosis of delirium, dementia, amnestic or other cognitive disorders, schizophrenia, patients on any other concomitant psychiatric medications (mood stabilizers, antipsychotics other than aripiprazole or quetiapine, bupropion, nefazodone, thyroid hormone used as augmentation of antidepressants, stimulants, mirtazapine >15mg, trazodone >300mg, buspirone). For our first co-primary outcome of comparing antidepressant augmentation with aripiprazole and quetiapine and their effects on time to inpatient psychiatric admission and time to discontinuation, a 2 x 2 table, chi squared analysis will be completed. For the 2 x 2 squared table with an alpha of 0.05, a power of 0.80, a sample size of 197, we will be able to detect a moderately small effect size of 0.20.

Results: For the co-primary outcome, time to inpatient psychiatric admission from initiation, there were no significant difference between patients who were augmented with aripiprazole compared to those augmented with quetiapine. Time to augmenting agent discontinuation did not differ significantly. For secondary outcomes, there was no significant difference in reason for discontinuation. The majority of medications were considered discontinued due to patient non-adherence as determined by calculation of refill history in CPRS or by provider documentation.

Conclusion: The results of this study do not support the use of aripiprazole over quetiapine for the augmentation of SSRIs or SNRIs in patients with treatment-resistant major depressive disorder or bipolar disorder. In the future, larger studies need to be conducted in order to detect a difference.

References:
Background: The prevalence of morbid obesity in the U.S. has been trending upwards since 2005. Obesity significantly affects the pharmacokinetics of low molecular weight heparins such as 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. 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 extrapolate results to the entire morbidly obese population.

Objective: The primary objective of this study was to evaluate incidence and odds of major bleeding between different enoxaparin dosage strategies in patients weighing 120 kg or more receiving enoxaparin with the intent of full anticoagulation.

Methodology: Patient data was extracted from the electronic medical records of three community hospitals in Cleveland, Ohio from the past five years. Patients were 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 was collected for patients with a creatinine clearance less than 30 mL/min for the purposes of an ad-hoc subgroup analysis, but this data was excluded from the primary analysis. Patients less than 18 years old, patients with no creatinine or weight data, pregnant patients, and patients with documented heparin induced thrombocytopenia were excluded. The incidence of primary outcomes occurring within seven days of discontinuation of therapy or discharge was compared between patients receiving an enoxaparin dose less than 90% of the FDA approved dose dose and greater than or equal to 90% of the FDA approved dose and also between patients weighing greater than or equal to 150 kg and less than 150 kg.

Results and Conclusions: A total of 462 patients were eligible for the primary analysis, and 25 patients were eligible for the subgroup analysis. No difference in major bleeding was observed when comparing different dosage regimens (p=0.12) nor when comparing different weight groups (p=0.36). No difference was observed in rates of VTE or ischemic stroke when comparing different dosage regimens (p=0.52 and p=0.60 respectively) nor when comparing different weight groups (p=0.39 and p=0.48 respectively). Similar results were observed in the subgroup analysis. Results were not altered when patients were propensity matched on baseline characteristics. Reducing the dose of enoxaparin does not seem to reduce the odds of major bleeding or increase the odds of ischemic stroke or VTE; however, the study may have been underpowered to detect a significant difference.

References:
Optimizing Central Pharmacy Workflows using Automated Dispensing Cabinets’ Percentage Trigger Threshold Refill Technology

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Background: The proper use of medication automated dispensing cabinets (ADC) may enhance patient safety, reduce medication errors and optimize pharmacy processes and procedures. Hillcrest Hospital utilizes Pyxis™ medication cabinet technology, which is capable of assigning maximum and minimum drug levels. Pyxis™ ADCs can be refilled with a scheduled fill or a percentage trigger threshold. Both methodologies refill ADCs based upon minimum par levels, but differ in the time of day in which the refills occur. The purpose of this study was to demonstrate how percentage trigger thresholds were similar to scheduled fills in reducing the incidence of medication stock outs. We hypothesized that percentage trigger threshold refill methodology would adjust pharmacy technician workflows by moving refills earlier in the day. We also sought to show that this convention permitted technicians to focus on other tasks such as unit dose packaging, cart fill and other assignments later in the day because of the workflow change to the refill process.

Objective: The primary objective of this study is to demonstrate the capability of percentage trigger thresholds to provide a similar medication stock out incidence compared to scheduled fills. Secondary objectives for percentage trigger thresholds and scheduled fills include the following: hourly ADC refill rate, total hourly carousel fills (ADC refills, STAT, cart fill, new orders) and hourly remaining carousel queue orders.

Methodology: The study was conducted at Hillcrest Hospital, a 510-bed acute, tertiary care hospital. Data was collected over a 14-day period in adult-only patient beds, including general medicine, critical care and intensive care units, emergency department, and labor and delivery floors. Researchers established ADC medications’ maximum and minimum par levels with equations based on safety stock and the mean average quantity dispensed between deliveries. The primary endpoint compared stock out rates between scheduled fills and percentage trigger thresholds. Percentage trigger threshold stock out incidences were simulated from scheduled fills. Classification of percentage trigger threshold stock out consisted of less than a 2 hour interval from the previous medication vend to when the stock out occurred during a scheduled fill. Adjustments in technician workflows were determined with a comparison of hourly medication fill rates. The study was designed as a non-inferiority trial with a non-inferiority margin of 0.01%. McNemar’s chi square test demonstrated statistical significance between groups. Secondary outcomes were reported using descriptive statistics.

Results and conclusions: Percentage trigger thresholds (0.03%) were non-inferior to scheduled fills (0.08%) in reducing medication stock outs. McNemar’s chi square resulted in a statistical significance between the refill methodologies (p <0.00001). There was a combined 40% decrease in hourly ADC refills during 2nd and 3rd shifts with percentage trigger thresholds. Total hourly carousel refills had a combined 11% decrease during 2nd and 3rd shifts with percentage trigger thresholds. In conclusion, percentage trigger thresholds are non-inferior to scheduled fills in reducing medication stock outs. Percentage trigger thresholds minimize interruptions to both pharmacy and nursing workflows and eliminate the dedicated delivery rounds for scheduled fills. This refill method altered refills to earlier in the day, allowing technicians to complete other tasks in the afternoon and evening shifts.

References:

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).\(^1\)\(^2\) 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 (UA). Other studies have evaluated the use of urine studies, but there are inconsistencies in the literature whether a UA with reflex to culture leads to an increase or decrease in the number of urine cultures (UCxs) resulted.\(^2\)\(^3\) Previous reflex testing has proven that the microscopic finding ≥5 WBC/hpf had an excellent negative predictive value (97%), but weak positive predictive value (47%) for a positive UCx.\(^4\) It has been reported that as many as 80% of urine samples submitted for culture are negative for bacteria, resulting in higher cost.\(^5\) 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 UA criteria to determine when to perform a culture results in a decrease in the number of UCxs performed and a trend toward a decrease in antibiotic use, the impact of simply offering a UA with reflex culture has not been evaluated.\(^1\)\(^3\)

Objectives: The overall study objective was to determine the impact of offering a UA with 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 UA performed upon admission to an internal medicine teaching service (urine studies and antibiotic usage).

Methods: This was a retrospective, single center, pre-post study approved by the hospital’s Institutional Review Board. The primary outcome was to assess the impact of offering a UA with reflex culture on the usage of antibiotics and urine studies for adult patients on an internal medicine service. The impact on urine studies was also assessed across the entire health system.

Results and Conclusions: A total of 308 charts were reviewed and 206 were included in the study. Antibiotics were administered to 34 patients (33%) pre-implementation and 41 patients (40%) post-implementation (p=0.31). A total of 55 UCx were collected with 22 UCxs (21%) resulted pre-implementation and 33 UCxs (32%) post-implementation (p=0.08). A subgroup analysis was performed on patients post-implementation that had a UCx resulted. Within the subgroup analysis 9 ordered (47%) and 4 reflexive (29%) UCxs were positive. Of the patients in the subgroup 16 (67%) and 8 (33%) received an antibiotic (p=0.27 and p=0.12, respectively). The proportion of positive UCx across the health system was 4,182 (33%) versus 4,454 (35%) pre- and post-implementation respectively (p=0.005). Overall, this study enhances the limited literature available regarding the impact of reflexive urine studies. Further research should be directed at the reflexive UCx compared to ordered UCx in patients with a suspected UTI and evaluate the proportion of positive cultures that are resulted. Further studies will look into if the threshold to reflexively culture needs to be adjusted.

References:
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 (≥1000 mg/m2). Corneal toxicity is related to the concentration and duration of exposure to cytarabine in the aqueous humor. Conjunctivitis may present as symptoms including blurred vision, discomfort or burning, photophobia, decreased visual acuity, tearing, and foreign body sensation and may include vitreous hemorrhage or corneal opacities on ophthalmic exam.1 Topical prophylaxis with corticosteroid eye drops has been effectively used to prevent this toxicity.2 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%.3 One study found that 13/29 (45%) of patients who received dexamethasone, experienced conjunctivitis, with 12/13 having grade 2-3 ocular toxicity.2 Another study with 9 patients that received prednisolone eye drops, 5/9 (55%) patients experienced conjunctivitis.4 Since no head-to-head study has been conducted to date that directly compares the efficacy of dexamethasone vs. prednisolone eye drops, the goal of this project is to determine if there is a difference in the rate of conjunctivitis between these two agents.

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

Methodology: Data was retrospectively collected through a non-interventional medical chart review. Patients were included if they were ≥18 years old and received high-dose cytarabine for acute myeloid leukemia (AML) post-remission therapy (patients can receive up to 4 cycles). Patients were excluded if they received eye drops other than prophylactic dexamethasone 0.1% or prednisolone 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 dexamethasone or prednisolone eye drops. Patients with pre-existing eye conditions (infection, glaucoma, etc) or patients who received concomitant chemotherapy in addition to cytarabine were excluded. The primary endpoint was the incidence of conjunctivitis. Secondary endpoints include the severity (per National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03) of conjunctivitis and the incidence of conjunctivitis following first cycle of high-dose cytarabine in patients receiving prednisolone eye drops vs. dexamethasone eye drops for prophylaxis.

Results and Conclusions: A total of 68 patients were included for analysis. The median age was 53 (28-68), the majority of patients were female (57.4%) and had an underling disease of AML. 186 cycles of high-dose cytarabine were analyzed. Only 45.6% of patients completed all 4 cycles. The most common dose was 3000 mg/m2 (75.0%). Of 168 cycles, 99 cycles used dexamethasone eye drops (53.2%) and 87 used prednisolone eye drops (46.8%) for conjunctivitis prophylaxis. A total of 9 patients experienced 11 episodes of conjunctivitis. There were a total of 3 episodes of conjunctivitis in patients who received dexamethasone eye drops (3.0%) and 8 episodes in patients who received prednisolone eye drops (9.2%) (p=0.078). There was not a statistically significant difference in the incidence of conjunctivitis after cycle 1 (2.6% vs. 17.2%, p=0.068) or in the severity of conjunctivitis (p=0.39). Overall, the incidence of conjunctivitis in this study is lower than previously reported. No difference seen between prednisolone and dexamethasone eye drops for prevention of conjunctivitis.

References:

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 high rates of UTIs over-diagnosis and over-treatment. 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. This is especially harmful in the older adult population as it leads to bacterial resistance and potential adverse drug events. Pharmacists can provide beneficial services in the emergency department which impact overall optimization of antimicrobial stewardship. This can be completed through chart review, analyzing cultures results, and contacting the patient for follow up. While this impact is generally identified, few studies have analyzed the impact solely on UTI. 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 was to evaluate the potential for pharmacy to intervene based on urinary culture results in patients ≥ 65 years without a chronic indwelling or foley catheter presenting to the emergency department who received a diagnosis of UTI within a seventeen month time frame. Pharmacist interventions included potential for discontinuation based on resulting cultures, antibiotic recommendations, and medication counseling. Secondary outcomes included presentation of symptoms in the older adult population based on the Loeb criteria antibiotic treatment choice, number of unnecessary days of antibiotic therapy, and incidence of negative urine cultures and negative urinalyses.

Methodology: This evaluation was 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 was identified based on urinary cultures collected between January 2015 and September 2016. Patients were included if they were ≥ 65 years old, diagnosed with a UTI, and prescribed antibiotics on discharge. Exclusion criteria included 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.

Results and conclusions: Between January 1, 2015 and September 2016, 1,670 patients were ordered urine cultures in the emergency department. Of these, 1,064 patients were reviewed until 150 patients met all inclusion criteria. Eighty seven (58%) patients included met Loeb Criteria for UTI diagnosis. While 33 (22%) did not meet Loeb Criteria, a similar number of patients were unable to be assessed for criteria inclusion due to a lack of documentation concerning dysuria (n=30, 20%). The potential of a new note template for providers to utilize during evaluation is being discussed. For treatment, ciprofloxacin (52.7%) and sulfamethoxazole/trimethoprim (20.7%) were the most commonly prescribed antibiotics. While gram negative organisms had low resistance to these antibiotics, Escherichia coli specifically showed lower resistance to cefazolin and nitrofurantoin. This as well as other concerns with fluoroquinolone use in the older adult population supports the sparing of these agents. Overall, pharmacists intervened in 44 (29.3%). However, over half (56.0%) of the patients who were evaluated and treated for a UTI had no growth on finalized cultures, indicating a potential additional role for pharmacists in discontinuing antibiotic therapy.

References:


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 in the United States. Eighty five percent (115.6 million) were discharged home. The Centers for Medicaid and Medicare Services began penalizing hospitals for high readmission rates; this is due to avoidable hospital readmissions costing CMS approximately $17 billion annually. 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. One systematic review examined pre-discharge, bridging, and post-discharge intervention bundles on the effect of 30 day readmission rates. It was determined that bundled interventions may have an additive effect compared to isolated interventions. No single intervention was shown to decrease 30 day readmission rates. In addition, a follow-up telephone call by a pharmacist was shown to reduce 30-day readmission rates and reduce the incidence of unplanned hospital utilization.

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 was approved by the Northeast Ohio Medical University Institutional Review Board. Upon patient admission to the Emergency Department from November 1-30, 2016, the pharmacist completed a medication reconciliation and provided medication education. Patients that were discharged with a new prescription or were diagnosed with a new disease state were counseled by the pharmacist at discharge. In addition, the pharmacist conducted a follow up phone call for patients 48-72 business hours after the initial visit to review changes, answer questions, and reinforce education topics. Daily ED activity reports were collected via the hospital's electronic medical record system (EMR) to track which patients received the intervention, standard of care medication reconciliation, or were in the control group. On February 28, 2016, readmission rates at 30 and 90 days post initial presentation to the ED were collected. The readmission rates for the intervention group were compared to the standard of care and control groups to determine if the pharmacist interventions had an impact on readmission rates. Other information that was collected included the number of pharmacist interventions, Emergency Severity Index (ESI), number of patients that left the ED without being seen, number of MTM opportunities for patients, age, insurance provider, number of chronic disease states, number of medications at discharge compared to admission, and number of medications that are scheduled compared to as needed.

Results/Conclusion: A total of 66 patients received at least one intervention by the pharmacist; twenty-one patients received all three interventions. The overall 30 day readmission rate for the intervention group was 26% and at 90 days was 27%. Ninety-seven patients were in the standard of care medication reconciliation group. At 30 days, the readmission rate was 16% and at ninety days was 23% for this group. The control group had 2253 patients and 13% were readmitted in 30 days and 21% in 90 days. Overall, there was no overall reduction in 30 and 90 day readmission rates in the intervention group. Patients that received all 3 interventions had a lower 30 days readmission rate but still had a higher readmission rate than the standard of care and control group. Continuous efforts and interventions need to be identified to reduce 30 and 90-day readmission rates.

References

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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Background: Acute bacterial skin and skin structure infections (ABSSSI) have seen an increased occurrence. There were 1.2 million emergency department visits in 1993 associated with ABSSSI, which increased to 3.4 million in 2005.\(^1\) According to current guidelines for the treatment of ABSSSI, the standard therapy for patients with a severe infection includes vancomycin, linezolid or daptomycin.\(^2\) Dalbavancin is a lipoglycopeptide antimicrobial given as a one-time intravenous (IV) dose for the treatment of ABSSSI.\(^3\) 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: 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, antibiotic allergies, length of stay, local signs/symptoms of infection, temperature, laboratory results (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 a deep seated infection during hospitalization, intravenous drug use, and 30 day readmission. Patients will qualify for dalbavancin if the following criteria are met: requirement of IV therapy for at least 3 days but less than 14, no gram negative organisms or anaerobic organisms 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 Conclusions: Results and conclusions to be presented at the Ohio College of Clinical Pharmacy Spring Meeting 2017.

References:
Therapeutic drug monitoring of anti-epileptic medications in a pediatric epilepsy population

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Background: 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.¹ There are currently no widely accepted pediatric guidelines defining “appropriate” TDM for pediatric epilepsy. Some practices have developed site-specific criteria to define when an AED serum level order is indicated. In a study by Schoenenberger and colleagues at another large hospital institution, it was concluded only 27% of TDM levels were ordered according to predefined criteria, leading to over $300,000 in unnecessary spending.² Other institutions have analyzed AED TDM orders and report similar results.³ The philosophy behind the acquisition and utility of AED serum levels at Cleveland Clinic Children’s Hospital is unknown.

Objective: The primary objective of this study was to define how therapeutic drug monitoring of antiepileptic medications is applied in pediatric patients diagnosed with epilepsy at Cleveland Clinic Children’s Hospital. The secondary objectives were to assess the utility of anti-epileptic medication serum level orders and to evaluate potential cost-savings if drug monitoring practices could be improved.

Methodology: An IRB-approved, non-interventional, retrospective medical chart review was performed for pediatric patients with epilepsy (<18 years) admitted to Cleveland Clinic Children’s Hospital between February 1, 2016 and May 31, 2016. Patients prescribed at least one AED with a minimum of one serum AED level result were included. Patients admitted as part of an antiepileptic clinical study or who were pregnant were excluded. For the primary outcome, patients were evaluated for the number of AEDs prescribed and number of laboratory requests for AED levels. In addition, the number of levels appropriately indicated based on predefined criteria and the cost associated with those not indicated per criteria were defined. The data was analyzed using descriptive statistics such as mean, median, mode, and standard deviation.

Results and conclusions: A total of 287 AED levels obtained from more than 150 patient encounters were reviewed and included in study analysis. Seventy-five percent of all resulted levels were ordered from the epilepsy unit. The medications with the most ordered levels include levetiracetam, lamotrigine, and topiramate. The most common indications for TDM were admission laboratory work and breakthrough seizures. Forty-seven percent of all levels ordered were supported by the study-specific criteria. Future actions will be taken to determine the best practice for obtaining and using drug serum levels in our epilepsy service.

References:

Evaluation of Perioperative Medication Regimens in Bariatric Surgery Patients

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Background: Patients who undergo bariatric surgery present a unique challenge with regard to medication efficacy and safety. While medication-specific data is limited, alteration in the pharmacokinetics of some medications can be anticipated. Clinical practice guidelines published in 2013 recommend medications and supplements that should be used by bariatric surgery patients and also recommend medications that should be avoided. In addition to these recommendations, other medications will need continuous monitoring as weight loss occurs, presenting an opportunity for pharmacist intervention. Currently there is limited available literature evaluating the role of the pharmacist in the care of bariatric surgery patients. 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.

Objectives: The primary objective of this study is to describe the medication-related issues that exist in patients undergoing bariatric surgery. The secondary objectives are to identify the time points where medication issues exist, and to identify opportunities for pharmacist intervention.

Methods: This study was a retrospective, electronic chart review of patients who underwent bariatric surgery at Cleveland Clinic Akron General by a pre-identified surgeon from the Bariatric Center from January 1, 2016 to December 31, 2016. Medication lists were 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 was the total number of possible medication-related issues identified at each of the defined time points, as well as the total number of possible medication-related issues in each of the following categories at each time point: absence of recommended medications; presence of medications not recommended; and presence of medications that may require close monitoring. The secondary outcome was the identification of possible predictors of having greater than or equal to the median number of medication-related issues at each of the defined time points.

Results/Conclusions: There were 48 patient charts included in the study. The total number of possible medication-related issues for each time point were as follows: pre-surgery, total of 313 issues (48 patients); hospital admission, total of 292 issues (47 patients); hospital discharge, total of 298 issues (47 patients); first post-surgery follow up visit, total of 231 issues (45 patients); and six month post-surgery follow up visit, total of 19 issues (7 patients). The highest proportions of medication-related issues per patient in each category were as follows: absence of recommended medications, 3.92 at the pre-surgery time point; presence of medications not recommended, 0.96 at the pre-surgery time point; presence of medications requiring close monitoring, 1.67 at the first post-surgery follow up visit. Predictors of having at least the median number of medication-related issues at different time points included hypertension and diabetes for the pre-surgery and admission time points, and hypertension for the hospital discharge time point. There were multiple medication-related issues found in the period of time surrounding bariatric surgery. Pharmacist intervention may aid in addressing these issues.

References:
Characterizing dexmedetomidine use for sedation in neonates during therapeutic hypothermia; a retrospective review

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Background: No data exist evaluating dexmedetomidine (DXMT) use during therapeutic hypothermia (TH) for the treatment of neonatal hypoxic ischemic encephalopathy (HIE). TH is a first-line treatment for HIE and has been shown to decrease morbidity and mortality1,2. The discomfort of lowering body temperature in TH and invasive monitoring with HIE necessitates the use of sedative agents like DXMT. Traditionally, benzodiazepine, barbiturate, and opioid infusions have been used as sedative agents. Several animals studies have indicated that these agents may cause neuronal injury or accelerate neuronal apoptosis and cause subsequent learning deficits in neonatal rodents3,4. However, the pharmacodynamic effects of DXMT in neonatal TH are unknown. The primary purpose of this study was to evaluate the safety of DXMT on cardiovascular function and secondarily analyze efficacy in achieving goal sedation with DXMT during TH for HIE.

Objective: Investigate the safety and efficacy of DXMT use for sedation in neonates receiving TH for HIE in a neonatal intensive care unit (NICU).

Methodology: A retrospective review was performed from January 1, 2012 through September 1, 2016 at Cleveland Clinic Children’s Hospital NICU. Neonates (age <28 days old) who were treated with TH for HIE and received DXMT during the study time frame were included for review. Patients were excluded if they transferred into the NICU already receiving DXMT, were diagnosed with neonatal abstinence syndrome, or had incomplete documentation of Neonatal Pain, Agitation and Sedation Score (N-PASS). To evaluate the primary outcome, mean arterial pressure (MAP) and heart rate (HR) were recorded at during TH based on the incidence of hypotension (MAP <gestational age in weeks), and bradycardia (HR <60 bpm). To evaluate efficacy, N-PASS scores were collected and reviewed to assess achievement of the goal (≤3) during TH. Other clinically relevant collected for evaluating trends and potential confounding variables. Descriptive statistics of mean, median, mode and standard deviation will be used to analyze baseline characteristics and primary and secondary endpoints.

Results and conclusions: Sixty-five patients were reviewed for initial study inclusion. Thirty-one patients were identified and included for characterization. During TH, three patients (9.7%) experienced bradycardia and 8 patients (25.8%) experienced hypotension requiring an intervention. A majority of patients (87.1%) were found to have achieved adequate sedation for greater than 90% of the cooling period. Seventy-five percent of patients who experienced a hypotensive event requiring an intervention during TH were either on continuous morphine or received an intermittent dose of morphine. There were no observed correlations of DXMT side effects and administration of antiepileptic medications or other sedatives during TH. DXMT was observed to be safe with cardiovascular monitoring and provided adequate sedation during TH in neonates.

References:

Pharmacist management of vancomycin doing in the critical care unit of an acute care urban hospital

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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). When given intravenously, there is a potential for harmful adverse events including nephrotoxicity. Monitoring trough concentrations allows clinicians to minimize adverse effects, while ensuring efficacy.1,2 In a study conducted by Marquis et al., it was shown that pharmacist-guided vancomycin improved optimal dosing regimens. 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).3 In another study conducted by Masuda et al., 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 was to compare pharmacy management of vancomycin versus non-pharmacist management. The ultimate goal of this research is to implement a hospital-wide pharmacy-to-dose vancomycin protocol.

Methodology: Pharmacy managed all vancomycin dosing and monitoring for patients admitted to the intensive care unit (ICU) during the months of November 2016 and January 2017. Management included 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 were retrospectively compared with patients who were prescribed vancomycin in the ICU in November 2015 and January-April 2016. The primary outcome of the study was the percentage of troughs therapeutic at first draw. Secondary outcomes of this study included percentage of subtherapeutic troughs (<10 mcg/mL) and percentage of supratherapeutic troughs (>20 mcg/mL).

Results and Conclusions: 26 patients were included in the pharmacist management, and 21 patients were included in the non-pharmacist management of vancomycin. 18 (69.2%) of patients had therapeutic troughs at first draw in the pharmacist management group compared to 10 (47.6%) in the non-pharmacist management group (P=0.133). Supratherapeutic troughs were reported in 4 (15.4%) and 2 (9.5%) (P=0.678) and subtherapeutic troughs were reported in 4(15.4%) and 9(42.9%) (P=0.036) in pharmacist and non-pharmacist management groups, respectively. Pharmacist management of vancomycin showed no statistical significance in therapeutic first troughs, but showed a statistically significant decrease in subtherapeutic troughs.

References:

Evaluation of a pain, agitation, and delirium order-set protocol

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Background: Pain, agitation, and delirium (PAD) 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,1 while the prevalence of delirium in ICU patients is as high as 32%.2 The PAD 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.3 In June 2016, The Louis Stokes Cleveland Veteran Affairs Medical Center implemented an ICU order-set to facilitate the optimal selection and titration of medications, and increase the documentation of patients’ assessments; ultimately aimed at reducing patient’s PAD in the ICU.

Objectives: The primary objective is to assess whether patients’ PAD scores are at goal (CPOT, RASS, CAM) for the first 72 hours of intubation or until extubation. Secondary objectives include the frequency that the protocol is followed for CPOT and RASS scores, and the most frequent rationale CPOT and RASS scores were not titrated appropriately based on the PAD order-set.

Methodology: This is a quality assurance retrospective chart review of mechanically ventilated patients intubated greater than 24 hours in the ICU. Patients charts were reviewed from July 1st, 2016 to January 30th, 2017. Patients were excluded if they had indications to use midazolam first line, i.e. intubated for seizures or alcoholic withdrawal. Patients were identified by the “Respiratory Airway Management Note” or “Ventilator Oral Care” order in the computer personal records system and filtered by a location of “wMICU” or “wSICU”. Definition of PAD goals are as followed: CPOT scores of 0 to ≤2, RASS scores of -2 to 0, and CAM scores of negative.

Results and conclusions: A total of 151 patients were identified as being intubated in the ICU. After exclusion, 50 patients remained for data collection. Intubation less than 24 hours was the most common exclusion. The percentage of CPOT scores at goal were 72.5% (198/273). CPOT scoring was done 42.9% (273/637) of the time, while the numerical pain scale was used 46.6% (297/637) of the time. The percentage of RASS, and CAM scores at goal were 73.4% (469/639) and 67.3% (380/565), respectively. Overall 53% (141/266) of CPOT and 66% (406/611) RASS scores were appropriately adjusted according to the protocol. The most frequent rationale CPOT and RASS scores were not adjusted appropriately were pain (68%; 84/124) and agitation (56%; 115/205) medications should have been decreased or not given. Implementation of the PAD order-set in the ICU showed patient’s CPOT, RASS, CAM were well documented and mostly at goal. Development of a titration protocol for other pain scales would improve upon the protocol.

References:

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 the Hospital Readmission Reduction Program. In 2011, there were approximately 3.3 million adult 30-day hospital readmissions, resulting in $41.3 billion in hospital costs. It is estimated that 20% of discharged patients experience adverse events, and nearly two-thirds of them are medication-related. Pharmacist involvement in patient care decreases 30-day readmissions up to 30%. Bellone et al. compared post discharge pharmacist visit to no visit and showed a statistically significant difference in readmission rates, 18% versus 43.1% (p=0.002). Of all 30-day readmissions, the majority occur within 15 days of hospital discharge.

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 study was conducted from October 7th to December 31st, 2016. Patients discharged from the Mercy Medical Teaching Service were scheduled for a hospital follow-up appointment within ten days in the Ambulatory Care Clinic. The pharmacist contacted the patients prior to their scheduled appointment to serve as a reminder call and encouraged patients to bring their medications with them. At the appointment, patients completed an optional adherence screen using the 4-item Morisky Medication-Taking Adherence Scale, and the pharmacist completed a medication history/reconciliation assessing for any interventions. Patients completed an optional pharmacist satisfaction survey. The pharmacist contacted the patient seven days later, via telephone, to reiterate the face-to-face findings. Physicians were also provided an optional pharmacist satisfaction survey.

Results and conclusions: A total of 28 patients were included. Three patients (10.7%) were readmitted within 30 days. The median adherence score was 3 (range 1 – 4). The pharmacist made a total of 31 recommendations to the physicians, with an acceptance rate of 80.6%. Additionally, the pharmacist educated 26 patients (92.9%) on adherence, medications, and/or their disease state. The pharmacist spent a median of 16.5 minutes per patient (range 11 – 30). Twenty-four patients completed the survey and 95.8% were satisfied with the pharmacist. Fourteen physicians completed the survey and 100% were satisfied with the pharmacist. Pharmacy involvement in patient care post-discharge potentially may help reduce 30-day readmission rate. When compared to the overall hospital 30-day readmission rate of 11.7%, rates were lower in the study group. According to the satisfaction surveys, patients and physicians valued the pharmacist interactions.

References:
Effectiveness, safety, and economic comparison of inhaled Flolan and inhaled Veletri in cardiothoracic surgery patients

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**Background:** Epoprostenol is a prostacyclin and potent pulmonary vasodilator, which when administered via the inhaled route may mitigate some of the adverse systemic effects associated with intravenous epoprostenol use. Flolan and Veletri are two available brands of epoprostenol which vary in stability, diluent, and inactive ingredients which may lead to differences in effectiveness, safety and cost between these products. A previously published study of patients with mixed indications for use showed no difference in the PaO$_2$/FiO$_2$ ratio one hour after initiation between inhaled Flolan or inhaled Veletri (P= 0.54). Differences noted in secondary outcomes were likely due to differences in the study’s baseline characteristics. The purpose of this project was to evaluate a formulary conversion from inhaled Flolan to inhaled Veletri to determine if there are differences in the effectiveness, safety, or cost when used in mechanically ventilated cardiothoracic surgery patients. By focusing on cardiothoracic surgery patients, we hope to evaluate if true differences in effect exist between inhaled epoprostenol formulations.

**Objectives:** The primary outcome was to evaluate the difference in the change in the PaO$_2$/FiO$_2$ ratio one hour after administration of inhaled Flolan compared to inhaled Veletri. The secondary outcomes are to evaluate differences in effectiveness, safety, and cost between inhaled Flolan and inhaled Veletri.

**Methodology:** This was a retrospective, non-inferiority study performed at a single, large academic medical center comparing inhaled Flolan and inhaled Veletri in cardiothoracic surgery patients. This study was approved by the Institutional Review Board. Included subjects were ≥18 years old, who were admitted to the cardiothoracic intensive care unit at Cleveland Clinic and received inhaled Flolan or inhaled Veletri therapy for ≥1 hour while mechanically ventilated between January 1, 2015 to December 1, 2016. The study was powered using a 1-sided test of non-inferiority and α of 0.025, assuming a difference in the change in the PaO$_2$/FiO$_2$ ratio after 1 hour of therapy of 20 mmHg. One hundred and sixteen patients were needed in each group (232 total patients) to achieve 80% power to detect the non-inferiority margin. Categorical data were analyzed with Chi-Square test or Fisher exact test, while continuous variables were analyzed with Student's t-test or Mann-Whitney U test.

**Results and Conclusions:** A total of 313 patients were screened for inclusion, and 244 patients were included in the primary outcome analysis. There were no significant differences in baseline characteristics between the inhaled Flolan and inhaled Veletri groups. The primary outcome, change in the PaO$_2$/FiO$_2$ ratio one hour after administration of inhaled Flolan or inhaled Veletri, did not cross the lower limit of the non-inferiority margin (CI -14.8 to 65.4). The mean difference was 48.1 ± 171.9 mmHg in the inhaled Flolan group and 73.5 ± 144.9 mmHg in the inhaled Veletri group. Significant differences in secondary outcomes included duration of mechanical ventilation (4.4 vs 2.6 days; p< 0.01), number of tracheostomies (24 vs 9; p= 0.01), number of patients initiated on dialysis (25 vs 12; p= 0.02), and cost per median duration of therapy ($257.08 vs $183.30; p= 0.02) for inhaled Flolan and inhaled Veletri, respectively. Differences in secondary outcomes that reached statistical significant were likely a result of change in practice at the institution. In conclusion, inhaled Veletri is non-inferior to inhaled Flolan when comparing change in PaO$_2$/FiO$_2$ ratio after one hour post therapy initiation and the conversion from inhaled Flolan to inhaled Veletri was likely justified.

**References:**

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 a therapeutic intervention made to support the nutritional needs of patients unable to receive adequate enteral nutrition. Currently, seven standard TPN formulations are utilized in the NICU at Rainbow Babies and Children’s Hospital. The patient’s age and weight dictate which standard formulation is used to provide nutrition. TPN formulations are high risk medications requiring extensive clinical expertise to ensure safe and effective utilization. A need has been identified to assess the rate of deviation from standard formulations. Deviation from standard formulations are driven by patient specific electrolyte laboratory values.

Objective: The primary objective of this study is to describe the frequency at which the calcium and phosphorus concentrations are customized in standard TPN formulations for patients admitted in the NICU

Methodology: This descriptive study is a single site, retrospective evaluation of patients receiving TPN in the NICU from August 1, 2015 until November 30, 2015. This study received IRB approval to include patients from the first day of TPN therapy until discontinuation. A subgroup analysis for patients weighing less than 1500 grams was completed. Data was collected from the electronic medical record (EMR). Data collection included patient age, weight, standard TPN duration, custom TPN duration, dose of calcium and phosphorus administered from the TPN each day, composition of the daily TPN, and pertinent laboratory values. Descriptive statistics will be utilized to analyze data.

Results and conclusions: The complete results of this retrospective descriptive study are 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.

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

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Background: Tigecycline is a glycyclcline 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.1-3 Due to increasing bacterial resistance, tigecycline is often used off-label to treat bloodstream 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).2 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.4,5 It is unknown whether this in vitro effect on tigecycline activity translates to worse clinical outcomes in vivo.1 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.

Objective: Compare clinical outcomes in patients with BSI receiving tigecycline with or without pantoprazole (PPI).

Methodology: This non-interventional, retrospective cohort study was 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 >4 mg/L) and who received PPI other than pantoprazole were excluded. Patients were divided based on those receiving tigecycline plus PPI and those receiving tigecycline without PPI. The primary outcome compared 28-day all-cause mortality. Secondary outcomes included favorable clinical response, microbiologic cure, and incidence of breakthrough infection between groups. Favorable clinical response was defined as resolution of fever (temperature ≥38.3 °C), leukocytosis (WBC≥11×10^9 /L), and hypotension (MAP≤ 65 mm Hg) without requiring vasoactive agents. Microbiologic cure was defined as documentation of microbiologic eradication within 7 days of the first positive blood culture after at least 48 hours of active antimicrobial therapy. Variables describing severity of illness at baseline, acid suppressive therapy, and infection-related data were collected.

Results and conclusions: A total of 367 patients were screened with 86 meeting inclusion criteria (tigecycline without PPI, n=42 and tigecycline with PPI, n=44). Baseline characteristics between groups did not differ, however, more patients not receiving PPI were admitted for medical vs. surgical reasons (71.4% vs. 56.8%, p=0.16) and had BSI with Klebsiella pneumoniae as the infecting pathogen (59.5% vs. 34.1%, p=0.06) when compared to those receiving PPI. The most common PPI regimen was pantoprazole 40 mg once daily (65.9%). In those not receiving concomitant PPI therapy, there was no difference in all-cause 28-day mortality (28.6% vs. 25.0%, p=0.71), favorable clinical response (52.4% vs. 56.8%, p=0.68), or median time to favorable clinical response (3 days vs. 2 days, p=0.63) when compared to those receiving concomitant tigecycline and PPI. Although not statistically significant, microbiologic cure was numerically higher in those not receiving PPI therapy compared to those receiving PPI therapy (92.9% vs. 81.8%, p=0.13). No patients experienced breakthrough infection within 7 days. In conclusion, the use of PPI did not affect clinical outcomes in patients being treated with tigecycline for BSI.

References:
Evaluating the Impact of a Pharmacist on Guideline Directed Medical Therapy in Patients with Reduced Ejection Fraction Heart Failure

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Background: Heart failure continues to be one of the world’s foremost health problems and is the most frequent principal diagnosis of patients discharged from a hospital and the most common diagnosis for hospital readmission. 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. This pilot study aimed 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 was to evaluate the time (number of weeks and number of clinic visits) to achieve individualized target doses of GDMT. Beta-blocker titration was 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 (LVEF) of ≥35 after maximal beta-blocker titration. Additional secondary endpoints included average revenue generate per visit as well as the change in number of all cause and heart failure-specific hospital admissions (HA) and emergency department (ED) visits.

Methodology: Retrospective chart review was completed on patients who were referred to the pharmacist-run, outpatient heart failure management clinic at MetroHealth Medical Center. Data reviewed included 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 HA and ED visits. Analysis of continuous variables was completed using a Wilcoxon signed rank test. All other endpoints were reported using descriptive statistics.

Results and conclusions: A total of 36 patients were identified for inclusion. The average time to complete medication titration per patient was 4.9 visits over 12.7 weeks. Seventy-eight percent (n=28) achieved full beta-blocker titration, with fatigue (n=1), bradycardia (n=5), and hypotension (n=3) being the reasons for inability to titrate. Twenty-one patients completed repeat echocardiogram following titration. Forty-three percent (n=9) had a LVEF ≥35% at baseline compared with 76% (n=16) after titration. The change in HA and ED visits was evaluated 13 weeks prior to enrollment versus the average 13 week study period. The total number of all cause ED visits 13 weeks prior to enrollment was seven versus four during the study period. The total number of heart failure ED visits 13 weeks prior to enrollment was one versus two during the study period. The total number of all cause HA 13 weeks prior to enrollment was 12 versus three during the study period (p<0.05). The total number of heart failure HA 13 weeks prior to enrollment was five versus two during the study period. Additionally, the HA and ED visit data during the study period were extrapolated to evaluate 12 months post enrollment. The total number of all cause ED visits 12 months prior to enrollment was 19 versus 16 during the extrapolated 12 month period (p=0.056). The total number of heart failure ED visits 12 months prior to enrollment was three versus eight during the extrapolated 12 month period. The total number of all cause HA 12 months prior to enrollment was 39 versus 12 during the extrapolated 12 month period (p<0.05). The total number of heart failure HA 12 months prior to enrollment was 15 versus eight during the extrapolated 12 month period (p=0.152). The average per-visit revenue generated for this pharmacist clinic was approximately $90, which estimates >$50,000 revenue generated from 0.2 full time equivalent pharmacists assuming 576 visits per year and a 25% no show rate. These results support the idea that pharmacist managed medication titration clinics contribute to completing titration and improving LVEF. Although the inferential statistical analyses for hospitalization and ED visits are hypothesis generating and require further evaluation to draw conclusions, the results of this study may indicate a pharmacist managed titration clinic reduces the rate of hospitalization for heart failure patients with reduced ejection fraction.

References:
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 recommends that comatose patients with return of spontaneous circulation (ROSC) after cardiac arrest undergo therapeutic hypothermia (TH)\(^1\). Therapeutic hypothermia is a constant temperature between 32-36° C for at least 24 hours\(^1\-4\). Cleveland Clinic Akron General has a standardized electrolyte replacement protocol, but the incidence and type of electrolyte abnormalities in each phase of TH have not been established.

Objectives: The primary objective of this study was 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 reported the incidence of magnesium, glucose, phosphorus, and ionized calcium abnormalities during each phase of TH; reported the treatment of hyperkalemia; reported the amount of electrolytes treated during TH; and reported predictors of potassium abnormalities.

Methodology: This was a retrospective, single center, cohort study approved by the Institutional Research Review Board. The electronic medical record identified patients who were charged for Arctic Sun\(^\circledR\) Hypothermia Cooling Pads and received at least 12 hours of TH after cardiac arrest. Data collected included: electrolyte abnormalities, patient specific factors, and cardiac arrest data. Electrolyte abnormalities were compared between phases. Data analysis included: proportions, means with SD, ANOVA, chi squared test, Fisher’s exact test, and student’s t test. A statistician aided in the statistical analysis.

Results and Conclusions: One hundred and fifty patients were included in the study. Potassium values were lowest during the maintenance phase of TH, although averages for all three phases were within normal range. Potassium abnormalities occurred in 33% of measured potassium levels in the cooling and maintenance phases and 28% in the rewarming phase. In all three phases, hypokalemia was the most common potassium abnormality occurring in 25% of potassium values. Ionized calcium, magnesium, and phosphorus values were within normal range during all three phases. Glucose values were highest in the cooling phase with 65% of values being elevated. Given the findings in this study, future studies should look at increasing the rewarming rate of TH as well as targeting a higher potassium goal and potassium replacement amount to avoid hypokalemia.

References:
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 2017 GOLD guidelines recommend the use of antibiotics in patients who have at least two of the three cardinal symptoms, increase in dyspnea, sputum volume, and sputum purulence, of AECOPD if one of the symptoms is increased purulence. However, little guidance is provided regarding the selection of antibiotic therapy. Guideline cited antibiotics include empiric treatment with an aminopenicillin with or without clavulanic acid, a macrolide, or a tetracycline. (2) Clinical opinion, epidemiological studies, and post-hoc analysis of major clinical trials have supported utilizing a risk stratification approach in selecting antimicrobial therapy. Most of this data suggests broader spectrum antibiotics in four groups of patients at higher risk for poor outcomes, including the elderly (age >65 years), though, no study has specifically evaluated broad versus narrow spectrum antibiotics in elderly patients hospitalized with AECOPD.

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

Methodology: 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: An interim analysis of 150 patients was completed with 61 patients in the narrow spectrum group and 89 patients in the broad spectrum group. Incidence of the primary composite outcome occurred in 32 (52.5%) and 51 (57.3%) of patients in the narrow and broad spectrum group respectively (p=0.56). Continued data collection is underway.

References:


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. Due to its complex pharmacokinetic and pharmacodynamic properties, dosing vancomycin is challenging. 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, actual practices are not universal between hospitals. At University Hospitals St. John Medical Center (UHSJMC), pharmacists are consulted to manage vancomycin. While utilizing the established protocol, pharmacists have hypothesized that adjustments may be necessary in the young, renally impaired, and elderly populations. Upon incorporation into University Hospitals (UH), UHSJMC adopted UH’s vancomycin dosing guideline. 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 dosing.

Objective: 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 collected includes: patient weight (kg), white blood cell count (WBC), temperature (T), age divided into categories (young: < 40 years, middle-age: 40-64 years, and elderly: > 65 years), serum creatinine (sCr), creatinine clearance (CrCl) divided into categories (normal > 50 mL/min, mild impairment 30-50 mL/min, and severe impairment < 30 mL/min), and vancomycin indication.

Methods: A retrospective review of patients on vancomycin dosed by pharmacists was conducted from November 2015 to March 2016 (pre-UH guideline). This data was compared to patients on vancomycin dosed by pharmacists from November 2016 to March 2017 (post-UH guideline). A sample size of 84 patients per study group was required to achieve a power of 90%. Patients were excluded if they were receiving dialysis at the time of vancomycin dosing, less than 18 years of age, or if a trough was never drawn during the vancomycin consult. Primary objectives and secondary data were analyzed using a comparison t-test, chi-square test, and descriptive statistics reported with mean, median, and standard deviation. A p-value of <0.05 was considered statistically significant.

Results: A total of 1096 patients were reviewed for inclusion in this study. Of this, 510 were excluded due to hemodialysis or a trough never being drawn while the patient was on consult. A total of 586 patients were included in the study analysis. There was no difference in demographics between the pre and post-UH guideline groups. Both primary endpoints were statistically significant in their results. Days of vancomycin therapy were shorter in the post-UH guideline implementation group (P=0.018), whereas time to goal trough was longer (P=0.054). Reasons for these results include variability in vancomycin dosing frequency, which impacts the time of monitoring the trough. A regression analysis was completed post-study which revealed age, days of vancomycin therapy, and trough goal as predictors for 77% of cases in the post group. This information can be used as a predictive model in future studies analyzing vancomycin therapeutic drug monitoring.

References:
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: Extended-infusion dosing of time-dependent antibiotics provides enhancements in the pharmacokinetics of antibiotics and direct cost savings for institutions.\(^1\) Retrospective cohort studies comparing intermittent-infusion versus extended-infusion piperacillin-tazobactam in various populations have shown mixed results regarding clinical outcomes.\(^2,3\)

Objective: The objective of this study is to compare clinical, economic, and safety outcomes between intermittent-infusion and extended-infusion piperacillin-tazobactam for selected gram-negative infections.

Methodology: A retrospective study was conducted by obtaining hospital billing records and microbiology reports to identify patients with *Escherichia coli*, *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Pseudomonas aeruginosa*, *Serratia* spp., and *Citrobacter* spp. infections who received piperacillin-tazobactam for at least 48 hours. Patients were enrolled into two main piperacillin-tazobactam arms including the intermittent-infusion group and the extended-infusion group. The primary outcome was the difference in inpatient mortality between groups. Secondary outcomes were length of stay, duration of piperacillin-tazobactam therapy, number of intravenous catheters inserted after initiation of piperacillin-tazobactam, incidence of *Clostridium difficile* infection, incidence of acute kidney injury, and cost of drug acquisition per admission over the study period.

Results and conclusions: Of 187 patients screened, 160 were included in the study with 80 subjects in each group. There was no difference in baseline characteristics between groups except for creatinine clearance (p=0.03). The primary outcome of inpatient mortality occurred in 2% of the intermittent-infusion group and 0% of the extended-infusion group (p=0.50). No statistical difference between groups was detected for secondary outcomes. There was no increased risk of adverse effects including acute kidney injury (p=0.65) and Clostridium difficile infection (p=0.58) or amount of intravenous catheters placed (p=0.74) in the extended-infusion group. Average wholesale price drug cost per admission ($435.12 versus $380.12) was trending lower in the extended-infusion group but not statistically different (p=0.095). No statistical difference was found between outcomes in patient subgroups including ICU stay greater than 48 hours, creatinine clearance groups, body mass index greater than 40 kg/m\(^2\), concomitant fluoroquinolone use, and culture source. Our preliminary data showed no difference in inpatient mortality between extended-infusion and intermittent-infusion groups. However, there may be advantages with extended-infusion piperacillin-tazobactam compared to intermittent-infusion with regard to economic outcomes.

References:

The clinical and economic impact of extended-infusion versus intermittent-infusion piperacillin-tazobactam for selected gram-negative infections at a community medical center

Kevin Krivanek, PharmD, Rph; Amy Rybarczyk, PharmD, BCPS, Rph; James Reissig, PharmD, BCPS, Rph; Patrick Gallegos, PharmD, BCPS, Rph; Ken Koon Wong, MD.

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Background: Extended-infusion dosing of time-dependent antibiotics provides enhancements in the pharmacokinetics of antibiotics and direct cost savings for institutions. Retrospective cohort studies comparing intermittent-infusion versus extended-infusion piperacillin-tazobactam in various populations have shown mixed results regarding clinical outcomes.

Objective: The objective of this study is to compare clinical, economic, and safety outcomes between intermittent-infusion and extended-infusion piperacillin-tazobactam for selected gram-negative infections.

Methodology: A retrospective study was conducted by obtaining hospital billing records and microbiology reports to identify patients with *Escherichia coli*, *Enterobacter* spp., *Klebsiella* spp., *Proteus* spp., *Pseudomonas aeruginosa*, *Serratia* spp., and *Citrobacter* spp. infections who received piperacillin-tazobactam for at least 48 hours. Patients were enrolled into two main piperacillin-tazobactam arms including the intermittent-infusion group and the extended-infusion group. The primary outcome was the difference in inpatient mortality between groups. Secondary outcomes were length of stay, duration of piperacillin-tazobactam therapy, number of intravenous catheters inserted after initiation of piperacillin-tazobactam, incidence of *Clostridium difficile* infection, incidence of acute kidney injury, and cost of drug acquisition per admission over the study period.

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References:

Impact of Cleveland Clinic Specialty Pharmacy on Time to Treatment Start of Hepatitis C Therapy

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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 needs 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 primary objective of this study was 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.

Methodology: This retrospective cohort included adult patients who received a prescription for HCV treatment between July 2015 and July 2016 and had detectable HCV RNA at the time of study start. Patients were excluded if they did not meet this criteria. The date of the receipt of prescription through the electronic medical record to time of prior authorization approval was determined. Additionally, dates of prior authorization requests, initial approvals, denials, and appeal approvals were gathered to assess total turnaround time. Descriptive statistics were used to analyze results and the median was used to describe non-parametric data. The Kruskal-Wallis test was used to describe time to treatment start based on insurance and therapy variables.

Results and Conclusions: A total of 317 patients were included during this retrospective analysis. A median total time from receipt of prescription to prior authorization approval was 6 days. Sixty-three prescriptions received approval after undergoing the appeals process, with a total time from appeal submission to appeal approval of 3 days. The most common reason for initial prior authorization denial was that the patient hadn’t tried a formulary agent as specified by the insurance. There was a significant difference in time to treatment start based on insurance carrier, with Medicare showing the fastest turnaround time of 4 days. Time to treatment start of hepatitis C therapy when managed by Cleveland Clinic Specialty Pharmacy shows an expedited turnaround time when compared with other specialty pharmacies and will result in a better understanding of the time frame expectation we can provide for our patients.

References:
Impact of Caregiver Medication Counseling on Unplanned 30-day Readmissions and Recurrent ED Visits based on Selected Cognitive and Behavioral Nursing Assessment Criteria

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Background: Studies have concluded the important role a caregiver plays in medication adherence. The long-term effect on medication adherence and health literacy with caregiver education is unclear, especially those suffering from cognitive issues.1-5 Currently, Cleveland Clinic Akron General performs a daily nursing assessment on each patient for cognition and behavior as part of the standard of care. There is opportunity to put a systematic process in place that routinely identifies high-risk patients based on this nursing assessment who may require further assistance beyond direct patient education provided by a pharmacist or nurse at discharge.

Objective: The primary objective of the study is to determine the impact of medication counseling involving a caregiver for patients identified through selected behavioral and cognitive nursing assessment criteria on composite unplanned 30-day readmissions and emergency department (ED) visits.

Methodology: A prospective, quasi-experimental study was performed at Cleveland Clinic Akron General from December 1, 2016 to February 24, 2017. Patients who are 65 years or older, have a documented caregiver in the medical record, and have at least six scheduled medications at discharge were included. Patients who met the selected nursing assessment criteria at any point in their admission had their caregiver educated about their medications either at discharge or as a follow-up phone call within 5 days of discharge. The primary outcome was the composite number of 30-day unplanned readmissions and ED visits between the prospective cohort of patients (N=17) who had their caregiver’s counseled versus a retrospective cohort (N=17) of patients who met the same inclusion criteria.

Results and conclusions: Caregiver counseling of patients in the prospective cohort was found to have no difference in composite 30-day unplanned readmissions and ED visits compared to those in retrospective cohort (6 vs. 4 readmissions and ED visits, OR = 1.77, 95% CI 0.40-7.93). There were no significant differences in readmissions or ED visits between the two cohorts related to chronic obstructive pulmonary disease (COPD), myocardial infarction (MI), pneumonia, or congestive heart failure (CHF) disease states. Caregiver education of high risk patients appears to have a negligible impact on reducing readmissions and/or ED visits. However, further studies should be performed to see if caregiver education of patients with known medication compliance issues can improve readmissions or ED visits.

References:

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

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Background: Intracranial hypertension is defined as an intracranial pressure (ICP) of greater than 20 mmHg. Hypertonic sodium solution (HSS) induces an osmotic gradient to draw water from the interstitial space to the intravascular space reducing intracranial volume and ICP. HSS is typically administered as repeated bolus doses of up to 23.4% sodium chloride or as a continuous infusion. The majority of evidence using HSS for ICP management is with the bolus administration compared to the use of continuous infusions. The current practice for HSS administration at University Hospitals Cleveland Medical Center (UHCMC) is either bolus administration, continuous infusion or a combination of bolus with a continuous infusion.

Objective: The objective of the study is to evaluate the guideline compliance rate among patients prescribed hypertonic sodium solutions at UHCMC.

Methodology: This single-center, retrospective chart review evaluated the use of HSS during the calendar year of 2015. Patients who received HSS, ordered from the HSS order set, were eligible for inclusion into the study. Adult patients were included if they received HSS for ICP management and not for correction of hyponatremia. The primary endpoint was compliance with the UHCMC HSS guideline defined as: HSS IV bolus volume and administration rate within guideline recommendations, HSS IV continuous infusion volume and rate within guideline recommendations. Secondary endpoints include quality assurance defined as appropriate documentation, changes in serum sodium concentration post bolus administration, ICP measuring device, median number of excursions of ICP > 20 mmHg per day, median ICP measurement during HSS therapy, utilization of concomitant therapies to reduce ICP, hospital mortality, mortality stratified based on initial hyperosmolar therapy (HSS vs. mannitol), adverse events, and discharge status.

Results and conclusions: Of the 99 patients evaluated for inclusion, 94 met inclusion criteria for the baseline demographics. The five patients excluded from the baseline demographics was due to the use of HSS for hyponatremia correction. In total, 91 patients with documented administration were included in the outcome analysis. The final results will be presented at OCCP Spring Meeting 2017.

References:

Optimal norepinephrine-equivalent dose to initiate epinephrine in patients with septic shock

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**Background:** The 2016 Surviving Sepsis Campaign recommends the use of norepinephrine as the first-line vasopressor for septic shock with epinephrine and vasopressin as potential second agents. The specific norepinephrine dose at which a second agent should be added has not yet been identified, and the addition of a second vasopressor has occurred at a broad range of doses in literature and is driven mainly by clinician preference. Given the varied approaches, improvement in patient outcomes can likely be achieved by better understanding vasopressor dosing. This study aimed 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 was to determine the breakpoint for norepinephrine-equivalent dose at which epinephrine initiation was associated with hemodynamic stability in septic shock patients. Secondarily, two cohorts of patients were identified: optimal norepinephrine-equivalent dose and non-optimal norepinephrine-equivalent dose. Differences between the two cohorts in the time to achieve mean arterial pressure (MAP) goal, shock-free survival, ICU-free days, hospital length of stay, change in sequential organ failure assessment (SOFA) score at 48 hr, and safety outcomes were determined. Safety outcomes included significant arrhythmias, lactic acidosis, and hyperglycemia.

**Methodology:** This study was a retrospective cohort study. Adults admitted to the Medical, Surgical, or Neurological ICU at the Cleveland Clinic between August 1, 2010 and August 31, 2016 were 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 were excluded if norepinephrine and epinephrine were started concomitantly. Classification and regression tree (CART) analysis was conducted to determine the breakpoint in norepinephrine-equivalent dose. Secondary outcomes were compared between the two cohorts using appropriate inferential statistical tests.

**Results and conclusions:** A total of 803 patients were screened, and 199 patients were included in the study. The optimal norepinephrine-equivalent dose breakpoints identified were > 37 mcg/min and ≤ 133 mcg/min (n=138). Baseline characteristics were similar between the two groups with the exception of vasopressin use. Patients in the optimal dose group achieved hemodynamic stability significantly more often than those in the non-optimal dose group (p=0.032). No differences were seen in the secondary outcomes or safety outcomes. In a multivariable analysis to adjust for factors that influence the effect of dosing group on hemodynamic stability, the optimal dose group was three times more likely to achieve stability (p=0.016). Clinicians should consider adding epinephrine in septic shock patients when norepinephrine is optimized and should not delay initiation until norepinephrine-equivalent doses are > 133 mcg/min. Norepinephrine-equivalent dose is one of many patient-specific factors that should be considered in determining when to start epinephrine.

**References:**

The Impact of Achieving Virologic Response from Hepatitis C Direct-Acting Antivirals on Diabetes Control

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Background: Approximately 2.7-3.9 million people in the United States are infected with hepatitis C virus (HCV). The prevalence of patients with HCV and type 2 diabetes (T2DM) may be as high as 50%.1 A relationship has been described with improved glycemic control upon achieving a cure, defined as sustained virologic response (SVR), from HCV treatment.2,3 A new era of HCV treatment uses short course direct acting antivirals (DAAs) that achieve SVR rates greater than 90%.4 Implications of successful HCV treatment beyond the liver have yet to be explored, including the impact on glucose control.

Objectives: The primary objective of this study is to assess the change in HbA1C from baseline to 4 months post HCV treatment among patients who achieve SVR 12 weeks post-treatment (SVR12). Secondary objectives include assessing the sustained change in HbA1C, assessing change in antihyperglycemic therapy, and comparing these changes in those who achieve SVR12 to those who relapse.

Methodology: This study is IRB approved. Medication dispense history identified 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 were excluded if they were not taking any diabetic medications prior to the start of HCV treatment. The primary endpoint was change in HbA1C from baseline to 4 months post HCV treatment. Secondary endpoints include sustained change in HbA1C 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 change in HbA1c and diabetes medications was compared among those who achieved SVR12 and those who relapsed. A paired t-test analyzed HbA1C changes, while descriptive statistics were used for secondary endpoints.

Results: 157 patients were eligible for this study, comprised of 151 (96%) males, mean age of 64 years. 146 (96%) achieved SVR12, 7 (4.5%) relapsed, and 4 (2.5%) were lost to follow-up. 122 patients (78%) were treated with ledipasvir/sofosbuvir +/- ribavirin, 9 (5.7%) with elbasvir/grazoprevir, 26 (16.6%) with one of the other included regimens. Mean baseline HbA1C was 7.67% [5-13.2%]. After a mean of 2 months post-treatment, the immediate mean change in HbA1C was -0.69% (p < 0.01). The sustained HbA1C at 12 months post-treatment demonstrated a mean change of -0.29% (n = 107, p = 0.158). Forty-four (30%) patients who achieved SVR12 had a de-escalation of antihyperglycemic medications at 3 months post-treatment, compared to 0% of patients who relapsed.

Conclusions: Treatment with DAAs decreased HbA1C by 0.69 percentage points immediately following HCV clearance in those patients who achieved SVR12. This is comparable to drug effects seen with antihyperglycemic medications. Since HbA1C can decrease rapidly upon HCV treatment initiation and immediately post-treatment, providers should be aware of this HbA1C improvement, with possible pre-emptive dose decreases of medications or closer follow-up with diabetic patients undergoing treatment for HCV.

References:

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

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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 was utilized to identify patients with respiratory cultures having been drawn within the previous 24 hours. Patients were screened for the necessity of double anti-pseudomonal coverage by assessing antibiotic use within the previous 90 days. Other patients that received a recommendation for double coverage included those with septic shock and those with increased risk of mortality. Patients were followed until culture results were obtained, and therapy narrowed when appropriate. Patients were included in the study if they had a positive Pseudomonas aeruginosa respiratory culture. Beta-lactam administration was optimized by providing extended-infusion cefepime and piperacillin/tazobactam, as well as meropenem at doses recommended by the HAP and VAP guidelines if indicated. A Monte Carlo simulation was run to ensure probability of target attainment of 90% on select patients. Patients were followed daily by a clinical pharmacist. When patients met clinical criteria for resolution, and after at least 7 full days of treatment, a call was made to the physician recommending discontinuation of anti-pseudomonal therapy. If the recommendation was not accepted, an additional call was made on days 10 and 14 of therapy.

Results and conclusions: A total of 30 patients were included in the before-after analysis; 16 in the pre-intervention arm and 14 in the post-intervention arm. The mean duration of anti-pseudomonal antibiotics was reduced from 13.1 days in the pre-intervention to 8.76 days in the post-intervention arm (p=0.012). There was also a statistically significantly decreased hospital length of stay in the intervention arm (25.75 days vs. 13.93 days, p = 0.043). In conclusion, a clinical-pharmacist driven stewardship effort targeting patients with pseudomonas pneumonia had a substantial impact on clinical outcomes.

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

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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.1 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 2016.2 Previous studies have shown that medication reconciliation led by pharmacists post-discharge can decrease readmissions and provide cost savings.3,4 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 focused specifically on patients discharged to nursing facilities.

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

Methodology: This study was 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 were evaluated to identify patients discharged to a SNF or LTAC were randomized equally into two groups: patients who will receive post-discharge medication reconciliation and patients who will not. The nursing facility was contacted to conduct a medication reconciliation within three days of discharge for those patients randomized into the intervention group. The following baseline data was 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 were documented. A medical record review was completed to determine readmission rate to a Cleveland Clinic inpatient facility within thirty days of discharge. All data was recorded in a secure database to maintain patient confidentiality. This study was approved by the local Institutional Review Board.

Results and conclusions: A total of 121 patients were included in this study. The pharmacy team called nursing homes and requested the patient MAR be faxed to the pharmacy, minimizing time required for the phone call (average time 5 minutes). The pharmacy team attempted medication reconciliation in 82 patients. Patients were only included in the statistical analysis if the pharmacy was able to reconcile medications with the nursing home, which was 46 patients (56.1% of original intervention group). There was no statistical significance in regard to 30-day readmission rate between the intervention (23.1%) and control groups (30.4%), p=0.474. At least one discrepancy was identified in 22 patients in the intervention group (47.8%), with a total number of identified discrepancies equaling 42. The most common discrepancy was a gap in therapy, which totaled 36. The number of unsuccessful medication reconciliation attempts has been identified as an area to improve upon with the continuation of this project.

References:

Clinical and Humanistic Outcomes of Face-to-Face and Telehealth Warfarin Management

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Background: 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. Evaluating clinical outcomes of face-to-face and telehealth warfarin management and assessing patient satisfaction can help health-systems select which modality to offer; telehealth vs face-to-face.

Objective: The primary objective was to evaluate whether the time in therapeutic range (TTR) of warfarin patients managed by telehealth (TH) was non-inferior to face-to-face (FTF) management. Secondary objectives assessed the safety, compliance, and satisfaction of patients managed by telehealth care.

Methodology: This study was a retrospective, non-inferiority, repeated measures analysis of a select population that transitioned from a MetroHealth satellite anticoagulation clinic to the newly acquired, telephone-based Medication Management Clinic (MMC) for warfarin management during August or September of 2016 in Cleveland, Ohio. Data was collected from six months prior to transitioning to MMC through six months following the transition. Patients must have been aged 18 years or older, prescribed warfarin, and managed by a MetroHealth satellite clinic at least six months prior to transitioning to MMC. Patients were excluded if warfarin was discontinued during the study period or if the patient used home INR testing or the face-to-face clinic instead of telehealth more than 25% of the time. The primary outcome was time in therapeutic range (TTR). Secondary outcomes included extreme INR incidence (INR ≥ 4.5, or ≤ 1.5), noncompliance to follow-up (> 7 days late), hospitalizations/ER visits stratified by primary outcome and BARC (Bleeding Academic Research Consortium) bleeding score, and patient satisfaction with telehealth. Other data included demographics, goal INR range, use of chronic NSAIDs or antiplatelet medications, use of vitamin K, encounter type, INR, and procedural interruptions. Satisfaction was assessed via mailed surveys. Seventy patients were required to meet 99% power.

Results and conclusions: A total of 144 patients transitioned from a MetroHealth satellite clinic to the newly acquired MMC for warfarin management between August 15 and September 30, 2016. Of the 144 eligible patients, 82 met inclusion and exclusion criteria and therefore were included in the study. The primary outcome, TTR, was not significantly different between the FTF and TH phases (66.17% ± 23.45%, 65.50% ± 23.96%, p=0.82). Incidence of extreme INRs, noncompliance to follow-up, and hospitalization/ER visits were also not significantly different between phases. There were significantly fewer encounters required in the TH phase vs FTF (7.43 ± 3.05, 8 ± 2.22, p=0.0049). A total of 34 (41.5%) patients returned the mailed satisfaction survey. Patient satisfaction was comparable to the average CAHPS scores reported by the Agency for Healthcare Research and Quality (AHRQ) in 2015. This study supports current literature that warfarin patients managed by telehealth can be adequately and safely managed while utilizing fewer resources. Additionally, patients remain compliant and report satisfaction with TH services. TH not only expands the reach of pharmacists specially trained in anticoagulation, but also allows other specialists such as advanced practice nurses and physicians to focus on acute patient care, without warfarin management interruptions.

References:
Impact of a Pilot, Pharmacy-Led Tobacco Cessation Medication Protocol at Discharge in a Community Hospital

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Background: Tobacco use is the leading cause of preventable disease and death in the United States.1 Providing support through healthcare interventions has been proven to help tobacco users quit more effectively. A study by Puschel et al. revealed that a minimal intervention lasting less than three minutes decreased the overall prevalence of tobacco use.2 Pharmacists have the specific skill set required to share information about medication options for quitting.3 The Joint Commission has created The Tobacco Treatment (TOB) measure set to address tobacco cessation for all hospitalized patients. The TOB-3 (Tobacco Use Treatment Provided or Offered at Discharge) and TOB-3a (Tobacco Use Treatment at Discharge) measures provide an optimal opportunity for pharmacy intervention.4 A pharmacy-led tobacco cessation medication education initiative was implemented at University Hospitals St. John Medical Center (UHSJMC). Per the approved protocol, patients were seen by a pharmacy representative and given an education sheet reviewing available over-the-counter (OTC) nicotine replacement therapies (NRTs). The pharmacist was authorized to order the patient’s preferred NRT upon discharge. Follow-up phone calls occurred within 30-60 days of discharge for patients who expressed initial interest in tobacco cessation medications.

Objectives: The primary objective is to assess the impact of a pharmacy-led tobacco cessation protocol based on the number of medication and education interventions made before discharge. The secondary objectives are to determine percentages of tobacco users given OTC NRT recommendations and referred to the Ohio Tobacco Quit Line, respectively.

Methodology: A retrospective review of the pharmacy-led protocol was completed from November 2016 through April 2017. UHSJMC inpatients identified as current tobacco users were included in the study. Each tobacco cessation intervention was documented in the patient’s medical record. The total number of interventions during the study period was documented as the primary outcome. The percentage of tobacco users given OTC NRT recommendations and the percentage referred to the Ohio Tobacco Quit Line were documented as secondary outcomes. The number of patients who purchased an NRT and/or quit using tobacco post-discharge was also documented. Prior data from the comparator group (November 2015 through April 2016) was analyzed against the study group using descriptive statistics.

Results and Conclusions: A total of 607 tobacco cessation medication education interventions were made during the study period. Of the 607 patients seen in the hospital, 379 (62.4%) were given an OTC NRT recommendation upon discharge and 148 (24.4%) were referred to the Ohio Tobacco Quit Line for further follow-up. The TOB-3/3a measure was met in 44.1% of patients abstracted from the study period compared to 0% in the comparator group. Of the 75 patients who were reached via follow-up phone call within 30-60 days of discharge, 23 (30.7%) had purchased an OTC NRT to help them quit, while 22 (29.3%) had completely quit using tobacco. Pharmacy-led tobacco cessation interventions during hospitalizations have a positive impact on the Joint Commission TOB-3/3a quality measure results as well as patients’ readiness to quit post-discharge.

References:
Evaluating hemodynamic effects of clevidipine in cardiothoracic surgery patients with reduced ejection fraction

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Background: Clevidipine is an ultra-rapid acting intravenous dihydropyridine calcium channel blocker indicated for the reduction of blood pressure1. It is particularly beneficial in the post-operative surgical setting due to its ability for rapid titration. The medication is restricted at University Hospitals Cleveland Medical Center for management of intraoperative and postoperative hypertension after cardiac surgery. Currently, there is limited data regarding the efficacy and hemodynamic effects of clevidipine in patients with heart failure with reduced ejection fraction (HFrEF)2, 3.

Objective: The primary objective of this study was to evaluate the hemodynamic effects of clevidipine in post-cardiothoracic surgery patients with reduced ejection fraction. Secondary objectives included evaluating the percentage of mean arterial pressure readings at goal, intensive care unit (ICU) and hospital length of stay, presence of arrhythmias, and rehospitalization and mortality within 1 year of follow up.

Methodology: This study was a single center, retrospective chart review of cardiothoracic surgery patients who received clevidipine between December 1, 2012 and November 30, 2016. Patients were included if they underwent cardiothoracic surgery, had invasive hemodynamic monitoring, left ventricular ejection fraction of 40% or less, and were 18 years or older. Patients on extracorporeal membrane oxygenation or concomitant vasopressor or inotropic therapy, with the exception of milrinone and dobutamine, were excluded.

Results and conclusions: A total of 633 patients received clevidipine during the study period. Only 11 patients met all inclusion criteria. The mean clevidipine rate was 5.07 mg/hr with a median length of infusion of 18.1 (IQR 10.4- 44.8) hours. The cardiac index increased from baseline to time of clevidipine discontinuation in 7 patients, but the mean change in cardiac index from baseline to time of clevidipine discontinuation was -0.04 ± 1.1 L/min/m². The mean pulmonary artery pressure trended down in most patients (72.7%) when compared at clevidipine initiation and discontinuation. All patients saw a reduction in their mean arterial pressure to a value of 90 mmHg or less within the first 6 hours of clevidipine administration. The mean ICU and hospital length of stay was 15.1 ± 12.5 days and 22.3 ± 9.5 days. There were 4 patients that developed an arrhythmia during the clevidipine infusion. All patients survived to hospital discharge, with 63.6% of patients discharged to home and the remaining discharged to a rehab facility. No patients died within 1 year of discharge. The results of this study showed that the use of clevidipine in cardiothoracic surgery patients was associated with quick and effective blood pressure management. Patients did not have any sustained adverse effects thought to be contributed to the administration of clevidipine. The main limitation of this study was that concomitant medications may have impacted patient hemodynamic profile and outcomes. Future prospective studies are needed to assess the safety and efficacy of clevidipine in this population.

References:
Evaluation of antimicrobial use and the impact of pharmacist and provider education in the treatment of asymptomatic bacteriuria in a community teaching hospital

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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. One randomized trial showed that treatment of ASB in premenopausal women did not have a benefit in frequency of symptomatic infections. In a variety of institutional settings, treatment with antibiotics may occur in as many as 68% of patients with ASB. 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.

Objectives: The objective of the study is to assess the impact of education on antibiotic prescribing practices for ASB patients.

Methodology: This retrospective before and after study compared the number of ASB patients treated in accordance with IDSA guidelines before and after medical staff education led by pharmacy. The primary endpoint was the number of patients with ASB who were treated in accordance with IDSA guidelines. The secondary endpoints included duration of antimicrobial therapy and number of patients discharged on antibiotics. The control (before) group was obtained through a hospital medical record search for adult patients diagnosed with a urinary tract infection, ASB, or if they had a positive urine culture at any point during their admission for patients admitted between November 2015 - February 2016. The study (after) group was obtained through the same process using the dates from November 2016 - February 2017. The study included three internal medicine services with the same attending physician for both study periods. Education consisted 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 were included. Patients were excluded if pregnant, had a history of renal transplant, or were undergoing a urological procedure during admission.

Results and Conclusions: 171 patients were initially screened to be included in the study. A total of 32 patients were included in the pre-education group and 19 patients in the post-education group. With regards to the primary endpoint, 25% (n=8) of patients in the pre-education group had antibiotics appropriately withheld as compared to 26.3% (n=5) of patients in the post-education group (p=0.9147). The educational intervention within the time frame studied was not found to have a statistically significant difference in guideline recommended management of ASB. Pharmacists can play a significant role in management of ASB; however, more studies need to be completed in order to identify optimal interventions for appropriate management.

References:
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 heart failure annually, accounting for a total Medicare expenditure surpassing $17 billion.1-2 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.3 Therefore, this study sought to determine if an individualized and comprehensive medication education approach led to a significant reduction in heart failure readmissions.

Objectives: The primary objective of this study was to determine if pharmacist-provided bedside education significantly reduced 30-day all-cause hospital readmission rates of heart failure patients at Cleveland Clinic Main Campus. The secondary objective was to compare the proportion of patients who successfully filled their prescriptions within 30 days after discharge in the individualized education group versus the standard of care education group.

Methodology: In this prospective, open label, parallel-group study, adult patients diagnosed with heart failure were assigned to the standard of care education group or the individualized education group. Patients in the individualized education group received one-on-one bedside medication education provided by the PGY2 cardiology pharmacy resident prior to discharge. The education session involved a comprehensive medication review, and patients were supplied with pill organizers and pill splitters to help increase adherence. The resident reviewed the process of filling prescriptions at a pharmacy with the patients and ensured they were able to open a prescription bottle. Both groups continued to receive the current standard of practice education on the heart failure service, which included a heart failure class taught by a nurse, pharmacist, and nutritionist, or bedside education from these caregivers if the patient was unable to attend the class. In addition, patients in both groups received follow-up phone calls within 30 days of discharge, and a follow-up medical visit was scheduled for all patients.

Results and Conclusions: From November 2016 to March 2017, 60 patients participated in this study. Thirty patients were assigned to the standard of care education group and 30 patients were assigned to the individualized education group. Baseline characteristics were well balanced between the groups. No difference was observed in the rates of 30-day hospital readmissions. Five patients (16.7%) who received standard of care education had a hospital readmission within 30 days after discharge compared to seven patients (23.3%) who received individualized education (p=0.519). However, there was a statistically significant increase in the proportion of patients filling their prescriptions within 30 days after discharge in the individualized education group compared to the standard of care education group [29 (96.7%) vs. 21 (70%) patients, respectively; p=0.006]. In the standard of care education group, there were 15 patients (50%) who had drug class changes made to their medication regimen after they received education, compared to only four patients (13.8%) in the individualized education group (p=0.003). In both groups, a similar number of patients had assistance from home health care and/or care coordination. The majority of patients in each group received a follow-up phone call within 30 days of discharge and attended their scheduled medical visit. In conclusion, the implementation of individualized comprehensive medication education by a pharmacist did not lead to a significant difference in 30-day all-cause hospital readmissions in heart failure patients at Cleveland Clinic Main Campus in comparison to standard of care pharmacist heart failure counseling, but it was associated with a greater proportion of patients who filled their prescriptions within 30 days after discharge.

References:

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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Background: Hyperglycemia in hospitalized patients affects approximately 38-46% of non-critically ill patients and 70-80% of critically ill patients.1 This is concerning because hyperglycemia has been associated with increased risks of infection, impaired wound healing, multi-organ failure, prolonged hospital stay, and death.2 Sliding scale insulin is intended to retroactively manage elevated glucose levels and supplement scheduled prandial and basal insulin.3 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. 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. Our current protocol states that nurses should contact the provider to increase sliding scale insulin when there are two consecutive blood glucose readings ≥ 250 mg/dL and no change in insulin within 24 hours. Through anecdotal experience, this protocol was not being utilized to its full capacity and glycemic control could be further optimized. It was hypothesized that a pharmacist-driven protocol for sliding scale insulin dosage adjustment would improve glycemic control in the study population.

Objectives: Primary endpoints evaluated both safety and efficacy defined by the number of hypoglycemic events and change in mean random blood glucose values after pharmacist intervention, respectively.

Methodology: This was a single-center, retrospective, quality improvement, before and after pilot study. Data was extracted from the electronic medical records for the time period of 3 months pre and post pharmacist intervention. Pre-implementation data was collected from December 1, 2015 to February 29, 2016 and compared to post implementation data collected from December 1, 2016 to February 28, 2017. Patients included were ≥18 years old, managed on internal medicine floors with clinical pharmacist coverage, had a length of stay ≥72 hours, and had two consecutive blood glucose readings ≥250 mg/dL within 24 hours. We assessed change in mean glucose at 72 hours from baseline.

Results and Conclusions: A total of 72 patients were included in the pre-pharmacist intervention group and 28 patients in the post-pharmacist intervention group. The two groups had similar characteristics at baseline. Mean change in blood glucose values at 72 hours were -8±70.1 and -42±47.9 for the pre and post pharmacist intervention groups, respectively (P=0.02). Hypoglycemia (blood glucose level, <70 mg/dL) was reported in 18 patients (25%) in the pre-pharmacist group and 2 patients (7%) in the post-pharmacist group (P=0.04). Pharmacist intervention on sliding scale therapy had a statistically significant impact on glycemic control in hospitalized non-ICU patients.

References:
Evaluation of hyperglycemic crises 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 there were 170,000 emergency department visits for hyperglycemic crises in 2009 costing $2.4 billion to the health care system. The American Diabetes Association (ADA) published a consensus statement which outlines the recommendations for the management of DKA/HHS, which include fluid and electrolyte management along with insulin therapy. Beik and colleagues evaluated the impact of utilizing a standardized nomogram based on the ADA guidelines. Investigators compared patient outcomes prior to and post implementation of the nomogram. Medical intensive care unit (MICU) length of stay and time to anion gap closure were significantly shorter in the post group. A significant decrease in mean episodes of hypokalemia was also seen.

Objectives: The purpose of this study was to evaluate whether the management of hyperglycemic crises in the MICU at Cleveland Clinic Marymount Hospital is consistent with the ADA recommendations. The primary objective was to assess adherence to the existing DKA/HHS order set. Secondary objectives included time to resolution of hyperglycemic crises, MICU length of stay, incidence of hypoglycemia and hypokalemia, assessment of appropriate transition to subcutaneous insulin and incidence of recurrent hyperglycemic crises.

Methods: This was a single-center, retrospective chart review of patients 18 years or older admitted to the MICU on intravenous insulin infusion for the treatment of hyperglycemic crises between January 1st and June 30th 2016. Patients were excluded if they received an insulin infusion for another indication, were transferred to another hospital or had an incomplete electronic medical record. Data collection included patient demographics, MICU length of stay, blood glucose levels, presence of urine ketones or serum β-hydroxybutyrate, serum osmolality and pH levels, timing and dosage of intravenous insulin infusion, duration of insulin infusion, time of subcutaneous insulin initiation, incidence of hypoglycemia or hypokalemia, and presence of endocrinology consult. Data was assessed using descriptive statistics.

Results and conclusions: Forty-seven patients met the inclusion criteria. Prescriber utilization of the order set was 52.6% (n=20). Mean time from MICU admission to resolution of crises was 48.9 ± 54.3 hours. Average MICU length of stay was 64.1 ± 89.7 hours. Incidence of hypoglycemia or hypokalemia were 21.3% (n=10) and 17.0% (n=8), respectively. Mean time from discontinuation of intravenous insulin infusion to initiation of subcutaneous therapy was -0.11 ± 5.1 hours. Recurrent hyperglycemic crises occurred in 29.7% of patients (n=14). Overall prescriber adherence to the DKA/HHS order set was low. Regardless of order set utilization, the secondary outcomes identify several opportunities for improvement in the management of hyperglycemic crises at our institution.

References:
Impact of pharmacist lead disease state management in a primary care clinic

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Background: The prevalence of diabetes in the United States was 10.9% in 2013, and in 2012, diabetes’s estimated cost in the US was $245 billion.\(^1,2\) Clinical pharmacy involvement in primary care clinics has shown a benefit in hemoglobin A1c (HbA1c) control when compared to usual care.\(^3,4\) However, the impact of a clinical pharmacist on medication adherence, comorbidity management, patient satisfaction, and sustainability of clinical pharmacy services has received little investigation. At MetroHealth, clinical ambulatory care pharmacy services were implemented in May 2016. Clinical pharmacists work under a consult agreement where physicians can refer patients for chronic disease state management.

Objective: The primary objective of this study evaluated change in HbA1c over six months in diabetic patients managed by a clinical pharmacist (intervention) compared to usual care (control) in primary care offices. Secondary objectives included the difference in the percent of patients that have HbA1c less than seven or nine percent and prescribed statin or aspirin therapy between the two groups during the study period. The study also evaluated patient satisfaction, medication adherence, and the financial implications of clinical pharmacy services.

Methodology: This two-part study was conducted within the MetroHealth System at three of its outpatient medical offices. Patients were included if they had a diagnosis of diabetes and at least 2 provider appointments within six months. Exclusion criteria included pregnancy, insulin pumps, age less than 18, and recent or upcoming appointment with endocrinology. The first part of this two-part study was a retrospective chart review where patients were matched based on age and gender in a 2:1 manner intervention to control. The second part of the study assessed patient satisfaction using an optional, anonymous, abbreviated CG-CAHPS survey.

Results and Conclusions: A total of 206 patients were included with 137 patients in the intervention group. The average age of patients was 62 years with 39% male and 81% African-American. Average duration of diabetes was 12 years. There were no differences in baseline characteristics except the intervention group had more patients on statin therapy at baseline (83.9% vs. 72%; \(p=0.034\)) and higher baseline HbA1c (10.1% vs. 9.3%; \(p=0.0125\)). A significant decrease in HbA1c was observed at 6 months compared to baseline in the intervention group (10.1% to 7.8%; \(p<0.0001\)), versus no change in the control group (9.3% to 9.6%; \(p=0.5211\)). There was a significant increase in the percentage of intervention patients with HbA1c less than seven percent and nine percent compared to the control group at 6 months (38% vs. 6%, \(p<0.0001\); and 78% vs. 47%, \(p<0.0001\) respectively). Eighty unique respondents rated pharmacists positively >90% of the time for all items in the abbreviated CG-CAHPS survey. Clinical pharmacists managing patients under a consult agreement in primary care generated revenue and resulted in improved diabetes management and high levels of patient satisfaction.

References:
Implementation and evaluation of pharmacist-managed vancomycin per hospital protocol- a pre and post analysis

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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). 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. 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. Another study showed a statistically significant difference in reaching therapeutic troughs when vancomycin dosing was managed by pharmacists. 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 purpose of this study is to implement a pharmacy vancomycin consult service. The secondary purpose is to assess the outcomes of pharmacist-managed vancomycin regimens as compared to physician-managed vancomycin regimens. 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, troughs within range, appropriateness of dose adjustments, and occurrence of side effects due to vancomycin. Prior to implementation of the vancomycin consult service, pharmacist involvement in vancomycin dosing was 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 was not implemented prior to the start of this study.

Methodology: This study was determined by IRB to be exempt as non-human subjects research. 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 28, 2016, while post-implementation charts will be reviewed from February 1, 2017 to March 31, 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 renal function, WBC, indication, prescriber, culture results, dosing information, other nephrotoxic medications, appropriate first dose, trough, dose regimen changes, time to therapeutic trough, renal function, and other side-effects.

Results and conclusions: Results and conclusions are currently in progress

References:
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.1-4 The treatment of choice for medically assisted withdrawal of opioids at Summa Health System (SHS) has traditionally been a 6-day tramadol taper. On August 8, 2014, tramadol became a Schedule IV medication. Only DEA registered narcotic treatment programs can administer controlled substances for acute opioid withdrawal for greater than 72 hours in patients admitted without another medical reason. Because Summa Health System’s St. Thomas detoxification unit is not a DEA regulated opioid treatment program, the traditional tramadol taper was truncated to a 3-day taper.

Objectives: The purpose of the study was to describe patient outcomes with a 3-day tramadol taper on the detoxification unit at SHS for acute opioid withdrawal. The primary endpoint was the change in Clinical Institute Narcotic Assessment (CINA) score from the start of the taper until completion or discharge. Secondary endpoints were length of stay, use of adjuvant medications, detoxification completion rates, highest CINA score, adverse events, and 30-day readmission rates.

Methodology: A retrospective, chart review, quality improvement study was performed describing outcomes of opioid dependent patients in acute withdrawal admitted on the detoxification unit between September 2014 and September 2016 receiving the 3-day tramadol taper. All patients >18 years of age admitted for opioid dependence were included. Pregnant patients were excluded. Data collected included patient demographics, treatment dates, doses administered, drug abuse history, CINA scores, use of adjuvant medications, adverse events, 30-day readmission and 30-day emergency department visit rates.

Results and Conclusions: Forty-six patients were included in the analysis. Patient ages ranged from 18-67 and 25 (55.6%) were male. The full taper was completed in 67.7% of admissions and 75.8% of patients were discharged by the physician. The median pre-taper CINA score was 6, and there was a significant change from this pre-taper score until completion or discharge in the per protocol group (-1.58, p=0.010), but not in the intention to treat group (-0.76, p=0.106). There were no reported seizures or falls. The truncated 3-day tramadol taper proved to be safe and effective therapy for treating acute opioid withdrawal. At SHS detoxification unit, patients treated with a 3-day tramadol taper for acute opioid withdrawal had their pre-taper CINA scores reduced by over 25% at the completion of the taper or discharge.

References:
Characterization of therapies used for post-operative pulmonary hypertension: Phase I

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Background: Pulmonary hypertension is a complication encountered in patients following cardiothoracic surgery. Occurrence of post-operative pulmonary hypertension in this patient population is a poor prognostic indicator and is associated with increased morbidity and mortality. Two therapies that have been used to decrease mean pulmonary arterial pressure (mPAP) in patients who experience post-operative pulmonary hypertension are inhaled nitric oxide (iNO) and inhaled epoprostenol (iEPO). Both iNO and iEPO act as local vasodilators and increase blood flow to well ventilated areas of the lungs. Due to comparable efficacy and safety of the two agents and high costs associated with iNO use, many institutions have transitioned from the use of iNO to iEPO.

Objective: 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). An institutional guideline for the use of inhaled epoprostenol is under development at our institution. This is phase one of a planned two phase study to evaluate the efficacy and safety of post-operative pulmonary hypertension management. Phase one will characterize current institutional usage of iNO and phase two will evaluate use of iEPO and compare the use of iNO to iEPO.

Methodology: This study was approved by the Institutional Review Board. Phase one of this project was a single center, retrospective chart review examining use of iNO in patients with post-operative pulmonary hypertension. Patients treated in the SICU with iNO for pulmonary hypertension following cardiothoracic surgery from April 1, 2015 through March 31, 2016 were included. Patients were excluded if they were less than 18 years of age or experienced pulmonary hypertension following heart or lung transplant. The primary outcome was a decrease in mPAP to less than 30 mmHg within 6 hours of SICU admission. Secondary outcomes were duration of mechanical ventilation, SICU and hospital length of stay, adverse events including bronchospasm and bleeding, and median daily milrinone requirement. Data has been analyzed using descriptive statistics.

Results and Conclusions: Final results and conclusions will be presented at the Ohio College of Clinical Pharmacy Spring Meeting.

References:
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. 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. The American Association for the Study of Liver Diseases support the use of albumin for the following indications; hepatorenal syndrome, spontaneous bacterial peritonitis, and large volume paracentesis. The American Heart Association/American Stroke Association support the use of albumin for volume expansion during vasospasm post-subarachnoid hemorrhage. Given the increased cost associated with 25% albumin and limited patient populations where it may provide benefit, this study sought to evaluate the prescribing practices of 25% albumin at a large tertiary academic medical center.

Objectives: The primary objective of the study was to describe the prescribing patterns and indications for use of albumin 25% within the ICUs at the Cleveland Clinic main campus. The secondary objectives were 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 albumin 25% pharmacy turn-around time.

Methodology: This study was a retrospective, non-interventional, descriptive study of albumin 25% use between June 1st, 2015 and February 28th, 2016 involving 150 patients. Inclusion criteria consisted of patients with an age ≥ 18 years old and who received at least one dose of albumin 25% while admitted to the Cleveland Clinic main campus ICUs. Exclusion criteria were any patients without administration documented in the electronic medical record.

Results and conclusions: A total of 539 albumin orders were placed for the 150 encounters. The neurosciences ICU had 13 encounters with 69 orders totaling 2,162 grams. The medical ICU had 34 encounters with 160 orders totaling 8,705 grams. The surgical ICU had 17 encounters with 75 orders totaling 3,205 grams. The coronary ICU had 9 encounters with 21 orders totaling 625 grams. The cardiovascular ICU had 77 encounters with 214 orders totaling 7,275 grams. After 150 encounters were reviewed, 8% of the encounters had primary literature studied indications and 1% of the total cost aligned with dosing regimens implemented within primary literature. The majority of patient encounters (61%) did not have an indication listed for albumin 25% use and 31% were prescribed for reasons outside of the predefined clinical criteria. Of the patients prescribed albumin for indications not supported by primary literature, the most common reasons for albumin were hypotension, acute kidney injury and volume resuscitation. Pharmacy turn-around time had a median of 25 minutes (IQR 9 to 63 minutes). Albumin 25% cost was approximately $828 per patient with a total cost of $124,198 for the 150 encounters. Overall, regarding supported criteria and dosage of albumin 25%, prescribing habits for albumin 25% were inconsistent with currently established primary literature.

References:
Evaluating the Outcomes of Lurasidone versus Quetiapine for Bipolar Depression

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Background: Bipolar I disorder has an estimated prevalence of 1% of the population. While symptomatic, patients experience depressive symptoms approximately threefold longer than manic symptoms and contribute significantly to health care costs. 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 and due to recent use at Louis Stokes VAMC, it is unknown whether patients experience similar benefit as shown in previous clinical trials compared to quetiapine.

Objectives: The primary objective of this study is to assess time to medication discontinuation over a one year period in veterans prescribed lurasidone versus quetiapine for the treatment 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. Secondary outcomes will assess the average dose of lurasidone and quetiapine prescribed, 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” on the first prescription for lurasidone.

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.

Results and Conclusions: A total of 1014 patient charts were reviewed of which 102 met inclusion criteria. Of the patients included, 72% (n=37) of patients on quetiapine discontinued therapy (average dose at discontinuation= 229mg ± 174.16mg) versus 78% (n=40) in those treated with lurasidone (average dose at discontinuation= 44.50mg ± 23.75 mg). There was a statistically significant difference in time to medication discontinuation in patients treated with quetiapine (237.05 days ± 243.52) versus lurasidone (112.05 days ± 100.34) [p=0.006]. Results showed a trend toward more neuromuscular (p=0.079) and GI side effects (p=0.079) in patients on lurasidone versus quetiapine. Of 102 patients included, 90% (n=92) were on concomitant therapy in addition to lurasidone or quetiapine and there was a trend toward use of antidepressants (p=0.101) and anxiolytics (p=0.071) in the lurasidone group. Psychiatric-related hospitalizations were not found to be statistically significant between groups. In those patients prescribed lurasidone (n=51), 37% of patients did not have accurate directions of “take with food” on the first prescription, potentially warranting an automatic placement of these directions on all lurasidone prescriptions.

References:
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. Concern has been raised regarding antibiotic resistance patterns of Neisseria gonorrhoeae.¹ Previous research has been conducted to address the concerns of overtreatment, undertreatment, and follow-up treatment success of chlamydia and gonorrhea along with studies to help determine predictor variables of sexually transmitted diseases (STDs).²–⁴ However, there have been limited studies evaluating predictors of positive assays while also evaluating empiric treatment of STDs. This study fills gaps in literature regarding the evaluation of positive assays and predictor variables and allows providers to better identify patients with potential STDs to streamline antibiotic treatment.

Objective: The primary objective of this study is to determine the incidence of positive assays 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 assays.

Methodology: The study is a retrospective cohort chart review. All adult patients who presented to the ED between January 1, 2016 and December 31, 2016 who received the gonorrhea and chlamydia screening were identified. Subjects were excluded if they were victims of sexual assault, left AMA or eloped from the ED.

Results and Conclusions: In this study, 490 patients met inclusion criteria. Of those included, 84 patients (17%) were positive for gonorrhea or chlamydia and 73 patients (87%) were treated empirically. Patients with a positive assay received significantly more empiric antibiotic treatment than those with a negative assay (p<0.001). However, of the 278 patients who were treated empirically, 205 patients (74%) had a negative assay. Risk factors for the prediction of positive assay found to be significant included: men, women less than 25 years of age, women with concomitant BV, PID, penile discharge, inconsistent condom use, additional risk factors, previous or coexisting STDs, uninsured, and concomitant trichomonas (p<0.05). This study showed that more patients were positive for gonorrhea or chlamydia than previously reported, but had a lower rate of empiric treatment. This study helped confirm certain risk factors outlined by the CDC and additional risk factors for gonorrhea or chlamydia.

References:

Evaluation of an electrolyte replacement protocol in critically ill patients at a community hospital

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Background: Electrolyte imbalances in critically ill patients have been correlated with increased morbidity and mortality.1,2 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.3 Cleveland Clinic Medina Hospital implemented a nursing-driven electrolyte replacement protocol for patients in the intensive care unit (ICU) in 2016, which targets hypokalemia, hypomagnesaemia, and hypophosphatemia. This retrospective study evaluates the safety and efficacy of the new protocol.

Objectives: The primary efficacy outcome is to 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 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, and in-hospital mortality.

Methodology: This retrospective chart review included 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 those 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 were excluded: serum creatinine greater than 2 milligrams per deciliter, dialysis, rhabdomyolysis, diabetic ketoacidosis, anuria, or weight less than 40 kilograms. Patient’s receiving scheduled electrolyte replacement or non-protocol replacement were also excluded. Fisher’s Exact, Mann-Whitney U and Student’s t-test were utilized in the statistical analysis, as appropriate.

Results and conclusions: For the primary outcome, 47 patients included in the post-protocol group were compared with 47 randomly-selected patients from the pre-protocol group. The morning values for serum potassium concentration within normal range were similar between groups (68% versus 64%; p=0.83). There was no significant difference in mean time from low serum potassium level discovery to electrolyte replenishment (5.7 hours versus 4.6 hours; p=0.085). For all other safety and efficacy secondary outcomes, there was no difference between groups. The current nursing-driven electrolyte replacement protocol is as safe and effective as the previous standard-of-care in electrolyte repletion.

References:
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 ≥80 years, weight ≤60 kg, or serum creatinine ≥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. 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. An additional study investigated the use of reduced-dose apixaban, rivaroxaban, and dabigatran. Frequent non-adherence to manufacturer recommendations was observed. Further research is required to determine the incidence of adherence to manufacturer recommendations for both standard and reduced dosing of apixaban, rivaroxaban and dabigatran.

Objective: This study compares 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 9/30/2015-9/30/16 was performed using records from a large integrated health system and included patients ≥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 included treatment for deep vein thrombosis (DVT), pulmonary embolism (PE), secondary prevention of recurrent DVT or PE, or postoperative thromboprophylaxis. The primary outcome was the incidence of inappropriate dosing for apixaban compared to rivaroxaban and dabigatran therapy. Chi-Squared analysis with an alpha level of 0.05 was performed on the primary outcome. A logistic regression model was developed to identify predictors of nonadherent prescribing patterns. A total study population of 128 was required to meet power.

Results and Conclusion: A total of 136 patients were included. There were no significant differences in baseline characteristics between groups, with the exception of the incidence of cardiology consults in patients receiving dabigatran (49%) when compared to patients receiving rivaroxaban (74%), and apixaban (71%, p=0.02). Upon analysis of the primary outcome, a significant difference was observed in the incidence of nonadherence to manufacturer recommended dosing strategies when apixaban (15.6%) was compared to rivaroxaban (30.4%), and dabigatran (40%, p=0.035). Upon utilization of a logistic regression model to identify predictors of nonadherence to manufacturer recommended dosing strategies, it was found that when compared to patients receiving apixaban therapy, those who received dabigatran therapy where at least three times more likely to receive incorrect doses (OR: 3.52: 95% CI 1.21-10.30). When compared to patients without a history of bleeding events, patients who had a history of bleeding were at least 4 times more likely to receive incorrect doses (OR: 4.61: 95% CI 1.06-20.02).

References:
Evaluating the Impact of Alvimopan 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. 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. 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. 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 was to determine the impact of alvimopan on clinical outcomes in patients undergoing RC.

Methodology: This retrospective cohort study was conducted at Cleveland Clinic Main Campus from February 2016 to February 2017. Patients were divided based on pre and post implementation of alvimopan into the care path. All patients who underwent a RC were included. Those that underwent additional unplanned surgical interventions during the RC were excluded. The primary outcome was hospital length of stay (LOS). Secondary outcomes included time to upper and lower GI recovery. Lower GI recovery was determined based on time to first bowel movement and upper GI recovery was determined by time to tolerating ≥ 50% of solid diet. Additionally, the total number of alvimopan doses, concomitant laxative use, and analgesia regimen were assessed.

Results and Conclusions: A total of 90 patients were identified for inclusion during the study period with 31 patients included in the pre-alvimopan group and 44 patients included in the post-alvimopan group after exclusion. Baseline characteristics were similar between groups, however, those in the post-alvimopan group experienced a shorter duration of surgery (5.9 hours vs. 6.9 hours, p=0.01), received more acetaminophen after surgery (1.8 grams vs. 0.98 grams, p=0.01), and more frequently underwent a laparoscopic surgical approach (79.5% vs. 51.6%, p=0.01) compared to those in the pre-alvimopan group. Those receiving alvimopan had a shorter hospital LOS (6.1 days vs. 7.4 days, p<0.01), shortened time to first bowel movement (3.8 days vs. 4.8 days, p<0.01), and shortened time to solid diet (0.77 days vs. 2.6 days, p<0.01) compared to those not receiving alvimopan. After accounting for length of surgery and surgical approach, alvimopan was shown to reduce hospital length of stay by 2.8 days on multivariable linear regression. In conclusion, when incorporated into an ERAS protocol, alvimopan significantly reduced hospital length of stay and time to gastrointestinal recovery in patients undergoing RC.

References:
Pharmacy Driven Services in an Outpatient Multiple Myeloma Clinic: a Pilot Program

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Background: Oral chemotherapy has become a mainstay in management of many malignancies. Transition of cancer management from traditional intravenous chemotherapy to oral chemotherapy offers many patient satisfaction and logistical benefits; however, this transition also leaves room for potential errors and complications. Oncology pharmacists are optimally trained to provide clinical oversight of oral chemotherapy prescribing and monitoring [1]. There have been several successful pharmacist-run oral chemotherapy clinics [2-4]. Our aim was to pilot clinical pharmacy services in an outpatient multiple myeloma clinic.

Objectives: The goal of this study is to evaluate the feasibility of pharmacist-driven monitoring of oral chemotherapy in the multiple myeloma clinic at Cleveland Clinic. The primary objective is to design a workflow for pharmacist intervention on pharmacotherapy related issues in management of multiple myeloma. Secondary objectives include analyzing patient volume, quantifying and qualifying the interventions made and time needed to perform interventions, and assessing the impact of pharmacist interventions on patient perceived outcomes.

Methods: During December 2016, the pharmacist participated in clinic visits with the multiple myeloma patients at Cleveland Clinic. During pharmacist appointment, the pharmacist collected survey information to assess patient-perceived medication information. The pharmacist reviewed the medication profile with the patient and physician and made any necessary updates. If any medication related problems were found, the pharmacist communicated with the ordering prescriber to reconcile the problem. A standardized note was placed in each patient chart to document the encounter. Descriptive statistics were used to describe the findings.

Results: During a 2 week pilot period, the pharmacist met with 34 multiple myeloma patients. Each patient visit lasted an average of 18.5 minutes. Medication counseling was provided to all patients. During the pilot, 65 interventions were made including drug interaction identification, side effect amelioration, prophylactic agent initiation, and duplicate medication discontinuation. We concluded, having a pharmacist in outpatient oncology clinics leads to meaningful clinical interventions and patient and provider satisfaction.

References
Evaluation of Sepsis-3 recommendations and derivation of new criteria to predict the risk of mortality in sepsis.

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Background:
The SEPSIS-3 consortium introduced the quick sequential organ failure assessment (qSOFA) and recommended that it be utilized to identify patients at an increased risk for mortality in the non-ICU setting. Within the SEPSIS-3 study, qSOFA demonstrated a sensitivity to identify patients at risk for death in the non-ICU setting of 55%, versus the Systemic Inflammatory Response Syndrome (SIRS) score at 64%. 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 sensitive for sepsis albeit lacking in specificity. Preliminary analysis of qSOFA and SIRS in our own institution did not produce significant clinical findings indicating that qSOFA may not accurately identify patients at risk for death from sepsis.

Objectives:
To identify criteria that are predictive for an increased risk of mortality due to sepsis, that are readily assessable, and can be formulated into an assessment tool with acceptable sensitivity and specificity.

Methodology:
All encounters including patients 18 years and older with suspected or confirmed sepsis between September 1, 2016 and September 30, 2016 were evaluated. Patients who received empiric antibiotic treatment and had cultures drawn within 24 hours of each other met the criteria for suspected sepsis. All lab values and vital signs for each encounter were obtained and analyzed using AUROC to identify those with predictive value for mortality in sepsis. Logistic regression was used to assess to identify potential confounding factors. The most promising variables were formulated into a tool and further validated against SIRS and qSOFA. To validate the tool, all sepsis encounters (defined using the same inclusion criteria as the derivation cohort) from October 1, 2016 through February 28, 2017 were obtained. The qSOFA, SIRS, and new validation tool score were obtained for each patient and compared for predictive validity in our health-system. Information was obtained by query of the EPIC® electronic record management system. The study was approved by Cleveland Clinic IRB.

Results & Conclusions:
Our derivation yielded a tool entirely based on lab values with an AUROC of 0.87, sensitivity of 88.9%, and specificity of 86% in our derivation cohort. Variables included are magnesium, lactate, creatinine kinase, and chloride. Completed analysis against qSOFA and SIRS in the validation cohort is pending.

References:
Outpatient Antimicrobial Stewardship Intervention Targeting Cytomegalovirus (CMV) Viremia in Solid Organ Transplant (SOT) Recipients

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Background: There is a demand for stewardship implementation and research in ambulatory and SOT populations. Few studies focus on outpatient stewardship interventions, and none have focused on timely recognition of CMV in outpatient SOT recipients. This study sought to determine the effect of real-time CMV result notification paired with pharmacist intervention on virologic and clinical outcomes in outpatient SOT recipients.

Objective: The primary endpoint was rate of viremia eradication at 21 days from therapy initiation. Secondary endpoints included time to antiviral initiation and viremia eradication, rate of CMV invasive disease and hospital admission, and adverse drug events.

Methodology: Quasi-experimental study comprised of two 6-month phases. In the pre-intervention phase, pharmacists were not involved in management of outpatient CMV viremia. In the intervention phase, pharmacists received real-time email notification of positive blood CMV results for review and intervention as necessary.

Results and conclusions: Eighty eight of 213 screened patients were included in the primary analysis (n=49 and 39 in the pre-intervention and intervention groups, respectively). Baseline characteristics were similar, including transplant type (34% vs 41% liver, 24% vs 28% kidney, 14% vs 17% lung, 14% vs 10% heart), CMV serostatus (53% vs 64% high risk D+/R-), and maintenance immunosuppression. A total of 73 recommendations were made with 89% acceptance. Baseline CMV viral load >10,000 IU/mL occurred in 12 (24%) vs 6 (15%) patients (p= 0.29). Of treated patients, 42 (85%) vs 32 (82%) patients achieved CMV eradication at 21 days (p=0.64), 10 (20%) vs 5 (12%) required admission for CMV management (p=0.35), 7 (14%) vs 3 (7%) developed CMV invasive disease (p=0.50), and 29 (60%) vs 25 (66%) received antiviral within 5 days (p=0.61). There were no statistically significant differences in time to antiviral initiation (45 vs 41 hours; p=0.64) or viremia eradication (19 vs 18 days; p=0.44).

CMV eradication at 21 days was not significantly different between groups, though several secondary endpoints suggest possible benefit from the intervention and warrant further characterization and study.

References:
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 requires that hospice patients receive care by an interdisciplinary team and employ/consult a licensed pharmacist. 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 can fulfill many roles, including promotion of cost-effective medication use, monitoring therapeutic outcomes and providing education to families and healthcare professionals. 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.

Objective:
The objective of this study is to survey hospice patients and caregivers, allowing a pharmacist to provide individualized education that will safely enhance symptom control and provide better satisfaction with therapy.

Methodology:
All patients enrolled in Alliance Community Hospice in November 2016 were evaluated for inclusion regardless of terminal diagnosis, comorbid conditions, and location of hospice care. Specialized hospice nurses were utilized to facilitate the consent process, as well as initial and follow-up medication related survey responses from patients and/or their caregivers. The initial survey asked the responders to evaluate their confidence in medication knowledge, their current symptom control and topics of concern regarding their care using Likert scales. A care meeting with the pharmacist was arranged, during which education was given on all medications with an emphasis on patient and/or caregiver identified areas of concern and empowering appropriate medication administration. Any additional concerns that were identified were communicated to the hospice care team and documented. Follow-up surveys were sent at two weeks following education to assess how perceptions and symptom control were impacted.

Results and conclusions:
Research evaluation in progress. Descriptive statistics will be used to evaluate changes in patient and caregiver medication perception. Results and conclusions will be presented at the Ohio College of Clinical Pharmacy Poster Session.

References:


Comparison of Total Cumulative Dose 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 2015, the Centers for Disease Control and Prevention reported that 29.9 per 100,000 deaths in Ohio were attributed to drug overdose and 63% of these deaths involved opioids.¹ 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.²,³ There is a perception that the administration of naloxone intranasally correlates with an increase in total amount of naloxone required in patients with opioid overdose when compared to intravenous (IV) administration. Previous studies have assessed naloxone use in the field; however, a comparison of total cumulative dose of intranasal (IN) naloxone versus IV has yet to be evaluated in patients also treated with naloxone in the emergency department (ED).

Objective: The primary objectives of this study were to determine if patients who received IN naloxone for initial resuscitation required a greater cumulative dose to elicit a clinical response compared to patients who initially received IV naloxone and to determine if the time to clinical response after initial naloxone dose was longer in the IN group. The secondary objectives of this study were to determine if the administration of the first dose of naloxone intranasally corresponded to worse patient outcomes when compared to IV administration and to identify predictors of increased cumulative dose requirements.

Methodology: This was a single center, retrospective cohort study in the ED of an acute care, teaching hospital in Northeast Ohio. Patients included in the study received at least one dose of IN or IV naloxone administered by first responders or ED personnel between January 1, 2014 and December 31, 2016. Electronic medical records were reviewed to determine total naloxone dose administered and time to clinical response after initial naloxone dose. Clinical response was defined as an increase in respiratory rate to ≥10 breaths/minute.

Results and conclusions: A total of 140 patients were included in the study, including 109 patients treated with IN naloxone and 31 with IV naloxone. The IN group required a greater average cumulative dose to elicit a clinical response (3.21 vs. 1.88 mg, p<0.001). The mean time between naloxone administration and clinical response was longer for the IN group (10.4 vs. 4.45 min, p<0.001). There was a significant difference between the IN and IV group with regards to average ESI score (2.28 vs 1.80, respectively, p<0.001), with the IV group having the more severe score. There was a significant difference between the IN and IV group with regards to length of stay in the ED (184.6 vs. 141.5 min, respectively, p=0.05). There was no difference between the groups involving discharge disposition from the ED, with the majority of patients being discharged home. In the IN group, 25% of patients were admitted, and in the IV group, 19% were admitted (p=0.47). The results of this study showed that IN naloxone administered by first responders or ED personnel was associated with a greater average cumulative dose required to elicit a clinical response. Additionally, IN naloxone administration was associated with a longer time to clinical response compared to IV administration. These results are similar to the results of previous studies. This evaluation will add to the limited literature available for providing guidance in determining the most appropriate initial route of naloxone administration.

References:
Impact of obesity shared medical appointments on weight loss and other cardiometabolic risk factors

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Background:
More than one-third of US adults are obese and weight loss in obese individuals reduces risk factors for diabetes and cardiovascular disease. An obesity shared medical appointment (SMA) program was designed to promote weight loss for patients enrolled. Few studies have been published evaluating the effectiveness of obesity SMAs.

Objectives:
The primary objective was to evaluate the change in weight over 3 months and the percent change in weight at 3 months. The secondary objectives were evaluating the change in glycolated hemoglobin (A1c), lipids, blood pressure (BP), and body mass index (BMI) and the proportion of patients achieving 5% weight loss at 3 months and the end of the study period. The correlation between the number of appointments attended and change in weight and the change in weight in relation to weight loss medication was also evaluated.

Methodology:
This retrospective observational study evaluated weight loss in patients who attended at least 1 obesity SMA over a 9 month period. Weight loss and other cardiometabolic risk factors were compared from the time of the patients’ first SMA, 3 months after the first SMA, and at the end of the study period. The correlation between appointments attended and weight was also evaluated.

Results and conclusions:
A total of 173 patients attended at least one obesity shared medical appointment. The mean weight loss was 4.0 ± 5.1 kg (3.8%) at 3 months and -4.4 ± 5.9 kg (4.1%) at the end of the study period. At 3 months, 38.7% of patients achieved 5% weight loss, and 41% of patients achieved 5% weight loss at the end of the study period. There was a significant reduction in weight, body mass index, blood pressure, and glycolated hemoglobin. There was a significant correlation between the number of SMA visits attended and the amount of weight lost. Patients who attended an obesity shared medical appointment lost weight and improved cardiometabolic laboratory values and vital signs.

References:
2) 2013 AHA/ACC/TOS Obesity Guideline., Medical Economics 2011, 68-76.
4) J Clin Endocrinol Metab. 2015 Feb;100(2):342-62.
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.1 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.1,2 In a retrospective study, hemodynamic response to AVP was associated with decreased odds of mortality.3 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.3 This study sought 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 was conducted to compare plasma vasopressin concentrations in hemodynamic responders and non-responders to AVP in the setting of septic shock. Hemodynamic response was defined as a MAP ≥65mmHg with a decrease in total catecholamine dose from the time of AVP initiation until the time of the vasopressin blood sampling. Blood samples were collected 3-6 hours after initiation of fixed-dose AVP. Adult patients were included if they were treated in a medical, surgical, or neurosciences ICU with fixed-dose AVP as an adjunct to catecholamines for at least 3 hours. Patients were excluded if AVP was the sole vasoactive therapy, was used for an indication other than septic shock, or was titrated prior to 3 hours or before a blood sample was obtained.

Results: 33 blood samples have been collected. The primary outcome has not been evaluated due to failure of the selected assay. Alternative testing methods are being explored. Responders as compared to non-responders were more likely to be treated in surgical ICUs (50.0% vs. 23.1%, respectively) than medical ICUs (40.0% vs. 69.2%, respectively, p=0.25 for comparison between ICU types) and had numerically lower median baseline SOFA (10.5 (IQR 9-14) vs. 14.1 (IQR 10-16), respectively, p=0.09) and median baseline lactate (2.5mmol/L (IQR 1.4-4.2) vs. 4.1mmol/L (IQR 1.9-6.2), respectively, p=0.28). However, none of these differences were statistically significant. Mean arterial pressure and change in norepinephrine equivalent dose from time of AVP initiation to sample collection were both significantly higher in responders, as would be expected based on our definition of hemodynamic response. ICU mortality was significantly lower in responders than non-responders (35.0% vs. 84.6%, p=0.005), although in-hospital mortality was not significantly different (50.0% vs. 84.6%, p=0.07). Vasopressor-free days at day 14 were more common in responders than non-responders (11.6 (IQR 0-12.9) vs. 0 (IQR 0-0), p=0.003), although ICU-free days did not differ.

References: