Prevalence and predictors of butalbital utilization in adults for migraine treatment

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Purpose: The objective of this study is to evaluate rates of butalbital use in patients presenting with migraine and identify factors associated with butalbital use.

Background: In 2000, the US Headache Consortium published guidelines for abortive therapies in migraine treatments. Butalbital containing products were given a Level B recommendation. Evidence butalbital causes medication overuse headaches and is ineffective was established in clinical trials in 2008 and 2012. New guidelines downgraded butalbital containing products to a level C recommendation or did not include them in any recommendation as abortive therapies. Though butalbital was removed from the European market, in 2010, 42,000 patients were treated with butalbital when presenting to the emergency department in the United States. Due to its lack of efficacy, ability to worsen episodic migraines to chronic migraines, and addictive properties, it is important to identify those at risk of inappropriately receiving and prescribing butalbital.

Methods: This national cross-sectional study will use data from the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS). Data from NAMCS will reflect data from 2010-2014 and NHAMCS will reflect data from 2010-2015. Upon IRB approval, de-identified data will be collected from these databases. Patients will include those who had a visit associated with migraine and are ≥18 years of age. Those who are pregnant and breastfeeding at the time of the survey will be excluded. The incidence of butalbital prescribing will be analyzed using descriptive statistics. Additional information including patient and provider specific factors will be analyzed using multivariate logistic regression. This analysis will then identify predictors associated with butalbital use including patient demographics (e.g. age, sex, geographical location), patient specific factors (e.g. cardiovascular disease, opioid use, substance use disorder, concurrent abortive and/or chronic preventative therapy) and prescriber characteristics (e.g. physician or non-physician, neurologist or other specialty, and practice setting).

Results: Results are pending and will be presented at the OPRC Spring Meeting in 2018.

References:
Evaluation of Levetiracetam Levels in Patients Receiving Continuous Renal Replacement Therapy

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Background: Prescribing information for levetiracetam (LEV) provides dose adjustment recommendations for patients with renal impairment, including end-stage renal disease. However, dosing recommendations are not provided for patients receiving continuous renal replacement therapy (CRRT). Tertiary resources recommend a LEV dose of 250 to 750 mg twice daily in these patients, but this recommendation is derived from pharmacokinetic characteristics exhibited by LEV during intermittent hemodialysis, as well as characteristics of LEV that may aide in its removal during CRRT. Data evaluating the effect of CRRT on removal of LEV is limited to four case reports, leaving considerable uncertainty regarding the extent of LEV removal by this treatment modality. Furthermore, these reports indicate that higher LEV doses may be warranted than indicated by current recommendations. The goal of this study is to characterize the effect of LEV dosing regimen and CRRT parameters on LEV levels in patients who are receiving concurrent LEV and CRRT.

Objectives: The primary objective of this study is to describe the effect of LEV dosing regimen and CRRT parameters on LEV levels. The secondary objectives are to describe the effect of dosing regimen on LEV levels in patients receiving CRRT and to describe the effect of CRRT dialysate flow rates on LEV levels.

Methodology: This is a retrospective chart review of adult patients (18 years of age or older) who had a LEV level collected after a minimum of 48 hours of concurrent LEV and CRRT therapy (defined as first steady-state level). Patients receiving slow continuous ultrafiltration will be excluded. Only the first steady-state level meeting the definition will be evaluated. LEV parameters that will be collected include first steady-state level, receipt of bolus doses, maintenance dose regimen, route of administration and indication. CRRT parameters that will be collected include CRRT type, dialysate, ultrafiltrate and blood flow rates, replacement fluid, residual urine output during CRRT and time off of CRRT in the 48 h preceding the LEV level. Additional data points to be collected include vasopressor use, number of concomitant anti-epileptic drugs, first documented serum creatinine on admission, and consulting service. Data will be collected from the electronic medical record and will be analyzed utilizing descriptive statistics.

Results and Conclusions: Pending.

References:

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Background:
Infections are a common complication seen in patients with end-stage renal disease (ESRD) who are receiving hemodialysis. Nearly 30% of hospitalized patients receiving hemodialysis are diagnosed with an infection1. Specifically, these patients are 26 times more likely to be diagnosed with bacteremia compared to the general population1. A study within the United States reported that bacteremia was the most common cause of hospitalization in patients receiving hemodialysis2. In 2014, the National Healthcare Safety Network (NHSN) conducted a dialysis event surveillance report on the incidence of bacteremia in the hemodialysis population3. This report noted that nearly 70% of all access related bloodstream infections (BSIs) were associated with the use of a central venous catheter (CVC) with half of these infections leading to hospitalization3. The NHSN report also noted that S. aureus is the most common infectious organism associated with BSIs in patients receiving hemodialysis and approximately 40% of all S. aureus isolates were methicillin-resistant3. Although gram-positive organisms are the most prevalent cause of bacteremia, gram-negative organisms also have the potential to cause bacteremia in patients receiving hemodialysis. The NHSN dialysis surveillance report noted that gram-negative bloodstream infections account for about 12.5% of bacteremia cases in patients receiving hemodialysis. Within this report, there was data concerning the percentage of multi-drug resistant organisms (MDROs) isolated. Over 10% of all E. coli and Klebsiella isolates were considered MRDOs3. Appropriate empiric coverage of MDROs of both gram-positive and gram-negative organisms is essential for improving patient outcomes. Determining the most prevalent risk factors for MDRO isolation will allow appropriate empiric regimens to be implemented based on these patient specific factors.

Objectives: The primary objective is to determine the prevalence of pathogens responsible for patients hospitalized with bacteremia and receiving hemodialysis at the University of Toledo Medical Center (UTMC). The secondary objective is to identify risk factors associated with the isolation of MDROs in patients with bacteremia receiving hemodialysis at UTMC.

Methodology: This study is an IRB-approval pending retrospective surveillance report including all hospitalized patients receiving hemodialysis at UTMC with at least one positive uncontaminated blood culture between January 1, 2012 through June 30, 2017. Included patients must have at least a 3-month history of intermittent hemodialysis (IHD). Patients will be excluded if they are immunocompromised, under the care of hospice, receive more than one dose of empiric antibiotics outside of UTMC, or are initiated on intermittent hemodialysis during the same hospitalization as the positive blood culture. We anticipate 600 patients will be eligible for inclusion in this study based on previous institutional rates of patients with bacteremia and receiving hemodialysis.

Results and Conclusions: To be determined.

References:
Double trouble: incidence of nephrotoxicity with concomitant vancomycin and piperacillin-tazobactam use in pediatric patients

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Background: Vancomycin is the antibiotic of choice for methicillin-resistant *Staphylococcus aureus* and is often used as empiric therapy for Gram-positive infections in critically ill patients. Vancomycin is associated with nephrotoxicity through accumulation in the proximal tubule and results in acute tubular necrosis and glomerular destruction [1]. Risk factors for vancomycin induced nephrotoxicity include use of a loading dose, trough levels >15mg/L, extended infusions, and prolonged duration of therapy [2,3]. Vancomycin’s spectrum of activity limits its use to Gram-positive infections and an additional agent must be added to cover for Gram-negative infections. Piperacillin-tazobactam (TZP), a β-lactam antibiotic, has coverage against Gram-negative organisms (including *Pseudomonas*) and anaerobes. TZP demonstrates high concentrations in the nephron which can lead to acute interstitial nephritis and nephrotoxicity. Current literature suggests that concomitant vancomycin and TZP therapy may result in an increased risk of acute kidney injury compared to vancomycin monotherapy [2,3]. This study aims to expand on existing pediatric literature by evaluating the incidence of nephrotoxicity with concomitant vancomycin and TZP use in all pediatric patients, including neonates and cystic fibrosis patients. Information generated from this study may be used to guide antibiotic prescribing to reduce the risk of nephrotoxicity.

Objectives: The primary objective of this study is to evaluate the incidence of nephrotoxicity associated with concomitant use of vancomycin and TZP in neonatal and pediatric patients. The secondary objective is to determine if admission to an intensive care unit, higher serum vancomycin trough concentrations (>15 mg/L), or receipt of concomitant nephrotoxic medications are related to development of nephrotoxicity in neonates, pediatrics, and cystic fibrosis patients. Primary endpoint will be acute kidney injury defined by pRIFLE criteria (decreased CRCL by 25% or urine output <0.5mL/kg/hr for eight hours).

Methodology: This is a retrospective chart review of patients from August 1, 2015 and August 1, 2017. Patients will be identified through a medication audit report in AllScripts electronic medical record. All patients less than 18 years old receiving concomitant vancomycin and TZP for more than 48 hours will be included in this study. Patients with pre-existing renal disease, receiving hemodialysis, receiving continuous renal replacement therapy, or on extracorporeal membrane oxygenation will be excluded. Patients will also be excluded if they do not have a baseline serum creatinine documented 48 hours prior to initiating vancomycin or a lack of trough during the entire treatment period or if they received vancomycin and TZP monotherapy prior to combination therapy. Data to be collected and reviewed will include: 1) patient information: sex, age, weight, location, and PRISM score 2) nephrotoxic medications: aminoglycosides, amphotericin B, intravenous contrast, calcineurin inhibitors, acyclovir, loop diuretics, ACE inhibitors, nonsteroidal anti-inflammatory drugs, and vasopressors 3) antibiotic information: current regimen, indication, duration of therapy, and trough level 4) renal function. Chi squared test will be used to analyze independent nominal data. Paired ordinal data will be analyzed using Wilcoxon signed rank statistical test. Paired continuous data will be analyzed using a paired t-test. Descriptive statistics will also be utilized.

Results and Conclusions: Pending

References:

Evaluation of an enterprise-wide emergency department pharmacist culture callback and antimicrobial management program

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Background: Antimicrobial resistance is a clinically growing issue across the United States and antimicrobial stewardship is an important method to increase appropriate use of antimicrobials and decrease resistance. Antimicrobial stewardship can be implemented in multiple departments throughout the hospital, including the emergency department (ED). Antimicrobials are frequently prescribed empirically in the ED, where patients are typically discharged prior to cultures being finalized. A culture callback program is a systematic process to ensure these therapies are appropriate. Prior studies comparing pharmacist managed programs to other provider managed programs have shown that pharmacists can decrease the time for patients to receive their results and increase the number of therapy optimization based on culture results. Randolph et al showed the pharmacist's role significantly decreased the number of unplanned readmissions from 19% to 7%. Additionally, Davis et al showed that a pharmacist-driven program lead to an increase of 30% in the number of interventions made on post-discharge therapy regimens when compared to ED nurse management. This study aims to provide a qualitative assessment of the culture callback process throughout an enterprise which has not been evaluated before.

Objectives: The primary objective of this study is to evaluate the total number of interventions pharmacists made after implementation of the pharmacy-driven culture callback process. The quality of the protocol will be determined by the number of interventions pharmacists were capable of making post-discharged across a healthcare system. Secondary objectives include time to make an intervention, characterize the different types of interventions, evaluate the total possible interventions that could have been made, and examine the incidence of readmission.

Methodology: This is a multi-center, retrospective chart review of patients who had a positive culture and required post discharge follow-up from the ED. Positive cultures are diagnosed based on therapeutic guides and include: blood, throat, respiratory, sexually transmitted diseases, stool, urine, and wound cultures. All positive cultures are analyzed by a pharmacist and recommendations for therapy changes are discussed with an ED physician. Overall descriptive statistics will be conducted on all variables.

Results and Conclusions: Pending; results will be presented at the OCCP spring meeting.

References:
Characterization of Urinary Tract Infections Post-renal Transplant

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Background: Urinary tract infections (UTIs) are the most commonly occurring infectious complication following renal transplantation.1 The estimated incidence of UTIs following renal transplant varies between 6-86%, and these UTIs have been associated with increased risk for graft loss and death.1-4 The American Society of Transplantation recommends UTI prophylaxis with trimethoprim/sulfamethoxazole (TMP/SMX) daily for at least 6 months following renal transplantation.5 Patients allergic to TMP/SMX alternatively receive ciprofloxacin 250 mg PO daily for UTI prophylaxis at Cleveland Clinic – Main Campus for an unspecified duration. Variations in practice also exist regarding use and duration of instrumentation and the management of asymptomatic bacteriuria in this population at Cleveland Clinic – Main Campus.

Objectives: The primary objective of this study is to summarize the overall incidence of UTIs post-transplant and timing of first episode. Secondary objectives are to report differences in antimicrobial resistance between varying UTI prophylaxis regimens and surgical techniques, classify and compare post-transplant positive urine cultures, and identify risk factors for developing multidrug-resistant (MDR) UTIs post-transplant. The primary outcome is one-year incidence of UTIs post-transplant. Secondary outcomes include 1 year incidences of asymptomatic bacteriuria, recurrent UTI, and relapsed UTI, time to first UTI post-transplant, antimicrobial susceptibility patterns, and presence/absence of MDR UTI risk factors.

Methodology: This study is a retrospective medical chart review of patients undergoing kidney transplantation at Cleveland Clinic – Main Campus between January 1, 2013 and October 1, 2016. Data will be collected on all patients with positive urine cultures during the first year following transplantation; those without positive urine cultures will be counted for calculation of one-year UTI incidence. UTIs will be classified as either asymptomatic bacteriuria, cystitis, or pyelonephritis. Baseline characteristics, transplant-related characteristics, and UTI-related data will be collected via medical chart review of EPIC® and the transplant database. Approximately 350 patients will need to be included to analyze the goal of 100 UTIs based on an estimated institutional event rate of 25-30%.

Results and Conclusions: Pending

References:
Multidisciplinary approach to inpatient medication education and its impact on patient satisfaction scores

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Background: The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is a standardized survey tool and data collection method that was developed in 2006 by Centers for Medicare and Medicaid Services (CMS).² Because survey results are linked to hospital reimbursement from CMS, organizations have placed great emphasis on improving HCAHPS scores.¹ While pharmacists have been shown to play a role in improving survey scores, opportunity still exists for multidisciplinary collaboration efforts to maximize patient education.³⁻⁵

Objectives: The objective of this study is to evaluate the implementation of a pharmacist-developed multidisciplinary approach to medication education and its impact on HCAHPS survey scores.

Methodology: University Hospitals Portage Medical Center (UHPMC) is a rural, community hospital where a three-pronged approach to multidisciplinary collaboration will be utilized to improve patient medication education. First, pharmacists will develop and distribute tools in order to educate and empower nurses to counsel patients on new inpatient medications at the time of medication administration. Second, a “Consult Pharmacy” order will be created in the electronic health record to allow nurses, physicians, social work, and care coordinators to consult pharmacists if a patient qualifies for in-depth medication education or discharge counseling. Third, a medication question hotline will be made available for patients to ask pharmacists medication-related questions post-discharge. All patients admitted to UHPMC will be eligible for the new medication education services. The primary outcomes will be HCAHPS scores on communication about medicine and transition of care domains. The secondary outcome will be 30-day hospital readmission rates. Outcomes will be evaluated and compared pre- and post-implementation of the new processes.

Results and conclusions: Pending Institutional Review Board approval, results will be presented at the Ohio Pharmacy Resident Conference in May 2018.

References:


Effect of pharmacist provided medication education on patient satisfaction at a community teaching hospital

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Background: The Healthcare Consumer Assessment of Hospital Providers and Systems (HCAHPS) survey has been used since 2006 to compare patient experiences at different hospitals in domains such as communication, environment, pain management, and the discharge process.1 Starting in 2013, the Centers for Medicare and Medicaid Services (CMS) linked 1% of hospital reimbursement to HCAHPS scores.2 Two questions of the HCAHPS survey focus on medication communication. Pharmacists are ideal candidates to positively impact medication-related HCAHPS scores and it has been shown that pharmacist integration into medical teams increases patient satisfaction, improved patient outcomes, and decreases drug costs.3,4 Currently at Cleveland Clinic South Pointe Hospital, clinical pharmacists complete medication reconciliation and education. To improve transitions of care, discharge prescription services are offered for medication adherence and patient satisfaction. Patients that utilize this service are able to have newly prescribed medications delivered to their room before leaving the hospital. Post-discharge, patients are contacted by a nursing-driven service for a follow-up phone call. The goal is to have 70% of patients complete this follow up service; however, only 55% of patients currently do so.

Objectives: The primary objective is to compare overall medication communication HCAHPS scores before and after implementation of pharmacist-provided medication education to patients on or after day three of admission. Secondary objectives include the utilization rate of discharge medication program and whether updating patient contact information will lead to an increased completion rate of post-discharge follow up phone calls.

Methodology: Pharmacists will provide medication education to patients on one medical floor of Cleveland Clinic South Pointe Hospital on or after day three of admission. Patients will be educated utilizing a standardized script on any new medications, home medications that have changed as well as updating patient contact information for post-discharge follow up. The study timeline will compare HCAHPS scores three months prior and three months after pharmacist intervention. Patients who received pharmacist education and returned an HCAHPS survey will be included in the study. There are no exclusion criteria. Baseline demographics include age, gender, admission diagnosis and number of medications prescribed prior to admission. Other data to be collected includes the number, name and class of new medications, number of medication changes, overall HCAHPS scores, medication-related HCAHPS scores, participation rate in discharge follow-up phone call, utilization of pharmacy discharge prescription services as well as pharmacist time spent during patient education encounter. Statistical analysis will include a Student’s t-test for continuous data, a Mann-Whitney U test for ordinal data and a Chi-squared test for dichotomous data. Statistical significance will be set at a p-value of <0.05.

Results and Conclusions: To be determined.

References:

Evaluation of serum vitamin B12 levels and supplementation utilization in ambulatory patients prescribed metformin for type 2 diabetes mellitus

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Background: There is extensive published data on the association between metformin use and vitamin B12 deficiency. The overall incidence has varied greatly in the literature, ranging from 5.8-52 percent, and there is a clear dose and duration dependent mechanism involved. The 2017 American Diabetes Association guidelines recommend periodic assessment of vitamin B12 in patients taking metformin. There are few published studies that evaluate monitoring of vitamin B12 in these patients. Based on these studies, the overall percentage of patients being monitored is approximately 35-45 percent. Appropriate monitoring and management of these patients could allow for more cost-effective and improved patient care. An additional gap in the current literature is addressing the use of B12 supplementation in patients treated with metformin.

Objectives: The primary objective is to determine the proportion of ambulatory patients with type 2 diabetes mellitus prescribed metformin for at least 6 consecutive months that have had a serum vitamin B12 level ordered while on metformin during the study period. Secondary objectives will aim to describe B12 levels and supplementation use as well as predictors of monitoring.

Methodology: This is a descriptive retrospective cohort spanning from June 1, 2016 to December 1, 2017. Ambulatory patients, at least 18 years of age, with type 2 diabetes mellitus on metformin for at least 6 consecutive months that have had at least one office visit at either an internal medicine practice or endocrine practice will be included. Patients will be identified through a query based on a diagnosis of type 2 diabetes and the use of metformin on their outpatient medication list within Epic®. The primary outcome of the study is the proportion of eligible patients who have had a serum vitamin B12 level ordered. The secondary outcomes include: the number of times a serum B12 level was ordered in subjects who had a level ordered throughout the study time period, the proportion of patients who had a B12 level ordered before January 1, 2017 and after this date, the proportion of patients who had a resulted B12 level who are considered normal (>300pg/mL), subclinical (200-300pg/mL), or deficient (<300pg/mL), the proportion of patients that have a vitamin B12 supplement (as defined in the study) on their outpatient medication list, and the relative risk of a B12 level being ordered if any of the identified predictors are present.

Results and conclusions: Pending

References:
Evaluation of timing of first dose antibiotic administration in patients with suspected sepsis in the Medical Intensive Care Unit at University Hospitals Cleveland Medical Center

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Background: Sepsis and septic shock affects more than 700,000 patients per year and leads to high rates of fatality and significant morbidity.1 Currently, the 2016 Surviving Sepsis Guidelines recommend initiation of empiric antibiotic treatment within one hour of sepsis recognition and diagnosis.2 One study demonstrated that each hour of delay in antibiotic administration, following the onset of hypotension in septic shock patients, decreases patient survival by 7.6%.3 As shown in common practice, there can be delays at different points in the medication administration process. These delays can occur at the point of ordering, dispensing and administration of these medications.4 In addition to appropriate antibiotic timing, adequate antibiotic dosing and selection are essential. It is strongly recommended in the Surviving Sepsis Guidelines that broad spectrum antibiotics with good coverage and penetration to the suspected site of infection are selected when empirically treating patients with sepsis.2 Currently UHCMC does not have an ICU sepsis order set for ordering antibiotics, but does have a guideline that lists the preferred antibiotics, with respective dosing based on suspected source of infection. The aim of this study is to determine the impact of readily available broad-spectrum antibiotics on administration time.

Objectives: The primary objective of this research project is to evaluate the median time to first dose antibiotic administration for patients with a confirmed or suspected diagnosis of sepsis or septic shock in the UHCMC medical intensive care unit (MICU). Secondary endpoints include identifying priority of antibiotic when ordered, defining delays in care, evaluating selection and dose of antibiotics ordered based on sepsis guidelines, and reviewing duration of hypotension, patient ICU mortality, and length of stay.

Methodology: This is a retrospective chart review of patients from December 2016 to March 2017 and April 2017 to July 2017 who received a new start of antibiotics for diagnosed or suspected sepsis or septic shock in the MICU. The patients’ electronic medical records will be reviewed for patient-specific information, data regarding antibiotic ordering, verifying, and administration, as well as patient outcomes in regards to complications and mortality. Data will be analyzed using descriptive statistics.

Results and Conclusions: Pending

References:
Effects of non-insulin anti-hyperglycemic agents in overweight and obese patients with type 1 diabetes

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Background: Insulin is the traditional treatment for patients with type 1 diabetes as the main pathophysiology is thought to be a lack of insulin secretion. A newer model called the beta cell-centric classification proposes that all forms of diabetes originate from an abnormal pancreatic β-cell and includes eleven interconnected pathways that promote hyperglycemia. Anti-hyperglycemic agents such as metformin and glucagon-like peptide 1 (GLP-1) receptor agonists target these pathways. When used as adjunctive therapy in type 1 diabetes, these agents have the potential benefits of insulin sparing effects, weight loss, and blood pressure lowering. There are limited studies evaluating the use of adjunctive agents in type 1 diabetes. Many of the studies have been retrospective with small sample sizes and did not focus on overweight or obese patients, who may experience the greatest impact due to weight loss and insulin sparing qualities. A large database in the U.S. showed that over 5% of patients with type 1 diabetes already receive adjunctive agents. The site of this study, Cleveland Clinic’s Diabetes Center, encounters a high volume of patients with type 1 diabetes, allowing for a large sample size to address the question if adjunctive agents are beneficial in overweight and obese patients with type 1 diabetes.

Objectives: The objective of this study is to evaluate the use of non-insulin agents as adjunctive therapy in overweight and obese patients with type 1 diabetes. The primary endpoint is to determine the effects of non-insulin agents on hemoglobin A1C and BMI (body mass index) when added to insulin. The secondary endpoints include comparing the incidence of emergency department (ED) visits, hypoglycemia-associated ED visits, and hospitalizations in patients who had a 3 month history prior to non-insulin agent initiation. This study will also compare the change in hemoglobin A1C and BMI from baseline and clinical success rates among non-insulin agent drug classes.

Methodology: This is a retrospective, pre-post study of overweight and obese adult patients with type 1 diabetes from January 1, 2012 to July 1, 2017. Through a non-interventional chart review, using Cleveland Clinic’s shared medical records (Epic®), patients will be enrolled who were prescribed a non-insulin agent. For our primary endpoint, patients will serve as their own control to compare hemoglobin A1C, BMI, ED visits, hypoglycemia-associated ED visits, and hospitalizations from “baseline” to “follow-up.” For our secondary endpoints, comparison of cohorts will be based on different non-insulin drug classes. Statistical analysis will include a paired t-test for the primary endpoint and an unpaired t-test for secondary endpoints.

Results and conclusions: Pending

References:
A prospective cohort study on long-acting injectable antipsychotics and its effects on readmission and adherence rates

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Background:
Per Diagnostic and Statistical Manual of Mental Disorders fifth edition, schizophrenia is defined as presentation of two or more positive and/or negative symptoms in a span of greater than or equal to six months, which includes an active phase of symptoms of greater than or equal to one month.1 First line therapy for schizophrenia is antipsychotics, most commonly in oral formulation. One of the main concerns in schizophrenia treatment is relapse. Relapses can occur when patients are non-adherent to their antipsychotics.2 Relapses lead to hospitalizations, which ultimately results in higher health care costs.3 To improve medication adherence, long-acting injectable (LAI) antipsychotics can be an alternative treatment option. Per the American Psychiatric Association, the recommendation for LAI antipsychotics usage is for patients who are repeatedly nonadherent to pharmacological treatment and are not in acute phase.4 Although guidelines only recommend giving LAI antipsychotics to nonadherent patients, LAI antipsychotics can be given in patients with first-episode of schizophrenia in hopes to lower relapse rates and improve medication adherence rates.2

At Southwest General, there are seven different long acting injectable antipsychotics on formulary. Currently, medication adherence rates and 30-day readmission rates on oral antipsychotics and LAI antipsychotics are not collected for patients who are discharged from and readmitted to Oakview Behavioral Health Center. Therefore, a prospective study will be completed to determine if discharging patients on LAI antipsychotics increase medication adherence and decrease readmission rates.

Objectives:
The objective of this study is to determine if discharging patients on long-acting injectable antipsychotics decrease readmission rates and increase medication adherence.

Methodology:
After IRB approval, each long acting injectable started on a patient with schizophrenia, bipolar disorder, or schizoaffective disorder will be collected. The patient’s chart will be reviewed to see how many readmissions occurred 90 days prior to the start of the injectable and 90 days after. The readmissions will count if the patient was discharged from Oakview Behavioral Health Center and readmitted to Oakview Behavioral Health Center. The number of patients who return to Oakview Behavioral Health Center for follow up LAI antipsychotic injections will be calculated. LAI antipsychotic adherence will be verified through external refill history and/or follow-up in physician’s office. Oral antipsychotic adherence will also be verified through external refill history, which can be seen through Cerner (electronic medical records).

Results and conclusions: Not available.

References:
Itraconazole versus posaconazole for antifungal prophylaxis in patients with acute myeloid leukemia undergoing intensive chemotherapy

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Background
Invasive fungal infections (IFIs) account for a major cause of illness and death in patients with hematologic malignancies when combined with neutropenia. Patients with acute myeloid leukemia (AML) undergoing intensive chemotherapy have the highest incidence of IFIs compared to patients with other malignancies.¹⁻² Antifungal prophylaxis is initiated to avoid IFIs and is essential to decrease mortality in high-risk patients. The Infectious Diseases Society of America (IDSA) recommend antifungal prophylaxis against Aspergillus with posaconazole in patients older than 13 years of age and undergoing intensive chemotherapy for AML.³⁻⁴ The National Comprehensive Cancer Network (NCCN) recommend the use of posaconazole for antifungal prophylaxis in AML patients as a category 1 recommendation. NCCN also states early-generationazole antifungals, such as itraconazole, are not used commonly due to toxicities, drug interactions, and limited spectrum of activity.⁴ Prior to July 2017, itraconazole was standard of care for antifungal prophylaxis in AML patients receiving intensive chemotherapy at the Cleveland Clinic. In July 2017, the standard of care for antifungal prophylaxis was changed to posaconazole.

Objectives
The primary objective of this study is to compare the incidence of deviation or change in standard antifungal prophylaxis from the institutional protocol in patients with AML receiving itraconazole versus posaconazole. Secondary objectives include evaluate the reason for change, compare the rate of continuation of antifungal regimens upon discharge, and evaluate the incidence of antifungal diagnostic work-up components in patients receiving itraconazole versus posaconazole.

Methodology
The study design is a non-interventional, retrospective cohort study. Patients will be included if they had a diagnosis of AML, received itraconazole or posaconazole for antifungal prophylaxis, and received intensive chemotherapy (induction (7+3) and relapsed (MEC) chemotherapy). Patients will be excluded if they were less than 18 years of age, initially received other antifungal agents for prophylaxis, and patients with translocation 15:17 (acute promyelocytic leukemia). Data will be extracted from the shared electronic medical record (Epic®). Data points to be collected include: patient demographics, chemotherapy regimen, duration of neutropenia, prophylactic antifungal agent, change in antifungal agent, reason for change, antifungal agent continued at discharge, CT chest/sinus, bronchoscopy/biopsy, serological tests, fungal cultures, azole drug levels, length of stay, disposition, and unplanned 30-day readmission. Statistics will include chi-square test or fisher’s exact test for nominal variables and students T-test or wilcoxon rank sum based on normality for continuous variables.

Results and Conclusions
Research is currently in progress.

References
Impact of an order set modification on pharmacologic venous thromboembolism prophylaxis in patients with class III obesity

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Background: Venous thromboembolism (VTE) is a common preventable illness in hospitalized patients. The relative risks of deep vein thrombosis and pulmonary embolism in patients with obesity are 2.5 and 2.2 times higher than in non-obese patients, respectively.1 The study site has an order set based on the Caprini score for assistance with the assessment of VTE risk and selection of a prophylaxis regimen for newly-admitted patients. The Caprini score has been validated for the assessment of VTE prophylaxis.2 The site-specific order set was updated in 2015 to include risk factors for multiple body mass index (BMI) ranges, automatic selections for age and BMI, and an increase in number and recategorization of other risk factors. Weight-adjusted heparin and enoxaparin selections (7,500 units subcutaneously [SQ] three times daily and 40 mg or 60 mg SQ twice daily, respectively) were made available for obesity class III (BMI ≥ 40 kg/m²) patients. This represented an increase from the previous, non-weight adjusted dosing (heparin 5,000 units SQ three times daily or enoxaparin 40 mg SQ daily). A number of studies have shown that weight-adjusted dosing for VTE prophylaxis in patients with obesity can lead to similar or fewer occurrences of VTE when compared to non-weight adjusted dosing, with a similar or slightly elevated risk of bleeding.3,4,5

Objectives: The objective of this study is to evaluate the effect of an updated VTE risk assessment order set on prescribing patterns and to analyze the safety and efficacy of weight-adjusted heparin and weight-adjusted enoxaparin compared to non-weight adjusted doses of the same drugs when used for VTE prophylaxis in patients with class III obesity at UHCMC. Another objective is to analyze the prevalence of individual risk factor selection in the risk assessment order set.

Methodology: This is a retrospective chart review of adult (age ≥ 18 years) patients who received heparin or enoxaparin for VTE prophylaxis at UHCMC between July 1, 2014, and June 30, 2015 (pre-modification), and between October 1, 2015, and September 30, 2016 (post-modification). Patients will be excluded if they had VTE or clinically significant bleed on admission, therapeutic anticoagulation during hospital stay, pregnancy/peripartum status, admission for hip/knee replacement or trauma, length of stay < 48 hours, or a serum platelet count < 50 x 10⁹/L on admission. The primary outcome will be measured by proportion of patients receiving weight-adjusted versus non-weight adjusted prophylactic doses of antithrombotics. Secondary outcomes will be measured by clinically significant bleeding, documented VTE, and prevalence of individual VTE risk factor selection. In order to show an increase from 10% to 25% in patients receiving weight-adjusted thromboprophylaxis with 95% confidence and 80% power, a sample size of 97 patients will be needed in both the pre- and post-modification groups. Enrollment will be limited to 200 eligible patients using a random number generator.

Results and conclusions: Results and conclusion will be presented at the Ohio College of Clinical Pharmacy Spring Meeting 2016.

References:
Testing the Untestable: Evaluation of monitoring direct oral anticoagulants (DOACs) in an ambulatory care anticoagulation clinic

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Background: Prescribing patterns of direct oral anticoagulants (DOACs) such as rivaroxaban and apixaban are on the rise. DOACs are prescribed for the prevention and treatment of blood clot formation, such as in the case of atrial fibrillation, venous thromboembolisms, and pulmonary embolisms. The CHEST Guidelines recommend DOACs as first-line agents for the treatment of venous thromboembolisms and pulmonary embolisms. Package inserts for these agents suggest monitoring renal, hepatic, and hematologic laboratory values, but do not define a frequency or provide laboratory parameters that may indicate change in dose or discontinuation of the agent. Currently, the Louis Stokes Cleveland VA Medical Center's pharmacist-run anticoagulation clinic (ACC) has a standard in place for monitoring these agents. Lab work for complete blood cell count and comprehensive metabolic panel must be completed one month after initiation of the agent. Follow-up lab draws are scheduled every three months for the first year of therapy, then every six months thereafter. Because of the lack of literature and guidelines for specific monitoring of these agents, the focus of this project is to determine the safety benefit for monitoring DOAC agents across different time intervals so that care provided by the ACC can be optimized.

Objectives: The primary objective of this project is to identify differences in the number of interventions for rivaroxaban and apixaban monitoring done at one-month, three-month, and six-month intervals in a pharmacist-run anticoagulation clinic. The primary endpoint is the number of interventions. The secondary objective is to identify differences in the reason for and type of interventions for rivaroxaban and apixaban monitoring done at one-month, three-month, and six-month intervals in a pharmacist-run anticoagulation clinic. The secondary endpoints are the reasons for and types of interventions.

Methodology: This is a retrospective chart review of patients enrolled in the Cleveland VA ACC as of October 1, 2016 and are prescribed either rivaroxaban or apixaban. Data search will include all encounters documented in the VA’s Computerized Patient Record System (CPRS ®) generated between October 1, 2015 through October 1, 2017. A clinic visit is defined as documented evaluation of lab results by ACC. An intervention is defined as one or more of the following: change in medication dose, discontinuation of therapy, and/or change in follow-up frequency. Interventions may be due to change in renal/hepatic function or documentation of a bleeding event.

Results and Conclusions: Pending

References:
Implementation and Evaluation of an Optimized Pharmacist Sidebar Report for Order Verification

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Background: Clinical information can be displayed in various areas of a patient's electronic medical record. Finding the location of all relevant data can be time consuming for the pharmacist and result in an increased amount of time to verify orders. The pharmacist sidebar report is a customizable optional Epic tool that allows pharmacists to access relevant clinical patient data without leaving order verification. The pharmacist sidebar report may act as a checklist by displaying pertinent clinical data that may be beneficial during pharmacist order verification. The pharmacist sidebar report conforms to the five rights of clinical decision support by displaying the right information for the pharmacist in a report on the same verification screen in which they are already working.

Objective: The primary objective of this study is to determine the change in awareness and usage of an optimized pharmacist sidebar report at an academic medical center.

Methodology: The study will be conducted at the Cleveland Clinic and will include the main campus and all regional hospitals. Phase 1 (planning) of the study will include the following: identifying relevant clinical data for targeted therapeutic drug classes; developing pre and post surveys; sending out the pre-implementation survey; and collecting and assessing the results from the survey. Phase 2 (design, build and test) of the study will include the following: designing and building the optimized pharmacist sidebar report based on survey responses; developing test scripts for the new functionality; executing test scripts; and identifying any errors and usability concerns. Phase 3 (delivery and assessment of results) of the study will include the following: delivering new code to the production environment; sending out a post survey; and developing considerations for future release of the pharmacist sidebar report based on survey responses. Survey data will be collected during the pre and post phases for 2 weeks. The primary endpoint is to determine the level of awareness and usage of the pharmacist sidebar report during the pre and post implementation phases. Secondary endpoints include the following: (1) pharmacist satisfaction of the pharmacist sidebar report and (2) pharmacist perception pertaining to accessibility to clinical data; awareness of clinical data; and time to verify an order. All data for the primary and secondary endpoints will be collected from survey responses. Statistical tests will include two proportion z-test for awareness and descriptive statistics for all other primary and secondary outcomes.

Results and conclusions: To be determined

References:

1. Howell P. Improving Efficiency and Safety for Inpatient Pharmacist Workflows. Presented at: Epic XGM (Expert Group Meetings); April 14, 2016; Madison, WI.
2. Watt I, Wu T. A Smarter Rx Sidebar Snapshot Report for Verification. Presented at: Epic XGM (Expert Group Meetings); April 24, 2017; Madison, WI.
Evaluation of empiric antibiotic resistant urine cultures in patients discharged from the emergency department

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Background: Urinary tract infections (UTIs) are commonly treated empirically in the emergency department (ED). Many of the patients treated will have a urine culture collected before they are discharged. The most common pathogen in UTIs is *Escherichia coli* (E. coli), but other pathogens, such as *Klebsiella pneumoniae*, *Staphylococcus saprophyticus*, and *Proteus mirabilis*, may be found.¹ Commonly prescribed empiric treatment includes cephalosporins, nitrofurantoin, ciprofloxacin, and sulfamethoxazole-trimethoprim (SMZ-TMP).² One prospective study found resistance rates of E. coli to ciprofloxacin, levofloxacin, and SMZ-TMP in ED patients to be 2%, 2%, and 16%, respectively.³ Another study determined risk factors for emergency room return visits (ERVs) within 30 days in patients treated with UTIs. The study found that ERVs were significantly more likely in patients with the following: age ≥ 65, skilled nursing facility resident, pregnancy, dementia, psychiatric disorder, obstructive uropathy, healthcare exposure, temperature ≥ 38°C, heart rate > 100, and bacteremia.⁴ A different study found that the following factors were associated with extended-spectrum beta-lactamase (ESBL)-producing *E. coli* in community-acquired UTIs: genitourinary pathology, previous bacterial infection, intravenous antibiotic treatment, hospitalization in the previous 12 months, and previous exposure to second generation cephalosporins.⁵ The aim of this study is to evaluate urine cultures in patients discharged from the ED, regardless of prescription of antibiotics, and to determine risk factors for empiric therapy resistant UTIs.

Objectives: The primary objective of this study is to determine the incidence of positive urine culture in patients discharged from the ED. The primary endpoint is percentage of patients with a positive urine culture in patients discharged from the ED. Secondary endpoints include proportion of patients with both positive and negative cultures treated with empiric antibiotics, incidence of empiric antibiotic resistance, and predictors for empiric antibiotic resistance.

Methodology: This is a retrospective, single center cohort chart review of patients from December 2016 through November 2017 who had a urine culture collected in the ED prior to being discharged from the ED. Patients over the age of 18 who received a urine culture and were discharged from the ED will be included in the study. Patients admitted to the hospital, eloped from the ED or left AMA will be excluded. All data will be recorded without patient identifiers to maintain confidentiality. A statistician will aid in the evaluation of data.

Results and Conclusions: To be reported upon approval from the IRB and completion of data collection.

References:
Impact of Pharmacist Anticoagulation Monitoring on Safety and Efficacy of Warfarin Use

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Background: Warfarin, an oral anticoagulant, requires careful monitoring and dose adjustment, as many inter-individual factors can affect the ideal dose for a patient. Warfarin is monitored using the international normalized ratio (INR). A subtherapeutic INR may lead to clotting and a supratherapeutic INR may lead to bleeding events; thus, close monitoring is required to maintain an optimal INR goal range. It has been previously shown that services provided by pharmacists may help improve anticoagulation control. For example, one hospital evaluated pharmacist dosing consultations during warfarin initiation and found that pharmacist intervention significantly improved outcomes: the number of patients reaching therapeutic range within 5 days increased from 38% to 88%, the number patients with INR values over 4 decreased from 27% to 2%, and the number of patients being discharged with subtherapeutic INRs decreased from 15% to 0%. The mean time to therapeutic INR and length of stay were also significantly decreased.1

Another study found the rate of thromboembolism, major bleeding, or INR>5 decreased by 32% with pharmacist intervention.2 A meta-analysis including 646 patients also showed a significantly increased percentage of time in the therapeutic range with pharmacist-managed warfarin.3

Objectives: The objective of this study is to evaluate the efficacy of pharmacist warfarin monitoring by assessing two items: 1) the time in days to therapeutic INR for patients who are new starts or had INRs <1.5 upon admission by assessing percentage of patients at therapeutic goal by day 5 and 2) percentage of time in goal INR range. Secondary objectives will be to assess length of stay and safety measures, including significant bleeding events and frequency of supratherapeutic INRs.

Methodology: A clinical pharmacist at Richmond Medical Center will be reviewing a list of inpatients on warfarin therapy every day. All adult inpatients on warfarin therapy (new starts and continuations) will be included, with the exception of surgical patients or those with warfarin intentionally held or discontinued not due to elevation in INR. The pharmacist will evaluate the charts for each patient and using both clinical judgment and a provided dosing protocol, will assess if the warfarin dose ordered for a patient is appropriate. If not, the pharmacist will contact the provider and make a recommendation. All recommendations and changes will be documented in the electronic medical record and evaluated. A retrospective chart review from September 2015 – August 2017 will also be performed to evaluate the primary and secondary outcomes before pharmacist intervention began. The data will then be analyzed to compare patients before and after pharmacist warfarin monitoring was implemented.

Results and Conclusions: Pending

References:
Background: Neuromuscular blocking agents (NMBAs) are used as an adjunct to general anesthesia to facilitate rapid sequence and routine tracheal intubation, as well as to provide skeletal muscle relaxation during surgical procedures or mechanical ventilation. At the end of surgical procedures, the complete return of neuromuscular function should be achieved unless mechanical ventilation is planned. Residual neuromuscular block following surgery, also known as postoperative residual curarization (PORC) is associated with muscle weakness, oxygen desaturation, pulmonary collapse and acute respiratory failure. Within the Cleveland Clinic Health System (CCHS), the use of sugammadex (Brindon®; Merck & Co., Inc.) has increased markedly over the past year. Because there are currently no health system protocols, guidelines, or formulary restrictions describing which agent should be used for which patient population, it is largely the anesthesiologist’s discretion on whether neostigmine or sugammadex is administered. Additionally, the majority of the current published literature defines adequate neuromuscular blockade by a train of four ratio (TOFR) measured by accelomyography. Accelomyography is a technique that is not widely utilized by anesthesiologists. This study aims to examine extubation rate as a marker of neuromuscular blockade reversal, which would allow for a greater real-world understanding of the effectiveness of sugammadex versus neostigmine for neuromuscular blockade reversal.

Objectives: The goal for this study is to compare the effectiveness of sugammadex versus neostigmine for neuromuscular blockade reversal in Cleveland Clinic operating rooms. The primary objective is to compare the rate of extubation in patients who received sugammadex versus neostigmine in operating rooms. Secondary objectives include evaluating the adverse effects and to compare the time to complete reversal following administration of sugammadex versus neostigmine.

Methodology: This is a retrospective, non-inferiority trial including patients within the CCHS. Patients will be identified into the study based upon the administration of neostigmine between May 1, 2015–April 30, 2016 or sugammadex between June 1, 2016–May 31, 2017. Patient data will be retrieved using Advanced Clinical Guidance (ACG) and from the shared medical record (Epic). Non-inferiority will be concluded if the 2-sided lower bound of the 95% CI for the differences in extubation rate is no greater than 10% lower than sugammadex. An estimated 384 patients are required to achieve 80% power to detect the non-inferiority margin. A propensity score will be used to match patients’ baseline characteristics. An intention-to-treat and per-protocol analysis will be conducted, with per-protocol defined as no crossover between reversal agents and patients must have received a full dose of reversal agents. The primary endpoint will be analyzed using a paired Chi-square test and secondary endpoints will be analyzed using descriptive statistics, the student’s t-test, and the Kaplan-Meier survival analysis.

Results and conclusions: Pending

References:
Pre-transplant vaccination adherence in pediatric solid organ transplant patients at a large academic medical center

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PGY-1 Pharmacy Practice Resident
Research Site: Cleveland Clinic (Main Campus) Cleveland, Ohio

Background: Historically, adherence rates for recommended pre-transplant vaccinations in pediatric patients has been low.\(^1\)\(^-\)\(^3\) Recent studies demonstrate pre-transplant vaccination adherence rates are highly variable and dependent on specific hospital practices.\(^4\)\(^-\)\(^6\) Cleveland Clinic uses an interdisciplinary team approach to optimize care for pediatric solid organ transplant patients. Adherence rates for pre-transplant vaccinations in this population has not been described previously at Cleveland Clinic Children’s Hospital (CCCH). This study aims to describe individual pre-transplant vaccination adherence rates for select vaccines at CCCH solid organ transplant center. The results of this evaluation will be used to identify potential opportunities to improve pre-transplant rates at our institution.

Objectives: The primary objective of this study is to describe individual pre-transplant adherence rates for select Advisory Committee on Immunization Practices (ACIP) and Infectious Disease Society of America (IDSA) recommended vaccinations (hepatitis B, influenza, pneumococcal conjugate vaccine, and pneumococcal polysaccharide vaccine) in pediatric heart, kidney, liver, or multi-visceral/intestinal transplant patients at CCCH. Secondary objectives include defining the pre-transplant adherence rate to hepatitis A vaccination for at-risk patients, differentiating patients who were partially adherent due to early transplantation or due to non-compliance/loss to follow-up, identifying the percentage of patients with an infectious diseases pre-transplant evaluation, and describing adherence rates across the different solid organ transplantation teams.

Methodology: This retrospective cohort study will include patients who underwent initial pediatric heart, kidney, liver, or multi-visceral/intestinal transplantation at CCCH between January 1, 2014 and July 31, 2017. Data collection will be conducted via manual chart review and the Ohio Department of Health ImpactSIS (Statewide Immunization Information System). Important data that will be evaluated includes patients’ demographics, CCCH transplant related data, immunization administration history, and laboratory quantitative or qualitative values pertaining to vaccine efficacy. The authors anticipate analyzing approximately 35 to 40 patients. Statistics will be descriptive in nature and data will be reported as number (percent), median (interquartile range), or mean ± standard deviation, as appropriate.

Results and conclusions: Pending

References:
Geriatrics Polypharmacy Post-Discharge Clinic

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Background: Hospitalization can be a confusing and frightening experience for patients. Discharge can be especially overwhelming as medication changes are often made, warranting adjustments to home regimens. Patients are counseled by a pharmacist at hospital discharge to review medication changes, however, studies show that 40-80% of medical information provided by healthcare practitioners is forgotten immediately, and half of the remembered information is incorrect1. Factors such as mode of information, health-literacy, and age can provide further barriers to patient understanding2–3. The Geriatrics Evaluation and Management (GEM) Unit at the Louis Stokes Cleveland VA Medical Center is an 8-bed, sub-acute rehabilitation unit run by an interdisciplinary team of healthcare professionals that treat a targeted group of predominately older patients, and others with medical complexity. The Unit consists of a geriatric attending physician and fellow, geriatric pharmacist and resident, psychology resident, nurse practitioner, and medical students. The team specializes in the clinical assessment and care management of geriatric patients, including services such as discharge counseling by the pharmacist, and transitions to post-discharge care. The purpose of this quality improvement project is to pilot a pharmacist-driven Geriatric Polypharmacy Post-Discharge Clinic for patients discharged from the GEM unit.

Objectives: The primary objective of this quality improvement project is to pilot a pharmacist-driven Geriatric Polypharmacy Post-Discharge Clinic, implement a standardized process to guide clinicians through patient inclusion and appointment structure, and evaluate the number of patients and number of interventions the service would sustain.

Methodology: This quality improvement study will utilize prospective data collection and intervention tracking. Geriatric patients who are discharged from the GEM unit and followed by our outpatient geriatric clinic will be included. Patients will be excluded if they are discharged to the Community Living Center (CLC) or non-VA nursing home. Patients who meet the inclusion criteria will be identified on GEM rounds. A consult will be placed at the time of discharge. The patient will be scheduled to meet with the pharmacist one hour prior to the physician clinic appointment. This process implementation study will evaluate the number of patients captured, any barriers to patient care, and the resulting improvements made to the clinic design. A customized “Pharmacy Post-Discharge Note” will be utilized to collect visit information. The number and type of interventions made will be documented using the PhARMD tool. A “Post-Discharge Hand-Off Summary” will be used to communicate to the physician any medication-related problems identified during the meeting, as well as any recommendations.

Results and Conclusions: Pending

References:
Mirtazapine versus SSRIs, SNRIs, and bupropion for the treatment of depression and suicidal ideation in patients with suspected sleep apnea

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Background:
Sleep apnea is prevalent within the United States, affecting 13% of men and 6% of women within the general adult population. While sleep apnea is commonly comorbid with several chronic health conditions, recent studies have also shown an association between sleep apnea and mental health conditions. Among mental health conditions, the most highly comorbid appear to be mood, anxiety, and post-traumatic stress disorder. Because of the association between sleep apnea and mood disorders, suicidal ideation and behavior has also been examined in patients with sleep apnea; however, data pertaining to suicidal ideation in these patients is limited to smaller studies and case reports. Currently, there are no published studies which look at potential pharmacotherapy as a way to ameliorate suicidal ideation in patients with diagnosed or suspected sleep apnea. The aim of this study is to evaluate pharmacotherapy options for treatment of both major depressive disorder (MDD) and suicidal ideation in patients with suspected sleep apnea.

Objectives:
The objective of this study is to evaluate if mirtazapine is a more effective treatment option for patients with MDD and suspected sleep apnea who have also been screened for suicide risk versus SSRIs, SNRIs, and bupropion. The primary endpoint is a reduction in suicidal ideation indicated by Clinically Useful Depression Outcome Scale (CUDOS) questions 14 and 15. Secondary endpoints include assessing use of mental health services, concomitant treatment of sleep apnea, patient medication history for treatment of MDD, dose and duration of pharmacotherapy treatments MDD, patient adherence to treatment, and adverse effects of pharmacotherapy treatments for MDD.

Methodology:
This study is retrospective chart review including patients from November 2015 to September 2017. Patients will be included if they are at least 18 years old, have a diagnosis of MDD and suspected or diagnosed sleep apnea, and recorded use of mirtazapine, SSRI, SNRI, or bupropion for the treatment of MDD. Patient charts will be reviewed in the electronic medical record and the data collected on prescribed antidepressant medications, CUDOS scores, and mental health utilization (inpatient psychiatry hospitalizations, ER usage, crisis hotline calls). It is estimated that 40 patients will meet inclusion criteria. Data will be analyzed using descriptive statistics and paired sample t tests.

Results and conclusions: Pending

References:
Potential Impact of Rapid Diagnostics for Treatment of Gram-negative Bacteremia

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PGY-2 Specialty: Infectious Diseases

Research site/ Institution: Louis Stokes Cleveland VA Medical Center (LSCVAMC)

Background: Gram-negative bloodstream infections (BSIs) treated with inappropriate antimicrobial therapy are associated with significantly higher rates of mortality as compared to patients treated with appropriate antimicrobial therapy. Traditional microbiology testing procedures require at least 24 to 72 hours to report the identification (ID) of the organism and the antimicrobial susceptibilities. Rapid molecular diagnostic tests have made it possible to receive results within hours. The Accelerate PhenoTest™ BC Kit (Accelerate Diagnostics, Inc., Tucson, AZ, USA) is an automated molecular diagnostic test for the ID and antimicrobial susceptibility testing (AST) for organisms isolated directly from blood cultures. The test provides ID within 90 minutes and AST within 7 hours; therefore, the Accelerate PhenoTest™ provides the opportunity to potentially decrease the time to optimal antimicrobial therapy.

The aim of this study is to determine the potential impact of Accelerate PhenoTest™ on time to de-escalation of therapy and the initiation of targeted therapy in patients with Gram-negative bacteremia.

Objectives: The primary objective of this study is to determine the potential impact of Accelerate PhenoTest™ versus standard microbiology laboratory testing methods at the LSCVAMC. Primary endpoints include time to organism ID and AST, and time to effective and/or optimal antimicrobial therapy. Secondary endpoints include all-cause mortality, infection-related mortality, length of stay, and ICU length of stay.

Methodology: This is a retrospective chart review including adult patients from January 2016 through September 2017 with at least one positive blood cultures with an organism detectable by the Accelerate PhenoTest™: Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterobacter cloacae, Enterobacter aerogenes, Proteus spp., Citrobacter spp., Serratia marcescens, Pseudomonas aeruginosa, and Acinetobacter baumannii. Standard microbiology laboratory procedures were used for ID and AST of organisms (pre-intervention). This same patient population was used to predict the theoretical primary endpoints if Accelerate PhenoTest™ were used, according to operating procedures (theoretical post-intervention). Patients were excluded if they expired or discharged before culture results, transferred from an outside facility, on hemodialysis, or an outpatient at the time of blood culture positivity. Effective therapy was defined as antimicrobial therapy that is active against the organism based on antimicrobial susceptibility results. Optimal therapy was defined as de-escalation or escalation of empiric therapy to active antimicrobial therapy based on a verified antimicrobial spectrum of activity scale.

Results and conclusions: To be presented at the 2018 Spring OCCP Meeting

References:

Therapeutic Anticoagulation in a Pediatric Patient Population

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Background:
Pediatric patients at the highest risk for venous thromboembolism (VTE) events include those with hematologic malignancies, undergoing surgical procedures, inflammatory bowel disease, obesity, congenital heart disease, or venous catheterization.\(^1\)\(^-\)\(^2\) Common anticoagulants of choice in the pediatric population include warfarin and heparin. There are currently no universally accepted guidelines that dictate pediatric dosing, both initial and maintenance, of these medications.\(^1\) The goal of treatment is to either prevent a VTE event or, if an event occurs, prevent the extension of the thrombus as well as postphlebitic syndrome (PPS). There is evidence to support the idea pediatric patients are sub-therapeutically anticoagulated, and therefore, not optimally treated.\(^3\) The consequences associated with VTE necessitate better understanding and management of anticoagulation in this patient population. Currently, Cleveland Clinic Children’s Hospital does not have dosing guidelines or pharmacist-managed services for warfarin or heparin. The aim of this study is to assess the time it takes for patients to achieve their first therapeutic anticoagulant goal with the previously mentioned agents. This will lead to a better understanding of current patient treatment practices and identify if there is need for innovative management techniques, such as pharmacist-led anticoagulation services or a standardized pediatric heparin nomogram, to ensure optimal care and treatment of patients.

Objectives: The primary objective of this study is to evaluate the effectiveness of heparin and warfarin dosing strategies in an inpatient pediatric population. The primary endpoint is time in hours from initiation of therapeutic anticoagulation to first therapeutic level in patients treated with heparin or warfarin. Secondary endpoints include the percent change in and number of dose adjustments from initial dose to administered dose at time of first therapeutic level, percentage of treatment time within therapeutic range with warfarin therapy, and number of readmissions related to either bleeding or recurrent or worsening VTE within 90 days of anticoagulant initiation.

Methodology: A retrospective chart review will be performed for all pediatric patients from July 1, 2012 until July 1, 2017 who were prescribed either therapeutic heparin and/or warfarin while admitted to the Children’s Hospital. It is estimated 150 patients will meet the inclusion criteria. For primary evaluation, the initial medication dose (per kg), the amount of medication bolused (if applicable), the date and time of first medication administration, baseline monitoring values (aPTT, INR, antiXa), subsequent monitoring values, date and time of first monitoring value within target goal range, and medication dose (per kg) at time of first therapeutic goal will be collected. Secondary endpoints of interest include the medication dose (per kg) both before and after monitoring values result, treatment time within therapeutic range for warfarin therapy, and ICD-9 and -10 codes for any readmission within 90 days of anticoagulation initiation.

Results and conclusions: Pending

References:
Ascorbic Acid, Thiamine, and Hydrocortisone: Targeted Therapy for the Management of Septic Shock

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Research Site: St. Elizabeth Youngstown Hospital

Background: Sepsis accounts for approximately 15 per 1000 hospital admissions in the United States. The incidence has continued to rise over the last decade, likely the result of advancing population age, increased use of immunosuppressants, and the emergence of multidrug resistant infections. According to the Third International Consensus Definitions for Sepsis and Septic Shock, sepsis is defined as: “life-threatening organ dysfunction caused by a dysregulated host response to infection”. The Surviving Sepsis Campaign, recently published in 2017, details the current management of sepsis and septic shock. Evidence-based treatment of sepsis includes adequate fluid resuscitation, appropriate and timely antibiotic initiation, use of vasoactive agents to ensure tissue perfusion, and the addition of corticosteroids in select patients. Despite widespread adoption of the Surviving Sepsis Campaign recommendations, mortality rates in patients with septic shock remain in excess of 40%. One of the challenges in the management of sepsis is the complex pathophysiology driving this disease state. Septic shock is the result of vasodilation due to excessive vasoactive substances and hyporesponsiveness of the vasculature, immunosuppression, endothelial dysfunction, tissue hypoperfusion, hypercoagulation, and excessive release of proinflammatory mediators. The treatment of sepsis is complex and multifaceted, but often fails to achieve desired outcomes. For this reason, clinicians are challenged to consider innovative strategies targeting the multifactorial pathophysiology of sepsis. Some limited clinical evidence suggests that antioxidant therapy may affect mechanisms of sepsis not completely reversed by fluids, antibiotics, and vasopressor therapy. A recent study published in CHEST evaluated ascorbic acid, thiamine, and hydrocortisone in patients with severe sepsis and septic shock and demonstrated a significant reduction in hospital mortality (40.4% vs 8.4%, p= 0.002).

Objective: To investigate the impact of a novel sepsis treatment comprised of ascorbic acid, thiamine, and hydrocortisone, in addition to standard care, on mortality in patients with septic shock

Methodology: This is a before and after studying comparing a retrospective cohort to prospectively treated patients receiving standard care for septic shock with the addition of intravenous ascorbic acid, thiamine, and hydrocortisone. Criteria for inclusion in the study includes a diagnosis of septic shock, lactate > 2 mmol/L and a SOFA score > 2. Patients will be excluded if they are less than 18 years of age, have limitations of care, or if the protocol is initiated > 24 hours after the start of vasopressor therapy. Study patients will be identified utilizing a daily computerized report of active orders for vasopressor therapy. Patients receiving vasopressors will be evaluated for inclusion criteria. Upon enrollment, study medications will be initiated including: ascorbic acid 1500 mg IV every 6 hours for 4 days, thiamine 200 mg IV every 12 hours for 4 days, and hydrocortisone 50 mg IV every 6 hours. Hydrocortisone will be started if fluid resuscitation and vasopressor therapy are unable to achieve hemodynamic stability. The primary outcome of the study is hospital mortality. Secondary outcomes include: length of intensive care unit and hospital length of stay, duration of vasopressor therapy, and development of organ dysfunction.

Results and conclusions: Pending

References:
Evaluation of an outpatient pharmacist consult service at the Cleveland Clinic Health System.

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PGY-1 Community Pharmacy Resident

Cleveland Clinic ambulatory pharmacies in Beachwood, Independence, Strongsville and Twinsburg, OH.

**Background:** Community pharmacists are unique and accessible members of the patient’s ambulatory healthcare team. Pharmacist roles continue to expand with the implementation of consult agreements, allowing pharmacists to provide additional services to patients in ambulatory care settings. Medication therapy management (MTM) services have increased significantly over time, with 60% of pharmacists providing MTM in 2014, compared to 13% in 2004. Benefit-generated MTM referrals may include ineligible patients with questionable relevance to providers and pharmacists, while consult services recommended to the pharmacist by the provider would create a new method for clinically-relevant MTMs to be conducted. Provider recommended consults have the opportunity to increase provider satisfaction with pharmacist provided services, improve patient education and reduce the need for additional appointments. The outpatient pharmacists at Cleveland Clinic have access to the electronic medical record (EMR) evaluate patient medications, labs and office visit progress notes to provide more comprehensive MTM services. A pilot outpatient pharmacist consult service was initiated at 4 outpatient pharmacies in August 2017. It is our goal to evaluate this outpatient pharmacist consult service to determine if implementation across all Cleveland Clinic pharmacies is feasible and to determine impact on patient affordability of medications, pharmacist and provider satisfaction, and provider acceptance of pharmacist recommendations.

**Objectives:** The primary objective of the study is to characterize the types and duration of consult services conducted by outpatient pharmacists. Secondarily, provider acceptance of pharmacist’s recommendations, cost-savings to patients, and provider and pharmacist satisfaction will also be assessed.

**Methodology:** This is a retrospective review of an ongoing, quality improvement, pilot program. Adult patients with a consult completed at Cleveland Clinic outpatient pharmacies in Beachwood, Independence, Strongsville, or Twinsburg, Ohio from September 21st, 2017 to January 31st, 2018 will be included. Patients will be excluded if they had a consult completed at a site other than the 4 pilot sites. We estimate 200 patients will have completed consults across the 4 sites based on current volume. Data will be analyzed using descriptive statistics.

**Results and conclusions:** Pending

**References:**
External validation of a hypoglycemia risk model in patients admitted to medical/surgical units

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PGY-1 Pharmacy Practice Resident
Research Site: Cleveland Clinic Akron General

**Background:** Diabetes is a growing problem in the United States, with an estimated 30.3 million people having diabetes in 2017. With multiple complications and indications for hospitalization for diabetes, there is a need to focus resources on the aspects with the greatest potential impact to the patient and the healthcare system. Many complications, such as cardiovascular conditions, are associated with uncontrolled diabetes for an extended period of time. Conversely, there are growing numbers of emergency room visits due to hypoglycemia compared to hyperglycemia. The rate of hospitalization due to hypoglycemia increased by 11.7% from 1999 to 2011 in individuals older than 65 years, compared to a 38.6% reduction in the rates of hospitalization for hyperglycemia in the same patient population. The rates for hypoglycemia were 2-fold higher in patients greater than 75 years of age. Efforts have been made to predict the risk of an individual developing severe hypoglycemia (blood glucose <40 mg/dL) while being admitted to the hospital. A model was created and tested on patients in a Mid-Western academic teaching hospital to predict the odds of a patient developing severe hypoglycemia during their hospital stay. The model was able to correctly predict severe hypoglycemic episodes 70% of the time, and the protocol that was established from this model was able to reduce the incidence of severe hypoglycemia by 68% at their hospital. This model has been proven to work at a single health system but has not been externally validated to determine its efficacy at other institutions. The aim of this study is to externally validate the hypoglycemia risk model in a community teaching hospital.

**Objectives:** The objective of this study is to externally validate a risk model for a patient developing severe hypoglycemia while admitted to the medical/surgical units of a community teaching hospital. The primary outcomes are sensitivity, specificity, positive predictive value, and negative predictive value of the model, with regard to predicting severe hypoglycemia in the patient population at our hospital.

**Methodology:** This is a retrospective chart review of patients admitted to a medical/surgical unit between January 1, 2016 and December 31, 2016 who are prescribed any antidiabetic agent and develop a blood glucose value of <90 mg/dL at any time during the hospitalization.

**Results and conclusions:** Pending

**References:**

Effect of phenylephrine pushes prior to continuous infusion norepinephrine in patients with septic shock

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Background: Phenylephrine is a vasoactive agent which may be administered to patients with septic shock to maintain sufficient mean arterial pressure (MAP) to preserve adequate organ function. Phenylephrine is a selective α1-receptor agonist causing vasoconstriction of large arterioles increasing afterload, however this may result in a decreased stroke volume and cardiac output in the setting of myocardial dysfunction. Recently, a large retrospective, multi-center cohort study evaluated mortality outcomes in patients with septic shock during a shortage of norepinephrine in the United States in 2011. The authors found an increase in in-hospital mortality during this shortage compared to non-shortage times (39.6% vs. 35.9%) with an absolute risk increase of 3.7% (95% CI, 1.5%-6.0%; p=0.03). Phenylephrine was found to be the most frequent vasoactive agent utilized during the shortage period, suggesting clinical concerns with the use of phenylephrine in patients with septic shock. The most recent Surviving Sepsis Campaign does not discuss or recommend phenylephrine as an option in this patient population and there are limited data comparing phenylephrine vs. norepinephrine in septic shock. However, phenylephrine intravenous pushes are utilized in practice at our institution with the goal of achieving hemodynamic stability quicker during septic shock. The aim of this retrospective study is to evaluate the clinical efficacy and safety of utilizing phenylephrine pushes prior to continuous infusion norepinephrine in patients with septic shock. Objectives: The primary objective is to compare the time to achieving hemodynamic stability in patients with septic shock who received a phenylephrine push prior to continuous infusions of norepinephrine with patients who did not receive phenylephrine pushes. The secondary objectives are to compare mortality rates, intensive care unit (ICU) and hospital lengths of stay, and vasopressor requirements between patients who received phenylephrine pushes compared to those who did not. Methodology: This is a retrospective, cohort study performed at the 10 hospitals of a large health-system. Included subjects will be ≥18 years old, who were admitted to the ICU at Cleveland Clinic Health System and received continuous norepinephrine infusions between January 1, 2012 to September 30, 2017. This study is powered using a two-sided α of 0.05, assuming a standard deviation of 4 hours. Seven hundred and fifty six patients will be required to achieve 80% power to detect a 1 hour difference in time to hemodynamic stability. A multivariable cox proportional hazard regression will be utilized to determine time to hemodynamic stability. Hemodynamic stability will be defined as the time at which continuous infusion vasoactive medications have not been uptitrated for 6 hours and MAPs are ≥65 mmHg, with hemodynamic stability defined at the start of the 6 hour period. Categorical data will be analyzed with Chi-Square test or Fisher exact test, while continuous variables will be analyzed with Student’s t-test or Mann-Whitney U test. Results and Conclusions: To be determined.

References:
Evaluation of Vaccination Coverage and Infections in Patients Undergoing Splenectomy Due to Trauma

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Background:
The spleen plays an essential role in regulating immune homeostasis by protecting the body against invasive encapsulated bacteria, particularly Streptococcus pneumoniae, Haemophilus influenzae type b (Hib), and Neisseria meningitidis. Splenic rupture due to trauma may necessitate emergent splenectomy. Asplenic patients are at an increased risk of developing overwhelming post splenectomy infection (OPSI). OPSI most commonly occurs within the first-year post-splenectomy and is associated with a mortality rate of 50-70%. The Centers for Disease Control and Prevention recommend vaccinating asplenic patients with pneumococcal, meningococcal, and Hib vaccines. Despite these vaccine recommendations, vaccination rates remain low for trauma patients at many centers.

Objectives:
The primary objective of this study is to determine the number (%) of patients who received a complete vaccination series against Streptococcus pneumoniae, Haemophilus influenzae type b, and Neisseria meningitidis after splenectomy due to trauma. Secondary objectives include the number (%) of patients who received appropriate vaccinations prior to discharge from splenectomy and the number (%) of patients who developed infections with encapsulated organisms within one year after splenectomy due to trauma.

Methodology:
The study will be submitted to the Institutional Review Board for approval. This is a single center, retrospective, descriptive chart review of adult patients who underwent emergent splenectomy due to trauma between January 1, 2012 and March 31, 2017. MetroHealth Medical Center’s trauma registry will be used to identify patients. Inclusion criteria are 18 years of age or older and emergent splenectomy due to trauma. Patients with elective splenectomy, contraindications to vaccinations, active encapsulated bacterial infection at the time of splenectomy, or pregnancy will be excluded from the study. The following data points will be collected from the electronic medical record: Age, gender, race, preferred language, allergies, indication for splenectomy, date of splenectomy, length of hospital stay, if the admission required intensive care stay, vaccination history any time prior to splenectomy, before discharge from splenectomy, and any time after splenectomy, utilization of electronic medical record order set, vaccination adverse reactions at any time, refusal of vaccination at any time, outpatient clinic visit or admission to the hospital for infection with positive culture within 1 year of splenectomy, length of hospital stay for infection, microbiology, and death from any cause. Descriptive statistics will be used to analyze the primary and secondary objectives.

Results and Conclusions:
To be presented at OCCP spring meeting 2017.

References:
Evaluation of transition from continuous insulin infusion to long acting basal insulin in the medical intensive care unit

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Background: Hyperglycemia is a common complication in critically ill patients that has been associated with increased ICU and hospital length of stay in addition to increased morbidity and mortality\(^1\). Transition from continuous insulin infusion to basal insulin is often associated with uncontrolled blood glucose levels due to ineffective dosing regimens\(^2\). A small retrospective study evaluating insulin transition at Cleveland Clinic Main Campus found that doses of basal insulin were frequently much less than 80% total insulin requirements during infusion\(^3\). The goal of this study is to determine an appropriate dosing method for transition from a continuous intravenous insulin infusion to a subcutaneous insulin regimen in patients in the medical intensive care unit.

Objectives: The primary objectives of this study are to compare rates of blood glucose control in the 36-hour transition period between patients and the incidence of hyperglycemia during the study period. The secondary objectives are to describe the incidence of hypoglycemia and severe hypoglycemia.

Methodology: This study is a retrospective chart review of adult patients in the medical intensive care unit on a continuous insulin infusion. The ICU hyperglycemia IV insulin order set administration and long acting basal insulin administration will be identified at the initial transition episode through a report from the electronic medical record. Baseline characteristics (i.e. history of diabetes, hemoglobin A1c, antidiabetic therapy prior to admission, nutritional status, and concomitant medications altering blood glucose levels) and all variables related to blood glucose control will be collected from data reports and manual chart review. The primary and secondary outcome will be analyzed using ANOVA or Kruskal-Wallis and descriptive statistics.

Results and conclusions: Pending

References:

Personalized Antimicrobial Stewardship in the Management of Hospitalized Patients with Pneumonia

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Background: Antimicrobial stewardship (AS) intervention has been shown to improve appropriate prescribing in patients hospitalized with pneumonia without negatively impacting their clinical outcomes\(^1\,^2\). Specifically in the ICU setting, prospective audit and feedback has been associated with favorable effects on clinical outcomes as well as overall antimicrobial use and emergence of antimicrobial resistance\(^3\,^4\). Despite this, barriers still exist in optimizing the management of patients with pulmonary disease\(^5\). One way to potentially improve guideline adherence and de-escalation is to enhance AS through personalized, consensus building strategies. At the University of Toledo Medical Center, pulmonary physicians are primarily responsible for the management of patients admitted to the medical intensive care unit (MICU) and pulmonary services. The (MICU) has a dedicated clinical pharmacist, however the pulmonary service does not.

Objectives: The objective of this study is to identify if the delivery of antimicrobial stewardship intervention via a dedicated clinical pharmacist improves the management of hospitalized patients with pneumonia. Additionally, the study will describe factors associated with suboptimal antimicrobial use in patients hospitalized with pneumonia.

Methodology: This IRB-approval pending study will be a retrospective cohort of all adult inpatients \(\geq\) 18 years of age who were treated with \(\geq\) 48 hours of systemic antibiotic therapy at the University of Toledo Medical Center for a primary or secondary diagnosis of pneumonia between July 1, 2012 – June 30, 2017. Included patients must be admitted to either pulmonary or MICU services and remain on that service until the time of primary outcome assessment. Patients will be excluded if they were completing a previously prescribed course of antimicrobials; were immunosuppressed; or had a pre-existing lung condition. Patients will be grouped according to the admitting service. The primary outcome is the rate of antimicrobial de-escalation at day 4 of therapy. Secondary outcomes include duration of therapy, clinical success in the clinically evaluable population, hospital and ICU lengths-of-stay, 30-day readmission and Clostridium difficile infection rates, rate of antimicrobial re-escalation, and in-hospital and 30-day all-cause mortality.

Results and conclusions: To be determined.

References:
Evaluation of 5-HT₃ Receptor Antagonists for Prevention of Chemotherapy-induced Nausea and Vomiting in Ambulatory Oncology Patients

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Research Site: Cleveland Clinic Taussig Cancer Center

Background: Chemotherapy-induced nausea and vomiting (CINV) is one of the most common adverse effects associated with chemotherapy. 5-HT₃ receptor antagonists are common agents recommended by the National Comprehensive Cancer Network (NCCN) for the prevention of acute and delayed CINV in patients receiving highly emetogenic chemotherapy regimens. A meta-analysis consisting of 2,057 patients evaluated the efficacy of palonosetron in comparison to ondansetron, granisetron, and dolasetron. The results suggested that patients on palonosetron had significantly less acute and delayed nausea and vomiting. At the Cleveland Clinic, ondansetron is standard 5-HT₃ receptor antagonist in combination with a NK-1 receptor antagonist and a corticosteroid for highly emetogenic chemotherapy regimens. Given the recent growing evidence on palonosetron and that more providers are replacing ondansetron with palonosetron, the goal of this project is to evaluate the effectiveness of our current standard 5-HT₃ receptor antagonist in preventing CINV associated with highly emetogenic chemotherapy.

Objectives: The primary objective is to evaluate the clinical outcomes of patients receiving 5-HT₃ receptor antagonists for the prevention of CINV associated with highly emetogenic chemotherapy. The primary endpoint is incidence of acute complete response to 5-HT₃ antiemetic regimen after receiving highly emetogenic chemotherapy. Secondary endpoints include incidence of nausea and vomiting events requiring hospitalization or clinic visit in a 28-day period, overall complete and delayed complete response rate at follow up, number of rescue medications used during first 24 hours and 24-120 hours after chemotherapy, and the potential costs associated with nausea and vomiting management.

Methodology: This is an observational, prospective study that will take place between October 2017 and January 2018 with an expected sample size of 50-75 patients who will meet the inclusion criteria. Patients who will receive doxorubicin and cyclophosphamide will be identified using Taussig Cancer Center daily schedule. A follow up telephone interview will be conducted between day 5 and 7 using the Multinational Association for Supportive Care in Cancer (MASCC) Antiemesis Tool, a validated tool created to assess nausea and vomiting control. A chart review using Epic (electronic medical record system) will be conducted on day 29 to identify incidence of nausea or vomiting events requiring hospitalization or clinic visit. Lastly, the costs associated with nausea and vomiting management is calculated by accounting for both service and medication costs.

Results and Conclusions: Pending

References:
1. Botrel TE, Clark OA, Clark L et al. Efficacy of palonosetron (PAL) compared to other serotonin inhibitors (5-HT3R) in preventing chemotherapy-induced nausea and vomiting (CINV) in patients receiving moderately or highly emetogenic (MoHE) treatment: systematic review and meta-analysis. Support Care Cancer. 2011 Jun;19(6):823-32
Comparison of the incidence of nephrotoxicity between two dosing regimens of piperacillin/tazobactam

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PGY-1
Research site: Cleveland Clinic – Hillcrest Hospital

Background:
Piperacillin/tazobactam (PTZ) is a semi-synthetic penicillin-β lactamase inhibitor combination with a broad spectrum of activity, including activity against *Pseudomonas aeruginosa*. Historical trials with PTZ concluded that nephrotoxicity occurred in <1% of patients. There have been several recent studies that have identified the combination of vancomycin and PTZ as having higher rates of nephrotoxicity than either agent alone, and post-marketing surveillance of PTZ has also reported increased incidence of renal failure and nephritis in patients that were receiving PTZ. A recent study in critically ill patients receiving PTZ identified it as an independent risk factor for nephrotoxicity, and this finding has led to an addition in the product’s package insert regarding the risk of nephrotoxicity in critically ill patients.

Objectives:
This study aims to compare the difference in nephrotoxicity between two different PTZ intermittent dosing strategies, according to RIFLE criteria, at two large community hospitals. Secondary objectives include: overall incidence of AKI per RIFLE criteria, stratification of AKI per RIFLE criteria, mortality @ 30 days, hospital length of stay, 30-day readmission for same or related indication, progression to hemodialysis, and return to baseline serum creatinine.

Methods:
This will be a retrospective matched cohort study conducted at two large community hospitals in Cleveland, OH between the dates of August 1, 2016 – August 1, 2017. Patients will be included if they are ≥ 18 years old, receive PTZ for > 72 hours, and received < 24 hours of concomitant nephrotoxic medications. Patients will be excluded if they are pregnant, are on hemodialysis or continuous ambulatory peritoneal dialysis at baseline, or if an extended or continuous infusion protocol was used. Cohorts will be matched based on: age, sex, duration of PTZ use, CrCl at baseline, indication for PTZ use, and ICU admission. Creatinine clearance will be calculated via the Cockcroft-Gault equation utilizing ideal body weight (IBW) (unless actual body weight is >120% of IBW, then use adjusted body weight). Acute kidney injury (AKI) will be defined by the RIFLE criteria.

Results:
Study results and conclusions will be presented upon finalization of the study.

References:
Quality Initiative Review on Statin Adherence at 90 Days Post-Discharge in ST-Segment Elevation Myocardial Infarction (STEMI) and Non-ST-Segment Elevation Myocardial Infarction (NSTEMI) Patients

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Research Site: University Hospitals St. John Medical Center (UHSJM)

Background: Barriers to medication adherence for patients continues to be an issue throughout the healthcare setting. To date, the most effective way to improve upon patient outcomes and decrease readmissions is by ensuring patients understand the importance of their medications, any potential side effects and that they have access to the medications. In a 2017 systematic review and meta-analysis evaluating adherence and persistence among statin users aged 65 and older, 48.2% were non-adherent within the first year and 23.9% discontinued altogether within the first year. A part of the Centers for Medicare and Medicaid Services (CMS) evaluates medication adherence using the Proportion of Days Covered (PDC) calculation. The PDC calculation assesses patient adherence based on the number of days that the patient was in possession of all of their medication(s). This in turn impacts the pharmacies’ Star Ratings and reimbursement rates established by Medicare. One way to increase adherence is via a Meds-to-Beds program. Recent studies have shown that as many as 50% of patients cannot recall discharge orders and of these, 70% will likely be readmitted. Pharmacists play a vital role in the importance of ensuring patients understand their new prescriptions and any potential side effects. As UHSJMC is in the development phase of a Meds-to-Beds program, the goal of this study is to establish whether patients are adherent to their statin 90 days post-discharge and any barriers to medication adherence that could be addressed via this program.

Objectives: The primary objective is to determine if STEMI and NSTEMI patients are adherent to their statin therapy after 90 days post-discharge. For those patients that are non-adherent at 90 days post-discharge, the following causes of non-adherence will be collected and reviewed: side effects, cost, logistics of picking up/receiving the medication, days supply of the prescription, and any other barriers identified by patients affecting medication adherence.

Methodology: A retrospective review of all NSTEMI and STEMI patients included in the American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR) ACTION registry discharged from UHSJMC with a prescription for a statin was collected. Data to be utilized for this review will be from January 2017 through December 2017. Patients will be called via telephone at minimum post 90 days and asked about the following information: if they are still taking their prescribed statin, the days supply that they were given at discharge, which physician they saw post-discharge and the area of specialty for this physician, if changes were made to their statin regimen, the date of the follow up appointment post-discharge, if their insurance requires them to fill their prescription using a mail order pharmacy and if they had been readmitted to the hospital. If the patients did discontinue statin therapy without a prescribers consent, a subset of questions will be asked including if cost, side effects, ease of filling/picking up the prescription and any other reasons the patient may not be taking their statin as indicated. Data will be analyzed using both descriptive and inferential statistics. Descriptive statistics will provide percentage data on the primary outcome of adherence to therapy at 90 day. Logistic regression will be utilized to see what factors may have influenced adherence to the statin therapy.

Results and conclusions: Pending
References:
3. Are Engineered Hospital Discharge Programs Decreasing Re-hospitalization, 2009; Centers for Medicare and Medicaid
Impact of Vasopressors on Post-Operative Atrial Fibrillation in Cardiac Surgery

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Background:
Postoperative atrial fibrillation (POAF) is the most common arrhythmia in the surgical setting, occurring in 3% and 40% after non-cardiac surgeries and cardiac surgeries, respectively.\textsuperscript{1,3} Patients who develop POAF may experience hemodynamic instability, reduced ventricular filling and cardiac output, and atrial pooling with predisposition to thrombus formation, and has been associated with increased morbidity and mortality, increased hospital and ICU length of stay, as well as a three-fold increase in risk of stroke.\textsuperscript{1,2} Research efforts have placed great emphasis on the prevention of POAF; however, much of this data is surrounding the preoperative and intraoperative period. In a study by Almassi and colleagues, the use of inotropes following cardiopulmonary bypass was associated with the development of POAF (OR 1.36, 95% CI 1.16 – 1.59).\textsuperscript{3} Due to the lack of data assessing the effect of post-operative vasoactive agents on the development of POAF in the cardiac surgery population, the goal of this study is to evaluate the impact of vasopressor and inotrope selection on the development of post-operative atrial fibrillation in patients.

Objectives;
Primary Objective:
- Compare the incidence of post-operative atrial fibrillation in patients following coronary artery bypass grafting (CABG) or aortic valve replacement (AVR) in cohorts receiving drug therapy combinations of norepinephrine, epinephrine, dobutamine, and milrinone, and combinations without norepinephrine

Secondary Objectives:
- Identify preoperative and intraoperative risk factors for the development of POAF
- Evaluate the effects of vasopressor combinations on 30-day mortality, 6-month mortality, and other morbid post-operative events

Methodology:
A retrospective chart review will include all adult patients who received isolated primary CABG or isolated primary AVR performed at Cleveland Clinic Main Campus from March 2015 through August 2017. Exclusion criteria include a previous diagnosis of atrial fibrillation or atrial flutter, multi-valve replacement procedures, CABG plus AVR, redo-sternotomy, or emergent salvage surgery as defined by the Society of Thoracic Surgeons (STS). Patients will be assessed by cohort based on the administration of vasoactive agent regimens: norepinephrine alone, norepinephrine and epinephrine, norepinephrine and epinephrine and milrinone, and combinations with norepinephrine. Baseline demographics, preoperative, intraoperative, and postoperative information will be collected from the STS Adult Cardiac Database and the electronic medical record. Descriptive statistics and univariate analyses will be reported for the primary outcome. A multivariable analysis using logistic regression will be completed to determine risk factors for development of POAF.

References:
Incidence of *Clostridium difficile* infection and impact of treatment with a proton pump inhibitor on recurrence at Summa Health System – Akron Campus

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PGY-1 Pharmacy Resident

Research Site: Summa Health System – Akron Campus

**Background:** *Clostridium difficile* is a Gram-positive, anaerobic bacterium nearly ubiquitous within the natural environment and is commonly found in feces. It reproduces via formation of spores, which can remain viable for up to several months on inhospitable surfaces, and survive cleansing via alcohol-based hand sanitizer. *Clostridium difficile* infection (CDI) is the most common health care-associated infection. CDI may occur in the community setting, often as a result of contact with the healthcare system. Most often, CDI is associated with hospitalization. There are multiple well-established risk factors for CDI, including treatment with an antibiotic, immunodeficiency, chronic systemic corticosteroid use, and proton pump inhibitor (PPI) use. CDI causes significant morbidity and mortality, and is responsible for approximately 453,000 infections and 29,300 deaths per year. 1 out of every 5 patients with CDI experience recurrence; 1 out of 11 patients over 65 years of age die within 30 days of diagnosis. *Clostridium difficile* associated disease (CDAD) is estimated to cause a $4.8 billion burden to the acute care system within the U.S. alone. Incidence of both CDI, and multiply recurrent *Clostridium difficile* infections (mrCDI) are increasing. Summa Health System – Akron Campus currently tracks CDI recurrence through 4 weeks, but not beyond; the rate of CDI recurrence at 60, and 90 days is currently unknown. The risk of PPI use with regard to recurrent CDI remains to be elucidated in the patient population at Summa Health. It is also unclear how many patients with CDI or recurrent CDI are taking a PPI, and how often PPIs are discontinued in patients with CDI.

**Objectives:** The objective of this study is to assess whether patients with previous CDI who were put on a PPI were more likely to experience CDI recurrence than patients not taking a PPI. The primary endpoint is the rate of CDI recurrence in patients taking a PPI compared to patients not taking a PPI. Secondary endpoints include the overall rate of CDI recurrence and comparative risk between groups within 30, 60, and 90 days, the percentage of patients with recurrent CDI taking a PPI at the time of recurrence, and the percentage of PPI discontinuation in patients with CDI and recurrent CDI.

**Methodology:** This is a retrospective cohort study requiring review of inpatient medical charts through Mercy Health CarePATH EPIC and Allscripts CPOE September 1st 2015 to September 1st 2017 who were diagnosed with CDI. PPI use will be assessed in patients diagnosed with CDI via Illumigene® PCR assay, and will be defined as administration of ≥ 3 doses of a PPI while inpatient. Once patients are stratified based on PPI use vs. no PPI use, recurrence will be defined as a positive *C. diff* PCR result ≥ 14 days after the initial CDI. Any differences in CDI risk factors or baseline characteristics will be accounted for through logistic regression. Preliminary data from Summa infection control estimates approximately 650 patients with CDI during this 2 year timeframe. Based on a retrospective cohort study by McDonald et al., it is estimated that 60.7% of study participants are likely to be on a PPI, and 28.8% of these patients will likely experience recurrence. A Chi squared test will be used to determine statistical significance of the primary endpoint. Relative risk will be used to determine the risk of recurrence with PPI use vs. no PPI use with a 95% confidence interval. This study has been approved as a quality improvement initiative, as Summa currently does not track CDI recurrence beyond 30 days and the proportion of patients with CDI taking a PPI as well as the discontinuation rate of PPIs up diagnosis of CDI are unknown.

**Results and conclusions:** Pending

**References:**

The Effect of a Therapeutic Guideline on Discharge Pain Prescriptions from an Emergency Department

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Background: The abuse of opioids has dramatically increased leading to increased overdose deaths. The Center for Disease Control and Prevention (CDC) reports a 2.5-fold increase in age-adjusted rates of overdose-related deaths from 1999 to 2015. Many national and state level practice-based guidelines were implemented to encourage proper prescribing of opioids. The purpose of this study is to evaluate whether the implementation of a therapeutic guideline based on patient-specific pain levels will more appropriately assist providers with the treatment of patients’ pain at discharge from the ED.

Objectives: The primary objective for this study is the percent change in total oral milligrams of morphine equivalents (MME) prescribed to a patient at discharge from the ED. Secondary objectives include provider satisfaction, percent change in classes of pain medications prescribed, and differences in prescribing patterns among the various provider types.

Methodology: This will be a retrospective cohort study evaluating the differences in discharge prescribing habits from the ED after implementation of a therapeutic guideline. The therapeutic guideline was created using the current treatment guidelines for acute, chronic, and specific pain pathologies. It was designed to create a patient-specific outpatient treatment regimen from his or her individual ED pain requirements. Included in the guideline is an opioid conversion table to assist providers with intravenous to oral converting. Education regarding the guideline was provided at an ED provider staff meeting and physical copies were posted in common areas throughout the ED and available as a pocket guide. The opioids recommended in the guideline have low street-value in hopes to reduce the illegal selling of opioid medications. The pre-guideline implementation period will be from November 1st, 2016 to January 31st, 2017 and the comparator, post-guideline implementation period will be from November 1st, 2017 to January 31st, 2018. Patients receiving treatment for pain both in the ED and at discharge during these time periods will be included in the study. Exclusion criteria include patients younger than 18 years, those with cancer-associated pain, and pregnant patients. A report through the electronic medical record (EMR) system will be run to collect any patient receiving pain medications meeting this criteria. Demographic patient data, outpatient pain prescriptions including therapeutic class and MME per prescription, provider prescribing records and provider satisfaction survey data will be collected. Data will be recorded and maintained in Research Electronic Data Capture (REDCap). Student t-tests will be used to analyze continuous data, and Wilcoxon rank sum test and analysis of variance will be used for ordinal data. Regression analysis will be completed to account for confounding factors including provider ED practice experience.

Results and Conclusions: Pending

References:
Assessing Retention of Anticoagulation Knowledge in an Outpatient Pharmacist-Run Anticoagulation Clinic

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Background: Warfarin is still the mainstay of oral anticoagulant treatment. Safe and effective oral anticoagulation therapy requires an individualized approach to each patient’s past medical history, indication for treatment, and risk factors for bleeding. Though patients are given initial, comprehensive education, recalling key components of this instruction can still be challenging. Most educational materials are often provided at a ninth-grade reading level, but may still be rendered as inaccessible to the average US resident.\(^1\) Studies have found that a lack of patients’ knowledge of warfarin therapy directly correlates to poor adherence, and consequently poor anticoagulation management and control.\(^2\)\(^-\)\(^3\) There is limited literature suggesting the best means of measuring the adequacy of knowledge obtained from initial start of warfarin therapy to several months after initiation. Several validated questionnaires have been used in the past, and all assess similar components of warfarin therapy, though can take up valuable clinic time. The Short Oral Anticoagulation Knowledge (SOAK) test is a 10-item questionnaire that has been validated and takes 3-5 minutes to complete.\(^4\)

Objectives: The purpose of this study is to ascertain patients’ retention of anticoagulation knowledge who are newly initiated or referred on warfarin in pharmacist-run anticoagulation clinics. The primary objective will be to compare scores of the SOAK questionnaire at baseline and at two months post-referral in the pharmacist-run anticoagulation clinics. Secondary objectives include evaluating the association of follow-up anticoagulation knowledge retention scores with scores assessing health literacy. This study will also evaluate the association of scores assessing anticoagulation knowledge with the number of anticoagulation clinic encounters as documented in the electronic health record.

Methodology: This study application was submitted for approval to the IRB on September 26, 2017. It will be a multicenter, prospective, pre- and post-survey descriptive study as newly referred naïve anticoagulation patient referrals to the Cleveland Clinic anticoagulation clinics will be targeted. Patients will watch the standard warfarin patient education video that is administered to all Cleveland Clinic patients. Immediately following this video education, they will be given the initial SOAK questionnaire with a single-item health literacy screening question. Face-to-face pharmacist counseling will follow at the first visit. Patients will return for multiple follow-up encounters with the anticoagulation clinic per standard of care. After >60 and ≤90 days, patients will return to the clinic and be given an identical, follow-up SOAK questionnaire to assess knowledge retention.

Results and conclusions: Pending evaluate

References:
1. Collins S, Barber A, Sahm LJ. Pharmacist’s counselling improves patient knowledge regarding warfarin, irrespective of health literacy level. Pharmacy 2014, 2(1), 114-123
Review of the Management of Acute Agitation in the Inpatient Setting Following the Implementation of a Pilot Emergency Department (ED) Acute Agitation Protocol

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Background: Intramuscular (IM) ziprasidone, an atypical antipsychotic, is being used often for acute agitation at University Hospitals St. John Medical Center (UHSJMC). As IM ziprasidone is not indicated first-line for the management of acute agitation and the higher cost associated with this formulation, a review of its use was conducted. From this review, it was discovered that IM ziprasidone use in the ED only accounted for about a quarter of overall use. An original acute agitation protocol was then developed for the ED which was extrapolated for inpatient use. The purpose of this study is to evaluate if the implementation of an acute agitation protocol in the inpatient setting helps reduce the unnecessary use of IM ziprasidone.

Objectives: The primary objective of this study is to evaluate the amount of IM ziprasidone used for patients admitted in-house pre- versus post-implementation of the acute agitation protocol. Furthermore, it will be determined if the acute agitation protocol was followed that only allows one dose of IM ziprasidone without a psychiatric consult.

Methodology: A retrospective chart review will be conducted from November 2016 to March 2017 (pre-agitation protocol) and November 2017 to March 2018 (post-agitation protocol) for patients who received IM ziprasidone at UHSJMC. The data will be reviewed through the electronic medical records (EMR) of patients who received IM ziprasidone and stored in a secured document. Information that will be collected include: patient age, sex, QTc level, past psychiatric history, antipsychotic agents used, timing of administration of antipsychotic agents, doses dispensed, psychiatry consult, location of patient, and any other important information. Data will be evaluated to assess the amount of overall IM ziprasidone utilized using descriptive and inferential statistics. Mann Whitney U will be used to compare the pre-post data after the protocol implementation. A logistic regression analysis will be completed to determine factors that influenced compliance with the one dose protocol prior to psychiatric consult.

Results and conclusions: Pending

References:

Utilizing bedside auditing of infusion pumps to evaluate programming compliance and drug library accuracy

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PGY-1
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Background: From 2005 through 2009 the FDA received an estimated 56,000 infusion pump related adverse event reports, which included injuries and deaths. Numerous medications infused through smart pumps are considered high-alert medications where more harm can occur with an error. Smart pump technology may show how pumps are programmed by the end user. Some nursing leaders view using the smart pump drug library for every infusion a professional obligation. At University Hospitals Alaris smart pumps are used system wide. This smart pump technology affords patient safety by the drug library, known as guardrails in Alaris pumps. The technology also serves as a secondary form of documentation as all data programmed into the pumps is retrievable. Despite infusion drug libraries providing safety features, pumps may still be used in basic infusion therefore, bypassing the intended protection. Basic infusion negates the safety features built into the smart pumps and relies on the nurse to input all infusion details including volume and rate. The accuracy of the drug library has to be maintained in order for nurses to be compliant in the programming of infusions. University Hospitals set a system compliance goal of 90% with the basis of compliance being, programming pumps through the drug library. This goal was achieved and sustained at University Hospitals Rainbows Babies and Children by bedside auditing. The intensive care unit can be a great target for bedside auditing due to the large volume of high risk drug infusions in acute care patients. The goal of this project is to repeat the bedside auditing at Ahuja Medical Center to achieve the system compliance goal of 90% in the ICU.

Objectives: The objective of this project is to increase the amount of infusions programmed through the drug library. The primary endpoint is percent compliance of infusions programed with guardrails. The secondary endpoint is the percent of infusions programmed through basic infusion that University Hospitals has listed as high alert medications.

Methodology: This project will involve twice weekly bedside auditing of programmed infusion pumps lasting for a total of 10 weeks in the intensive care unit. Auditing tool will be used to identify infusions that are not programmed through the drug library. Infusions that are inappropriately programed will be documented for follow up. Inappropriate programming practices will be reported weekly to the nursing manager to address nursing practices. Drug library follow up will be done by alerting the system drug librarian on proposed improvements. An estimated 250 individually programed infusions will be audited over the 10 week period. Goal is to see ICU percent compliance to improve to 90%.

Results and conclusions: Pending

References:
1. Infusion Pumps. [Internet]. Silver Spring (MD): U.S Food and Drug Administration, Division of Industry and Consumer Education. [2016]- [cited 2017 October 04]. Available from: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/
Association of average tacrolimus concentrations in the first twelve months post-transplant and long-term graft survival in kidney transplant recipients.

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Background: Kidney transplant is the best therapy available for most patients with end-stage kidney disease as it improves quality of life and prevents the need for long term dialysis. The National Kidney Foundation recently reported that approximately 100,791 people await a kidney transplant, with a median wait time of approximately 3.6 years. The national 1-year and 5-year graft survival rates for patients following kidney transplant is 96.5% and 83.9% for deceased donors, and 98.8% and 92.4% for living donors, respectively. Short-term outcomes following kidney transplant, including acute rejection and one-year graft survival, have dramatically improved over the past several decades, in large part due to improvements in post-transplant immunosuppression therapy. A staple of many post-transplant immunosuppression therapies has become the calcineurin inhibitor tacrolimus. Due to its narrow therapeutic index, trough concentrations are closely monitored to minimize adverse effects and optimize efficacy. Despite this, specific tacrolimus trough levels that minimize a patient’s risk of acute or chronic rejection have yet to be identified.

Objective: To evaluate the association between average tacrolimus trough concentrations during the first 12 months post-transplant and long-term graft loss.

Methodology: Patients 18 years and older who underwent a renal transplant between October 1, 2006 to July 31, 2016, received alemtuzumab induction therapy, and received tacrolimus and mycophenolate for maintenance therapy at University of Toledo Medical Center were eligible for inclusion. Patients were excluded if they were treated with agents other than tacrolimus, mycophenolate and prednisone for long-term immunosuppression, those pregnant or breast-feeding, those with documented allergy to agents in the post-transplant protocol, patients without sufficient outpatient labs, and those without a one-year tacrolimus level. A mean tacrolimus trough level will be calculated for each patient based on values obtained throughout the 12-month post-transplant period. Tacrolimus concentrations at 12 months will then be stratified into quartiles and compared to the mean tacrolimus trough. Kaplan-Meier curves will be used to analyze the probability of graft loss over time. The primary endpoint will be to compare the incidence of death-censored graft failure based on average tacrolimus trough concentrations. Secondary endpoints will include the incidence of acute rejection episodes and adverse effects, including new onset diabetes mellitus, hyperlipidemia, and opportunistic or surgical site infections over the 12 months post-transplant. A sub-group analysis of deceased versus live donor transplants will be done for all outcomes.

Results and Conclusion: Pending

References:

Rate of culture-positive ventriculitis in patients initiated on empiric antimicrobial therapy in a neuroscience intensive care unit

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Background: Neurocritically ill patients often require placement of external ventricular drains (EVDs) as a component of their care. A common complication associated with EVDs is healthcare-associated ventriculitis with reported rates in this patient population ranging from 2% to as high as 22%1. The diagnosis of ventriculitis is complicated by the frequent occurrence of non-infectious fever. In the neurocritically ill the etiology of fever is non-infectious in almost 50% of patients2. Patients may be initiated on empiric antimicrobial therapy when signs and symptoms of infection are present while the full infectious work-up, including cerebrospinal fluid analysis and culture, occurs. A limited number of those initiated on empiric therapy will have culture positive bacterial ventriculitis. Hoogmoed and colleagues investigated the rate of culture-proven bacterial ventriculitis in subarachnoid hemorrhage patients with EVDs. The investigators found that only 23% of patients initiated on empiric therapy for clinical suspicion of ventriculitis had culture-proven ventriculitis3.

Objectives: The primary objective of this study is to assess the rate of culture-positive (CP) bacterial ventriculitis in all patients with EVDs initiated on empiric antimicrobial treatment for suspected ventriculitis. Secondary objectives will include the following: determination of average duration of antimicrobial therapy, evaluation of patient outcomes (ICU and hospital length of stay, in-hospital mortality, occurrence of antimicrobial-related adverse effects, and need for invasive antimicrobial-related procedures), assessment of adherence to institutional antimicrobial prophylaxis guidelines, identification of risk factors for the development of CP ventriculitis, and quantifying the cost of antimicrobial treatment and hospitalization.

Methodology: This will be a retrospective chart review of all adult patients with EVDs initiated on empiric antimicrobial therapy for ventriculitis from October 1, 2015-September 30, 2017. The intent-to-treat population will be identified by reviewing the electronic medical record (EMR) and a neurosurgical database for patients on the neurosurgery service with orders for cefepime, ceftazidime, meropenem, and aztreonam, suspected ventriculitis as the indication for antimicrobial therapy, presence of fever, and an EVD. It is estimated that approximately 100 patients will meet the criteria for the intent-to-treat cohort. These patients will be cross-referenced with a list of patients with positive CSF cultures generated by the EMR to identify the cohort with CP-bacterial ventriculitis. The authors will assess the institutional rate of CP-bacterial ventriculitis, management of patients with suspected bacterial ventriculitis, and associated patient outcomes.

Results and Conclusions: Pending

References:
Evaluation of Inpatient Palivizumab Utilization

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Background: While palivizumab has been demonstrated to decrease hospitalizations when compared to placebo, it has not shown to decrease overall RSV incidence or mortality.1-3 In 2014 the American Academy of Pediatrics (AAP) recommended that immunoprophylaxis be restricted to pediatric patients at high risk of RSV hospitalization, particularly infants born before 29 weeks gestational age (GA), infants born before 32 weeks GA with chronic lung disease requiring oxygen for 28 days, and infants with hemodynamically significant heart disease. Inpatient administration of palivizumab is not recommended for the purpose of preventing nosocomial RSV infection.4 At the Cleveland Clinic Health-System (CCHS), inpatient use of palivizumab is currently restricted to the Department of Pediatrics without further restriction criteria. It is suspected that there are opportunities to improve guideline concordance for inpatient palivizumab administration throughout the health-system. The goal of this study is to evaluate inpatient use of palivizumab in order to identify opportunities for antimicrobial stewardship.

Objectives: The primary objective of the study is to quantify the percentage of inpatient palivizumab doses given in concordance to the 2014 AAP guideline updates. Secondary objectives include: total number of palivizumab doses administered to patients during admission, median number of days from palivizumab administration to patient discharge, percentage of patients who received palivizumab and were subsequently diagnosed with a RSV infection during the same season, percentage of patients prescribed palivizumab with an Infectious Disease (ID) consult service, and percentage of palivizumab administrations that were recommended by ID consult services.

Methodology: This is a non-interventional, retrospective medical record review evaluating all inpatients at CCHS who have received at least one dose of palivizumab during hospital admission from November 1st 2014 to June 1st 2017. Study variables include: age at first dose, GA, birth weight, multiple gestation, race, gender, hospital location, primary service, patient unit, ventilation status/duration, RSV workup during the RSV season, criteria for palivizumab administration, microbiology testing for RSV, date of microbiology testing, days from administration to discharge, ID consultation ordered, doses recommended by ID consultation. Data will be reported as number (%), median (interquartile range), or mean ± standard deviation. A Chi-square or Fischer's Exact test will be used to compare concordance to the 2014 AAP guideline updates when an ID consult was placed versus when an ID consult was not placed.

Results and conclusions: Pending

References:
**Impact of oral versus intravenous corticosteroids on hospital length of stay for medical patients with exacerbations of chronic obstructive pulmonary disease (COPD)**

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**Background:** Adults with COPD are more likely to experience complications, including emergency room visits or overnight hospital stays. In 2009, there were approximately 739,000 hospital admissions for COPD exacerbations and had an approximate hospital length of stay (LOS) of 4.9 days. Current guidelines recognize that the use of systemic glucocorticoids in COPD exacerbations improve lung function and oxygenation, decrease the risk of treatment failure and early relapse, and shorten recovery time and hospital LOS. Studies have found that oral and intravenous (IV) glucocorticoids are equally effective for the treatment of COPD exacerbations. Current guidelines recommend that patients receive systemic steroids, IV or oral, for a total duration of 5-7 days. The IV route can be considered in the setting of severe exacerbation, lack of response from oral glucocorticoids, unable to tolerate enteral route or impaired enteral absorption. Based on anecdotal experience, current practice at this institution utilizes a higher proportion of IV glucocorticoids compared to oral despite guideline recommendations.

**Objectives:** The primary objective of this study is to determine the impact of the route of administration of systemic corticosteroids for COPD exacerbation on the hospital LOS. Secondary objectives include the number of days of systemic steroids based on route, number of days until IV steroids converted to oral, number of days of systemic and inhaled steroids, total steroid dose in prednisone equivalents, average steroid cost per day, 30-day re-admission, and number of patients discharged on systemic steroids.

**Methodology:** This is a retrospective observational study at a 173 bed acute care community teaching hospital. Inclusion criteria are ≥18 years of age, admission to the medical floor, and a prior diagnosis of COPD with an acute COPD exacerbation. Exclusion criteria include acute asthma exacerbation, requirement of invasive or non-invasive mechanical ventilation or admission to the intensive care unit (ICU). Baseline demographic data include age, gender, smoking history, number of COPD exacerbations in preceding year and co-morbid conditions. Other data points will include inpatient daily doses of systemic steroids, inhaled steroid use, hospital LOS, contraindication to enteral route, discharge steroid regimen and 30-day re-admission. Patients will be divided into two groups based on duration of intravenous steroid therapy which will be stratified by ≤72 hours and >72 hours. A Student’s t-test will be used for continuous variables and a Chi-squared test will be used for categorical variables. Statistical significance will be set at a p-value of <0.05.

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

**References:**
A pre- and post-analysis of non-penicillin antimicrobial usage after a pharmacist-driven detailed beta-lactam allergy interview

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Background: Penicillin allergies are reported in approximately 10% of patients in the United States. These can be old, outdated, or inaccurate, which may lead to inappropriate usage of alternative antimicrobial agents that are more expensive, less effective, and potentially more toxic. Up to 90% of patients with a documented penicillin allergy are able to tolerate a beta-lactam antimicrobial agent after formal penicillin allergy skin testing (PST). While PST provides an accurate assessment and de-labeling of penicillin allergies, it may not be feasible at all institutions. Detailed allergy interviews can be performed as an alternate to PST and could potentially lead to de-escalation or optimization of therapy. Sigona and colleagues evaluated the impact of detailed allergy interviews on patients with a documented penicillin allergy and found that 65% of patients were able to be successfully transitioned to a beta-lactam antimicrobial agent resulting in an optimal antimicrobial regimen. At our institution, patients are frequently prescribed a non-penicillin antimicrobial, such as a carbapenem, if they have a documented beta-lactam allergy. Currently, we do not have a formal process of clarifying these allergies. By implementing a pharmacist-driven detailed beta-lactam allergy interview (DBLAI), it is hypothesized that the use of empiric non-penicillin and carbapenem antimicrobial agents will be decreased.

Objectives: The primary objective of this study is to compare the days of therapy of non-penicillin antimicrobial agents pre- and post-pharmacist-driven DBLAI. Secondary objectives are to measure the time from admission to DBLAI, characterize the outcomes, interventions, and acceptance rate of interventions made as a result of the DBLAI, measure the time from admission to initiation of the recommended antimicrobial, and to compare the number of patients converted to a beta-lactam antimicrobial pre- and post-pharmacist-driven DBLAI.

Methodology: This is a single-center pre- and post-analysis of a pharmacist-driven DBLAI. The pre-phase is a retrospective chart review of patients admitted with documented beta-lactam allergy and receiving systemic antimicrobials between December 17, 2016 and March 17, 2017. The post-phase is a retrospective chart review of patients admitted between December 17, 2017 and March 17, 2018 who receive a pharmacist-driven DBLAI as well as systemic antimicrobials during their admission. Pharmacist-driven DBLAI will be implemented on December 17, 2017. Patients with a documented beta-lactam allergy will be identified for DBLAI Monday through Friday based on a list derived from the electronic medical record (EMR). A standardized questionnaire will be utilized for the interview. Following DBLAI, the allergy section of the patient’s EMR will be updated and the provider will be contacted with a therapy recommendation if indicated based on an intervention decision algorithm. Patients will be excluded if the interview cannot be completed or is declined, if the patient is pregnant, or if systemic antimicrobials are not administered during hospital admission. Data collection will include patient demographics, admission date, beta-lactam allergy initially reported, initiation and discontinuation dates of antimicrobials, date of DBLAI, allergy classification based on DBLAI, recommendation indicated based on DBLAI, and initiation date of recommended antimicrobial. Primary objective will be analyzed using Student’s t-test or Wilcoxon matched pair test. Secondary objectives will be analyzed using descriptive statistics and chi-squared or Fisher’s Exact test. This study is currently under review by the Institutional Review Board.

Results and conclusions: Pending

References:
Protecting the pump: Evaluation of warfarin therapy in left ventricular assist device (LVAD) patients

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Background: Left ventricular assist devices (LVADs) have significantly improved survival rates in patients with advanced heart failure, but they are associated with potentially serious complications, including alterations in normal coagulation that may result in thrombosis\(^1\). Warfarin is considered to be the anticoagulant of choice in reducing the risk of thrombosis, as the pharmacokinetics of newer oral anticoagulants in LVAD patients are unknown and their safety and efficacy have not been determined\(^1\). However, warfarin therapy has proven to be difficult to manage in LVAD patients, who are at increased risk of both thromboembolism and bleeding and are therefore often provided with narrow international normalized ratio (INR) ranges\(^2\). While the general population is in therapeutic range an estimated 58 to 68 percent of the time\(^3,4\), LVAD patients have been found to have a time in therapeutic range (TTR) of only 31 to 51 percent\(^2,5\). This suboptimal management may lead to increased incidence of thromboembolic and bleeding events and contribute to increased healthcare costs.

Objectives: The objective of this study is to determine how successful the current management of LVAD patients’ warfarin therapy is in terms of safety and efficacy, and to determine the impact on patient outcomes and costs. The primary endpoint is the percentage of time in therapeutic range of LVAD patients’ warfarin therapy. Secondary endpoints include determination of the rates of bleeding and thrombotic events in LVAD patients and the performance of a cost analysis of warfarin therapy-related outpatient monitoring and inpatient admissions.

Methodology: This retrospective cohort study will be conducted via chart review and will include data generated from November 1, 2011 through October 31, 2017. Patients are eligible for inclusion in the study if they are 18 years or older, have had an LVAD placement, and have received maintenance anticoagulation therapy with warfarin. Data collected will include demographic information (date of birth, gender, height, weight, date of LVAD placement, type of LVAD, comorbid conditions, and medications), anticoagulation clinic information (date of appointment, INR, medications, dietary changes, signs and symptoms of bleeding and/or thrombotic events, and cost information), and hospital admission data (date of admission, date of discharge, daily INR, medications, diet, bleeding and/or thrombotic events, and cost information).

Results and Conclusions: Pending

References:
2. Bishop MA, Streiff MB, Ensor CR, Tedford RJ, Russell SD, Ross PA. Pharmacist-managed international normalized ratio patient self-testing is associated with increased time in therapeutic range in patients with left ventricular assist devices at an academic medical center. ASAIO J. 2014;60:193-8
Evaluation of a newly implemented amiodarone dosing strategy for the prevention of postoperative atrial fibrillation

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Background: Atrial fibrillation can occur in up to 65% of patients following CABG. This complication is associated with longer hospital stay, increased costs, and increased morbidity and mortality. With appropriate prophylaxis, the risk of POAF can be decreased to as little as 5% to 35% depending on what pharmacologic regimen is used. Amiodarone is frequently used to reduce the incidence the POAF in patients who have undergone cardiothoracic surgery. Numerous studies have demonstrated the efficacy of amiodarone in preventing atrial fibrillation at cumulative prophylactic doses ranging from 2 grams to 18 grams given over the course of days to multiple weeks. Current guidelines provide little guidance for the optimal dosing of amiodarone for prevention of atrial fibrillation following open-heart surgery. The previous amiodarone regimen used for POAF prophylaxis at an academic medical center was 200 mg orally once daily started postoperatively until discharge. Given the pharmacokinetics of oral amiodarone, this regimen may not provide adequate time for the drug to exert its antiarrhythmic effect prior to the 48 to 72-hour high-risk window. The hospital implemented a new amiodarone dosing regimen for the prophylaxis of postoperative atrial fibrillation on September 15, 2017. The newly implemented regimen for POAF prophylaxis is amiodarone 1000 mg administered by intravenous infusion over 24 hours, followed by 400 mg orally twice daily for seven days, and then 200 mg daily for the completion of 30-days of therapy. The purpose of this study is to determine if the newly implemented amiodarone dosing regimen significantly decreases the incidence of POAF compared to the hospital's previous standard of care.

Objectives: The primary objective of this study is to compare the incidence of POAF associated with the hospital’s previous amiodarone POAF prophylaxis regimen versus the newly implemented amiodarone regimen in patients who have undergone CABG at an academic medical center. The secondary objectives are to assess differences in rates of adverse effects and hospital length of stay between study groups.

Methodology: The present study is a quasi-experimental retrospective cohort study evaluating the incidence of POAF in patients who have undergone CABG at an academic medical center between September 1, 2016 to May 1, 2018. Inclusion criteria include age greater than 18 years, coronary artery bypass grafting, and receipt of at least 48 hours of amiodarone postoperatively. Exclusion criteria includes hypersensitivity to amiodarone, resting sinus bradycardia, second or third degree heart block, cardiogenic shock, pregnancy, history of atrial fibrillation, thyroid dysfunction, liver dysfunction, interstitial lung disease, pulmonary fibrosis, or chronic use of amiodarone prior to admission. Data will be collected via retrospective review of the hospital’s electronic medical record.

Results and Conclusions: Pending.

References:
Discontinuation of proton pump inhibitors (PPIs) in patients with CKD

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Background: Proton pump inhibitors (PPIs) are very commonly used medications in the US and are historically considered to be well tolerated. Recent studies have linked PPI use to development of chronic kidney disease (CKD) and end-stage renal disease (ESRD).¹-⁴ One retrospective study performed via the Veterans Affairs National Database, found that patients on PPIs, who had healthy kidneys at baseline, were 28% more likely to develop CKD than those on histamine 2 receptor blockers.¹ Chronic kidney disease is associated with increased risk of death and financial burdens. Given the growing concerns about the safety of PPI use and their recent link to causing CKD, this study will serve to provide evidence on whether discontinuing PPIs in patients with CKD will slow the worsening of their disease progression. This could impact prescribing practices of PPIs in our patients with CKD.

Objectives: The objective of this study is to assess the difference in renal function (eGFR) between patients who have PPI discontinued versus patients with continuous therapy over a 1 year period. The primary endpoint is the change in eGFR in patients with continued PPI therapy (≥70% medication possession ratio) versus patients with PPI therapy discontinued.

Methodology: This study is a retrospective chart review of patients with established chronic kidney disease (CKD) who were on a PPI from January 1, 2014 to December 31, 2014. It will consist of 2 groups, a continuous PPI group and a discontinued PPI group. Patient’s eligible for inclusion in this study will be those with established CKD, defined as 2 eGFR measurements of < 60 ml/min/1.73m² at least 90 days apart, who were on a PPI from January 1, 2014 to December 31, 2014, with a medication possession ratio (MPR) of ≥70. Patients on dialysis during this period will be excluded. Patients must have baseline and follow up eGFR data to be included. We will target an enrollment of 200 patients; 100 who discontinue their PPI between January 1, 2015 to December 31, 2015 for at least 180 consecutive days and 100 patients who are continued on a PPI between January 1, 2015 to December 31, 2015 with an MPR ≥70%. We will compare baseline eGFR data to a final eGFR value after at least 6 months of discontinuation or continuation of PPI. The authors hypothesize that patients with CKD exposed to at least one year of PPI followed by discontinuation will exhibit slower decline in renal function (measured by eGFR) compared to those continuously exposed to a PPI.

Results and conclusions: Pending

References:

Glycemic control in the intensive care unit: A pharmacist driven approach

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Background:

Hyperglycemia is common in critically ill patients. It is associated with an increased risk of infection and death among patients admitted to intensive care units. The Society of Critical Care Medicine (SCCM) recommends initiating insulin therapy in critically ill patients when a blood glucose ≥150 mg/dL is detected. They recommend keeping blood glucose < 150mg/dL for most adult ICU patients and to maintain blood glucose values absolutely <180mg/dL using a protocol that achieves a low rate of hypoglycemia (blood glucose ≤ 70 mg/dL). A number of studies have looked at more intensive blood glucose control in this setting such as a target range of 80-110 mg/dL. This more intensive target has been associated with increased risk of hypoglycemia and increased mortality. The SCCM Guidelines for the use of an insulin infusion for the management of hyperglycemia in critically ill patients recommend that insulin infusion is the preferred route for patients with type 1 diabetes, hemodynamically unstable patients, and in patients whom long acting insulin would be inappropriate due to changing clinical status. They also recommend that subcutaneous (SQ) basal-bolus regimens may be started after stabilization with IV insulin. However, initial SQ insulin regimens may be appropriate for patients with low insulin requirements who are clinically stable.

Objectives:

The primary objective of this study is to assess the percentage of blood glucose readings within the range of 70-180 mg/dL when a pharmacist is managing therapy. The goal of this research is to demonstrate that pharmacists can make a significant impact on glycemic control within the ICU setting. Secondary outcomes in this study will include number of blood glucose readings >180 mg/dL, number of blood glucose readings <70 mg/dL, and average glucose through ICU stay with standard deviation.

Methodology:

This study will be conducted in two separate phases. The first phase will be prospective and conducted during October 2017. This will involve blood glucose management by a pharmacist on patients meeting inclusion criteria. During the first phase, a pharmacist will initiate and adjust insulin therapy as deemed necessary and monitor glycemic control throughout the patient’s ICU stay. Initial subcutaneous basal-bolus regimens will be based on a pharmacy driven hyperglycemic protocol while intravenous insulin infusions will be started at the pharmacist’s discretion. Data from these interventions will be collected and compared to a retrospective cohort. The patient data for the retrospective cohort will be collected from October 2016 and will be screened for the same inclusion and exclusion criteria. Inclusion criteria will be all hyperglycemic ICU patients over 18 years of age that are admitted to the Unity Health Network service at MMC.

Results and Conclusions: Pending

References:

Assessing the Impact of Pharmacy Resident Interventions on Medication Costs

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PGY-1

University of Toledo Medical Center

Background: The positive financial impact of pharmacists on patient outcomes and healthcare expenditure has been established in previously existing literature. In particular, pharmacy resident interventions have been associated with reductions in length of stay, readmission rates, and medication costs. Pharmacoeconomic analyses have shown a positive benefit-cost ratio for pharmacy residency programs; thus, while the overarching purpose of a residency program is to promote the professional development of residents, investment in a pharmacy residency program is soundly justified by the financial return resulting from resident interventions. Consistent limitations in the existing literature include lack of statistical analyses and absence of a control group.

Objectives: The objective of this study is to determine the impact of pharmacy resident participation in clinical services on institutional and patient medication costs. This will be determined for the primary endpoint by comparing the average medication acquisition costs per discharge at an academic medical center for months in which pharmacy residents participate in clinical services (rounding months) versus months in which residents are removed from clinical services (non-rounding months). Secondary endpoints include comparing average medication costs billed to patients at discharge on rounding and non-rounding months, as well as determining if a correlation exists between the number of pharmacy residents on clinical services and medication acquisition costs.

Methodology: This is a retrospective cohort of patients admitted to the University of Toledo Medical Center from July 2012 to June 2017. Examples of resident interventions will be illustrated by evaluating the free text of 200 sample interventions from the Pharmacist Intervention Tool database. Study subjects will be grouped according to whether they were admitted during a rounding or non-rounding month. In order to determine if the presence of pharmacy residents has a statistically significant impact on medication costs, a student’s t-test will be conducted to compare averages for each endpoint. Demographic and acquisition cost information will be extracted from internal billing software and departmental records. To evaluate the impact of the number of residents on clinical services, average medication costs to the hospital will be compared between months with established numbers of residents using a one-way ANOVA to reduce the risk of type I error.

Results and conclusions: Pending

References:

4. Truong JT, Backes AC. The impact of a Continuum of Care Resident Pharmacist on heart failure readmissions and discharge instructions at a community hospital. SAGE Open Med.
Retrospective Review of Anticoagulant Use in Cancer Patients: Direct Oral Anticoagulants Versus Vitamin K Antagonist

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Background: Patients with active malignancy are known to be in a hypercoaguable state which predisposes these individuals to venous thromboembolism (VTE)\(^1\)-\(^3\). The mechanism of this state is not completely understood but factors include tumor cells expressing and releasing procoagulants\(^2\). Guidelines discuss anticoagulant recommendations for cancer patients, stating that low molecular weight heparin (LMWH) is the preferred agent over vitamin K antagonist (VKA) and direct oral anticoagulant (DOAC) therapies, based off the results of the CLOT trial\(^1\)-\(^3\). The trial concluded that the probability of recurrent thromboembolism at 6 months was 17 percent in the VKA group versus 9 percent in the LMWH group, with no significant difference in the rate of major bleeding\(^3\). Cancer patients can be more difficult to maintain in therapeutic range on VKA therapy due to vomiting, inconsistent diet, and the use of chemotherapy agents that affect VKA metabolism. However, LMWH is often costly, lacks patient assistance programs and is burdensome for patients regardless of cancer status\(^1,2\). Most DOAC agents have prescription assistance programs, and VKA therapy is generally inexpensive. It is for these reasons that cancer patients presenting to Mercy Medical Center are more likely to be using oral anticoagulation over LMWH. While LMWH was shown to be preferred over VKA therapy, this conclusion cannot be extended to the DOACs. At the time of the CLOT trial, the DOACs were not available, and currently, data is still lacking for their use in cancer patients\(^1,3\). DOACs have been shown to be as effective and safe as LMWH and VKA therapy for prevention of VTE recurrence in patients without cancer. A meta-analysis evaluated six studies, which included cancer patients, that looked at VTE recurrence and major bleeding rates, finding no statistical significance between DOACs and conventional therapy\(^4\). With the increased use of DOACs as the anticoagulant of choice in patients without cancer, it is likely that oncologists are facing the question of the use of these agents in their patients.

Objectives: The objective of this study is to determine the efficacy and safety of DOACs compared to VKA in patients with active malignancy. The primary endpoint is the occurrence of a VTE. Secondary endpoints include occurrence of clinically overt bleeding (both major bleeding and any bleeding) and death (due to bleeding or VTE).

Methodology: This is a retrospective chart review of patients from January 2012 to November 2017 with a diagnosis for active malignancy receiving oral anticoagulation. It will be submitted to the Institutional Review Board for approval. Patients will be screened through the inpatient and emergency department electronic medical records using diagnosis codes for cancer. Patients not receiving oral anticoagulation prior to hospital presentation will be excluded. The following data will be collected: patient age, gender, type of oral anticoagulant, reason for anticoagulation, international normalized ratio (INR) if on VKA therapy, and reported adverse medication effects. Rates of VTE, clinically overt bleeding, and death due to either will be determined.

Results and Conclusions: Pending

References:
Ketamine Safety in the Emergency Department for Analgesia and Severe Agitation/Excited Delirium: A Health System Experience

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Background: Multiple single-center studies have reported that ketamine is an effective treatment for pain in the emergency department (ED) and severe agitation/excited delirium in the pre-hospital setting.\(^1\)\(^-\)\(^3\) However, the optimal dosing range and administration method of subdissociative dose ketamine (SDDK) with the least adverse events is unclear.\(^1\)\(^-\)\(^2\) Additionally, limited studies have assessed the safety of intramuscular (IM) ketamine for severe agitation/excited delirium in an ED setting.\(^3\) Ketamine administration may lead to respiratory, cardiovascular, and neuropsychiatric adverse events.\(^2\)\(^-\)\(^4\) The Cleveland Clinic Emergency Services Institute (ESI) ketamine protocols were developed to assist prescribers in utilizing ketamine for these two off-label indications. This multi-center study seeks to evaluate the safety of SDDK for analgesia and dissociative sedation ketamine for severe agitation/excited delirium in the ED.

Objectives: The goal of this study is to evaluate the safety of SDDK for analgesia and dissociative sedation ketamine for severe agitation/excited delirium in patients at Cleveland Clinic Health System (CCHS) EDs. The primary objective of this project is to describe the incidence of respiratory and cardiovascular adverse events requiring intervention after ketamine administration. Secondary objectives include determining the percentage of ketamine orders in the ED for analgesia or severe agitation/excited delirium that were adherent to the approved ESI protocols, evaluating the impact of ketamine ESI protocol adherence on the incidence of adverse events, and describing the incidence of neuropsychiatric adverse events after SDDK administration.

Methodology: A retrospective chart review will be conducted to evaluate all adult patients who received SDDK for analgesia and dissociative sedation ketamine for severe agitation/excited delirium in CCHS EDs, (excluding Cleveland Clinic Akron General) between May, 09 2017 and November, 09 2017. A query of Cleveland Clinic’s electronic health record (EHR) will be conducted to initially identify all patients who received either IV push or IM ketamine at a CCHS ED within that time frame. A standardized data collection form will be used to record patient information regarding ketamine use and concomitant medications or co-morbidities that may impact the incidence of adverse events identified. Serious respiratory adverse including endotracheal intubation or predefined non-invasive positive pressure ventilation use after ketamine administration will be identified through a review of the flowsheet tab, medication administration report (MAR), and progress note within the EHR. Other adverse events will be identified in a similar manner. All data will be analyzed and reported using descriptive statistics.

Results and Conclusions: Pending

References:
Evaluation of the long-term pharmacoeconomic impact of clinical pharmacist managed diabetes care

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Background: Type 2 diabetes mellitus (DM) is a prevalent and growing disease state; approximately 30.3 million Americans have diabetes.¹ It is projected that one in three American adults will have diabetes by 2050 if current trends continue.² Clinical pharmacists can play a significant role in improving both access to care and patient outcomes related to DM. Many studies have shown the benefit of having a clinical pharmacist provide medication management of disease states such as diabetes, with regards to A1c reduction and interventions made. However, few have shown the pharmacoeconomic impact of clinical pharmacists in this setting. Yu et. al assessed the cost-effectiveness of clinical pharmacist management of DM at two primary care clinics with regards to preventing estimated long-term cardiovascular disease outcomes over 10 years using the Markov Model.³ The authors reported a decreased risk for stroke and coronary heart disease over 10 years. To our knowledge, this was the only study that has been published specifically assessing cardiovascular and diabetes related outcomes that have been prevented with a clinical pharmacist managing DM.

Objectives: This study aims to assess the long-term pharmacoeconomic impact of clinical pharmacist managed diabetes care within multiple primary care clinics. Primary endpoints include the estimated cost avoidance for diabetes-related complications for change in A1c from baseline to best A1c achieved in DM patients. All endpoints will be evaluated in two groups; subjects with a baseline A1c ≥10% or 9 to <10%. Secondary endpoints will assess the estimated cost avoidance for diabetes-related complications in the two subject groups with alternative comparator A1cs. These include baseline to last A1c achieved in DM patients and baseline vs. the average of all study A1cs obtained during study period.

Methodology: This study is a retrospective chart review that will be reviewed by the LSCDVAMC IRB. Diabetes-related complications that were prevented will be estimated for a 10-year time frame using the Archimedes Model, a validated pharmacoeconomic tool. The prevented diabetes-related complications that are found to be statistically significant will be used to determine cost avoidance. Cost comparisons will include the cost of the prevented complication as compared to the cost of a pharmacist to manage the patient’s DM in clinic. Subjects with a baseline A1c ≥9% who are seen at least twice by the pharmacist between January 1, 2016-January 1, 2017 will be included in the study. Follow-up must have occurred within six months of initial visit and subjects will be followed for one year or clinic discharge, whichever occurs first. Subjects with type 1 DM will be excluded.

Results and conclusions: Pending

References:
Evaluation of antibiotic prescribing for urinary tract infection in the emergency department: A retrospective chart review

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Background: Approximately 20-30% of antibiotics prescribed in acute care hospitals are either unnecessary or inappropriate. This may contribute to the healthcare problem of increasing antimicrobial resistance. Due to increased resistance patterns, the CDC estimates more than 2 million people are infected with antibiotic-resistant organisms per year, leading to 23,000 deaths annually. For example, urinary tract infections (UTI) are one of the three most commonly treated infections in the acute care setting. A recent study of U.S. urine samples demonstrated increased rate of resistance to *Escherichia coli* from 2000-2010 for the antibiotics ciprofloxacin and sulfamethoxazole-trimethoprim, which are commonly prescribed for UTI. Therefore, addressing quality measures to improve antibiotic prescribing is necessary. Joint Commission in 2017 requires mandating antimicrobial stewardship (ASP) in all healthcare settings to minimize antimicrobial resistance, including emergency departments. Barriers to implementation of ASP in the ED are rapid decision-making and limited diagnostic information during time of visit. However, maximizing ASP efforts to enhance antibiotic prescribing in the ED is warranted.

Objectives: The objective of this study is to evaluate antibiotic prescribing for UTI in the emergency department and identify potential quality improvement measures to enhance prescribing. The primary endpoint is the evaluation of number of days of inappropriate antibiotic therapy prescribed. Secondary endpoints include assessment of percentage of appropriate antibiotic dose, frequency, and duration of antibiotic prescribed and correlation of urine analysis (UA) components with prescribing patterns.

Methodology: This is a retrospective chart review of patients over a 3-month period with diagnosed UTI discharged from the emergency department on antibiotics. Data will be collected through the electronic medical record and documented in a secure password protected system. Adult patients 18 years or older discharged from the emergency department with antibiotics for a UTI will be included in this study. Patients who are admitted to the hospital or discharged on antibiotics for multiple indications will be excluded. Evaluation of appropriateness of therapy will be based off the Infectious Disease Society of America (IDSA) guidelines for Asymptomatic Bacteriuria, Acute Cystitis and Pyelonephritis, and Catheter-Associated UTI. Data collection will include gender, age, allergies, renal function, diagnosis, symptoms, UA, antibiotic name, dose, duration, frequency, and urine culture results. Results will be presented during spring 2018 ED providers meeting.

Results and conclusions: Pending

References:
Effectiveness of pharmacist-led intervention on COPD outcomes at a small community hospital

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**Background:** Patients who are hospitalized for COPD have an increased risk of death and a poorer prognosis.¹ In 2010 $32.1 billion dollars were spent nationally on medical costs for COPD and this is estimated to increase to $49 billion dollars by 2020.² Nonadherence to inhaled therapy contributes to rising costs and hospitalizations. Barriers to adherence include low health literacy and affordability of medications.³ Alliance Community Hospital is located in Stark County and is in close proximity to Mahoning County and Columbiana County. The percentage of people living in poverty in these three counties is close to or higher than the statewide percentage.⁴ Alliance Community Hospital’s 30 day readmission rate for COPD is 20.5%; compared to the national rate of 19.8%.⁵ Alliance Community Hospital is currently implementing a pharmacist-led intervention targeted towards COPD patients.

**Objectives:** The primary objective of this study is to determine if a multifactorial pharmacist-led intervention is effective in reducing 30 day readmission rates and mortality.

**Methodology:** Between November 1, 2017 and February 28, 2018 patients admitted to Alliance Community Hospital for a COPD exacerbation or patients admitted with a past diagnosis of COPD will receive a bundle of interventions from a pharmacist or pharmacy intern. When a patient is admitted to the hospital meeting inclusion criteria they will first receive admission medication reconciliation and counseling with a focus on identifying COPD medication related problems. The next step in the bundle is education that consists of COPD pathophysiology, nonpharmacologic treatments, and inhaler technique. The “5 A’s” of smoking cessation will be implemented at this time. During this education piece we will administer the St. George Respiratory Questionnaire for COPD patients to assess quality of life and the COPD Assessment Test to assess symptoms. The pharmacist or pharmacy intern will ensure appropriateness of inhalers and inhaler technique. Prior to discharge, each patient will go through a discharge medication reconciliation and education with a focus on ensuring appropriate COPD medication use and affordability post-discharge. Each patient will receive three follow up phone calls. The first phone call will be 2-3 days post-discharge to assess symptoms and ensure prescriptions were filled. The second phone call will be 7-10 days post-discharge and will address adherence and the patient’s symptoms again. The third phone call will be approximately 30 days post-discharge to assess symptoms, remind patient they will be due for refills on their inhalers, and perform a quality of life survey.

The primary outcome is a composite of readmission rates and mortality. The secondary outcomes are a reduction in symptom severity, number and type of pharmacist interventions, and the impact of patient demographics on the primary outcome.

**References:**

Cost efficacy analysis of pharmacist led diabetes management in a primary care clinic

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Background: In the United States (U.S.), approximately 12.2% of adults aged 18 and older have diabetes (type I and II). This number is expected to increase to 33% by the year 2050. The average annual cost per patient is $9,975 for diagnosed diabetes in the U.S. Along with extreme cost and high prevalence, there is a shortage of primary care providers available to care for diabetic patients. Due to the shortage of primary care providers (PCPs), ambulatory care pharmacists (ACPs) as part of the interdisciplinary team have shown improved patient outcomes through chronic disease state management. Despite these improved outcomes, it is not standard to have an ACP as part of the patient care team. A key reason is the lack of evidence to support the sustainability of ACP services.

Objectives: The primary objective of this study is to determine the cost effectiveness of pharmacist led diabetes management within a primary care office. The secondary objectives include estimating revenue for services rendered from ACP services, assessing overall change in hemoglobin A1c (HbA1c), analyzing the difference in all cause and diabetes related emergency department visits and diabetes related hospitalizations, and determining the percentage of patients who achieve standard quality measures based on HbA1c and statin use.

Methodology: This is a multi-site study that includes a retrospective chart review of patients referred to the ACP versus usual care within an academic health system. In the intervention group, patients see ACPs who work under a collaborative care practice with the PCP. The control group will have patients where no ACP is available in the primary care team. The ACPs’ financial impact will be assessed with an incremental cost effectiveness ratio (ICER) to determine how much it costs for one additional percentage of HbA1c decrease in the ACP group (ACP plus primary care) versus the usual care group (primary care only). Cost will be calculated based on standard wages and benefits. The index visits will occur between May 1st, 2015 and January 31st, 2017 and each patient will be followed for at least 12 months. Patients will be matched based on type of diabetes, index HbA1c, age, gender, ethnicity, body mass index, comorbid conditions, and treatment classification at baseline. Data will be collected from subjects’ electronic medical record including demographic information, labs, and treatment data at the index visit and 6 and 12 months post index visit.

Results and Conclusions: Pending

References:
Evaluation of dextromethorphan with select antidepressant therapy for the treatment of depression in the acute-care psychiatric setting

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Background: Major depressive disorder (MDD) is a common condition in the United States and is a major source of morbidity and cost. Although considered effective, currently available antidepressants are similar in their mechanisms of action, targeting the monoaminergic system, and have a delayed onset of clinical efficacy of weeks to months.1 Despite effective treatment for MDD, approximately 40% of patients are treatment resistant.2 Dextromethorphan is a N-methyl-D-aspartate receptor antagonist and may have ketamine-like rapid acting antidepressant effects.3 Dextromethorphan is extensively metabolized via cytochrome P450 (CYP) 2D6, and its half-life in extensive metabolizers is two to four hours.1 Therefore, it is paired with a strong CYP2D6 inhibitor, like quinidine, in a commercially available product in order to prolong its duration of action. Dextromethorphan could offer significant benefits to those suffering from depression if shown to be effective due to its low cost, ease of administration, and proposed rapid-acting effects as compared to current treatment options. Currently, there is very little literature investigating the use of dextromethorphan in depression. The purpose of this study is to evaluate the effects of dextromethorphan on depression in an acute-care psychiatric setting.

Objectives: The objective of this study is to determine the impact of dextromethorphan on depressive symptoms when combined with select antidepressants that are moderate to strong CYP2D6 inhibitors, as well as investigate the incidence of psychotropic side effects in the study population. The primary endpoint is the difference in time to clinical improvement defined as an average of: time to first documented improvement by the psychiatrist, time to first 24 hours without as needed anxiolytic or antipsychotic medication, and time to first recorded improvement by nursing.

Methodology: This is a retrospective chart review evaluating the difference in the average time to clinical improvement for depressive symptoms in patients who received dextromethorphan with select antidepressant therapy as compared to patients who did not receive dextromethorphan. Patients will be identified by discharge diagnosis of depressive disorder diagnosis code and whether or not they received scheduled dextromethorphan. The study group will include patients who received scheduled dextromethorphan and select antidepressant therapy, and the control group will include patients who received the select antidepressant therapy only. The select antidepressant therapy includes fluoxetine, bupropion, or paroxetine. For this study, the null hypothesis suggests there will be no difference in time to clinical improvement in depressive symptoms when using dextromethorphan as augmentation therapy when compared to current first-line antidepressant therapy alone.

Results and conclusions: Pending

References:
Impact of discontinuation of amiodarone on warfarin dosing and INR in patients taking warfarin managed through an anticoagulation clinic

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Background: Warfarin and amiodarone are commonly used together, particularly in patients with atrial fibrillation. The drug interaction between these medications is well known and has been studied extensively. Amiodarone augments the anticoagulant effect of warfarin and increases the risk of serious bleeding, particularly several weeks after amiodarone is started in a patient on a stable warfarin regimen. Empiric warfarin dose reduction at the initiation of amiodarone with close INR monitoring has been recommended. Although the impact of adding amiodarone to warfarin has been well described, little data exists to characterize the interaction or assist in managing warfarin when a patient discontinues amiodarone. One observational case study by Hamer and colleagues outlines a patient case that describes increased prothrombin activity after amiodarone was removed from a patient's medication regimen. Under this particular circumstance patients may be at a higher risk for subtherapeutic INR and thromboembolic events.

Objectives: The primary objective of this study is to describe the effect of amiodarone discontinuation on warfarin dosing and INR in patients previously stabilized on warfarin and amiodarone. The objective will be assessed over a period of sixteen weeks after amiodarone has been stopped. The outcomes for the primary objective are weekly mean INR and weekly mean warfarin dose. The secondary objective of this study is to describe the predictors of warfarin dose change of greater than or equal to twenty percent after discontinuation of amiodarone in patients previously stabilized on warfarin. The predictors for the secondary objective include patient age, sex, amiodarone duration, amiodarone dose at discontinuation, weekly warfarin dose during amiodarone therapy, documentation of an adverse reaction as the indication of amiodarone cessation, and addition of a maintenance medication with a known interaction with warfarin.

Methodology: This is a retrospective cohort study of patients taking concomitant warfarin and amiodarone with a diagnosis of atrial fibrillation monitored through the Internal Medicine Center of Akron (IMCA) pharmacist-managed anticoagulation clinic from July 21, 2009 to November 30, 2017. Demographic data, INR results, amiodarone dose, warfarin dose, medication duration, and diagnoses will be identified using electronic health records. The medication list and documentation from anticoagulation clinic, cardiology, or primary care provider will be reviewed.

Results and Conclusions: Pending

References:
Comparison of outcomes of benzodiazepine users versus non-users in adults with community acquired pneumonia (COBRA-CAI)

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Purpose: In recent research, benzodiazepines, along with some non-benzodiazepines, have been associated with increased risk of hospitalization for pneumonia. This risk is thought to be attributed to benzodiazepine-induced immunosuppressive effects. Though such studies correlated risk with benzodiazepines and incidence of pneumonia, the outcomes of benzodiazepine users versus non-users treated for community-acquired pneumonia has yet to be elucidated. This study will seek to establish the correlation between use of benzodiazepines or non-benzodiazepines and outcomes in adult community acquired pneumonia patients.

Methods: A retrospective chart review encompassing the dates of 01/01/2011 to 12/31/16 will be performed. All information and records will be gathered from a large, integrated health system and will be inclusive of individuals ≥ 18 years of age who have received a benzodiazepine or non-benzodiazepine upon admission, have had >48 hours of antibiotics, and diagnosed with pneumonia via chest x-ray and ICD 9/10 codes. Exclusion criteria include patients with chronic immune suppression, acute exacerbation of heart failure, admission to the intensive care unit (ICU), acute pulmonary embolism, taking an antipsychotic medication, intubation, mechanical ventilation, chest tube or pneumothorax, and antimicrobial use within the past 30 days. The primary objective is a composite of the following outcomes: antibiotic dose escalation at 48 hours, transfer to ICU at 48 hours, increased oxygen requirements at 48 hours, and readmission for pneumonia within 30 days. Secondary objectives include individual components of the primary outcomes as well as length of stay, clinical decompensation after 48 hours [defined as any 2 of the following: respiratory rate > 22 respirations per minute (RPM), heart rate > 100 beats per minute (BPM), temperature > 37.9 C, and systolic blood pressure < 100 mmHg], and all cause 30 and 90 day readmission. Collection of baseline characteristics include patient demographics, chronic kidney disease, indication for benzodiazepine, duration of benzodiazepine exposure, Charlson comorbidity score, previous pneumonia events within one year prior to index date, diagnosis of alcoholism, current smoking status, underlying lung disease, and antibiotic utilization. Nominal data will be evaluated using a Chi-Square test and continuous data will be evaluated with a student’s-t-test.

Results and Conclusions: Results and conclusions pending IRB approval and data collection

References
Neuropsychiatric profile of dolutegravir in an outpatient HIV clinic

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Background: Dolutegravir is an integrase strand inhibitor (INSTI) used in combination with other antiretrovirals as a first line treatment of HIV. \(^{(1)}\) Recent European studies have shown a higher incidence of side effects and a higher incidence of discontinuation of dolutegravir than were reported in clinical trials. \(^{(2-5)}\) The main reason for discontinuation of dolutegravir reported were neuropsychiatric side effects such as sleep disturbances, abnormal dreams, insomnia, depression, anxiety, and agitation. \(^{(2-5)}\) Risk factors identified for dolutegravir discontinuation include regimens containing abacavir, age over 60 years, and female gender. \(^{(3-5)}\)

Objectives: The primary objectives of this study are to determine the incidence of neuropsychiatric side effects of dolutegravir, discontinuation rates of dolutegravir, and reasons for discontinuing dolutegravir compared to other INSTI-based regimens in an outpatient HIV clinic. Secondary objectives include determining risk factors for dolutegravir discontinuation and determining the incidence of other post-marketing side effects of dolutegravir compared to other INSTI-based regimens.

Methodology: This is a retrospective chart review of patients 18 years or older receiving care at the University of Toledo Medical Center Ryan White Clinic, who were initiated or switched to an INSTI-based antiretroviral regimen from January 2010 to September 2017. The INSTI's being evaluated in the study are dolutegravir, elvitegravir, and raltegravir. The INSTI could be paired with one of the following nucleoside reverse transcriptase inhibitor backbones: tenofovir disoproxil fumarate/emtricitabine, tenofovir alafenamide/emtricitabine, or abacavir/lamivudine. Electronic medical records will be used to assess for the presence/absence of neuropsychiatric side effects for included patients during the first calendar year after initiation or of change to an INSTI-based regimen. Neuropsychiatric side effects are defined as new onset or worsening abnormal dreams, insomnia, depression, anxiety, agitation, dizziness, fatigue, weakness, headaches, poor concentration, slow thinking, confusion, or numbness or tingling in the hands or feet.

Patients taking dolutegravir-containing regimens will be compared to patients taking raltegravir- or elvitegravir-containing regimens for the following outcomes: the differences in the incidence of neuropsychiatric side effects, overall discontinuation rates, and rate of discontinuation due to neuropsychiatric side effects. Other side effects such as weight gain will also be assessed.

Results and conclusions: Pending

References:
Comparison of Short-course Versus Prolonged Antimicrobial Therapy in the Management of Intra-Abdominal Infections

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Background: Intra-abdominal infections (IAI) are associated significant morbidity and mortality. Successful treatment typically requires a combination of source control interventions and antimicrobial treatment. Current guidelines and recent literature support a treatment course of 4 to 7 days, as long as adequate source control and clinical response are achieved. This shortened course is recommended over longer durations as a means to minimize the risk of developing antimicrobial resistance without compromising clinical cure. Additionally, longer durations can increase the financial burden on the patient and society. Despite these recommendations, therapy is often administered for 10-14 days due to concern for subsequent complications.

Objectives: The objective of this study is to compare clinical outcomes between patients treated for IAI with short-course versus prolonged antimicrobial therapy.

Methodology: This study is an IRB-approval pending retrospective cohort. Adult patients admitted between January 1, 2012 to June 30, 2017 with a documented intra-abdominal infection requiring hospitalization and managed with at least 48 hours of antimicrobial treatment will be included. Patients will be included if they have at least one sign of IAI; temperature greater than 38°C or less than 36 °C, white blood cell count greater than 12,000 cells/mm³ or less than 4,000 cells/mm³, or documented nausea, vomiting, or abdominal pain. Patients with IAI classified as pancreatitis, primary peritonitis, or peritoneal dialysis-related peritonitis, IAI that progressed to bacteremia, were immunocompromised or treated for a concomitant infection at a site other than the abdomen will be excluded. Variables to be collected include baseline characteristics, antimicrobial therapy, and clinical cure and failure. Patients will be grouped according to the duration of treatment with antimicrobials. Patients treated for 7 days or less will be in the short course group; patients treated for more than 7 days will be in the long course group. The primary endpoint is clinical cure at day 10 as defined as: lack of death, lack of need for antimicrobial escalation or unplanned or repeated intervention, and resolution of signs of IAI. Secondary endpoints include hospital length of stay, intensive care unit length of stay, 28 day all-cause mortality and 30 day readmission rates.

Results and conclusions: To be determined.

References:

Vaccination Rates in Adults Awaiting Liver Transplant

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Background: Although national guidelines recommend vaccinations in adult solid-organ transplant candidates, wide variations in immunization practices occur, resulting in low vaccination rates in an immunocompromised population.¹ By recommending and monitoring appropriate recommended immunizations at an appropriate time prior to LT, vaccination receipt may increase. At the Cleveland Clinic, an infectious diseases consult is a part of the LT evaluation. Therefore, the goal of this study is to evaluate vaccination rates in adult liver transplant candidates at Cleveland Clinic prior to transplantation.

Objectives:
The primary objective of this study is to describe pneumococcal, influenza, hepatitis A (HAV), and hepatitis B (HBV) vaccination or immunity rates prior to liver transplantation. The secondary objectives are to describe the vaccination rates for additional vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), measure frequency of adherence to vaccines after infectious disease (ID) recommendations, and summarize pre-transplantation vaccination rates in patients undergoing splenectomy during liver transplantation.

Methodology:
This is a single center, retrospective chart medical chart review of adults greater than or equal to 19 years old who received a liver transplant at Cleveland Clinic Main Campus between January 1, 2013 to December 31, 2016. A report generated from EDIT, the Cleveland Clinic electronic transplant database, will identify transplant recipients receiving a liver transplant at the Cleveland Clinic from January 1, 2013 to December 31, 2016, to allow one year for clinicians’ practices to incorporate the most current recommendations. Pre-transplant vaccination history and serologies, baseline demographics, and transplant-related data will be retrieved either via EDIT report generation or manually collected from the subjects’ electronic medical records. Contingent on approval by the Cleveland Clinic IRB, access to the Ohio Department of Health (ODH) IRB in order to utilize their public immunization database (Impact SIIS) will be pursued. With granted approval, Impact SIIS will be used to supplement EDIT and Epic vaccination data for patients residing in Ohio; if not approved by the ODH IRB, data from this source will not be included in the study.

Results and conclusions: Pending

References:
Impact of clinical pharmacist interventions on readmission rates of hospitalized patients with heart failure

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Background: Heart failure is one of the leading causes of morbidity and mortality in the United States. In 2016, approximately 5.7 million adults in the United States had heart failure. Projections show that by 2030, the prevalence of heart failure in the United States will increase by 46% with the average cost increasing by 127% to 69.7 billion dollars. Due to the high prevalence and cost of heart failure, the Centers for Medicare and Medicaid Services (CMS) implemented financial reimbursement penalties for hospitals with a higher than expected number of readmissions within 30 days of discharge for six conditions; heart failure is one of those conditions. In response to this, many hospitals and health systems have implemented different types of interventions to decrease the number of readmissions within 30-days. The aim of this study is to evaluate the impact pharmacist disease state education and medication counseling has on 30-day readmission rates for patients with heart failure in a small community hospital.

Objectives: The objective of this study is to determine if pharmacist disease state and medication counseling, along with follow up phone calls after discharge, decreases the number of readmissions to the hospital. The primary endpoint is 30-day all cause readmissions and mortality. The secondary endpoints include: 30-day heart failure readmission, 30-day all cause Emergency Department visits, number of pharmacist interventions, impact of patient demographics on the primary outcome, and symptomatic evaluation.

Methodology: This is a single-center pilot study run between November 2017 and February 2018 for patients who have a heart failure exacerbation or have a past medical history of heart failure. These patients will receive medication reconciliation and counseling completed by a pharmacist or pharmacy intern upon admission with a focus on identifying CHF medication related problems. Disease state and medication counseling will occur prior to discharge. A discharge medication reconciliation with a focus on appropriate home medications will be conducted. Follow up phone calls at 2-3 days, 7-10 days, and approximately 30 days post discharge will focus on follow up with primary care physician, accessibility to medications, and symptom management. The authors hypothesize that there will be a decrease in hospital readmissions for heart failure patient when the trial period starts.

Results and conclusions: pending

References:
Impact of medication therapy management services on 30-day readmission rates in a nurse-led heart failure clinic

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Background: Since the implementation of the Hospital Readmissions Reduction Program by the Centers for Medicare and Medicaid Services, hospitals that readmit patients with certain diseases within 30-days of prior admission are penalized financially through quality metrics. Heart failure (HF) is a chronic medical condition associated with significant morbidity, mortality, costs, and frequent readmissions due to exacerbations. In addition, this patient population has multiple medication regimens which may increase the complexity of transitions due to having more medication discrepancies or drug therapy problems. Previous research shows that having a multidisciplinary team including a clinical pharmacist reduces the prevalence of drug therapy problems and readmission rates while improving quality of care across the continuum.\textsuperscript{1-3} However, while these studies provide robust clinical findings, some lack statistically significant reduction in readmission rates due to lack of control group or study design. Therefore, further research is warranted to determine if there is a statistical significant reduction in 30-day readmission rates utilizing a multidisciplinary team in the heart failure clinic.

Objective: This study will evaluate the effect of medication therapy management services in a HF clinic on 30-day readmission rates compared to usual nurse-led care. The primary outcomes are the 30-day heart failure readmission rates following discharge from a heart failure hospitalization. Secondary outcomes include drug therapy problems such as needs additional therapy (% of patients on beta-blocker, ACE inhibitor, ARB, ARNI, aldosterone antagonist, hydralazine, nitrate, diuretic, and ivabradine), inappropriate drug therapy, inappropriate medication frequency, supratherapeutic dosage, subtherapeutic dosage, adverse drug reaction, drug-drug interactions, drug-disease interactions, failure to receive drug, and non-adherence to drug therapy.

Methodology: This is prospective quasi-experimental study spanning from October 2016 to March 2018 in patients with a diagnosis of heart failure who attend the UH Portage Medical Center heart failure clinic. Exclusion criteria include patients who are not interested in participating in the service, whose emergency department visit did not result in an admission, and patients who are discharged to a long-term care facility. With the multidisciplinary team approach, patients will receive a comprehensive medication review, medication education, a medication action plan, and communication of changes to the primary care physician in addition to the usual care. An initial sample size of 197 patients is necessary to demonstrate a 20% effect with 80% power. It is hypothesized that there will be a reduction in 30-day all-cause readmission rates.

Results and Conclusion: To be determined

References:
Emergency Department Management of Acute Pain Crisis in Adults with Sickle Cell Disease

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Research site: MetroHealth Medical Center, Cleveland, OH

Background: Sickle cell disease (SCD) affects roughly 100,000 individuals in the United States and remains a public health concern.¹ According to the Centers for Disease Control and Prevention (CDC), sickle cell disease (SCD) caused approximately 75,000 hospitalizations from 1989 to 1993, costing nearly 475 million dollars. One of the most common complications of sickle cell disease is acute pain crisis, also known as vaso-occlusive crisis (VOC). Due to these acute pain events, sickle cell patients have a high rate of acute healthcare utilization in the emergency department (ED) and hospital.² However, treating these patients is difficult due to their underlying chronic pain and routine use of high dose analgesics. With the common misconception about SCD patients as drug seekers, physicians are hesitant to treat ED patients with opioids.³ Consequently, this causes longer triage times for these patients and possible undertreatment of their pain crisis. There is limited literature to support a standardized approach for adult patients. The MetroHealth System has no standardized care for sickle cell disease patients experiencing acute pain crisis and no criteria defining hospital admission. Therefore, MetroHealth is looking for ways to optimize the emergency department management of vaso-occlusive crisis pain events.

Objectives: The primary objectives of this study are to characterize the medication management and cost impact of adult sickle cell disease patients in the ED for acute pain crisis. Also, to identify whether MetroHealth is meeting the Centers for Medicare and Medicaid (CMS) Inpatient Admission Criteria and time to first analgesic dose benchmarks.

Methodology: This trial is an observational, retrospective, chart review conducted at the MetroHealth System. All sickle cell patients ages 18 years and older seen at any MetroHealth emergency department from January 1, 2017 until June 30, 2017 will be included. A list of patients will be requested through the hospital information services based on the vaso-occlusive crisis diagnosis-related group 10 codes (all ICD-10-CM D57). Data will be extracted from the MetroHealth electronic medical record system (EPIC™, including Care Everywhere™) and stored in a secure electronic database called REDCap™. Data points include: patient demographics including sickle cell type, vital signs, abnormal laboratory results, number of admissions meeting Centers for Medicare and Medicaid criteria, mean time to first dose of analgesic, number of emergency department visits, number of patients with emergency department care plans, number of patients on vaso-occlusive crisis prevention, types of interventions made during emergency department encounter (types of analgesics and supportive care), home pain regimen, the number of other healthcare related outpatient visits, allergies or contraindications to analgesics, pain scores, length of emergency department visit, and average visit cost. Descriptive statistics will be utilized for the data analysis. Local institutional review board (IRB) approval is in process.

Results and conclusions: Pending

References
Characterization of Vasopressin Use in the Management of Septic Shock at an Academic Medical Center

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Background: Administration of low doses of vasopressin (AVP) decreases norepinephrine (NE) requirements and increases mean arterial pressure in patients with septic shock.\(^1\) There is currently a lack of evidence to support the use of AVP as monotherapy for septic shock.\(^2\) AVP use is associated with a decrease in mortality when used in patients with less severe septic shock defined by NE dose.\(^3\) Recent reanalysis of previously published data using the Sepsis-3 definitions demonstrated a mortality benefit with use of AVP to treat patients with less severe sepsis defined by serum lactate.\(^4\) This study aims to describe frequency of use of AVP in patients with low and high severity of sepsis and describe patient outcomes when treated with and without AVP.

Objectives: The objective of this study is to characterize the vasopressors used in more and less severe septic shock in the medical intensive care unit (ICU) at the study institution. In addition to describing the severity of illness of patients treated with various vasopressor regimens, the project will examine outcomes of patients with varying disease severity managed with or without AVP. The primary outcome will be a description of severity of illness of patients treated with and without AVP. Secondary outcomes include discharge status, ICU and hospital length of stay, NE doses at time of initiation and discontinuation of AVP, and rate of AVP charge capture.

Methodology: This is a retrospective cohort study of patients greater than or equal to 18 years of age who received NE in the medical ICU from July 1, 2016 through June 30, 2017. Patients will be identified using a drug use report of NE and data will be collected from the institutional electronic medical record. Adult patients treated in the medical ICU with continuous infusion NE orders during the study time period will be included. Patients with a cumulative time on vasopressors less than 12 hours or use of a vasopressor regimen at time 0 that does not include NE will be excluded. Study time 0 will be the first administration of vasopressors in the ICU. Patients will be considered to have less severe disease if lactate is less than or equal to 2 mmol/L and NE dose is less than or equal to 0.2 mcg/kg/min at study time 0. Patients not meeting either of the aforementioned criteria will be considered to have more severe disease. Division into four cohorts will occur based on patients having less or more severe disease per the study definition and treatment with a vasopressor regimen that does or does not include AVP. Patient enrollment will be capped at 100. Study investigators hypothesize that the majority of patients receiving AVP have more severe disease per the study criteria.

Results and conclusions: Results and conclusions will be presented at the Ohio College of Clinical Pharmacy Spring Meeting 2018.

References:
Effects of a Process Improvement Project on Perioperative Antibiotic Documentation in the Same Day Surgery Center

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Background: Summa Health System – Akron Campus recently transitioned to a new electronic health record (EHR). The transition prompted procedural changes regarding documentation of pre-operative antibiotic administration for patients in the Same Day Surgery Center (SDSC). On the new EHR, the documentation is completed by a registered nurse in the post anesthesia care unit who is responsible for manually recording the antibiotic on the electronic medication administration record (eMAR). The manual recording process for antibiotic administration at Summa has resulted in a marked decrease in documentation rates. Perioperative care has more medications administered per patient than other areas of the hospital and often involves high risk medications. However, many technologic safeguards are omitted in the operating room, such as bar code medication administration (BCMA). BCMA is used to increase safety of medication administration. BCMA has been shown to reduce medication errors and has been a meaningful use measure used by the Centers for Medicare and Medicaid Services since 2012. Perioperative antibiotics are recommended for many surgical procedures for prevention of surgical site infections. Perioperative antibiotics should be given within 60 minutes prior to the surgical incision. Accurate documentation of antibiotic administration in relation to incision time is an important tracking measure for Joint Commission standards.

Objectives: The primary objective is to develop a process improvement intervention to increase patient safety at Summa Health System – Akron Campus in the SDSC by accurately documenting antibiotics. The secondary objective is to minimize revenue loss from undocumented antibiotics.

Methodology: This is a retrospective chart review of patients in the SDSC with a pre-post design comparing before and after the process improvement intervention. Chart review of the eMAR will occur for SDSC patients with a pre-operative antibiotic order from July 2017 through December 2017. The primary endpoint is the percentage of antibiotics documented on the eMAR and will be assessed with a chi-squared test. The secondary endpoint is the average revenue lost per day from undocumented antibiotics and will be assessed with a two-sided t-test. Data collection will include surgery date, antibiotic order, and documentation on the eMAR.

Results and conclusions: Pending

References:
Evaluation of a “Time-Out” on Antimicrobial Utilization at a Large Health System

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Background: The Infectious Diseases Society of America and the Society for Healthcare Epidemiology Guidelines for implementing an Antibiotic Stewardship Program and the CDC Core Elements of Hospital Antibiotic Stewardship Programs include antimicrobial time-outs as an example of an intervention for stewardship programs to undertake. An antimicrobial time-out is a structured process to review antimicrobial therapy at a designated time point (typically 48-72 hours) to evaluate appropriateness. There is limited data evaluating the impact of antimicrobial time-outs on antimicrobial use outcomes. Cleveland Clinic Health-System implemented a 72 hour antimicrobial time-out for antimicrobials with an empiric indication and no stop date within the electronic health record. This study aims to assess the effect of an antimicrobial time-out on antimicrobial utilization.

Objectives: The primary objective of this study is to compare the Days of Therapy (DOT) per 1000 patient days of broad spectrum agents before and after implementation of an antimicrobial time-out. Secondary objective will include comparing the antimicrobial indications for use, describing the actions taken as a result of the antimicrobial time-out, and comparing the rate of hospital-acquired Clostridium difficile infections.

Methodology: This is a retrospective, quasi-experimental study of patients between October 1-December 31, 2016 and October 1-December 31, 2017 who received at least once systemic antibiotic agent while admitted to a US-based Cleveland Clinic Health-system hospital. Patients at Akron and Avon Hospital will be excluded from the comparison analysis but included in the descriptive analysis. To describe and define the actions taken as a result of the antibiotic time-out by providers, a window of 6 hours post alert acknowledgement will be used for assessment. To define classifications of antibiotics, the definitions created by the National Healthcare Safety Network Antimicrobial Use and Resistance Module will be implemented. Assessment of therapy de-escalation will be done using a validated spectrum score method from Madaras-Kelly, et al. The study will be performed through electronic data retrieval and received IRB approval.

Result and Conclusion: Pending

References:
The Impact of Pharmacist Intervention on Healthcare Utilization in an Outpatient Oncology Infusion Center

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Background: The WHO reports that cancer is the second leading cause of death worldwide, claiming responsibility for approximately 8.8 million deaths in 2015.1 It has been approximated that individual cases of cancer will increase by 50% between the years 2012 and 2030. The amount of deaths caused by cancer is expected to increase by 60%, from 8 million to 13 million, in the same time period.2 As the number of patients receiving chemotherapy begins to rise, the need for individualized medication assessment and planning becomes more essential. One way to ensure patients are receiving the best possible care is to take a well-rounded approach. This includes allowing pharmacists to use their training to analyze and identify medication related problems to improve patient care. A literature review revealed a gap in patient care where pharmacists are not being utilized to the best of their abilities. A vital component of a pharmacists’ duties is to evaluate patient medications for safety and efficacy. Several studies have revealed that a pharmacist’s intervention may aid in the reduction of hospital readmission in patients with cardiovascular disease. Data are limited and more studies need to be done in order to fully understand the implications of pharmacist intervention on overall readmission rates and healthcare expenditure. A study conducted by Budiman and colleagues was able to evaluate pharmacists’ education and follow-up in reducing hospital readmissions in patients with ST segment elevated myocardial infarction (STEMI). It was reported that all cause 30-day readmission decreased from 13% to 5% with pharmacists’ intervention. The study was not able to show statistical significance due to not reaching power. Despite this, it was shown that there was a lower absolute amount of hospital readmissions within 30 days. This clinically significant result shows that pharmacists being involved in programs that allow them to view, manage, and intervene on medication profiles can reduce hospital readmissions, thereby reducing cost.

Objectives: The objective of this project is to determine the impact that pharmacists’ have on overall healthcare utilization in an outpatient oncology infusion center.

Methodology: This study is an IRB approval pending retrospective, quasi-experimental study of patients receiving care at Dana Cancer Center between the dates of July 1, 2012 to September 15, 2017. Patients will be selected for inclusion according to the following criteria: outpatients receiving chemotherapy at the Dana Cancer Center, subjects aged 18 and older, patients initiated on new chemotherapy regimens, patients initiated on new immunotherapy regimens, patients with ≥ 1 medications on their profile. Patients will be selected for exclusion based on the following criteria: Patients admitted to the hospital for chemotherapy, pregnant women, patients receiving non-chemotherapeutic medications. The following data will be collected: age, gender, cancer diagnosis, chemotherapy regimen prescribed, other medications prescribed, number of medications at baseline, profile reviewed by a pharmacist. The primary endpoint will be healthcare utilization defined as 30-day hospital readmission rates. Secondary outcomes include adverse drug reactions or drug interactions as cause for readmission, number and types of interventions made, emergency department visits within 7 days.

Results and Conclusions: To be determined.

References:

Evaluation of Pharmacist Gout Management: Impact of Timely Urate-Lowering Therapy Titration

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Background: Gout is a rheumatic disease, resulting from chronic elevations of uric acid (UA) that leads to deposition of monosodium urate crystals in and around the joints. This ultimately leads to painful episodes of peripheral joint synovitis, or even joint damage and deformity.¹ According to the American College of Rheumatology (ACR), it is recommended patients with tophaceous or recurrent gout be treated with urate-lowering therapy (ULT) to a target UA level less than 6 mg/dL to eventually lead to a cessation of gout flares. Additionally, per the ACR, xanthine oxidase inhibitors (allopurinol or febuxostat) are recommended as first-line ULT, with daily colchicine recommended as first-line for acute gout attack prophylaxis and treatment. Gradual titrations of the ULT maintenance dose should be made every 2-5 weeks until the target UA level is reached, with UA levels being monitored every 2-5 weeks during ULT titration.² Prophylaxis with colchicine is to continue along with ULT for 3-6 months after achieving target UA in patients without tophi or 6 months after achieving target UA in patients with tophi. A medication use evaluation (MUE) done in 2015 at the Louis Stokes Cleveland VA Medical Center revealed that UA laboratory levels were not being rechecked in a timely manner. Consequently, ULT was not appropriately titrated to a target UA level of less than 6 mg/dL. This led to suboptimal ULT doses and extended durations of colchicine, thus resulting in suboptimal gout control. In July 2016, Wade Park Patient-Aligned Care Team (PACT) pharmacists were integrated into gout management to more efficiently optimize gout therapy management.

Objectives: The purpose of this quality improvement project is to determine the effectiveness of the PACT pharmacy gout management service on achieving target uric acid levels. The primary endpoint is the percentage of patients at target uric acid level. Secondary endpoints include mean time between each UA laboratory test, mean difference of UA levels, duration of time required to achieve target UA level, quantity of ULT titrations required to achieve target UA level, mean dose of each ULT, percentage of patients with discontinued prescription for colchicine, characteristics of origin to PACT pharmacy gout management service, quantity of titrations made by each PACT pharmacist evaluated using PharmD tool, quantity of PACT pharmacist phone interventions, and time spent by PACT pharmacists per encounter code.

Methodology: This project has been presented to the Louis Stokes Cleveland VA Medical Center’s Executive Leadership Board and has been approved. A chart review will be conducted utilizing the VA’s Computerized Patient Record System (CRPS) of patients with a diagnosis of gout and a documented Pharmacy Urate Lowering Therapy Note (T) or Pharmacy Urate Lowering Therapy Consultation (C) from July 1, 2016 through June 30, 2017. Data to be collected through March 31, 2018.

Results and conclusions: Pending

References:
Implementing a Pharmacy-Led Dexmedetomidine Stewardship Program

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Background: Critically ill patients in the intensive care unit (ICU) frequently require medications for the management of pain, agitation, and delirium (PAD). Research has shown that hospitals who adhere to sedation policies demonstrate significant improvements in reducing the duration of mechanical ventilation, length of hospital stay, and potentially mortality.¹ The recommendations derived from the 2013 Society of Critical Care Medicine guidelines on PAD, have prompted hospitals to revise sedation protocols.² A major recommendation from these guidelines is to use nonbenzodiazepines, such as propofol or dexmedetomidine over benzodiazepines for ICU sedation. Dexmedetomidine is a selective alpha-2 agonist that uniquely produces sedation and analgesia without compromising respiration.³ Its recommended infusion duration in critically ill patients is no more than 24 hours.⁴ One of the major pitfalls associated with dexmedetomidine is acquisition cost compared to other sedatives.³ Nonetheless, recent pharmacy-driven dexmedetomidine stewardship programs have seen success in curtailing hospital costs and decreasing the length of mechanical ventilation in ICU patients.³,⁵ The goal of this study is to evaluate the impact of usage guidelines and monitoring on dexmedetomidine use at a community hospital.

Objectives: The primary objective of this project is to implement a pharmacy-driven dexmedetomidine stewardship program that standardizes care practices to ensure appropriate use of dexmedetomidine in ICU patients. The primary outcome will be adherence to these guidelines and secondary outcomes will consist of the following: amount of dexmedetomidine used, length of infusion, duration of mechanical ventilation, length of ICU stay, need for reintubation, concurrent sedatives or opioids taken, cost of hospital stay and dexmedetomidine, reported adverse events, and mortality.

Methodology: This quality improvement study is pending approval by University Hospitals’ institutional review board. Dexmedetomidine appropriate use guidelines will be created to outline indications for dexmedetomidine use, dosing recommendations, and to set infusion duration limits. Pharmacists rounding in the ICU will then undergo training and be responsible for monitoring adherence to the guidelines. Patients over 18 years old, who receive dexmedetomidine for sedation, at a single center’s ICU will be included. Exclusion criteria include patients receiving concurrent alpha-2 agonists, dexmedetomidine for fast-track cardiac procedures or intraoperable dexmedetomidine. A retrospective chart review will be conducted to evaluate data from pre-implementation and post-implementation of the guidelines. Electronic medical records of the pre-implementation group will be reviewed from December 2016 to February 2017 and the post-implementation group will be reviewed from December 2017 to February 2018. The following data will be collected: demographics, amount of dexmedetomidine administered, intubation status, length of therapy and ICU stay, concurrent sedatives or opioids, and incidence of adverse events and mortality.

Results and Conclusions: Pending

References
4. Precedex (dexmedetomidine) [prescribing information]. Lake Forest, IL: Hospira Inc; April 2016.
Immunotherapy for advanced non-small cell lung cancer: Experience at the Cleveland VA

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Background: Lung cancer is the second most commonly diagnosed cancer in the United States annually and is the leading cause of cancer-related death. In 2017, it is estimated that there will be 222,500 new cases and 155,870 deaths from lung cancer. The survival rate for lung cancer is dismal with a 5-year survival rate of 18.1% being reported from 2007-2013. Similar to the national estimates, lung cancer is the second most commonly diagnosed cancer at the Louis Stokes Cleveland VA Medical Center (LSCVAMC). In the past few years, immunotherapy has become incorporated into the standard treatment of NSCLC and is often used as second-line therapy. This new therapy has transformed the way lung cancer is treated and has improved the survival of patients with NSCLC. Utilization of immunotherapy in the veteran population with lung cancer is not well described. The purpose of this study is to evaluate the use of immunotherapy, specifically nivolumab, versus chemotherapy in veterans with previously treated advanced NSCLC at LSCVAMC.

Objectives: The objective of this study is to assess the survival benefit of nivolumab versus chemotherapy for veterans with previously treated advanced NSCLC. The primary endpoint is overall survival percentage at one year following treatment with nivolumab or chemotherapy as second-line therapy and beyond. Secondary objectives are to assess the response of nivolumab versus chemotherapy as second-line therapy and beyond for veterans with previously treated advanced NSCLC, to assess adverse events of nivolumab versus chemotherapy. We will also describe the systemic treatment received for NSCLC.

Methodology: This study is a single center retrospective chart review of patients who received nivolumab or chemotherapy at LSCVAMC for previously treated advanced NSCLC from January 1, 2010 to August 31, 2017. Patients will be identified for inclusion in the study through a search of the Corporate Data Warehouse (CDW). The CDW search will include all patients with an encounter diagnosis code for malignant neoplasm of the lung and bronchus (ICD9 code: 162 or ICD10 code: C34) and have a CPRS note titled "Hem/Onc Treatment Note" that both occurred between January 1, 2010 to August 31, 2017. Patients will be included in the study if they have previously treated NSCLC and received at least one dose of chemotherapy or nivolumab. Patients who received immunotherapy in the first-line setting, or have a known EGFR or ALK mutation will be excluded. Targeted enrollment is 100 patients, with 50 patients in the nivolumab group (Group 1) and 50 in the chemotherapy group (Group 2). Patients in Group 1 will be matched 1:1 to patients in Group 2 based on the line of therapy nivolumab was used (second-line, third-line, etc). The primary endpoint is overall survival percentage at 1 year following treatment with nivolumab or chemotherapy as second-line therapy or beyond. Key secondary endpoints include overall response rate based on RECIST criteria, incidence of adverse events, and rate of discontinuation of treatment due to adverse events for nivolumab versus chemotherapy as second-line therapy and beyond. Treatment characteristics will also be described.

Results and conclusions: Pending

References:
The evaluation of midodrine as an oral vasopressor: A retrospective chart review

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Background: Intravenous (IV) vasopressors are often used to provide hemodynamic support in patients who experience severe hypotension or shock. The administration of continuous IV vasopressors is commonly restricted to an intensive care unit (ICU) due to the need for central line placement, hemodynamic monitoring and associated drug complications. This restriction remains a barrier for clinically stable patients who are eligible for ICU discharge, aside from requiring IV vasopressors. Recent studies have evaluated midodrine as a possible oral vasopressor due to its action as an alpha-1 agonist.1,2,3 These studies have shown promising results for midodrine’s ability to help wean ICU patients off IV vasopressors and possibly reduce ICU length of stay.1,2,3

Objectives: The purpose of this study is to evaluate the possible clinical and cost saving benefits of midodrine as an oral vasopressor in ICU patients. The project’s primary objective is to evaluate the effect of midodrine on the duration of IV vasopressor therapy in ICU patients. Secondary objectives include evaluating the effect of midodrine on ICU length of stay, rate of restarting IV vasopressors after initial discontinuation, direct drug cost savings, and incidence of hypertension or bradycardia. A subgroup analysis evaluating the effect of different midodrine dosing on clinical outcomes will also be included.

Methodology: This study will be submitted to the Institutional Review Board for approval. The study design is a two-arm retrospective chart review of patients from August 2011 to August 2017 from two community hospitals. The maximum targeted sample size is 200 patients. The intervention group will include all adult ICU patients receiving midodrine while on continuous IV vasopressor therapy. IV vasopressor therapy will include norepinephrine, epinephrine, phenylephrine, dopamine, and vasopressin. Patients will be excluded from the intervention group if they received midodrine <12 hours prior to starting IV vasopressors, received < 2 doses of midodrine, received midodrine dosed at a frequency of once daily, or received IV vasopressors for an indication other than hemodynamic support. Data will be extracted from a shared electronic medical record and uploaded into a secured collection database. Collected data points will include age, gender, weight, ICD diagnosis codes, ICU transfer times, and drug order details, including drug, dose, duration, and administration time. The vasopressor control group will be matched to the intervention group by the following parameters: ICU admission date within 6 months, ICD diagnosis code, SOFA score, and vasopressor therapy.

Results and conclusions: In progress

References:
National Trends in Statin Medication Prescribing in Patients with a History of Stroke or Transient Ischemic Attack

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Background: One out of every twenty deaths results from a stroke.\(^1\) When considered independent from other cardiovascular diseases, stroke is the fourth leading cause of death after heart disease, cancer and chronic lower respiratory disease.\(^2\) Approximately 87% of all strokes are ischemic strokes.\(^3\) High-intensity statin therapy is recommended to reduce the risk of stroke and cardiovascular events among patients with ischemic stroke or transient ischemic attack (TIA) presumed to be of atherosclerotic origin.\(^4\) In patients with a recent stroke or TIA without known coronary heart disease, 80 mg of atorvastatin daily reduced the incidence of strokes (11.2% versus 13.1%, \(p=0.03\)) and major coronary events (3.4% vs. 5.1%, \(p=0.003\)) during a mean follow-up period of 4.9 years when compared to placebo.\(^5\) However, one small study identified that only 48.7% of patients hospitalized with stroke were prescribed statins upon discharge.\(^6\) Additional literature evaluating the prevalence and predictors of statin prescribing for patients in the outpatient setting with a history of stroke or TIA on a national level is warranted.

Objectives: The objective of this study is to assess the national prevalence and predictors of statin medication use in the ambulatory care setting in patients with a history of stroke or TIA. The primary endpoint is the percentage of patients with a history of stroke or TIA receiving statin therapy. Secondary endpoints include the association between specific patient demographics including sex, age, race, region, BMI/body weight, payor type, prescriber type, and statin use.

Methodology: This is a retrospective, cross-sectional, national, secondary analysis utilizing data from the 2010-2014 National Ambulatory Medical Care Survey (NAMCS) database that will include visits for patients with a history of stroke and/or TIA. Stroke patients will be identified based upon past medical history and ICD-9 codes for stroke and/or TIA. An association between specific patient demographics including sex, age, race, region, BMI, payor type, and statin use will be investigated. Sample weights will be used upon statistical analysis to calculate national estimates.

Results and Conclusions: To be presented at the Ohio Pharmacy Resident Conference.

References:
1) CDC, NCHS. Underlying Cause of Death 1999–2014 on CDC WONDER Online Database, released 2015. Data are from the Multiple Cause of Death Files, 1999–2013, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.
Effectiveness of Chronic Care Management in a Pharmacist-led Outpatient Clinic

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Background:
In the United States, it is estimated that chronic diseases are responsible for 7 out of every 10 deaths that occur each year. It is also reported that 1 in every 2 adults has a chronic disease and 1 in every 4 adults has at least two chronic diseases. Specifically in Ohio, 70% of Medicare patients 65 years and older have 2 or more chronic conditions. Due to the morbidity and mortality seen with these chronic conditions, the Centers for Medicaid and Medicare Services (CMS) has placed a focus on improving the management of these disease states. CMS recognizes Chronic Care Management (CCM) as an essential component to patient care and reimburses separately for CCM services. CCM services through CMS are defined by a practitioner spending defined clinical time per calendar month with a patient that has at least 2 chronic conditions expected to last at least 12 months. Since chronic diseases require close monitoring and extensive patient education to maximize patient outcomes, frequent follow-up with these patients is desired. A barrier to providing this type of care to patients has historically been the amount of time each month that is necessary to spend with these patients. Currently, less than 2% of eligible patients are utilizing these CCM services. To provide this care for patients, a pharmacist-led clinic to provide chronic care management services in conjunction with an affiliated physician group is being implemented.

Objectives:
To develop a process in which chronic care management services can be utilized to care for patients within the existing anticoagulation clinic patient population. To determine the impact of implementing a chronic care management service in conjunction with a specific provider group.

Methodology:
Chronic disease state care plans will be developed for the following conditions: atrial fibrillation, heart failure, asthma, COPD, diabetes, and hypertension. Eligible patients will then be identified within the existing Coumadin clinic patient population. An initial visit will be completed with the patient to identify needs and a care plan will be developed with the primary care provider. Patients will be followed up with on a monthly basis per the pre-determined care plan utilizing the pre-approved disease state management protocols. Data on CCM billing and patient outcomes will be collected. The hypothesis is that the amount of patients that CCM billing is utilized for will increase by at least 100% from the previous year.

Results and conclusions: Pending

References:
Evaluating the Utilization of Prescribing Atypical Antipsychotics for ICU Delirium at Transitions of Care

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Background: Delirium is prevalent in intensive care unit (ICU) patients, affecting up to 80% of the population, and is associated with increased length of ICU stay, mortality and long term cognitive impairment.¹ The most recent iteration of the Society of Critical Care Medicine Pain, Agitation and Delirium guidelines provides a low-level evidence recommendation that atypical antipsychotics (AA) may reduce the duration of delirium in the ICU.¹ Despite this paucity of data, the administration of AA for the treatment of delirium has become widespread, however, the use of these agents are not without risks. Side effects associated with long term use of AA include new-onset diabetes, hyperlipidemia and extrapyramidal side effects. In addition these medications carry a US Food and Drug Administration black box warning for risk of death in patients with dementia related psychosis.² The benefits of these agents are unlikely to outweigh the long term adverse effects when continued beyond hospital discharge. Recent studies have reported that 24% to 47% of patients prescribed an AA for ICU delirium were continued with a prescription at hospital discharge.³⁻⁵ The aim of this study is to describe the utilization of AA for the treatment of ICU delirium at transitions of care from an intensive care unit at the Cleveland Clinic Health System (CCHS).

Objective: The primary objective of this study is to determine the frequency of patients initiated on an AA in the ICU and continued on therapy upon hospital discharge. Secondary objectives include frequency of AA continuation at ICU discharge and incidence of AA tapering at transitions of care.

Methodology: This multicenter, retrospective chart review will be conducted for patients admitted from April 2016 to September 2016. All patients admitted to the ICU, administered an AA during ICU admission, and discharged from the hospital will be included. Those that were on an AA prior to admission or received less than 24 hours of AA therapy will be excluded. Continuation of atypical antipsychotic therapy at transitions of care will be identified from the medication administration record and the discharge summary note within the electronic medical record. Additional data points including duration and type of delirium, ICU and hospital length of stay and psychiatric consults during admission will be collected. Baseline characteristics and outcomes will be analyzed using descriptive statistics.

Results and Conclusions: Pending

References:
Impact of a pharmacist-driven vancomycin stewardship initiative utilizing Staphylococcus aureus nasal polymerase chain reaction assays in pneumonia patients

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Purpose:
Nasal polymerase chain reaction (PCR) assays that can detect methicillin-resistant Staphylococcus aureus (MRSA) have been shown to have a 98-100% negative-predictive value in ruling out MRSA in community-acquired and healthcare-associated pneumonia. Efforts have been made to utilize this tool to guide de-escalation of empiric treatment targeting MRSA pneumonia. In an effort to improve antibiotic utilization, Cleveland Clinic Medina Hospital implemented a pharmacist-driven initiative that allows direct ordering of nasal MRSA PCR swabs in pneumonia patients receiving intravenous vancomycin. This study will evaluate the efficacy and safety of the new initiative.

Objectives:
The primary objective is to compare the length of intravenous vancomycin therapy used in community and healthcare-associated pneumonia patients during the pre-protocol period versus the post-protocol period. Secondary outcomes will include assessment of 30 day mortality and hospital readmission rates, hospital length of stay, time to clinical improvement, incidence of vancomycin-induced nephrotoxicity, and quantity of vancomycin blood draws used for therapeutic monitoring.

Methods:
This retrospective chart review will include patients 18 years and older admitted to Cleveland Clinic Medina Hospital who received intravenous vancomycin for suspected community or healthcare-associated pneumonia between August 15, 2016 through December 15, 2016 (pre-protocol period) and August 15, 2017 through December 15, 2017 (post-protocol period). Patients who develop pneumonia 48 hours or more after hospital admission or who receive intravenous vancomycin for concurrent infection will be excluded. Data collection will include patient demographics and comorbidities, pneumonia severity characteristics, microbiological data, and antimicrobial use data. T-test or Mann-Whitney U test and Fisher’s exact test or Chi-squared test will be utilized in the statistical analysis, as appropriate.

Results and conclusions: N/A.

References:
The Effects of CYP2D6 Inhibitors on a High-dose Tramadol Taper for Opioid Detoxification

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Background: A 3-day high-dose tramadol taper is the current treatment of choice for patients undergoing opioid detoxification at Summa Health System (SHS). Tramadol is a centrally acting synthetic opioid with additional inhibition of norepinephrine and serotonin reuptake. Tramadol is metabolized in the liver by the Cytochrome P450 (CYP) enzyme system into two major metabolites: M1 an active metabolite through CYP2D6 and M2 an inactive metabolite through CYP3A4. Tramadol’s active metabolite has as much as 200 times more affinity for µ-opioid receptors and six times the analgesic potency as the parent drug. Many patients undergoing opioid detoxification may also be on treatment for underlying psychiatric conditions, and many psychiatric medications are moderate-to-strong inhibitors of CYP2D6. By Pharmacokinetic studies have shown decreased levels of the active metabolite M1 when the CYP2D6 pathway is inhibited; however, the clinical significance of this interaction is not well understood. Decreased levels of the active metabolite may significantly diminish drug effects, leading to increased symptoms of withdrawal, prolonged length of stay, and hospital readmissions.

Objectives: The purpose of this study is to determine if concurrent administration of moderate to strong CYP2D6 inhibitors and a high-dose tramadol taper adversely effects patient outcomes in opioid detoxification. The primary outcome is the area under the curve of Clinical Institute Narcotic Assessment (CINA) scores from baseline to discharge. Secondary outcomes include peak CINA score, time to peak CINA score, average scores of individual CINA items, adjuvant medication use, detoxification completion rates, length of stay, and readmissions.

Methodology: This study will be conducted as a retrospective chart review of patients admitted to the detoxification unit at SHS St Thomas Hospital from May 8, 2017 to December 11, 2017. The study will compare outcomes for patients with concurrent moderate-to-strong CYP2D6 inhibitors as defined by the Indiana University CYP450 Interaction Table, during their detoxification stay to patients without concurrent therapy. The primary analysis population will be the intent to treat (ITT) population including patients who received at least one dose of the tramadol taper and at least one CINA assessment. All analyses will also be performed using the per-protocol subset defined as those patients receiving at least one CINA score prior to starting the tramadol taper and a final CINA score after the last dose of the completed taper. The primary outcome will be analyzed with an independent samples t-test and linear regression modeling for the area under the curve adjusted for baseline CINA score and covariates such as age, gender, race, substance use history, and concurrent phenobarbital use. For all secondary outcomes, continuous data will be assessed with two-sided independent samples t-tests (or Mann-Whitney U tests) and nominal data will be assessed with \(\chi^2\) or Fisher’s Exact Test where applicable.

Results and conclusions: Pending.

References:
Incidence of Venous Thromboembolism With Aspirin Versus Enoxaparin Prophylaxis After Major Orthopaedic Surgery

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Background: Venous thromboembolism (VTE) incidence following major orthopaedic surgery is a highly recognized and concerning complication. The three major orthopaedic surgeries include total hip arthroplasty (THA), total knee arthroplasty (TKA) and hip fracture surgery (HFS). Many patients undergoing these types of surgeries are already at an increased baseline risk for VTE due to obesity, immobility and age. Patients are at highest risk for VTE within several days after surgery which is why pharmacologic prophylaxis is recommended for at least 10 to 14 days. Both the American College of Chest Physicians (ACCP) as well as the American Academy of Orthopaedic Surgeons (AAOS) recommend the following agents for pharmacologic prophylaxis: low-molecular-weight heparin (LMWH), fondaparinux, dabigatran, apixaban, rivaroxaban, low-dose unfractionated heparin, adjusted-dose vitamin K antagonist and aspirin. Although both guidelines agree that the utilization of pharmacologic prophylaxis is warranted there is no consensus on agent selection or duration of therapy. The ACCP prefers LMWH to other agents while the AAOS does not recommend a preferred agent. Due to this lack of guidance and given the variability that has anecdotally been observed at our institution, the investigative team would like to evaluate the treatment practices at Marymount Hospital and throughout the Cleveland Clinic Health System over the past five years.

Objectives: The primary objective of the study is to evaluate the incidence of VTE as a composite endpoint of pulmonary embolism and deep-vein thrombosis for patients receiving prophylactic therapy with enoxaparin or aspirin after major orthopaedic surgery. The secondary objectives are to characterize prescribing patterns for thromboprophylaxis selection and duration of therapy as well as to measure incidence of major bleeding.

Methodology: This is a non-interventional, retrospective cohort study of patients who are 18 years of age or older who underwent major orthopaedic surgery between January 1, 2012 through December 31, 2016 within the Cleveland Clinic Health System (Euclid, Fairview, Hillcrest, Lutheran, Main Campus, Marymount, Medina, South Pointe). Patient charts will be evaluated up to 90 days after surgery for incidence of VTE or hemorrhage. Patients with hypercoagulable states including current malignancy, protein C and S deficiency, antiphospholipid syndrome, and pregnancy will be excluded from the study. Additionally, patients who were previously on anticoagulation therapy prior to surgery will be excluded. An estimated 12,000 patients will be reviewed. Reports will be generated from the electronic medical record and data will be analyzed utilizing the Student’s t-test, Chi-squared analysis, and descriptive analysis.

Results and Conclusions: Pending

References:
Impact of Pharmacy Consults On Heart Failure 30-Day Readmission Rate

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Background: Heart failure is a serious medical condition, causing over one million hospital admissions and costing the United States over $30 billion in 2012.¹ The Centers for Medicare and Medicaid Services began to reduce payments to hospitals with 30-day readmissions to increase focus on outcomes for heart failure patients. There have been multiple studies evaluating ways in which hospitals can reduce readmissions. One previous study demonstrated that increased adherence to evidence based medications lowered odds of readmissions to 79% (95% CI: 0.71-0.89).² Another study evaluated the efficacy of nurse educators providing discharge counseling, which lowered the odds of readmission to 65% (p=0.018).³ Finally, a study evaluated the effect of improving a patient’s transition of care through outpatient visits and telephone calls within 30 days of discharge and found the odds of readmissions were lowered to 81% (95% CI: 0.70-0.94).⁴ These studies show that interventions aimed at improving medication adherence, providing discharge counseling, and improving transition of care can reduce heart failure readmissions, and are all services that can be provided as part of a pharmacy consult service.

Objectives: The primary outcome of this study is to determine the impact of a pharmacy consult service on 30-day heart failure readmission rate versus those who did not receive a pharmacy consult. Secondary endpoints include the types of recommendations made during the service, percentage of recommendations accepted, readmissions for reasons other than heart failure, and medications provided as part of the service.

Methodology: A pharmacy consult service for heart failure was initiated at University Hospitals Richmond Medical Center in October 2017. Consults are placed by care coordinators, residents, and physicians. As part of the consult service, pharmacists review medication profiles for EBMs at maximum tolerated doses, counsel patients at discharge with extensive focus on EBMs, stress the importance of post-hospital discharge follow-up, and provide a free 7-day supply of select EBMs (lisinopril or losartan, metoprolol or carvedilol, spironolactone, and furosemide) to help the patient transition to their follow-up. The electronic medical record will be searched to identify patients admitted prior to the consult service with a discharge diagnosis of heart failure exacerbation meeting inclusion and exclusion criteria to serve as the control group. Patients admitted after the initiation of the consult service who received the service will be used as the intervention group. This prospective quality improvement study will analyze the effect of pharmacy consults on 30 day readmission rate, as well as the other secondary outcomes.

Results and conclusions: Pending

References:
2. Ruppar TM, Cooper PS, Mehr DR, Delgado JM, Dunbar-Jacob JM. Medication Adherence Interventions Improve Heart Failure Mortality and Readmission Rates: Systematic Review and Meta-Analysis of Controlled Trials. J Am Heart Assoc. 2016 Jun 17;5(6)
The effect of dexmedetomidine versus propofol on the incidence of post-cardiac surgery atrial fibrillation

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Background: Post-operative atrial fibrillation (POAF) is a known complication of cardiac surgery, estimated to occur in up to 50% of patients.1,2 Following cardiac surgery, many patients will return to the intensive care unit mechanically ventilated requiring sedative medications. Dexmedetomidine, a selective alpha-2 agonist, is a sedative medication with favorable cardiac effects including decreases in tachycardia due to its effects on the sinus and atrioventricular nodes.3,4 Only one randomized controlled trial to date, conducted by Liu, et al, has evaluated the use of dexmedetomidine versus propofol on the incidence of POAF in an elective coronary artery bypass graft (CABG) patient population. This study found that dexmedetomidine decreased the incidence of atrial fibrillation following cardiac surgery compared to propofol. This study evaluated the occurrence of POAF up to 96 hours after cardiac surgery, but it is unknown how many of these patients required treatment for atrial fibrillation at hospital discharge, which can occur more than 96 hours after surgery.2 The aim of this study was to compare the incidence of POAF in patients who underwent both urgent and elective cardiac surgeries who received either dexmedetomidine or propofol for sedation.

Objectives: The primary objective of this study is to determine the incidence of POAF after elective and urgent cardiac surgery in patients who received dexmedetomidine versus those who received propofol. Secondary objectives include the need for atrial fibrillation treatment at hospital discharge and differences in hospital length of stay for those received dexmedetomidine versus propofol.

Methodology: This is a retrospective cohort study of adult patients without pre-existing atrial fibrillation admitted to Cleveland Clinic Akron General between January 2011 and August 2017 for an elective or urgent cardiac surgery (CABG, valve repair, and combined CABG/valve repair procedures) who received either dexmedetomidine or propofol for sedation after surgery. Data collection will include age, gender, the use of beta-blockers, non-dihydropyridine calcium channel blockers, or anticoagulation prior to admission, comorbid conditions, type of cardiac surgery, and if the surgery was urgent or elective. Documentation in the electronic health record will be used to determine if patients developed POAF, to determine if patients required treatment for POAF at hospital discharge, and to determine hospital length of stay. It is estimated that two hundred patients will be included in the final analysis. The authors hypothesize that dexmedetomidine will be associated with a decrease in the incidence of POAF in patients undergoing both urgent and elective cardiac surgeries compared to propofol.

Results and conclusions: Pending

References:
Description of Pharmacy Interventions during Transitions of Care of Inpatients Consulted to the Palliative Care Service.

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Background:
Medication errors are common during care transitions and have been well-documented in previous literature.\(^1,2,3\) Palliative care patients represent additional challenges due to the complexity of their past medical history and the number of care providers involved. A recent in-house quality improvement project, the Summa Transitions Excellence Program (STEP), placed pharmacists and pharmacy interns within an interprofessional group to improve transitions on one unit of Summa Health System (SHS) Akron Campus. STEP at SHS demonstrated decreased readmissions for the unit, with the largest improvement observed when all components of the medication intervention were completed.\(^4\) The current STEP process includes the following: Verification of home medication list; Admission medication reconciliation/adherence screen; Therapeutic evaluation; Disease state and new medication counseling; Confirmation and communication of post-discharge follow-up; Discharge medication reconciliation; Provision of “After Visit Summary”; Follow-up phone call within 2 business days.

Objectives:
The purpose of this initiative is to describe patient outcomes when extending the pharmacy interventions of the STEP program into patients with an active palliative care consult located throughout the hospital. The primary outcome is the number of clinically significant interventions within each STEP component performed by pharmacy staff. The secondary outcomes include predictors of 30 and 60 day readmission rates, percentage of accepted pharmacy interventions, change in HCAHPs medication communication scores and the average time spent on each component of STEP.

Methodology:
This is a quality improvement initiative involving patients admitted to SHS Akron Campus and consulted to the palliative care service after November 1st 2017, without a hospice designation at admission. The investigating pharmacist will communicate with the current STEP team for coordination of care for their current patients with palliative care consults. Interventions performed by the primary investigator and STEP pharmacy staff will be included in the results. Descriptive statistics will be used to evaluate the primary and secondary objectives with regression models used for predictors of readmission.

Results and conclusions: Pending

References:
Characterization of sugammadex use and retrospective comparison to neostigmine for reversal of neuromuscular blockade at a community hospital

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Background: It is important to achieve complete and quick reversal of neuromuscular blockade (NMB) post-anesthesia to prevent risks associated with residual NMB. Until sugammadex was recently introduced to the market, neostigmine was the primary agent used for reversal of NMB after surgery. Due to the novel and rapid mechanism of sugammadex in NMB reversal, it has been embraced by anesthesiologists. Due to an increased use of sugammadex at our community hospital, a Drug Utilization Evaluation was performed and a 50:50 use of sugammadex to neostigmine was agreed upon due to the high costs associated with sugammadex. There are no major studies comparing the effectiveness and safety of these two medications.

Objectives: The objectives of the first phase are to characterize the various patient populations and the surgery types in which sugammadex is currently being used at the institution. The objectives of the second phase of this study are to compare the effectiveness and safety of sugammadex to neostigmine in regards to reversal of NMB.

Methodology: This retrospective study will be completed in two phases. In the first phase, sugammadex use will be characterized by renal function, age, gender, weight/BMI, cardiac history, and surgery type. In the second phase of the study, a two-month cohort of sugammadex use will be identified and compared to a similar cohort of neostigmine prior to the approval and addition of sugammadex to the formulary. The sugammadex cohort will be taken from May-June 2017 and the neostigmine cohort will be from May-June 2016 in an effort to control for bias. The following data will be collected and compared among the two cohorts: time to transfer out of the operating room (OR), length of stay in the post-anesthesia care unit (PACU), tidal volumes, time to recovery of train-of-four (TOF) ratio to 0.9, post-operative tachycardia, post-operative nausea and vomiting (PONV), and anaphylaxis. Appropriate statistical analysis for continuous and nominal data will be conducted.

Results and Conclusions: Pending

References:
The Use of Chloral Hydrate in Mechanically Ventilated ICU Patients

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Background: Patients in the intensive care unit (ICU) can require intubation for respiratory support and need sedation, commonly with benzodiazepines and opioids. Chloral hydrate is a hypnotic without analgesic effects that slows the activity of the nervous system due to its active metabolite trichloroethanol. It is a rapidly absorbed medication and has a lower adverse effects profile than other sedatives with its major side effects including hypotension, gastric irritation, and arrhythmias. In March 2012, the commercially available products were voluntarily discontinued, which led to the use of the reconstituted crystals. It has been mostly used for short-term sedation prior to surgery or procedures and for mild insomnia, but with a lack of information concerning its long term use. The reconstituted crystals are now being used at Rainbow Babies and Children’s Hospital for patients requiring mechanical ventilation for prolonged periods of time, and are already on high doses of continuous intravenous sedatives. Currently main sedation medications include benzodiazepines and opioids which can cause significant side effects including respiratory depression and withdrawal. The use of chloral hydrate as adjunct therapy may result in lower doses of benzodiazepines and opioids, resulting in fewer side effects.

Objectives: The objective of this study is to determine the efficacy of chloral hydrate in reducing benzodiazepine and opioid use in intubated ICU patients. The primary endpoint is a reduction in total morphine equivalents and midazolam equivalents by 10-15%. The secondary object is to determine the safety of chloral hydrate in intubated ICU patients.

Methodology: This is a retrospective chart review that will compare a historical control from before chloral hydrate was on formulary to a recent treatment group of patients who were put on chloral hydrate. The historical control will be patients from July 2014 through July 2015 matched 2 to 1 to chloral hydrate patients from July 2016 to July 2017 with similar diagnoses, ages, and number of days ventilated. A reduction in total morphine and midazolam equivalents will be defined as a reduction by 10-15% per ventilated days. To determine safety, side effects such as hypotension, arrhythmias, and emesis will be monitored using the lowest blood pressure of the day, a baseline and after treatment EKG, and any antiemetic use within 30 minutes after a chloral hydrate dose. An unpaired t-test will be used to analyze independent continuous variables, and a chi-square test will be used to analyze nominal data. We estimate about 96 patients will meet the inclusion criteria. Data will be collected using electronic medical records at Rainbow Babies and Children’s Hospital.

Results and conclusions: Pending

References:

Pharmacists Intervention on the Prevention and Treatment of Delirium in the Intensive Care Unit

Samantha Wilkosz, PharmD

Objectives:
1. To determine the incidence and length of delirium after the implementation of a prevention protocol and delirium treatment order set
2. To determine the impact of a pharmacist’s involvement in the prevention and treatment of delirium

Background:
Delirium as defined by the Pain, Agitation, and Delirium (PAD) guidelines is a syndrome characterized by the acute and rapid onset of cerebral dysfunction with a change or fluctuation in baseline mental status, inattention, and either disorganized thinking or an altered level of consciousness.¹ The main features present in a delirious patient include: disturbed level of consciousness with a reduced ability to focus, change in cognition, or the development of a perceptual disturbance. Delirium has been associated with increased length of stay, increased cost of care, and increased mortality. On average, patients will stay upwards of 14 extra days, pay an extra $2500, and will have an increased mortality rate ranging from 22% to 76%.²

The best way for a patient to avoiding delirium is prevention. According to the PAD guidelines performing early mobilization of adult ICU patients whenever feasible will help reduce delirium incidence and duration. The Mayo Clinic also suggests promoting good sleep habits (i.e., noise level, lighting, proper sleep schedule), helping the patient remain well oriented (i.e., time and day), providing visual and hearing aids, and preventing further health complications.³

When monitoring for delirium, the most valid and reliable tool is The Confusion Assessment Method for the ICU (CAM-ICU).⁴ This tool assesses acute onset or fluctuating changes, inattention, altered level of consciousness, and disorganized thinking. After completion of the assessment the patient will either be CAM-ICU positive indicating delirium is present or CAM-ICU negative indicating delirium is not present. Currently there is no standard treatment regimen proven to be effective for decreasing delirium duration.

Methodology:
Prior to the implementation of the delirium order set baseline data will be collected in order to determine a baseline incidence of delirium in the intensive care unit (ICU). Data that will be collected includes admitting diagnosis, risk factors, risk factor score, CAM-ICU, onset of delirium, and duration of delirium. Every newly admitted patient in a four week period will be evaluated on all the data being collected on a daily basis. I will be the sole data collector for the first month. Following the baseline data collection the delirium order set will be implemented. After one month of order set implementation the same data will be collected.

Results and Discussion: To be determined

Resources:
Adherence and Treatment Attrition Among Veteran Patients
Prescribed Buprenorphine for Opioid Use Disorder Treatment

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Background: The current United States opioid epidemic is a systemic and pervasive issue threatening the public’s health through the perpetuation of addiction and overdose. This is especially concerning in the veteran population which possess unique risk factors for opioid use and addiction, including mental health disorders and chronic pain syndromes.1 Furthermore, readjustment from service has been identified as a potential risk factor for opioid abuse; with social isolation, rehabilitation from physical injury or disability, lack of secure housing and income, and poor access to services and support representing potential vulnerabilities among veterans.2 The expanding use of buprenorphine/naloxone for opioid use disorder within the Veterans Health Administration has increased access to treatment for many veterans who qualify for this modality. Examining buprenorphine/naloxone use, there is evidence suggesting that less than 80% adherence to treatment (22/28 days) is a predictor of relapse, with non-adherent patients experiencing a 10 times greater likelihood of relapse.3 In patients retained to treatment programming for up to a year, one study found that 90% were no longer abusing opioids.4 Among veterans newly started on buprenorphine/naloxone, 61.6% were likely to be retained into treatment programming for more than one year.5 The relationship between level of adherence to medication therapy and retention within the treatment program has not been established.

Objectives: To evaluate the difference in attrition from opioid abuse treatment programming at one-year from induction between veterans inducted onto buprenorphine/naloxone treatment for the first time who exhibited adherence and those who were non-adherent. A key secondary objective will be the assessment of difference in days to attrition from the treatment program among veterans who left the program and were adherent to treatment versus those who were non-adherent.

Methodology: This will be a retrospective cohort study using chart review of veteran's inducted onto buprenorphine/naloxone treatment for the first time between 1/1/2016 and 1/1/2017. Unique patients will be included based on the diagnosis of opioid use disorder, age ≥ 18 years old, and medication management by the Louis Stokes Cleveland Department of Veterans Affairs Medical Center. Exclusion criteria include any previous induction to buprenorphine therapy. The prespecified hypothesis is that the veteran sample exhibiting any period of non-adherence will be more likely to drop-out of treatment at one-year from induction.

Results and Conclusions: Pending

References:
Effect of flumazenil pre-treatment on electroconvulsive therapy seizure duration and clinical effectiveness

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Background: Electroconvulsive therapy (ECT) is among the most effective treatments for many treatment-resistant psychiatric disorders. As with any therapy, there are constant efforts to make the treatment safer and more effective. A robust seizure with adequate duration is critical for a successful procedure. Flumazenil, a benzodiazepine antagonist, has been used to make ECT more effective however there are few published studies available. Currently, there is 1 case series (Yi et al., 2012) that describes the use of ECT and flumazenil not associated with any patient benzodiazepine use. It suggests that flumazenil can be used during ECT to maintain proper seizure duration despite no benzodiazepine use. The largest trial to date, a retrospective analysis of 84 patients compares patients taking benzodiazepines and undergoing ECT with flumazenil to patients who have had ECT without benzodiazepine use or flumazenil use. The current study will have a significantly higher number of patients than any study to date on the use of flumazenil during ECT. It is also unique in terms of analyzing the use of flumazenil and ECT seizure duration not associated with benzodiazepine use.

Objectives: The objective of this study is to investigate the use of flumazenil in ECT and its effect on seizure activity. The primary objective is to assess seizure duration in patients who have had ECT with and without flumazenil. The secondary objectives are to analyze flumazenil pre-treatment in ECT and clinical outcomes. These outcomes include: Montgomery Åsberg Depression Rating Scale (MADRS) Scores as well as post-procedure adverse effects including panic, anxiety, mania, seizures, and cardiac side effects. The ultimate goal is increased effectiveness and standardization.

Methodology: This retrospective chart-review study will be submitted to the Institutional Review Board for approval. Patients receiving flumazenil who are older than 18 years of age, and are admitted as inpatient or outpatient for the purpose of ECT treatment, will be identified through the electronic medical record system. All data will be recorded without patient parameters and maintained confidentially. Inclusion and exclusion parameters will be applied to the initial data collected. Patients who are using flumazenil for purposes other than ECT will be excluded. Patients will only be included if they initially tried an ECT session without flumazenil then subsequently with flumazenil. Data collected will be used to analyze if flumazenil has an effect on seizure duration. Additionally, the analysis will help elucidate any changes in several clinical outcomes and adverse effects. The following data will be collected from eligible patient charts: demographic information, weight, pregnancy status, all psychiatric diagnoses, seizure threshold-altering medication use, Montgomery Asberg Depression Rating Scale (MADRS) scores, seizure length, cardiac comorbidities, seizure dose and frequency including electrode placement, length of stay, number of admissions and any adverse effects noted (seizure, death, mania, post-procedural anxiety or panic). Statistical analysis will be applied for significance.

Results and Conclusions: Pending

References:
Analysis of direct oral anticoagulant use at an academic medical center

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Background: Anticoagulants are the mainstay of therapy for the prevention and treatment of various thromboembolic disorders, including atrial fibrillation (AF), deep vein thrombosis (DVT), and pulmonary embolism (PE). For many years, vitamin K antagonists (e.g. warfarin) were the sole oral treatment modalities for these disease states. However, since the introduction of dabigatran in 2010, direct oral anticoagulants (DOACs), including dabigatran, rivaroxaban, and apixaban, have become increasingly popular due to their ease of administration and lack of monitoring parameters. Proper management of DOACs is imperative to ensure therapy efficacy, reduce risk of bleed, and optimize patient safety.

Objectives: The primary objective of this study is to determine the prevalence of appropriate DOAC prescribing in patients admitted to an academic medical center before and after the implementation of a pharmacy-managed anticoagulation transition procedure. Secondary objectives include: 1) to assess the prevalence of inappropriate DOAC prescribing due to patient-specific factors, and 2) to determine the prevalence of adverse effects, bleeding and thromboembolic events, associated with inappropriate DOAC use.

Methodology: This retrospective, quasi-experimental study was approved by the Biomedical Institutional Review Board. Adult patients admitted to an academic medical center from February 1, 2014 to January 31, 2016 who received DOAC therapy during hospitalization are eligible for inclusion. Patients in the outpatient setting or those admitted to an intensive care unit will be excluded. The pre-pharmacy-managed anticoagulant transition procedure (pre-implementation) group includes patients admitted from February 1, 2014 to January 31, 2015 which will be compared to the post-pharmacy-managed anticoagulant transition procedure (post-implementation) group which includes patients admitted from February 1, 2015 to January 31, 2016. Data extracted from electronic medical records and paper charts will include patient demographics, length of stay, surgical procedures, indication for anticoagulant use, the number of anticoagulant doses received, the duration of anticoagulation therapy, and pertinent labs. To assess for potentially interacting medications, home and hospital medication lists will be reviewed. Patients who were inappropriately prescribed a DOAC will be evaluated for the incidence of adverse event, thrombosis or bleeding per standard and validated clinical definitions, associated with anticoagulant use. Based on previously published data, a total of 290 subjects are needed to meet power.

Results and Conclusions: pending

References:

Evaluation of Multi-Drug Resistant Pathogens in a Critically Ill Trauma Population

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Background: The increasing incidence of drug resistant organisms is a growing healthcare concern and is particularly concerning in intensive care units. Clinicians are challenged with choosing effective initial empiric therapy in the setting of increased resistance rates. A study by Zilberberg and colleagues showed that failure to use initially appropriate antibiotic therapy was the best predictor of hospital death among patients with gram-negative severe sepsis or septic shock. Identifying risk factors associated with multi-drug resistant (MDR) organism growth could affect empiric antimicrobial therapy selection. Previous studies have identified risk factors associated with MDR pathogen growth in critically ill patients in medical and surgical intensive care units (ICUs). To date, no studies have evaluated MDR organism growth in critically ill trauma patients. This study aims to identify the incidence and risk factors of MDR organism growth in this population.

Objectives: The objective of this study is to describe the incidence of MDR organism growth in critically ill trauma patients and to identify risk factors associated with MDR organism growth in these patients. The primary endpoint is the incidence of MDR organism growth based on the institution’s susceptibility reports. Secondary endpoints include the incidence of extensively-drug resistant (XDR) organism growth, the incidence of pan-drug resistant (PDR) organism growth, and the association of various risk factors with MDR organism growth in critically ill trauma patients. The rates of multi-drug resistance, stratified by organism, will also be reported.

Methodology: This study is a retrospective cohort chart review of adult patients from July 2016 through June 2017 who were admitted to an ICU under the institution’s trauma service. Patients will be included if a culture is obtained at any time during their hospital course of stay. Organism growth will be identified via microbiological results of blood, body fluid, respiratory, urine, or wound cultures. To be included, a patient must be at least 18 years of age, admitted under the trauma service to an ICU for a minimum of 24 hours, and cultured during their hospital course. Exclusion criteria include pregnancy, inmates, cultures drawn less than 48 hours after admission, and cultures with no susceptibility data reported. Antibiotic resistance will be determined according to susceptibility data generated by the microbiology lab. The risk factors that will be assessed include comorbidities, recent hospitalization, recent antibiotic use, ICU length of stay, prior MDR organism growth, and type of trauma. A statistician will aid in the data analysis.

Results and conclusions: Pending

References:

Evaluation of Pharmacist Medication Review Service in an Outpatient Heart Failure Clinic

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Background: Heart failure affects 5.7 million adults in the United States and costs the nation approximately $30.7 billion annually.¹ One in four patients have multiple chronic disease states including iron deficiency anemia, hypertension, diabetes, tobacco use and hyperlipidemia. Interdisciplinary team management can help to achieve treatment goals.² A pharmacist can decrease the complexity of medication regimens while addressing drug related problems.³,⁴ The heart failure pharmacist at MetroHealth provides a unique service performing medication reviews and recommending interventions to reduce drug related problems to the heart failure providers and primary care providers.

Objectives: The primary objective is to compare the total number of drug related problems identified in the intervention group versus the control group. The intervention group will include patients who have had a medication review completed by the pharmacist. The control group will receive usual care. Secondary objectives include categorizing the types of recommendations being made, identifying the categories of recommendations most commonly accepted, describing the recommendations made to a non-heart failure provider and determining the level of impact of pharmacist recommendations.

Methodology: This is a retrospective chart review of patients in the MetroHealth ambulatory heart failure clinic from June 2017 to December 2017. The primary and secondary endpoints will be assessed through study subjects’ charts in the electronic medical record database. Investigators will capture the total number of drug related problems per patient that exist two weeks after pharmacist intervention and compare this to the total number of drug related problems per patient in the control group. We hypothesize that pharmacist intervention will result in a reduction in the total number of drug related problems per patient compared to the control group. Patients who received a pharmacist medication review will be considered for inclusion in the intervention group. Patients who have not previously had a pharmacist medication review will be considered for inclusion in the control group. Patients will be excluded if they have no comorbidities in addition to heart failure or have been seen in the pharmacist led heart failure medication titration clinic in the past. The drug related problems will be categorized into low, medium, or high impact based on whether or not a medication change is made as a result of pharmacist intervention. All continuous data will be analyzed using the student’s t-test, and nominal data will be analyzed using either Fisher’s Exact test or Chi-square test. The authors hypothesize that there will be 25% fewer drug related problems in the intervention group versus the control group. To achieve 80% power (beta = 0.2, alpha =0.05) with an estimated mean number of three drug related problems per patient and a standard deviation of 1.5, a sample size of 64 patients per group will be required.

Results and conclusions: Pending

References:
1. CDC Division for Heart Disease and Stroke Prevention. [Internet]. Heart Failure Fact Sheet. [Updated 16 June 2016; Cited 3 Aug 2017].