

Comparison of treatment outcomes for vancomycin alone versus combination therapy in severe *Clostridium difficile* infection

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Background: According to the SHEA and IDSA guidelines for treatment of *Clostridium difficile* infection, the recommended treatment of severe infection is oral vancomycin 125 mg four times daily for 10-14 days.^{1,2} Only in complicated cases with shock, ileus, or toxic megacolon is combination therapy with metronidazole recommended.^{1,3} However, often many patients with severe infection are treated with combination therapy. To date, no comparison studies have been published on the *in vivo* effect of combination therapy with vancomycin and metronidazole.⁴ Therefore, this project will evaluate whether patients with severe *C. difficile* infection treated per the guideline recommendations of oral vancomycin alone or with combination therapy have better outcomes.

Objective: To evaluate differences in treatment outcomes for patients with severe *C. difficile* infection treated with oral vancomycin alone or with combination therapy.

Methodology: This study is a non-interventional, retrospective chart review to evaluate differences in treatment outcomes for patients with severe *C. difficile* infection treated with oral vancomycin alone or with combination therapy. The primary objective of the study is to assess time to clinical cure of *C. difficile* infection defined as resolution of diarrhea without development of a complication. Secondary objectives include comparing rates of complications defined as death within 30 days or toxic megacolon, colonic perforation, or emergency colectomy within 10 days, and comparing rates of recurrence of *C. difficile* infection within 30 days. Adult patients with severe *C. difficile* infection receiving either oral vancomycin (125, 250, or 500 mg four times daily) or combination therapy for at least 72 hours will be included. Exclusion criteria includes patients with mild, severe-complicated or recurrent *C. difficile* infection, irritable bowel disease, graft versus host disease, neutropenia, or cirrhosis. Data describing patient demographics, anti-*C. difficile* agents used, daily *C. difficile* infection symptoms, complications, and *C. difficile* infection recurrence will be collected. The student's t-test or Mann Whitney-U test will be used to evaluate continuous data as appropriate, while nominal data will be assessed with either the Chi-square test or Fisher's exact test. Time to clinical cure will be evaluated with Cox proportional hazards method.

Results and Conclusions: To be determined.

References:

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Management of Bone and Joint Infections (BJI) with Outpatient Parenteral Antimicrobial Therapy (OPAT) in a Veterans Population: Outcomes and Risk Factors

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Background: The use of outpatient parenteral antimicrobial therapy (OPAT) has been increasingly adopted due to evidence of reduced risk of nosocomial infection, decreased healthcare-related costs, and improved quality of life for many patients.^{1,2} Bone and joint infections (BJI) are some of the most common diagnoses documented in OPAT programs today.^{1,2,3} Treatment with OPAT may be delivered via two modalities: healthcare-administration, in which therapy is administered by a healthcare professional, or self-administration, in which therapy is administered by the patient or caregiver.^{3,4} Despite the well-documented benefits of OPAT, information describing the outcomes of this therapy is lacking. Furthermore, there is a general lack of guidance surrounding patient selection criteria with regard to delivery modality. This study will assess outcomes and identify possible risk factors for OPAT failure in patients who underwent self-administration of therapy.

Objectives: (1) To identify risk factors that may contribute to OPAT failure; (2) To describe the OPAT failure and success rate at the Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC)

Methodology: A retrospective chart review will be conducted to evaluate patient outcomes following treatment of BJI with OPAT. The study population will be identified from a registry of patients enrolled in the LSCDVAMC OPAT program from August 2009 – August 2011. Patients having a diagnosed or clinically suspected (in the opinion of the caring provider) BJI and who also underwent self-administration of therapy will be included. Patients will only be included for their first course of therapy during the study period. Data will be collected regarding demographics, past medical history, social history, diagnosis, antimicrobial therapy, treatment duration, microbiology, source of cultures, intravenous line, adverse effects, adherence, and outcome. Patients will be classified as a treatment failure if one of the following criteria are met: requiring an extension of IV therapy or addition of suppressive oral antimicrobial therapy, having a relapse of infection within 60 days after end of therapy, requiring admission or unanticipated surgical intervention for the site of initial treatment within 60 days after end of therapy, or failure to complete the full course of therapy. Multivariate logistic regression will be used to assess for the relationship between potential risk factors and treatment failure. Data will be reported as odds ratios, confidence intervals, and p-values.

Results and Conclusions: To be determined

References

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Treatment of Diabetic Ketoacidosis (DKA): Insulin Nomogram vs. Prescriber-Specified Insulin Infusion

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Background: Diabetic ketoacidosis (DKA), a metabolic derangement associated with an absolute/relative insulin deficiency and an increase in counterregulatory hormones, is the most serious complication of diabetes mellitus. Insulin therapy is the standard of care in the treatment of DKA. According to the American Diabetes Association (ADA), the administration of regular insulin via a continuous intravenous infusion is preferred in DKA due to its short half-life and ease of titration.¹⁻⁴ However, there has been no consensus on whether a prescriber-specified insulin infusion or a DKA insulin nomogram provides comparable efficacy and/or safety outcomes. Because of this, patients presenting to the Cleveland Clinic with DKA are either initiated on a DKA insulin nomogram or prescriber-specified insulin infusion depending on whether admitted to the General Internal Medicine (GIM) floor or Medical Intensive Care Unit (MICU), respectively.

Objective: To evaluate the efficacy and safety of a DKA insulin nomogram as compared to a prescriber-specified insulin infusion.

Methodology: A non-interventional, retrospective medical record review of adult DKA patients admitted to the Cleveland Clinic between January 1, 2008 to March 31, 2010. All adults (≥ 18 years old) with DKA (identified by ICD-9 codes) admitted to either the GIM or MICU and initiated on intravenous insulin will be included. Patients initiated on subcutaneous insulin therapy will be excluded. For the purposes of this study, DKA will be as an initial serum glucose (>250 mg/dL) and anion gap (>12 mEq/L). The primary objective of the study is to evaluate the mean time (in hours) to resolution of ketoacidosis between the DKA insulin nomogram vs. a prescriber-specified insulin infusion. Secondary endpoints include evaluating the incidence of a blood glucose reduction rate greater than 75 mg/dL/hr, incidence of hypoglycemic episodes (blood glucose <70 mg/dL), initial insulin infusion rate (Units/kg/hr), and initial insulin bolus (Units/kg). Data describing patient demographics, blood glucose (point-of-care and laboratory drawn), anion gap, and prescribed insulin doses will be collected. An alpha of less than 0.05 will be considered statistically significant. A t-test will be used to evaluate continuous data and a chi-squared test will be used to evaluate categorical data.

Results and Conclusions: To be determined.

References:

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Evaluation of Mortality Outcomes Following the Use of Recombinant Human Activated Protein C in the Previous 9 Years at a 500 Bed Tertiary Care Hospital

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Background: In November 2001 the Food and Drug Administration (FDA) approved recombinant human activated protein C (rhAPC) for the reduction of mortality in patients with severe sepsis and high risk of death as determined by APACHE II score.^{1,2} A subgroup analysis of the prospective placebo controlled randomized PROWESS study found septic patients with an APACHE II score from 25 to 29 had mortality rates of 41.4 and 22.3% for treatment with placebo or rhAPC respectively.³ Controversy has surrounded the use of rhAPC following revelation of protocol and product changes which occurred during the PROWESS study.⁴ A 2008 *Cochrane review* meta-analysis of rhAPC in patients with severe sepsis found pooled 28 day mortality RR 0.92 (95% CI 0.72 to 1.18 I²=72%) for rhAPC versus placebo and concluded that additional data was necessary to evaluate the effect of rhAPC on mortality.⁵ The same authors published a subsequent *Cochrane review* of rhAPC in April 2011. The review included one additional adult placebo controlled study. The pooled 28-day mortality relative risk was 0.97 (95% CI 0.78 to 1.22, I²=68%). A subgroup analysis of patients with APACHE II scores greater than 25 identified a pooled relative risk of 0.90 (95% CI 0.54 to 1.49 I²= 84%). The conclusion of this most recent meta-analysis was rhAPC did not have a statistically significant effect on 28 day mortality.⁶

Objective: To determine the mortality rate of patients treated with rhAPC at Mercy St. Vincent Medical Center

Methodology: A retrospective chart review trohoc study evaluating the mortality rates in patient treated with rhAPC versus a control group with sepsis and APACHE II score greater than 25. Secondary endpoints will include length of hospital stay and bleeding events. Patients treated after January 2008 and those patients who completed the 96 hour rhAPC infusion will be evaluated as a part of prespecified subgroup analysis. The control sepsis group will be identified by selecting a random sample of patients with the medical billing codes for severe sepsis, septic shock, or unsepcified sepsis January 2008 to July 2011. Control patients will be excluded if their APACHE II score is less than 25, they have contraindications to rhAPC treatment, or they were treated with rhAPC. Patients will be included in the rhAPC group if they received rhAPC infusion since it became available February 2002 until July 2011. Baseline characteristics collected for both groups will include: age, gender, APACHE II score, number of organs with dysfunction, presence of 2 or more systemic inflammatory response criteria, suspected site of infection, culture results, vasopressor use, mechanical ventilation, admission from healthcare facility, antibiotic therapy. Baseline data will be compared using the Chi-Square or Fisher's exact tests. Mann Whitney U and Student's t-tests will be used for ordinal and continuous data. Mortality will be assessed using odds ratios.

Results and conclusions: To be determined

References:

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Potentially Inappropriate Medications in a Community Living Center

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Background: Potentially inappropriate medication (PIM) use is highly prevalent among older people. Certain drugs are considered potentially inappropriate in older patients because of the higher risk of intolerance related to adverse pharmacodynamics, pharmacokinetics or drug-disease interactions¹. These observations have formed the basis for various sets of criteria for PIMs in older people, the best known of which is Beers criteria¹. The Beers criteria is widely known and accepted by many geriatric practitioners as an aid in the identification of PIMs in the elderly. One would therefore reasonably expect a significant association between PIMs and adverse drug events (ADEs). However, 2 recent large-scale retrospective studies that specifically examined the association between Beers criteria PIMs and the incidence of ADEs found no significant association^{2,3}. Due to the lack of a reproducible, statistically significant association between Beers criteria PIMs and ADEs, a research group recently devised and validated a new set of PIM criteria in older people, called STOPP (Screening Tool of Older Persons potentially inappropriate Prescriptions)^{1,4}. A recently published study assessed whether PIMs defined by new STOPP criteria are significantly associated with ADEs in older people with acute illness⁵. The authors concluded that the STOPP criteria are more sensitive to PIMs that result in ADEs than Beers criteria and are therefore more clinically relevant⁵.

Objective: To compare the prevalence of PIM prescribing before, during and after admission to a Community Living Center (CLC).

Methodology: Retrospective chart review of patients age 65 years or greater who were discharged from the CLC between June 2010 and June 2011. Patients will be excluded if they have insufficient medication records, hospice patients and patients who expire prior to discharge from CLC. The data regarding patient demographics, comorbidity, number of medications at admission and discharge, number of hospital admissions and reason for each admission, and number of falls will be collected for each patient. Medications will be reviewed from before, during and at discharge from CLC for PIMs, defined by the 2008 STOPP criteria. ANOVA will be used for continuous variables, and chi-squared test for ordinal data.

Results and conclusions: Results to be determined.

References:

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Determination of factors associated with bleeding in patients receiving alteplase for pulmonary embolism: a focus on body weight

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Background: Patients who present with massive or submassive pulmonary embolism (PE) may require immediate intervention using thrombolytic agents. Previous trials have indicated an increased rate of PE resolution and improved hemodynamics¹ for patients receiving thrombolytics plus heparin versus heparin alone.²⁻⁴ In a recent study, alteplase 50 mg infused over 2 hours showed similar efficacy to the FDA-approved dose of 100 mg infused over 2 hours.⁵ Subgroup analyses maintained similar efficacy while total bleeding was significantly lower in the 50 mg group, especially in patients weighing less than 65 kg.

Objective: Determine if body weight influences the safety of a 2 hour infusion of alteplase 100 mg for the treatment of pulmonary embolism.

Methodology: A non-interventional, retrospective, case-control chart review to evaluate the effect of body weight on the incidence of bleeding within 72 hours of alteplase administration in patients who receive alteplase 100 mg for pulmonary embolism. Case patients will include those experiencing bleeding while control patients are those who did not bleed. The influence of known risk factors for bleeding on the incidence of bleeding after alteplase for the treatment of pulmonary embolism will be evaluated as a secondary objective. All patients at least 18 years of age who received alteplase 100 mg over 2 hours for a confirmed diagnosis of PE will be included. Exclusion criteria include administration of alteplase for indications other than PE or use of alternative dosing regimens. A total of 90 patients will need to be included to detect a difference of body weight of 20 kg between groups. Data describing patient demographics, indication for alteplase, laboratory data, imaging data indicating bleeding, concomitant therapies including heparin, and risk factors for bleeding will be collected.

Results and Conclusions: To be determined

References:

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Assessing pharmacists' confidence in counseling patients with mental illness

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Background: Pharmacist interaction with physicians has been shown to optimize the treatment of their patients by improving their adherence and attitudes toward antidepressant and antipsychotic medications used to treat psychiatric conditions.¹ Despite these results, only 21% of patients on these medications are being counseled.² It has been documented that antipsychotic medications as a therapeutic class is in the top five for medication spending in the United States in 2010.³ Although psychotropic medications are widely prescribed and dispensed, the number of hours devoted to psychiatric disorders in pharmacy school curricula throughout the United States average only 2.5 hours each to major depression and schizophrenia/psychosis. Other areas of mental illness covered are varied both in topic and time allotment.⁴ There are little data to show that pharmacists are confident and knowledgeable in counseling patients on psychotropic medications.

Objective: This study will be assessing the confidence and knowledge of practicing pharmacists in counseling of patients with mental illness on psychotropic medications. Overall, this information will be analyzed to determine the need for curricular changes in colleges of pharmacy in order to better prepare pharmacists for educating those who suffer from mental illness.

Methodology: Application for IRB approval will be completed followed by the initiation of data collection upon approval. An online survey will be sent to licensed pharmacists who are graduates of the University of Toledo College of Pharmacy and Pharmaceutical Sciences. To increase response rate in the target population, an email reminder and survey request will be sent out at week one, two, and three from the original email request. The survey will be a modified questionnaire to evaluate social distance, antipsychotic and antidepressant therapeutic knowledge, and confidence in communicating this knowledge to patients suffering from a mental illness. To compute and analyze results, assessment will be completed using a four-point Likert scale. Respondents will also be asked to provide demographic information including gender, years in practice, current practice setting, degrees and certifications and/or further educational training.

Results and conclusions: To be determined.

References:

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Antibiotic use for bacteria on urinalysis in patients presenting to the emergency department

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Background: Inappropriate antibiotic treatment can lead to bacterial resistance, adverse effects, and increased health care costs.¹⁻³ Antibiotics for asymptomatic bacteriuria are not indicated in a majority of patients, yet many receive treatment.^{4,5}

Objective: To determine the proportion of patients presenting to the emergency department (ED) with bacteria on urinalysis without major signs or symptoms of a urinary tract infection (UTI) receiving antibiotic treatment for UTI.

Methodology: The study protocol will be submitted to the Institutional Review Board for approval. ED electronic records will be searched via the Logicare system to retrospectively identify patients presenting to the ED from January 1, 2008 to November 1, 2011 with a diagnosis of chest pain and in whom a urinalysis was completed. Patients 18 years or older with bacteria on urinalysis will be included. Any patients whom have confirmed pregnancy, are scheduled to undergo transurethral resection of the prostate, are immunocompromised, were recorded as unable to give a history upon presentation, had documented signs or symptoms of a UTI, or whom UTI is not listed as an indication for antibiotic treatment in ED chart documentation and history and physical reports will be excluded. Baseline demographics will be collected in addition to the presence of certain comorbidities and other positive urinalysis findings. ED chart documentation and history and physical reports will be analyzed for signs and symptoms of a UTI. Patients without criteria for symptomatic UTI will be divided into two groups: those treated for bacteria on urinalysis and those not treated for bacteria on urinalysis. For treated patients, urine culture results and antibiotic treatment data will be collected. The primary outcome of this study will be the proportion of patients with bacteria on urinalysis without criteria for symptomatic UTI that were inappropriately treated with antibiotics. Secondary outcomes include the odds of receiving inappropriate antibiotic treatment for bacteriuria on urinalysis in the presence of certain comorbidities or other positive findings on urinalysis, the percentage of completed urinary cultures in treated patients, the percentage of patients treated with specific antibiotics, the percentage of treated patients with an organism resistant to the chosen antibiotic, the duration of antibiotic treatment, and the total cost for antibiotic treatment. Descriptive statistics will be used. This information will be used to identify patients inappropriately treated for bacteria on urinalysis, triggers for ordering antibiotics, and the additional cost of treatment to the healthcare system.

Results and conclusions: To be determined.

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Effects of a Pharmacist-Initiated Outreach Program on Controller Medication Use and Asthma Control in Non-Adherent Asthmatics

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Background: Short-acting-beta-agonist (SABA) overuse can lead to an increased risk of experiencing adverse side effects such as jitteriness and tachycardia. Overuse of SABA can also lead to the development of tolerance resulting in less effective responsiveness during an exacerbation, increased airway response to allergens, and worsened overall asthma control. Current asthma guidelines emphasize treating asthma patients with controlled medications such as inhaled corticosteroids (ICS) and reserving SABA use for acute exacerbations. Studies utilizing focused counseling on the importance and proper use of ICS have shown increased adherence to controller medications. In an effort to improve both ICS utilization and control of asthma symptoms, Kaiser Permanente Department of Clinical Pharmacy has implemented a pharmacist-initiated asthma outreach program. **Objective:** To assess the effects of a pharmacist asthma-outreach program on controller medication use and asthma symptoms in non-adherent asthmatic patients.

Methodology: A retrospective chart review will be performed to evaluate the effects of direct pharmacist-to-patient outreach on controller medication use and asthma symptoms in non-adherent asthmatic patients. Secondary endpoints include oral steroid prescriptions before and after pharmacist outreach and patient satisfaction with the outreach. Patients will be contacted via telephone by an ambulatory care clinical pharmacist or a final-year pharmacy student to discuss the importance of ICS adherence and the need to reserve SABA for acute exacerbations. The Asthma Control Test, or ACT, will be performed to assess current asthma control. All patients will receive a standardized packet in the mail with educational material reviewing ICS, environmental triggers, and proper inhaler technique. One month following the initial outreach, all patients will be mailed a survey evaluating improvement in asthma knowledge and patient satisfaction. ACT results and ICS use will be re-assessed at one month either by phone or mail. Impact on SABA and ICS use will be assessed through medication refill records three months before and three months after the pharmacist outreach. Improvement in asthma control will be assessed through the ACT test, survey results, and reviewing patient medication records for oral steroid burst therapy. Patients meeting the following criteria will be included in the review: diagnosis of asthma; ages 5 – 64; more than 6 albuterol inhalers in the last 6 months; emergency room visit, same day appointment, or oral steroid burst therapy for asthma exacerbation in the last 3 months; lack of ICS; or less than 50% adherence to ICS. Patients with co-morbid COPD or who are on long-term oral steroids will be excluded. Patients contacted between September 12, 2011 and December 31, 2011 will be included in the chart review. Patient demographics; ICS, SABA, and oral steroid medication refill records; ACT score results; and patient satisfaction data will be collected for analysis. An alpha of 0.05 will be considered statistically significant. Parametric data will be evaluated using paired-t tests and categorical data will be evaluated using the chi-squared test.

Results and conclusions: To be determined.

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Evaluation of the use of adjunct perphenazine in patients with SSRI-resistant PTSD

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Background: Selective serotonin reuptake inhibitors (SSRIs) are first line agents in treating post-traumatic stress disorder (PTSD). Augmentation of SSRIs with prazosin or atypical antipsychotics, like risperidone, olanzapine, and quetiapine is often tried in SSRI-resistant PTSD.¹ A previous study conducted at the Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC) determined that a typical antipsychotic, perphenazine, is being used as adjunct treatment for patients with PTSD.² Currently, antipsychotics lack an FDA approval for this indication. A recent study by Krystal and associates, evaluated adjunct risperidone for antidepressant-resistant symptoms of chronic military service-related PTSD and found it to be no more effective than placebo.³ The purpose of this study is to evaluate perphenazine use as adjunct treatment for SSRI-resistant PTSD in veterans at the LSCVAMC and provide guidance for future practice.

Objective: To evaluate the efficacy, defined by relapse rate, of adjunct perphenazine use in patients with SSRI-resistant PTSD.

Methodology: A case-matched, retrospective chart review will evaluate the relapse rate, defined as hospital admissions and psychiatric ER visits, of adjunct perphenazine versus adjunct risperidone for SSRI-resistant PTSD. Relapse is defined as a composite of one or more of the following: discontinuation due to lack of effect; psychiatric hospitalization with a discharge diagnosis ICD-9 code for PTSD; increase in symptoms; intentional self injury; new or increased suicidal ideation; homicidal ideation or violence. Secondary objectives will assess adherence and adverse effects. All patients with a prescription for perphenazine plus a SSRI for treatment of SSRI-resistant PTSD from October 2007 to October 2010 will be included. Patients will be excluded if they have a psychiatric indication for a typical antipsychotic (schizophrenia or bipolar), lack an adequate trial of perphenazine (at least 30 days on medication) or lack an adequate trial (dose and duration) of their previous SSRI as monotherapy (at least 30 days on medication). A power analysis was performed to determine the target sample population of 28 patients for each group. Patients who meet the study criteria will be matched based on demographics (age, sex, combat theater experience, and psychotherapy) to patients on an equivalent dose of risperidone plus SSRI for SSRI-resistant PTSD. Patients will be evaluated for the primary and secondary outcomes within 1 year of initiating perphenazine or risperidone. A t-test will be used to compare the relapse rate change between adjunct perphenazine and adjunct risperidone.

Results and Conclusions: To be determined.

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Assessment of the Effects of Adherence Interventions on Laboratory Test Acquisition Rate

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Background: Research investigating the use of adherence interventions like phone calls and letters has been shown to increase patient attendance rate at scheduled appointment times¹⁻³ but little research has been done to determine if these same interventions can increase attendance rate at unscheduled but required yearly laboratory testing. In an effort to increase adherence to laboratory draw attendance, the Kaiser Permanente Medication Management Clinic (MMC) instituted a range of adherence interventions: automated phone calls with a reminder message from the patient's primary care physician, automated phone calls with a reminder message from the pharmacists at the MMC, letters, and digital messages through the KP.org secure online interface.

Objective: To evaluate the Kaiser Permanente Medication Management Clinic's intervention strategy and determine which applied interventions increased adherence most.

Methodology: A non-interventional, retrospective chart review of interventions performed on patients who annually require lab testing for their ACE-Inhibitors (ACE-I), angiotensin receptor blockers (ARBs), or diuretic medications. Primary endpoint is rate of their acquisition within one month of intervention. Secondary endpoint is cost per intervention. All patients at Kaiser Permanente on an ACE-I, ARB, or diuretic medication who have not had an annual serum creatinine and potassium in 2011 are included in this study. Data describing patient demographics, type of intervention, and labwork draw date will be collected. An alpha of less than 0.05 will be considered statistically significant. The chi-squared test will be used to analyze categorical data.

Results and Conclusions: To be determined.

References:

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Evaluating the role of statins in the prevention of contrast-induced nephropathy

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Background: Contrast-induced nephropathy (CIN) is a well-known complication of using iodinated contrast media.¹ Studies have evaluated a wide range of pharmacologic interventions to prevent CIN, including statins.² Statins may have the ability to increase nitrous oxide production, provide beneficial effects on endothelial function, and scavenge free oxygen radicals.³ These pleiotropic effects may lend to their role in the prevention of CIN.^{2,3} A recently published meta-analysis on the subject of statins for prevention of CIN concluded that statin therapy might be associated with a reduction in the incidence of CIN and that further studies are needed.⁴ The current study assesses whether statins prevent CIN in patients at our institution.

Objective: To evaluate the role of statins in the prevention of CIN.

Methodology: Electronic medical records of patients who received contrast media and had a procedure code indicating a cardiac catheterization at the University of Toledo Medical Center between January 2009 and August 2011 will be retrospectively reviewed. This study will be submitted to the Institutional Review Board for approval prior to commencement. Patient's baseline demographics, risk factors, specific statin used, nephrotoxic drugs (including but not limited to: ACE inhibitors, ARBs, NSAIDs, diuretics, metformin) and measures used to prevent CIN (including but not limited to: hydration and type used, administration of N-acetylcysteine) will be obtained. Any patients over the age of 18 who received contrast media at the time of catheterization, had a baseline serum creatinine concentration obtained within 24 hours prior to receiving contrast media, serum creatinine concentrations for at least 48 hours after exposure to the contrast media, and a record of outpatient prescription medications will be included in the study. Patients who have end-stage renal disease requiring dialysis will be excluded from the study. The following data will be collected if available: reason for catheterization, nephrology consult, lipid panel, type and volume of contrast media used, and comorbid conditions. The primary outcome, contrast-induced nephropathy, will be defined as an increase in serum creatinine > 0.5 mg/dL or 25% from baseline within 48 hours following exposure to contrast media. This criteria for defining CIN has been used in multiple studies looking at statins for the prevention of CIN. Based on the definition, patients will be classified as having CIN or not having CIN. Degree of renal dysfunction will also be assessed according to the RIFLE criteria, specifically the GFR criteria that define the degree of renal dysfunction encountered by patients.⁵

Results and Conclusions: To be determined.

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Treatment and Outcomes of *Stenotrophomonas maltophilia* Bloodstream Infections (BSI)

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Background: *Stenotrophomonas maltophilia* is an intrinsically multi-drug resistant nosocomial pathogen that causes BSI in critically ill and immunosuppressed patient populations.¹ Historically, sulfamethoxazole-trimethoprim (SMX-TMP) has been the treatment of choice.¹⁻⁴ However, with a national shortage of intravenous SMX-TMP and the emergence of SMX-TMP resistance, Infectious Diseases practitioners have had to utilize other available agents for treatment.⁵ This project will characterize treatment of *S. maltophilia* BSI and outcomes of patients treated with alternative antimicrobial regimens.

Objective: Evaluate the role of therapy (SMX-TMP vs. alternatives) on all-cause mortality at fourteen days

Methodology: A non-interventional, retrospective, chart review of patients with *S. maltophilia* BSI will be conducted. Secondary endpoints include evaluating time to appropriate antimicrobial therapy, describing treatment with alternative antimicrobial therapies, and describing treatment and outcomes of SMX-TMP-resistant *S. maltophilia* bloodstream infections. All patients ≥ 18 years of age who are inpatients at the Cleveland Clinic from January 1, 2001 to January 1, 2011 and who have one or more positive blood cultures for *S. maltophilia* will be included. Patients with polymicrobial blood cultures will be excluded. Data describing patient demographics, comorbidities, microbiology and treatment will be collected. An alpha of less than 0.05 will be considered statistically significant. Nominal variables will be analyzed by Chi-square or Fisher exact test and continuous variables will be analyzed by Student's *t* test.

Results and conclusions: To be determined.

References:

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Barriers associated with the implementation of a pilot extended infusion piperacillin/tazobactam dosing program at a university medical center

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Background: Multi-drug resistant organisms are becoming more common in daily practice and the need to optimize the currently available antibiotics exists. Beta-lactam antibiotics, such as piperacillin/tazobactam, function by maximizing the free drug concentration time above the MIC (fT>MIC).¹ In order to take advantage of this pharmacodynamic property the infusion time can be extended in order to enhance the fT>MIC and minimize the IV catheter access issues associated with continuous infusion.² Recent literature has shown that giving each dose every 8 hours and extending the infusion time from 30 minutes to 4 hours has been at least equivalent, if not better than standard dosing measures.^{1,2,3}

Objective: To assess the obstacles within the pharmacy and nursing departments involved in implementing an extended infusion piperacillin/tazobactam dosing program within the Medical Intensive Care Unit (MICU).

Methodology: The first phase of this project will consist of education of the pharmacists, nurses and physicians within the MICU. During this phase, a pre and post education survey will be administered in order to assess healthcare providers' perceptions of the barriers involved with implementation of the pilot. Following completion of the educational phase, the pilot will be rolled out and an automatic substitution to a four hour infusion of piperacillin/tazobactam will occur within the MICU. The third phase of the project will be to administer a follow-up survey three months following implementation. This survey will be administered to the pharmacists, nursing staff, and physicians within the MICU. It will assess a variety of physical and educational issues that may have occurred during the progression of the pilot. Financial impact will be measured during this phase. Drug acquisition costs during this time period will be compared to previous years in order to gauge whether a cost savings exists within the program. Analysis of these barriers will allow for a smoother transition to a hospital-wide implementation in the future.

Results and conclusions: To be determined

References:

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Evaluation of factors associated with achieving glycemic control in a pharmacist-managed diabetes clinic

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Background: Pharmacist involvement in the management of diabetes has been associated with improved diabetes-related outcomes.^{1,2} Patients receiving diabetic management from a pharmacist have been shown to have an average reduction in A1c of 1.0-1.38% more than patients not receiving diabetic management from a pharmacist.^{3,4} The specific interventions resulting in improved glycemic control have not been well-described in the literature.

Objective: To identify specific factors that may be associated with a patient's likelihood of achieving or maintaining goal A1c after 6 months in a pharmacist-managed diabetes clinic.

Methodology: This study is a descriptive, retrospective chart review of patients seen at a pharmacist-managed diabetes clinic from July 2009 - November 2011. Upon approval of the Institutional Review Board, patients with a diagnosis of type 2 diabetes mellitus (DM2), adequate baseline and follow up A1c measurements at least 90 days apart, and at least 2 visits to the diabetes clinic within the first 6 months of enrollment will be included in the study. Exclusion criteria include patients with a documented A1c goal >7%, baseline A1c <7% or a diagnosis of type 1 diabetes mellitus. Collected data related to demographics will include: patient age, gender, race, baseline and follow up A1c measurements, and diabetic medications prescribed at baseline and at 6 months. Collected data related to identified factors will include: time since diagnosis of DM2, number of office visits attended and missed within 6 months, documented diabetes education referral, documented presence of a care manager, documented social worker involvement, blood glucose logs brought to office visits, documented interaction with patient based on blood glucose logs received in-between office visits, documented hypoglycemic events preventing change in therapy, initiation of insulin or non-insulin medications, medications discontinued due to adverse event or contraindication and increases in insulin or non-insulin medication doses. The primary endpoint will be the odds of each identified factor being associated with achievement of goal A1c after 6 months of enrollment in the diabetes clinic. The secondary endpoint will be the odds of each identified factor being associated with an achievement of at least a 2% decrease in A1c in patients with a baseline A1c >9%.

Results and Conclusions: To be determined.

References:

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Retrospective Evaluation of the Impact of an Antimicrobial Stewardship Program on Clinical and Economic Outcomes

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Background: As antimicrobial resistance continues to increase, national guidelines and recommendations have been published for the development of antimicrobial stewardship to combat resistance and improve clinical patient outcomes.¹⁻⁴ The primary goal of an antimicrobial stewardship program (ASP) is to improve patient care and outcomes.¹ The ASP works to fulfill this goal by limiting inappropriate use of antimicrobials, and optimizing antimicrobial selection, dosing, route and duration of therapy. Currently there are very few publications that have studied the impact of an ASP on clinical patient outcomes. In an effort to provide optimal patient care and improve outcomes, Summa Health System (Akron City campus) initiated a systematic, comprehensive ASP in September 2010.

Objective: to evaluate the impact of the ASP on clinical patient outcomes.

Methodology: A retrospective chart review to compare the clinical outcomes and cost in patients for whom an ASP recommendation was accepted verses patients for whom an ASP recommendation was not accepted. The outcome measures include total length of stay (LOS), ICU LOS, time to resolution of infection, mortality in-hospital, mortality at 30 days, readmission at 30 days, duration of antibiotic therapy, relapse of infection, re-infection and cost of post-recommendation antibiotic regimen compared to pre-recommendation regimen.

Inclusion criteria consist of patients 18 years and older admitted to Summa Health System, Akron City Hospital for whom the ASP made a recommendation from January 1, 2011 to August 31, 2011. Patients will be excluded if they were treated with an investigational antimicrobial agent or had a hospital stay of less than 48 hours. An alpha of less than 0.05 will be considered statistically significant. Continuous data will be analyzed using a student t-test, while nominal data will be analyzed using a Chi squared test.

Results and Conclusions: To be determined

References:

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A Retrospective Evaluation of Pharmacist Managed Vancomycin Dosing and Monitoring

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Background: Vancomycin is one of the most highly used antibiotics and requires patient specific dosing and monitoring.¹⁻³ Frequently vancomycin doses are determined incorrectly and monitoring is performed at inappropriate times leading to misinterpretation of vancomycin levels. A consensus review published by the American Society of Health – System Pharmacists, Infectious Diseases Society of America, and Society of Infectious Diseases Pharmacists recommends dosing vancomycin based on the patient's actual body weight and frequency based on their renal function. The recommendations also include appropriate monitoring of trough concentrations, which should be based on the individual patient, type of infection, and their co-morbidities.³ Research has shown that pharmacist run therapeutic drug monitoring has lead to more accurate dosing and better outcomes.⁴⁻⁵ Dosing and monitoring guidelines have been developed at the Louis Stokes Cleveland Veterans Affairs Medical Center based on the above dosing recommendations. These new guidelines are utilized by a newly implemented pharmacist managed vancomycin consult service.

Objective: To evaluate a newly implemented pharmacist managed vancomycin dosing and monitoring service

Methodology: A retrospective chart review will be conducted to evaluate vancomycin therapy managed by pharmacy (post - protocol group) compared to patients who received vancomycin prior to implementation of the pharmacy vancomycin consult service (pre – protocol group). The primary endpoint is percent of appropriately collected vancomycin levels within the the goal range. Secondary endpoints will include number of levels drawn, number of inappropriate levels, inappropriately held doses, dosage changes, critical trough values, out of range trough values, and cost associated with excess levels. Patients will be included in the study if they received at least three days of vancomycin therapy and had at least one trough level, and were on the medicine wards. Patients will be excluded if they are on hemodialysis, have an infectious diseases consult, or pharmacy notes in their charts addressing therapy, if they are in the pre – protocol group. Patients in the pre – protocol group must have received therapy from October 3, 2010 though January 31, 2011, and post – protocol group from October 3, 2011 through January 31, 2012.

A t-test will be used to evaluate continuous data and chi-squared test will be used to evaluate categorical data.

Results and Conclusions: Data collection will begin pending Institutional Review Board approval.

References:

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The relationship between low vitamin D levels and depression

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Background: Low vitamin D levels have become a widespread problem in the US¹, with a prevalence reported to range from one third to one half of adults². It has long been realized that vitamin D plays a role in bone health and regulation of cellular and systemic calcium and phosphate metabolism,³ but vitamin D has recently been shown to play a role in many other areas including cardiovascular disease, diabetes, and cancer.¹ Receptors have also been found in areas of the human brain.³ These facts along with recent studies have led to the theory that vitamin D plays a part in cognitive function, neuronal development, and mental health.

Depression is a leading cause of disability in the US, with a lifetime prevalence of mood disorders being reported as 20.8%.⁴ Not only is it a widespread issue, but high treatment failure rates can lead to hospitalizations and subsequently readmissions. Although a few studies have begun to show a link between vitamin D levels and overall mood³, many of these only included special populations or had exclusion criteria that eliminate patients at the greatest risk of depression. In addition, these studies have not looked at readmission rates in correlation to vitamin D levels.

Objective: To study the relationship between serum vitamin D levels and depression in hospitalized patients.

Methodology: A noninterventional, retrospective chart review to compare the rates of depression in patients with a documented vitamin D level. All patients 18 years or older admitted to Akron City or St. Thomas hospitals with a documented vitamin D serum result will be included. Exclusion criteria includes patients pregnant or lactating at the time of vitamin D levels. Patient charts meeting inclusion criteria will be searched for information based on chronological vitamin D levels (most recent first) beginning in January 2011 and going through January 2006. The primary endpoint of presence of depression will be analyzed by multiple factors including: admission for depression as found in the discharge summary, admission or transfer to a psychiatric unit for depression treatment, and by an answer of yes on the admission question "are you sad or depressed?" Secondary endpoints will include 30, 90 and 180 day readmission rates. As vitamin D levels can fluctuate, the search for positive depression status will be confined to three months before through six weeks after the serum vitamin D result. Vitamin D status will be analyzed as categorical data, defined as sufficient (≥ 30 ng/ml), insufficient (29-20 ng/ml), and deficient (< 20 ng/ml). An alpha of less than 0.05 will be considered statistically significant. To find an 11% difference between groups and to achieve an 80% power a total of 165 patients will be needed. Continuous data will be analyzed using a t-test, and nominal data will be analyzed using a Chi squared test.

Results and Conclusions: To be determined

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Effect of Intravenous vs. Subcutaneous Phytonadione in Patients in Need of Emergent Warfarin Reversal

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Background: Current Chest guidelines recommend intravenous phytonadione for the reversal of warfarin in the emergent setting. Compared to subcutaneous administration, delivery of phytonadione via the intravenous route is more predictable, rapid and effective¹. In addition, higher doses of phytonadione are often required for rapid reversal when administered subcutaneously, possibly leading to extended resistance to subsequent anticoagulation upon restarting warfarin².

Objective: To compare the length of stay in patients who were treated with intravenous or subcutaneous phytonadione for emergent warfarin reversal with bleeding.

Methodology: After Institutional Review Board approval, a retrospective chart review will evaluate hospitalized patients treated with intravenous versus subcutaneous phytonadione for emergent warfarin reversal within the University Hospital Health System. All patients will be 18 years or older and on warfarin therapy. The patient must have an INR between 4.5 and 10 upon admission to the emergency department. The patient must also be restarted on warfarin therapy upon hospital discharge. Exclusion criteria includes: patients given IM or oral phytonadione, patients given phytonadione by more than one route, patients given FFP or any other blood products containing clotting factors, patients with active or severe liver disease, and patients on other forms of anticoagulation. The primary endpoint is length of stay. Secondary endpoints are cumulative dose of phytonadione required to achieve an INR of ≤ 1.5 , time taken to achieve INR of ≤ 1.5 , time from first phytonadione dose to restart of warfarin therapy, and the difference between initial and subsequent INRs measured at <12 hours, 12 to 24 hours, >24 to 36 hours, >36 to 48 hours.

Results and Conclusions: Data collection will begin pending Institutional Review Board approval.

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Evaluation of Opioid Analgesic Usage in Postoperative Coronary Artery Bypass Graft Surgery Patients Pre and Post Implementation of Computerized Physician Order Entry

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Background: In the surgical setting, coronary artery bypass grafting (CABG) has become one of the most common cardiothoracic interventions today¹. Approximately two thirds of patients who have undergone CABG report moderate to severe pain following surgery². In many patients, postoperative pain following surgery remains one of the most feared events during their hospital stay³. Appropriately treating postoperative pain in this patient population is of high priority to reduce further complications after surgical intervention. The institution implemented Computerized Physician Order Entry with pre-specified order sets for postoperative pain management in April 2011.

Objective: To evaluate opioid analgesic usage in postoperative cardiothoracic surgery patients both before and after the implementation of CPOE. The average pre-dose and post-dose pain scores will be compared as secondary endpoints as well as the incidence of adverse drug reactions.

Methodology: A retrospective chart review was completed for patients who underwent coronary artery bypass graft surgery in the first and third quarter of 2011 in a 500-bed tertiary care medical facility. Patients must have undergone coronary artery bypass graft surgery and received opioid analgesic medications in the postoperative period. The data collection period for each patient will begin in the postoperative period after the close of surgery and continued for 72 hours. Patients were excluded if they were enrolled in other clinical trials within the institution and intubated for a period of 24 hours or greater after surgery. Nursing documentation of patient reported pain scores before and after analgesic medication administration will serve as the basis for data collection.

Results/Conclusions: Results and conclusions will be presented after data is collected and statistical analyses have been performed. Changes in current analgesic usage protocols and order sets will be implemented based on the results of this study.

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Comparison of phenytoin, levetiracetam and lacosamide following benzodiazepine administration in the management of status epilepticus

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Background: Status epilepticus is a medical emergency which can result in neurologic injury after 30 minutes of seizure activity and is associated with significant morbidity and mortality. Benzodiazepines have established efficacy as first-line therapy in status epilepticus, however, are only successful in 55-65% of patients. Patients who fail benzodiazepine therapy will require additional therapies, for which there is limited information regarding the appropriate selection of a second-line agent.¹⁻⁴ Evaluation of phenytoin, levetiracetam and lacosamide use in status epilepticus at the Cleveland Clinic will help identify appropriate second-line therapy.

Objective: Evaluate the role of phenytoin, levetiracetam and lacosamide following benzodiazepine administration in the management of status epilepticus.

Methodology: A non-interventional, retrospective chart review to compare the efficacy of phenytoin, levetiracetam and lacosamide in terminating seizures within 48 hours of administration. Secondary endpoints include evaluation of time to seizure termination, functional status at discharge and overall survival. All patients of at least 16 years of age with status epilepticus and a definitive time of seizure onset who received a benzodiazepine followed by phenytoin, levetiracetam, or lacosamide were included. Patients who were transferred from an outside facility for which information regarding initial management is unavailable were excluded. Data describing patient demographics, prior seizure history and therapy, presentation and treatment of status epilepticus, and patient outcomes will be collected. Data will be analyzed with descriptive statistics.

Results and Conclusions: To be determined.

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Safety, Efficacy, and Cost of Pharmacodynamic Dose Optimization of Beta-Lactam Antibiotics

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Background: Dosing based on the pharmacodynamic properties of beta-lactam agents, by extended or continuous infusion, improves the effectiveness of therapy¹⁻⁴. In 2007, Summa Health System adopted the extended infusion policy for piperacillin/tazobactam and doripenem as the preferred method of administration for critical care patients. In 2010, isolates of *Pseudomonas aeruginosa* and *Acinetobacter baumannii* were evaluated by Center for Anti-Infective Research and Development to determine antibiotic dosing regimens that will optimize the probability of microbiological and clinical success. This data precipitated the revision of the extended infusion policy to create the Pharmacodynamic Dose Optimization Protocol (PDOP). The PDOP incorporates dose escalation or de-escalation of antibiotic therapy based on organism minimum inhibitory concentration (MIC), as well as adding a dosing strategy for cefepime. The goal of the PDOP is to dose piperacillin/tazobactam, doripenem, and cefepime according to the MIC of the individual pathogen. This protocol theoretically incorporates the improved outcomes of extended infusion while providing some cost savings to the institution by de-escalating doses based on the pathogen's susceptibilities. Unfortunately, there is currently no data regarding PDOP regarding its efficacy versus extended infusion or its potential cost savings.

Objective: To evaluate the safety, efficacy, and cost of the PDOP protocol for beta lactam dosing.

Methodology: A retrospective cohort analysis of patient charts will be performed to compare the safety, efficacy, and cost of the two infusion protocols. Patients will be included if they were: (1) treated from October 2009 to present, (2) 18 years of age or older, (3) were hospitalized for 72 hours or more, (4) had a documented gram negative infection, (5) received one of the study antibiotics for at least 48 hours, and (6) had a documented MIC or pathogen susceptibilities. Patients will be excluded if they: (1) received more than 24 hours of antibiotics before they received one of the study antibiotics, (2) had an infection proven to be resistant to initial therapy, (3) were infected with multiple organisms where initial therapy was proven inappropriate, (4) were pregnant. The following data will be collected and entered into the database: patient age, race, gender, estimated creatinine clearance, gram negative organism, source of infection, concomitant antibiotics they received, duration of therapy, hospital length of stay, ICU length of stay, cost of antibiotics used, MIC of organism, mortality data if available, APACHE-II score, length of time admitted to the hospital, number of days on a ventilator, mortality at day of discharge and at day 30. 100 cases will be included in each group. Continuous data will be analyzed using a student t-test, while nominal data will be analyzed using a Chi squared test.

Results and conclusions: To be determined.

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Low white blood cell (WBC) count and absolute neutrophil count (ANC) in patients receiving clozapine

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Background: The rare, but potentially fatal side effect of agranulocytosis has caused the use of clozapine to be regulated more than any other antipsychotic medication. All patients must be registered in the Clozapine National Registry and frequent monitoring of WBC count and ANC must be performed every 7-28 days depending on the current duration of treatment ¹. According to the clozapine monitoring guidelines provided by the Clozapine National Registry, a WBC count less than 3000/mm³ or ANC less than 1500/mm³ requires interruption of clozapine therapy ². However, interrupting therapy puts the patient at risk to decompensate ³. Also, rechallenging patients that have experienced reductions in ANC or WBC count can lead to a more rapid redevelopment of the blood dyscrasia ¹. While the monitoring guidelines are a useful tool for practitioners, they are not always followed in clinical practice.

Objective: Compare clinical outcomes in patients who did and did not discontinue clozapine therapy as a result of a WBC count less than 3000/mm³ or ANC less than 1500/mm³.

Methodology: The VA's computerized patient record system will be used to retrospectively identify patients who, over a 10-year time period, have experienced a WBC count less than 3000/mm³ or ANC less than 1500/mm³ while actively taking clozapine for the treatment of schizophrenia or schizoaffective disorder. Patients who received clozapine for another diagnosis will be excluded. Patients will then be stratified into two groups; those who continued or discontinued clozapine therapy according to the national monitoring guidelines and will be matched according to age and gender. Data collection will include age, gender, ethnicity, diagnosis, WBC, ANC, clozapine dose, pertinent concomitant medications, and patient outcomes. Patient outcomes will be obtained via chart review of electronic medical records. Research has been approved by the hospital's institutional review board (IRB).

Results and conclusions: To be determined.

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Warfarin discharge counseling pilot evaluation

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Background: The National Quality Forum in response to National Patient Safety Goals (NPSG) regarding anticoagulation therapy has mandated an implementation of a formalized anticoagulation management program to reduce potential for patient harm with the use of anticoagulation therapy. The 2011 NPSG guidelines described patient education as a “vital component” and required that organizations provide education to staff, patients and families. The guidelines also recommend that patient/family education includes importance of follow-up in order to monitor patients. To evaluate potential means to meet these goals the Cleveland Clinic Department of Pharmacy has implemented a warfarin discharge counseling pilot. The pilot involves pharmacists counseling patients on their warfarin therapy before discharge and ensures continuity of care post discharge.

Objective: To evaluate pharmacy warfarin discharge counseling pilot to determine quality assurance of patient education at discharge and to determine continuity of care post-discharge.

Methodology: It is a descriptive concurrent study using a phone follow-up survey and quality assurance survey. The primary objective is to determine the percentage of patients attending a post discharge follow-up appointment to monitor warfarin therapy using a phone follow-up survey. The secondary objective is to determine patient’s level of warfarin understanding after a warfarin counseling session by a pharmacist prior to discharge via a quality assurance survey. All patients 18 years or older discharged to home on warfarin therapy from cardiology floors (J7 -1, -2, -3) will be included. Exclusion criteria includes patients discharged from cardiology floors (J7 -1, -2, -3) on warfarin therapy to nursing facility and patients who are unable to speak and understand English. Also patients who are unable to be reached by pharmacy practice resident will be excluded from the primary outcome analysis. The timeframe for the pilot is November 1 – November 30, 2011. Primary and secondary objectives will be analyzed using descriptive statistics. Fisher’s exact test or Chi-square will be used when appropriate. An alpha level <0.05 will be deemed statistically significant.

Results and conclusions: To be determined

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Characterization and Outcomes of Androgen Deprivation Therapy in Patients with Prostate Cancer at MetroHealth Medical Center (MHMC)

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Background: Androgen deprivation therapy (ADT) is the main therapeutic option for men with metastatic prostate cancer, but is also considered for select men with early stage localized disease as an alternative to radical prostatectomy, radiation therapy, or active surveillance.¹ Increased attention has been paid to the quality of life in men receiving ADT therapy, since prostate cancer mortality rates have fallen by 39% from 1990-2006, and five-year survival rates are well-over 90%.² Many men receiving treatment are relatively young, otherwise healthy, and without symptoms. Unfortunately, long-term usage of GnRH (gonadotropin-releasing hormone) agonists has recently been associated with the development of metabolic disorders including diabetes and cardiovascular disease³, with only a modest improvement in survival. Other literature presents data suggesting that GnRH agonist increases the risk of diabetes, but not myocardial infarction or cardiovascular death.⁴ In October 2010, the FDA released an updated warning of increased risk in patients taking GnRH agonists for developing diabetes and cardiovascular events (heart attack, stroke, sudden cardiac death).⁵ In addition, MetroHealth is an inner city hospital that has a high number of minority patients including African Americans, whom tend to have more aggressive prostate cancer and a higher incidence of diabetes-related mortality and heart disease. This retrospective study will attempt to characterize the incidence of negative metabolic outcomes associated with long-term GnRH agonist therapy, and ascertain the level of surveillance of these comorbidities at MetroHealth Medical Center (MHMC).

Objectives: This study will characterize the incidence of diabetes and cardiovascular disease associated with long-term GnRH agonist treatment (> 6 months) for prostate cancer at MHMC, as well as changes in the indicators associated with these disease states. The data will then be used to increase awareness and modify or validate the current standard of practice at MHMC for prostate cancer patients receiving long-term GnRH treatment.

Methods: A retrospective data review will be conducted on all adult male patients (18-90+) who received leuprolide (GnRH agonist used at MHMC) for prostate cancer for more than six months from January 2001-December 2010. Prior to commencement, the study will be reviewed and approved by the MHMC Institutional Review Board (IRB). Patients eligible for the study will be identified using pharmacy records and data collected using MHMC's electronic medical record system, EPIC. Study data will be analyzed through the use of descriptive statistics to assess changes in the indicators of metabolic syndrome (obesity, cholesterol, blood pressure, and fasting glucose), as well as the incidence of diabetes and cardiovascular events in this patient population. The level of surveillance and management of these GnRH agonist-related complications will also be assessed during this study using nationally-accepted standards of care.

Results: To be determined.

References:

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Physician perceptions of the current level of pharmacy practice in a community teaching hospital

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Background: Current pharmacy practice model initiatives are promoting an increased collaboration between pharmacists and physicians in order to provide safe, effective, efficient, and accountable care.^{1,2} Limited studies have been done to assess physicians' expectations of pharmacist roles in collaborative practice.³⁻⁵

Objective: The objective of this study is to determine whether the current level of pharmacy practice within our health system meets our physicians' expectations.

Methodology: Prior to commencement, this study will be submitted to the Institutional Review Board for approval. A mixed-mode survey will be distributed to physicians for self-administration. All resident physicians and physicians with Active medical staff privileges will be included. Physicians without an active email and mailing address will be excluded. First contact will be through email and a web-based survey. Second contact will be through a mailed paper survey identical to the web-based survey. The following data will be collected from the survey: current position (i.e. Private practice, hospitalist, etc.), years in practice, practice area, interactions with pharmacists, and perceptions on experiences with and expectations of pharmacists. All data will be recorded without specific identifiers and maintained in a password protected file. Data will be analyzed descriptively as a whole and then analyzed comparatively by the independent variables. The primary outcome is to describe the difference between physicians' experiences with and expectations of pharmacy services within our health system. Secondary outcomes include demographic influence on primary outcome and physician assessment of the following: physician/pharmacist and patient/pharmacist affect on outcomes, pharmacist provided drug therapy management, and pharmacist accountability.

Results and conclusions: To be determined

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The effect of selegiline therapy on the onset of dementia in patients with Parkinson's disease

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Background: Dementia is a common non-motor complication in patients with Parkinson's disease with few therapeutic options. The use of selegiline therapy in Parkinson's disease is primarily as monotherapy in early stages or to reduce on-off fluctuations in later stages. Literature evaluating the potential neuroprotective benefits of selegiline in patients with Parkinson's disease is limited and focuses on motor complications.¹ Recent studies have shown a potential benefit of selegiline therapy in the treatment of Alzheimer's dementia and HIV-associated dementia.^{2,3} To date, amantadine is the only medication to be evaluated as potentially neuroprotective with regards to the onset of Parkinson's disease dementia.⁴ The progressive neurodegenerative nature of Parkinson's disease has driven therapeutic approaches to neuroprotective therapies which may prevent or slow disease progression. Although literature suggests the possible neuroprotective benefits of available medications on motor complications, evidence is inconclusive to currently recommend these therapies for use in slowing the progression of motor and non-motor complications in Parkinson's disease.

Objective: To determine the effect of selegiline therapy on the onset of dementia in patients with Parkinson's disease

Methodology: A retrospective chart review to evaluate differences in time from Parkinson's disease diagnosis to the diagnosis of dementia between patients treated with selegiline (experimental group) vs. those that have not (control group). All patients with a diagnosis of Parkinson's disease as documented in the computerized patient records system or with a patient encounter coded for Parkinson's disease between 2000 and 2005 with at least 5 years of follow-up since diagnosis of Parkinson's disease will be considered for inclusion. Exclusion criteria includes a change in the diagnosis of Parkinson's disease, a diagnosis of dementia prior to selegiline therapy or prior to the diagnosis of Parkinson's disease, concomitant diagnosis of HIV, concomitant diagnosis or significant history of schizophrenia, schizoaffective disorder, or bipolar disorder, a Parkinson's disease diagnosis prior to the age of 50, a diagnosis of dementia and Parkinson's disease in the same year, or documented treatment with rasagiline or amantadine. The data to be collected will include patient demographics, date of diagnosis of Parkinson's disease and dementia, patient's age at these time points, and medications the patient has received in the treatment of Parkinson's disease. If the patient has received selegiline therapy, in addition to the above mentioned, the date selegiline therapy was started and discontinued, and reason for discontinuation will be documented. For continuous data a t-test will be used and for categorical data a chi squared test will be used, with an alpha less than 0.05 being significant.

Results and conclusions: To be determined

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Vitamin D therapy for rosuvastatin induced myalgia

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Background: Myositis and myalgia are common adverse effects associated with statins and are a major cause for discontinuation of therapy. Specifically for rosuvastatin, myalgia has been reported to occur in 3-13% of patients with the incidence increasing as the dose increases. Current recommendations for treatment of patients experiencing myalgia are rechallenging patients with a lower dose of the same statin or trying a low dose of another statin.¹ The mechanism of statin induced muscle injury is not well understood. One hypothesis is that a deficiency in vitamin D levels leads to decreased nuclear vitamin D receptor gene transcription of proteins that prevent subsarcolemmal rupture and are needed for repair of the T-tubular system inside muscle cells.²

Research has shown that a strong association exists between low serum levels of vitamin D (25(OH)D) and myositis.³ Upon supplementation in vitamin D deficient patients, improvements can be seen in muscle strength and reduced falls.⁴ This is hypothesized to be due to a reduction in type II muscle fiber atrophy from deficiency in vitamin D.⁵

Objectives: (Primary) To assess the ability to tolerate rosuvastatin after adequate vitamin D replacement therapy in patients who had an adverse drug reaction of myalgia with rosuvastatin and were vitamin D deficient.

(Secondary) Evaluate the number of patients able to reach LDL goals with rosuvastatin after adequate vitamin D replacement.

Methodology: This retrospective chart review will be conducted on patients at Louis Stokes Cleveland VA Medical Center (LSCVAMC) who had a reaction of myalgia associated with rosuvastatin and a serum 25(OH)D level of less than 40 ng/mL. Patients must have received supplementation with ergocalciferol or cholecalciferol and reached a serum 25(OH)D level of 40 ng/mL or greater. If patients achieved a level greater than 30 ng/mL with a baseline level less than 15 ng/mL, they may be included. Patients will be assessed in reverse chronological order for meeting inclusion criteria and patient charts will be reviewed using the LSCVAMC Computer Patient Record System (CPRS) database. Exclusion criteria consists of patients with comorbidities that could result in muscle or bone pain such as arthritis, fibromyalgia, peripheral vascular disease, and sensory neuropathy. Also, patients with a Cockcroft-Gault calculated creatinine clearance <30 mL/min at the time of myalgia will be excluded due to inability to metabolize ergocalciferol and cholecalciferol. The sample size was calculated to be 100 patients assuming a power of 80%, alpha of 0.05, and an effect size of 0.64. Both the primary and secondary outcomes will be assessed by logistic regression analysis using Microsoft Excel software.

Results and conclusions: Data collection will begin pending Institutional Review Board approval.

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Comparison of length of stay in two treatment severity criteria for *Clostridium difficile* infections

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Background: The 2010 Infectious Diseases Society of America (IDSA) *Clostridium difficile* treatment guidelines stratify disease severity based on expert opinion. These guidelines cite a study by Zar et al. as their main resource providing evidence of superiority with vancomycin in severe disease. However, not all components of the Zar criteria were incorporated into the IDSA stratification of disease severity.

Objective: To determine which criteria for stratifying *Clostridium difficile* infection severity is a better predictor of length of stay.

Methodology: This is a descriptive retrospective chart review of patients with *Clostridium difficile* admitted to Akron General Medical Center between January 1999 and December 2011. Upon approval from the Institutional Research Review Board, adult patients ≥ 18 years of age with an ICD-9 diagnosis code (008.45) for *Clostridium difficile* and a positive diagnostic test will be included. Patients will be excluded if they received >4 doses of either metronidazole or vancomycin and then were switched to a different agent at any point, received combination metronidazole and vancomycin therapy at any point, or were prescribed nitazoxanide, fidaxomicin, rifaximin, IVIG, tigecycline, or other medication used for *Clostridium difficile* any time after diagnosis. Data collection will include: demographic data (age, sex, race), serum creatinine (baseline and presentation), albumin, WBC count, temperature, ICU status, ventilator status, evidence of pseudomembranous colitis, discharge date, date of toxin positive, date treatment for *Clostridium difficile* began, admission date, date of readmission due to *Clostridium difficile*, date antibiotics for *Clostridium difficile* were discontinued, treatment used, date of previous antibiotic use, comorbid conditions (COPD, CAD, CHF, diabetes, malignancy, chronic kidney disease), hypotension/shock, and ileus. The primary outcome will be the difference in length of stay between the IDSA criteria group compared to the Zar criteria group in patients treated with metronidazole. Secondary outcomes will include the difference in length of stay between the IDSA criteria group compared to the Zar criteria group in patients treated with vancomycin, readmission rates for each criteria group based on treatment received, the percentage of patients that were readmitted with *Clostridium difficile* in each group, calculated economic impact of additional length of stay, and the percentage of patients that were prescribed appropriate therapy for *Clostridium difficile*, as defined the Zar criteria versus the 2010 IDSA guidelines criteria. Subgroup analysis will be performed for the primary outcome, excluding patients in intensive care units.

Results and conclusions: To be determined.

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Effect of a urinary tract infection stewardship program in an emergency department

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Background: Urinary tract infections (UTIs) are one of the leading causes of emergency department (ED) visits in the United States.¹ The ED at MetroHealth Medical Center, an urban level 1 trauma center, averages 100,000 visits annually² during which approximately 120 patients per month are diagnosed with urinary tract infection, pyelonephritis, or cystitis. On December 30, 2010, MetroHealth Medical Center implemented an electronic UTI order set in the ED to increase adherence to the Infectious Diseases Society of America (IDSA) 2010 practice guidelines for antimicrobial treatment of acute uncomplicated cystitis and pyelonephritis in women.³ Preliminary results showed that the number of patients receiving ciprofloxacin for the treatment of uncomplicated cystitis and pyelonephritis decreased by 69% and adherence to IDSA guidelines increased by 88%. However, 48% of cases of cystitis diagnosed by ED personnel were either found to have an alternative diagnosis or did not meet study criteria for cystitis. Twelve percent of cases of pyelonephritis diagnosed by ED personnel were either found to have an alternative diagnosis or did not meet study criteria for pyelonephritis. A retrospective study demonstrated an antimicrobial stewardship program in the ED significantly improved antimicrobial use and overall patient care.⁴

Objective: The primary objectives are (1) to determine if UTI stewardship intervention will improve the appropriateness of treatment for uncomplicated UTI and (2) to reduce the inappropriate treatment of abnormal urinalyses in asymptomatic patients in the ED. The secondary objective is to assess the compliance rate to the previous ED UTI order set, based on the IDSA guideline on the treatment of acute uncomplicated cystitis and pyelonephritis in women.

Methodology: Addendum to the already Institutional Review Board approved study will be submitted. Study population will include women ages 18 – 65 years. A retrospective chart review will be conducted to collect baseline data during the 4-8 weeks prior to the intervention (100 cases). The intervention will occur over an 8 week time period and will consist of four components. The first component will be an educational session for ED providers consisting of a power point presentation which will be available to all providers unable to attend the session in person. The second component will be the implementation of a symptoms checklist for providers to complete during their evaluation of patients suspected of having UTIs as well as an algorithm recommending empiric vs. withholding of therapy. The third component will be an audit and feedback to providers regarding the management of patients diagnosed with UTIs. The fourth component will consist of study personnel support in which study personnel will be available to review and follow up on significant culture results and/or to follow up on patients in whom empiric therapy was withheld. Post-intervention data will be collected during the 4-8 weeks after the intervention (100 cases). Data collected will include demographic information, laboratory test results, past medical history, documented signs and symptoms, prescribed antibiotic therapy, and adverse events. Appropriateness of UTI testing and treatment will be determined.

Results and conclusions: To be determined

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Evaluation of time to care and outcomes in heart failure patients enrolled in telehealth

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Background: Management of heart failure (HF) exacerbations are time dependent to prevent emergency department (ED) visits or hospital admissions. The average cost for a HF exacerbation hospital admission is \$6,000 to \$12,000¹. A meta analysis of twenty-one original studies performed by Polisen and colleagues demonstrated that patients followed by telemonitoring had a lower mean number of ED visits per patient per year compared to usual care². Telehealth is one way to manage HF symptomatology while encouraging patient self-management. The Veterans Health Administration (VHA) implemented telehealth services in July 2003. At the Louis Stokes Cleveland VA Medical Center (LSCVAMC), nurse managers monitor patients' vitals daily through a Health Buddy machine™. Vitals are uploaded from the patient's home to the nurse at a remote location. The nurse evaluates the patient's uploaded information to determine if they are at baseline or are deteriorating. The software program assigns the uploaded vitals a color code (green, yellow, or red) with red being the most alarming and requiring same day attention. If there is a red alert and the patient requires further evaluation, a note is placed in the computerized patient record system (CPRS) and the primary care physician (PCP) is alerted. At present, the nurses rely on the PCP to make interventions, as there are not any treatment protocols in place. The length of time it takes for a provider to respond to the alert is essential to prevent worsening of HF symptoms. Torres and colleagues found that the average response time within the VA for providers to acknowledge an alert was 18-43 days³. The PCP has several other responsibilities in addition to alert management. In the VA, pharmacists act as mid-level providers in various ambulatory clinics. In order to more efficiently manage red alerts, a pharmacist could have dedicated time for red alert management which would assist in alert management for the PCP.

Objective: To determine the length of time for PCP's to respond to alerts, what type of interventions are being made, and the patient outcomes based on the interventions.

Methodology: Once approved by the IRB and R&D committees, the computerized patient record system (CPRS) will be used to identify 100 patient notes meeting the inclusion criteria: active with Cleveland VA system for at least 3 months prior to red alert, enrolled in Telehealth for HF management, one red alert that occurred between 11/1/10 to 2/28/11, and a progress note titled "Care Coordination Home Telehealth (CCHT) Subsequent Evaluation Note" or "CCHT Subsequent Evaluation Note Follow-up" specific for HF. Baseline data collection will include: demographic data, time period for provider to acknowledge alerts, type of intervention made (i.e., start, stop, titrate medication), and patient's outcome (ED visit, hospital admission, and bed days of care).

Results and conclusions: To be determined.

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Pharmacy Practice Model Initiative (PPMI) implementation in a community hospital setting

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Background: The pharmacy profession is evolving from a dispensing oriented model to a patient-centered care model, as a result of the initiative from the American Society of Health-System Pharmacists (ASHP) practice model summit.¹ The Pharmacy Practice Model Initiative (PPMI) is a framework for advancing the health and well-being of patients in hospitals and health systems by developing and disseminating optimal pharmacy services based on the effective use of pharmacists as direct patient care providers.¹ Successful implementation of the PPMI is well documented in academic health care systems, however Hillcrest hospital is a community based non-teaching medical center.³²⁻⁴ The recent implementation of Computerized Physician Order Entry (CPOE) allowed us to evaluate our current order entry and dispensing model and evolve into a nursing unit based order verification model with a focus on patient counseling. To facilitate our PPMI, the staff pharmacist will embark upon a didactic educational program over the next two years. We hypothesize staff pharmacists will demonstrate increased clinical knowledge through didactic education, while maintaining exceptional core measure and improving HCAPHS scores.

Objective: To increase educational acumen of the pharmacist staff through didactic education from the clinical pharmacy staff. Consistency of core measure quality will be assessed as secondary end points.

Methodology: This will be a single center, prospective, paired, cross-over study designed to test the change in pharmacists' knowledge after didactic education. The primary endpoint will be change in staff pharmacist knowledge, and will be tested by a pre-test and post-test. The primary endpoint will be analyzed by student paired t-test. To ensure integrity of current core measures, fall outs will be assessed via six sigma u-chart. Data collection time intervals will include three months pre-PPMI and three months post-PPMI.

Results and Conclusions: Results and conclusions will be reported after data is collected and statistical analysis has been performed.

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The use of metoclopramide for the treatment of neonatal reflux

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Background: Gastroesophageal reflux (GER) is a common problem in preterm and term infants. Metoclopramide is amongst the treatment options for this condition.¹ The safety and efficacy of metoclopramide in this patient population has not been well validated however in many practices it is commonly used despite the lack of clear benefit and risk of possible side effects.^{2,3} Furthermore, the 2009 Pediatric Gastroesophageal Reflux Clinical Practice Guidelines stated there is insufficient evidence to justify the routine use metoclopramide for the treatment of GER.⁴ Apnea and bradycardia associated with GER and enteral feedings is common in the neonatal patient population. One way to identify and quantify the clinical significance of GER is to document apnea, bradycardia and desaturation episodes then consider treatment based on the frequency of these events.⁵ This study will investigate the change in frequency of episodes after initiation of metoclopramide therapy.

Objective: To evaluate the clinical utility of metoclopramide for the treatment of neonatal reflux

Methodology: A non-interventional medical record review of approximately 90 patients admitted to the neonatal intensive care unit at the Cleveland Clinic Main Campus who received at least 72 hours of metoclopramide therapy will be conducted. The average number of apnea, bradycardia and desaturation episodes before treatment will be compared to the average number of episodes after 72 hours of treatment with metoclopramide. Exclusion criteria include patients who received metoclopramide therapy for less than 72 hours, are immediately post-operatively prescribed metoclopramide, present with confirmed bowel obstruction, GI hemorrhage, necrotizing enterocolitis, a history of seizures or dystonic reactions and have a significant medically recognized immunodeficiency disorder or malignancy. Data describing patient demographics, GER medications, average number and type of episode, and presence or absence of enteral feeds will be collected. An alpha of less than 0.05 will be considered statistically significant. A paired student's t-test and chi-squared test will be used to evaluate the data as appropriate.

Results and conclusions: To be determined

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Medication reconciliation and discharge counseling pilot program for adult solid tumor patients

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Background: It is estimated that up to 60% of patients have at least one medication discrepancy on admission with approximately 43% having the potential to be harmful.¹ It has also been shown that approximately 6% of patients admitted to the hospital will have an inadvertent drug discontinuation of serious nature.² Additionally, 60% of postdischarge adverse drug events (ADEs) that occur can be prevented or ameliorated and studies have shown that pharmacy involvement at discharge may reduce ADEs after discharge, hospital readmissions, and return visits to the ED.³ Currently there is no formal pharmacy involvement in medical reconciliation or discharge education in adult patients with solid tumors. The combination of recorded and reported medication use may increase the accuracy of the medication reconciliation process. Implementation of the pharmacy department in discharge counseling may also improve patient safety and satisfaction. This project will evaluate the feasibility of implementing a medication reconciliation and discharge counseling program for adult solid tumor patients.

Objective: develop the process by which the department of pharmacy will implement a medication reconciliation and discharge counseling program for adult solid tumor patients

Methodology: A medication reconciliation and discharge counseling pilot program to evaluate the time required for medication reconciliation, discharge counseling, and time to complete the quality assurance survey. Secondary endpoints include evaluating the number of medication discrepancies resolved as well as pre- and post-study Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scores. The study will include all patients 18 years of age or older admitted to the chemotherapy service or adult solid tumor service and discharged to home. Patients who are unable to speak or understand English, readmitted and already included in the study, discharged to subacute facility, skilled nursing facility, rehabilitation facility, other acute facility, or palliative care service or hospice will be excluded. The timeframe for the study is from December 9, 2011 to January 27, 2012. Data describing patient demographics, number and type of medication discrepancies will also be collected. Descriptive statistics using means, medians, and percentages will be applied to evaluate collected data.

Results and Conclusions: To be determined.

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