

## **A Survey to Determine the Quality of Self-Care of Children with Asthma in Southwest Georgia**

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### Background:

A 2006 National Institute of Health survey states that 9.9 million US children have asthma with greater incidence in non-hispanic black children. The implication of such information is grave for underserved populations.

### Objective:

To investigate if parents of children with asthma can correctly identify rescue and maintenance inhalers and whether proper technique is used. To identify how many parents are using spacers.

### Methodology:

Approval was granted by the Phoebe Putney Memorial Hospital Institutional review board. Forty-seven patients were identified as having asthma, aged 5-20 years, and seeking follow-up care at Albany Area Primary Healthcare during the month of July 2008. Parents of children with asthma consented to a four-part survey inquiring 1) which inhalers were rescue and which were maintenance 2) if their child used a spacer and 3) if parents used a peak flow meter. Parents were then asked to demonstrate proper use of the devices. Parents were considered any legal guardian present with child at the time of appointment.

### Results and conclusions:

24 patients were male and 45 were African American. 45% of parents were able to identify both inhalers, while 23% could not identify either. 55% used spacer devices, while 82% did not use peak flow meters. 55% of parents were unable to demonstrate proper technique.

The alarming rate of parents unable to identify or use asthma devices has great implications on the persistency of asthma as a disease state, the development of complications and exacerbations, as well as increased medical expenditures for patients, health-systems, and communities.

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4. Schramm CM, Carroll CL. Advances in treating acute asthma exacerbations in children. *Current Opinion in Pediatrics* 21(3):326-32, 2009.
5. Wechsler ME. Managing asthma in primary care: putting new guideline recommendations into context. *Mayo Clinic Proceedings* 84(8):707-17, 2009.

# Assessment of patient outcomes after the implementation of a pharmacist-coordinated Lipid Shared Medical Appointment (Lipid SMA) within the Primary Care Clinic at a Veterans Affairs Hospital

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Background: Cardiovascular disease (CVD) remains the number one cause of death in the United States; CVD total mentioned deaths accounted for about 56 percent of all deaths in the United States in 2005.<sup>1</sup> Among lipids, elevated low-density lipoprotein (LDL) cholesterol has been clearly demonstrated to be independently associated with increased CHD risk.<sup>2-3</sup> The latest guidelines from the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) continues to identify LDL-C as the primary target for cholesterol-lowering therapy.<sup>3</sup> In the fall of 2007, the Louis Stokes Cleveland VA Medical Center (LSCVAMC), Wade Park Division in Cleveland, OH implemented a Lipid Shared Medical Appointment (Lipid SMA) clinic. The Lipid SMA targets patients with elevated LDL-C which has not responded to usual care provided by their primary care provider.

Objective: The primary objective of this study is to test the null hypothesis that there is no difference in the percentage of patients who achieve their LDL-C goal in the pharmacist-coordinated Lipid SMA versus usual care provided by other health care practitioners in the same setting.

Methodology: Retrospective chart review of patients age 18-89 years of age with LDL-C goal of 100 mg/dl or less determined according to NCEP ATP III guideline who received lipid management in the LSCVAMC pharmacist-coordinated Lipid SMA or by a primary care provider other than a clinical pharmacist between January 1, 2008 and April 1, 2009. The primary outcome of this study is the percent of patients who attained LDL-C goal in the Lipid SMA group compared with the usual care group. Charts will be randomly reviewed by selecting every other patient listed for each group until 80 patients are deemed appropriate for each study group (N= 160 total subjects) according to defined inclusion and exclusion criteria. Chart review data will be entered and analyzed in a Microsoft Excel spreadsheet. All comparisons of nominal data will be performed using chi-square or Fishers's exact test when appropriate. For comparison of all continuous variables, the student's t test will be used. This study has been reviewed by the IRB committee.

Results and conclusions: Results to be determined.

## References:

1. American Heart Association. Heart Disease and Stroke Statistics-2009 Update. Dallas, Texas: American Heart Association; 2009.
2. Castelli WP, Anderson K, Wilson PW, et al. Lipids and risk of coronary heart disease: the Framingham Study. *Ann Epidemiol.* 1992;2:23-28.
3. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA.* 2001;285(19):2486-2497.

# Characterization and Outcomes of Treatment with Chemoembolization for Hepatocellular Carcinomas in Adult Patients at MetroHealth Medical Center

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Background: Hepatocellular carcinoma (HCC) is a serious disease with an increasing incidence worldwide.<sup>1</sup> Approximately 75% of patients with HCC are not eligible for curative therapies such as resection or liver transplantation.<sup>2-5</sup> One of the options available to those who are not eligible for curative therapies is chemoembolization, which has been shown to have survival benefits over conservative treatment.<sup>6</sup> However, chemoembolization treatment is not standardized and different institutions have various standards for selecting patients deemed likely to benefit from treatment and use differing chemotherapeutic agents.

Objective: To characterize both the patients as well as their outcomes to treatment with chemoembolization for HCC at MHMC and compare these outcomes with those of other institutions.

Methodology: A retrospective data review will be conducted on patients who received at least one chemoembolization treatment from 2000-2009 at MHMC. All adult patients (18-90+) identified through pharmacy records as having received at least one chemoembolization treatment will be included in the study. Data will be collected from MHMC's electronic medical record system, EPIC, as well as the Electronic Registry System Database through the Oncology Data Center (ODC). The ODC links to the National Cancer Database and the Ohio Cancer Incidence Surveillance System. Extensive demographic information will be collected for the study. All treatments used for hepatocellular carcinoma will be collected, as well as, date(s) of treatment, components of the chemotherapy, number of treatments, and cumulative chemotherapy doses. Laboratory values such as, hepatic panels, complete blood count, basic metabolic panel, coagulation studies, alpha fetal protein, lactate dehydrogenase, renal studies, and cardiac studies will be collected in addition to, tumor stage by AJCC criteria, imaging studies, pathology reports, performance status and patient outcomes. Study data will be analyzed through the use of descriptive statistics. When appropriate, a student's t-test will be used to compare the outcomes of chemoembolization at MHMC to the outcomes of other institutions. This study will begin pending IRB approval.

Results and conclusions: Results to be determined

## References

1. Bosch FX, Ribes J, Borrás J. Epidemiology of primary liver cancer. *Semin Liver Dis* 1999; 19:271-85.
2. Llovet JM, Bru C, Bruix J. Prognosis of hepatocellular carcinoma: the BCLC staging classification. *Semin Liver Dis* 1999; 19:329-39.
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5. Bruix J, Sherman M, Llovet JM, et al. Clinical management of hepatocellular carcinoma: conclusions of the Barcelona-2000 EASL Conference. *J Hepatol* 2001; 35: 421-30.
6. Llovet JM, Real MI, Montana X, et al. Arterial embolisation or chemoembolisation versus symptomatic treatment in patients with unresectable hepatocellular carcinoma: a randomized controlled trial. *Lancet* 2002; 359:1734-39.

## **Dexmedetomidine for procedural sedation during dressing changes for burn patients**

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### **Background:**

Burn victims must undergo painful dressing changes and wound debridement frequently. These dressing changes can be traumatic and, to tolerate them, patients may require procedural sedation and analgesia. Traditionally, procedural sedation is done with agents such as propofol or midazolam, both of which can cause respiratory depression and neither provides any analgesia. Dexmedetomidine is a novel agent that produces sedation and some analgesia without causing respiratory depression. Because of these unique features, dexmedetomidine may be an ideal agent for use during dressing changes in patients with burns.

### **Objective:**

The primary objective is to evaluate the efficacy of dexmedetomidine for use as a sedative agent for use during burn dressing changes.

### **Methodology:**

A prospective evaluation of a new protocol detailing the use of dexmedetomidine in adult (>18 years) burn patients requiring procedural sedation for dressing changes will be conducted from November 2009-April 2010. IRB approval is pending. Patients will be excluded if they are intubated or have hypotension or bradycardia at baseline. Dexmedetomidine will be given as a 1 mcg/kg bolus over 10 minutes; followed by a continuous infusion starting at 0.5 mcg/kg/hr. The infusion can be titrated every 5 minutes by 0.2mcg/kg/hr as needed to achieve a target Riker sedation score of 2 or a RASS of -4. Analgesia with fentanyl or morphine will be administered to all patients. All medication given to the patient during the dressing change will be noted. Vitals will be monitored every 5 minutes and the infusion will be stopped if the heart rate or blood pressure goes outside the protocol defined limits. Nurses and physicians will subjectively evaluate their satisfaction with the quality of sedation dexmedetomidine provides.

### **Results and Conclusions:**

Results will be presented at the 2010 Great Lakes Pharmacy Residency Conference.

### **References:**

1. Berkenbosch JW, Wankum, PC, Tobias JD. Prospective evaluation of dexmedetomidine for noninvasive procedural sedation in children. *Pediatr Crit Care Med* 2005;6(4):435-9.
2. Tobias, JD. Dexmedetomidine: Applications in pediatric critical care and pediatric anesthesiology. *Pediatr Crit Care Med* 2007;8(2):115-31.
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4. Mason KP, Zurakowski D, Zgleszowski SE, et al. High dose dexmedetomidine as the sole sedative for pediatric MRI. *Paediatric Anaesthesia* 2008;18(5):403-11.
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## Assessment of the choice of nutritional support in acute pancreatitis

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**Background:** An estimated 210,000 patients in the United States are admitted to the hospital for acute pancreatitis each year. Pancreatitis associated with organ failure and/or local complications such as necrosis, abscess or pseudocyst is considered severe and is associated with longer hospitalizations, more frequent critical care area stays and mortality rates of 10-25%. Nutritional support should be initiated when it becomes evident that the patient will not be able to consume adequate nourishment by mouth for several weeks. Practice Guidelines in Acute Pancreatitis (PGAP), endorsed by the American College of Gastroenterology, recommend use of enteral feeding as the initial nutritional support attempt in severe pancreatitis patients. For patients unable to tolerate enteral nutrition or have a contraindication to enteral nutrition, it is then recommended to use total parenteral nutrition (TPN).<sup>1</sup>

**Objective:** The primary objective of this study is to determine the proportion of patients who receive appropriate nutritional support according PGAP in acute pancreatitis patients at AGMC. The secondary objectives of this investigation are to assess the prescribing physician service and the associated readmission rates secondary to pancreatitis.

**Methodology:** This study will be submitted to the Institutional Review Board for approval. An observational retrospective cohort study will be performed to evaluate nutritional support of patients with a diagnosis of acute pancreatitis. To be included in the study patients will have been admitted to AGMC between January 1st 2006 through November 30th 2009,  $\geq 18$  years at the time of admission, discharge diagnosis of acute pancreatitis and placed on TPN or received enteral feeding. Patients admitted on parenteral or enteral feeds and pregnant patients will be excluded. Data to be collected include: type of nutrition received, patient demographics, cause of pancreatitis, total length of stay, total length of feeding, feeding length of stay, readmission, contraindications to enteral nutrition and the prescribing physician service of nutritional support.

**Results and conclusions:** Results to be determined

### Reference:

1. Banks PA, Freeman ML, and the Practice Parameters Committee of the American College of Gastroenterology. Practice guidelines in acute pancreatitis. Am J Gastroenterol 2006; 101:2379-2400.

## Evaluation of an Intensive Insulin Use Protocol in the ICU

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Background: Hyperglycemia is common in critical illness, the result of multiple physiologic responses associated with stress.<sup>1</sup> Intensive glycemic control for critically ill populations was demonstrated to improve morbidity and mortality outcomes in 2001,<sup>2</sup> and was rapidly implemented by healthcare institutions around the country, including the Cleveland Clinic. The benefit of intensive insulin control in the intensive care unit (ICU) setting has been called into question by recently published studies, including VISEP<sup>3</sup> and NICE-SUGAR.<sup>4</sup> In contrast to previous studies, NICE-SUGAR found increased mortality among adults in the ICU setting with intensive glucose control.<sup>4</sup> The insulin infusion protocol used hospital wide in ICUs has recently been changed to reflect this new data, with less stringent targets for blood glucose. In this study, we will assess efficacy of the revised insulin protocol in achieving glucose targets, quantify rates of hypoglycemia and assess healthcare provider adherence to the protocol.

Objectives: 1) Evaluate the efficacy and safety of the revised insulin protocol in the ICUs at our institution. 2) Assess healthcare provider adherence to the updated insulin protocol.

Methodology: This concurrent non-interventional chart review will include 110 consecutive patients in the medical, surgical, cardiothoracic, cardiac and neurologic ICUs receiving an insulin infusion for at least 48 hours. Inclusion criteria are patients age 18 years or older who were admitted to an ICU after November 1, 2009 and started on an intensive insulin protocol while in the ICU, remaining on the protocol at least 48 hours. Patients receiving an insulin infusion for treatment of diabetic ketoacidosis will be excluded from the study. Subjects receiving insulin infusions will be identified via a report generated from the EPIC<sup>®</sup> integrated medical record. Data collected for each subject include baseline demographic information (age, gender, weight, diagnosis, history of diabetes mellitus, nutrition status and concurrent steroid use), insulin infusion rates, rate adjustments and blood glucose measurements. Outcome measures for efficacy include insulin dose, mean daily blood glucose, time to target glucose and percentage of glucose readings at target. Safety outcome measures include incidence of hypoglycemia and treatments administered for hypoglycemia. Rates of insulin protocol adherence will be determined, with adherence defined as fewer than five incorrect incidents within a 48 hour time period. Data will be analyzed using descriptive statistics.

Results and Conclusions: Results to be determined.

### References:

1. McCowen KC, Malhotra A, Bistrian BR. Endocrine and metabolic dysfunction syndromes in the critically ill. *Crit Care Clin* 2001;17:107-24.
2. Van den Berghe G, Wouters P, Weekers F, Verwaest C, Bruyninckx F, Schetz M, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med* 2001;345:1359-67.
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4. NICE-SUGAR Study Investigators. Intensive versus conventional glucose control in critically ill patients. *N Engl J Med* 2009;360:1283-97.

# Efficacy and safety of palifermin to reduce mucositis in allogeneic stem cell transplant patients

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**Background**<sup>1-3</sup>: Patients undergoing hematopoietic stem cell transplantation (SCT) for treatment of hematologic malignancies commonly experience severe oral mucositis as a result of chemotherapy and/or radiation. Palifermin (Kepivance®), a human recombinant keratinocyte growth factor, was FDA approved in 2004 for the prevention of oral mucositis in patients undergoing SCT with myeloablative chemotherapy. Recently the Cleveland Clinic incorporated palifermin into several increased-intensity allogeneic SCT regimens. Data are limited regarding efficacy of palifermin in allogeneic SCT patients and the cost associated with palifermin is significant. In light of the recent integration of palifermin into several regimens, validation of efficacy and safety is warranted.

**Objective:** To compare the incidence of severe mucositis in allogeneic SCT patients receiving palifermin versus standard care.

**Methodology:** This study will be conducted as a retrospective, non-interventional chart review. Patients  $\geq 18$  years of age that received an allogeneic SCT with a treatment regimen containing myeloablative total body irradiation and/or methotrexate will be included. The primary endpoint to be evaluated is incidence of severe mucositis. Secondary endpoints to be evaluated include: utilization of intravenous/transdermal narcotic analgesia and total parenteral nutrition, incidence and duration of neutropenia and bacteremia, length of stay, and economic impact of palifermin. Adverse events consisting of rash, taste disturbances, and mouth changes will also be recorded. The primary objective will be evaluated using Fisher's exact test and a multivariate Cox regression model. Secondary objectives will be evaluated using T-tests, Fisher's exact tests, and descriptive statistics. This study is under review by the Cleveland Clinic's IRB committee.

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

## References:

1. Spielberger R, Stiff P, Bensinger W, Gentile T, Weisdorf D, Kewalramani T, et al. Palifermin for oral mucositis after intensive therapy for hematologic cancers. *N Engl J Med* 2004;351:2590-98.
2. Langner S, Staber PB, Schub N, Gramatzki M, Grothe W, Behre G, et al. Palifermin reduces the incidence and severity of oral mucositis in allogeneic stem-cell transplant recipients. *Bone Marrow Transplant* 2008;42:275-80.
3. Bensinger W, Schubert M, Ang K, Brizel D, Brown E, Eilers JG, et al. NCCN Task Force Report: Prevention and management of mucositis in cancer care. *J Natl Compr Canc Netw* 2008;6:S1-21.

## Evaluation of Osteoporosis Treatment After Hip Fracture

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**Background:** Patients with hip fracture are estimated to have a 10% - 20% increased risk of mortality within one year and a 2 to 6 fold increased risk of future fractures. Due to the significance of complications, the National Osteoporosis Foundation, Surgeon General, and National Institute of Health have developed guidelines for the prevention and treatment of osteoporosis. Treatment is especially important for patients with a prior low impact fracture due to the increased risk of recurrent fractures. However, recent data indicate that patients with low impact hip fractures do not receive appropriate osteoporosis therapy upon hospital discharge. The purpose of this study is to determine the prevalence of osteoporosis treatment at discharge among patients admitted to Akron General Medical Center (AGMC) for low impact hip fracture.

**Objective:** To determine the prevalence of osteoporosis treatment at discharge among patients admitted to Akron General Medical Center for low impact hip fracture.

**Methodology:** This study is a descriptive, retrospective chart review of patients with low impact hip fractures admitted to AGMC between January 1, 2005 and December 31, 2008. Upon approval of the Institutional Review Board, patients will be identified through electronic billing records using International Classification of Diseases, ninth revision codes for low impact hip fracture. Patients eligible for inclusion include those 18-49 years of age with a history of corticosteroid use, or any patient greater than 49 years of age. Exclusion criteria include patients with a hip fracture secondary to trauma, or a pathologic fracture related to metastatic cancer or metabolic bone disease. A standardized data collection form will be created and used to obtain information from patients' charts who meet inclusion criteria. Data collection will include demographic information; home medications used for osteoporosis treatment and prevention; prior hip, spine, or wrist fracture; corticosteroid use; documented diagnosis of osteoporosis upon admission or at discharge; use of Dual-energy x-ray absorptiometry scan to diagnose osteoporosis; prescribing service of osteoporosis medications during hospitalization; prescribed osteoporosis treatment at discharge; and osteoporosis treatment listed on the home medication list at any re-admission one year following initial fracture. The data will be analyzed to determine if patients admitted with low impact hip fracture are prescribed an osteoporosis treatment regimen upon discharge. The presence of osteoporosis treatment will also be assessed in those patients re-admitted to AGMC within one year of hip fracture.

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

### References:

1. Panneman MJM, Lips P, Sen SS, Herings RMC. Undertreatment with anti-osteoporotic drugs after hospitalization for fracture. *Osteoporos Int* 2004;15: 120-124.
2. Petrella RJ, Jones TJ. Do patients receive recommended treatment of osteoporosis following hip fracture in primary care. *BMC Fam Practice* 2006;7(31).
3. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. *Bone Source* 2008: 1-36.
4. Follin SL, Black JN, McDermott MT. Lack of diagnosis and treatment of osteoporosis in men and women after hip fracture. *Pharmacother* 2003;23(2): 190-198.
5. Bahl S, Coates PS, Greenspan SL. The management of osteoporosis following hip fracture: how we improved out care. *Osteoporos Int* 2003;14: 884-888.
6. Simonelli C, Chen Y, Morancey J, Lewis AF, Abbott TA. Evaluation and management of osteoporosis following hospitalization for low impact fracture. *J Gen Intern Med* 2003;18: 17-22.

# Evaluation of a pharmacist-managed epoetin alfa clinic in outpatients with non-dialysis dependent chronic kidney disease

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**Background:** Erythropoiesis stimulating agents (ESAs) are indicated in the treatment of anemia secondary to chronic kidney disease (CKD) to increase hemoglobin to positively impact a patient's quality of life.<sup>1,2</sup> Few published studies have evaluated the role of clinical pharmacists in managing epoetin alfa in outpatients with non-dialysis dependent chronic kidney disease.<sup>3,4</sup> The Kaiser Permanente Ohio Region implemented a pharmacist-managed epoetin alfa clinic in May 2008.

**Objective:** To assess the safe and effective use of epoetin alfa in a pharmacist-managed ESA clinic by evaluating adherence to NKF KDOQI guidelines and the epoetin alfa package insert, and to determine those factors of the clinic that are correlated with patient satisfaction.

**Methodology:** A retrospective chart review will evaluate the pharmacist-managed epoetin alfa clinic. Included in the study will be patients who were on epoetin alfa for at least one year, had a diagnosis of anemia secondary to CKD, and did not require dialysis. Approximately 100 patients who were managed prior to the clinic will be compared to a randomly matched number of patients who were on epoetin alfa therapy monitored by the pharmacist-managed clinic. The collected data will include: demographics (age, gender, race, history of diabetes mellitus or hypertension, and stage of CKD); hemoglobin, transferrin saturation, and ferritin lab values; frequency of lab parameter monitoring within a 12 month period; if IV iron was administered in accordance with guidelines; the amount of epoetin alfa doses held; and the percentage of time that hemoglobin spent in therapeutic range. Descriptive statistics will be used to describe demographic and clinical characteristics of the two groups. A paired t-test and regression analysis will evaluate the values of the hemoglobin, transferrin saturation, and ferritin values. A patient satisfaction survey will be mailed to patients who are currently enrolled in the clinic. The survey will evaluate knowledge about disease state and satisfaction with staff interaction. Patient demographics will be collected, and survey data will be analyzed using multi-variate regression analysis to determine those variables that are correlated with patient satisfaction.

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

## References:

1. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease. Am J Kidney Dis 2006 May; 47:S1-S146, suppl 3.
2. National Kidney Foundation. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 update of hemoglobin target. Am J Kidney Dis 2007 Sep;50(3):471-530.
3. Clapp S, Bardo JA, Chrymko MM. Implementation of a pharmacist-managed clinic for patients receiving erythropoietin-stimulating agents. Am J Health-Syst Pharm. 2008;65:1458-63.
4. Gilmartin C. Pharmacist's role in managing anemia in patients with chronic kidney disease: potential clinical and economic benefits. Am J Health-Syst Pharm. 2007;64 (Suppl 8):S15-22.

# Vincristine Dose Modification during Concomitant Use of Fluconazole in Pediatric Cancer Patients

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## *Background:* <sup>1-3</sup>

Vincristine is an antineoplastic, vinca alkaloid that is a common agent used in the treatment of pediatric acute lymphoblastic leukemia (ALL). Vincristine causes cell death by inhibiting microtubule formation in the mitotic spindle, which is also responsible for the neurologic toxicities seen in patients (due to the structural changes in the axon of nerve cells). Vincristine is hepatically metabolized and is a major substrate of the CYP3A4 enzyme system. The azole antifungals are known inhibitors of the CYP3A4 enzyme, which could lead to increased levels of vincristine and possibly, profound toxicity for the patient. Published case reports have described neurologic toxicities associated with concomitant administration of itraconazole (for fungal prophylaxis) and vincristine in pediatric cancer patients. However, the use of fluconazole and its potential drug interaction with vincristine has not been studied or reported in the literature.

## *Primary Objective:*

The primary study objective is to determine the frequency of vincristine dose modification due to increased toxicity experienced by pediatric patients who received concomitant administration of fluconazole for fungal prophylaxis compared to a historical control group.

## *Methodology:*

The study will be conducted by a non-interventional, retrospective chart review utilizing the electronic medical record. Patients will be included if they meet the following criteria: diagnosis of ALL, less than 18 years of age, and receiving combination therapy with vincristine and fluconazole. Patients will be excluded if they were receiving a different azole for the treatment or prophylaxis of fungal infections or if they were receiving a potent inhibitor or inducer of CYP3A4. The following data will be collected from the patient's medical record: age, gender, height, weight, disease risk stratification, chemotherapy and antifungal prophylaxis doses/frequencies/dates/dose adjustments, CYP3A4 interacting drugs, autonomic and peripheral neurotoxicities, and sodium and bilirubin levels. Study data will be entered into a Microsoft Access database at the completion of data collection. Data will be analyzed between the treatment group and a historical control group using appropriate statistical tests for the pre-specified outcome.

## *References:*

1. Harnicar S, Adel N, Jurcic J. Modification of vincristine dosing during concomitant azole therapy in adult acute lymphoblastic leukemia patients. *J Oncol Pharm Practice* (2009);15:175-82.
2. Bermudez M, Fuster J, Llinares E, Galera A, Gonzalez C. Itraconazole-related increased vincristine neurotoxicity. *J Pediatr Hematol Oncol* (2005);27:389-92.
3. Lexi-Comp Online, Lexi-Drugs Online, Hudson, Ohio: Lexi-Comp, Inc.; 2009; September, 2009.

# Evaluation of the Frequency, Acknowledgement and Appropriate Documentation of Critical Drug Interactions

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**Background:** Adverse Drug Reactions (ADRs) are defined as “an unintended response related to a drug” ADRs are a significant cause of mortality, hospitalization, and emergency department visits yearly.<sup>1</sup> Many studies have identified computerized physician order entry (CPOE) as an efficient system for decreasing injury from adverse drug events.<sup>2</sup> CPOE can reduce critical drug interactions (CDIs) when clinical decision support features such as drug-drug interaction (DDI) alerts are activated in the system. At the Louis Stokes Cleveland Veterans' Affairs Medical Center (LSCVAMC) there are both significant and critical DDI alerts that pop-up as alerts in the CPOE computerized patient record system (CPRS). Significant drug interactions do not require a provider comment, but CDIs do require both the provider and the pharmacist to place a comment that specifies the action taken. If the provider does not have a satisfactory comment, it is up to the pharmacist to contact the provider to ensure that they want the patient on the critically interacting drug pair. Contacting providers sounds simple enough, but it is complicated by the fact that providers have multiple practice sites and write prescriptions/orders in both outpatient and inpatient settings.<sup>3</sup>

In January 2009 the clinical staff looked at list of CDIs and determined the twenty-five most common CDIs and added recommendations into the CPOE system. These required the provider to evaluate the recommendations and place comments. The goal of this additional safety check was to have the provider realize the interaction and adjust the drug choice prior to the order being received in the pharmacy. This study will evaluate the frequency, acknowledgement, and appropriate action and documentation by pharmacy staff when providers order critically interacting drug pairs.

**Objective:** To determine the frequency of, acknowledgement and appropriate documentation of specific critical drug interactions in both the inpatient and outpatient settings at Louis Stokes Veteran's Administration Medical Center.

**Methodology:** Retrospective chart review of patients ages 18-99 years, currently prescribed one of the critically interacting drug pairs: nitroglycerin/vardenafil, dofetilide/moxifloxacin, methotrexate & trimethoprim, dofetilide/hydrochlorothiazide, clarithromycin/simvastatin, erythromycin/simvastatin, cyclosporine/simvastatin, hydrochlorothiazide/lithium, allopurinol/mercaptopurine, allopurinol/azathioprine, and amiodarone/digoxin. The comparison will occur before the recommendations were added to the CPOE system (May 1st- October 31<sup>st</sup> 2008) and after (May 1st- October 1<sup>st</sup>, 2009). The following data will be collected: age, gender, action taken by physician and pharmacist, appropriateness of the action. Chart review data will be entered and analyzed in a Microsoft Excel Spreadsheet. This study will be reviewed by the IRB committee.

**Results/conclusions:** Results to be determined.

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# Stability of clozapine in oral suspension: a comparison of high performance liquid chromatography (HPLC) and mass spectrometry assays from day zero through day sixty

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**Background:** Clozapine related side effects may be dose-related, thus it is very important for patients to receive a consistent amount of medication from day to day. More research is needed to determine whether clozapine concentrations remain consistent in compounded suspensions.

For patients who cannot or will not take medications in tablet form, a liquid formulation of clozapine may be utilized; however, no commercial oral liquid or suspension exists. When a liquid formulation is utilized, clozapine suspension is compounded in the pharmacy. Very limited data is available investigating the stability of clozapine in suspension. No studies have been conducted to date using High Performance Liquid Chromatography system with Mass detector (LC – MS<sup>2</sup>) to investigate the stability of such a compounded suspension.

Depending on a patient's monitoring interval refills of clozapine suspension occur once a week or every two weeks. The limited amount of data describing the stability of clozapine suspensions makes it difficult to know if patients are receiving consistent amounts of clozapine throughout each refill. Furthermore, this compounded suspension may not remain in a controlled, refrigerated environment once it leaves the pharmacy. Given that side effects of clozapine may be dose-related, it is very important for patients to be receiving a consistent amount of medication from day to day. More research is needed to determine whether clozapine concentrations remain consistent in compounded suspensions.

**Objective:** This study seeks to determine the stability of clozapine suspension using a standard recipe by assessing the purity of clozapine in suspension at days 0, 3, 7, 14, 30, and 60 using a High Performance Liquid Chromatography system with Diode array detector (HPLC/DAD) and LC – MS<sup>2</sup>.

**Methodology:** The pharmacy resident will compound a 10mg/mL clozapine suspension using 100mg uncoated tablets of clozapine. This suspension will be dispensed into six separate 30mL aliquots (three to be stored at room temperature and three to be stored under refrigeration). The standard Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC) recipe will be used to compound the clozapine suspension.

A purity analysis will be conducted by the pharmacy resident on days 0, 3, 7, 14, 30, and 60 on all six aliquots utilizing an HPLC/DAD. This analysis will help to determine whether there are any minor or major breakdown products.

If any degradation products are found using the HPLC/DAD a secondary stability study will be conducted to validate the HPLC/DAD results utilizing an LC – MS<sup>2</sup>. The samples for the LC – MS<sup>2</sup> study will be batched from the proper interval time and stored at -80° C to be analyzed at the end of the study.

The null hypothesis is that the purity of the clozapine suspension at day sixty will be equal to the purity of the suspension at day zero.

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

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# Evaluation of an Electronic Reminder to Adjust Insulin Regimens in NPO Diabetic Inpatients

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**Background:** Recent retrospective studies have found that hypoglycemia in hospitalized diabetic patients is a common problem and may be associated with increased length of stay and higher mortality rates.<sup>1-2</sup> Inpatient diabetics on insulin are at an increased risk of hypoglycemia when they become NPO (nothing by mouth). An electronic reminder was added to the NPO diet order set at our medical center on September 11, 2009 reminding providers to reduce the dose of basal insulin by 50% and discontinue active orders for prandial insulin and sulfonylureas for diabetic patients who become NPO.<sup>3</sup> Previously, these instructions appeared only when insulin was initially ordered, but not when the NPO diet was ordered.

**Objectives:** The primary objective of this study is to determine if implementation of an electronic reminder in the NPO diet order set improves insulin prescribing practices among NPO diabetic patients in a general medicine population. Secondary objectives of this study are to: evaluate glycemic outcomes among patients who were appropriately adjusted versus those who were not, determine if larger percentage reductions in basal insulin doses correlate with fewer hypoglycemic episodes, and explore current nursing practices.

**Methodology:** Retrospective chart review. General medicine inpatients at the Louis Stokes VA Medical Center with an NPO diet order and concurrent basal insulin order between April 11, 2009 and February 11, 2010 will be eligible for chart review. Fifty patients prior to and 50 patients after the implementation of the electronic reminder will be evaluated. Patients will be excluded if they had a previous NPO order during the same admission which met all inclusion criteria, were transferred to another unit or received enteral or parenteral nutrition while NPO. A Chi-square test will be used to compare the proportion of NPO patients who had their basal insulin dose decreased before and after implementation of the electronic reminder. The proportion of NPO patients who had their prandial insulin order discontinued before and after the electronic reminder will also be compared. Point-of-care blood glucose readings and Bar Code Medication Administration data will be collected to evaluate glycemic outcomes among these patients and to characterize current nursing practices.

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

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# Evaluation of Appropriateness of Erythropoietin-Stimulating Agents in a 400 bed Tertiary Care Medical Center

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**Background:** FDA supports targeting lower hemoglobin (Hg) when treating anemia with erythropoietin stimulating agents (ESAs).<sup>1</sup> Several key organizations suggest targeting an upper limit Hg of 12 mg/dL in chronic kidney disease and myelodysplastic syndrome, and not initiating ESAs until Hg  $\leq$  10 mg/dL for chemotherapy induced anemia.<sup>2-4</sup> Hillcrest Hospital instituted a blood management program that allows ESA use preoperatively to increase Hg with the goal of decreasing blood transfusions postoperatively. Blood management experts recommend target Hg  $\leq$  13 mg/dL; however, it is reasonable to consider lowering target Hg to  $\leq$  12 mg/dL in postoperative patients prescribed ESAs based on recent safety data regarding other causes of anemia.<sup>1</sup> Historical ESA data at Hillcrest suggest less than optimal use based on current safety guidelines.

**Objective:** To assess if pharmacist monitoring and intervention of ESA orders will increase compliance with current safety guidelines.

**Methods:** A prospective pilot study will be conducted over three months. A pharmacist will review all orders prior to dispensing and data will be compared to historical data of a similar time frame. A pharmacist will call physicians to confirm necessity of ESA use in patients with Hg above defined target ranges. Orders received after 6 PM will be processed the following day. All inpatient ESA orders will be included while all outpatient ESA orders will be excluded. Our primary outcome will be rate of change in inappropriate orders. Secondary outcomes will assess change in pharmacist auto-substitution from epoetin to darbepoetin and change in overall darbepoetin use. Nominal data will be analyzed with Chi-square using Sigma Stat 3.5 software. Descriptive data analysis will include appropriate, inappropriate, and total number of orders by discipline. The number of epoetin versus darbepoetin orders, as well as DAW orders, will also be assessed by discipline.

**Results and conclusions:** Results to be determined

## References:

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## Utilization of a reminder mailing to improve blood glucose log reporting in an outpatient diabetes clinic

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Background: Improving glycemic control has been proven to reduce complications in patients with type 1 diabetes, and it is reasonable to believe that this holds true in type 2 diabetics as well.<sup>1,2</sup> Several trials have explored the use of various interventions to achieve control in these patients, such as patient education, disease management and the use of information technology. Specifically, self-monitored blood glucose (SMBG) has been a widely-used strategy to help attain tighter glycemic control in diabetic patients. An important note is that, if diabetic patients are unwilling to adjust their own therapy and/or behavior in response to SMBG readings and patterns, it is unlikely that they will achieve improved glycemic control.<sup>3</sup> In addition, if patients do not report their SMBG readings to the clinicians managing their diabetes, it becomes difficult to infer which interventions are appropriate.

Objective: To assess the impact of a reminder mailing on response rates to requests for self-monitored blood glucose logs.

Methodology: The study protocol will be submitted to the Institutional Research Review Board for approval prior to initiation. Adult (at least 18 years old) patients diagnosed with type 1 or 2 diabetes mellitus who are independently managing their own disease will be recruited from the Internal Medicine Center of Akron (IMCA) Diabetes Management Clinic at the time a request for an SMBG log is made between November 2009 through January 2010. Follow-up will be continued through February 2010. Patients who do not have a mailing address will be excluded. The following data will be collected: date of recruitment, patient demographics (age, gender, ethnicity), date of first diabetes clinic visit at IMCA, concomitant medical conditions, most recent hemoglobin A1c (HbA1c) and date of last reading, and current anti-diabetic medication list. At follow up, similar data will be collected, along with whether the requested SMBG log was returned (and, if returned, whether the SMBG log was considered fulfilled based on the study definition), any interventions made to anti-diabetic therapy, and whether the clinic appointment was kept. This data will be compared with patients seen at the IMCA diabetes clinic from November 2008 through February 2009 using a retrospective chart review. All data will be recorded without patient identifiers and will be maintained confidentially. Primary outcome data (rate at which SMBG logs are returned) will be reported at the end of the trial, and will be represented as both proportion of all requested SMBG logs returned as well as the proportion of patients returning at least 25%, 50% and 75% of all personal requests. Secondary outcomes will include the following: (1) rate at which the returned SMBG logs are fulfilled per the study definition, (2) rate at which diabetes clinic appointments are kept, and (3) number of interventions made to anti-diabetic therapy, including lifestyle modifications and medication changes.

Results and conclusions: Results to be determined.

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# Safety of Combination Alteplase and intra-arterial Glycoprotein IIb/IIIa Inhibitor Therapy for Acute Ischemic Stroke

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Background: Stroke is the third leading cause of death and the leading cause of long term disability in the United States.<sup>1</sup> While ischemic strokes account for over 80% of all strokes, consistently safe and effective therapies for its management in a broad population have yet to be identified. The American Stroke Association guidelines for the management of acute ischemic stroke (AIS) recommend the use of intravenous alteplase (rtPA) in appropriate candidates, with intra-arterial (IA) rtPA administration considered an option in certain patients.<sup>2</sup> Additional pharmacological therapies such as glycoprotein (GP) IIb/IIIa inhibitors for AIS have been evaluated. Intravenous use of GP IIb/IIIa inhibitors are associated with increased bleeding risk without benefit and therefore not recommended.<sup>3</sup> However, IA administration of GP IIb/IIIa inhibitors are utilized in select patients although limited data exists regarding the safety and efficacy in AIS.<sup>3-6</sup>

Objective: To evaluate the safety of combination alteplase and intra-arterial glycoprotein IIb/IIIa inhibitors for the treatment of acute ischemic stroke.

Methodology: This retrospective study will include all adult patients treated for AIS at the Cleveland Clinic who received any combination of rtPA and IA GP IIb/IIIa inhibitor. Data to be collected includes patient demographics, size and location of the infarct, National Institute of Health Stroke Scale (at baseline, 24 and 48 hours), symptomatic intracranial hemorrhage or other bleed within 48 hours, recanalization rates as determined by Thrombolysis in Myocardial Infarction Score, thrombolytic and antiplatelet medication, dose, and route used, anticoagulant and antiplatelet use prior to admit, and mortality at discharge. Data will be analyzed using the appropriate statistical tests. Prior to study commencement, IRB approval will be obtained.

Results and conclusions: Results and conclusions to be determined.

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# Impact of Pharmacist-Provided Nursing Education on Medication Reconciliation Accuracy

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**Background:** Among hospital inpatients, medication errors are a leading type of adverse event.<sup>1</sup> An accurate medication history is an integral part of the patient assessment on admission to the hospital regarding patient safety.<sup>1,2</sup> Errors in the medication history could potentiate errors in the medication reconciliation process. Up to 60% of patients admitted to the hospital will have at least one discrepancy in their admission medication history.<sup>1</sup> One of The Joint Commission's goals since 2005 is for hospitals to accurately and completely reconcile medications across the continuum of care.<sup>3</sup> The methods hospitals currently use to perform medication reconciliations have not been shown to be accurate.<sup>4,5</sup> Pharmacists have been found to be an ideal resource for obtaining medication histories due to their knowledge base and extensive training in this area.<sup>5</sup> In spite of this, many hospitals do not utilize pharmacists for this function due to financial and staffing barriers. This study will identify the different types of inaccuracies in medication histories before and after a pharmacist- provided nursing education program.

**Objective:** To determine the most common types of errors in medication histories and construct a pharmacy provided education to admission nurses and show the effectiveness of that education on accurate medication reconciliations.

**Methodology:** Patients admitted by admission nurses to a medical-surgical general medicine floor will be randomly chosen to be included in the study. Patients who have decreased cognition, are sedated, or are otherwise unable to give a medication history will be excluded. Once chosen and informed consent is obtained, a pharmacist will obtain a medication history from the patient (or appropriate care provider) and update the medication reconciliation form. This new pharmacist obtained list will be compared to the list obtained by the admission nurses. All discrepancies will be noted. After 100 pharmacist interviews are completed, the types of discrepancies will be tabulated and with this information a plan for nursing education will be developed. When the education is complete the pharmacist will interview 100 more patients and note the discrepancies found.

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

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## Evaluation of Acid Suppression Medication Use at the Louis Stokes VA Medical Center

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Background: Acid suppression medications (ASM) are prescribed for a variety of indications, including treatment of gastrointestinal disorders and stress ulcer prophylaxis. ASM include proton pump inhibitors (PPIs) and histamine-2 receptor blockers. The inappropriate use of PPIs has been reported at rates as high as 65%.<sup>1</sup> Although generally believed to be benign, ASM increase gastric pH and are associated with side effects and drug interactions. The LSVAMC Pharmacy and Therapeutics Committee exhibited interest in a PPIs order set in the spring of 2009 following recent literature and a statement by the Food and Drug Administration (FDA) identifying awareness of a possible drug interaction between omeprazole and clopidogrel.<sup>2,3</sup> Omeprazole is the focus drug of this trial due to the heightened publicity about the drug interaction recently.

Objective: To compare the use of omeprazole and ASM at the LSVAMC before and after implementation of a quick-order set.

Methodology: A retrospective chart review will evaluate ASM use in inpatients admitted to general medicine floors, the progressive care unit, and the medical and cardiac intensive care units during three phases: phase 1 - October 2008 (baseline prescribing habits), phase - 2 May 2009 (prescribing habits following FDA statement and literature release), phase - 3 February 2010 (after quick-order implementation). At least 100 patients will be enrolled chronologically in each phase in a percentage distribution based on past admission rates for each hospital ward. Information on patient demographics, diagnoses, ASM use, concurrent medication use history, lab values, and comorbidities will be collected using the LSVAMC electronic medical record system. The primary endpoint of the study will compare the percent of inpatients on oral omeprazole between phase 1 and phase 3. Secondary endpoints will also compare the overall usage of ASM, identify rates of gastrointestinal bleed during hospitalization and up to 3 months post discharge, compare the percent of patients prescribed both omeprazole and clopidogrel, compare the percent of patients initiated on ASM during hospitalization, and compare the indications for ASM use between each of the three phases. A t-test will be used to evaluate continuous data and a chi-square test will be used to evaluate categorical data.

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

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## De-escalation of Antimicrobial Therapy: A Pilot Study

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**Background:** Fifty to sixty percent of all nosocomial infections in the US are caused by antibiotic-resistant bacteria.<sup>1</sup> Infections caused by antibiotic-resistant, or multidrug-resistant (MDR), bacteria can lead to higher rates of mortality, longer ICU stays, longer hospital stays, and higher costs.<sup>2</sup>

De-escalation therapy consists of narrowing the antibiotic spectrum by changing from a broad spectrum agent to a narrow spectrum agent or by eliminating a drug from combination therapy as well as using the shortest adequate duration.<sup>3,4</sup> Modifications in antibacterial therapy should ideally occur as soon as possible with the availability of culture and susceptibility results.

Studies that have addressed de-escalation focus patients with ventilator-associated pneumonia (VAP) and even fewer have assessed effects on mortality. One observational study suggested that de-escalation for VAP patients led to improved outcomes as measured by mortality.<sup>5</sup> A prospective study of critically-ill, surgical and septic shock patients did not experience an increased rate of recurrent pneumonia after receiving de-escalation therapy compared to patients that did not receive de-escalation therapy.<sup>6</sup>

**Objective:** To determine the effects of de-escalation therapy on mortality at 30 days or discharge. The hypothesis is that patients receiving de-escalation therapy will have no difference in mortality. Secondary outcomes will be the assessment of incidence of de-escalation, recurrence of infection, antibiotic duration, clinical cure, days on ventilator, days in the intensive care unit (ICU), total length of stay (LOS) in the hospital, and cost comparison.

**Methodology:** This prospective observational study will assess antibiotic therapy in patients not only with VAP, but also any single site infection of the blood, urinary tract, respiratory tract, or a wound. Patients will be identified by positive microbiological results with clinician diagnosed single-site infections of the blood, respiratory tract, urinary tract, or wound. Patients will be included if they are identified by microbiological and clinical diagnosis, 18-90 years old, and have antimicrobials initiated in a critical care area. Patients will be excluded if they have an unclear diagnosis or multiple site infections, age < 18 years, pregnant women, and comfort care only/arrest or Hospice patients. Data collection will consist of demographical information, outpatient history including antibiotics and location, comorbidities and evaluation of clinical status, culture and susceptibility results, inpatient antibiotic therapy, and course of therapy. Statistical analysis will be performed to evaluate the data collected. The study is currently being reviewed by the IRB for approval.

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

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## Evaluation of Antibiotic Use in a Veterans Administration Community Living Center

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Background: Results from the 2004 National Nursing Home Survey estimate that 1.5 million Americans reside in nursing homes (NHs).<sup>1</sup> Impaired cognition, immunosuppression, use of invasive devices and the residential nature of NHs put elderly residents at high risk of contracting infections. This population commonly suffers from urinary tract infections, lower respiratory tract infections and gastrointestinal infections.<sup>2</sup> Use of antibiotics (ATBs) increases patients' risk of developing Clostridium difficile-associated disease (CDAD), which has become increasingly treatment-resistant in recent years.<sup>3</sup> Other risks of inappropriate ATB use include ATB resistance, drug-induced adverse reactions, drug interactions, and increased costs.<sup>2,4</sup>

Objective: To determine the frequency of, reasons for and adverse effects of inappropriate ATB treatment in the Louis Stokes Cleveland Veterans Affairs Medical Center (LSCVAMC) Community Living Center (CLC).

Methodology: Retrospective chart review of all CLC patients prescribed ATBs during a 6-month period. ATB regimens will first be classified as necessary or unnecessary. If ATBs are deemed necessary by the reviewer, further evaluation of all components of the regimen will be conducted. The need for a prescribed ATB will be determined by diagnostic and treatment guidelines from the Infectious Disease Society of America when available. If guidelines are not available, recommendations from textbooks and published articles will be considered, as well as the opinions of infectious disease physicians. Two infectious disease physicians will be the primary physician reviewers but, if their opinions differ, a third infectious disease physician will make the final decision regarding the appropriateness of ATB prescribing. Unnecessary ATBs will be categorized as treatment of noninfectious syndromes, treatment of colonizing microorganisms, longer than necessary duration of therapy, duplication in therapy, ATB coverage that is not indicated, and untimely adjustments following culture results. Outcomes to be assessed include development of CDAD, whether clinical cultures yield resistant organisms, 30-day hospital admission rate and mortality. This study will be submitted to the LSCVAMC Institutional Review Board.

Results and conclusions: The results of this study will be used to design an intervention to improve antimicrobial stewardship in the CLC.

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## Efficacy and safety of continuous infusion of labetalol for lowering blood pressure in intracerebral hemorrhage

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**Background:** Intracerebral hemorrhage (ICH) is a medical emergency that involves a focal bleed resulting from a spontaneous rupture of a blood vessel. Among various causes, chronic hypertension as well as severe transient increases in blood pressure (BP) are common triggering events<sup>1,2</sup>. Management of ICH requires immediate and aggressive reduction in BP<sup>3,4</sup>. Current American Stroke Association guidelines for BP management in ICH recommend the use of various antihypertensives including labetalol, nicardipine, and nitroprusside to achieve and maintain a goal systolic BP less than 160 mmHg. Labetalol can be administered as a continuous infusion at a rate of 2 mg/min until a maximum daily dose of 300 mg is reached. However, this maximum limit may be reached before the BP goal is achieved. Published data of prolonged continuous infusions of labetalol in hypertensive emergencies are limited in patients with ICH. Despite the lack of published data, continuous infusion labetalol is currently utilized at the Cleveland Clinic Neurology Intensive Care Unit for management of hypertension in patients with ICH. Therefore, this study aims at evaluating the efficacy and safety of continuous infusion of labetalol for the management of hypertension in patients with ICH.

**Objective:** The goal is to evaluate the clinical efficacy and safety of a continuous infusion of labetalol for hypertension management in patients with ICH. The primary objective consists of describing the time and the labetalol dose required to achieve the BP target. Secondary objectives include determining the use of additional antihypertensive medications needed to achieve BP goal as well as assessing for adverse events related to prolonged antihypertensive medication administration.

**Methodology:** A non-interventional retrospective chart review of patients admitted and treated in the Neurology Intensive Care Unit at the main campus of Cleveland Clinic with a diagnosis of ICH will be conducted. Data to be collected include demographic information: age, sex, weight, and past medical history. Additional antihypertensive medications received prior to admission, systolic BP, Glasgow Coma Score, and location and size of hemorrhage on admission will be recorded. Dosage of labetalol and total amount required to achieve target BP, percent of time at goal, adverse reactions including hypotension (BP<90 mmHg), bradycardia (heart rate<90 bpm), and abnormal liver function tests as well as other rescue antihypertensive medications will be collected. If labetalol was replaced with a different continuously infused rescue antihypertensive medication, its use and dose will also be recorded. Descriptive statistics will be reported for key patient characteristics and treatment outcomes.

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

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## Nesiritide Cohort Study in Total Artificial Heart Patients

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### Background:

Endogenous B-type natriuretic peptide (BNP) is produced by the ventricular cardiomyocytes. When the native ventricles are removed and a total artificial heart (TAH) is implanted in a patient it is hypothesized that this may impair their renal function and volume homeostasis due to lack of BNP.<sup>1</sup> Theoretically, administering nesiritide infusion could prevent abrupt withdrawal of endogenous BNP and improve patient outcomes. Support of this hypothesis is limited to case reports investigating nesiritide use in total artificial heart patients.

### Objective:

The goal of this study is to assess the safety of nesiritide in patients with a TAH at the Cleveland Clinic. The primary objective of the study is to assess the change in urine output in patients with a TAH who receive nesiritide. The secondary objectives are to assess: 1) the change in serum creatinine (SCr) in patients with a TAH who receive nesiritide 2) the incidence of hypotension in patients with a TAH who receive nesiritide 3) average daily nesiritide dose 4) average daily diuretic dose while on nesiritide therapy in comparison to baseline and in comparison to post-nesiritide therapy.

### Methodology:

Retrospective medical record review of patients who received a CardioWest™ TAH at the Cleveland Clinic and received therapy with nesiritide will be included in the study. Patients who received a TAH but did not receive therapy with nesiritide will be excluded. The following demographic data will be collected: age, gender, height and weight, heart failure diagnosis, heart failure duration, baseline ejection fraction, date of TAH, date of orthotopic heart transplantation (if applicable), date of expiration (if applicable). The following daily information from baseline up to 2 days after nesiritide therapy discontinuation will be collected: location (intensive care unit or regular nursing floor), TAH cardiac output/cardiac index, serum sodium, blood urea nitrogen, serum creatinine, daily fluid intake and output, nesiritide daily dose, daily diuretic dose, and vasopressor requirements. The following adverse events will be collected: number of incidents of hypotension (SBP <80 mm Hg), percent of patients experiencing hypotension. Medical record review data will be collected and analyzed in Microsoft Access. Descriptive statistics analysis will be used to evaluate the data. This study has been reviewed and approved by the IRB committee.

Results and conclusions: Results to be determined

### References:

- 1) Delgado R, Wadia Y, Kar B, Ethridge W, Zewail A, Pool T, et al. Role of B-type natriuretic peptide and effect of nesiritide after total cardiac replacement with the AbioCor total artificial heart. J Heart Lung Transplant 2005; 24:1166-70.

## Piperacillin/Tazobactam Drug Use Review

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**Background:** Piperacillin/tazobactam (P/T) is the number one antimicrobial at the Cleveland Clinic in usage and cost. P/T use is recommended empirically in patients with nosocomial infections due to its broad spectrum, including *Pseudomonas aeruginosa*. Risk factors for nosocomial organisms are skilled nursing facility residence, prior hospital admission in past 90 days, infection onset  $\geq$  48 hrs after admission, immunosuppression, and previous history of *Pseudomonas aeruginosa*. To minimize resistance and decrease cost of P/T, use must be optimized by discontinuing or de-escalating therapy when warranted. P/T drug use review on general medical floors will provide information on patients with nosocomial risk, and outcomes of therapy. This information will identify areas where P/T use may be optimized.

**Objectives:** Primary objective of this drug use review is to identify nosocomial risk factors and indications for P/T use. Secondary objectives are to identify duration of therapy in relation to length of stay, assess outcome of therapy (e.g., discontinued, de-escalated), and impact of Infectious Disease consults.

**Methodology:** Retrospective chart review of adult patients who received P/T on select internal medical floors will be included. The following data will be collected: 1) nosocomial/multidrug-resistant organism risk factors 2) previous infection history 3) immunocompromised 4) prior antimicrobial history during admission 5) Infectious disease consult 6) duration of therapy 7) source and pathogen 8) concomitant antimicrobials and 9) therapy outcome. Data will be analysed using descriptive methods.

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

### References:

1. Bad bugs, no drugs. Infectious Diseases Society of America White Paper. July 2004
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## Effect of omeprazole on clozapine pharmacokinetics in patients with chronic schizophrenia

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**Background:** Clozapine is a highly effective atypical antipsychotic used in refractory schizophrenia. It is hepatically transformed to N-desmethylclozapine (NDMC, norclozapine, primary metabolite) and clozapine-N-oxide (CNO) by the CYP450 system. Omeprazole is a commonly utilized proton pump inhibitor that is an inducer and inhibitor of the hepatic CYP450 1A2 isoform, as well as an inhibitor of CYP3A4, 2C19, 2C9 and 2D6. There are several case reports of omeprazole interacting with clozapine, however the observed change in clozapine concentration varies from report to report, both in magnitude and direction and there is much heterogeneity between baseline characteristics of the patients in the reported cases.

**Objective:** The primary objective of this study is to characterize the pharmacokinetics of clozapine alone and clozapine plus omeprazole in non-smoking patients with chronic schizophrenia. The secondary objective is to characterize the pharmacokinetics of NDMC and clozapine-N-oxide CNO when clozapine is administered alone and when clozapine is administered concurrently with omeprazole in non-smoking patients with chronic schizophrenia.

**Methodology:** This will be a prospective, paired, single group, pharmacokinetic study. After investigational review board approval, a list of patients that receive clozapine from the Cleveland VA Medical center that meet the entry criteria will be obtained, targeted enrollment is 10 subjects. The inclusion criteria are: DSM-IV diagnosis of schizophrenia or schizoaffective disorder; male; greater than 18 years old and receiving the same dose of clozapine from the Cleveland VA Medical Center for at least 28 days. Exclusion criteria are: patient received fluvoxamine, oral ciprofloxacin, cimetidine or nicotine within 14 days of study initiation; patient is actively receiving atazanavir, nelfinavir, posaconazole, oral ketoconazole, itraconazole, oral tacrolimus, oral mesalamine, erlotinib, dasatanib, delavirdine or cilostazol as part of their medication regimen; patient is consuming more than 400mg/day of caffeine, (approximately four 6 ounce cups of brewed coffee or ten 6 ounce cups of green/black tea); patient is currently on omeprazole; patient takes their first dose of clozapine after 12:00PM daily, if the patient has a documented heparin allergy and if the patient has a legal guardian. Upon enrollment into the study and after obtaining informed consent, baseline serum clozapine, NDMC and CNO pharmacokinetics will be obtained. Blood samples will be obtained just before, 0.5, 1, 2, 3, 4 and 6 hours after their morning dose of clozapine (day 1). At the end of day 1, each subject will receive a supply of omeprazole 20mg capsules, to be taken once daily in the morning at least 30 minutes prior to breakfast for 14 days. On day 15 blood samples will be obtained for the analysis of serum clozapine NDMC and CNO levels just before and at 0.5, 1, 2, 3, 4, 6, 8 and 12 hours after their morning dose of clozapine. This will be their last day of concurrent clozapine and omeprazole. Subjects will be evaluated for dietary habits of foods that can affect CYP450 1A2, medication compliance and safety and tolerability on days 8 and 15 of the study.

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

### References:

- 1) DeVane CL, Markowitz JS. Antipsychotics. In: Levy RH, Thummel KE, Trager WF. *Metabolic drug interactions*. Philadelphia: Lippincott Williams & Wilkins; 2000:245–57.
- 2) Rost KL, Brosicke H, Brockmoller J, Scheffler M, Helge H, Roots I. Increase of cytochrome P4501A2 activity by omeprazole: Evidence by the <sup>13</sup>C-[N-3-methyl]- caffeine breath test in poor and extensive metabolizers of S-mephenytoin. *Clinical pharmacology and Therapeutics*. 1992; 52: 170-80.
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- 7) Mookhoek EJ, Loonen AJM. Retrospective evaluation of the effect of omeprazole on clozapine metabolism. *Pharmacy World and Science*. 2004; 26: 180-182.

## Impact of Enterococcal PNA FISH on Antimicrobial Use at Cleveland Clinic

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**Background:** Enterococci are reported as the third most common cause of bloodstream infections (BSIs). Patients at risk for enterococcal BSIs include those with intravascular catheter devices, transplants and neutropenia. Mortality associated with enterococcal BSIs is estimated at 35%. The most common species are *E. faecalis* and *E. faecium*. *E. faecalis* is often susceptible to ampicillin and vancomycin, *E. faecium* is susceptible to ampicillin in only 10% of cases and vancomycin 10-40% of cases. Thus empiric coverage with agents active against vancomycin-resistant enterococci (VRE) is needed. These agents are daptomycin or linezolid which are more expensive than the standard agents. Peptide nucleic acid fluorescent in situ hybridization (PNA FISH) probes use molecular methods for rapid identification of *Enterococcus* species compared to traditional methods. The use of this technology may allow more rapid and appropriate directed therapy for patients with enterococcal bacteremia. The results of this project will be used in evaluating its impact on clinical practice at our institution.

**Objectives:** The primary objective is to predict the impact of enterococcal PNA FISH to determine if it results in earlier initiation of targeted antimicrobial therapy and/or decreases time to de-escalation of therapy. A secondary objective will include a cost-benefit analysis.

**Methodology:** This non-interventional, retrospective, chart review will include 150 patients with blood cultures positive for enterococci over an 18 month period. Patients included must be 18 years of age or older and have at least one blood culture positive for enterococci. Patients with death or discharge within 24 hours of positive blood cultures will be excluded. The following data will be collected: age, gender, primary service, admission and discharge dates, underlying medical conditions, culture results, enterococcal isolate, initial antimicrobial agent, time of initiation of therapy, start and stop dates of antimicrobials, reasons for changes in therapy and date of change. Data analysis will include descriptive statistics, t-test for continuous data and Fisher's exact test or chi-square for nominal data. A cost benefit analysis will also be performed. This study has been submitted to the Institutional Review Board.

**Results and Conclusions:** Results are to be presented at the Great Lakes Pharmacy Residency Conference.

### References

1. Wisplinghoff H, Bischoff T, Tallent SM, Seifert H, Wenzel RP, Edmond MB. Nosocomial bloodstream infections in US hospitals: analysis of 24,179 cases from a prospective nationwide surveillance study. *Clin Infect Dis* 2004;39:309-16.
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# A Comparison of Vancomycin to Metronidazole for the Treatment of *Clostridium difficile*

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Background: *Clostridium difficile* is an anaerobic, spore-forming gram-positive bacillus that is frequently the cause of nosocomial-associated diarrhea. The severity of *Clostridium difficile*-associated disease (CDAD) can range from uncomplicated diarrhea to sepsis or even death. Antimicrobial use is strongly linked to the development of CDAD because it destroys the normal flora of the gastrointestinal tract, allowing for the overgrowth of *C.difficile*.<sup>1</sup> Since 2000 there has been a notable rise in the number and severity of *C. difficile* infections accompanied by an increase in metronidazole failure.<sup>2</sup> The main catalyst behind this dramatic rise is believed to be the new strain of *C.difficile*, known as the NAP1/BI/027. This strain is more virulent than its previous counterparts and has frequently been associated with a more severe disease and higher mortality rates.<sup>3</sup>

Objective: To evaluate the outcomes related to *Clostridium difficile* infection for patients receiving metronidazole or vancomycin.

Methodology: An observational retrospective chart review of all patients at least 18 years or older with a positive *C. difficile* toxin, diarrhea ( $\geq 3$  unformed stools in 24 hours), and at least one of the following: fever ( $>38.3^{\circ}\text{C}$ ), abdominal pain and/or leukocytosis. Patients with an intolerance to metronidazole or vancomycin, pregnant, colostomy; or diagnosis of ulcerative colitis, Crohn's disease, short bowel syndrome, bowel obstruction or death within twenty-four hours after positive *C. difficile* toxin will be excluded. The following data will be collected: age, gender, place of residence, past medical history; dose, route and frequency of treatment antibiotic; days to symptom resolution, treatment in the intensive care unit, prior antibiotics, day prior antibiotics were discontinued; antiperistaltic medications, bile acid sequestrants and probiotics received during treatment period. Severe *C. difficile* is defined as any of the following: septic shock, megacolon, perforation, colectomy or pseudomembranous colitis. Chart review data will be entered and analyzed in Microsoft Access. Descriptive data analysis will include assessment of demographic data, initial study treatment, changes in study treatment, comorbid conditions, prior antibiotics, day prior antibiotics discontinued, days to symptom resolution and other ancillary medications used during treatment including: antiperistaltic medications, bile acid sequestrants and probiotics.

Results and conclusions: Results to be determined

## References:

1. McDonald LC, Coignard B, Dubberke E, Song X, Horan T, Kuty PK. Recommendations for surveillance of Clostridium difficile-associated disease. *Infect Control Hosp Epidemiol*. Feb 2007;28(2):140-145.
2. O'Connor JR, Johnson S, Gerding DN. Clostridium difficile Infection Caused by the Epidemic BI/NAP1/027 Strain. *Gastroenterology*. 2009;136:1913-1924.
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# Evaluation of Systemic Corticosteroid Dose for the Inpatient Management of COPD Exacerbation

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**Background:** The use of systemic corticosteroids as a treatment for chronic obstructive pulmonary disease (COPD) exacerbation is supported by many controlled trials<sup>1</sup>, however there is conflicting evidence as to the proper dose, duration of treatment, and if there is a need to taper the dose. Currently, there are no trials that directly compare high or medium dose systemic corticosteroids to low dose systemic corticosteroids.<sup>1</sup> The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommend a dose of 30-40 mg prednisolone per day for 7 to 10 days based on efficacy and safety, with oral therapy being the preferred route of administration.<sup>2</sup> Although the optimal dose for treatment of COPD exacerbation is not known, high doses of systemic corticosteroids are associated with an increased risk of side effects.

**Objective:** The study's objective is to determine if there is a difference in the efficacy and safety of high dose systemic corticosteroids compared to low dose systemic corticosteroids for the management of COPD exacerbations.

**Methodology:** This is a prospective, randomized, open label, clinical trial which will be reviewed by the IRB Committee for approval prior to commencement. Patients who meet the following inclusion criteria will be included in the study population after informed consent is obtained: admitted to the hospital and assigned to an Internal Medicine house team at St. Elizabeth Health Center in Youngstown, Ohio, receiving treatment as an inpatient for a COPD exacerbation (as diagnosed by the physician or defined as a change in the patient's baseline dyspnea, cough, and/or sputum that is beyond normal day-to-day variations), and the patient's physician is planning to initiate systemic corticosteroids which includes intravenous (IV) methylprednisolone for the management of the COPD exacerbation. Exclusion criteria include the following: hypersensitivity or contraindication to systemic corticosteroid administration, concurrent pneumonia as diagnosed by chest x-ray, patients requiring mechanical ventilation, admission to the intensive care unit, use of systemic corticosteroids within the previous 30 days with the exception of receiving one dose of IV methylprednisolone  $\leq$  125 mg (or equivalent) in the emergency department (ED) prior to randomization, or discharge from a hospital within the last 30 days for management of a COPD exacerbation.

Patients will be randomly assigned to one of two treatment groups. Group 1 will receive IV methylprednisolone 60 mg every 6 or 8 hours (high dose). Group 2 will receive IV methylprednisolone 60 mg every 24 hours (low dose). Following the initial dosing regimen, both groups will receive a systemic corticosteroid taper at the physician's discretion for a total duration of 14 days. The primary outcome of the study is inpatient treatment failure (defined as patient mortality, need for intubation/mechanical ventilation, intensification of systemic corticosteroid therapy from the dosing regimen initiated at randomization, or transfer to another nursing unit for a higher level of care or monitoring due to worsening COPD exacerbation). Secondary outcomes include: Modified Borg's dyspnea scale scores at baseline and 72 hours after randomization, pulse oximetry data at baseline and 72 hours after randomization, hospital length of stay, corticosteroid-related adverse drug events, readmission (or ED visit) to St. Elizabeth for management of a COPD exacerbation within 30 days of discharge, and inpatient treatment failure rate in patients who did and did not receive inhaled corticosteroids as a maintenance therapy at home.

**Results and Conclusions:** Results to be determined

## References:

1. Vondracek SF, Hemstreet BA. Is There an Optimal Corticosteroid Regimen for the Management of an Acute Exacerbation of Chronic Obstructive Pulmonary Disease? *Pharmacotherapy* 2006;26(4):522-32.
2. World Health Organization. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. <http://www.goldcopd.com/> (accessed 2009 Aug 18).

# Therapeutic troughs in individualized versus standard dosing of vancomycin

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## Background

Vancomycin has been an extensively studied antibiotic since its debut on the market over 50 years ago. Recently, it was found that monitoring levels of the drug should be required to assess efficacy and prevent resistance.<sup>1</sup> In earlier years, it is unclear as to whether or not patients were being optimally dosed while on vancomycin since appropriate dosing and monitoring methods were not well-defined. Consequently this could have attributed to the development of resistant organisms over a period of years. It has been found that low concentrations of vancomycin are associated with the development of vancomycin-intermediate organisms.<sup>2,3</sup> Thus, having studies that analyze dosing strategies based on maintaining optimal target levels may help minimize the development of resistance and retain effectiveness. The vancomycin guidelines developed and published in Clinical Infectious Disease and American Journal of Health-System Pharmacy acknowledges that there are two different dosing strategies used in the treatment of infections, however they do not specify which method is more appropriate.<sup>4,5</sup>

## Objective

The primary objective of this study is to determine the proportion of patients in each group who attain an initial target trough after at least two doses.

## Methodology

This is a retrospective cohort design that will be conducted at Akron General Medical Center. Upon approval by AGMC's Institutional Research Review Board, an electronic chart review will be performed to evaluate each potential subject for inclusion. The study will include adult patients who received Vancomycin between January 1, 2008 and December 31, 2008. Patients with severe renal dysfunction (i.e. CrCl less than 30ml/min) will be excluded from this study. The following data will be collected: age, height, weight, serum creatinine, creatinine clearance, vancomycin doses, troughs, and duration of treatment. Patients will be divided into two groups based on the dosing strategy used: individualized (30mg/kg/d in divided doses) or standard (1g every 12 or 24 hours). After patients are chosen, a review of the vancomycin dosing regimen, trough levels, and dosing adjustments will be conducted.

**Results and Conclusions:** Results to be determined

## References

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## Retrospective Cohort of Extended-Infusion Piperacillin/Tazobactam (RECEIPT): A Multicenter study

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Background: Ever increasing resistance among gram negative infections<sup>1</sup> and increasing mortality associated these organisms has led to the reevaluation of the optimal method to administer current antibiotics. As suggested by Lodise in 2004,<sup>2</sup> extending the administration time of piperacillin/tazobactam maximizes the time free drug is available at concentrations in excess of the MIC ( $fT > MIC$ ) without the notable line access drawbacks of continuous infusions. This novel administration technique takes advantage of the pharmacodynamic properties of this extended spectrum  $\beta$ -lactam/ $\beta$ -lactamase inhibitor combination. Lodise and colleagues<sup>2</sup> showed extended-infusion piperacillin/tazobactam improves 14 day mortality and length of stay in critically ill patients with *Pseudomonas aeruginosa* infections. A multisite, retrospective cohort study compared extended-infusion piperacillin/tazobactam to intermittent infusion piperacillin/tazobactam in documented gram negative infections, but found no impact on 30 day mortality or length of stay.<sup>3</sup> However, some limitations within these previous studies have led to the need to further characterize the effects of extended infusion on mortality, length of stay, and intensive care unit (ICU) length of stay and to describe the patient population which benefits most from extended-infusion administration. By using multiple study sites, this study aims to increase the power to detect a mortality benefit proposed by the Lodise model.

Objective: To compare the efficacy of extended-infusion piperacillin/tazobactam against alternative effective therapies using mortality as a primary endpoint.

Methods: Each corresponding author will conduct an independent retrospective chart review of adult patients treated with extended-infusion piperacillin/tazobactam or intermittent-infusions of cefepime, imipenem/cilistatin, meropenem, doripenem, or piperacillin/tazobactam for more than 48 hours. Included will be patients with any infection in which a gram negative organism is identified as the causative pathogen. Excluded will be any patient who received greater than 24 hours of effective antibiotics before the initiation of study drug, any patient who receives less than 5 continuous days of study medication, any patient whose infection is proven resistant to empiric therapy, or any patient who is inadequately treated for a concurrent resistant pathogen (such as methicillin-resistant *Staphylococcus aureus*). Demographic data, APACHE II score, comorbid conditions, culture results, treatment strategy, treatment days, concurrent antibiotics, ICU days, hospital days, as well as mortality data will be collected.

Results and conclusions: To be determined.

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# Atorvastatin 80 mg daily therapy for acute coronary syndrome: an assessment of short and long term tolerability

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Background: HMG-CoA reductase inhibitors, referred to as statins, lower serum cholesterol and reduce cardiovascular events in patients with coronary heart disease.<sup>1</sup> The Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction 22 (PROVE-IT-TIMI 22) demonstrated that an intensive lipid-lowering regimen with high-dose statin therapy (atorvastatin 80 mg) significantly reduces cardiovascular risk by 16 percent after acute coronary syndrome (ACS) compared to moderate lipid-lowering with standard dose therapy (pravastatin 40 mg).<sup>2</sup> These results led to the prescribing of atorvastatin 80 mg daily in ACS patients discharged from University of Toledo Medical Center (UTMC).

Objective: To assess use and tolerance of atorvastatin 80 mg daily in ACS patients. Specifically, if a dosage adjustment or therapy discontinuance has occurred during follow-up consultation and the documented reason for a therapy change.

Methodology: Retrospective chart review of adult patients admitted with a diagnosis of ACS discharged on a statin from UTMC during September 1, 2005 to August 31, 2009 and follow-up with UTMC Cardiology Clinic will be included in the study. Subjects will be evaluated for up to 36 months following discharge. The following data will be collected: patient demographics, type of ACS (NSTEMI, STEMI, or unstable angina), past medical history, home and discharge medications, laboratory values (liver function tests, creatine phosphokinase, serum creatinine, and cholesterol). Data collected from follow-up visits will include reason for office visit, patient complaints, statin type and dose, current medications, adverse events or intolerances. Data will be collected on data collection forms and analyzed using Microsoft Excel. This study has been reviewed and approved by the UTMC IRB.

Results and conclusions: Results to be determined.

## References:

1. Pedersen, T.R., et al., *Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S)*. 1994. *Atheroscler Suppl*, 2004. 5(3): p. 81-7.
2. Bavry, A., et al., *Long-Term Benefit of Statin Therapy Initiated during Hospitalization for an Acute Coronary Syndrome*. *Am J Cardiovasc Drugs*, 2007. 7(2): p. 135-141.
3. Cannon, C.P., et al., *Intensive versus moderate lipid lowering with statins after acute coronary syndromes*. *N Engl J Med*, 2004. 350(15): p. 1495-504.