ABSTRACTS

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ORIGINAL RESEARCH

ADR/Drug Interactions

1. Comparison of online drug interaction databases to evaluate antiretroviral medication interactions. *Tomasz Z. Jodlowski, Pharm.D., BCPS, (AQ-ID)*[1], Priti N. Patel, Pharm.D., BCPS[1], Nicole M. Maisch, Pharm.D.[1], Donna Mildvan, M.D.[2]; (1)St. John's University College of Pharmacy and Allied Health Professions, Queens, NY; (2)Beth Israel Medical Center, New York, NY

PURPOSE: Treatment of the human immunodeficiency virus (HIV) is complex and clinicians often look to drug interaction evaluation tools to assist in daily patient care. Although technology has been shown to improve patient safety, the use of online drug interaction tools to evaluate antiretroviral interactions has not been evaluated. The purpose of this study was to compare online drug interaction databases with a focus on antiretroviral medications.

METHODS: Twelve online drug interaction databases were evaluated: Micromedex Thomson Healthcare Series (MM),University of Liverpool (UL), Clinical Pharmacology (CP), Clinical Care Options (CCO), AIDSmeds (AM), Medscape Drug Reference (MDR), Lexi-Complete (LC), Johns Hopkins HIV Guide (JHHIVG), Facts and Comparisons eAnswers Drug Interaction Interactive Tool (FC), Epocrates online free (EOF), HIV In Site (IS) and Drug Interaction Facts eBook (DIF). The databases were evaluated for scope (database correctly identify the presence of a drug interaction) and comprehensiveness (depth of information provided for a correctly identified drug interaction) using 40 drug pairs. Subsequently the databases were ranked based on scope and comprehensiveness scores (Excellent: ≥ 90%, Satisfactory: 89–60%, Poor: < 60%).

RESULTS: MM, UL, CP and CCO were considered excellent based on scope (≥ 90%) and MM, UL, CP, LC, MDR and CCO were considered satisfactory based on comprehensiveness score (89–60%). No database was ranked as excellent in comprehensiveness. There was no statistically significant difference in scope between free and subscription databases ($p>0.05$) or between HIV-specific and general databases ($p>0.05$). There was a statistically significant difference in comprehensiveness favoring subscription databases ($p<0.05$), however no difference was observed between general and HIV specific software ($p>0.05$).

CONCLUSION: MM, UL, CP, and CCO were the only databases in the study that achieved highest rank for both scope (excellent) and comprehensiveness (satisfactory). Clinicians should periodically evaluate their preferred database and consider checking multiple resources when evaluating drug interactions.

2. Comparing the type and severity of drug interactions among different ICUs. *Pamela L. Smithburger, Pharm.D., BCPS*, Sandra L. Kane-Gill, Pharm.D., MSc, FCCM, FCCP, Amy L. Seybert, Pharm.D.; University of Pittsburgh School of Pharmacy, Pittsburgh, PA

PURPOSE: Mortality and morbidity are increased in patients experiencing drug-drug interactions (DDIs), and there is a lack of literature describing clinically significant DDIs in the intensive care unit (ICU). It is also unknown if there are differences in severity and type of DDIs between different ICUs. Our objective is to identify DDIs occurring in the medical ICU (MICU), cardiovascular ICU (CCU), and the cardiothoracic ICU (CTICU) and compare the severity and types of medications involved in the DDIs between the units.

METHODS: This prospective, observational study was conducted for 4 weeks in each of the 3 ICUs (MICU, CCU, CTICU) of an academic medical center. Patients ≥18 years of age and admitted to the ICU under observation during the month of study were included. Lexi-Interact™ and Micromedex® interaction databases were utilized daily to screen each patient's medication profile for interacting drug pairs. Severity of the DDI was assessed by each databases' severity rating scale.

RESULTS: Overall, 736 patient medication profiles were evaluated with 343 profiles possessing ≥ 1 DDI. There were a total of 1670 DDIs identified (2.27 DDI/ patient-day) with 813 being unique interacting drug pairs. DDIs were major or contraindicated in 4.7% (14/296), 8.9% (19/213), and 2.5% (8/355) of the CCU, CTICU, and MICU DDIs, respectively. Upon evaluation of the agreement of severity ratings between the interaction databases, more variance was noted in the MICU DDIs. Differences also existed between the medications involved in the most common DDIs in the MICU compared to the other units.

CONCLUSION: DDIs occur frequently in the ICU setting, and the type and severity of DDIs may be influenced by the patient population, co-morbid disease states and reason for admission. When developing an alerting system for DDIs, patient characteristics and location should be taken into consideration to develop an optimal warning system.

3. Incidence, characteristics, and outcomes of adverse drug events resulting in intensive care admission in oncology patients. *Lama H. Nazer, Pharm.D., BCPS*, Feras I. Hawari, M.D., Rana A. Eljaber, Pharm.D.; King Hussein Cancer Center, Amman, Jordan

PURPOSE: to determine the incidence, characteristics, and outcomes of adverse drug events (ADEs) that necessitate admission to the intensive care unit (ICU) in oncology patients.

METHODS: This was a 5-month prospective observational study conducted between August 1st and December 31st, 2010 at a comprehensive academic cancer center. Patients admitted to the ICU were screened within 48 hours to determine if the admission may have been due to a drug related adverse event. An ADE was defined as an injury or patient harm resulting from medical intervention related to a drug. ADEs were characterized based on the suspected medication, organ system involved, and severity and preventability. Patient demographics, length of stay, and mortality were recorded.

RESULTS: During the study period, 249 patients were screened. The majority of patients had solid tumors (n=179; 72.2%); the remaining had hematological malignancies (n=79; 31.7%). Of the patients admitted, 134 (53.4%) were males and the average age was 52.1 ±15.8 (SD) (range: 19-88) years. An ADE was determined as the primary cause of 58 (23.3%) admissions. The most common medications associated with an ADE requiring an ICU admission were antineoplastics (n=38; 62.3%) and analgesics (n=9; 14.8%). Other medications associated with an ADE requiring an ICU admission were: anticoagulants, diabetes medications, corticosteroids, immunosuppressants, and contrast agents. The most common types of adverse events were hematological/immune (n=33; 54.1%), neurologic (n=10; 16.4%), and respiratory (n=7; 11.5%). Five (8.6%) of the ADEs were considered preventable. The average length of stay for the patients admitted with ADEs resulting in ICU admission was 5.95 days ±9.43(SD) and the mortality rate was 27.1%.

CONCLUSION: To our knowledge, this is the first study to report on ADEs resulting in ICU admission in oncology patients. The incidence of ADEs in this patient population is high and often life-threatening and fatal.

4E. Evaluating the occurrence of QT prolongation resulting from drug-drug interactions. *Michael J. Armahizer, Pharm.D.*[1], Sandra Kane-Gill, Pharm.D., M.S., FCCM[2], Pamela L. Smithburger, Pharm.D., BCPS[2], Amy L. Seybert, Pharm.D.[2]; (1)UPMC Presbyterian, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA

PURPOSE: Over 50 medications cause QT prolongation, which can deteriorate into Torsades de pointes. Information is lacking on the frequency of QT prolongation due to drug-drug interactions (DDIs) accounting for temporal sequence in intensive care units (ICUs). This evaluation is of particular interest to clinicians in cardiac ICUs, since there is at heightened risk for adverse outcomes. The primary objective was to determine the frequency of QT prolongation from potentially interacting drugs in the coronary ICU and cardiothoracic ICU.

METHODS: A retrospective evaluation was performed using the institution's electronic data repository. Inclusion criteria were admission to the cardiac ICUs between January 2009 and July 2009, age ≥ 18 years, and electrocardiographic (EKG) evidence of a QTc ≥ 500 ms. Medications known to prolong the QT interval were identified using the Arizona CERT database. Patients receiving two concomitant medications known to prolong the QT interval were considered to experience a pharmacodynamic DDI. Medications known to be CYP450 enzyme inhibitors of QT prolonging medications were considered to cause pharmacokinetic DDIs. Interactions were evaluated for temporal relationship and causality related to the QT prolongation.
RESULTS: 187 (54.5 % male) patients, with a mean age of 62 years, experienced QT prolongation out of a total of 501 patients (37%) admitted during the study period. 154 and 163 patients had a potential pharmacodynamic and pharmacokinetic interaction, respectively, receiving an average of 2.9 QT prolonging medications during their admission. Of these patients, 43% (66/154) had 133 pharmacodynamic interactions confirmed by temporal sequence, and 47% (77/163) of patients experienced 179 potential pharmacokinetic interactions temporally related to QT prolongation.
CONCLUSION: DDIs may be a significant cause of QT prolongation in cardiac ICUs. These data can be used to educate clinicians on safe medication use. Computerized clinical decision support could be applied to aid in the detection of these events.
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5E. Improving adverse drug event detection in critically ill patients through intensive care unit transfer summary screening. *Ananth Anthes, Pharm.D.*[1], Lisa M. Harinstein, Pharm.D., BCPS[2], Pamela L. Smithburger, Pharm.D., BCPS[3], Amy L. Seybert, Pharm.D.[3], Sandra L. Kane-Gill, Pharm.D., MSc, FCCM, FCCP[3]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)Cleveland Clinic, Cleveland, OH; (3)University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Hospital discharge notes have been studied as a form of surveillance; however, ICU transfer summaries have not been studied for this purpose. Improving ADE prevention strategies relies upon improving detection.
METHODS: A retrospective electronic medical record review was conducted among medical ICU patients. Inclusion criteria included patients ≥18 years of age admitted between January through April 2009 with an ICU length of stay ≥24 hours. Two scales were utilized to assess chart documentation for ADEs: 1) Harvard Medical Practice Scale (MPS) and 2) Leonard Evidence Assessment Scale. The Harvard MPS was used to rank the strength of the wording in the medical record with a score of 4 (more than 50-50) up through 6 (virtually certain) indicating the presence of an ADE. The Leonard criteria were used to score causality with 1 out of 4 criteria indicating unlikely presence of an ADE and 4 out of 4 indicating a definite ADE occurrence.
RESULTS: Demographic information indicates 50% of the patients were male with a mean age of 60.3 years (+/- 16). 258 unique patients had ICU transfer summaries screened and evaluated for ADEs. 105 patients had at least 1 ADE with a total of 139 ADEs. The Harvard MPS scores collected were 4 (39.6%), 5 (51.8%) and 6 (7.9%). The Leonard scores were 2 of 4 (17.3%), 3 of 4 (54.7%) and 4 of 4 (28.1%). Most common medications associated with an ADE were furosemide, ciprofloxacin, warfarin and heparin. Most common ADEs were Clostridium difficile, hypotension, acute kidney injury and hyperglycemia.
CONCLUSION: 41% of ICU transfer summaries contained a description of an ADE; therefore, reviewing ICU transfer summaries is a useful method of detecting ICU-specific ADEs and should be considered as part of an ADE surveillance system. Understanding contributing medications and resulting reactions of ADEs will aid in future prevention strategies.
Presented at Presented at the Society of Critical Care Medicine Congress, San Diego, CA, January 15–19, 2010.

6. Glyburide versus glipizide: a comparison of glycemic control in a selected veteran population. *Bharti Sharma, Pharm.D.*, Anne Lubischer, R.Ph., Ronald R. Brown, M.S., R.Ph.; Portland VA Medical Center, Portland, OR
Glyburide versus Glipizide: A Comparison of Glycemic Control In A Selected Veteran Population. Bharti Sharma, Pharm.D., Anne Lubischer, R.Ph., Ronald R. Brown, M.S., R.Ph.; Portland Veterans Affairs Medical Center, Portland, OR.
PURPOSE: This study documented HbA1c changes in 70 patients who were switched to glipizide between August 2009 and January 2010 due to concerns of hypoglycemia with glyburide.
METHODS: Medical records of these 70 patients at the Portland Veterans Affairs Medical Center were reviewed to gather HbA1c and weight data up-to a year before the switch and up-to a year after the switch. Glyburide and glipizide doses and number of other anti-diabetic agents were also collected. Safety endpoints included documented symptomatic hypoglycemia, blood glucose values <60mg/dL and reduction in glipizide dose after the switch.
RESULTS: Majority of the patients (54%) were switched to glipizide at doses equivalent to their glyburide dose. Mean daily dose of glyburide was 8.5mg and glipizide was 9.86mg (P=0.269). The mean conversion ratio was 1mg glyburide to 1.3mg of glipizide. The switch resulted in a mean increase in HbA1c of 0.09% (CI -0.9 to 0.7, p=0.763). The proportion of patients who remained at goal HbA1c of <7% did not change significant after the switch (p=0.986). Change in mean weight was not significant (CI -0.50 to 2.4, p=0.194). One incident of symptomatic hypoglycemia was noted before and one after the switch. Similarly, one blood glucose value of < 60mg/dL was documented before and one after the switch. Both of these safety endpoints were under-documented. Only 8.6% of patient needed their original glipizide dose to be reduced.
CONCLUSION: The switch from glyburide to glipizide at equivalent doses did not result in any negative impact on patients' glycemic control or adverse effects on their weight. No conclusions regarding safety outcomes can be made due to lack of documentation.
Adult Medicine

7. Evaluation of an ipad to provide warfarin video education in the inpatient setting. *Jenny J. Kim, Pharm.D.*[1], Rima A. Mohammad, Pharm.D.[2], Kim C. Coley, Pharm.D.[2], Amy C. Donihi, Pharm.D.[2]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Traditionally, hospitalized patients receive medication education immediately before discharge by written and/or verbal communication. Improving patient education about warfarin therapy is important because warfarin is among the top 10 medications with the largest number of reported adverse events. This quality improvement project evaluated the use of an iPad to provide video education to improve patient education regarding warfarin therapy.
METHODS: This project was prospectively conducted to include adult (>18 years of age) hospitalized patients on warfarin. Patients completed pre- and post-test knowledge questionnaires on the iPad before and after viewing the warfarin educational video. The primary objective was to evaluate the use of a warfarin educational video as an effective tool on an iPad. The secondary objective was to evaluate patients' satisfaction with using an iPad to view the warfarin video and complete the questionnaires.
RESULTS: A total of 40 patients were educated and included for evaluation. Most patients were new to warfarin therapy (65%). For the primary outcome of warfarin knowledge test scores, 42.5% of patients passed the pre-test and 90% of patients passed the post-test, p<0.001. There were no significant differences observed among test scores when comparing by age, gender, level of education, and use of CNS depressant drugs. Overall, 82.5% of patients reported they liked using the iPad and it was easy to use. A greater percent of younger patients (< 65 years) and females liked using the iPad compared to older patients (p=0.01) and males (p=0.02), respectively. Also, more patients < 65 years reported the iPad was easy to use compared to older patients, p=0.01.
CONCLUSION: Providing warfarin video education to hospitalized patients using an iPad was effective. The knowledge questionnaire identified concepts patients did not understand and prompted further discussion. Educating patients by video using an iPad may be an alternative to traditional education.

8. Evaluation of a pharmacy-driven renal dosing program. Katherine J. Rable, Pharm.D., *Andrew J. Crannage, Pharm.D., BCPS*; St. John's Mercy Medical Center and St. Louis College of Pharmacy, St. Louis, MO

PURPOSE: The objective of this study was to determine the impact of a pharmacy-driven renal dosing program on appropriate dosing of medications.

METHODS: In April 2010, St. John's Mercy Medical Center implemented a pharmacy-driven renal dosing program for levofloxacin and piperacillin/tazobactam allowing pharmacists to independently adjust dosage and/or frequency of these medications based on a patient's renal function, estimated via the Cockcroft-Gault equation. An investigation was conducted to evaluate this program. Patients hospitalized during September 2009 (pre-implementation) or September 2010 (post-implementation) who received IV levofloxacin and/or IV piperacillin/tazobactam and had a serum creatinine measured prior to medication initiation were included.

RESULTS: One hundred patients were included in the pre-implementation group [levofloxacin (n=50), piperacillin/tazobactam (n=50)] and 100 patients were included in the post-implementation group [levofloxacin (n=50), piperacillin/tazobactam (n=50)]. There was no significant difference in mean age, mean creatinine clearance (CrCl), percentage of female patients, or percentage of patients on hemodialysis between groups. The percentage of patients most likely to require a renal adjustment to their therapy (CrCl <50mL/min) was similar between the pre- and post-implementation groups at 42% and 44%, respectively (p=0.89). Seventy-nine percent of patients in the pre-implementation group (levofloxacin 66%; piperacillin/tazobactam 92%) were dosed appropriately compared to 94% in the post-implementation group (levofloxacin 90%; piperacillin/tazobactam 98%), (p=0.0032).

CONCLUSION: Implementation of a pharmacy-driven renal dosing program significantly improves appropriate dosing of levofloxacin and piperacillin/tazobactam. Additional pharmacist education will be necessary to ensure that appropriate dosing continues to improve. Based on these findings, pharmacist autonomy to independently adjust dosages and/or frequencies, with an institution approved protocol, could be expanded to other renally-eliminated medications to improve appropriate dosing. Expansion of this program would also allow pharmacists to further apply clinical knowledge to optimize patient care. An evaluation specifically designed to evaluate potential cost-savings would provide additional justification for expansion.

9. Risk factors for venous thromboembolism in patients with cirrhosis. *Kelly A. Walsh, Pharm.D.*; University of Kentucky HealthCare, Lexington, KY

PURPOSE: Pharmacologic venous thromboembolism (VTE) prophylaxis in patients with cirrhosis presents a unique challenge due to complications associated with the disease, including esophageal varices, thrombocytopenia and elevated international normalized ratios (INR). When evaluating whether these patients require VTE prophylaxis upon hospitalization, practitioners must weigh the risk of bleeding, and their perceived 'auto-anticoagulation', against the risk of developing VTE. Therefore, it would be advantageous if risk factors for the development of VTE in this population were identified. This study was designed to identify risk factors associated with the development of VTE in cirrhotic patients.

METHODS: This study is a retrospective, case control study. Patients at the University of Kentucky Chandler Hospital with a diagnosis of cirrhosis and VTE from October 2006 to July 2010 were matched in a 1:3 fashion with cirrhotic patients without VTE. The primary objective was to determine if there were significant differences in laboratory values between the 2 groups. Secondary objectives include examining the relationship between VTE incidence and INR.

RESULTS: During this time period, 27 patients with cirrhosis (1.0%) were diagnosed with VTE. These patients had significantly lower median aspartate aminotransferase (AST) (47 U/L versus 70, p=0.04), alanine transaminase (ALT) (24.5 U/L versus 36, p=0.02), albumin (2.1 g/dL versus 2.4, p=0.02) and hematocrit (28.3% versus 32, p=0.03) compared to the control patients. There was no correlation between INR and VTE incidence (p=0.70).

CONCLUSION: Patients with cirrhosis who developed VTE had significantly lower AST, ALT, albumin, and hematocrit, compared to control patients. There was no correlation between INR and VTE incidence. Therefore, in the absence of contraindications, use of pharmacological VTE prophylaxis in non – ambulating, hospitalized cirrhotic patients should be considered.

10. As needed intravenous antihypertensive therapy and blood pressure control. *Melissa Lipari, Pharm.D.*[1], Lynette R. Moser, Pharm.D.[2], Elizabeth A. Petrovitch, Pharm.D., BCPS[1], Margo Farber, Pharm.D.[3], John Flack, M.D., MPh[4]; (1)Harper University Hospital, Detroit, MI; (2)Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI; (3)Detroit Medical Center, Detroit, MI; (4)Wayne State University School of Medicine, Detroit, MI

PURPOSE: As needed intravenous antihypertensive therapy (IVAHT) is not indicated for asymptomatic blood pressure (BP) elevations or hypertensive urgencies. This study describes IVAHT use and the impact on asymptomatic patients.

METHODS: We conducted a prospective chart review of hypertensive patients who were prescribed as needed or one time only IV hydralazine, enalapril, labetalol or metoprolol between November 2010–January 2011. Data obtained through the electronic medical record included demographics, oral antihypertensive regimen changes during admission and at discharge, the prescriber type, IVAHT drug prescribed, type of order, whether the ordered drug was administered, BP and heart rate. The frequency of IVAHT related adverse outcomes was also assessed.

RESULTS: 247 patients were prescribed an IVAHT, 166 (67%) patients received IVAHT and 81 (33%) did not. Average baseline BP was higher in the administered vs. the not administered group, 162.1±2/86.96 vs. 151.7/83.33 mmHg, respectively (p = 0.011). Hydralazine represented 81% of orders, metoprolol 15% and labetalol 4%. Residents were the most common prescribers (48%), followed by physician's assistants/nurse practitioners (37%) and attending physicians (15%). After IVAHT administration only 42% of patients received a change to their oral antihypertensive regimen and 48% had changes to their oral regimen at discharge. BP was lowered more between admission and discharge in patients who experienced a change in their oral antihypertensive regimen after IVAHT administration compared to those who did not. Adverse events within 6 hours of IVAHT administration were: 14.4% decreased BP >25% baseline, 1.4% tachycardia, 0.8% bradycardia, 0.6% IV fluid administration, 1.7% scheduled BP medication held.

CONCLUSION: IVAHT is used in patients with BP elevations below minimum thresholds for hypertensive urgencies. Excessive BP lowering occurs in a significant proportion of those receiving IVAHT. The majority of patients receiving IVAHT have no changes made to their oral AHT regimen.

11. Pharmacy department commitment to a multidisciplinary stroke response team. Matthew J. Korobey, Pharm.D., BCPS[1], *Andrew J. Crannage, Pharm.D.*[2], Julie A. Murphy, Pharm.D., BCPS[2], Judd Jensen, M.D.[1], B.J. Hipsky, RN, MSN[1]; (1)St. John's Mercy Medical Center, St. Louis, MO; (2)St. Louis College of Pharmacy and St. John's Mercy Medical Center, St. Louis, MO

PURPOSE: On August 15, 2010, a multidisciplinary (neurology, interventional radiology, pharmacy, and nursing) stroke response team (SRT) was implemented at St. John's Mercy Medical Center. The objective of this study was to determine 1) the number of stroke calls received, 2) the average and total duration of time devoted to stroke calls, and 3) the difference in the absolute number of stroke calls with regards to time of day after implementation of a multidisciplinary SRT.

METHODS: Data was collected on each individual response of the multidisciplinary SRT for patients presenting with symptoms of acute ischemic stroke from August 15, 2010 through May 31, 2011. This data included absolute number of SRT activations, pharmacist time spent per stroke team response, if tissue plasminogen activator (t-PA) was administered, and shift during which the SRT was activated.

RESULTS: During the first 9.5 months following implementation of the multidisciplinary SRT, 224 responses were required. An average of 24 minutes of pharmacist time was required per SRT activation, resulting in an overall time commitment of 570 minutes per month. Twenty-five (11%) SRT activations resulted in patients receiving t-PA.

SRT activations resulting in t-PA administration required an average of 64 minutes of pharmacist time devoted to patient/disease assessment, dose calculation, verification, and medication preparation. Fifty-one percent of these responses occurred during day-shift, 42% during evening-shift, and 7% during night-shift.
CONCLUSION: Implementation of a multidisciplinary SRT, to improve care of the acute ischemic stroke patient, requires a commitment from clinical pharmacy and the department of pharmacy as a whole. Requiring 24-hour pharmacy coverage of the SRT pager, increases opportunities for application of clinical skills by all pharmacists to optimize patient care. Non-captured pharmacy time includes training of department staff and residents by clinical pharmacy specialists.

Ambulatory Care

12. Impact of change in duration of therapy with Ursodiol after gastric bypass surgery. *Margaret Malone, Ph.D., FCCP*[1], Jennifer Lindstrom, M.D.[2], Christine Gallati, B.S.[2]; (1)Albany College of Pharmacy and Health Sciences, Albany, NY; (2)Albany Medical College, Albany, NY
PURPOSE: Ursodiol is commonly used after gastric bypass surgery to reduce the formation of gallstones associated with rapid weight loss experienced in the first post operative year. The duration of therapy varies between centers from no therapy to up to 12 months.
METHODS: IRB approval to conduct a retrospective chart review was obtained. The incidence and time of occurrence of gallstones and associated cholecystectomy (CCY) between 1/2006 and 4/2009 (40 months) when patients were prescribed 12 months of therapy were compared with the period 5/2009 to 4/2011 (24 months) during which patients were prescribed 6 months of therapy. All patients underwent Roux-en-Y gastric bypass (RYGB).
RESULTS: 513 patients were included in the first study period (x females). 93 patients had CCY at the same time as the RYGB (18.1%). 29 (5.5%) patients developed gallstones and had CCY after surgery [2/29 had CCY within 90 days of RYGB]. 16/29 developed gallstones in the first post operative year. The mean (SD) time to CCY was 520 (400) days, range 16–1649 days. In the second study period, 351 patients (x females) had RYGB, 39 (11.1%) had CCY at the time of RYGB. 14 (4%) patients had CCY for gallstones after RYGB. The mean (SD) time to CCY was 216 (165) days, range 4–537 days. 6/14 developed gallstones while taking ursodiol in the first 6 months, [4 within 90 days of RYGB]. 4/14 developed gallstones after one year.
CONCLUSION: Patients in both groups developed gallstones during treatment and after the ursodiol was discontinued. The percent of patients developing gallstones was similar between groups. Patients in the second group developed gallstones earlier. Reducing the duration of therapy did not adversely affect the number of patients requiring post RYGB CCY.

13. Effectiveness of dietary sodium intervention provided by a clinical pharmacist to ambulatory patients with heart failure. *Grace L. Earl, Pharm.D.*[1], Annette Lista, Pharm.D., candidate[1], Susan Youssef, Pharm.D., candidate[1], Laura Pontiggia, Ph.D.[2], Andrew Peterson, Ph.D.[3]; (1)University of the Sciences, Philadelphia College of Pharmacy, Philadelphia, PA; (2)University of the Sciences, Misher College of Arts and Sciences, Philadelphia, PA; (3)University of the Sciences, Mayes College of Healthcare Business and Policy, Philadelphia, PA
PURPOSE: Evaluation of the impact of a clinical pharmacist intervention to promote dietary sodium adherence.
METHODS: A prospective interventional cohort study enrolled adult patients and engaged them during 4 meetings lasting 15–30 minutes (2 face-to-face, 2 phone calls). The intervention was designed to enhance understanding of dietary overindulgences and impact on heart failure. Four 24-hr dietary recalls were used to counsel on low-sodium food choices and achieving sodium intakes under 2000 mg per day. Data are presented as the mean (95% CI) and were analyzed with a paired *t*-test. LOCF was used for missing data, and IRB approval was obtained.
RESULTS: Thirty-six patients were enrolled and 33 completed the study (mean age 52.1 years, 82% African-American, and mean EF 32.3%). All 4 dietary recalls were obtained in 89.1% of patients. Baseline sodium intake was 1987.4 mg (95%CI 1580.6–2394.2) and 1591.2 mg (95%CI 1249.4–1933.1) at follow-up demonstrating a 19.9% relative reduction in dietary sodium intake ($p > 0.05$). There was no difference in vital signs at follow-up. The percent of patients reporting medication adherence was 51.5% at baseline versus 65.6% at follow-up. The incidence of heart failure hospitalizations in prior 6 months was 51.5% at first meeting and 18.8% at follow-up (p=0.009, Fisher's exact test).
CONCLUSION: This educational program can serve as a model for clinical pharmacists who are engaged in providing services to patients with cardiovascular disease or other conditions where excessive dietary sodium intake can adversely affect their medical condition. New guidelines promote dietary sodium goals under 1,500 mg for many groups, and we encourage development of teaching tools and self-care tools to engage patients in adopting healthy dietary lifestyles.

14. Assessment of insulin pens in an urban teaching hospital outpatient clinics. *Andrea R. Gauld, Pharm.D.*[1], Brigitte L. Sicat, Pharm.D.[2], Brian Baird, Pharm.D.[1]; (1)Virginia Commonwealth University Health System, Richmond, VA; (2)Virginia Commonwealth University School of Pharmacy, Richmond, VA
PURPOSE: Insulin pens were added to the Virginia Commonwealth University Health System (VCUHS) drug formulary in June 2010. The availability of insulin pens to patients may improve adherence and glycemic control, however, patients must be educated on proper use of the pen device. The objective of this project is to determine if there was a change in A1c or insulin utilization when patients were switched from insulin vials to pens, and to describe patients' knowledge of proper use of insulin pen devices.
METHODS: A retrospective review was conducted of all patients switched from receiving vials to pens at VCUHS outpatient pharmacies from January 1, 2009 to February 28, 2011. Additionally, a telephone survey was attempted on all patients who filled a prescription for an insulin pen from June 1, 2010 to February 28, 2011.
RESULTS: There were 31 patients included for medical record evaluation. From the January 1, 2009 start date, patients received vials for an average of 14.7 months before transitioning to pens for an average duration of five months of pen use during the study period. The A1c decreased from 9.55% to 9.03% (p=0.11) and average insulin utilization significantly increased in patients from 63 to 85 units per day ($p<0.01$). Twenty-one patients participated in the telephone survey: 38% of patients did not prime the insulin pen prior to each dose and 34% of patients did not properly dispose of pen needles. Patients were educated by a variety of sources: nurses (38%), package insert (24%), pharmacists (24%), and physicians (14%).
CONCLUSIONS: Changing patients to insulin pens significantly increased insulin utilization but did not have a significant impact on A1c. Patients may require more comprehensive insulin pen teaching upon initiation and/or reassessment of proper pen use over time.

15. Homeless and housed patients' access to treatment at a pharmacist-led smoking cessation clinic. *Sharon E. Connor, Pharm.D.*[1], Deborah M. Scharf, Ph.D.[2], Lauren J. Jonkman, Pharm.D., BCPS[1], Mary I. Herbert, M.S., M.P.H.[3]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)Department of Psychiatry, University of Pittsburgh and RAND Corporation, Pittsburgh, PA; (3)UPMC Department of General Internal Medicine, Pittsburgh, PA
PURPOSE: Although homeless adults report wanting to quit smoking at rates similar to their housed peers, the prevalence of smoking among the homeless remains disproportionately high. Few studies have investigated the role that pharmacists might play in promoting smoking cessation among the homeless. To address this need, we compared housed and homeless persons' access to, and use of a pharmacist-led smoking cessation clinic for the homeless and medically underserved.
METHODS: Participants were homeless (n=260) and housed (n=226) medically underserved adults who received services at the Birmingham Free Clinic between April 2010 to December 2010. Data collection began immediately following implementation of new screening, referral and treatment procedures designed to promote participation in the smoking cessation program. All clinic patients were to be asked about their smoking status, advised to quit and

referred to the smoking cessation service (a 9-session smoking cessation counseling protocol with free nicotine replacement therapy).
RESULTS: Overall 97% of the sample had their smoking status assessed. Smoking was more common among the homeless (vs. housed) patients (59% vs. 39%; p<0.008). Among current smokers, there were no between-group differences in cigarettes smoked per day, breath CO, readiness to quit smoking (all p's > 0.14). There were also no between-group differences in receipt of advice to quit smoking (84% vs. 78%; p=0.79) or referral to the treatment program (39% vs. 31%; p=0.46). Among clients receiving a referral to treatment, homeless clientele were half as likely to attend at least one treatment session (18% vs. 37%; p=0.15).
CONCLUSION: We did not identify disparities in homeless clients' access to screening or referrals. However, homeless clients were half as likely to attend treatment once a referral was made. Supplemental strategies to increase treatment utilization may be needed to improve homeless clients' treatment attendance and retention in smoking cessation programs.

16. Malignancy and warfarin-mediated anticoagulation: lower initial dose requirements, but greater long-term instability, adverse events, and intensity of management. *Holly H. Chiu, Pharm.D.*[1], Megan B. Bestul, Pharm.D.[1], Peter Whittaker, Ph.D.[2]; (1)Beaumont Hospital, Royal Oak, MI; (2)Wayne State University School of Medicine, Cardiovascular Research Institute and Dept of Emergency Medicine, Detroit, MI
PURPOSE: Emerging evidence indicates
METHODS: Our retrospective chart-review, examined 20
RESULTS: *Initial:* There was no difference in time to achieve target INR, however, cancer patients required a lower daily dose than the comparison group (7.5±2.8 vs. 4.7±1.9mg; *P*=0.002). *Long term:* cancer patients were unstable; indicated by lower TTR (48±15 vs. 79±10%; P<0.0001), and fewer INRs within target range (46±14 vs. 74±8%; P<0.0001). Furthermore, cancer patients required increased management; double the proportion of visits which required dose changes (43±16 vs. 20±7%; P<0.0001) and one week less between visits (10±19 vs. 17±26 days; *P*<0.0001). Cancer patients experienced a 10-fold increase in the proportion of visits with AE (6.0±8 vs. 0.6±1%; P=0.0039); AE correlated inversely with TTR (P=0.006).
CONCLUSIONS: Cancer patients' initial

17. Use of low molecular weight heparin (LMWH) in pregnancy: a pharmacodynamic modeling study. *Tara E. Gleason, Pharm.D.*[1], Nancy L. Shapiro, Pharm.D.[1], Larisa H. Cavallari, Pharm.D.[1], Edith A. Nutescu, Pharm.D.[1], Michelle Kominiarek, M.D.[2], Judith U. Hibbard, M.D.[2]; (1)University of Illinois at Chicago College of Pharmacy, Chicago, IL; (2)University of Illinois College of Medicine, Chicago, IL
PURPOSE: Low molecular weight heparins (LMWH) are the main treatment option for women needing anticoagulation during pregnancy. Guidelines for dosing LMWH in pregnancy exist, however there is no clear recommendation for the need and frequency of monitoring of anti-Factor Xa activity. The pharmacokinetics of LMWH are altered significantly during pregnancy, with increased renal clearance and volume of distribution. Pharmacodynamic data is needed to support the pharmacokinetic data that already exists for LMWH.
METHODS: A consecutive cohort of pregnant women who received LMWH therapy during pregnancy and delivered between January 1, 1998–November 1, 2010 were included in the study. Data was extracted through review of the electronic medical records. The primary outcome was to determine the pharmacodynamics of LMWH in pregnancy. The dosing requirements of LMWH for each case throughout pregnancy (mg/kg) to achieve a corresponding target anti-Factor Xa activity were plotted and linear correlation coefficients were calculated. Secondary outcome measures included frequency of monitoring of anti-Factor Xa activity, thromboembolic events, and bleeding complications with LMWH use in pregnancy.
RESULTS: A total of 115 consecutive patients (123 pregnancies) were included. Average age was 28.4 years (16–45) and 45% of patients had a pre-pregnancy BMI > 30. The majority of patients were Black or Hispanic. There were 66 pregnancies involving prophylaxis indications and 57 pregnancies involving treatment indications for LMWH. Calculations of the mg/kg dose requirement throughout pregnancy to achieve the targeted anti-Factor Xa activity showed nonlinear dosing requirements for all groups with the following correlation coefficients: all treatment(r=0.086), all prophylaxis (r=0.001), obese treatment (r=0.154), nonobese treatment (r=0.029), obese prophylaxis (r=0.25), nonobese prophylaxis (r=0.01).
CONCLUSION: Initial pharmacodynamic modeling showed poor linear correlation for all groups of patients when comparing dosing requirements with week of pregnancy, supporting the need for further studies with non-linear modeling methods and monitoring anti-Factor Xa activity throughout pregnancy.

18. Increased Goal Attainment After Conversion From Rosuvastatin to Simvastatin in a Community Health Clinic. *Joel C. Marrs, Pharm.D., BCPS*[1], Sarah L. Anderson, Pharm.D., BCPS[1], Karen E. Snow, Pharm.D.[2], Joseph J. Saseen, Pharm.D., FCCP, BCPS[1]; (1)University of Colorado School of Pharmacy, Aurora, CO; (2)Denver Health Medical Center, Denver, CO
PURPOSE: This retrospective observational cohort study evaluated LDL-C goal attainment before and after implementation of a therapeutic statin conversion among patients with dyslipidemia in a community health clinic. Secondary endpoints included LDL-C goal attainment stratified by cardiovascular risk, number of equipotent conversions, changes in other lipoprotein values, and financial impact.
METHODS: Refill records for adults with a prescription for rosuvastatin between June 1, 2009 and November 24, 2009 identified patients for conversion to simvastatin. Patients who were eligible for conversion were included in this analysis. Patient demographics, cost data, fasting lipid panel (FLP) and alanine aminotransferase (ALT) results were collected.
RESULTS: One hundred sixty-six patients were eligible for conversion from rosuvastatin to simvastatin. Seventy-five of these patients (45.2%) received a follow-up FLP and further analysis. LDL-C goal attainment increased from 64.0% at baseline to 82.7% after conversion (p=0.001). When stratified by cardiovascular risk, 100% of low- and moderate-risk, 79.4% of high-risk and 57.1% of very high-risk patients attained goal LDL-C post conversion (p=0.002). Sixty-three patients (84.0%) were converted using an equipotent dose and 12 (16.0%) required conversion with dose titration by the clinical pharmacist. Average LDL-C was 85.3±38.5 mg/dL at baseline and 80.2±30.6 mg/dL after conversion (p=0.29). Average non-HDL-C was 116.2±36.0 mg/dL at baseline and 110.0±28.8 mg/dL after conversion (p=0.09). All other lipoprotein and ALT values were not statistically different pre- and post-conversion. Cost data demonstrated a savings of $13,500 for the community health clinic over a 12 month period for the 75 patients with follow-up FLPs.
CONCLUSION: A therapeutic substitution protocol that included individual patient assessment by a clinical pharmacist is an effective strategy for converting patients from a high- to medium-potency statin. This approach maintained therapeutic efficacy and resulted in both an improvement in LDL-C goal attainment and cost savings.

19. Evaluation of two education methods for patient knowledge in patients recently started on warfarin. *Lisa Potts, Pharm.D., BCPS*, Cari Cristiani, Pharm.D., BCPS, Jun-Yen Yeh, Ph.D.; Cleveland Clinic, Cleveland, OH
PURPOSE: In order to maximize clinic efficiency while maintaining quality education, this study was done to compare anticoagulation knowledge levels in patients before and after two different anticoagulation education methods.
METHODS: This study was approved by the IRB. Newly referred naïve (warfarin use for <2 months) anticoagulation patients were given warfarin education via face-to-face pharmacist counseling (group I) or video education (group II). Patients were given the Short Anticoagulation Knowledge Test (SOAK), a previously validated instrument, before and after education. A sample size of 106 patients was required to detect a 15% change in knowledge with 80% power and alpha of 0.05.
RESULTS: A total of 108 (54:54) patients were enrolled. Baseline demographics were similar between groups with 52.3% female, 52.8% over 65 years old and 67.9% with high school or some college education. The SOAK scores prior to educational intervention were similar between the groups (p=0.383) and were significantly improved

after education intervention (group I: 55.9%±26% to 75.8%±21%, p<0.001; group II: 60.4%±26% to 70.7%±22%, p=0.030). The mean change in pre-post SOAK scores was significantly higher in group I (+21%±23%) than in group II (+10%±23%, p=0.011). However, the post-education SOAK scores were not significantly different between groups (p=0.228).
CONCLUSIONS: Patients receiving warfarin education via video had similar post-education warfarin knowledge score to patients receiving face-to-face warfarin education. This may allow anticoagulation clinics to effectively and efficiently provide warfarin education in a busy anticoagulation clinic.

20. Impact of a Medication Therapy Management Program on Hemoglobin A1c Values in a Health Resources and Services Administration Patient Safety and Clinical Pharmacy Services Collaborative. *Heather B. Congdon, Pharm.D.*[1], Iliana Cheng, Pharm.D.[1], Hoai An Truong, Pharm.D.[2], Faramarz Zarfeshan, R.Ph.[3], Thomas C. Dowling, Pharm.D, Ph.D[4]; (1)University of Maryland School of Pharmacy, Rockville, MD; (2)University of Maryland School of Pharmacy, Baltimore, MD; (3)ALFA Specialty Pharmacy, Silver Spring, MD; (4)University of Maryland, School of Pharmacy, Baltimore, MD
PURPOSE: To evaluate the impact of Medication Therapy Management (MTM) visits on diabetes control in patients enrolled in an underserved, safety-net clinic participating in the Health Resources and Services Administration (HRSA) Patient Safety and Clinical Pharmacy Services Collaborative (PSPC).
METHODS: Patients with type 2 diabetes who received pharmacy-based MTM during the period of October 1, 2009 and March 31, 2011 were included. Pharmacist interventions included a medication therapy review and diabetes education as appropriate. Written summaries of pharmacists' findings and recommendations were provided to physicians prior to physician-patient encounter. Baseline values were collected within 3 months prior to the first MTM encounter. Post-MTM A1c values were collected at least 3 months after the last MTM visit. Patients were stratified by frequency of MTM visits. Pre and post-A1c values in each group were compared using Wilcoxon signed rank or Mann Whitney U, where appropriate.
RESULTS: A total of 64 patients had at least 1 MTM visit with pre- and post-MTM A1c data. The A1c for all patients decreased from 8.1% to 7.8% (95% CI: -0.73, 0.06; p=0.1127). Of the 35 patients who participated in only one MTM visit, the values decreased from 7.4% to 7.3% (95% CI: -.06024, 0.4538, p=0.93). Of the 29 patients who participated in at least two MTM visits (range: 2–6 visits), values were significantly reduced from 9.0% to 8.3% (95% CI: -1.263, 0.03336, p=0.02). Pre values were significantly higher in the multiple MTM group compared to the single visit group (9.0±2.0 7.4±1.5, respectively, p<0.001).
CONCLUSIONS: Patients enrolled in a HRSA PSPC safety-net clinic having multiple interactions with an MTM pharmacist are more likely to have a higher baseline , but a larger reduction in A1c than those without repeat MTM visits.

Cardiovascular

21E. Lipid Target Attainment by Switching Statin Monotherapy to Fenofibric Acid + Statin in Patients With Mixed Dyslipidemia and at High-/Highest-Risk for Coronary Heart Disease. Peter H. Jones, M.D.[1], Syed M. Mohiuddin, M.D.[2], Christie M. Ballantyne, M.D.[1], Michael H. Davidson, M.D., FACC, FACP[3], *Kamlesh Thakker, BPharm, Ph.D.*[4], Carolyn M. Setze, M.S.[4], Aditya Lele, M.S.[4], Maureen T. Kelly, M.D.[4]; (1)Baylor College of Medicine, Houston, TX; (2)Creighton Cardiac Center, Omaha, NE; (3)University of Chicago, Pritzker School of Medicine, Chicago, IL; (4)Abbott, Abbott Park, IL
PURPOSE: This post hoc analysis evaluated attainment of individual/combined target levels of LDL-C, non-HDL-C and Apo B following 52-week treatment with open-label fenofibric acid (FA) + moderate-dose statin (MDS) in patients with mixed dyslipidemia previously treated with statin monotherapy for 12 weeks.
METHODS: Patients included were at high risk for coronary heart disease (CHD or CHD risk equivalent, including diabetes) or highest risk (a subset of the high-risk group with diabetes + CHD, or diabetes + 10-yr CHD risk >20%), were treated with statin monotherapy (rosuvastatin 10, 20 or 40 mg; simvastatin 20, 40 or 80 mg; or atorvastatin 20, 40 or 80 mg) for 12 weeks in 1 of 3 controlled studies and subsequently treated with open-label FA 135 mg + MDS (rosuvastatin 20 mg, simvastatin 40 mg or atorvastatin 40 mg) for 52 weeks, and had lipid/lipoprotein values both at baseline (start of open-label extension) and Week 52. Target levels were defined in high-/highest-risk patients as LDL-C <100/<70 mg/dL, non-HDL-C <130/<100 mg/dL, and ApoB <90/<80 mg/dL. McNemar's test was used for comparisons.
RESULTS: At Week 52 compared with baseline, FA + MDS resulted in a similar % of high-risk patients achieving LDL-C target (N=204, 72.1% vs 74.0%, P=0.652), a significantly greater % achieving target levels of non-HDL-C (N=204, 75.5% vs 63.2%, P<0.001), Apo B (N=203, 70.0% vs 56.7%, P<0.001), and significantly greater % achieving all combined targets (P <0.05). A numerically greater % of highest-risk patients (N=26) achieved LDL-C (38.5% vs 26.9%), non-HDL-C (38.5% vs 23.1%), ApoB (46.2% vs 38.5%), and combined targets at week-52 vs baseline (P>0.05 for all).
CONCLUSION: In high-/highest-risk patients previously treated with statin monotherapy for 12 weeks, long-term FA + MDS resulted in greater percentages of patients attaining LDL-C (highest-risk only), non-HDL-C, Apo B and combined targets of these parameters.
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22E. Long-Term Efficacy and Safety of Fenofibric Acid in Combination with Statins in Patients with Mixed Dyslipidemia and Type 2 Diabetes Mellitus. Maureen T. Kelly, M.D.[1], *Kamlesh M. Thakker, BPharm, Ph.D.*[1], Carolyn M. Setze, M.S.[1], Inderjit S. Mandair, M.D.[2], Patrick Aubonnet, M.D.[2]; (1)Abbott, Abbott Park, IL; (2)Abbott, Allschwil, Switzerland
PURPOSE: Mixed dyslipidemia (MD) characterized by elevated LDL-C and triglycerides (TG) and low levels of HDL-C is common in patients with type 2 diabetes mellitus (T2DM). Short-term treatment with fenofibric acid (FA) + statin comprehensively improves multiple lipid parameters more effectively than either monotherapy in patients with MD and T2DM. The long-term efficacy and safety of FA + statin in this population was assessed.
METHODS: Patients included had MD and T2DM, completed 12 weeks treatment in 1 of 3 controlled studies (evaluating FA + statin vs corresponding-dose monotherapies), and subsequently were treated with open-label FA 135mg + moderate-dose statin (simvastatin 40 mg, atorvastatin 40 mg, or rosuvastatin 20 mg) for 52 weeks. Efficacy measurements were pooled across treatment groups and were calculated from baseline (start of the controlled studies) to specific time points across the controlled and open-label studies. Adverse events occurring during either the controlled studies or the extension study were included in the safety analysis.
RESULTS: A total of 413 patients with MD and T2DM received combination therapy and were included in this analysis. Treatment with FA + moderate-dose statin led to improvements in all efficacy variables that were sustained over 52 weeks of the extension study. Mean % changes from baseline to week 64 were: LDL-C (-43.0), HDL-C (+17.9), non-HDL-C (-47.5), Total-C (-37.7), VLDL-C (-50.0), and ApoB (-43.8). Median % changes from baseline to week 64 in TG and hsCRP were -50.3 and -32.6, respectively. Overall, 117 (28.3%) patients experienced treatment-related adverse events (AEs), and 49 (11.9%) patients discontinued therapy due to an AE. No cases of rhabdomyolysis or treatment-related deaths were reported.
CONCLUSION: Long-term therapy with FA + statin resulted in sustained improvements in multiple lipid values and was generally well tolerated in patients with MD and T2DM.
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23. Dose escalation of β-Blocker Therapy Following Initiation of Cardiac Resynchronization Therapy. Frank A. McGrew, M.D.[1], Eric E. Johnson, M.D.[1], Mark A. Coppess, M.D.[1], Jessica Foon, B.S.[1], Thomas A. Charlton, B.S.[2], Sandy Charlton, BSN[2], *J. Jason Sims, Pharm.D.*[2]; (1)Stern Cardiovascular Foundation, Germantown, TN; (2)Medtronic, Mounds View, MN
PURPOSE: Many trials show that β-blockers reduce morbidity and

mortality at specific target doses. However, beta blocker dose escalation is limited due to several factors including heart rate, hemodynamic status, and whether a dedicated heart failure (HF) cardiologist is involved in the management of the patient. In patients indicated for cardiac resynchronization therapy (CRT), the addition of pacing and improved hemodynamics may allow for β-blocker dose escalation. We sought to determine the percent of target β-blocker dose in patients managed by general cardiologist and a HF dedicated cardiologist before and after CRT at a large, private practice cardiology clinic.

METHODS: A retrospective analysis of our CRT database was performed in December 2010. All patients with an FDA approved CRT device were evaluated. The date of first CRT implant was documented along with the dose of β-blocker prior to implant. The dose of β-blocker at last follow up visit was also documented. β-blocker doses were normalized as percent of target dose based on target doses from published trials.

RESULTS: HF cardiologist patients (n=135) averaged 70+66% of target β-blocker dose pre-implant. Following CRT implant, HF cardiologist patients averaged 104+74% of target β-blocker dose (p=0.0001). General cardiologist patients (n=226) averaged 39 ± 40% of target dose pre-implant and 49±41% of target dose post-implant (p=0.008). The percent β-blocker target dose increase post-implant was significantly greater by the HF cardiologist (34% versus 10%, p=0.0007).

CONCLUSION: β-blocker dose escalation can be accomplished after CRT implant by both general and dedicated HF cardiologists and should improve patient clinical status. This dosage increase may be more pronounced with a dedicated heart failure cardiologist involved in the management of the patient. Patients managed by general cardiologists and a HF dedicated cardiologist before and after CRT at a large, private practice cardiology clinic.

24. The antiplatelet effects of sustained-release niacin. Matthew Agosti, Pharm.D., Nicholas Bacon, Pharm.D., Candidate, *Nicholas B. Norgard, Pharm.D.*; University at Buffalo- School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY

PURPOSE: Heightened platelet reactivity is an independent predictor of poor outcome following an acute coronary syndrome. Contemporary antiplatelet agents may not always be sufficient to provide therapeutic platelet inhibition. This has inspired clinical investigation into the use of alternative and/or adjunct agents to intensify platelet inhibition. Niacin is used for the modulation of cholesterol but may also have antiplatelet effects. This study investigated the ability of niacin to inhibit platelet aggregation.

METHODS: Part I: Blood samples were drawn from normal volunteers at baseline and then 1 hour after the administration of 1 gram of sustained-release niacin. Part II: Blood samples were drawn from normal volunteers at baseline and then 12 hours after the administration of 2 grams of sustained-release niacin. Platelet aggregation was measured using the

RESULTS: A significant 26% reduction in collagen-induced aggregation and a 7% reduction in ARU

	Baseline (mean±ISD	Post-Niacin	Mean Change	p-value
1-hr Results				
Collagen (ohms)	19.4 ± 1.7	14.38 ± 2.9	5.0 (1.05 to 8.95)	p=0.0275
Aspirin (ARU)	622.4 ± 7.3	582.3 ± 46.4	40.1 (4.8 to 75.4)	p=0.0311
12-hr Results				
Collagen (ohms)	15.8 ± 2.5	14.1± 3.3	1.6 (-0.007 to 3.3)	P=0.051
Aspirin (ARU)	630 ±26	630 ±22	-0.36 (-19.6 to 18.9)	p=0.48

CONCLUSION: Niacin has a small, direct effect on platelet aggregation. The platelet inhibition is transient as it is no longer evident 12 hours after drug administration. The clinical significance of niacin's antiplatelet effect remains unknown.

25E. Aspirin reduces transient flushing and glucose increases during therapy with niacin extended-release. *Robert J. Padley, M.D.*[1], Roopal B. Thakkar, M.D.[1], Ping Jiang, M.S.[1], Scott L. Krause, BSN, B.S.(L&S)[1], Michael H. Davidson, M.D., FACC, FACP[2], Henry A. Punzi, M.D.[3]; (1)Abbott, Abbott Park, IL; (2)The University of Chicago Pritzker School of Medicine, Chicago, IL; (3)Texas Woman's University, Dallas, TX

PURPOSE: Proprietary niacin extended-release reduces most pro-atherogenic lipids while increasing anti-atherogenic lipids. Therapy with niacin has been associated with flushing and a transient increase in blood glucose levels, although long-term effects on HbA_{1c} are not usually observed. Both flushing and increases in blood glucose may be mediated via associated pathways. Aspirin has been demonstrated to mitigate flushing during adaptation to niacin extended-release therapy. We evaluated the effects of aspirin on changes in blood glucose in patients with mixed dyslipidemia treated with niacin extended-release.

METHODS: Data are from a double-blind, parallel group, multi-center, placebo-controlled study. Patients were randomized to receive niacin extended-release (500 mg/day week 1; 1000 mg/day week 2; 2000 mg/day weeks 3–6) and either 325 mg/day aspirin (n = 90) or placebo (n = 90). Both maximum severity of flushing [1- to 10-point scale] and the mean % change from baseline in fasting blood glucose were compared between treatment groups using one-way analysis of variance.

RESULTS: Over the entire 6 weeks of treatment, aspirin reduced mean maximum flushing severity by 33% (3.5 aspirin vs 5.2 placebo; $P<0.001$). Baseline fasting blood glucose levels were similar for both groups (niacin extended-release + aspirin, 109.1 mg/dL, niacin extended-release + placebo, 107.3 mg/dL, $P=0.66$). Aspirin use reduced the magnitude of the increase in fasting blood glucose by 55%. The mean % increases in fasting blood glucose over the 6 weeks of treatment were 5.6 ± 17.7, with aspirin, and 12.5 ± 25.2, with placebo, $P=0.03$.

CONCLUSION: Among patients with mixed dyslipidemia, aspirin effectively mitigates flushing symptoms during adaptation to niacin extended-release therapy. Treatment with aspirin may also reduce the magnitude of the increase in fasting blood glucose associated with niacin extended-release therapy.

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26E. Aliskiren/Valsartan combination is more effective than valsartan monotherapy in dipper and non-dipper hypertensive patients. Thomas D. Giles, M.D.[1], *Thomas Alessi, M.D.*[2], Das Purkayastha, Ph.D.[2], Dion H. Zappe, Ph.D.[2]; (1)Tulane University School of Medicine, New Orleans, LA; (2)Novartis Pharmaceuticals Corporation, East Hanover, NJ

PURPOSE: A "non-dipping"circadian BP pattern is a significant marker of CV risk. Since renin-angiotensin system (RAS) activation is higher at night time; we compared the efficacy of combination direct renin inhibitor, aliskiren + angiotensin receptor blocker, valsartan (A/V) 300/320 mg with V 320 mg as assessed by ABPM in both dipper (D, nocturnal BP fall of at least 10%); and non-dipper (ND, less than 10% nocturnal BP fall) hypertensive patients (pts).

METHODS: This was a pooled analysis of ABPM data measured over 24h at baseline and week 8 (Spacelabs 90207 device) from 2 clinical trials with A/V and V treatment arms, in pts with mean age 54.6 yr, BMI 30.6 kg/m^2, mean clinic BP 157.2/97.4 mmHg and mean ABP 144.0/91.1 mmHg. Eligible pts in study 1 were those with msDBP 95–109 mmHg and 8-h daytime ADBP ≥90 mmHg and in study 2 with msSBP ≥160 to <180 mmHg. In both studies, pts received A/V 150/160 mg→A/V 300/320 mg and V 160 mg→V 320 mg. For this pooled analysis, A/V (70D; 60 ND) was compared with V (68D; 72 ND) respectively. Statistical analyses were based on ANCOVA model.

RESULTS: At baseline mean ABP profiles were similar in A/V and V within D and ND. ND had higher baseline ABP at night-time than D. At week 8 in D, A/V provided significantly greater reduction from baseline in mean 24-h ASBP, and daytime ASBP than V. In ND, significant ASBP reduction in favor of A/V in mean 24-h; daytime and nighttime was observed; the reductions were almost twice than that of V. Similar results were observed for ADBP.

CONCLUSION: Addition of aliskiren to valsartan resulted in a restoration of nighttime BP in NDs to a similar level as Ds suggesting a more effective inhibition of RAS in non-dipper hypertensive patients.

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27. Left-ventricular assist device implantation does not alter the pharmacodynamic response to warfarin. *Douglas L. Jennings, Pharm.D., BCPS, (AQ-CV)*, Celeste Williams, M.D., Robert Brewer, M.D.; Henry Ford Hospital, Detroit, MI

PURPOSE: Left-ventricular assist devices (LVAD) represent a life-saving modality in patients with advanced heart failure (HF). LVAD implantation necessitates long-term anticoagulation with warfarin to prevent device thrombosis. Patients with HF tend to require lower doses of warfarin due an altered pharmacodynamic response. It is unclear if this altered response persists in HF patients after LVAD implantation. The purpose of the present study is to describe the effect of LVAD implantation on the pharmacodynamic response to warfarin in patients with advanced HF.

METHODS: All patients with LVAD implantation at our institution between January 1st, 2008 and May 1st, 2010 were screened for inclusion. Patients were excluded if they were not taking warfarin prior to implantation or if they were started on an interacting (i.e., amiodarone) at the time of implantation. Data collection included demographics, INR measurements, and warfarin dosages. The primary endpoint is the difference in mean weekly warfarin dosage required to maintain a therapeutic INR (2-3) before and after LVAD implantation. Warfarin requirements pre- and post-implant were determined by the weekly dosage that that produced at least two consecutive therapeutic INR measurements.

RESULTS: Of 50 patients who were screened, 14 met inclusion criteria (53±11.9 years, 86% male, 57% Caucasian, 71% bridge to transplant). All patients received a continuous flow LVAD. The mean weekly warfarin dosage required to maintain a therapeutic INR were similar pre- and post-LVAD implantation, 38.5 mg/week versus 36.7 mg/week (p=0.26). Five patients required a lower dose of warfarin, while three patients required slightly higher doses of warfarin. Furthermore, there was no difference in warfarin dosage requirements between the bridge to transplant (p=0.28) and the destination therapy (p=0.75) patients.

CONCLUSIONS: This project indicates that LVAD implantation may not have a significant impact on the pharmacodynamic response of warfarin in patients with advanced HF.

28. Lack of significance between use of statins and cardiovascular events in carriers of the Kinesin Family Member 6 Gene 719Arginine Allele. *Randall P. Sharp, Pharm.D., BCPS*[1], Lisa A. Appeddu, Ph.D.[2], Akm Islam, M.B.B.S.[3], Riaz Sirajuddin, M.D.[3]; (1)Southwestern Oklahoma State University College of Pharmacy, Weatherford, OK; (2)Southwestern Oklahoma State University School of Health Sciences, Weatherford, OK; (3)Heart Solutions of Oklahoma, Oklahoma City, OK

Prior genetic studies have shown increased cardiovascular events (CV) in carriers of the KIF6 719Arginine allele (KIF6 positive), as well as significant reduction in CV events in carriers treated with HMG-CoA reductase inhibitors (statins). However, this is controversial since recent published studies have shown a lack of significant difference in CV event reduction between KIF6 positive versus KIF6 negative patients treated with statin drugs.

PURPOSE: To investigate whether a significant difference exists between KIF6 positive versus KIF6 negative patients taking statin drugs and having a history of CV events.

METHODS: Laboratory data was collected in a private cardiologist's clinic over a one year period on 110 patients. Data was then analyzed retrospectively using the Pearson χ^2 test. In addition to KIF6 allele status, other included parameters were patient sex, previous history of CV events, body mass index (BMI), and whether or not a patient had ever taken a statin.

RESULTS: The population was 64.5% female and 35.5% male (average age= 61.2 years). Approximately 33% had a history of at least one CV event, defined as myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, stroke, or transient ischemic attack. Approximately 64% of patients were KIF6 positive, which is not different (P=0.44) from previously published population estimates (60%). No difference was found in CV events between the proportion of KIF6 positive and KIF6 negative patients who had never taken a statin (P=0.42), or had taken a statin (P=0.82). The results remained non-significant (P>0.05) even when patient sex and BMI were considered.

CONCLUSION: The results are similar to recent studies which have shown no significant difference in cardiovascular event reduction in KIF6 positive versus KIF6 negative patients taking statin drugs. Using statins to reduce cardiovascular events based on patients' KIF6 allele status remains inconclusive, and requires further investigation.

29. The impact of a clinical pharmacist on a cardiovascular surrogate endpoint: A pilot study. *Toni L. Ripley, Pharm.D.*[1], Donald L. Harrison, Ph.D.[1], Tiffany Sanders, Pharm.D., Student[1], Thomas A. Hennebry, M.D.[2], R. Chris Rathbun, Pharm.D.[1]; (1)University of Oklahoma College of Pharmacy, Oklahoma City, OK; (2)University of Oklahoma Health Sciences Center, Department of Medicine, Oklahoma City, OK

PURPOSE: A pharmacist-managed cardiovascular clinic was initiated in a faculty-based adult cardiology clinic in 2/2009. Patients are referred by cardiologists for cardiovascular disease (CVD) pharmacotherapy management. No data currently exist comparing cardiologist plus clinical pharmacist to cardiologist management alone when the pharmacist's scope of practice is broad and patient care decisions are independent of a protocol or physician consultation. This report evaluated the impact of a clinical pharmacist on one CVD surrogate marker.

METHODS: A retrospective, matched-cohort, pilot study comparing patients managed by cardiologists alone versus cardiologist plus a clinical pharmacist was conducted. Patients with hypertension and at least two blood pressure (BP) results ≥3 months apart between 2/1/2009 – 4/30/2011 were included. Age- and disease-matched patients not referred to the pharmacist were consecutively identified from five internal cardiologists to serve as controls (3:1 match). BP results proximal to the beginning and end dates of the study period were compared.

RESULTS: Patients in the pharmacist intervention group (n=57) were more likely to have heart failure (48.5% vs. 13.6%, p<0.001) and take more anti-hypertensives (3.5 vs. 2.6, p<0.001) compared to the cardiologist control (n=155); other characteristics were similar between groups. The number of patients with Stage-2 hypertension was significantly reduced in the intervention group (p=0.02), but not in controls (p=0.73). Diastolic BP was reduced by 2.6mmHg in the intervention group (p=0.05); systolic BP reductions did not achieve statistical significance (4.3mmHg, p=0.16). Conversely, non-significant increases in both systolic and diastolic BP (1.0/0.3mmHg, respectively) were observed in the controls.

CONCLUSION: BP improvements occurred with clinical pharmacist management, but not with cardiologist management alone. While prior literature shows BP improvement in pharmacist specialty management clinics (e.g., hypertension clinic), this is the first report documenting the benefit of a clinical pharmacist on one established surrogate marker while managing diverse CVD compared to usual cardiologist care.

30. Description of antihypertensive use in patients with resistant hypertension prescribed four or more agents. *Michele R. Hanselin, Pharm.D.*, Joseph J. Saseen, Pharm.D., Richard R. Allen, M.S., Joel C. Marrs, Pharm.D., BCPS, Kavita V. Nair, Ph.D.; University of Colorado School of Pharmacy, Aurora, CO

PURPOSE: American Heart Association (AHA) recommended treatment for resistant hypertension includes maximizing diuretic therapy (e.g., chlorthalidone as the preferred thiazide, adding an aldosterone antagonist) and using effective antihypertensive combinations. The purpose of this study was to describe the use of antihypertensives in patients with resistant hypertension prescribed four or more agents.

METHODS: This retrospective cohort study evaluated adults with resistant hypertension defined as concurrent use of four or more antihypertensive agents. The Medstat Marketscan Claims Databases, representing over 100 employers, were used to identify patients with resistant hypertension based on ICD-9 and National Drug Codes between May 1, 2008 and June 30, 2009. The primary objective was to describe the use of antihypertensive agents in this population, and the secondary objective was to assess whether prescribing reflects AHA recommendations.

RESULTS: A total of 140,263 patients met study criteria. The mean age was 63.8 years. Patients were most frequently prescribed an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) (96.2%), diuretic (93.2%), calcium channel blocker (83.5%), and/or beta-blocker (80.0%). Only 3.0% and 5.9% of patients were prescribed chlorthalidone or an aldosterone antagonist, respectively. A fixed-dose combination product was used in 63.2% of patients and 10.1% were on at least two different fixed-dose combination products. A total of 5.7% of patients were on two agents from the same drug class and 15.6% were prescribed the combination of an ACEi with ARB.
CONCLUSION: First-line antihypertensives recommended by evidence-based guidelines were the most frequently prescribed agents in this resistant hypertension population. However, controversial treatments (i.e., ACEi with ARB, combination of two agents from the same drug class) were prescribed more often than AHA recommended treatments for resistant hypertension. These data demonstrate that use of chlorthalidone and aldosterone antagonists are underprescribed in patients with resistant hypertension.

31. Does Magnesium L-Lactate Improve Quality of Life in Patients with an Implantable Cardioverter Defibrillator?
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PURPOSE: The objective of this prespecified substudy of the Adjuvant Magnesium Trial was to evaluate the impact of oral magnesium l-lactate on quality of life (QoL) in patients with an implantable cardioverter defibrillator (ICD).
METHODS: In this prospective, double-blind, placebo-controlled trial, 70 patients with an ICD were randomized to receive oral magnesium l-lactate (n=35) (6 tablets supplying a total of 504mg elemental magnesium daily) or matching placebo (n=35). Quality of life was measured using self-administered Ferrans & Powers QoL Index (Cardiac Version) questionnaires at baseline and at 3 and 6 months of therapy. This tool assesses QoL in persons with heart disease including satisfaction and health perception, functioning, socioeconomic factors, psychological and spiritual well-being, and family life. Participants rated their satisfaction over 35 questions with choices from 1 ("very dissatisfied") to 6 ("very satisfied"). Total scores ranged from 0 to 30 points with higher scores indicating better QoL. Changes from baseline were compared between groups with the Mann-Whitney U or Student t-test (SPSS version 17.0, Chicago, IL).
RESULTS: No significant differences in baseline characteristics, total QoL score or subscale QoL scores were seen. Due to the large number of tablets needed per day, long-term adherence was poor. Overall, 45 (64%) and 30 (43%) randomized patients completed questionnaires at 3 and six months. Magnesium l-lactate did not significantly impact the change from baseline in overall or subscale QoL scores versus placebo at 3 months. At 6 months, magnesium l-lactate did not significantly impact the change from baseline in overall QoL scores but significantly improved the health/functioning subscale score versus placebo (1.04 vs. -1.22, p=0.04).
CONCLUSION: Overall, high dose magnesium l-lactate therapy does not appear to appreciably impact QoL in patients with an ICD over a 6-month period.

32E. Cardiac events, infections and bleeds contribute to higher vascular and non-vascular mortality with clopidogrel compared to ticagrelor treatment in patients undergoing coronary artery bypass grafting.
Christoph MH Varenhorst, M.D., Ph.D.[1], Ulrica Alström, M.D.[2], Benjamin M. Scirica, M.D., M.P.H.[3], Charles W. Hogue, M.D.[4], Nils Åsenblad, PhLic, M.S.[1], *Jay Horrow, M.D., M.S.*[5], Gunnar Brandrup-Wognsen, M.D., Ph.D.[6], Lars Wallentin, M.D., Ph.D.[1], Claes Held, M.D., Ph.D.[1]; (1)Uppsala Clinical Research Center, Uppsala, Sweden; (2)Uppsala University, Uppsala, Sweden; (3)TIMI Study Group / Brigham and Women's Hospital, Boston, MA; (4)The Johns Hopkins University School of Medicine, Baltimore, MD; (5)AstraZeneca, Wilmington, DE; (6)AstraZeneca, Mölndal, Sweden
PURPOSE: In the PLATO (Platelet Inhibition and Patient Outcomes) trial, patients assigned to ticagrelor as compared to clopidogrel undergoing coronary artery bypass graft surgery (CABG) had a reduction in total and cardiovascular mortality. This study further investigated the differences in causes of post-CABG deaths.
METHODS: In the 1261 patients with CABG within 7 days after stopping study drug, adjudicators blinded to treatment classified post-CABG deaths into subcategories of causes of vascular and non-vascular deaths, and identified bleedings and infections contributing to, although not necessarily directly causing the fatality.
RESULTS: Numerically fewer vascular deaths from myocardial infarction, heart failure, sudden death/arrhythmia and hemorrhagic stroke/bleeding occurred in the ticagrelor compared to the clopidogrel group. Among nonvascular deaths, infection was a less common cause of death with ticagrelor than clopidogrel, as were both bleeding and infection as contributing causes.
CONCLUSIONS: Myocardial infarction, heart failure, sudden death and infections constituted the majority of post-CABG causes of death. Mortality was lower with ticagrelor due to fewer cardiac events, infections and bleedings than with clopidogrel.

Primary cause of death (n=1261)	Ticagrelor (n=632) (%)	Clopidogrel (n=629) (%)
Total vascular death	25 (4.0)	47 (7.5)
Acute myocardial infarction	10 (1.6)	14 (2.2)
Heart failure	6 (0.9)	9 (1.4)
Arrhythmia/Sudden death	3 (0.5)	9 (1.4)
Ischemic stroke	1 (0.2)	1 (0.2)
Hemorrhagic stroke/Intracranial hemorrhage	0 (0)	3 (0.5)
Bleeding/Other hemorrhage	2 (0.3)	4 (0.6)
Other vascular death	3 (0.5)	7 (1.1)
Total non-vascular death	4 (0.6)	11 (1.7)
Infection	2 (0.3)	8 (1.3)
Gastrointestinal (not bleeding), MODS (Multiple Organ Dysfunction Syndrome)	2 (0.3)	2 (0.3)
Suicide	0 (0)	1 (0.2)
Infection contributed, but did not directly cause death (all deaths)	4 (0.6)	8 (1.3)
Bleeding contributed, but did not directly cause death (all deaths)	7 (1.1)	20 (3.2)

Presented at Data will be presented at the European Society of Cardiology congress, Paris, France, Aug 17–31

33. Meta-analysis of the relationship between aspirin dosing and efficacy and bleeding outcomes in medically managed patients with acute coronary syndromes (ACS).
Jeffery S. Berger, M.D., M.S., FACC, FAHA[1], Rachel H. Sallum, B.S., BA[2], *Brian G. Katona, Pharm.D.*[3], Juan Maya, M.D., M.S.[3], Gayatri Ranganathan, M.S.[2], Mkaya Mwamburi, M.D., Ph.D.[4]; (1)New York University Medical Center, New York, NY; (2)United BioSource Corporation, Lexington, MA; (3)AstraZeneca LP, Wilmington, DE; (4)Tufts University School of Medicine, Boston, MA
PURPOSE: Acetylsalicylic acid (ASA) dosing guidelines for ACS treatment are inconsistent and lack supporting data. This analysis evaluated the relationship between ASA maintenance dosing and clinical outcomes in patients with ACS who did not undergo revascularization and are managed medically.
METHODS: A meta-analysis was conducted with random-effects modeling to estimate the frequency of clinical outcomes for low (75–149 mg) and high (150–325 mg) doses of ASA, using data from worldwide clinical and observational trials published from Jan 1995 to Feb 2010, available from PubMed, EMBASE and Current Contents. Clinical outcomes measured were: revascularization rate (overall rate, percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG]), cardiovascular (CV) death, all-cause death, myocardial infarction (MI), stroke, and bleeding at 1, 3, 6 and 12 months.
RESULTS: Sixty-eight studies including 207,523 patients were accepted and appraised for quality using Oxford Centre for Evidence-Based Medicine scoring. Significant heterogeneity was seen in the results (quantified using the Cochran's Q statistics and the I^2

measures), due to differences in enrolment procedures, medical management regimens and timing of administration, study designs and some inconsistencies in the definitions of bleeding and MACE. At one month, the incidence of clinical outcomes with high- and low-dose ASA groups were 4.9% and 5.0% for MI; 6.3% and 3.7% for revascularization; 1.4% and 1.3% for stroke; 5.5% and 3.4% for CV death; 5.7% and 4.3% for all cause death; and 4.0% and 1.7% for major bleeding, respectively. Meta regression demonstrated a significant association between aspirin dose and major bleeding (p=0.037). Further data will be presented at the meeting.
CONCLUSIONS: This analysis suggests that in patients receiving medical management for ACS, major bleeding occurred more frequently in patients who received higher doses of ASA. ASA dose does not have a statistically significant impact on the other outcomes analyzed.

34. Comparative Effectiveness of Endothelin Receptor Antagonists for the Treatment of Pulmonary Arterial Hypertension (A Pilot Study). Heather A. Wong, Pharm.D, Shirley Yan, B.S., Dana P. McGlothlin, M.D., *Jaekyu Shin, Pharm.D.*; University of California, San Francisco, San Francisco, CA
PURPOSE: Bosentan and ambrisentan are two endothelin receptor antagonists (ERA) used to treat pulmonary arterial hypertension (PAH). Because their comparative effectiveness is unknown, we compared changes in 1) pulmonary arterial systolic pressure (PASP), 2) New York Heart Association (NYHA) functional class and 3) severity of tricuspid regurgitation (TR) in patients with PAH who received either bosentan or ambrisentan for at least 3 months.
METHODS: Adult PAH patients who initiated either bosentan or ambrisentan in the UCSF Medical Center between January 1, 2008 and December 30, 2010 and continued an ERA for at least 3 months were identified by chart review. Patients were excluded if echocardiography and NYHA functional class data were not available 6 months before and 3 months after an ERA treatment. Primary outcome was the change in PASP and secondary outcomes were the changes in NYHA functional class and severity of TR before and after an ERA treatment. PASP and severity of TR were measured by echocardiography. The Wilcoxon Rank Sum test was used to compare the outcomes between the groups.
RESULTS: Sixteen patients were eligible for the study. Pre-treatment and post-treatment characteristics were not significantly different between the bosentan (n=7) and ambrisentan (n=9) groups except that TR was more severe in the bosentan group. Median change in PASP was not significantly different between the groups (-2.0 mmHg (interquartile range 14.0) in the bosentan group vs. - 10.0 mmHg (IQR 38) in the ambrisentan group; P=0.92). In addition, median changes in NYHA functional class and severity of TR were not significantly different between the groups.
CONCLUSION: Our data suggest that bosentan and ambrisentan may not be different in changing PASP 3–6 months after the initiation in PAH patients. Due to the pilot nature of the study, studies with larger sample sizes are needed to confirm our findings.

35. Changes in RIFLE criteria after coronary artery bypass graft surgery in patients with recent exposure to angiotensin converting enzyme inhibitors and angiotensin receptor blockers. *Jennifer L. Neill, Pharm.D.*[1], Shannon W. Finks, Pharm.D.[2], Ronald L. Braden, Pharm.D.[1], Kelly C. Rogers, Pharm.D.[2]; (1)Veterans Affairs Medical Center, Memphis, TN; (2)University of Tennessee College of Pharmacy, Memphis, TN
PURPOSE: Acute kidney injury (AKI) is a potential complication of coronary artery bypass grafting (CABG) and can be identified by RIFLE criteria (Risk, Injury, Failure, Loss, End-stage kidney disease). The role of angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB) in AKI after CABG remains undefined. This study evaluated the use of preoperative ACEI and ARB in patients undergoing CABG and their effects on changes in postoperative RIFLE criteria.
METHODS: Medical records of patients undergoing CABG between October 1, 2007 and October 30, 2010 at the Veteran Affairs Medical Center in Memphis, Tennessee were reviewed. Patients who received preoperative (within 24 hours) ACEI or ARB were compared to patients who did not. Patients with estimated glomerular filtration rate < 15 ml/min/1.73m^2, on hemodialysis, or with preoperative cardiogenic shock were excluded. The primary endpoint was a change in baseline renal function classified by RIFLE criteria within 7 days of the procedure.
RESULTS: A total of 211 patients met inclusion criteria. Of these, 67% (n=142) received an ACEI or ARB within 24 hours of CABG and 33% (n=69) did not. The following changes in RIFLE criteria were seen in patients receiving preoperative ACEI or ARB compared to those who did not, respectively: Risk: 4.9% (n=7) vs 5.8% (n=4); Injury: 2.8% (n=4) vs 0%; Failure: 1.4% (n=2) vs 0%. Loss and end stage kidney disease were not observed. A statistically significant difference was found between groups in mean postoperative SCr (1.26 vs 1.11, p<0.05), mean preoperative K (4.29 vs 4.08, p<0.05), and mean postoperative K (4.57 vs 4.46, p<0.5). No difference in mortality or mean length of stay was seen.
CONCLUSIONS: ACEI or ARB use prior to CABG was not associated with an increase in AKI, and these agents should not be held prior to CABG in hopes of preventing AKI.

36. National Cholesterol Education Program (NCEP) Lipid Goal Achievement Beyond Low-density lipoprotein cholesterol (LDL-C) in Patients with Diabetes Mellitus (DM): Focus on Non-High Density Lipoprotein Cholesterol (nonHDL-C) in the Practice Innovation and Cl. *Sarah Spinler, Pharm.D.*[1], Mark J. Cziraky, Pharm.D.[2], Paul F. Chan, M.D., M.S.[3], Feng-ming Tang, M.S.[3], Thomas M. Maddox, MD, MSc[4], Tyan Thomas,Pharm.D.[1], Gladys G. Duenas, Pharm.D.[1], Jennifer A. Reinhold, Pharm.D.[1], Vincent J. Willey, Pharm.D.[1]; (1)Philadelphia College of Pharmacy, University of the Sciences, Philadelphia, PA; (2)HealthCore, Inc, Wilmington, DE; (3)St. Luke's Mid-America Heart Institute, Kansas City, MO; (4)Denver VA Medical Center, Cardiology Section, Denver, CO
PURPOSE: To determine rates of attainment of NCEP lipid goals in patients with DM within NCDR's cardiology outpatient PINNACLE Registry.
METHODS: Patients in PINNACLE from 7/1/2008 to 12/31/10 with DM plus dyslipidemia and at least 1 fasting lipid panel were identified. A hierarchical modified Poisson regression model was used to identify factors associated with attainment of LDL-C (≤ 100 mg/dL), nonHDL-C (≤ 130 mg/dL), and both goals.
RESULTS: Of 576,787 patients enrolled in PINNACLE, 36,188 (6.27%) had a history of dyslipidemia and DM with at least 1 fasting lipid panel. Mean age was 67.5 ± 11.0 yrs, 58.5% were male and 82.8% were white. Prevalence rates of co-morbidities were CAD 73.6%, MI 23.2%, peripheral arterial disease 16.1%, and stroke/TIA 5.8%. Mean LDL-C was 84.6±37.1 mg/dL, HDL-C 43.5±14.0, triglycerides 150.5±92.9 and nonHDL-C 114.7±43.3 mg/dL. LDL-C, nonHDL-C and both goals were achieved by 73.9%, 72.0%, and 68.3%, respectively. Older patients were more likely (Risk Ratio per 5 yrs 1.04, 95% CI 1.04–1.05), and females less likely (Risk Ratio 0.88, 95% CI 0.87–0.90) to achieve nonHDL-C goals. The presence of atherothrombotic disease did not impact likelihood of achieving either LDL-C, nonHDL-C, or both goals. Use of statins, non-statin lipid-lowering agents, and their combination were the best independent predictors of achieving goals. Compared to the use of statin alone, combination therapy was not associated with a greater likelihood of achieving nonHDL-C goal (Risk Ratio 1.00, 95% CI 0.98–1.03).
CONCLUSION: In a large, outpatient cardiac registry, the majority of patients with DM were at or below LDL-C and nonHDL-C goals and more than two-thirds achieved both goals. Predictors of goal attainment were similar. These data suggest current treatment patterns by cardiologists successfully achieve nonHDL-C goals in the majority of DM patients. Additional research is needed on the role of combination therapy for achieving nonHDL-C goals.

37. A Comparison of Management Strategies in Patients with Acute Coronary Syndrome Based on Clopidogrel Use. *Paul P. Dobesh, Pharm.D.*[1], Julie H. Oestreich, Pharm.D., Ph.D.[1], Sarah M. Hanigan, Pharm.D.[2], Hiedi L. Brink, Pharm.D.[1], Sloane M. Schneider, Pharm.D.[1], Janelle M. Weber, Pharm.D.[1]; (1)University of Nebraska Medical Center, Omaha, NE; (2)The Nebraska Medical Center, Omaha, NE
PURPOSE: This study documented the management strategies in patients that present to the emergency department with an acute

coronary syndrome (ACS) already on clopidogrel versus patients not presenting on clopidogrel. Patients presenting on clopidogrel are already taking maximal antiplatelet therapy. It is also documented that over 30% of patients taking clopidogrel can be classified as "nonresponders" and these patients are at high-risk for adverse outcomes. Therefore, patients already taking clopidogrel could be classified as higher-risk patients and may warrant more aggressive therapy.
METHODS: This study was a retrospective review of medical records for all patients presenting to our institution with the primary diagnosis of ACS between 1/9/2008 to 12/31/2010. Comparisons were made based on baseline demographics, clinical presentation, interventional procedures, and utilization of antiplatelet/anticoagulation therapy.
RESULTS: We identified 493 patients who met the inclusion criteria for this study. Of those patients 73 (15%) presented on clopidogrel and 420 (85%) were clopidogrel naïve. Patients presenting on clopidogrel were significantly more likely have a history of hypertension, dyslipidemia, prior myocardial infarction, and prior coronary revascularization, yet were less likely to present with STEMI (8% vs. 28%; p<0.01). Patients already on clopidogrel were more likely to receive clopidogrel after admission (89% vs. 60%; p<0.001), but the use of prasugrel did not differ (5% for both). The use and type of anticoagulants did not differ between the groups. Patients undergoing percutaneous coronary intervention already on clopidogrel were less likely to receive a 600 mg loading dose of clopidogrel (18% vs. 73%; p<0.001) and a glycoprotein IIb/IIIa inhibitor (50% vs. 74%; p<0.001).
CONCLUSION: We did not identify major differences in the management strategies used for patients that present with ACS despite taking clopidogrel. This is probably due to the reduced severity of ACS in these patients. Further analysis of management within ACS classifications will be conducted.

38. Increasing the efficacy of heparin infusions through computer-calculated weight-based infusions with auto-populated infusion doses and partial thromboplastin time orders. *Lindsay M. Arnold, Pharm.D.*, Paul Huiras, Pharm.D., BCPS; Boston Medical Center, Boston, MA
PURPOSE: This study assessed whether computer-calculated weight-based heparin infusion order sets with auto-populated dosing and partial thromboplastin time (PTT) orders increased the percentage of heparin infusions that lead to therapeutic PTT values within 24 hours.
METHODS: All patients receiving heparin infusions for greater than six hours for acute coronary syndrome or venous thromboembolism were assessed. Patients treated with heparin prior to the revision of heparin order sets (January 2010 through March 2010) were compared to post-order set treated patients (January 2011 through March 2011). Primary outcome was the percentage of patients with a therapeutic PTT within 24 hours. Time to therapeutic PTT and the percentage of subtherapeutic, therapeutic and supratherapeutic PTT values were compared. A subgroup analysis was conducted on a random sampling of patients to assess accuracy of weight-based dosing.
RESULTS: A therapeutic PTT was achieved in 145 patients in the post order set group (53.1%) compared to 151 patients (44.9%) in the pre-order set group (p=0.0048). Mean time to therapeutic PTT was 17.9 hours in the post-order set group compared to 21.3 hours in the pre-order set group, p=0.01. A larger percentage of PTT values were in therapeutic range in the post order set group (50.5 vs 43.7%, p<0.0001). This difference was driven by a smaller percentage of subtherapeutic PTT values in the post order set group (27.8 vs 35.6%, p<0.001). A subgroup analysis revealed a larger percentage of heparin infusions the post-order set group were accurately weight based (96 vs 75%, p=0.0488), were accompanied by an initial bolus (68 vs 33.3%, p=0.0277) and adjustment bolus doses (22.2 vs 0%, p =0.0059).
CONCLUSION: Computer-calculated weight-based heparin infusion order sets with auto-populated infusion dosing and partial thromboplastin time (PTT) orders increased the percentage of patients on heparin infusions that obtained a therapeutic PTT within 24 hours.

39. Determinants of Worsening Renal Function with Diuretic Dose Escalation in a Chronic Heart Failure Ambulatory Population. *Vicki L. Groo, Pharm.D.*, Krista M. Williams, Pharm.D., Larisa H. Cavallari, Pharm.D., Thomas D. Stamos, M.D.; University of Illinois at Chicago, Chicago, IL
PURPOSE: Heart failure (HF) patients often require diuretic (D) escalation to treat signs/symptoms of volume overload. Increasing doses of D may worsen renal function (WRF). The purpose of this study was to identify patient characteristics that predict (WRF) after D escalation.
METHODS: Retrospective chart review of ambulatory HF patients who had an increase in oral D for volume overload between 07/01/2007 and 06/30/2010. For repeat patients, only the first encounter was recorded. WRF was defined as a rise in serum creatinine > 0.3 mg/dL after D therapy escalation. Baseline characteristics were compared between WRF and stable renal function (SRF) patients. Logistic regression was used to analyze variables with p value of < 0.10. Related hospitalizations were collected for 3 months.
RESULTS: Eighty-six patients met inclusion criteria of which 30 had WRF. Demographics, vitals, PMH, HF medications, diuretic regimen, ejection fraction, and BNP were similar between groups. Patients with WRF had a higher baseline BUN (34 + 19 vs 26 + 20 p=0.018) and lower eGFR (48 + 19 vs 59 + 25 ml/min p=0.047). Loop D was intensified in 75 cases and metolazone was added in 14 (2 patients had both interventions). Average time to follow-up labs was 13 + 8 days. Creatinine and BUN rise in WRF versus SRF was 0.63 + 0.44 vs -0.03 + 0.18mg/dl and 19 + 30 vs -0.56 + 10 mg/dl respectively. Of the variables included in the regression PND (p=0.028, CI 0.13–0.89) and eGFR (p=0.042, CI 0.95–0.099) were predictive of WRF. Related hospitalizations were not different between groups.
CONCLUSION: Ambulatory heart failure patients requiring D dose escalation are more likely to develop WRF if they are experiencing PND or have more severe renal dysfunction at baseline. WRF did not result in more hospitalizations.

40E. Influence of Global Region on Outcomes in Large Heart Failure β-Blocker Trials. *Mona Fiuzat, Pharm.D.*[1], Christopher O'Connor, M.D.[1], Karl Swedberg, M.D.[2], Michael Caron, Pharm.D.[3], Bruce R. Koch II, Pharm.D.[3], Peter E. Carson, M.D.[4], Wendy A. Gattis-Stough, Pharm.D.[5], Gordon Davis, MSPH[6], Michael R. Bristow, M.D., Ph.D.[7]; (1)Duke University Medical Center, Division of Clinical Pharmacology, Durham, NC; (2)Sahlgrenska University Hospital, Goteborg, Sweden; (3)Gilead, Foster City, CA; (4)Department of Veterans Affairs, Washington, DC; (5)Expert Medical Communications, Durham, NC; (6)ARCA biopharma, Inc., Broomfield, CO; (7)University of Colorado Health Sciences Center, Denver, CO
PURPOSE: Several HF trials have demonstrated differences in outcomes by geographic region. We aimed to describe the United States (U.S.) and the rest of the world (ROW) outcomes from the major β-blocker heart failure (HF) trials.
METHODS: Randomized, double-blind, placebo-controlled studies that evaluated β-blockers in HF patients, had a primary endpoint of mortality, and enrolled U.S. patients were included (MERIT-HF, COPERNICUS, and BEST). CIBIS-II was also included in the pooled analysis. Cox proportional-hazards regression was used to generate the hazard ratio and the 95% confidence interval (CI) for all-cause mortality among the U.S. and ROW subgroups within each trial. A meta-analysis of the combined mortality rates was performed using the Cochran-Mantel-Haenszel statistic, with stratification by study.
RESULTS: A total of 8,988 patients were enrolled in the MERIT-HF, COPERNICUS, and BEST studies; 4198 (46.7%) were from the U.S. In the U.S. cohort, the relative risk reduction for each β-blocker was of smaller magnitude than in the overall cohort and no longer significant, whereas in the ROW subgroup the mortality benefit for β-blockade persisted. In the pooled analysis (n=11,635), the relative risk of death was reduced by 23% (p<0.001) with β-blockade as compared to placebo. In contrast, the mortality reduction associated with β-blockade in the U.S. cohort was small and not statistically significant (RR 0.92, 95% CI 0.82–1.02, P=0.117). The survival benefit persisted in the ROW cohort (RR 0.64, 95% CI 0.56–0.72, P<0.001).
CONCLUSIONS: Among patients enrolled in the U.S., β-blockade was associated with a lower magnitude of survival benefit, whereas the ROW response was similar to the total study population. This geographic difference in treatment response may be a reflection of

population differences, genetics, cultural or social differences in disease management, or low power and statistical chance.
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Clinical Administration

41. Impact of pharmacist involvement at discharge on compliance with The Joint Commission heart failure core measure. *Holly Herring, Pharm.D.*, Toni Ripley, Pharm.D., Kevin Farmer, Ph.D., Winter Smith, Pharm.D.; The University of Oklahoma College of Pharmacy, Oklahoma City, OK
PURPOSE: Pharmacists have been granted authority to document heart failure (HF) core measures to improve compliance with accreditation bodies. The optimal role for pharmacists has yet to be fully described. This current study sought to explore the potential role of pharmacist involvement to improve hospital compliance with The Joint Commission HF core measures.
METHODS: A prospective, historical-control study of patients admitted to the University of Oklahoma Medical Center with HF during January–March 2009 (control) and January–March 2010 (intervention) was conducted. The primary endpoint was the proportion of patients in compliance with individual components of the HF core measure prior to and after pharmacist involvement. Patients were included if they were ≥ 18 years old and had a primary diagnosis of HF. The pharmacist intervention included assessment and correction of the 4 HF core measures if deficiencies were identified. A post-hoc exploratory analysis assessed the proportion of patients who received pharmacist intervention and the obstacles to pharmacist participation.
RESULTS: Forty-three charts were screened by the pharmacist; 29 patients were excluded due to incorrect admission coding, leaving 14 that received pharmacist intervention. No significant changes were found when the pharmacist was included compared to historical control (p=0.39). However, the pharmacist was only able to participate in core measure assessment in a small proportion of eligible patients (23.7–63.6% of the individual parameters). Core measures compliance was high at baseline (93.3–100%) and at follow-up (100%) with all core measures except discharge instructions (80.6% baseline; 78.9% follow-up). Limited pharmacist availability, after-hours discharging, and lack of notification were identified as obstacles to participation.
CONCLUSIONS: No change in HF core measure compliance was observed. The lack of improvement may be due to high baseline compliance or limited patients exposed to pharmacist intervention. Discharge instructions may be the core measure in which future pharmacist interventions should be targeted.

Community Pharmacy Practice

42. Evaluation of a community pharmacy-based influenza screening and management program versus pharmacy screening and referral to standard of care. *Michael E. Klepser, Pharm.D.*[1], Jennifer Hagerman, Pharm.D.[2], Donald G. Klepser, Ph.D.[3], Stephanie A. Klepser, Pharm.D.[4], Scott J. Bergman, Pharm.D., BCPS[5]; (1)Ferris State University, Kalamazoo, MI; (2)Ferris State University, Flint, MI; (3)University of Nebraska Medical Center, Omaha, NE; (4)KCMS Pharmacy, Kalamazoo, MI; (5)Southern Illinois University Edwardsville, Springfield, IL
PURPOSE: This study assessed the impact of a community pharmacy-based influenza management program on the time to first dose of antiviral compared to referral to standard-of-care. Background: Influenza and complications result in 36,000 deaths and 226,000 hospitalizations each year in the United States. Vaccination, rapid diagnosis, and early detection of influenza activity are key components for impacting this disease. The first healthcare interaction many patients with influenza have occurs in community pharmacies.
METHODS: This was a prospective, randomized, multi-center study conducted from October 2009 to May 2010 in 13 community pharmacies in 4 states. Pharmacists screened individuals 18 years of age and older who presented with signs/symptoms consistent with influenza-like illness (ILI) (onset of cough and fever or body aches within the previous 5 days). Pharmacists collected and evaluated vital signs (i.e., pulse, blood pressure, respiratory rate, temperature, and oxygen saturation). On site rapid diagnostic testing for influenza was performed and a specimen for viral culture was obtained via throat swab. Patients with ILI, regardless of rapid diagnostic test results, were randomized to initiate treatment with oseltamivir in the pharmacy (treatment group) or referred to their prescriber (referral group). Telephone follow-ups were conducted with patients 1, 2, 7, and 14 days following enrollment.
RESULTS: Twenty-seven patients were enrolled. Five had risk factors placing them at high-risk for complications and were referred to their caregivers. Of the remaining 22 patients, 12 were randomized into the treatment group and 10 into the referral group. The mean (SD) time to the first dose of oseltamivir was 1hr (0.7hr) and 6.4hr (7hr) in the treatment and referral groups, respectively (p=0.04). No differences in patient outcomes were noted.
CONCLUSION: A community pharmacy-based influenza management program significantly reduces the time to first dose of antiviral among individuals with ILI compared to those referred to prescribers.

43. Pharmacists and pharmacy students knowledge and attitudes regarding patients with disabilities in Qatar. *Sara Al-Dahir, Pharm.D., BCPS*[1], Barbara Hong, Ph.D.[2], Rihab Kaissi, B.S.[3], Amaal Gulied, B.S.[3]; (1)Xavier University of Louisiana, New Orleans, LA; (2)Pennsylvania State University, Altoona, PA; (3)Qatar University, Doha, Qatar
PURPOSE: This study was conducted to evaluate community pharmacists and pharmacy student's knowledge and attitudes regarding patients with disabilities in Qatar.
METHODS: This cross-sectional, observational study was conducted among pharmacy students and pharmacists in Doha, Qatar between February and May 2011. This mixed-methods study consisted of a survey which encompassed demographics, a truncated LEEDS Attitude Towards Concordance Scale, Attitudes Toward Patients with Disabilities Scale and a Social Distance Scale. Two follow-up focus groups were conducted to extrapolate on results. Descriptive statistical analyses and group comparisons were carried out using correlation statistics and linear regression analysis. Bivariate correlation was used to determine any association between dependent and independent variables identified a priori. Predictor factors were determined using linear regression and Anova test.
RESULTS: A total of 107 (30%, N=362) participants responded to the survey, resulting in a confidence level of 95% (8% confidence interval). The first survey of its type in Qatar, a Cronbach's Alpha score equal to 0.826 was found for reliability. The majority of participants (35%; $n = 35$) reported more than 10 years experience and 32% ($n = 33$) interact with patients with disabilities on a monthly basis. Whereas scores related to concordance were high (Likert Scale score > 3.5), community pharmacists and pharmacy students were found to have relatively neutral (Likert score of 2.6-3.4) score of attitudes toward patients with disability and social distance. Professionalism, attitudes toward patients with disability, and social distance were significantly impacted by years of practice (P=0.010), education (P=0.05) and self reported experience with patients with disabilities (P=0.011), respectively.
CONCLUSION: Results suggest that pharmacy students and pharmacists have inconsistent attitudes toward patient care when discussing patients with disabilities versus patients without disabilities. Qualitative findings support the need for increased education and professional development regarding patients with disabilities.

44. Smoking cessation counseling in the State of Qatar: community pharmacists' attitudes and practices. *Maguy S. El Hajj, Pharm.D.*, Reem R. Al Nakeeb, BSPharm, candidate, Rajaa A. Al Qudah, BSPharm, candidate; Qatar University College of Pharmacy, Doha, Qatar
PURPOSE: Smoking is a major public health problem in Qatar. Community pharmacists are uniquely situated to offer smoking cessation counseling. The study objectives were to determine the smoking cessation practices of community pharmacists in Qatar, to assess their attitudes about providing smoking cessation counseling and to determine their perceived barriers for pharmacist-provided smoking cessation counseling

METHODS: The study objectives were addressed in a cross sectional survey of community pharmacists in Qatar. The survey was designed based on surveys done in Canada, and other countries. A phone call was made to all community pharmacists in Qatar requesting their participation. Consenting pharmacists anonymously completed the survey either online or as paper based using fax. Data was descriptively analyzed using Statistical Package of Social Sciences version 18.
RESULTS: Over 5 months, we collected 127 surveys (40% response rate). Only 20% of respondents reported that they always or most of the time asked their patients if they smoke. Advising quitting and assessing readiness to quit were always or most of the time performed by 66% and 52% of respondents respectively. Use of nicotine replacement therapy was always or most of the time suggested by 66% of respondents. Only 15% always or most of the time arranged follow-up with smokers and 22% always or most of the time made smoking cessation referrals. At least 80% believed that smoking cessation counseling was an important activity for pharmacists and was an efficient use of their time. The top two perceived barriers for smoking cessation counseling were lack of time (65% of respondents) and lack of patients' interest in discussing smoking cessation (54%).
CONCLUSION: Qatar community pharmacists have good attitudes toward smoking cessation counseling. These attitudes need to be translated into action. Interventions should be implemented to overcome perceived barriers and to improve smoking cessation activities among pharmacists.

Critical Care

45. Comparison of short-term pulmonary improvement associated with inhaled nitric oxide and inhaled epoprostenol for acute respiratory distress syndrome. *Bridget A. Scoville, Pharm.D.*, Paul Tan, Pharm.D., Donald W. Johnson, Pharm.D., Patrick Aaronson, Pharm.D.; Shands Jacksonville Medical Center, Jacksonville, FL
PURPOSE: The study evaluated the degree of pulmonary improvement in patients with acute respiratory distress syndrome (ARDS) before and after an inhaled vasodilator protocol was implemented.
METHODS: Patients were included if they had a primary or secondary diagnosis of ARDS, mechanically ventilated, and treated with inhaled nitric oxide (iNO) between February 2007 and July 2008 or inhaled epoprostenol(iEPO) between February 2009 and July 2010. The percentage improvement in response was recorded for the following oxygenation measurements on days 0-3: SaO2, PaO2, FiO2, PEEP, and PaO2:FiO2 ratio.
RESULTS: There were no differences in baseline characteristics such as age, gender, incidence of vasopressors, and organ dysfunction. When looking at PaO2, FiO2, PEEP, and SaO2 on days 0-3, there were no differences between the two groups except for in two instances. There was a difference in PaO2 between the iNO group (mean change 82.9%) and the iEPO group (mean change 93.1%) on day one (p=0.031) as well as a difference in FiO2 in the iNO group (mean change 0.38%) and the iEPO group (mean change 11.6%) on day zero (p=0.021).
CONCLUSIONS: The significant effects on PaO2 on day one and FiO2 on day zero were most likely due to the properties of iNO. iNO works the most effectively within the first 24 hours of initiation and as a patient continues on iNO the body will become tolerant to the effects. iEPO worked better on day one at increasing PaO2 most likely because there was tolerance built up to the iNO. Overall this study shows that iNO and iEPO seem to be reasonable options in terms of short-term pulmonary improvement.

46. Medication errors and associated factors in the intensive care unit Jimma University specialized hospital in Ethiopia, April, 2011. *Asrat Agalu, B.Pharm, M.S.*; Wollo University, Dessie Ethiopia, Jimma, Ethiopia
PURPOSE: To assess medication errors and associated factors during prescribing and administration of medications in the intensive care unit (ICU) of Jimma university specialized hospital (JUSH) from February 7–April 15, 2011.
METHODS: Prospective cross-sectional study was conducted in the ICU of JUSH from February 7–April 15, 2011. All physician and nurse interventions to all patients admitted to the ICU during the study period were included in the study. All physicians and nurses who prescribed and administered medications were also included. Data were collected by direct observation, self administered questionnaire, in-depth interview, review of medication documentation charts and patient cards. Data was edited, coded, entered to SPSS windows version 16.0 and finally cleaned. Descriptive statistics and chi-square test was used.
RESULTS: Frequency of prescribing and administration MEs in the ICU of JUSH was 209 (52.5%) and 621 (51.8%), respectively. Common prescribing errors were wrong combination (25.7%), wrong frequency (15.5%) and wrong dose (15.1%), while administration errors were wrong timing (30.3%), omission due to unavailability (29.0%) and missed doses (18.3%). MEs associated with antibiotics took the lion's share in both medication prescribing (32.5%) and administration (36.7%) errors. Errors related to cardiovascular drugs, analgesic/antipyretics and anticonvulsants were also common in both cases. Among the factors that contributed to medication errors complexity of regimen (p=0.015), time of drug administration (p=0.000), and type of diagnosis for which medications were indicated (p=0.017) among others.
CONCLUSION: MEs at the prescribing and administration phases were frequent in the ICU of JUSH and the causes were multifactorial. Error reporting systems, awareness creation among health care professionals, and inclusion of clinical pharmacists as member of hospital health care team in general and ICU in particular might reduce MEs and its aftermath.

47E. Severity and preventability of drug-induced hypotension. *Sandra L. Kane-Gill, Pharm.D., MSc*[1], Jaclyn M. LeBlanc, Pharm.D.[2], Joseph Dasta, M.Sc.[3], Critical Care Pharmacotherapy Trials Network, Pharm.D.[1]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)Atlantic Health Sciences Corporation, Saint John, NB; (3)The University of Texas College of Pharmacy, Austin, TX
PURPOSE: While hypotension is common in critically ill patients, the incidence of drug-induced hypotensive events has not been reported. The purpose of this study is to evaluate the incidence of drug-induced hypotension in the ICU. By identifying hypotension as a drug-related hazardous condition, prevention strategies could be developed to minimize hypotention-related injury.
METHODS: In this observational study, clinical pharmacists in 53 ICUs from 23 hospitals recorded episodes of hypotension during a 24-hour period. Hypotension was defined as SBP < 90 mm Hg or a decrease in SBP of 30 mm Hg over two hours in a previously non-hypotensive patient. Each hypotensive episode was assessed for the degree of a drug-related cause using the Kramer algorithm. Each episode of drug-induced hypotension was further evaluated whether it was due to a medication error.
RESULTS: Of the 690 patients evaluated, 238 (34.5%) experienced at least one episode of drug-induced hypotension. SBP < 90 mmHg occurred in 42% of episodes and 55% were from a decrease in SBP of 30 mm Hg over two hours. Fifty six percent of episodes were possibly related to a drug, and 10.2% were considered probable or definite. The most common identified drugs were beta-blockers, narcotics, propofol, furosemide, benzodiazepines and hydralazine. 36.4% resulted from a medication error of which 4.3% reached the patient resulted in no harm, 3.5% caused no harm but required monitoring or intervention to prevent harm, 3.5% may have resulted in harm, and 0.3% may have contributed to patient's death in 0.3%. The most common error types were improper dose (54%), wrong time (19%), and prescribing (16%). Approximately 75% of patient required intervention for this episode of hypotension including crystalloids, norepinepherine, colloids, dopamine and phenylepherine.
CONCLUSION: Drug-induced hypotension occurs in one-third of ICU patients, often requires active intervention and can result in harm. One-third of drug-induced hypotensive events are preventable.
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48. Pharmacist publications in critical care literature over a period of ten years. *Christopher A. Paciullo, Pharm.D.*[1], Catherine Kim, Pharm.D., Student[2], Yannolis Hernandez, Pharm.D., Student[3], Sandra L. Kane-Gill, Pharm.D., M.S., FCCM, FCCP[4]; (1)Emory University Hospital, Atlanta, GA; (2)University Of Pittsburgh School

of Pharmacy, Pittsburgh, PA; (3)Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (4)University of Pittsburgh School of Pharmacy, Pittsburgh, PA

PURPOSE: The number of pharmacists caring for critically ill patients have increased through the years but their contributions to scholarly work in critical care is unknown. This evaluation analyzed the impact of pharmacists in critical care literature over a period of ten years.

METHODS: A search of Critical Care Medicine (CCM) and Intensive Care Medicine (ICM) was conducted for the calendar years 1999, 2004 and 2009 and classified into one of two categories—"Pharmacist publication" or "Non-pharmacist publication." Criteria for "Pharmacist publication" were at least one of the authors having a credential of B.Pharm., Pharm.D., R.Ph. or having a primary affiliation with a college or department of pharmacy. Pharmacist publications were further analyzed to determine the scope and role of the pharmacist.

RESULTS: 3265 manuscripts were evaluated for inclusion. In 1999, 2004 and 2009 pharmacists participated in 3.79% (n=31), 2.2% (n=24) and 3.6% (n=37) of all publications screened, respectively. Of these, pharmacists were first authors in 16 (1999), 7 (2004), and 19 (2009) publications. The majority of these publications were authored by a multidisciplinary group, with publications written only by pharmacists accounting for 14% (n=5), 13% (n=3) and 5% (n=2) of all pharmacist publications in 1999, 2004 and 2009, respectively. The number of prospective studies involving pharmacists decreased over time (19 in 1999, 14 in 2004 and 8 in 2009). All of the pharmacist publications evaluated were written on disease states, patient safety, pharmacoeconomics or pharmacotherapy.

CONCLUSION: Positively, there appears to be multidisciplinary collaboration on pharmacist-authored publications. However, manuscripts written by pharmacists are poorly represented within critical care literature and the rate of publications has not increased over time. Potential explanations could be a preference for pharmacists to publish in pharmacy-specific journals, pharmacists have a high clinical demand and little time for scholarship or pharmacists have limited research training.

49. Continuous neuromuscular blockade and train-of-four monitoring in patients treated with therapeutic hypothermia. *James M. Hollands, Pharm.D.*, Mollie Gowan, Pharm.D.; Barnes-Jewish Hospital, Saint Louis, MO

PURPOSE: Although therapeutic hypothermia is being used increasingly for the management of post-cardiac arrest patients, the associated pharmacokinetic and pharmacodynamic changes are not well understood for medications, including neuromuscular blocking agents (NMBA). This study is an evaluation of resolution of neuromuscular function in patients receiving a continuous infusion of NMBA during hypothermia.

METHODS: Twenty-six post-cardiac arrest patients managed with therapeutic hypothermia were included in this study. The primary endpoint was time to return of neuromuscular function, defined as return to 4/4 twitches on train-of-four (TOF) monitoring. Other outcomes included hospital and ICU length of stay, duration of mechanical ventilation, return of neurologic function based on Glascow coma scale, and adverse events.

RESULTS: Median time to recovery of neuromuscular function was seven hours, ranging from one to 36 hours. The duration of NMBA infusion and the total dose received varied across the patient population. In univariable analysis, creatinine clearance was significantly higher in patients who recovered neuromuscular function ≤6 hours compared to >6 hours, though this did not remain statistically significant in multivariate analysis. At baseline, patients with delayed recovery were older with more comorbidities, although these differences were not significant. A total of eight patients (30%) survived to hospital discharge, all exhibiting an improvement in neurologic function. Hospital and ICU lengths-of-stay and duration of mechanical ventilation were not significantly longer in patients who recovered neuromuscular function >6 hours compared to ≤6 hours, nor in survivors compared to nonsurvivors.

CONCLUSION: Patients treated with therapeutic hypothermia may have prolonged paralysis with continuous infusion of NBMA. Intermittent bolus dosing with close TOF monitoring could be an alternative strategy to prevent shivering and avoid prolonged paralysis.

50. Impact of the propofol shortage on patient outcomes in a cardiothoracic surgical intensive care unit. *Rachelle Whiteside, Pharm.D.*, Edward Horn, Pharm.D., BCPS, David Pavlik, Pharm.D., Robert Simpson, Pharm.D., BCPS; Allegheny General Hospital, Pittsburgh, PA

PURPOSE: On June 16, 2010 Allegheny General Hospital was affected by the national shortage of propofol. The preferred alternatives to propofol included lorazepam or midazolam as intermittent doses on an as needed or scheduled basis; if patients failed to achieve adequate sedation with these agents, then the use of a continuous infusion of either agent could be considered. This study attempted to determine whether the recent shortage of propofol significantly impacted outcomes in cardiothoracic surgical patients

METHODS: Medical records of 353 patients in the surgical intensive care unit (ICU) on a continuous infusion of sedation following cardiac surgery were retrospectively reviewed four months before and after the propofol shortage. Patients' sedative agent(s) and dose, indication for cardiothoracic surgery, duration of mechanical ventilation, ICU length of stay (LOS), post-procedure LOS, Richmond Agitation-Sedation Scale (RASS) scores, and duration of sedation were documented.

RESULTS: In both the pre and post-shortage groups a large number of patients were excluded because they were not on a scheduled sedation regimen, resulting in 31 patients in the pre-shortage group and 19 patients in the post-shortage group. The shortage did not result in any differences with respect to duration of mechanical ventilation (p=0.861), ICU LOS (p=0.873), post-procedure LOS (p=0.954), and time from termination of scheduled sedation to extubation (p=0.860). The percentage of time spent at goal RASS score for patients in the pre-shortage group was 70.1% and 67.2% in the post-shortage group (p=0.741).

CONCLUSION: The propofol shortage did not have a negative impact on patient outcomes in cardiothoracic ICU patients with use of a continuous infusion of midazolam or lorazepam. Approximately 60% of patients were excluded because they were not on a scheduled sedation regimen, demonstrating that the majority of cardiothoracic surgical patients can be managed adequately with intermittent injections of sedation.

51. Evaluating dosing of erythropoiesis-stimulating agents on hemoglobin levels in bloodless medicine patients. *Louise-Marie Gillis, Pharm.D.*, Edward T. Horn, Pharm.D., Robert W. Simpson, Pharm.D.; Allegheny General Hospital, Pittsburgh, PA

PURPOSE: There is currently limited data regarding the use of erythropoiesis-stimulating agents (ESAs) as an alternative to blood transfusions in bloodless medicine patients. The purpose of this study was to determine if high-dose ESAs are associated with a greater increase in hemoglobin levels than low-dose ESAs, and to evaluate the effect of intravenous iron supplementation on hemoglobin levels in bloodless medicine patients with anemia.

METHODS: This was a retrospective, observational study, between July 2007 and July 2010. Data for 200 patients was collected using medical records. Patients were categorized as having received either a high-dose (> 900 units/kg/week) or a low-dose (< 900 units/kg/week) of epoetin equivalent.

RESULTS: A total of fifty-eight patients were included in the study. For patients with a baseline hemoglobin of less than 7g/dL, the change in hemoglobin per day was not significantly different between patients who received high-dose (mean 0.153 g/dL, SD 0.209) and low-dose (mean 0.108 g/dL, SD 0.097) ESAs (p=0.279). For all patients included in the study, neither the baseline hemoglobin (<7 g/dL or 7–10 g/dL) nor the ESA dosing group had a significant effect on the change in hemoglobin per day (p=0.772 and p=0.142 respectively). However, the use of intravenous iron supplementation was a significant predictor for the change in hemoglobin per day (p=0.009).

CONCLUSION: Results of this study suggest that when using ESAs as an alternative to blood transfusion in bloodless medicine patients, using higher ESA doses may not provide an additional benefit. Given the small sample size of this study, further investigation is warranted. In the absence of more data, doses beyond those listed in the product

labeling should be used cautiously and with an evaluation of the risks versus benefits. When using ESAs for this indication, the concomitant use of intravenous iron supplementation is recommended.

52. Effect of home β-blocker use in patients presenting with subarachnoid hemorrhage. *Kevin W. McConeghy, Pharm.D.*[1], Eljim P. Tesoro, Pharm.D.[2], Jeffrey J. Mucksavage, Pharm.D.[2], Keri S. Kim, Pharm.D.[3]; (1)University of Illinois at Chicago Medical Center, Chicago, IL; (2)University of Illinois at Chicago, Chicago, IL; (3)University of Illinois Medical Center at Chicago, Chicago, IL

PURPOSE: Cardiac dysfunction is a significant complication of subarachnoid hemorrhage (SAH) defined as: EKG abnormalities, elevated troponin or LVEF <45%. Propranolol has been associated reducing mortality and improved neurologic outcomes in patients with SAH. However, incidence of neurocardiogenic injury was not investigated in these trials. We conducted a retrospective study investigating whether β-blocker use versus no β-blocker use at time of ictus reduces incidence of cardiac dysfunction.

METHODS: Patients admitted for SAH were included if they were: 18 years or older, positive diagnosis of SAH, and had aneurysm identified by cerebral angiography. Patients were excluded if they had evidence of: non-aneursymal bleed, non-adherence to beta-blocker therapy or spent >24 hours at an outside hospital. The primary outcome was neurocardiogenic injury. Univariate and multivariate analysis was conducted using SPSS version 19.0 (Chicago, Ill).

RESULTS: 200 patients were included. The mean age was 54±13.8 years, 69% of patients were female, 55% of patients had hypertension and 45% were smokers. Overall, 42% of patients demonstrated neurocardiogenic injury, 28 (14%) of patients had documented history of β-blocker use on admission. In the β-blocker and control groups respectively, 46.4% versus 41.8% of patients demonstrated neurocardiogenic injury. An LVEF <45% was demonstrated in 7.1 vs. 10.4% of patients respectively in β-blocker and control groups. An elevated troponin was demonstrated in 28 vs. 19% of patients respectively in β-blocker and control groups. Pulmonary edema was found in 32.1 versus 25.6% of β-blocker and control patients respectively. None of these differences were statistically significant. Coronary artery disease was significantly associated with neurocardiogenic injury in regression analysis (OR 6.57 95% CI: 1.1–36).

CONCLUSION: We found no association between neurocardiogenic injury and home beta-blocker use at the time of ictus. Patients admitted with a history of coronary artery disease are at high risk of neurocardiogenic injury.

53. Selective Decontamination in the Cardiovascular Intensive Care Unit: Analysis of the Consumption of Different Groups of Antimicrobial Agents. *María de la Paz Pacheco,* Alejandro Santiago, Miguel Sánchez, Head, M.D., Virginia Puebla, Rocío Manzano, José A Peña, Ainhoa Arenaza, Pharm.D.; Hospital Clínico San Carlos, Madrid, Spain

PURPOSE: To analyze reductions in the consumption of groups of antimicrobial agents in a cardiovascular ICU and to analyze the effect on costs of the reduction of antimicrobial agents by group.

METHODS: We established an SDD protocol for patients undergoing mechanical ventilation for more than 2 days. Patients were treated with a decontamination solution in the form of an oral suspension, an oropharyngeal paste and suppositories (first 3 days). The patients also received prophylactic treatment with ceftriaxone for 3 days. We recorded the Defined Daily Dose (DDD) of antibiotics before the SDD protocol was implemented and during the SDD protocol period. The physicians were unaware of data collection to avoid interference with drug prescription. Data analysis was based on total DDD and DDD per patient day (PPD).

RESULTS: DDD (PPD): Control Period (Sept 09-Jan 10) SDD Period (Sept 10- Jan 11) Difference Total antibiotics 5085 (2.42) 3615 (2.04) -1470 (-0.38) Carbapenems 685.17 (1.63) 471 (1.29) -214.17 (-0.34) Anti-MRSA* 869.5 (2.06) 545.36 (1.82) -324.14 (-0.24) 3rd-generation cephalosporins 297.5 (0.71) 255 (0.72) -42.5 (0.01) Total antifungal agents 440 (0.21) 154 (0.09) -286 (-0.12) Amphotericin 107.14 (0.05) 0.00 (0.00) -107.14 (-0.05) Echinocandins 189.4 (0.09) 49 (0.03) -140.4 (-0.06) Fluconazole 83 (0.04) 55 (0.03) -28 (-0.01) *Linezolid, daptomycin, vancomycin, teicoplanin. Cost (Cost PPD): The following list shows the overall difference in cost in Euros of using an SDD protocol during the 2 periods. The cost PPD is shown in brackets. Carbapenems: -10,458.67€ (-17.69) Anti-MRSA*: -19,431.07€ (-34.26) Amphotericin: -8,623.04€ (-4.11) Echinocandins: -34,104.13€ (-29.96) Fluconazole: -119.01€ (-0.05)

CONCLUSION: The implementation of an SDD protocol leads to reductions in the use of antimicrobial agents. Similarly, the use of antifungal agents is reduced. These reductions are affected, in particular, by the reduced use of the more expensive antibiotic agents such as anti-MRSA agents and echinocandins.

54. Impact of a pharmacist sedation program on the medical and surgical mechanically ventilated patient population in a level II trauma center. *Lisa Lederhouse, Pharm.D.*, Mary Beth Bobek, Pharm.D.; New Hanover Regional Medical Center, Wilmington, NC

PURPOSE: Determine the impact of a pharmacist monitoring sedation program in the mechanically ventilated patient population in a community hospital setting.

METHODS: This retrospective/prospective study was approved by the Institutional Review Board. The included population was any medical or general surgical mechanically ventilated patient receiving continuous sedatives and/or analgesics. Excluded from this study were neurosurgery patients, patients on neuromuscular blockers, and those with active seizures, withdrawal symptoms, evidence of increased intracranial hemorrhage, or profound neurological deficits. The primary outcome was length of mechanical ventilation time. Secondary outcomes included total doses of analgesics/sedatives, documentation of the daily wake up assessment, length of ICU stay, and adverse effects. In the retrospective study, data was collected on 50 patients admitted during the months of January and February 2010, which served as the control group. In the prospective study, ICU nurses received an in-service on daily wake up assessments by the pharmacist and also completed an online training module. The pharmacist then ensured wake up assessments were performed daily and made recommendations regarding appropriate sedatives and analgesics. The results of the prospective study were compared with the retrospective study for the primary outcome.

RESULTS: The average length of mechanical ventilation was reduced from 138.45 hours to 113.0 hours (P=0.6675). Improvements in secondary outcomes were seen, including amount of wake up assessments performed correctly increased from 12.5% to 67.8% (P<0.001) and death rate (14% vs. 36%, P=0.0111).

CONCLUSION: While the decrease in mechanical ventilation time was not statistically significant, there was an improvement in secondary outcomes, including the amount of wake up assessments performed correctly and death rate. As a result of the study, the nursing documentation system was updated to provide further guidance on the wake up assessment.

55. Cytochrome P450 eicosanoid levels in cerebrospinal fluid and delayed cerebral ischemia in subarachnoid hemorrhage patients. *Mark K. Donnelly, B.S.*, Elizabeth Crago, M.S.N., R.N., Paula Sherwood, Ph.D., R.N., CNRN, Michael Horowitz, M.D., Samuel Poloyac, Pharm.D., Ph.D.; University of Pittsburgh, Pittsburgh, PA

PURPOSE: Delayed cerebral ischemia (DCI) is a major complication in subarachnoid hemorrhage (SAH) patients. Eicosanoids formed by cytochrome P450 (CYP) enzymes have been shown to regulate cerebral blood flow (CBF) and contribute to DCI in animal models of SAH. However, there are few clinical studies investigating the role of CYP-eicosanoids in DCI due to the difficulty to measure these compounds in human CSF. The purpose of this study was to improve the ability to measure CYP-eicosanoids in CSF from SAH patients, develop temporal concentration profiles, and determine their relationship with DCI.

METHODS: CSF was collected from ventricular drains on 61 SAH patients every 12hrs over 14 days. CYP-eicosanoid CSF concentrations were measured using a published method with modifications to the collection and processing of the samples. DCI was determined by the simultaneous presence of neurological deterioration and either angiographic vasospasm or reduced CBF measured by transcranial Doppler ultrasound. The mean CYP-eicosanoid concentrations for each patient were dichotomized into low and high groups and their relationship with DCI was determined using

chi-square analysis.
RESULTS: The quantitation limit was lowered from 0.10 to 0.01ng/ml when compared to published methods. 20-hydroxyeicosatetraenoic acid (20-HETE) and 14,15- ,11,12- , and 8,9-dihydroxyeicosatrienoic acid (DHET) concentrations were detectable in the majority of samples. The maximum 20-HETE concentration (2.50ng/ml) observed was higher than levels reported to constrict isolated cat cerebral arteries. Also, SAH patients with high 20-HETE concentrations (>0.05ng/ml) were at higher risk to develop DCI (p=0.048).
CONCLUSION: 20-HETE and DHETs were quantitatively assessed in bag CSF from SAH patients. 20-HETE was present at physiologically relevant concentrations in CSF and may play a role in the development of DCI after SAH. Future studies can use CYP-eicosanoid temporal concentration profiles to investigate the ability of their trajectory patterns to predict SAH patients at high risk for DCI.

56. Improving adherence to an intensive care unit sedation protocol and effects on patient outcomes. *Edward D. Leaders, Pharm.D.*[1], Phil E. Grgurich, Pharm.D.[1], Garret L. Newkirk, Pharm.D.[1], William J. Peppard, Pharm.D.[1], Karen Brasel, M.D.[2]; (1)Froedtert Hospital, Milwaukee, WI; (2)Medical College of Wisconsin, Milwaukee, WI
PURPOSE: This study was designed to evaluate and implement new strategies to improve compliance with and optimize the use of a recently implemented intensive care unit (ICU) sedation protocol for mechanically ventilated (MV) patients at an academic medical center in an effort to improve patient outcomes.
METHODS: An interdisciplinary group was formed to identify opportunities to improve the current sedation protocol. Interventions were immediately implemented in the surgical ICU (SICU), accompanied by staff education, as a pilot prior to hospital-wide rollout. Retrospective data was gathered from the electronic medical records of SICU patients who had been on MV for at least 48 hours and met inclusion criteria for sedation protocol use at time of intubation. The patients were divided into two cohorts: pre-intervention (n=28) and post-intervention (n=29) to evaluate improvement to adherence and the effect on patient outcomes.
RESULTS: Baseline demographics were similar between groups. Patients were found to receive assessment and documentation of daily sedation vacation (0 vs 18; p=<0.001) and weaning trials (7 vs 24; p≤0.001) in the pre- and post-intervention, respectively. Medication use was not found to be statistically significantly different for total lorazepam (mg/kg) equivalents (1.46 vs 1.01; p=0.429), total propofol (mg/kg) (63 vs 32.8; p=0.232), or total fentanyl (mcg/kg) equivalents (72.4 vs 49.8; p=0.212), respectively between the two cohorts. Duration of MV (125.5 hours *vs* 172.5 hours; p=0.027), length of ICU stay (11.27 days *vs* 18.5 days; p=0.018), and duration of hospital stay (19.3 days *vs* 33.5 days; p=0.037) was found to be less in the post-intervention cohort.
CONCLUSIONS: Changes to the protocol improved compliance with sedation vacations, standardized the care of MV patient, and contributed to reductions in duration of MV and ICU length of stay in the SICU.

57E. Impact of quetiapine on the resolution of individual delirium symptoms: An a priori-designed analysis of a randomized, double-blind, placebo-controlled study. *John W. Devlin, Pharm.D., FCCP*[1], Yoanna Skrobik, M.D.[2], Richard Riker, M.D.[3], Eric Hinderleider, B.S.[4], Russel J. Roberts, Pharm.D.[5], Jeffrey J. Fong, Pharm.D., BCPS[6]; (1)Northeastern University, Boston, MA; (2)Maisoneuve-Rosemont Hospital, Montreal, QC, Canada; (3)Maine Medical Center, Portland, ME; (4)Northeastern University School of Pharmacy, Boston, MA; (5)Tufts Medical Center, Boston, MA; (6)Massachusetts College of Pharmacy and Health Sciences, Worcester, MA
PURPOSE: Resolution of individual delirium symptoms in ICU patients with delirium administered antipsychotic therapy is unclear. We calculated resolution over time and time spent with each of the 10 delirium symptoms measured by the Intensive Care Delirium Screening Checklist (ICDSC) for patients enrolled in a double-blind, randomized, placebo (P)-controlled study evaluating quetiapine (Q) for ICU delirium (Crit Care Med 2010;38;419–27).
METHODS: ICDSC symptom data was available for 29/36 patients randomized [Q (n=15);P (n=14)]. Time to resolution of each ICDSC symptom (from randomization to study drug discontinuation) was compared between the Q and P groups using a Kaplan-Meier analysis. For this post-hoc analysis, p<0.10 was considered significant and data was presented as a median (interquartile range).
RESULTS: At baseline, neither the ICDSC score [5(4–6) (Q) vs 5(4–6)] nor % with each ICDSC symptom: inattention [93(Q) vs 100], disorientation (93 vs 85), symptom fluctuation (92 vs 87), inappropriate mood (77 vs 43), sleep-wake disturbance (68 vs 71), hypoactivity (64 vs 60), altered level of consciousness (43 vs 40), agitation (36 vs 40) or hallucinations (25 vs 25) differed (all p>0.10). Use of Q led to a shorter time (hrs) to resolution of symptom fluctuation [4(Q) vs 14, p=0.004], inattention (3 vs 8, p=0.10) and disorientation (2 vs 10, p=0.10) and a longer time to resolution of agitation (5 vs 1, p=0.04). Q-treated patients spent less % time in study with inattention [47(0-67) vs 78(43-100), p=0.025], hallucinations [0(0-17) vs 28(0-43), p=0.10) and symptom fluctuation [47(19-67) vs 89 (33-100), p=0.04].
CONCLUSIONS: Q resolves many ICU delirium symptoms faster than placebo and results in less time spent with hallucinations, inattention and symptom fluctuation. However, psychomotor agitation, which may be a marker for lower mortality among delirious patients but is predictive of worse outcome among patients not delirious, does not resolve more quickly with Q.
Presented at Presented at the International Congress of the Society of Critical Care Medicine, San Diego, CA, January 15–19, 2011

58. Comparison of sodium acetate and sodium chloride on clinical outcomes in patients with intracranial injury. Ifeoma Asoh, Pharm.D.[1], Brian S. Smith, Pharm.D., BCPS[1], Raphael Carandang, M.D.[1], *Jeffrey J. Fong, Pharm.D., BCPS*[2]; (1)UMass Memorial Medical Center, Worcester, MA; (2)Massachusetts College of Pharmacy and Health Sciences, Worcester, MA
PURPOSE: Hyperchloremic metabolic acidosis (HMA) is a common complication associated with large volume use of normal saline (NS). Limited evidence supports the use of sodium acetate (NaAcet) in correcting HMA. We seek to investigate the effect of NaAcet on correction of acid-base derangements, ventilation status, and intracranial pressure (ICP) in an adult neurotrauma population.
METHODS: This is retrospective database review of patients with intracranial injury admitted between January 2008 and August 2010. Patients were included if they were adults, received NS or NaAcet and had hyperchloremia (HYPERCL) (chloride >115 mEq/L) or HMA (pH < 7.35, bicarbonate < 15mEq/L). They were excluded if the metabolic acidosis was attributable to other causes. Changes in pH, serum bicarbonate and chloride, minute ventilation and peak ICP were evaluated.
RESULTS: We included a total of 69 patients with 36 assigned to the acetate arm and 33 to the saline arm. Baseline demographics were similar with a mean age of 50 years, 84% requiring mechanical ventilation, and a median admission GCS score of 8. At baseline, HMA occurred in 7(19%) of the acetate and 4(12%) of saline arm. All patients had HYPERCL. At 48 hours, acidosis corrected in all patients with HMA with changes of pH > 0.1 unit occurring more often with NaAcet 47.8% vs. 18.1% (p=0.155). By 96 hours, chloride levels had normalized in more patients in NS 56.3% vs. 36.1% (p=0.096). There were no observed differences in minute ventilation (8534± 3828 vs. 9267±2654, p=0.557) or peak ICP readings (30.4±14 mmHg vs. 53±49.4 mmHg, p=0.19). NaAcet was associated with more metabolic alkalosis (75% vs. 21.2%, p=0.00000804).
CONCLUSION: NaAcet does not appear to correct HMA faster, negatively impact ventilation status or peak ICP, however, many patients developed metabolic alkalosis. Larger studies are needed to better describe the role of sodium acetate in critically ill patients.

Dermatology

59. Safety of biologic treatments for moderate to severe plaque psoriasis: a systematic review, basic meta-analysis, and Bayesian mixed treatment comparison. Erica L. Baker, Pharm.D.[1], Craig I. Coleman, Pharm.D.[2], Kurt M. Reinhart, Pharm.D.[1], Olivia J. Phung, Pharm.D.[3], Ajibade Ashaye, MBBS, M.P.H.[1], Lisa Kugelman, M.D.[1], Wendy T. Chen, Pharm.D.[4], C. Michael White, Pharm.D., FCCP,

FCP[2], Jeff Mather, M.S.[1], Carla M. Mamolo, Ph.D.[5], Joseph C. Cappelleri, Ph.D.[6], *William L. Baker Jr., Pharm.D.*[7]; (1)Health Outcomes, Policy and Economics (HOPE) Collaborative Group, Hartford, CT; (2)University of Connecticut, Hartford, CT; (3)Western University of Health Sciences, Pomona, CA; (4)Beth Israel Deaconess Medical Center, Boston, MA; (5)Pfizer Inc., Groton, CT; (6)Pfizer, Inc., Groton, CT; (7)University of Connecticut School of Pharmacy, Farmington, CT

PURPOSE: To conduct a systematic review and meta-analysis in order to evaluate the impact of biologics on various safety endpoints in adults with moderate-to-severe plaque psoriasis.

METHODS: A systematic literature search of MEDLINE and the Cochrane Database was performed through May 2009 to identify English-language trials of biologic agents versus either placebo or each other in adults with moderate-to-severe plaque psoriasis and that reported the desired outcomes. Basic [odds ratio (OR), 95% confidence interval] and Bayesian mixed treatment comparisons (MTC) [OR, 95% credible interval] meta-analyses were conducted for each end point. Biologics were evaluated both individually and by pharmacologic class. Safety endpoints included total withdrawals, withdrawals due to adverse events, total infections, upper respiratory infections, cancer, and various laboratory abnormalities.

RESULTS: Thirty-eight studies met eligibility criteria. Biologics included the anti-T cells agents (alefacept, efalizumab), anti-tumor necrosis factor alpha (TNF) agents (adalimumab, etanercept, infliximab), and anti-interleukin 12/23 agents (ustekinumab, briakinumab). Reductions in total withdrawals were seen with both the anti-TNFs (0.36, 0.22–0.60) and anti-interleukins (0.362; 0.23–0.57) versus placebo. The MTC model suggested that the anti-interleukins had lower odds of total withdrawals versus the anti-T cells (0.31, 0.10–0.92). Only the anti-interleukin agents significantly reduced the odds for withdrawing due to adverse events versus placebo (0.43, 0.20–0.90). The anti-T cells (1.29, 1.07–1.56) and anti-TNFs (1.30, 1.04–1.64) significantly increased the odds of infections versus placebo. No effects on cancer or upper respiratory infections were seen in any analysis. Data on laboratory abnormalities, including liver function and serum creatinine, was inconsistent and did not lend themselves to statistical pooling.

CONCLUSIONS: The anti-interleukins were amongst the best tolerated agents while anti-T cells increased events such as withdrawals and infections. Many endpoints were limited by poor data reporting, so no firm conclusions could be made about them.

Drug Information

60. The prevalence and quality of noninferiority studies in major medical journals. *McKenzie C. Ferguson, Pharm.D., BCPS*, Erin M. Timpe, Pharm.D., BCPS, Jeff Harp, Pharm.D.; Southern Illinois University Edwardsville, Edwardsville, IL

PURPOSE: This study evaluated the number and methods of noninferiority studies in 3 major medical journals over time. The aim was to determine if the number of noninferiority studies has increased and if so, to raise awareness and stress the importance of proper design and evaluation of these types of trials.

METHODS: Original research articles of three well-known medical journals, The New England Journal of Medicine (NEJM), The Journal of the American Medical Association (JAMA), and The Lancet were assessed for the number of noninferiority studies present during the years 2000 and 2010. Appropriateness of design was assessed by determining if the following were included: a defined margin of effect, sample size calculation, and confidence intervals. The type of analysis (per-protocol or intention-to-treat) was also evaluated. Per-protocol is the preferred method of analysis for noninferiority studies.

RESULTS: Of 1,238 studies assessed, 3.4% (n=42) were determined to be noninferiority studies. There was a statistically significant increase in the total number of noninferiority studies between 2000 and 2010. As a percentage of total studies assessed in 2000 and 2010, noninferiority studies represented 0.9% of total studies in 2000 and 6.5% in 2010. Of 48 equivalence and noninferiority studies, more than 95% had a defined margin of effect, sample size calculation and confidence interval reported. Six studies (12.5%) utilized only per-protocol analyses vs. 30 (62.5%) that utilized intention-to-treat and 12 (25%) which utilized both. In total, only 10 (20.8%) met all criteria for appropriateness.

CONCLUSION: In the past decade, the number of noninferiority studies published in major medical journals has increased. Healthcare professionals should understand how to properly evaluate noninferiority study methods.

Education/Training

61. Ready AND Willing: A Self-Assessment Tool to Determine Student Pharmacists' Confidence to Optimize Drug Therapy. *Stuart T. Haines, Pharm.D., BCPS*, Lisa Lebovitz, J.D., Deborah A. Sturpe, Pharm.D., BCPS, David Roffman, Pharm.D., BCPS; University of Maryland School of Pharmacy, Baltimore, MD

PURPOSE: Managing patient care and leading practice change requires self-confidence. We developed a tool to assess student self-confidence to perform the professional competencies needed to optimize drug therapy.

METHODS: The University of Maryland School of Pharmacy established sixteen terminal performance outcome (TPO) statements that describe specific abilities all graduates should possess. Three TPOs focus on the ability to optimize drug therapy outcomes in individual patients: (1) Participate in the development of patient-specific therapeutic plans; (2) Maximize appropriate drug use behaviors; and (3) Participate in the process of monitoring patient outcomes. Each TPO has a list of associated tasks. A survey tool was developed that describes three case scenarios: one community pharmacy, one hospital pharmacy, and one health maintenance organization. Each scenario includes a list of the key tasks that must be performed to address the problems faced in the case. Each task is anchored in the school's TPOs. Students are asked to envision themselves in each case scenario and rate their current ability/confidence to perform the tasks in the context of the scenario. Students are given the survey shortly after admission to the school and periodically thereafter as they progress through the professional curriculum.

RESULTS: At baseline, most students indicated they could not perform the key tasks in the given scenario "without substantial supervision" (ranging from 54 to 98% depending on task and scenario). As students progressed through the curriculum, the percentage of students who indicated they could not perform the task without substantial assistance declined significantly (ranging from 27 to 78% Spring P1 year and 1 to 5% Spring P2 year) ($p<0.001$).

CONCLUSIONS: This unique self-assessment tool may provide pharmacy educators valuable insights regarding student progression toward curricular outcomes and may be a useful adjunct to other institutional assessment methods to meet accreditation requirements.

62E. Assessment of Students' Readiness for Self-directed Learning. *Therese Poirier, Pharm.D., M.P.H.*[1], Radhika Devraj, Ph.D.[2]; (1)Southern Illinois University Edwardsville, Edwardsville, IL; (2)Southern Illinois University Edwardsville School of Pharmacy, Edwardsville, IL

PURPOSE: : To assess students' readiness for self-directed learning during the P1 year prior to beginning coursework; to determine the relationship of various students characteristics to students' self-directed learning readiness (SDLR) and its subscales; and to compare P1 students' SDLR and its subscales to pre-APPE and post-APPE data from another pharmacy school.

METHODS: Eighty-three P1 students completed the Fisher's SDLR electronic survey. Independent t- test, one way ANOVA, reliability analysis and Z-test analysis were completed.

RESULTS: Cronbach's alpha revealed high reliability (0.920) for the SDLR and its subscales. The mean SDLR score was 166.42 (Range: 131.53 to 197). 84% scored a high readiness (SDLR > 150). No significant differences in SDLR and subscales scores were documented based on gender, age, pre-pharmacy coursework and PCAT scores. Statistically significant differences ($p<0.05$) were noted in self control scores depending on leadership experiences. Similarly significant differences in self management scores based on pre-pharmacy GPA were noted. Z-test analysis revealed that P1 students had significant differences in SDLR, self control and desire for learning scores compared to pre-APPE students and significant differences in self management and desire for learning compared to post-APPE students from another pharmacy school.

CONCLUSION: Baseline analysis revealed high level of readiness for self-directed learning among P1 students and few differences associated with demographic variables. However, P1 students appeared to have higher readiness for self directed learning compared to more advanced students at another pharmacy school. This may imply that these students should be well prepared to navigate the pharmacy curriculum.
Presented at American Association of Colleges of Pharmacy Annual Meeting, July 2011

63. Improving student desires to advocate for the pharmacy profession after attendance to a state board of pharmacy meeting. *Kristine C. Willett, Pharm.D.*, Cheryl R. Durand, Pharm.D., Alicia R. Desilets, Pharm.D.; Massachusetts College of Pharmacy and Health Sciences, Manchester, NH
PURPOSE: Colleges and Schools of Pharmacy continue to emphasize the importance of professionalism in their curricula. The pursuit of professionalism requires students to understand the value of advocacy upon entrance into the profession. The purpose of this study is to determine change in student attitude toward pharmacy advocacy following attendance to a state board of pharmacy meeting.
METHODS: The methods of this study have been approved by the Institutional Review Board. Doctor of Pharmacy students enrolled in an accelerated pharmacy program were asked to attend a state board of pharmacy meeting. Students were asked to complete a short questionnaire to reflect on their experience. Analysis of data was done using frequencies and percentages. Student responses will provide information on the impact of attendance to a state board of pharmacy meeting on their desire to become actively involved in the advocacy of their profession.
RESULTS: Twenty-eight students completed the questionnaire following attendance to a state Board of Pharmacy meeting. Of the students that attended, 15 (53.5%) reported an increase in desired to become more involved in the advocacy for the profession of pharmacy. Seven (25%) students reported that attendance enhanced their existing desire to become involved. Additionally, students offered comments expressing the value of the Board of Pharmacy and how their experience altered their perception of the need to become actively involved to enhance the practice of pharmacy both locally and nationally.
CONCLUSION: There is value in exposing students to professional groups and organizations. Attendance at a state Board of Pharmacy meeting provided students with exposure the importance of becoming active in their profession as students and upon graduation.

64. Perception of Advanced Pharmacy Practice Experience students on inpatient internal medicine rotations: a healthcare provider perspective. *Jason W. Lancaster, Pharm.D., BCPS*, Margarita V. DiVall, Pharm.D., BCPS, Mark A. Douglass, Pharm.D., Michael J. Gonyeau, BSPharm, Pharm.D., BCPS, Adam B. Woolley, Pharm.D., Adrian Wong, B.S.; Northeastern University School of Pharmacy, Boston, MA
PURPOSE: Currently there are no known published reports of healthcare provider perception of Advanced Pharmacy Practice Experience (APPE) students within the inpatient internal medicine setting. We therefore seek to assess APPE students' perceived value by providers in this setting.
METHODS: A brief, anonymous online survey was distributed beginning in March 2011 via secure e-mail to inpatient internal medicine providers at medical centers where Northeastern University student pharmacists completed an internal medicine rotation. Data included extent of student pharmacists' involvement in patient care, appropriateness of therapeutic recommendations, participation in education of medical teams and overall benefit.
RESULTS: Of those surveyed, 32 responded (56.1%) and a majority had worked with ≥3 student pharmacists. A vast majority believed student pharmacists were 1) prepared for daily rounds (90.6%), 2) active participants in patient care (84.4%), 3) in possession of the necessary patient-specific information to be beneficial (93.8%), and 4) able to respond to drug information questions appropriately (87.5%) and accurately (96.9%). Additionally, half of those responding indicated student recommendations led to changes in medical management of patients. Furthermore, for those students providing topic discussions, providers reported that they were of great benefit (90%), as well as potentially leading to changes in their personal practice (90%). Overall, 96% of the providers reported that student pharmacist involvement within medical teams provided some level of benefit; with 47% stating they were 'very beneficial'.
CONCLUSION: Provider's perception of the value of pharmacy students was generally positive regardless of medical center. Findings indicate student pharmacists are beneficial to the responding providers in a variety of patient-care areas. Additional efforts to educate medical teams of potential roles of student pharmacists in the team are critical to further establish provider and medical team acceptance.

65. Qatar University pharmacy students interest and concerns related to international professional experience rotations. *Sara Al-Dahir, Pharm.D., BCPS*, Sarah Amering, Pharm.D.; Xavier University of Louisiana, New Orleans, LA
PURPOSE: This survey for Qatar University pharmacy students was conducted to determine 1) knowledge of global health; 2) interest in exchanges and 3) personal and logistic barriers to international professional experience rotation exchanges.
METHODS: In this on-line survey, conducted between January and June 2011, participants were recruited from all students enrolled in Qatar University Pharmacy professional degree program. The survey domains addressed 1) demographic characteristics of the respondents; 2) knowledge of global health trends; 3) knowledge of the regulatory status of select medications in different countries; 4) interest in an international exchange and 5) areas of concern related to participation in an international pharmacy student exchange program. Descriptive statistical analyses and group comparisons were carried out using correlation statistics and linear regression analysis.
RESULTS: A total of 60 surveys were collected from students in their first through fourth professional year (77% response rate, N=77). Eighty-eight percent of the students were interested or very interested in an international pharmacy exchange program, with Canada (87%) and the United States (88%) identified as preferred countries to engage in medication management (77%), pharmacy dispensing (72%) and research (60%). The Qatari students identified issues related to housing (67%), overall cost (57%), cultural differences (55%) and personal safety (52%) as areas of concerns regarding an exchange. In the domains of general global health trends related to infectious disease and medication regulation, the students performed at 32% and 18% correct responses respectively.
CONCLUSION: Students from the College of Pharmacy in Qatar, though interested in international exchange programs, have significant concern regarding safety and cultural barriers to such a program. Qatari students interested in an international exchange will require additional education on global health trends and medication regulation in North America. Host institutions should pursue opportunities to address these concerns as efforts are established toward reciprocal exchanges.

66E. BA_4LL: Bounce around 4 larger learning. Utilization of exercise balls for chairs on an internal medicine APPE. *Tracey L. Mersfelder, Pharm.D.*; Ferris State University, Big Rapids, MI
PURPOSE: Exercise balls are becoming popular in the classroom. Little has been published on their incorporation and acceptance into an adult learner environment. The main objective of this study was to determine the feasibility and acceptability of using exercise balls in place of chairs in a small group environment.
METHODS: Feasibility was evaluated by purchasing exercise balls for the clinical site and price, size, and limitations were recorded. To address acceptability, pre- and post-surveys were administered to the APPE internal medicine students at one site. This project was IRB approved.
RESULTS: A total of seven balls are available for the students. The cost of the balls ranged from $14–$23. The best universal size is the 75 cm ball. The biggest limitation was finding the correct ball size for each student with the fixed table height. To date, 16 students have completed the pre-survey, and fifteen students have completed the post survey. All students used the exercise balls at least once. One-half felt the balls would be a distraction at first but this decreased to 1/3. At the end of the rotation, 93% students stated that the exercise balls should be an option in other classroom settings.

CONCLUSION: Providing exercise balls for students on their internal medicine APPE is feasible and was accepted by the students. Consideration should be made to provide exercise balls for other classroom settings.
Presented at Lilly Conference on College and University Teaching in September 2011. (website:http://lillyconferences.com/tc/default.shtml).

67. Impact of a web-based learning module and faculty preceptor on experiential pharmacy students' pain management confidence and competence. Mark A. Douglass, Pharm.D.[1], *Jason Lancaster, Pharm.D., BCPS*[1], Margarita V. DiVall, Pharm.D., BCPS[2], Michael J. Gonyeau, BSPharm, Pharm.D., BCPS[2], Adam Woolley, Pharm.D., BCPS[1]; (1)Northeastern University Department of Pharmacy Practice/Boston Medical Center, Boston, MA; (2)Northeastern University School of Pharmacy, Boston, MA
PURPOSE: To evaluate the impact of a web-based learning module (WBLM) and faculty preceptor on experiential pharmacy students' pain management confidence and competence.
METHODS: Ninety nine pharmacy students completing their fourth professional year were invited to participate in a supplemental web-based learning module (WBLM), designed to improve the following pain management skills: managing chronic-continuous pain (CCP), equianalgesic dose conversion (EDC), breakthrough pain (BP), and opioid side effects (OSE). A questionnaire was then distributed which assessed students' self-reported comfort level (confidence) and their knowledge (competence) of these skills using standardized case vignettes. Students' were asked if they completed their internal medicine rotation with a university-based faculty preceptor. A Fisher's exact test was used to compare each outcome.
RESULTS: The questionnaire response rate was 76% and 24% completed the WBLM. WBLM participants were as or more confident than non-participants with three pain skills (CCP, 71% vs 67%, p=0.8; EDC, 79% vs 67%, p=0.4; BP, 75% vs 75%, p=1.0) and as or more competent with all skills (CCP, 38% vs 29%, p=0.6, EDC, 67% vs 65%, p=1.0, BP, 25% vs 16%, p=0.3, and OSE, 80% vs 61%, p=0.2). Faculty precepted students' reported more confidence with all skills: CCP, 73% vs 58%, p=0.2; EDC, 76% vs 62%, p=0.3; BP, 76% vs 70%, p=0.6, and OSE, 76% vs 73%, p=0.8, and were more competent with EDC (70% vs 58%, p=0.3), BP (20% vs 15%, p=0.7, and OSE (69% vs 65%, p=0.8).
CONCLUSION: Students who utilized the WBLM reported more confidence with CCP, EDC, and BP and were as or more competent with all pain skills. Faculty precepted students' reported more confidence with all skills and were more competent with EDC, BP, and OSE. A lower than expected number of students completed the WBLM, which may have accounted for the non-significant study findings.

68. Prospective evaluation of student-led presentations as a successful teaching method for achieving critical care competency. *Daniel R. Malcom, Pharm.D.*, Jennifer L. Hibbs, Pharm.D., BCPS; Sullivan University College of Pharmacy, Louisville, KY
PURPOSE: Guidance for critical care pharmacy didactic education is limited, both for instructional techniques and evaluation of outcomes. The study purpose was to assess the efficacy of student-led presentations and class discussions as a teaching method in a critical care elective course.
METHODS: In a critical care elective of a 3 year accelerated program, P2 students were asked to prepare and deliver 50-minute presentations on critical care topics generated using the ACCP Pharmacotherapy Toolkit. Designed to complement the pharmacotherapeutic curriculum, topics included: hypertensive crisis, COPD exacerbation, antifungal therapy, intensive care associated delirium, nutrition support, liver transplantation. A faculty generated critical care competency test of 20 multiple choice questions was administered before the start of the course and upon completion. Pre- and post-test scores were compared using student t- tests. Total mean scores and mean scores for questions related to material taught in the course were evaluated with significance set at 5%. Informed consent was received as part of institutional review board approval.
RESULTS: Of 24 students enrolled, all students completed the study. By the elective's conclusion, discussion related to 9 of 20 questions on the competency were conducted by student presentations. The total mean score significantly improved 11.5% on the post test compared to the pre-test score (pre-test 56% vs post-test 67.5%, $p<0.05$). 16.2% improvement was shown on the 9 questions which pertained directly to subject matter taught during the course (pre-test 59.2% vs post-test 75.2%, $p<0.05$).
CONCLUSION: Students displayed statistically greater mean scores on the post test for all 20 questions, and acheived 75.2% on questions related to material covered in class. Statistically significant improvement on questions specific to critical care material reviewed during the course indicate the use of student-led presentations is successful in improving student competency and may be a beneficial teaching method for critical care pharmacotherapeutics in an accelerated program.

69. Dietary supplement education in a senior population. *Kimberly G. Elder, Pharm.D.*[1], Sarah A. Nisly, Pharm.D., BCPS[2]; (1)Indiana University Health Methodist Hospital, Indianapolis, IN; (2)Butler University College of Pharmacy and Health Sciences, Indianapolis, IN
PURPOSE: Potential dangers with dietary supplements include the lack of regulation by the Food and Drug Administration and the possibility of drug-supplement interactions. The primary objective of this study was to determine the effectiveness of a pharmacist driven educational seminar in a local senior population.
METHODS: Initially, a needs-assessment interview was conducted at a health fair within a local senior organization. Interviews focused on dietary supplement use were delivered to study participants. Interview responses were then analyzed to determine the most commonly used dietary supplements. Next, an educational seminar focusing on general dietary supplement information and the most commonly used supplements in the initial population was created and delivered. Pre- and post-surveys were administered to gauge baseline knowledge and impact of pharmacist education. Additionally, results were analyzed for change in attitudes about supplements.
RESULTS: Forty-nine participants were interviewed about dietary supplement use at the initial health fair. Participants were primarily African American females with a mean age of 72.6 ± 7.8 years. Among those, 81.6% were taking at least one supplement. The most commonly used supplements were calcium (n=23), multivitamins (n=22), and fish oil (n=13). Approximately 180 seniors attended the subsequent educational seminar. Participants reported being mainly Hispanic females with a mean age of 72.3 ± 7.9 years. Knowledge statistically significantly improved from baseline for all six questions posed to study participants. The program was well received, and attitudes about dietary supplements changed as a result of viewing the seminar.
CONCLUSION: Dietary supplements were commonly used by the study population for various indications. Education by pharmacists is an effective method to increase knowledge and awareness about dietary supplements among this population.

70. Patient-focused pharmacotherapy notes in a cardiovascular therapeutics course: a standardized approach. *Angela O. Shogbon, Pharm.D., BCPS*, Lisa M. Lundquist, Pharm.D., BCPS, Kathryn M. Momary, Pharm.D., BCPS; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA
PURPOSE: To evaluate the effectiveness of utilizing a standardized approach to patient-focused pharmacotherapy notes, specifically Subjective Objective Assessment Plan Education (SOAPE) note format, to improve students' knowledge of patient-focused documentation in a cardiovascular therapeutics course.
METHODS: A total of five weekly patient-case discussion sessions were incorporated into a cardiovascular therapeutics course for second-year pharmacy students. Each week, students came prepared for small-group discussions on a patient case they completed ahead of time, utilizing the SOAPE note format. Then, students worked-up another patient case and submitted a SOAPE note for a grade. A SOAPE note approach to patient cases was also incorporated into all lectures throughout the course. A pre-test and post-test assessing students level of confidence in preparation of SOAPE notes were administered at the beginning and end of the course, respectively. Perception of confidence was ranked on a 4-point Likert scale with 4=strongly agree and 1=strongly disagree. Data collection for this

study was approved by the IRB and students voluntarily signed informed consent prior to participation. Scores on the pre-tests, post-tests, and student performance on SOAPE notes were compared utilizing descriptive statistics and paired *t*-tests.
RESULTS: A total of 121 (91.7%) students completed both the pre-tests and post-tests. There was significant improvement in student's confidence in writing SOAPE notes by the end of the course, with a mean(SD) score of 2.89(0.46) on pre-test and 3.53(0.36) on post-test ($p<0.001$). Students' mean(SD) performance on the first and final SOAPE note in the course was 89.6%(8.34) and 93.2%(6.71), respectively ($p<0.001$). There was no significant difference in confidence or performance scores between students with prior experience in writing SOAPE notes, and students without experience.
CONCLUSION: A standardized approach to patient-focused pharmacotherapy notes may enhance students' understanding and confidence to perform this vital task on experiential patient care rotations and in clinical practice.

71. Community pharmacists in the State of Qatar: a survey of their smoking cessation knowledge and educational interests. *Maguy S. El Hajj, Pharm.D.*, Reem R. Al Nakeeb, B.S.Pharm. Candidate, Rajaa A. Al Qudah, B.S.Pharm. Candidate; Qatar University College of Pharmacy, Doha, Qatar
PURPOSE: Cigarette smoking is one of the preventable causes of ill health in Qatar. Qatar community pharmacists are in an ideal position to play an important role in smoking cessation. This role necessitates adequate smoking cessation knowledge and education. The study objectives were to assess Qatar community pharmacists' smoking cessation knowledge and to gauge their perceptions of which aspects of smoking-related education would be most interesting.
METHODS: A pretested survey was used to solicit community pharmacists' anonymous responses. The survey was designed after reviewing relevant smoking cessation literature. A phone call was made to all community pharmacists in Qatar to request their participation. Interested pharmacists were sent the survey link by email or by fax. Data was descriptively analyzed using the Statistical Package of Social Sciences software version 18.
RESULTS: Over 20 weeks, we collected 112 surveys (35% response rate). Smoking cessation knowledge was evaluated using 8 true or false questions. Thirty seven percent of respondents scored less than 60% and 13% scored more than 80%. The mean score was 61% with a standard deviation of 17%. Eighty-nine percent of respondents indicated that they have not received before any smoking cessation education. Nevertheless, at least 70% indicated that they were interested in receiving additional smoking cessation education. Respondents were mostly interested in receiving education on motivating smokers to quit and on counseling on behavioral techniques (89% and 86% respectively). Sixty nine percent indicated a preference for mailings of printed materials as method of information delivery.
CONCLUSION: Despite their low smoking cessation knowledge, Qatar community pharmacists are interested in receiving additional smoking cessation education. A smoking cessation education program should be offered to these pharmacists to give them the knowledge they need to be competent smoking cessation counselors.

72. Pharmacy students' attitudes toward pharmaceutical care in Qatar. *Maguy S. El Hajj, Pharm.D.*, Ayat S. Hammad, BSPharm, Candidate, Hebataila M. Afifi, BSPharm, Candidate; Qatar University College of Pharmacy, Doha, Qatar
PURPOSE: Pharmacy practice has recently shifted from medication supply to pharmaceutical care (PC). Pharmacy educators must prepare students to provide PC. Their responsibilities are not only limited to give students knowledge and communication skills but to motivate them to perform PC. The study objectives were to investigate Qatar pharmacy students' attitudes toward PC, to identify the factors that influence their attitudes toward PC, and to recognize their perceived barriers for PC provision.
METHODS: Qatar University college of pharmacy is the only pharmacy college in Qatar. A cross sectional survey of Qatar University pharmacy students was made. The students completed an online anonymous survey designed based on Standard Pharmaceutical Care Attitudes Survey (PCAS). Data was descriptively analyzed using Statistical Package for the Social Sciences version 18. Influence of sociodemographic characteristics on students' attitudes was assessed using Kendall's tau_b test.
RESULTS: Over 4 weeks, 46 surveys were submitted (90% response rate). All respondents agreed that PC practice is valuable and that the pharmacist primary responsibility is to prevent and resolve medication therapy problems. Most respondents believed that PC provision is professionally rewarding (96% of respondents), and that all pharmacists should provide PC (91%). Highly perceived barriers for PC provision included lack of access to patient medical information (76% of respondents), inadequate drug information sources in the pharmacy (55%) and time constrains (53%). Professional year and practical experience duration were significantly inversely associated with students attitudes (correlation coefficients are -0.30 and -0.37 respectively $p<0.05$). No statistically significant correlations existed between other characteristics and students attitudes.
CONCLUSION: Qatar pharmacy students indicated positive attitudes toward PC. However, they perceived several barriers for PC provision. Efforts should be exerted by Qatar government to help these future pharmacists in overcoming these barriers.

73. Implementation of and experience with a locally-developed summative exit exam delivered to Pharm.D. students prior to graduation. *Lamis Karaoui, Pharm.D., BCPS*, Hani Dimassi, Ph.D.; Lebanese American University, Byblos, Lebanon
PURPOSE: To create a valid assessment tool to evaluate student knowledge and educational outcomes prior to graduation from the doctor of pharmacy program.
METHODS: The Lebanese American University School of Pharmacy – ACPE accredited – administers a summative locally-developed exam to fourth professional year (P4) graduating Pharm.D. students annually in June. In 2009, the Exit Exam (EE) was first delivered on BlackBoard®. In 2010, it was redesigned to simulate in content the 2010 NAPLEX competency statements. An EE committee of faculty members was formed to review and update the previously existing question pool, standardize exam questions, and supervise the process of implementing and administering the EE. The number of questions collected from each course is proportional to the number of credit hours devoted to that course in the curriculum. EE is an electronic exam consisting of 185 multiple-choice questions, each with a stem and four choices. The estimated time to complete the exam is 4.5 hours.
RESULTS: EE 2010 focused on the following three areas of the 2010 NAPLEX Blueprint: therapeutics (Area 1, 56%), preparation and dispensing (Area 2, 33%) and public health (Area 3, 15%). Overall student performance on the EE shows a quasi-consistent trend (overall mean ranged between 52.59 and 56.15 over 100) for the years 2007, 2009 and 2010, with mean scored below 50 in 2008. Interestingly, better results were observed on Areas 2 and 3 as opposed to Area 1 with means of 58.99, 61.89 and 51.96 over 100 respectively. EE does not bear weight on grade point average or graduation and students are not requested to prepare for it.
CONCLUSION: The obtained results measure retention of information of the graduating Pharm.D. student. EE is a promising tool for programmatic assessment; better yields are expected with grade allocation and mandatory preparation. EE provides guidance for Lebanese graduates sitting for the NAPLEX.

74. Evaluation of student pharmacists' awareness and perceptions of board certification. *Kristina D. Wood, Pharm.D.*[1], Bella H. Mehta, Pharm.D.[1], Maria Pruchnicki, Pharm.D.[1], Jennifer L. Rodis, Pharm.D.[1], Kyle Porter, MAS[2]; (1)The Ohio State University College of Pharmacy, Columbus, OH; (2)Ohio State University Center for Biostatistics, Columbus, OH
PURPOSE: The American Pharmacists Association (APhA) and the American College of Clinical Pharmacy (ACCP) have published papers on the importance and value of certification through the Board of Pharmacy Specialties (BPS) and have identified a role for schools of pharmacy to promote the value of certification to students. The objectives of this study were to: 1) determine awareness of BPS certification by current student pharmacists at all levels of pharmacy education, 2) evaluate student perceptions of effective educational formats for learning about BPS certification, and 3) assess students'

interest in obtaining BPS certification in future careers.
METHODS: State boards of pharmacy in all 50 states were contacted to request licensed intern contact information; all students with valid email addresses were invited to participate in an online survey. Participants were asked about awareness of BPS, where they learned about certification, interest in attaining certification, future professional plans, and demographics.
RESULTS: Nine state boards provided 7,251 eligible email addresses, with 1,108 survey responses (15.3% response) included for analysis representing students from schools in 39 states. A majority of respondents (73.2%; n=750) were aware of board certification and identified learning about BPS most from faculty members (n=509) and preceptors (n=289), primarily in required courses (n=311) and advanced pharmacy practice experiences (n=238). When asked about future plans, 43.3% (n=472) stated they were likely to pursue BPS certification, 41.1% (n=449) were undecided, and 15.6% unlikely (n=170).
CONCLUSION: Most respondents were aware of certification, learning the most through didactic and experiential activities, and many indicated they are likely to or undecided about pursuing BPS certification. Respondents unaware of or undecided about BPS certification represent an opportunity for colleges of pharmacy and professional organizations to formalize their role in student education about BPS and advocacy efforts.

75. Student-created public service announcements: a novel approach to attaining public health competency in the pharmacy curriculum. *Kim Coley, Pharm.D.*; University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: We set out to implement a more creative way to engage students in their own public health awareness in the pharmacy curriculum through the use of student-created public service announcement (PSA) videos. Students' perceptions of the process and outcomes were assessed.
METHODS: Students in the Professions of Pharmacy 6 course were assigned to create a 1–2 minute PSA video from a list of selected topics. Topics were important public health issues where pharmacists play a vital role as public health providers and educators (e.g., vaccinations, antibiotic resistance, medication adherence). Students posted their videos on YouTube so that their peers could evaluate them. PSAs were evaluated on creativity, content, message, and overall impact. Students also evaluated the overall process and outcomes of the project.
RESULTS: Students worked in groups of six to create 18 PSA videos. Sixty percent of the groups had at least one group member that was somewhat knowledgeable on how to make videos. Eighty-nine percent of students felt the take-home message of the PSAs was achieved and 96% rated their peers' PSAs as good to excellent. On a 5-point Likert scale, 30% strongly agreed that creating a PSA was an effective mechanism to learn about important pharmacy-related public health topics, 48% were neutral, and 22% felt it was ineffective. The ability to be creative, cited by 55% of students, was the aspect that they enjoyed most. The main criticism of the assignment was its timing, which was at the end of the semester and conflicted with several other course assignments.
CONCLUSION: PSA videos are a creative way to engage students in self-directed learning of important public health topics. Providing students with additional support on video-editing and improving the timing of the assignment should increase overall satisfaction with this learning activity.

76. Impact of Unlimited Access to Asynchronous Online Lecture Viewing on Student Outcomes in a Therapeutics course. *Suzanne G. Bollmeier, Pharm.D., BCPS, AE-C*, Amy Drew, Pharm.D., BCPS, Philip J. Wenger, Pharm.D., BCPS, Alicia B. Forinash, Pharm.D., BCPS; St. Louis College of Pharmacy, Saint Louis, MO
PURPOSE: The purpose of this study is to find a correlation between online lecture viewing with Therapeutics II (T2) 2010 course grades and attendance and also compare between final course grades with the previous year (2009).
METHODS: Lectures were recorded via ® software and available for 72 hours in 2009 and for the entire semester in 2010. Attendance was recorded in aggregate in 2009 and individually in 2010. Pearson's correlation was used to analyze lecture viewing with final grade and class attendance, and final grade and attendance. *T*-test was used to compare final course grades in 2009 and 2010, and ANOVA was used to compare final grades in 2008 (no online access), 2009, and 2010. Students completed a pre- and post-semester survey regarding lecture access in 2009 and 2010.
RESULTS: No correlation was found between: lecture viewing and overall grades, lecture viewing and individual attendance, or final grade and attendance. Course grades were not affected by amount of lecture access time. Pre survey results showed: 97% of students would access posted files in addition to previous study habits and they intended to view the files within one week of lecture (64%). Also 97% postulated it would not influence their class attendance. Post survey data showed: 85% used files to complete lecture handouts, 87% used files to answer questions instead of contacting the and 93% requested more lecture files be posted in future classes. When not in class, 77% reported they watched the posted file, and 94% reported ® did not influence their attendance.
CONCLUSIONS: Having access to posted lecture files for either 72 hours or the entire semester did not correlate to improved course grades or have an impact on class attendance. The routine use of lecture-capture devices may not be as important as students perceive.

77. Economic evaluation of clinical interventions from an integrated internal medicine and ambulatory care APPE. *Michael J. Gonyeau, BPharm, Pharm.D., BCPS*[1], Maureen McQueeney, Pharm.D., BCPS, CDE[2]; (1)Northeastern University School of Pharmacy/Brigham and Women's Hospital, Boston, MA; (2)Northeastern Univeristy School of Pharmacy/Brigham and Women's Hospital, Boston, MA
PURPOSE: Most APPEs occur from 4–6 weeks, a narrow window for students to feel comfortable and confident before moving on, affecting their ability to accurately and completely document clinical interventions. Our objective was to conduct an economic analysis of clinical interventions documented during an integrated 12 week APPE model compared to previous non-integrated APPE data and to quantify value added to students, preceptors and institutions.
METHODS: A 6 week ambulatory care (AC) and internal medicine (IM) APPE were integrated into a longitudinal 12 week APPE comprised of a fluid structure where students transitioned from inpatient to outpatient services multiple times with increased student exposure to patients transitioning from inpatient to outpatient care. Clinical intervention documentation was required via a web-based system and data from the integrated APPE was compared to previous students from each preceptor from stand-alone AC and IM rotations at the same hospital. Specific comparisons included adverse drug events (ADEs) and medication errors (MEs) prevented, as well as an economic evaluation to evaluate cost savings.
RESULTS: Twelve integrated APPE students documented 1984 interventions vs. 873 from 12 students completing separate APPEs with the same preceptors ($p < 0.001$). Intervention categories remained consistent with a significant increase in medication histories performed (11.5% to 18.3%) and level of significance increased in the integrated model. 1053 ADEs were prevented (936 integrated vs. 117 pre-integration, $p<0.001$) associated with a total cost savings of $332,985. Similarly, 274 MEs were prevented (168 integrated vs. 108 pre-integration, $p=0.07$) associated with a cost savings of $34,012. This averages $26,403 cost savings per student in the integrated model vs. $4086 pre-integration ($p<0.001$) over a 12-week period.
CONCLUSION: An integrated APPE decreases orientation time for students and preceptors, increases patient interaction, increases clinical intervention documentation and increased prevention of ADEs and MEs, resulting in increased institutional cost savings.

78. Communication of clinical recommendations during patient case-based cardiovascular therapeutics oral examinations. Lisa M. Lundquist, Pharm.D., BCPS, *Angela O. Shogbon, Pharm.D., BCPS*, Kathryn M. Momary, Pharm.D.; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA
PURPOSE: To compare students' self-assessment and faculty evaluation of communication of clinical recommendations during therapeutics oral examinations.
METHODS: For two consecutive years in the Cardiovascular / Renal

therapeutics course, one individual and one group patient case-based oral examination were given to all second-year pharmacy students. Students were provided with patient cases prior to each oral examination. In addition to evaluation of pharmacotherapy knowledge, faculty evaluated students' communication skills using a scoring rubric divided into two areas: rapport (confidence, non-verbal) and presentation of therapeutic recommendations (concise, pronunciation, well-prepared). Faculty evaluated these skills on a 4-point Likert scale with 1=needs significant development and 4=accomplished. Immediately following each oral examination, students self-assessed their communication skills using the same rubric. This study was approved by the IRB and students voluntarily signed informed consent prior to participation. Students' self-assessments were compared to faculty evaluation of their communication skills using descriptive statistics and paired *t*-tests.

RESULTS: A total of 261 (96.3%) students completed communication self-assessments following each oral examination. For the individual oral examination, mean(SD) student self-assessment and faculty's evaluation of communication were 3.27 (0.49) and 3.50 (0.41) year one; 2.98 (0.54) and 3.46 (0.47) year two. For the group oral examination, mean(SD) student self-assessment and faculty's evaluation of communication were 3.41 (0.49) and 3.60 (0.31) year one; 3.20 (0.45) and 3.60(0.37) year two. Faculty evaluations in both the individual and group oral examinations were statistically significantly higher than the students' self-assessments in both years ($p<0.001$). In addition, in both years, students' self-assessment of communication increased from the individual to the group examination ($p<0.001$).

CONCLUSION: Students' self-assessment of communication skills were consistently lower than the faculty's evaluation scores. Students' lower self-assessment may be due to a lack of practice in the verbal communication of clinical recommendations. Greater utilization of formal case-based oral examinations may help to improve student's confidence and self-assessment of their communication skills.

79. The process of assessing student performance; is creating a rubric the answer?. *Jayne E. Lepage, Pharm.D.*, Abir O. Kanaan, Pharm.D., Jennifer L. Donovan, Pharm.D.; Massachusetts College of Pharmacy and Health Sciences, Worcester, MA

PURPOSE: To comply with the Accreditation Council for Pharmacy Education (ACPE) assessment requirements in experiential education, a standardized rubric that includes formative and summative criteria was created to assess student performance and the experiential component of the curriculum. The purpose is to describe this process and to share the tool that was created.

METHODS: A faculty task force comprised of various pharmacy practice specialists and representatives from the Department of Experiential Education was assembled and charged with the development of a standardized evaluation rubric that would be utilized across all types of advanced pharmacy practice experiences (APPE) and that would facilitate assessment of the experiential component of the curriculum. A rubric was developed based on national practice guidelines published by the American College of Clinical Pharmacy and the school's student learning outcomes derived from the ACPE standards.

RESULTS: Rubrics were created and included criteria that assessed a student knowledge, skills and attitude within a particular activity outcome. The rubrics were then piloted by a subset of faculty, select adjunct faculty and students. A 5-item survey was administered at specific time periods throughout the APPE rotations to assess the content and applicability within each performance criteria, and the correlation between student performance, specified competencies, and grading criteria. Subsequently, adjustments were made to clarify the performance criteria and through this process a universal rubric was created. Since the rubric is based on ACPE standards and the school's student learning outcomes, a smooth transition for assessment of student performance and the experiential curriculum may now occur.

CONCLUSION: A systematic process that was faculty driven allowed for a standardized rubric to be created which will facilitate assessment of student performance and of the experiential component of the curriculum.

80. Current state of teaching oncology pharmacotherapy: focus on cancer as a chronic disease. *Michael Newton, Pharm.D., BCOP*[1], Myke Green, Pharm.D., BCOP[2], Christopher Campen, Pharm.D., BCPS[2], Terry Schwinghammer, Pharm.D., BCPS[1]; (1)Department of Clinical Pharmacy, West Virginia University School of Pharmacy, Morgantown, WV; (2)Department of Hematology and Medical Oncology, Arizona Cancer Center, Tucson, AZ

PURPOSE: The rapidly changing face of oncology pharmacotherapy represents a challenge in pharmacy education. Cancer accounts for nearly 25% of all deaths in the United States and will likely exceed heart disease as the number one cause of death in the near future. Pharmacotherapy options for patients with cancer are expanding rapidly and include many oral agents with novel mechanisms of action. While oncology has traditionally been the realm of specialists, the ability to manage many cancers as chronic diseases has moved anticancer treatment into mainstream pharmacy practice. The goal of this report is to examine how U.S. schools and colleges of pharmacy address oncology pharmacotherapy.

METHODS: A survey of pharmacy practice department chairs at schools and colleges of pharmacy in the United States was conducted using a 20-question survey instrument. The instrument captured oncology teaching methods, oncology pathophysiology and pharmacotherapy contact hours, education and background of instructors, and personal opinions regarding importance of oncology in the professional pharmacy curriculum.

RESULTS: Seventy-two (62%) of the 116 institutions responded. A median number of 28 contact hours were reported for oncology pharmacotherapy (range: 8–108 hours). Two-thirds of respondents reporting below 28 contact hours expressed no need to dedicate more time to oncology pharmacotherapy. About 60% of schools employ board-certified oncology specialists, but about 20% employ faculty without oncology expertise. Pharmacogenomics information is integrated into applicable pharmacotherapy lectures at 58% of responding schools. Ten percent of schools either do not teach pharmacogenomics or are currently evaluating how to best incorporate it into their curriculum.

CONCLUSIONS: These survey results provide insight to schools and colleges of pharmacy to help ensure that all pharmacists have sufficient training in oncology to provide competent care to patients with cancer.

81E. Using standardized colleagues to develop interprofessional communication skills. *Susan Meyer, Ph.D.*[1], Hollis Day, M.D.[2], Helen Burns, Ph.D.[3]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)University of Pittsburgh School of Medicine, Pittsburgh, PA; (3)Excela Health, Greensburg, PA

PURPOSE: Interprofessional communication is a critical element to patient care. This study compared two methods of teaching pharmacy students how to communicate with physicians in challenging scenarios: standardized colleagues (adaptation of standardized patients) and video triggers/group discussions.

METHODS: In spring 2010, 57 students interacted with medical faculty as standardized colleagues portraying particular professional roles, attitudes, and communication styles. Pharmacy and medical faculty provided feedback on demonstrated behaviors impacting communication effectiveness. Forty-seven (47) students viewed videos demonstrating interprofessional interactions and participated in facilitated discussions of the demonstrated interprofessional communication skills. A self-evaluation of comfort and confidence in communication skills adapted from a validated instrument was administered at baseline, three, and six months. Students completed an evaluation of the perceived helpfulness of the activity. Data from students with scores on all three time points were used in the analysis (n=92) using paired samples *t*-tests. An independent samples *t*-test was performed to determine differences in mean scores for the activities. The activity was repeated in spring 2011. Analysis focused on student perceptions of the teaching strategy for the purposes of improving interprofessional communication skills.

RESULTS: Results of the repeated measures ANOVA demonstrated an increase in comfort and confidence over time ($F=42.508$, = 2, $p<0.001$). Paired samples t-tests showed a significant increase between baseline and three months ($t =-7.615$, 99, $p<0.001$). An independent samples t-test revealed a significant difference in helpfulness, confidence, and comfort between the video and

standardized colleagues methods (t=-2.396, 82.69, p=0.019). Student feedback regarding the standardized colleague teaching strategy was overwhelmingly positive.
CONCLUSIONS: Using standardized colleagues can enhance students' abilities to communicate effectively in challenging situations.
Presented at Collaborating Across Borders III, Tucson, AZ, November 19–21, 2011.

82. Student Perceptions of Large Scale Interprofessional Education Events. *John E. Murphy, Pharm.D.*[1], Lynne Tomasa, Ph.D.[2], Andreas Theodorou, M.D.[2], Cathleen Michaels, Ph.D., RN[3], Nancy Coleman, B.S.[2], Doug Taren, Ph.D.[4]; (1)The University of Arizona College of Pharmacy, Tucson, AZ; (2)The University of Arizona College of Medicine, Tucson, AZ; (3)The University of Arizona College of Nursing, Tucson, AZ; (4)The University of Arizona College of Public Health, Tucson, AZ
PURPOSE: The Interprofessional Education Collaborative recently released its "Core Competencies for Interprofessional Collaborative Practice." Interprofessional Education (IPE) events at the University of Arizona Health Sciences Center have been designed to develop many of these competencies over the last six years. Student evaluations of the value of the events were collected and used to enhance future events.
METHODS: IPE events on communication and culture, disabilities, team behavior during cardiopulmonary resuscitation, and pandemic influenza were conducted for students from medicine, nursing, pharmacy, public health, and, in some cases, law and social work. The number of participants ranged from ~300 to 450 per event. Participants completed either a paper or online evaluation after each event. A consistent set of questions as well as questions specific to each event were used. Students also provided comments on what they liked and disliked.
RESULTS: All sessions led to improvements in student perceptions of their knowledge of the topics covered and understanding of the value of teamwork based on their before and after assessment. For example, pharmacy students rated their understanding of disruptive behaviors and the impact on teamwork as somewhat high or high before (69%) and after (100%) the activity. Occasionally there were differences in ratings based on profession, but these tended to be fairly small. Student comments tended to be constructive and targeted towards improvement. Occasionally students' complained that some members of small group discussions didn't participate well or that their time should be spent studying.
CONCLUSION: The IPE events were generally rated well by students across the professions. Before and after comparisons showed increased understanding of the issues covered in the sessions and students had greater appreciation of the importance of working together as an effective team. Further research should focus on whether such programs lead to better teamwork in practice.

83. Evaluation of pharmacy students' clinical interventions and estimated cost avoidance during a general medicine rotation. Daniel R. Stevens, B.S.[1], *Adam B. Woolley, Pharm.D., BCPS*[2], Michael T. Brennan, Pharm.D.[3]; (1)Northeastern University, Boston, MA; (2)Northeastern University Department of Pharmacy Practice, Boston, MA; (3)VA Boston Healthcare System, West Roxbury, MA
PURPOSE: To determine the estimated institutional cost avoidance resulting from pharmacy student interventions during an internal medicine rotation at an academic teaching hospital.
METHODS: Quantifi® is a clinical intervention database tool utilized by both pharmacists and pharmacy students. Fourth-year professional (P4) students were asked to document all interventions performed while completing their six-week general medicine Advanced Pharmacy Practice Experience (APPE). Quantifi® was retrospectively reviewed for interventions recorded by 17 students during a 36-week period between August 2010 and June 2011. Interventions were then evaluated by associated cost avoidance estimated by the intervention system, intervention category, and drug class.
RESULTS: A total of 727 interventions were recorded over the course of the study period. The Quantifi® algorithm generated an estimated total cost avoidance of $55,879. The most common intervention categories reported were dose evaluations (11.4%), recommendation for medication change or addition (10.3%), and medication reconciliation (8.7%). The intervention categories associated with the greatest cost avoidance were dose evaluation ($12,393), warfarin dosing ($5,355), and insulin dose titration ($4,437). A total of 198 unique medications were cited in the interventions. The four most commonly documented medications accounted for 29.9% of total interventions, and were associated with the most significant cost avoidance: warfarin ($8,274), vancomycin ($5,894), insulin ($5,126), and heparin ($1,866).
CONCLUSION: Fourth-year professional Doctor of Pharmacy students on APPEs represent a valuable resource to academic teaching hospitals and have the potential to make a significant contribution to overall cost avoidance and patient care.

84. Knowledge and attitude of clinical pharmacy faculty towards, and issues related to behind-the-counter drug program. *Vishal Bali, M.S.*, Digvijay Yeola, M.B.A., Sujit S. Sansgiry, Ph.D.; Department of Clinical Sciences and Administration, College of Pharmacy, University of Houston, Houston, TX
PURPOSE: Clinical pharmacy faculty members provide information and train pharmacy student's on Behind The Counter (BTC) drugs. The objective of this study was to determine knowledge and attitude of clinical pharmacy faculty towards, and issues related to BTC drug program. This study helps to identify factors that need to be addressed to develop and implement a strong BTC drug program.
METHODS: A prospective cross-sectional study using an online survey was conducted. Six hundred fifty clinical pharmacy faculty members from different practice settings were randomly selected for an electronic survey and responses were collected anonymously by using Qualtrics™. Knowledge and attitude of clinical pharmacy faculty were measured using previously validated scales adapted to our study. Data on respondent characteristics, and issues concerning BTC drug program were also collected. We hypothesized that clinical pharmacy faculty would have good knowledge and positive attitude towards BTC drug program. Statistical analyses were performed using SAS statistical package.
RESULTS: A total of 128 completed responses were received (20% response rate). Majority of participants (85%) were found to have fair knowledge regarding the BTC drug program (53.20%). Most (91%) felt the need for BTC drug program, and indicated that such a program would increase patient safety (81%). Respondents supported the need for private counseling areas within the pharmacy (93%), adequate counseling fee (87%), and proper reimbursement provisions (97%) for implementing a good BTC drug program. Sixty five percent of the participants agreed that pharmacy students should be trained to prescribe and dispense BTC drugs.
CONCLUSION: Clinical pharmacy faculty members had fair knowledge and positive attitude towards the BTC drug program. They need to improve their knowledge about BTC drug program so as to better train pharmacy students in providing BTC drug services. Considerations may be needed in evaluating pharmacy design and reimbursement provisions for BTC programs.

85. Faculty development activities in US pharmacy schools. Holley Rice, Pharm.D., *Michael G. Kendrach, Pharm.D., B.S.Pharm., FASHP*; McWhorter School of Pharmacy, Birmingham, AL
PURPOSE: Survey US schools of pharmacy to identify their faculty development program (FDP) content and requirements. Literature describing faculty development within health sciences has been published. However, specific information addressing pharmacy FDP is limited and FDP details from schools of pharmacy (SoRx) have not been published recently.
METHODS: An online survey consisting of 21 multiple-choice and 2 short-answer questions was created (surveymonkey.com) and reviewed by three school of pharmacy faculty. The Academic Deans of 106 US SoRx were identified via the American Association of Colleges of Pharmacy (AACP) website and sent an email requesting the best person at the SoRx to complete the survey. Samford University IRB approved this research.
RESULTS: A total of 38 surveys (35.8%) were completed with an equal number of responders from private and public SoRx. While many (71%) SoRx have a formalized FDP, 55.3% do not require

faculty to complete FDP activities, only 31.6% have a highly individualized FDP for each faculty that is approved by the SoRx, and 44.7% of faculty complete FDP activities at their own discretion without any oversight by SoRx. Although 55.3% include FDP activities in annual performance reviews, 65.8% do not factor FDP accomplishments in annual merit pay raises and most faculty do not want FDP part of the annual performance review. Few (34.2%) SoRx have assessed their FDP. The primary FDP activities (≥ 90% of responders) are scholarship/publications, teaching/pedagogy, active learning methods, test writing skills, and technology.
CONCLUSION: FDP are common at US SoRx, but faculty are not required to participate and many are not tailored to individual faculty needs. A formalized FDP should be established at each SoRx that is continually evolving and enables faculty to improve and fulfill the current requirements and definition of a faculty member. These data can be used in developing the SoRx FDP.

86. Pre-pharmacy biomedical literature experience: a survey of pharmacy student self-perception and ability to identify literature types. *Valerie A. Coppenrath, Pharm.D.*, Evan R. Horton, Pharm.D., Kimberly A. Pesaturo, Pharm.D.; Massachusetts College of Pharmacy and Health Sciences, Worcester, MA
PURPOSE: The purpose of this study is to characterize previous experiences with biomedical literature of students entering their first year of an accelerated doctor of pharmacy program.
METHODS: The primary objective of this study was to determine if correlations existed between student self-assessment of knowledge regarding sources of biomedical literature and ability to identify specific literature types. The secondary objective was to characterize students' previous experience with biomedical literature. A 17-question survey was distributed to 280 first-year pharmacy students at orientation. Participants were asked to indicate if they understood differences between primary, secondary, and tertiary literature, and were then asked to demonstrate understanding using three multiple choice questions. Participants who correctly responded to all three multiple choice assessment questions were considered "able to identify types of biomedical literature." Additionally, participants reported on previous biomedical literature experience.
RESULTS: Two hundred and forty-nine students completed the survey, and 237 students responded to the survey item regarding understanding differences between primary, secondary, and tertiary literature. One hundred thirty-seven participants (57.8%) indicated understanding, while 100 participants (42.2%) indicated non-understanding. Of the 137 students who indicated understanding, 19 students (13.9%) correctly identified types of biomedical literature; of the 100 students who reported non-understanding, 8 students (8%) correctly identified types of biomedical literature (OR 1.85, 95% CI 0.78 to 4.42). Two hundred and sixteen (86.7%) participants reported previously having been asked to read biomedical literature in their academic career.
CONCLUSION: Students reporting an understanding of the difference in literature types were no more likely to correctly identify literature types when compared to participants who reported not understanding. Students entering the accelerated Doctor of Pharmacy degree program reported varying degrees of instruction and exposure related to biomedical literature. Faculty teaching courses related to biomedical literature may consider these findings when developing course content.

87. Pharmacy student knowledge retention after completing a simulation utilizing high-fidelity mannequins compared to a written patient case. *Douglas Wylie, Pharm.D.*[1], Shaunta' Ray, Pharm.D., BCPS[2], Andrea S. Franks, Pharm.D., BCPS[2], A. Shaun Rowe, Pharm.D., BCPS[2]; (1)The University of Tennessee Medical Center, Knoxville, TN; (2)The University of Tennessee College of Pharmacy, Knoxville, TN
PURPOSE: To determine if participation in a simulated patient case improves knowledge retention and students' comfort level when compared to a written case.
METHODS: This was an IRB exempt, parallel group, randomized controlled trial. Students were randomized to either a simulation mannequin scenario or written patient case. The case involved the identification, triage and treatment of an oxycodone and acetaminophen overdose. Students were administered a multiple-choice test and a survey assessing the students' comfort before the case, immediately after the case, and twenty-five days later.
RESULTS: Twenty-six students were included in the study. There was no difference in knowledge retention or comfort level between the groups. A statistical difference was seen in test scores when comparing pretest to posttest, $p<0.01$. Participation in a simulated patient case did not improve knowledge retention or comfort with the material when compared to traditional patient cases.
CONCLUSION: Though no statistical differences were seen in the mannequin group vs. written patient case group, both instruction methods effectively improved knowledge retention.

88. Evaluating the impact of implementing pharmacy cardiology rounds on student exam performance in a pharmacotherapeutics course. *Fae Wooding, Pharm.D.*[1], Michael Steinberg, Pharm.D.[1], Kristine C. Willett, Pharm.D.[2], Jennifer L. Donovan, Pharm.D.[1], Abir O. Kanaan, Pharm.D.[1]; (1)Massachusetts College of Pharmacy and Health Sciences, Worcester, MA; (2)Massachusetts College of Pharmacy and Health Sciences, Manchester, NH
PURPOSE: Historical examination performance of students in our Pharmacotherapeutics course has indicated the cardiology module is challenging to students in our accelerated Doctor of Pharmacy Program. This course, which is taught utilizing distance education, is facilitated with a learner-centered, active-learning, case-based approach. Pharmacy cardiology rounds were incorporated to provide students an opportunity to further review and apply their conceptual knowledge prior to exams. The purpose of this study is to evaluate the impact of pharmacy cardiology rounds on student exam performance.
METHODS: Instructors submitted questions that were formatted into a faculty member-facilitated question and answer session held 2 days prior to the scheduled exam. During the cardiology rounds session, instructors proffered cardiology-related clinical scenarios and questions based on material from previous classes and self-study packets. Student attendance for the session was documented using the TurningPoint response system. Mean exam scores were calculated for students that attended cardiology rounds (attendees) and compared to those who did not attend (absentees). The scores were also evaluated within each of our two campuses. A two tailed-test was used to analyze the data for statistical significance of any differences identified.
RESULTS: A total of 166 students attended cardiology rounds. The mean exam score for attendees was 77.5% compared to 71.7% for absentees ($P<0.001$). Mean scores of attendees on the local campus performed better than absentees (77.4% vs. 72.0%; $P<0.001$). A significant difference was not observed on the distance campus (attendees, 77.7% vs. absentees, 70.0%; $P=0.09318$).
CONCLUSION: Students who attended cardiology rounds performed significantly better on subsequent examination compared to students who did not attend the sessions. Inclusion of a similar pharmacy rounds should be considered for other pharmacotherapeutic modules.

89E. Development and evaluation of a rubric to assess value of student WIKI contributions. *Bonnie A. Falcione, Pharm.D., BCPS*, Denise L. Howrie, Pharm.D., Susan M. Meyer, Ph.D.; University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Available quantitative assessment tools may not sufficiently measure individual student performance on WIKI-based group activities. This study aimed to develop and evaluate a rubric to assess the value of an individual student's contributions to WIKI-based collaborative cased-based group work.
METHODS: A rubric to assess "value" of individual student's WIKI contributions was developed and tested during a collaborative case-based activity in a pharmacotherapy course. Independent rubric application by two faculty members to 10 randomly selected student's work indicated initial reliability. A revised rubric was applied to the work of 30 randomly selected students. Faculty reviewed and scored each contribution with the rubric then assigned an "Overall Value" for each student. A Composite Score was calculated for each student from weighted contribution scores. Reliability of these measures and correlation with available quantitative assessment measures of student performance was evaluated with Spearman's Rank and Pearson Correlation.

RESULTS: A rubric modeled upon Bloom's Taxonomy with a 4-point value scale and six domains was created to evaluate student WIKI contributions. Comparison of the 30 student Overall Value scores demonstrated 66.7% rater concordance and moderate inter-rater reliability (κ=0.428, SE=0.143; p=0.003, 95%CI=0.148-0.707). A strong correlation was found for the raters' assigned Overall Values (r=0.603, p<0.001), the calculated Composite Scores (r=0.731, p<0.001) and these measures were also well correlated (r=0.421, p=0.023). A weak negative correlation was found for Composite Score and pages saved (r=-0.163, p=0.40), group grade (r= 10.153, p=0.42), and peer evaluations (r=-0.106, p=0.58). Faculty spent a median of 6–10 minutes (IQ range 6–15min) to evaluate a student's total WIKI contributions.
CONCLUSION: This unique Bloom's Taxonomy based WIKI rubric generated moderately reliable measures of individual student WIKI contributions to group work. A WIKI rubric may provide a better assessment of individual student performance than existing methods.
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Emergency Medicine

90. The combination of Prothrombin Complex Concentrate, Factor VIIa, and Phytonadione to reverse elevated international normalized ratio. *Bryce J. Bitton, Pharm.D.*, Kevin P. Myers, Pharm.D., C. Dustin Waters, Pharm.D.; McKay-Dee Hospital, Ogden, UT
PURPOSE: Little dosing consensus exists for clotting factor replacement in patients with elevated international normalized ratio (INR). This study analyzes the efficacy, dosing, and thrombogenicity of the combination of Prothrombin Complex Concentrate (PCC), Factor VIIa, and Phytonadione for lowering INR.
METHODS: Medical records of the 22 total protocol doses given were reviewed to assess dosage, baseline INR, resulting INR, and incidence of thromboembolism. Patients with an initial INR of 1.5-4.0 received PCC 25 units/kg Ideal Body Weight (IBW) and those with an INR > 4.0 received PCC 50 units/kg IBW (all PCC doses rounded to the nearest vial size). All patients received Factor VIIa 1 mg and Phytonadione 5–10 mg IV.
RESULTS: The protocol reduced INR to ≤ 1.3 in patients with an initial INR ≥ 1.5 (range 1.5-13.2) in 100% of cases. The mean baseline INR was 3.4 and resulting INR was 0.9. Fourteen patients (64%) had a resulting INR < 1. The mean PCC dose was 1938 units (28.6 units/kg IBW) for patients with an INR 1.5-4.0 and 2765 units (36 units/kg IBW) for patients with INR > 4.0. Thromboembolism occurred in 4 patients (18%).
CONCLUSION: The protocol is effective at quickly lowering INR in patients with an elevated INR. Dosing PCC based on INR and IBW appears to be appropriate. Thromboembolism is a genuine concern when giving clotting factor replacement. Based on the effectiveness of this protocol at lowering INR, the number of patients with a resulting INR < 1, and the cases of thromboembolism, further INR stratification and lower PCC doses should be considered.

91. Retrospective Review of NPO Status in Children Receiving Ketamine for Procedural Sedation in the Emergency Department. *Megan E. Foster, Pharm.D.*; Le Bonheur Children's Medical Center, Department of Pharmacy, Memphis, TN
PURPOSE: Guidelines for moderate sedation recommend fasting from liquids for two hours and solid food for eight hours. Strict adherence to these guidelines is difficult in the emergency department (ED). Recent studies have demonstrated no association between fasting times and adverse events. Our purpose is to evaluate pre-procedural fasting times and identify any adverse effects.
METHODS: We conducted an 18-month retrospective review of NPO status in patients who received procedural sedation in the ED from January 2010 to June 2011. Patients who received ketamine were identified utilizing computerized physician order entry (CPOE) and electronic medical record (EMR) data. Patients were excluded if sedation occurred in the operating room (OR), or if NPO status was not documented. NPO status and any adverse events that occurred were assessed to determine what our current practice entails.
RESULTS: A total of 318 patients were identified, of which 10 were excluded due to receiving sedation in the OR. Of the 308 included patients, NPO status was attainable by chart review in all patients. Patients ranged from 18 months to 17 years of age. Overall, 95% of patients sedated were by conservative NPO guidelines. Physicians who followed last liquid intake leaned towards waiting 4 hours versus the recommended 2 hours, whereas time from last solid food intake remained at 8 hours. In addition, 77% of procedural sedations occurred between 2000 and 0800, indicating a pattern in following conventional NPO guidelines, based on midday and evening meals. Nausea or vomiting occurred in 4% of patients, however all patients were 8 hours past their last oral intake.
CONCLUSION: Our ED physicians practice in accordance with traditional NPO guidelines. Further evaluation is needed to determine this impact on length of stay, staffing, and patient safety. Current guidelines should be re-evaluated based on recent literature support for reduced NPO times.

92. Incidence and characteristics of antithrombotic errors in the emergency department. Aaron J. Prince, Pharm.D.[1], *Stephen Rolfe, Pharm.D., BCPS*[2], Jeffrey Dandurand, Pharm.D., BCPS[3], Kimberly A. Pesaturo, Pharm.D., BCPS[4]; (1)UMass Memorial Medical Center, Worcester, MA; (2)University of New England, College of Pharmacy, Portland, ME; (3)Clinical Pharmacy Associates, Laural, MD; (4)Massachusetts College of Pharmacy and Health Sciences - Worcester/Manchester, Worcester, MA
PURPOSE: The goal of this study was to identify and characterize the incidence of antithrombotic errors by review of patients' medical records in an emergency department (ED) at a large academic medical center.
METHODS: All patients admitted to the emergency department between January 2010 and April 2010 with an order for one or more antithrombotic agents were considered for inclusion. An independent pharmacist abstracted demographic and medication-related data from the medical record for included patients. Next, two independent pharmacists evaluated the abstracted data for the presence of medication errors. If consensus was not reached between the two pharmacists, a third pharmacist was utilized to determine if an error was present. The primary endpoint was to determine the incidence of antithrombotic-related medication errors that occur in the ED. Secondary endpoints included categorization of errors by stage in the medication use process and by severity according to the NCC-MERP algorithm.
RESULTS: Of the 1550 antithrombotic orders identified, 957 met inclusion criteria, of which 432 were evaluated. Errors were present in 22.7% of the orders, most commonly occurring with heparin (46.5%), enoxaparin (28.1%), and warfarin (18.4%). The majority of errors (84.2%) transpired during the prescribing and ordering stage of the medication use process. Errors reached the patient 79.8% of the time with 14.3% experiencing temporary harm which required additional monitoring or medical intervention. Additionally, the most common sources or error were under-dosing, improper date and time documentation, no base line INR, and over-dosing. Lack of obtaining a patient's weight contributed to 32.7% of the orders written in error.
CONCLUSION: Errors were identified in over one-fifth of antithrombotic orders in the ED over the four-month study period. The majority of errors identified occurred during the prescribing and ordering stage. The majority of identified errors reached the patient, however only a small subset required intervention.

93. Intranasal Fentanyl and Midazolam Use in a Pediatric Emergency Department. *Megan E. Foster, Pharm.D.*; Le Bonheur Children's Medical Center, Department of Pharmacy, Memphis, TN
PURPOSE: Intranasal medication delivery is a fast and effective administration route, particularly in the emergency department (ED). Our ED recently implemented intranasal use of fentanyl and midazolam for short term procedures. This review identifies indications for intranasal medication use, dosing ranges, and any adverse effects observed.
METHODS: Patients who received nasal fentanyl or midazolam in the ED between April 1st–June 1st, 2011 were identified utilizing computerized physician order entry (CPOE) and electronic medical record (EMR) data. Patient age, indication for medication, dose ranges, adverse effects, and discharge status were evaluated. ED staff satisfaction and patient and family satisfaction with nasal medication

delivery versus alternative methods were evaluated through anonymous surveys.
RESULTS: A total of 102 patients were identified during the 2-month study period. The most common indications for intranasal medication delivery were abscess incision and drainage, laceration repair, and intravenous (IV) access and foley catheter insert. Several patients received pain control or anxiolysis with intranasal medication before IV access could be attained. Midazolam demonstrated to be most effective at 0.2–0.5 mg/kg/dose and fentanyl at 2–4 μg/kg/dose. Adverse effects included rash in one patient, which resolved with oral diphenhydramine, and paradoxical agitation to midazolam in one patient, which resolved with no intervention. The majority of patients were discharged home with no complications and positive experiences, according to ED staff, patient, and family satisfaction surveys.
CONCLUSION: Intranasal fentanyl and midazolam are advantageous alternatives to oral or intramuscular (IM) pain or anxiolysis medications, particularly in the ED. With a fast onset and short duration of action, many short procedures or exams can be performed effectively and quickly without waiting for oral or IM medication onset of action. Further medications should be evaluated for intranasal use in the ED.

Endocrinology

94. Utilization of home telehealth monitoring with active medication management by clinical pharmacists in poorly controlled diabetic patients. *Kristen J. Davis, Pharm.D.*[1], Jessica L. Wallace, Pharm.D.[1], Jim Wan, PhD[2], M. Shawn McFarland, Pharm.D.[1]; (1)Veterans Affairs Tennessee Valley Healthcare System, Nashville, TN; (2)University of Tennessee Health Sciences Center, Memphis, TN
PURPOSE: This study assessed the change from baseline in A1C over 6 months in a cohort of diabetic patients through medication management performed by a clinical pharmacy specialist (CPS) with telehealth intervention compared to a cohort without telehealth intervention. The percentage of patients meeting American Diabetes Association (ADA) treatment goals for A1C, amount of time spent, and the number of diabetic medication changes made were assessed.
METHODS: Records were reviewed in 103 type 2 diabetics on insulin therapy with an A1c >7% seen by a CPS between October 1, 2008 and April 1, 2010, and with two follow-up visits with the CPS. Patients were divided into those enrolled in telehealth versus those who were not. The A1c values at baseline, three and six months (±45 days) were documented as were the number of non face-to-face encounters and diabetic medication changes made by the CPS.
RESULTS: Baseline demographics were similar between groups with an initial A1c of 9% and 9.1% in the telehealth (n=36) and control groups (n=67), respectively (p=0.621). Telehealth versus control patients demonstrated a significant difference in mean A1c at three (7.2% vs. 8.0%, p=0.0002) and six months (6.9% vs. 7.5%, p=0.0066). The mean reduction in A1c from baseline to six months was not significant (p=0.1987). 69% of the telehealth group vs. 36% of the control group achieved the A1c goal of less than 7% (p=0.0011). More time was spent (p<0.001) and more diabetic medication changes were made (p<0.0001) in the telehealth group.
CONCLUSION: Management of diabetic patients on insulin may be optimized via CPS utilization of telehealth. Though no statistically significant difference was seen regarding mean change in A1c from baseline to six months, telehealth intervention did show significant differences in A1c at three and six months coupled with higher achievement of ADA A1c goals after six months.

95E. Trends in hyponatremia management and associated outcomes in hospital settings: Interim results from an observational, prospective, multi-center, global registry in hospitalized patients. *Joseph Dasta, M.S., R.Ph.*[1], Alpesh Amin, M.D.[2], Jun Chiong, M.D.[3], Arthur Greenberg, M.D.[4], Paul Hauptman, M.D.[5], Joseph G. Verbalis, M.D.[6]; (1)College of Pharmacy, The Ohio State University, Columbus, OH; (2)UC Irvine College of Medicine, Irvine, CA; (3)Loma Linda University, Loma Linda, CA; (4)Duke University Medical Center, Durham, NC; (5)St. Louis University School of Medicine, St. Louis, MO; (6)Georgetown University Medical Center, Washington, DC
PURPOSE: Although hyponatremia (HN) is the most common electrolyte abnormality in hospitalized patients, little is known regarding the influence of HN and its management on patient outcomes and healthcare resource usage. The HN Registry is a novel prospective effort to document the clinical and healthcare outcomes of HN and its management. The first 25 HN patients enrolled are described here.
METHODS: After informed consent or waiver, data were extracted from medical charts of enrolled patients. HN was defined as a serum sodium ≤ 130 mmol/L. The pilot data were summarized appropriately by sample size and for categorical data by percentage. Subjects who had HN on admission were categorized as pre-existing HN patients and those who were admitted for another reason and developed HN while in the hospital were categorized as hospital-acquired HN patients.
RESULTS: Overall, only 20% of the enrolled patients received any pharmacologic management for HN and approximately 44% were discharged with persistent HN (21% of treated vs. 79% of untreated). Among the patients discharged with HN, 55% had a previous episode of HN. In addition, among the patients with previous HN, 46% were discharged with persistent HN. The length of stay for patients with pre-existing HN was 1.3 days longer compared to patients with hospital-acquired HN. These findings will be further evaluated and reported as more data in this large registry study are accumulated.
CONCLUSION: Among hospitalized patients, HN is frequently untreated, and nearly half of patients are discharged without normalization of serum sodium. HN commonly persists through several hospital admissions.
Presented at Presented at the International Society for Pharmacoeconomics and Outcomes Research meeting, Baltimore, MD, May 22–25

96E. Dapagliflozin Monotherapy and Combination Therapy Reduces Hyperglycemia in Patients with Type 2 Diabetes. *John R. White Jr., Pharm.D., PA-C*[1], Arnaud Bastien, M.D.[2], Shamik Parikh, M.D.[3], Veronika Hruba, M.D.[4], Afshin Salsali, M.D.[2], Lisa Ying, Ph.D.[2], Jennifer Sugg, M.S.[3], James F. List, M.D., Ph.D.[2]; (1)Washington State University, Spokane, WA; (2)Bristol-Myers Squibb, Princeton, NJ; (3)AstraZeneca, Wilmington, DE; (4)AstraZeneca, Prague, Czech Republic
PURPOSE: Dapagliflozin (DAPA), a selective inhibitor of the renal sodium-glucose co-transporter 2, reduces excess plasma glucose independently of insulin secretion or action, by inhibiting renal glucose reabsorption, thereby increasing glucose excretion. Efficacy and safety data were analyzed from
METHODS: Patients were treated with DAPA 2.5, 5, or 10 mg or placebo once daily for 24 weeks as monotherapy in drug-naïve patients (Study 1, NCT00528372, N=485 [main cohort n=274]), as add-on therapy to GLIM (Study 2, NCT00680745, N=596), or as add-on therapy to MET (Study 3, NCT00528879, N=546). The primary
RESULTS: DAPA significantly
CONCLUSIONS: Dapagliflozin significantly improved glycemic control and reduced body weight, and
Presented at Presented at the Annual Physician Assistant Conference (AAPA-IMPACT), Las Vegas, NV, May 30–June 4, 2011.

97E. Linagliptin effectively reduces HbA1c independent of age in patients with type 2 diabetes. Marc Rendell, M.D.[1], Steven Chrysant, M.D.[2], Angela Emser, M.D.[3], Max von Eynatten, M.D.[3], Sanjay Patel, MB, ChB[4], *Angelina Trujillo, M.D.*[5], Hans-Juergen Woerle, M.D.[3]; (1)Creighton Diabetes Center, Omaha, NE; (2)Oklahoma Cardiovascular and Hypertension Center and University of Oklahoma School of Medicine, Oklahoma City, OK; (3)Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany; (4)Boehringer Ingelheim Corporation, Bracknell, United Kingdom; (5)Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT
PURPOSE: Previous studies have identified age as an underlying cause for heterogeneity of treatment response with antidiabetic agents. We analyzed pooled data from >2,000 linagliptin-treated patients to evaluate whether age had any effect on safety and efficacy of this DPP-4 inhibitor.
METHODS: Identical endpoints, dosing, and large cohort size

(N=2,258) in 3 randomized, double-blinded, placebo-controlled studies facilitate subgroup analyses (post-hoc) by pooled dataset. The 24-week primary efficacy outcome in all studies was mean change from baseline HbA1c. Any adverse events (AEs) were recorded. Age-based patient subgroups were: ≤50 (n=550), 51-64 (n=1134), 65-74 (n=465), and ≥75 years (n=75). **RESULTS:** Mean baseline BMI was 29.0±4.9 kg/m^2. Patients were 58% White, 42% Asian, and 50.4% female. Overall, 57% had diabetes duration >5 years. Mean baseline HbA1c (±SD) was 8.1% (±0.8). Mean ages for subgroups were 44±5, 58±4, 69±3, and 77±1 years. The pooled analysis of efficacy showed significant placebo-corrected HbA1c reductions with linagliptin in all subgroups, with no age effect on efficacy (P=0.48) and no age-treatment interaction (P=0.65). Mean adjusted, placebo-corrected changes from baseline HbA1c (±SE) were -0.58±0.08 (age ≤50), -0.68±0.06 (age 51–64), -0.60±0.09 (age 65–74), and -0.77±0.24 (age ≥75). Overall AE incidence among linagliptin-treated patients was similar to or less than placebo across subgroups. Serious AE rates were 2.5%, 3.1%, 4.3%, and 3.3% for linagliptin-treated patients, versus placebo: 3.7%, 2.6%, 4.8%, and 6.7%. Hypoglycemia incidence was 8.3%, 11.8%, 12.1%, and 28.3% for linagliptin subgroups, versus placebo: 4.3%, 7.2%, 12.9%, and 20%. However, hypoglycemia incidence was <1% in linagliptin monotherapy or metformin (MET) add-on studies. Increased frequency (>1%) of hypoglycemia only occurred in the study using MET+sulfonylurea as background. No linagliptin-related safety concerns were identified.
CONCLUSION: Linagliptin safety/efficacy did not differ among age groups. Linagliptin was effective for treating T2DM in all subgroups (including elderly), with safety profile comparable to placebo.
Presented at Presented at the 93rd Annual Meeting of the Endocrine Society, Boston, MA, June 4–7, 2011. Poster P3-497.

98. The effect of basal-bolus insulin vs. sliding scale insulin on quality indicators in hospitalized patients with type 2 diabetes mellitus on hemodialysis. *Francine D. Salinitri, Pharm.D.*[1], Neha Desai, Pharm.D.[2], Teuta Karanfili, Pharm.D., Candidate[1], David W. Satterthwaite, Pharm.D. Candidate[1], Opada Alzohaili, MD[3], David A. Wilpula, Pharm.D., BCPS[2]; (1)Wayne State University, Detroit, MI; (2)Oakwood Hospital and Medical Center, Dearborn, MI; (3)Sinai Grace Hospital, Detroit, MI
PURPOSE: Clinical trials evaluating the use of basal-bolus insulin (BBI) in hospitals often exclude patients with end-stage renal disease (ESRD). The aim of this study is to assess the effectiveness and safety of BBI treatment in hospitalized patients with type 2 diabetes mellitus (DM) and ESRD.
METHODS: This is a nonrandomized retrospective paired cohort study of hospitalized patients with type 2 DM and ESRD who received separate courses of BBI and sliding scale insulin (SSI) treatments at distinct time periods between January 2008 and May 2011. Patients were identified from coding reports of hemodialysis and insulin therapy. Patients received at least 3 days of insulin therapy in each treatment arm. The study excluded patients with age < 18 years, type 1 DM, previous solid organ transplant, or concomitant use of other hypoglycemic agents. Demographics, point of care glucose, diet, and medication administration records were collected for analysis. Outcome measures included quality indicators for glycemic control recommended by the Society of Hospital Medicine. A 1-tailed paired student's t-test was used for all statistical measures.
RESULTS: Seventeen patients were included in the analysis. BBI treatment improved unadjusted quality indicators of effectiveness: patient days with mean glucose < 140 mg/dL (10.9% vs 29.7%, p=0.024), patient days with mean glucose < 180 mg/dL (36.2% vs 63.0%, p=0.006) and patient days with glucose measurements > 300 mg/dL (22.0% vs 10.4%, p=0.046). Although not statistically significant, patients experienced more hypoglycemia (4.5% vs 10.9%, p=0.184), including one episode of severe hypoglycemia, during BBI treatment.
CONCLUSION: From a quality perspective, BBI significantly improved indicators of effectiveness and negatively impacted indicators of safety. BBI treatment may be a preferred therapeutic strategy for hyperglycemia management in hospitalized patients on hemodialysis, however caution should be taken to minimize the incidence of hypoglycemia.

99. Association between vitamin D deficiency and diabetic retinopathy in the Third National Health and Nutrition Examination Survey. *Luigi Brunetti, Pharm.D.*[1], Saira Choudry, Pharm.D.[1], Djibril S. Camara, M.D.[2], Jianming He, M.A., MEdev, M.S.[2]; (1)Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey, Piscataway, NJ; (2)University of Medicine and Dentistry of New Jersey, Piscataway, NJ
PURPOSE: This study was conducted to investigate if an association exists between serum 25-Hydroxyvitamin D (25OHD) deficiency and diabetic retinopathy (DR).
METHODS: A total of 847 subjects with self-reported diabetes mellitus (DM), aged 40 years or older from the Third National Health and Nutrition Examination Survey (NHANES III) were included in the analysis. The exposure of interest was deficiency in serum 25OHD (defined as < 20 ng/mL) and the outcome of interest was a composite of mild, moderate, or proliferative DR. Logistic regression was used to assess the association and account for potential confounders. The following covariates were included: age, gender, race, systolic blood pressure (SBP), DM duration, and hemoglobin A1c (HbA1c) level.
RESULTS: Subjects with acceptable serum 25OHD levels were 24% less likely to have DR; however, the reduction did not reach significance (OR=0.76; 95% CI: 0.49, 1.17). Likewise, after adjusting for SBP and DM duration, the association remained (OR=0.71; 95% CI: 0.44, 1.14). HbA1c was found to be an effect modifier; therefore, the analysis was stratified by HbA1c (≤ 7% or > 7%). After adjusting for SBP and DM duration, subjects with an HbA1c ≤ 7% with sufficient serum 25OHD were 64% less likely to have DR (OR=0.36; 95% CI: 0.16,0.80). The association was not observed in subjects with a HbA1c > 7% (OR=1.15; 95% CI: 0.63, 2.20).
CONCLUSION: Based on the results from this study, there may be a weak association between Vitamin D deficiency and DR for patients with DM in the U.S. After adjusting for SBP and duration of DM, subjects at goal HbA1c, with sufficient serum 25OHD, were less likely to have DR. Since cross-sectional data do not provide temporal relationships, further research is warranted in observing a relationship between 25OHD deficiency and DR.

Gastroenterology

100. Are proton pump inhibitors associated with the development of community acquired pneumonia: a meta-analysis. *Christopher A. Giuliano, Pharm.D.*[1], Sheila M. Wilhelm, Pharm.D., BCPS[2], Pramodini B. Kale-Pradhan, Pharm.D.[1]; (1)Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences and St. John Hospital and Medical Center, Detroit, MI; (2)Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences and Harper University Hospital, Detroit, MI
PURPOSE: Proton Pump Inhibitors (PPIs) are routinely utilized in both inpatient and outpatient settings. There are conflicting results that indicate PPIs are associated with pneumonia. This analysis will evaluate the association of PPI and community acquired pneumonia (CAP).
METHODS: This meta-analysis only included case controlled and cohort studies which were published in full in English and evaluated PPI use and CAP incidence. Studies were excluded if they included the following patients: pediatric, H.pylori treatment, and critically ill. PubMed was searched using the terms PPI, pneumonia, omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole. Hand searches of recent systematic reviews or other analyses or articles for additional references were completed. Quality of studies was assessed using the Newcastle Ottawa Quality Assessment Scale (NOQAS). Two investigators independently extracted data into standardized data collection forms which was confirmed by a third investigator. Data was analyzed based on current use of PPIs, duration of PPI use (< 30days, >180days), PPI dose (high versus low), and use of any acid suppressive therapy (Histamine2 Receptor Antagonist or PPI). Overall association of PPI and CAP was analyzed using the random effects model (Comprehensive Meta analysis® Ver 2.0).
RESULTS: Ten studies met all criteria. NOQAS scores ranged from 4-8 out of 9. Current use of PPIs (OR 1.39, 1.09–1.76), PPI use < 30days (OR 1.65, 1.25–2.19), PPI high dose (OR 1.50, 1.33–1.68) and PPI low dose (OR 1.17, 1.11–1.24) were significantly associated with CAP: There was no association between CAP and PPI use >180days

(OR 1.10, 1.00–1.21) or use of any acid suppressive therapy (OR 1.24, 0.99–1.55).
CONCLUSION: Patients currently receiving PPIs, particularly < 30days or high dose, showed an association with CAP. Practitioners need to be vigilant about adverse effects of PPIs and consider alternative therapies.

101E. A Multi-Center, Double-Blind, Parallel-Group Study to Evaluate Short-Term Safety and Efficacy and Long-term Maintenance of Two Dose Levels of Rabeprazole Sodium Delayed-Release Pediatric Bead Formulation in 1 to 11 Year-Old Pediatric Subjects with Endosco. *Gerhard J. Leitz, M.D., Ph.D.*[1], Ibrahim Haddad Sr., M.D.[2], Steven Silber, M.D.[3], Andrew Mulberg, M.D.[1]; (1)Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Titusville; (2)Pediatric & Adolescent Gastroenterology & Nutrition, Youngstown, OH, United States, OH; (3)Johnson and Johnson PRD, Titusville, NJ
PURPOSE: The primary objective of this study was to evaluate the efficacy and safety of two target dose level of a Rabeprazole Sodium Delayed-Release Pediatric Bead Formulation in pediatric subjects, 1 to 11 years of age with endoscopically proven gastroesophageal reflux disease (GERD).
METHODS: All subjects had to have a grade 1 or higher on the Hetzel and Dent and grade >0 on the Histological Reflux Esophagitis scales. Following screening, subjects were randomized in a multi-center, double-blind, parallel-group design to receive either 0.5 mg/kg or 1.0 mg/kg of Rabeprazole for 12 weeks. The primary endpoint was endoscopic/histological healing defined as grade 0 on the Hetzel & Dent Scale or grade 0 on the Histological Reflux Esophagitis Scale.
RESULTS: Thirty sites in the US, 38 sites in Europe and two sites in India randomized 127 subjects during 30-Jan-09 to16-May-2010. The overall healing rate after the 12-week treatment period was 81%: 78 % for 0.5 mg/kg and 83% for 1.0 mg/kg. Consistent with the endoscopic/histological healing rate, the frequency and severity of GERD symptoms decreased substantially. There was no apparent pattern between the two treatment arms regarding treatment emergent adverse events (TEAEs) and serious adverse events. The frequency of TEAEs was 74% for 0.5 mg/kg and 77% for 1.0 mg/kg.
CONCLUSIONS: Both, the 0.5 mg/kg and 1.0 mg/kg dose regimen of the Rabeprazole Sodium Delayed-Release Pediatric Bead Formulation were effective and safe in pediatric subjects, 1 to 11 years of age. The clinical effect and the safety profile were similar for both dose levels. No unexpected adverse events were reported in this population of children with endoscopically proven GERD.
Presented at Presented at DDW in Chicago, May 2011

Geriatrics

102. GFR equations overestimate creatinine clearance in elderly individuals enrolled in the NIA-Baltimore Longitudinal Study on Aging (BLSA). *Thomas C. Dowling, Pharm.D., Ph.D.*[1], John D. Sorkin, M.D., Ph.D.[2], Luigi Ferrucci, M.D., Ph.D.[3]; (1)Department of Pharmacy Practice and Science, University of Maryland School of Pharmacy, Baltimore, MD; (2)Division of Gerontology, University of Maryland School of Medicine, Baltimore, MD; (3)Biomedical Research Center, National Institute on Aging, Baltimore, MD
PURPOSE: Equations developed to estimate glomerular filtration rate (eGFR) have not been adequately validated for use in elderly individuals with impaired kidney function. The purpose of this study was to compare eGFR equations to creatinine clearance (CLcr) in a cohort of elderly participants in the NIA-BLSA study.
METHODS: A random cross-sectional sample of non-hospitalized BLSA study participants aged > 70 years who had 24-hour measured creatinine clearance (mCLcr) values < 70 mL/min and BMI < 40 kg/m^2 were evaluated. Kidney function was estimated using the Cockcroft-Gault (CG), Modification of Diet in Renal Disease Study (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations. The performance of eGFR equations was assessed by measuring bias and precision relative to mCLcr and CG.
RESULTS: The dataset included 269 participants aged 81±6 years with serum creatinine (Scr) of 1.2±0.3 mg/dL, body surface area of 1.8±0.2 m^2 and mCLcr of 53±13 mL/min. The CG equation (50±14 mL/min) was the only equation to provide an unbiased estimate of mCLcr. The MDRD and CKD-EPI were significantly positively biased compared to CG (+34±20% and +22±15%, respectively, p<0.001) and mCLcr (+29±47% and 18±40%, respectively, p<0.001). The CKD-EPI was more precise than MDRD but was 10±6% lower than MDRD (p<0.001). For subjects with Scr <1.0 mg/dL (n=103), rounding Scr up to 1.0 mg/dL resulted in CG values that were significantly lower than mCLcr (44 ±10 mL/min vs. 56±12 mL/min, respectively, p<0.001).
CONCLUSION: The MDRD and CKD-EPI eGFR equations significantly overestimate creatinine clearance (mCLcr and CG) in elderly individuals. These eGFR equations should not be substituted for the CG equation in elderly for the purpose of renal dose adjustments. The common practice among pharmacists of rounding serum creatinine up to the arbitrary value of 1.0 mg/dL in elderly for application in the CG equation should be avoided.

103. Targeting testosterone concentrations in elderly males using transdermal testosterone gel. *Joseph P. Vande Griend, Pharm.D.*[1], Tammie K. Nakamura, M.A.[2], Daniel W. Barry, M.D.[2], Pamela Wolfe, M.S.[3], John M. Kittelson, Ph.D.[3], Wendy M. Kohrt, Ph.D.[2], Robert S. Schwartz, M.D.[2]; (1)University of Colorado, School of Pharmacy, Aurora, CO; (2)University of Colorado, School of Medicine, Aurora, CO; (3)Department of Biostatistics and Informatics, Colorado School of Public Health, Aurora, CO
PURPOSE: Guidelines recommend testosterone replacement targeting total testosterone concentrations [TT] in the normal range (300–1000 ng/dL) for elderly males with androgen deficiency. However, safety and/or efficacy differences may exist throughout this wide range. This study sought to evaluate the ability of a dose-titration protocol utilizing transdermal testosterone gel (Androgel®) to target "low-normal" (400–550 ng/dL) and "high-normal" (600–1000 ng/dL) [TT].
METHODS: This titration protocol was used in a one-year, randomized, double-blind, placebo-controlled, trial (NIH RO1AG019339), in healthy older men (>60 years) with baseline [TT] of 200–350 ng/dL. Titration dose was initiated at 2.5 gm in "low-normal" (n=47) and at 5 gm in "high-normal" (n=50) subjects. Another 53 subjects received placebo gel. Doses were titrated (up/down) in 1.25–2.5 gm increments in response to serial 2-week [TT], with the goal of 2 consecutive values within range during the first 12 weeks. However, titration continued for up to 6 months in 44% of active drug-treated subjects.
RESULTS: At end of titration, "low-normal" and "high-normal" subjects were prescribed mean (SD) doses of 4.4 gm (1.2) and 7.3gm (1.5), respectively (p<0.0001). [TT] increased from 291 ng/dL (44.8) to 516 ng/dL (298; range: 131–1626 ng/dL) in "low-normal" subjects and from 301.5 ng/dL (40.3) to 532.8 ng/dL (299; range: 171–1351 ng/dL) in "high-normal" subjects (p=0.8 between groups). Placebo subjects had baseline [TT] of 292.3 ng/dL (39) and [TT] of 304 ng/dL (80.4) at titration end. Only 32% of "low-normal" subjects and 20% of "high-normal" subjects achieved target range at titration end. Adherence was not different among the 3 study groups (> 80%) and was not different between those who did/not achieve target range.
CONCLUSION: Despite a careful titration protocol, good adherence, and a 66% difference in prescribed dose, [TT] did not differ significantly between the active treatment groups. Achievement of target range was suboptimal. The marked variability in individual response to Androgel® treatment may make it clinically difficult to successfully target a specific [TT] range.

104. Assessing the appropriateness of proton pump inhibitor utilization in hospitalized elderly patients. *Cheryl R. Durand, Pharm.D.*, Kristine C. Willett, Pharm.D., Alicia R. Desilets, Pharm.D.; Massachusetts College of Pharmacy and Health Sciences, Manchester, NH
PURPOSE: The primary objective of this study is to assess the appropriate use of proton pump inhibitors (PPIs) in elderly hospitalized patients and determine if continuation after discharge was warranted. Recent early clinical studies suggest that PPIs may increase a person's risk of developing pneumonia, hip fracture, and gastrointestinal infection.
METHODS: This study was approved by the hospital's Institutional Review Board. A retrospective chart review was conducted using the

hospital's electronic medical record. A random sample of patients 18 and older who were ordered to receive an intravenous or oral PPI between March and April of 2010 were included. PPI therapy was considered appropriate if one of the following indications was documented in the patient's medical record: gastric ulcer, erosive esophagitis, gastroesophageal reflux disease, duodenal ulcer, Helicobacter pylori, risk reduction for NSAID-associated ulcer, Zollinger-Ellison syndrome, gastrointestinal bleed, or those meeting the criteria for stress ulcer prophylaxis. Appropriateness of PPI therapy upon discharge was determined based on the PPI indication and the duration of treatment recommended in the respective guidelines. Fisher's exact test was used to determine statistical significance.
RESULTS: A total of 180 patients were included in the study, 99 (55%) patients were age 65 and older and 81 patients were under age 65. PPI therapy was considered inappropriate in 52 of those age 65 and older as compared to 26 patients less than 65 (52.5% vs 32% respectively, p=0.0067). There was no statistically significance of inappropriate continuation of a PPI upon discharge between the two groups.
CONCLUSION: Inappropriate use of PPIs may exist more commonly in the hospitalized elderly population. Due to the potential of PPIs to increase the risk of pneumonia, hip fracture and GI infections, the risks of their use in some instances may outweigh the benefits.

Health Services Research

105. Evaluation of Specialized Medication Packaging Combined with Medication Therapy Management: Adherence, Outcomes, and Costs among Medicaid Patients. *Alan J. Zillich, Pharm.D.*[1], Margie E. Snyder, Pharm.D., M.P.H.[1], Heather Jaynes, RN, M.S.[1], Jeff Harrison, Ph.D.[2], Carl de Moor, Ph.D.[3], Dustin D. French, Ph.D.[4], Karen S. Hudmon, Dr.P.H., M.S.[1]; (1)Purdue University College of Pharmacy, Indianapolis, IN; (2)University of Auckland School of Pharmacy, Auckland, New Zealand; (3)REGISTRAT-MAPI, Lexington, KY; (4)Roudebush VA Medical Center, Health Services Reseach and Development, Indianapolis, IN
PURPOSE: This study evaluates the effect of a program using specialized medication packaging combined with telephonic medication therapy management on medication adherence, healthcare utilization, and costs among Medicaid patients.
METHODS: A retrospective cohort design compared Medicaid participants who voluntarily enrolled in the program (n=1,007) compared with those who did not (n=13,614). Main outcome measures were medication adherence at 12 months, hospital admissions and emergency department (ED) visits at 6 and 12 months, and total paid claim costs at 6 and 12 months. Appropriate regression models were used to adjust for the effect of age, sex, race, co-morbidities, and 12-month pre-enrollment healthcare utilization and costs.
RESULTS: Across 10 therapeutic classes, measures of medication adherence were significantly improved in the intervention cohort compared with the usual care cohort. At six months, adjusted all-cause hospitalization was marginally less in the intervention cohort compared with the usual care cohort (OR=0.73, CI:0.54–1.0, p=0.05). No statistically significant differences were observed between the two cohorts for any of the other adjusted utilization endpoints at 6 or 12 months. Adjusted total cost at 6 and 12 months were higher in the intervention cohort (6-month Cost ratio=1.76, CI:1.65–1.89; 12 month Cost Ratio=1.84, CI:1.72–1.97), due primarily to an increase in prescription costs. ED visits and hospitalization costs did not differ between groups.
CONCLUSION: The program improved medication adherence, but the effect on healthcare utilization and non-pharmacy costs at 6 and 12 months was not different from the usual care group. Reasons for these findings may reflect differences in the delivery of the specialized packaging and implementation of the MTM program, healthcare behaviors in this Medicaid cohort, unadjusted confounding, and time required for the benefit of the intervention to manifest.

106. Impact of pharmacist-led antimicrobial stewardship using a computerized system with prospective audit and feedback approach in a university hospital. *Chu-Chun Chen, B.S.*[1], Tzu-Hsuan Lu, B.S.[1], Yung-Ching Liu, M.D.[2], Shiu-Yu Chien, M.S.[1], Ming-Der Chao, M.S.[1], Wuan-Jin Leu, M.S.[1]; (1)Department of Pharmacy, Shuang Ho Hospital, Taipei Medical University, New Taipei, Taiwan; (2)Division of Infection Diseases, Department of Internal Medicine, Shuang Ho Hospital, Taipei Medical University, New Taipei, Taiwan
PURPOSE: Antimicrobial stewardship program is proven to reduce improper use, resistance and cost of antimicrobials in guidelines. A pharmacist-led program with computerized system support may be more feasible to provide stewardship service in a limited resources setting.
METHODS: In 2010, a dual antimicrobial stewardship program was conducted at a 500- bed university hospital in Taipei, Taiwan. The computerized antimicrobial system guided the use of 17 restricted antimicrobials by criteria-based order sets. A clinical pharmacist who works in conjunction with infectious disease physician provided stewardship service by prospective audit and feedback approach. Parenteral antimicrobial utilization was analyzed using defined daily doses (DDD) per 1000 patient-days (PDs). Financial impact expressed in the rate of antibiotics cost to total drug expenditure, and the absence of National Health Insurance (NHI) reimbursement estimated in NT Dollar, were also compared before and after program initiation.
RESULTS: During one year period, the intensive antimicrobial control program reduced the consumption of parenteral antimicrobials from 1152.8 DDD per 1000 PDs in 2009 to 1121.5 DDD per 1000 PDs in 2010. The absence of National Health Insurance reimbursement was declined from 13,730,127 NT Dollar in 2009 to 12,582,250 NT Dollar in 2010. Also, the percentage of antibiotics to total drug expenditure decreased significantly from 33% to 27%. Approximately eighty percent of stewardship recommendations were accepted using primarily a prospective audit and feedback approach by pharmacist.
CONCLUSION: Our program demonstrated that the computerized order sets provide guidance to clinicians in antimicrobial utilization, and pharmacist can take a leadership role to positively improve appropriate use and cost saving of antimicrobials at the institutional level.

107. Associations between communication climate and the frequency of medical error reporting among pharmacists within an inpatient setting. *Mark E. Patterson, Ph.D., M.P.H.*[1], Heather A. Pace, Pharm.D.[2], Linda Garavalia, Ph.D.[1], Jack E. Fincham, Ph.D., R.Ph.[1]; (1)University of Missouri-Kansas City School of Pharmacy, Kansas City, MO; (2)UMKC School of Pharmacy Drug Information Center, Kansas City, MO
PURPOSE: Open communication amongst pharmacists is an important factor in ensuring the success of medical error reporting systems. The likelihood of using these error reporting systems may be compromised within a work climate of poor communication, potentially resulting in the underreporting medical errors. The objective of this analysis is to identify the extent to which perceived communication climate among hospital pharmacists impacts medical error reporting rates.
METHODS: This cross-sectional study used survey responses from 5000 pharmacists originating from the 2010 Hospital Survey on Patient Safety Culture Comparative Database. Perceived communication climate was defined using scores from two survey domains: 1) communication openness and 2) feedback and communication about error. Within these two domains, pharmacist-level composite scores were constructed by calculating median Likert scale scores. Error reporting frequency was defined using responses from the survey question: 'In the past 12 months, how many event reports have you filled out and submitted?' Multivariable logistic regressions were used to estimate the likelihood of medical error reporting among pharmacists conditional upon perceived communication openness or feedback levels, controlling for pharmacist years of experience, hospital geographic region and ownership status.
RESULTS: Poorer communication openness scores were associated with decreased likelihood of medical error reporting (OR=0.75, 95% CI 0.57–1.0, p=0.03), while communication feedback scores were not associated with medical error reporting (OR=0.88, 95% CI 0.68–1.1, p=0.26).

CONCLUSION: Work climates not conducive to questioning clinical decisions that undermine patient care decreases the likelihood of pharmacists reporting medical errors, while work settings incorporating feedback based upon prior errors may not affect the likelihood of error reporting. Further studies need to be conducted to explore causal nature of these associations, most especially since communication climate potentially impacts patient safety.

108. Alternative Methods for Disseminating Evidence-Based Prescription Drug Information among Primary Care Clinicians in Rural Oregon: The Rural Oregon Academic Detailing (ROAD) Project. *Daniel M. Hartung, Pharm.D., M.P.H.*[1], Ann Hamer, Pharm.D.[2], Dean Haxby, Pharm.D.[2], Luke Middleton, B.S.[3], Lyle J. Fagnan, M.D.[4]; (1)Oregon State Univ/Oregon Health & Science Univ., College of Pharmacy, Portland, OR; (2)Oregon State University / Oregon Health & Science University, Portland, OR; (3)Oregon State University, Portland, OR; (4)Oregon Health & Science University, Portland, OR

PURPOSE: Academic detailing is technique for delivering non-commercial education to clinicians in an interactive, convenient, and user friendly approach. While a growing body of evidence suggests academic detailing is associated with a modest, but significant, impact on changing prescribing behavior, uncertainty exists about its generalizability. The goal of our study was to evaluate different approaches to delivering academic detailing to primary care clinicians in rural Oregon.

METHODS: We conducted a pilot project to assess the feasibility, effectiveness, and satisfaction of academic detailing delivered in a face-to-face format compared to a distance detailing approach in four rural primary care clinics within the Oregon Rural Practice-based Research Network. In order to assess needs, topic preferences, and infrastructure for receiving distance education we conducted focus groups and baseline surveys in each clinic prior to launch. Two clinics were allocated to receive face-to-face detailing and two received outreach through video conferencing or asynchronous web-based outreach. Surveys at midpoint and completion were used to assess effectiveness and satisfaction.

RESULTS: Each clinic received four outreach visits over a nine month period. Topics included treatment-resistant depression, management of atypical antipsychotics, drugs for insomnia, and benzodiazepine tapering. For all responses, differences between the face-to-face and distance detailing groups did not reach statistical significance. Overall, 90% of participating clinicians were satisfied with the program in general. Between 70–90% of respondents indicated they would change their prescribing practices consistent with our educational message. While 90–100% of respondents indicated they would continue to participate if the program was continued, the likelihood of participation declined when only distance approaches were offered.

CONCLUSIONS: We found strong support and satisfaction for our pilot program of academic detailing in rural primary care clinics. Participants favored in-person approaches to distance interactions. Future efforts will be directed at quantitative methods for evaluating the effectiveness of this approach.

109. Combining a clinical pharmacy economic intervention tool with an intervention documentation system. *Adam B. Pesaturo, Pharm.D.*, Erin Taylor, Pharm.D., Caryn Colburn, B.S., Audrey Bernard, Pharm.D., Mark Heelon, Pharm.D.; Baystate Medical Center, Springfield, MA

PURPOSE: To improve documentation of clinical pharmacy services/interventions and to associate those interventions with a cost avoidance value.

METHODS: The Department of Pharmacy partnered with the Department of Information Systems to create an intervention documentation tool within our existing electronic medical record (eMR) (Cerner Millennium, Cerner Corporation, Kansas City, MO). We tied this intervention tool with a clinical pharmacy economic tracking tool purchased by the hospital's finance department (Action O-I, Thompson Reuters, New York, NY). Retrospective tracking was performed for the purpose of quality improvement. The intervention rate was monitored monthly and standardized to the number of interventions per 1000 patient days. Prior documentation used an external database and the intervention rate from this period served as the comparator. The cost avoidance value was tracked monthly and converted into a return on investment (ROI) value.

RESULTS: A clinical pharmacy intervention tool was created that could be accessed from multiple locations within the eMR. The average monthly interventions per 1000 patient days increased after incorporation into the eMR (37±7 vs. 90±34, p=0.5). Pre-defined interventions were assigned a value based on available pharmacoeconomic studies, institution-specific acquisition costs, and average length of treatment. Monthly reporting allowed a cost avoidance dashboard to be maintained and a clinical pharmacy ROI. To date, the department of pharmacy has avoided $271,162 over two months and has an associated ROI of $0.54 for every $1.00 spent.

CONCLUSION: Through collaboration with the departments of Information Systems and Finance, the Department of Pharmacy was able to create a clinical pharmacy economic intervention documentation tool that is evidence-based, institution-specific, accepted by finance officials, incorporated into an existing patient care system, comprehensive, and widely applicable to different clinical settings. Future steps involve additional staff training to ensure accurate documentation and designing services that match those identified within the economic tracking tool.

Hematology/Anticoagulation

110. Implementation of a standardized computerized physician order entry set for warfarin reversal improves evidenced-based administration of vitamin K. Jane D. Portell, Pharm.D.[1], Craig A. McCammon, Pharm.D.[1], Jennifer N. Riney, Pharm.D.[1], Sebastian E. Perez, Pharm.D.[1], Aaron Pierce, Pharm.D.[2], Amber M. Sawyer, Pharm.D.[3], *Eli N. Deal, Pharm.D.*[1]; (1)Barnes-Jewish Hospital, St. Louis, MO; (2)BryanLGH Medical Center, Lincoln, NE; (3)University of Missouri Hospitals & Clinics, Columbia, MO

PURPOSE: Evaluate provision of vitamin K for warfarin reversal according to evidence-based guidelines following the implementation of a standardized order set incorporated into our institution's computerized physician order entry (CPOE) process.

METHODS: This study was conducted as an observational, before-after study at a large, academic medical center. Practices for the administration of vitamin K for warfarin reversal were compared in a pre-intervention group (April 2009) and a post-intervention group (April 2011) following implementation of a CPOE order set. Patients in each the pre- and post-intervention groups were compared based on appropriateness of vitamin K administration according to the 2008 American College of Chest Physicians Guidelines.

RESULTS: Doses of vitamin K in the pre-intervention group were appropriate in 18/105 (17.1%) cases, while 34/94 (36.2%) cases in the post-intervention group were appropriate (p<0.001). Patients that received vitamin K from the CPOE standardized order set had the highest proportion of correct vitamin K use (27/47, 57.4%). Vitamin K administration for patients experiencing a significant bleed improved in the post-intervention phase (7/40, 17.5% pre-intervention vs. 13/39, 33% post intervention, p=0.04). In the post-intervention phase, the most common reasons for incorrect vitamin K administration were as follows: no therapy needed (n=8), given by non-preferred route (n=39), incorrect dose (n=33), and incorrect duration of therapy (n=4). Use of non-preferred routes of vitamin K was reduced in the post-intervention phase (subcutaneous 17/105, 16.2% vs. 11/94, 11.7% and intramuscular 2/105, 1.9% vs. 0/94, 0%).

CONCLUSION: Administration of vitamin K for warfarin reversal according to evidenced-based guidelines was improved following the implementation of a standardized order set incorporated into CPOE at a large, academic medical center.

111. Obesity affects time to INR≥1.5 in surgical orthopedic patients initiated on warfarin for venous thromboembolism prophylaxis. *Nicole E. Cieri, Pharm.D.*, Cynthia Lackie, Pharm.D., Kristen Kusmierski, Pharm.D.; Millard Fillmore Suburban Hospital, Williamsville, NY

PURPOSE: Anticoagulation Management Service (AMS) pharmacists at Millard Fillmore Suburban Hospital initiate warfarin dosing based on a Pharmacy and Therapeutics Committee approved age-adjusted guideline. The objectives of this review are to determine

whether obese patients take longer to achieve an early INR target of ≥1.5 and if necessary, to propose revision to improve dosing in these patients.
METHODS: Data was collected via retrospective review. All surgical orthopedic patients initiated on warfarin for venous thromboembolism (VTE) prophylaxis, from September 1, 2009 to April 30, 2010, with INR maintenance range of 2–3 and dosed by the AMS for ≥ 3 days were included. Patients ≤18 years old, those with physician directed dosing, receiving epidural anesthesia, receiving vitamin K within the preceding two weeks or warfarin within one week were excluded. Data collected and analyzed included patient demographics, INR data, warfarin dose data, outpatient bleeding risk index criteria, and factors affecting warfarin sensitivity.
RESULTS: Obese surgical orthopedic patients (BMI ≥ 30) failed to reach an early target INR for VTE prophylaxis ($p<0.05$). Classification and regression tree analysis revealed thresholds for likelihood of achieving targeted INR as TBW 80.9 kg, BMI 29.8 kg/m^2 and age 76.5 years. All three thresholds were statistically significant via chi square analysis ($p<0.01$) as well as univariate analysis ($p<0.05$). Arbitrary thresholds (TBW=80kg and BMI =30kg/m^2) were also statistically significant using chi square analysis.
CONCLUSION: Obesity (based on either TBW or BMI) had an effect on time to an early target INR in surgical orthopedic patients initiated on warfarin for VTE prophylaxis. A higher dose pathway or separate protocol taking into account weight as well as age-adjustments (similar to the current protocol) may be necessary for obese patients to reach early target INR. The arbitrary values (TBW=80kg and BMI=30kg/m^2) may be more practical for implementation. Further investigations are recommended for increased starting doses of warfarin.

112. Majority of patients treated with warfarin for atrial fibrillation are willing to switch to dabigatran. *Hazem F. Elewa, R.Ph., Ph.D., BCPS*, Christina Deremer, Pharm.D., BCPS, Kimble Keller, Pharm.D., BCPS, Jaspal Gujral, MBBS, MRCP(UK), FACP ; Georgia Health Sciences University, Augusta, GA
Background: Warfarin is an anti-coagulant medication that is challenging to manage due to its multiple drug and food interactions, frequent laboratory monitoring and individually-based dosing. Therefore, it is often not maintained appropriately and its rate of discontinuation is high. Recently, dabigatran has been approved by the FDA for non-valvular atrial fibrillation as an alternative to warfarin. Dabigatran does not require routine monitoring, has an established dose and lacks many of the drug, herbal and food interactions that afflict warfarin.
PURPOSE: to evaluate patients' satisfaction with their current warfarin treatment through a brief survey in our pharmacy-based anti-coagulation clinic. In addition, patients with non-valvular atrial fibrillation were invited to express their opinion on switching to a newly marketed medication (dabigatran).
METHODS: survey questions were on the scale from 1-5, 1 being the least and 5 being the highest.
RESULTS: Our preliminary data included 110 out of 280 planned surveys. Patients expressed high satisfaction with warfarin treatment (median=5) (Answer "1" (1.8%); "2" (0.9%); "3" (3.6%); "4" (14.5%); "5" (75.5%) and 3.6% were missing). However, a vast majority of the patients were willing to switch to an agent that: requires less frequent follow-up visits (median=5) (Answer "1" (8%); "2" (8%); "3" (8%); "4" (22%); "5" (48%) and 6% were missing); lacks interaction with food or beverage (median=5) (Answer "1" (8%); "2" (2%); "3" (16%); "4" (10%); "5" (56%) and 8% were missing); is as efficacious as warfarin (median=4) (Answer "1" (12%); "2" (8%); "3" (16%); "4" (14%); "5" (42%) and 8% were missing). Patients expressed that out-of-pocket cost of >$50 would be a major barrier to switch to this new medication (<$10 (64%), $10-$50 (18%), $50-100 (2%), $100-300(2%) and 14% were missing).
CONCLUSION: patients are willing to consider a more convenient new anti-coagulant treatment but cost remains a significant barrier.

113. Chronic Kidney Disease and Anticoagulation Instability in Warfarin-Treated Patients: Insights into Potential Treatment Strategies. *Candice L. Garwood, Pharm.D.*[1], Jennifer L. Johnson, Pharm., D.[2], Shannon Habermas, Pharm.D., Student[1], Peter Whittaker, PhD[3]; (1)Wayne State University, Detroit, MI; (2)Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI; (3)Wayne State University School of Medicine, Cardiovascular Research Institute and Dept of Emergency Medicine, Detroit, MI
PURPOSE: Chronic kidney disease (CKD) is associated with anticoagulation instability in warfarin-treated patients. However, the characteristics of such instability and specific treatment approaches remain known. Therefore, we aimed to; (1) gain insight into CKD-associated instability by characterization of responses to interventions designed to correct out-of-range international normalized ratio (INR), and (2) investigate a potential method of mitigating instability.
METHODS: We examined records of patients (INR target 2.0–3.0) attending a pharmacist-managed clinic. To identify CKD-related instability characteristics, we collected data on response to both above-range (3.2–3.4) and below-range INRs (1.6–1.8), all preceded by in-range INRs. CKD patients had eGFRs <60 $mL/min/1.73m^2$; controls >60 $mL/min/1.73m^2$. The mitigation analysis compared anticoagulation instability in CKD patients with different diets; those who ate 1–3 weekly green leafy vegetables (GLV) servings (a proxy for vitamin K consumption), versus those who avoided GLVs. Our anticoagulation instability measure was INR standard deviation (INR-SD); the larger the INR-SD, the greater the instability. We compared CKD patients' INR-SD in the two GLV groups.
RESULTS: Patients (CKD=28; control=63) were predominantly female African Americans. CKD patients were older (66±10.8 vs. 60±10.7 years; $P<0.02$), but exhibited no other differences. After above-range INRs (279 cases), controls returned to target range at their next clinic visit 60% of the time versus 39% for CKD patients ($P=0.0079$). Importantly, there were no inter-group differences in treatment (dose adjustment or no intervention). After below-range INRs (244 cases), controls returned to target range 62% of the time versus 63% for CKD patients ($P=1.00$): no treatment differences. CKD patients who avoided GLVs had lower INR-SD (0.63±0.05) than those who ate GLVs (0.82±0.07; $P=0.043$), consistent with increased stability.
CONCLUSION: CKD-associated instability was mitigated by avoidance of vitamin K-containing food. Furthermore, differential responses to out-of-range INRs indicate that CKD patients cannot be treated using the same strategies applied to other patients.

114. Timing of venous thromboembolism following total knee or hip replacement. *Beth L. Nordstrom, Ph.D., M.P.H.*[1], Kathy Fraeman, SM[2], Edith A. Nutescu, Pharm.D.[3], Jeff Schein, Dr.P.H., M.P.H.[4], Brahim Bookhart, M.B.A., M.P.H.[4]; (1)United Biosource Corporation, Lexington, M.A.; (2)United BioSource Corp, Lexington, MA; (3)University of Illinois at Chicago College of Pharmacy, Chicago, IL; (4)Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, NJ
PURPOSE: To investigate the occurrence of in-hospital vs post-discharge venous thromboembolism (VTE) following total hip or total knee replacement (THR/TKR).
METHODS: A retrospective cohort analysis was conducted using an electronic medical record database. Data were obtained for patients undergoing THR or TKR between January 1, 2004 and January 31, 2009, who started warfarin within 3 days after surgery and had ?2 INR measurements. Individuals with a history of a previous VTE event were excluded from analysis. Patients were followed through their continuous warfarin therapy for up to 90 days to identify the presence of VTE. Diagnosis codes for VTE events were classified as occurring during the orthopedic surgery hospitalization or after discharge; the post-discharge events were further characterized by the number of days since index (warfarin start). [0][0]
RESULTS: A total of 1375 THR and 1667 TKR patients were included in the VTE analysis. VTE occurred in 41 THR patients (3.0%) and 56 TKR patients (4.1%). The majority of these events occurred during the hospitalization period; however, 34% of the THR-related events and 52% of the TKR-related events occurred during the post-discharge period, with the highest risk of post-discharge events occurring within the first 14 days after warfarin start.
CONCLUSIONS: In this analysis, although the majority of VTE events among orthopedic surgery patients occurred in-hospital following surgery, a third to one-half of VTE events were observed post-discharge in THR and TKR patients, respectively. These findings

underscore the need for improved prophylaxis for VTE in THR and TKR patients, in both the in-hospital and post-discharge periods. Improved strategies and treatments post-discharge for VTE prophylaxis may also be warranted.

115. Outcomes associated with enoxaparin use among patients with varying renal function. *Megan A. Clairmont, Pharm.D.*[1], Douglas D. DeCarolis, Pharm.D., BCPS[2], Joey Thorson, Pharm.D.[2], Amy Leuthner, Pharm.D.[2]; (1)Minneapolis Veteran Affairs Health Care System, Minneapolis, MN; (2)Minneapolis Veterans Affair Medical Center, Minneapolis, MN
PURPOSE: Enoxaparin is a low-molecular-weight heparin that has indications for use in many thromboembolic-related conditions. Enoxaparin is renally cleared and therefore package insert dosing calls for a 50% dose reduction when creatinine clearance (CrCl) is < 30ml/min. Despite linear pharmacokinetics, the full dose is recommended for all patients with CrCl > 30ml/min, which includes patients with moderate renal impairment (CrCl 30–60ml/min). Although there is data showing drug accumulation in these patients, there is limited outcome data.
METHODS: All patients who received therapeutic enoxaparin treatment courses between June 1, 2009 and November 30, 2009 were identified. Electronic medical records were retrospectively reviewed to identify baseline demographic, clinical, and bleeding risk information as well as outcomes of enoxaparin therapy. The primary outcome was major bleeding defined as a bleed resulting in hospitalization, emergency department visit or other unplanned ambulatory care visit. We compared the incidence of this outcome in patients with an estimated CrCl of ≥ 80ml/min versus those with a CrCl of 30–50ml/min. All patients received package insert recommended doses.
RESULTS: 170 patients with CrCl 30–50ml/min or ≥ 80 ml/min were included in the study. The primary outcome occurred in 23.3% of patients with CrCl 30–50ml/min group and 7.3% of patients in CrCl ≥ 80ml/min group (p=0.003). No thromboembolic events were found in either group. Baseline characteristics were not significantly different between each renal function group.
CONCLUSIONS: Patients with CrCl of 30–50ml/min had significantly more hospitalizations, emergency room visits and unplanned primary care provider visits than patients with creatinine clearance ≥ 80ml/min. Patients with moderately impaired renal function need empiric enoxaparin dose adjustments or additional monitoring to avoid bleeding events and improve patient outcomes.

116. Bleeding rates among patients with morbid obesity treated with enoxaparin. *Jennifer C. Hagopian, Pharm.D.*, Jennifer N. Riney, Pharm.D., James M. Hollands, Pharm.D., Eli N. Deal, Pharm.D.; Barnes-Jewish Hospital, St. Louis, MO
PURPOSE: Using actual body weight to dose enoxaparin may lead to over-anticoagulation and increased bleeding risk, as low molecular weight heparins (LMWHs) distribute into the intravascular compartment and not into tissues and body fat. The objective of this study is to determine if there is an increased bleeding risk in morbidly obese (body mass index [BMI] ≥40kg/m^2) patients on treatment doses of enoxaparin.
METHODS: Patients were included if they were on treatment doses of enoxaparin for at least 24 hours during the second half of 2009. Patients classified as morbidly obese comprised the study group and were matched to controls (BMI<40 kg/m^2) on a 1:2 ratio based upon renal dysfunction (serum creatinine >1.4mg/dL). The final analysis included 100 morbidly obese patients and 200 control patients. The primary endpoint was the development of bleeding events up to 24 hours after discontinuation of enoxaparin.
RESULTS: Initial (0.96 mg/kg versus 1.05 mg/kg, p<0.01) and final (0.98 mg/kg versus 1.04 mg/kg, p<0.01) enoxaparin doses in morbidly obese patients were significantly lower compared to control patients. The largest single dose given in either arm was 150 mg. The total number of bleeding events did not differ between the treatment arms at 29 (29%) and 47 (23.5%) events between cases and controls, respectively, p=0.30. Increased number of doses (adjusted odds ratio [AOR] 1.07, 95% confidence interval [CI] 1.02–1.20), female gender (AOR 2.79, 95% CI 1.46–5.30), and increased peak serum creatinine (AOR 2.55, 95% CI 1.19–5.49) were found to be independent predictors of bleeding. Avoidance of warfarin (AOR 0.51, 95% CI 0.26–0.98) and lower final enoxaparin dose (AOR 0.08, 95% CI 0.01–0.69) were protective against bleeding.
CONCLUSION: Morbid obesity was not associated with increased bleeding risk with therapeutic enoxaparin use. Results suggest that dosing using actual body weight is appropriate and in accordance with current CHEST guidelines.

117. Retrospective analysis of unfractionated heparin infusions in obese patients. *Ann N. Biesboer, Pharm.D.*[1], William J. Peppard, Pharm.D.[1], Garret L. Newkirk, Pharm.D.[1], David J. Hermann, Pharm.D.[1], Bethanne M. Held, Pharm.D.[1], James G. Gosset, M.D.[2]; (1)Froedtert Hospital, Milwaukee, WI; (2)Medical College of Wisconsin, Milwaukee, WI
PURPOSE: This study was designed to evaluate an institution's current ≥40 kg/m^2) patients compared to non-obese patients (BMI <30 kg/m^2) and to define an appropriate dosing strategy for all patient populations with respect to BMI and presence of thrombosis.
METHODS: Electronic medical records were retrospectively reviewed to identify 373 inpatients who received a
RESULTS: An association between BMI and UFH dose required to achieve two consecutive therapeutic partial ≥40 kg/m^2 and 46 (38%) patients with BMI 30–39.9 kg/m^2 were considered
CONCLUSIONS: A strong association between BMI and UFH dose to achieve two consecutive therapeutic

118. Determining optimal vitamin K dosing to reverse anticoagulation based on baseline INR, route of administration, and home warfarin dose. *Laura V. Tsu, Pharm.D.*, Erin Dienes, M.S., William Dager, Pharm.D.; University of California, Davis Medical Center, Sacramento, CA
PURPOSE: The objective of this study is to evaluate the impact of baseline INR, dose and route of vitamin K, and home warfarin dose on the reduction of the International Normalized Ratio (INR) by vitamin K.
METHODS: Medical records of 400 patients receiving vitamin K for warfarin reversal between February 2008 and November 2010 were reviewed. Patient demographics, home warfarin dose, INR at baseline and for 48 hours after vitamin K administration was collected.
RESULTS: The dose of vitamin K (p<0.001), route of administration (p<0.001), and baseline INR (p<0.001) significantly affected the INR. Compared to PO, IV vitamin K achieved more rapid and overall reductions in INR. Lower doses of IV vitamin K (0.5–1.25 mg) achieved a partial reversal in INR (1.5-2.0) at 48 hours, whereas higher doses (>1.25 mg) resulted in complete reversal (<1.5). Compared to patients with lower baseline INR, higher baseline INR readings had higher INR readings at 24–48 hours. While the effect of home warfarin dose was not significant with both IV (p=0.269) and PO (p=0.981) vitamin K, it appeared that INR response to IV vitamin K is similar irrespective of home warfarin dose. With PO vitamin K, higher home warfarin doses (>2 mg/day) seemed to require larger doses of vitamin K to achieve the same INR reduction compared to patients with lower home warfarin doses (≤2 mg/day).
CONCLUSION: Depending on the desired level and timing of INR reduction, baseline INR as well as the route and dose of vitamin K should be taken into consideration when developing a vitamin K dose to expedite reversal of warfarin.

Herbal/Complementary Medicine

119. Effect of CoEnzyme Q10 supplementation on HMG-CoA reductase inhibitor-induced myalgias. *Davd A. Bookstaver, Pharm.D.*, Nancy A. Burkhalter, Pharm.D.; Eisenhower Army Medical Center, Fort Gordon, GA
PURPOSE: The purpose of the study was to assess the effect of Coenzyme Q10 (CoQ10) supplementation on myalgias presumed to be caused by HMG-CoA reductase inhibitor (statin) therapy.
METHODS: Patients currently receiving a statin who developed new-onset myalgias in at least 2 extremities within 60 days of initiation or a dosage increase were eligible. Exclusions included a diagnosis of fibromyalgia or a serum creatine kinase level greater than 300 units/liter. Patients continued statin therapy and were randomized via a matched-design to either CoQ10 60 mg twice daily or a

matching placebo. Double-blind treatment continued for 3 months, and patients completed a 10 cm visual analog scale (VAS) and the Short-Form McGill Pain Questionnaire at baseline and at each monthly visit. The primary endpoint was the change from baseline at 1 month in the VAS, and the difference between groups was evaluated via the Student's *t*-test.
RESULTS: Seventy-six patients were enrolled (40 CoQ10, 36 placebo). The mean VAS was 6cm at baseline in both groups. At 1 month, there was no difference in the mean VAS between the groups, 3.9 cm CoQ10 and 4 cm placebo (p=0.97). Five patients in the CoQ10 group and 3 in the placebo group discontinued therapy during the first month due to myalgias. Both groups had a decrease to approximately 3.1 cm on the VAS at the 3-month visit. The median score on the Sensory Pain Rating Index subscale was 10 at baseline in the CoQ10 group and 11.5 in the placebo group. At 1 month, these scores decreased to 6.5 and 7.5, respectively, which were not statistically different (p=0.34).
CONCLUSION: CoQ10 supplementation was not effective in the treatment of presumed statin-induced myalgias.

HIV/AIDS

120. Comparison of clinical outcomes between ritonavir-boosted atazanavir and unboosted atazanavir in HIV patients on a regimen containing tenofovir. *James D. Scott, Pharm.D., M.Ed., FCCP*[1], Kevin T. Marx, Pharm.D.[2], Robert K. Bolan, M.D.[2]; (1)Western University of Health Sciences, Pomona, CA; (2)Jeffrey Goodman Clinic, Los Angeles, CA
PURPOSE: A significant drug-drug interaction occurs between tenofovir (TDF) and atazanavir (ATV), which results in decreased ATV levels. As such, ATV should be boosted with ritonavir (RTV) in pts on a TDF-containing regimen. However, many patients are intolerant of RTV. As a result, some clinicians have used a non-approved combination of unboosted ATV with TDF to increase adherence. Anecdotal reports suggest that this dosing of ATV with TDF usually results in undetectable viral loads (VL). We previously reported that subjects with unboosted ATV had better adherence than those with RTV boosted ATV (ATV/r). We now report on clinical outcomes associated with ATV vs. AVT/r when given with TDF.
METHODS: This retrospective cohort study compared 49 subjects on regimens containing TDF and ATV (400 mg: n=32; 600 mg: n=17) to 50 case-matched subjects on regimens containing TDF and ATV/r (300/100). Subjects were excluded based on age <18 yo, recent changes to their ART, and creatinine clearance (CrCl) < 50 mL/min. Effectiveness was compared using changes in VL and CD4. Bilirubin, serum creatinine, and diagnoses of diarrhea while on the regimens are also compared.
RESULTS: ATV/r trended to be better at decreasing VL compared to ATV (p=0.077), and attaining an undetectable VL was better in the ATV/r group compared to ATV (84% vs. 61%, p<0.05), but were not different between doses of ATV. Bilirubin increased more in the ATV/r subjects than ATV subjects (2.7 ± 2.5 vs. 1.2 ± 1.4, p<0.0005). CD4 count increases (ATV: 153 ± 154 cells vs. ATV/r: 213 ± 224) and CrCl decreases (9.9 ± 14.1 ml/min vs. 13.1 ± 18.2) were not different across groups. Reports of diarrhea were uncommon.
CONCLUSION: Despite better adherence with ATV compared to ATV/r, viral load response was weaker. At this time, we cannot recommend the use of ATV in combination with TDF unless the ATV is boosted.

121E. Hepatic Safety Profile of Fosamprenavir-Containing Regimens in HIV-1-infected Patients with or without Hepatitis C or B Co-infection. Belinda F. Ha, Ph.D.[1], Brian C. Wine, M.S.[1], Michael E. Wisniewski, Ph.D.[1], Felipe Rodríguez-Alcántara, M.D.[2], *Mark S. Shaefer, Pharm.D.*[3]; (1)GlaxoSmithKline, Research Triangle Park, NC; (2)ViiV Healthcare, Madrid, Spain; (3)ViiV Healthcare, Research Triangle Park, NC
PURPOSE: We compared the hepatic safety profile of fosamprenavir (FPV) in antiretroviral-naïve and experienced HIV-1-infected patients with or without hepatitis C (HCV, defined as anti-HCV positive) or hepatitis B (HBV, defined as HepB sAg positive) who had participated in 7 clinical trials.
METHODS: The following data were examined from 1319 HIV-infected adults treated with FPV in combination with either abacavir/lamivudine or tenofovir/emtricitabine: incidence of Grade 2-4 adverse events (AEs), serious AEs, Grade 3/4 liver enzyme elevations (LEE), and change from baseline in alanine aminotransferase (ALT), aspartate aminotransferase (AST), and AST platelet ratio index (APRI) score over 48 weeks.
RESULTS: In 205 co-infected patients (76% HCV, 28% HBV) and 1,114 HIV-mono-infected patients, FPV regimens at baseline included ritonavir 100 mg (60%) or 200 mg (40%); 73% of the patients were antiretroviral-naïve. Over 48 weeks, 38% (77/205) of co-infected patients reported Grade 2-4 drug-related AEs compared with 29% (320/1,114) of HIV-mono-infected subjects, and a similar proportion had treatment-related serious AEs (8% [16/205] and 6% [62/1,114]). At Week 48, change from baseline in median ALT (range) in the co-infected and HIV-mono-infected groups was -4 (-142–344; n=100) and -7 (-183–141; n=716), in median AST was -6 (-116–266; n=96) and -6 (-179–78; n=715), and in median APRI score was -0.12 (-4.58–3.04; n=87) and -0.08 (-2.61–1.26; n=638). With respect to treatment-emergent LEE observed in 202 co-infected patients and 1099 HIV-mono-infected patients over 48 weeks, the frequency of Grade 3/4 ALT was 29 (14%) vs 12 (1%) and of Grade 3/4 AST was 25 (12%) vs 16 (1%).
CONCLUSION: Over 48 weeks, the co-infected and HIV-mono-infected groups had comparable liver enzyme decreases and incidence of serious AEs, but the co-infected group had more Grade 2–4 drug-related AEs and treatment-emergent LEE.
Presented at the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Rome, Italy, July 17–20, 2011.

122E. Efficacy and Safety of Abacavir/Lamivudine Plus Raltegravir at Week 96 in Antiretroviral-Naive HIV-1-Infected Patients in the SHIELD Study. Benjamin Young, M.D., Ph.D.[1], Thanes J. Vanig, M.D.[2], Edwin DeJesus, M.D.[3], Trevor N. Hawkins, M.D.[4], Marty St.Clair, B.S.[5], Britt S. Stancil, B.S.[5], *Belinda F. Ha, Ph.D.*[5]; (1)Division of General Internal Medicine, University of Colorado, Denver, CO; (2)Spectrum Medical Group, Phoenix, AZ; (3)Orlando Immunology Center, Orlando, FL; (4)Southwest Care Clinic, Santa Fe, NM; (5)GlaxoSmithKline, Research Triangle Park, NC
PURPOSE: In the SHIELD study, a favorable efficacy and safety profile was previously reported with abacavir/lamivudine + raltegravir in treatment-naïve HIV-infected patients through 48 weeks. We now report long-term efficacy and safety findings.
METHODS: This 96-week, open-label, pilot multicenter study evaluated abacavir/lamivudine 600 mg/300 mg once daily + raltegravir 400 mg twice daily in patients with entry viral load (VL) >1,000 c/mL. Patients were excluded if they were HLA-B*5701-positive or had raltegravir, abacavir, or lamivudine resistance mutations.
RESULTS: SHIELD enrolled 35 patients. At baseline, median VL was 4.8 $\log_{10}$ c/mL, and median CD4+ 301 cells/mm^3. Seven patients (20%) discontinued study, five between Weeks 48-96 after 471-788 days of treatment (2 lost-to-follow-up [single site], 2 for non-compliance, 1 for lack of efficacy). At Week 48, 91% (32/35) had VL <50 c/mL (ITT:missing/discontinuation=failure analysis). At Week 96, the proportion of patients with VL <400 and <50c/mL was 80% (28/35) and 77% (27/35), respectively (ITT:missing/discontinuation=failure analysis); 74% (17/23) vs. 83% (10/12) had VL <50 c/mL in the low (<100,000c/mL) vs. high (≥100,000c/mL) baseline VL strata, respectively. Median CD4+ change from baseline was 304 cells/mm^3. Six patients (17%) reported drug-related grade 2–4 adverse events, 1 post-Week 48. Nine patients (26%) reported grade 3-4 lab abnormalities, 1 post-Week 48. No drug-related serious adverse events were reported. Week 96 fasting lipid changes [median (95% confidence intervals) mg/dL] were not different from baseline for total/HDL-cholesterol [-0.11 (-0.39, 0.46)] but increased for triglycerides [25 (1.5, 64.5)], LDL-cholesterol [11 (7.5, 21.5)], HDL-cholesterol [6 (4–11.5)], and total-cholesterol [28 (20–40)].
CONCLUSION: In this pilot study, abacavir/lamivudine + raltegravir provided continued/durable virologic suppression through Week 96 in patients who remained on treatment. The combination was generally well tolerated with few additional toxicities reported after Week 48.
Presented at the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Rome, Italy, July 17–20, 2011.

123E. Efficacy/Tolerability of Unboosted Atazanavir Versus Atazanavir/Ritonavir, Each in Combination with Abacavir/Lamivudine, after Initial Suppression with Abacavir/Lamivudine+Atazanavir/Ritonavir in HIV-1-infected Patients: 144-Week Results of ARIES. Kathleen E. Squires, M.D.[1], Benjamin Young, M.D., Ph.D.[2], Edwin DeJesus, M.D.[3], Nicholaos C. Bellos, M.D.[4], Daniel Murphy, M.D.[5], Henry Zhao, Ph.D.[6], Lisa L. Ross, M.S.[6], *Mark S. Shaefer, Pharm.D.*[7]; (1)Thomas Jefferson University, Philadelphia, PA; (2)Division of General Internal Medicine, University of Colorado, Denver, CO; (3)Orlando Immunology Center, Orlando, FL; (4)Southwest Infectious Disease Associates, Dallas, TX; (5)Clinique Medicale L'Actuel, Montreal, QC, Canada; (6)GlaxoSmithKline, Research Triangle Park, NC; (7)ViiV Healthcare, Research Triangle Park, NC

PURPOSE: Induction with a ritonavir-boosted protease inhibitor regimen followed by simplification (ritonavir deletion) may offer sustained virologic suppression while minimizing potential long-term adverse effects.

METHODS: In ARIES, North American antiretroviral-naïve patients initiated on abacavir/lamivudine+atazanavir/ritonavir with confirmed HIV-RNA 50 c/mL and no protocol-defined virologic failure (confirmed rebound of HIV-RNA ≥400 c/mL) at Week 36 were randomized 1:1 to maintain or discontinue ritonavir for 48 subsequent weeks. At Week 84, patients could continue their randomized regimen into an extension phase through 144 weeks.

RESULTS: Of 379 enrolled patients, 369 entered the extension phase, and 314 (85%) completed 144 weeks. Baseline demographics of the 369 extension-phase patients were similar between arms and to the Week 36 randomized population (mean age 39 years; 85% male; 64% white; HIV-RNA 5.06 $\log_{10}$ copies/mL; median CD4+ 198 cells/mm^3). At 144 weeks, intent-to-treat-exposed analysis showed that the abacavir/lamivudine+atazanavir (n=189) and abacavir/lamivudine/lamivudine+atazanavir/ritonavir (n=180) groups responded similarly with respect to proportion achieving HIV-RNA <50 c/mL (146[77%]) vs 132[73%], p=0.390) and <400 c/mL (159[84%] vs 144[80%], p=0.303 [Cochran-Mantel-Haenszel test/TLOVR algorithm], incidence of protocol-defined virologic failure (5[3%] vs 6[3%]), non-significant difference), and change from baseline in median CD4+ count (305 vs 302, non-significant difference). Drug-related grade 2–4 adverse event frequency did not differ between groups between baseline and week 144 (61[32%] vs 75[42%], p=0.675), although between Weeks 36 and 144 the abacavir/lamivudine+atazanavir simplification group had a lower frequency of these adverse events (25[13%] vs 42[23%], p=0.015) and hyperbilirubinemia (12[6%] vs 25[14%], p=0.023)(Fisher's exact test) and was associated with more favorable median changes in fasting lipids (mg/dL): total-cholesterol -10 vs. 3; HDL-cholesterol 3 vs. 3; LDL-cholesterol -4 vs. 0; and triglycerides -42 vs. -11.

CONCLUSION: Abacavir/lamivudine+atazanavir/ritonavir and abacavir/lamivudine+atazanavir simplification provided similar, sustained efficacy over 144 weeks, but the simplification arm was associated with a more favorable safety profile between Weeks 36 and 144.

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124E. Switch to Fosamprenavir with Addition of Lovaza for Management of Hypertriglyceridemia in HIV-Infected Patients on Boosted Protease Inhibitor Regimens: A Pilot Study (BuLLET). Franco Felizarta, M.D.[1], Anthony Scarsella, M.D.[2], Homayoon Khanlou, M.D.[3], John D. Stansell, M.D.[4], Winston Young, B.S.[5], Lisa L. Ross, M.S.[6], Henry Zhao, Ph.D.[6], Keith A. Pappa, Pharm.D.[6], *Belinda F. Ha, Ph.D.*[6]; (1)Franco Felizarta, M.D., Bakersfield, CA; (2)Pacific Oaks Medical Group, Beverly Hills, CA; (3)AIDS Healthcare Foundation, Los Angeles, CA; (4)Private Practice, Palm Springs, CA; (5)Statworks, Inc., Research Triangle Park, NC; (6)GlaxoSmithKline, Research Triangle Park, NC

PURPOSE: Use of fish oil has been shown to reduce serum triglyceride levels in HIV-infected patients receiving antiretroviral drug therapy. Since management of hypertriglyceridemia requires multiple pharmacologic strategies, we examined the therapeutic effect of switching patients on boosted protease inhibitor (PI) regimens to a PI with fewer drug interactions and adding a prescription fish oil/omega-3-acid ethyl ester formulation, Lovaza.

METHODS: In this multicenter, 24-week study, 36 patients on boosted PI therapy with screening triglycerides 200–1,200 mg/dL, LDL-cholesterol ≤160 mg/dL, and HIV-1 RNA <50 c/mL, were switched to fosamprenavir 1400 mg plus ritonavir 100 mg once daily at baseline. Lipid-lowering agents were discontinued at baseline and Lovaza 4 g once daily was added at Week 6.

RESULTS: 31 patients completed the study. Reasons for discontinuation were adverse events (2), non-compliance (1), loss-to-follow up (1), and protocol violation (1). Ten patients (28%) had a decrease in triglyceride levels between screening (≥200 mg/dL) and baseline (<200 mg/dL). Median triglyceride concentration was 303 mg/dL at screening, 262 mg/dL at baseline, 290 mg/dL at Week 6 (+8%), and 218 mg/dL at Week 24 (-30% from Week 6). At Week 24, 33% had triglycerides <200 mg/dL (intent-to-treat:missing-equals-failure analysis). Five patients (14%) had treatment-emergent grade 2–4 adverse events. No serious adverse event was reported. Median CD4 count increased by 55 cells/mm^3 between baseline and Week 24. Among patients completing study, 100% (31/31) had HIV-1 RNA <400c/mL and 90% (28/31) had <50 c/mL at Week 24. One non-compliant patient experienced confirmed virologic failure (HIV-1 RNA >400 copies/mL at or before Week 24) at Week 6. At time of virologic failure, no major treatment-emergent resistance-associated mutations were detected in virus isolated from this patient.

CONCLUSION: In this pilot study in boosted PI-treated HIV-infected patients with hypertriglyceridemia, switching to fosamprenavir 1400 mg plus ritonavir 100 mg once daily followed by Lovaza reduced triglyceride levels while maintaining virologic suppression.

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125. Effects of Darunavir, Ritonavir and Darunavir/Ritonavir on T-Cell Activation and Apoptosis using HIV-negative CD4+ Lymphocytes. *James D. Scott, Pharm.D., MEd., B.S.*, Stephen A. O'Barr, Ph.D.; Western University of Health Sciences, Pomona, CA

PURPOSE: Prior data from our group shows that treatment of HIV-negative CD4+ lymphocytes with LPV/r significantly increases mitochondrial membrane integrity and that LPV or EFV alone significantly increases T-cell activation by almost 40%, as measured by CD4 levels. RTV was also shown to increase CD4 labeling, though, at lower levels. In this study we hypothesized that darunavir/ritonavir (DRV/r) would result in T-cell activation and changes in apoptotic markers.

METHODS: 24cc of blood was drawn from 15 HIV-negative controls. Peripheral Blood Lymphocytes were washed and sub-cultured, then activated with IL-2. Cells were then exposed to 3.5uM and 10uM DRV, 1.0 uM RTV, 3.5 uM DRV/1 uM RTV, and 10 uM DRV/1 uM RTV for 72 hours, or unexposed for control. Cells were stained with fluorochrome-tagged monoclonal antibody to CD4, CD38, CD69, CD127, and HLA-DR. Analysis of surface marker intensity was performed by flow cytometry, gated against CD4. Apoptosis was assessed by measuring JC-1 aggregates (mitochondrial membrane integrity assay), caspases 3, 7, & 8 activity and TUNNEL staining (DNA integrity).

RESULTS: Treatment with RTV alone ($P<0.01$), and both doses of DRV/r ($P<0.05$), significantly increases HLA-DR expression (50–70%), compared with control. No change in HLA-DR was seen with DRV alone. There was a significant difference in HLA-DR expression between cells treated with RTV alone and DRV alone ($P<0.05$). While there were no statistically significant changes in CD38, 69, and 127 levels, substantial increases in CD69 expression were observed in RTV alone and DRV/r treated cells (20–25%). No treatments significantly altered markers of apoptosis.

CONCLUSION: RTV alone, and both doses of DRV/r, but not DRV alone, activated CD4+ T-cells as measured by significant increases in HLA-DR expression. Similar trends were seen in CD69 levels. This data complements our previous findings with LPV and EFV and suggest that other antiviral drugs may enhance T-cell activation in HIV-negative CD4+ lymphocytes.

126E. Changes in Inflammatory Biomarker Levels and Correlation with Framingham (FRAM) Risk Scores in

Antiretroviral-Naive HIV-infected Patients through 144 Weeks of Abacavir/Lamivudine-containing Therapy in ARIES (EPZ108859). Benjamin Young, M.D., Ph.D.[1], Kathleen E. Squires, M.D.[2], Lisa L. Ross, M.S.[3], Lizette Santiago, M.D.[4], Louis M. Sloan, M.D.[5], Henry Zhao, Ph.D.[3], Brian C. Wine, M.S.[3], Margaret W. Schultz, M.S.[3], David A. Margolis, M.D.[3], *Mark S. Shaefer, Pharm.D.*[6]; (1)Division of General Internal Medicine, University of Colorado, Denver, CO; (2)Thomas Jefferson University, Philadelphia, PA; (3)GlaxoSmithKline, Research Triangle Park, NC; (4)HOPE Clinical, San Juan, PR; (5)North Texas IDC, Dallas, TX; (6)ViiV Healthcare, Research Triangle Park, NC

PURPOSE: Chronic inflammation is believed to increase cardiovascular disease (CVD) risk. In addition to traditional FRAM-defined CVD risk factors, CVD risk has been linked with elevations in the inflammatory biomarkers Lp-PLA2, interleukin-6 (IL-6), and high-sensitivity C-reactive protein (hs CRP).

METHODS: In ARIES, 517 North American antiretroviral-naïve patients, including those with high CVD risk, received abacavir/lamivudine+atazanavir/ritonavir for 36 weeks, then were randomized 1:1 to either maintain or discontinue ritonavir for 108 subsequent weeks. CVD risk and inflammatory biomarker concentrations were evaluated combining data from ritonavir-boosted and non-boosted dosing periods. FRAM 10-year risk groups (<6% or ≥6%) were assigned at baseline. Concentrations of hsCRP, IL-6 and Lp-PLA2 were assessed at baseline and Week 144.

RESULTS: At Week 144, 93% of patients with biomarker assessments had an HIV-1 RNA <50 c/mL. Median (Q1–Q3) hsCRP (mg/L) in patients with a FRAM 10-year CHD risk score <6% did not differ significantly (Wilcoxon signed-rank test) between baseline (1.6 (0.6–3.4) [n=285]) and Week 144 (1.4 (0.6–3.4) [n=249])(p=0.535), nor did it for patients with a score ≥6% (1.9 (0.9–2.8) [n=61] vs 2.0 (1.2–5.0 [n=50]) (p=0.102). Median (Q1-Q3) IL-6 (pg/mL) in patients with a FRAM 10-year CHD risk score <6% was similar at baseline (1.6 (1.0-2.5)[n=287]) and Week 144 (1.4 (0.9–2.3) [n=249]) (p=0.267), as was the case with patients with scores ≥6% (2.0 (1.3–2.6) [n=61] vs 2.2 (1.5–3.5)[n=50]) (p=0.099). Conversely, median (Q1-Q3) Lp-PLA2 (nmol/min/mL) in patients with a FRAM 10-year CHD risk score <6% significantly (p<0.001) decreased between baseline (197 (162–238)[n=284] and Week 144 (168 (138–198)[n=249], as it did even more for patients with scores ≥6% (238 (166–250)[n=60] vs 175 (147–213)[n=50]).

CONCLUSION: In antiretroviral-naïve patients on abacavir/lamivudine-containing treatment, inflammatory biomarker levels generally correlated with the FRAM risk score. Between baseline and Week 144, hsCRP and IL-6 did not change, but Lp-PLA2 levels decreased significantly in both <6% and ≥6% risk-score groups.

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Infectious Diseases

127. Candidemia Pharmacotherapy Over Eight Years at a Tertiary Medical Center. Thy Le, Pharm.D.[1], *Jason C. Gallagher, Pharm.D*[2]; (1)Temple University Hospital, Philadelphia, PA; (2)Temple University School of Pharmacy, Philadelphia, PA

PURPOSE: We describe the characteristics, risk factors, choice of antifungal therapy, and outcomes of patients with candidemia over an eight-year period.

METHODS: This was a retrospective cohort study of patients ≥18 years old hospitalized for ≥48 hours with candidemia treated with antifungal therapy from 2003–2010. Data collected included demographics, risk factors for candidemia, microbiology and laboratory data, and antifungal therapy. APACHE II and Charlson scores were calculated. Empiric and definitive antifungal therapy was assessed for appropriateness. Inappropriate antifungal therapy was defined as use of fluconazole for *C. krusei,* or doses of fluconazole <800 mg per day for *C. glabrata*.

RESULTS: A total of 181 charts were reviewed (55% male, mean age 56±17, 11% immunocompromised). Common candidemia risk factors included: prior antibiotic therapy (89%), presence of central venous catheter (71%), mechanical ventilation (53%), and parenteral nutrition (49%). *C. albicans* was the most common species (38%) followed by *C. glabrata* (34%), and *C. parapsilosis* (16%). The mean length of treatment was 15±9 days. Average APACHE II score was 17±10 and average Charlson score was 3.6±3.3.

	2003	2004	2005	2006	2007	2008	2009	2010
Infections (n)	9	10	21	8	39	28	40	26
Initial Therapy (%)								
Fluconazole	56	70	66	50	30	43	47.5	42
Echinocandin	44	30	34	50	69	57	52.5	58
Appropriate	67	60	66	62.5	79	86	77.5	88
Definitive Therapy (%)								
Fluconazole	33	80	43	37.5	41	54	60	38.5
Echinocandin	67	20	57	62.5	59	46	35	50
Other							5	12
Appropriate	100	80	95	87.5	89	93	75	92
Microbiological cure	100	100	95	87.5	89	79	87.5	85
Positive clinical outcome	67	80	62	62.5	56	50	70	69

CONCLUSIONS: Microbiological and clinical outcomes remained consistent over time despite improvement in rates of appropriate initial antifungal pharmacotherapy.

128E. Predictors of mortality among elderly patients with Gram-negative bloodstream infection. *Travis Ledford, Pharm.D./MSCR, Candidate*[1], Chad Cannon, Pharm.D./MSCR, Candidate[1], John B. Hughes, Pharm.D./MSCR, Candidate[1], Christopher D. Pfeiffer, M.D., MHS[2], Luke F. Chen, MBBS, M.P.H.[2], Melissa Johnson, Pharm.D., MHS[3], Deverick Anderson, M.D., M.P.H.[2]; (1)Campbell University College of Pharmacy & Health Sciences, Morrisville, NC; (2)Duke University Medical Center, Durham, NC; (3)Duke University Medical Center and Campbell University College of Pharmacy & Health Sciences, Durham, NC

PURPOSE: Gram-negative (GN) infections cause significant morbidity and mortality among hospitalized patients. However, predictors of outcomes among elderly subjects with Gram-negative bloodstream infection (GNBSI) have not been well established. The purpose of this study was to investigate variables associated with mortality in these patients.

METHODS: We conducted an IRB-approved retrospective observational study to evaluate baseline clinical and microbiologic factors associated with 30-day all-cause mortality among subjects ≥ 65 years of age with GNBSI identified at 4 community hospitals affiliated with the Duke Infection Control Outreach Network (DICON) between 1994 and 2003. Variables with p<0.2 in χ^2 analysis were further analyzed using multivariable logistic regression.

RESULTS: 237 subjects with GNBSI were identified (Mean age: 74 yrs; 62% Male; 74% Caucasian). The most common pathogens were *E. coli* (30%), *P.* (22%), spp. (24%), and *Proteus* spp. (7%). Fifteen percent of subjects had organisms that were non-susceptible to ≥ 1 antibiotic in ≥ 2 antimicrobial classes (MDR2), and 7% had isolates non-susceptible to ≥ 3 classes. The overall 30-day mortality was 37%. The table shows predictors that were significantly associated with 30-day mortality on multivariable regression.

CONCLUSIONS: We identified several variables associated with 30-day mortality among elderly subjects with GNBSI, including: older age (≥ 80 years) and multi-drug resistance.

Predictors of 30-Day Mortality in Subjects with GNBSI

Variable	Odds Ratio (95% CI)	p-value
Age ≥ 80 years	2.52 (1.16–5.5)	0.0197
Vasopressors at baseline	3.12 (1.48–6.92)	0.0032
Pseudomonas spp.	2.27 (1.15–4.49)	0.0185
Proteus spp.	3.01 (1.01–8.98)	0.048
MDR2	2.19 (1.01–4.75)	0.0475
Diabetes mellitus	0.42 (0.19–0.91)	0.0273

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129. A comparison of patients with *Klebsiella* bacteremia with imipenem-resistance to those with 3rd generation cephalosporin resistance. *Jason Gallagher, Pharm.D*[1], Prachi D. Bhatt, Pharm.D[2], Elizabeth Marino, Pharm.D.[3]; (1)Temple University School of Pharmacy, Philadelphia, PA; (2)Temple University Hospital, Philadephia, PA; (3)Pennsylvania Hospital, Philadelphia, PA

PURPOSE: Carbapenem-resistant (CR) Enterobacteriaceae are a

relatively recent phenomenon with few treatment options. The purpose of this study was to describe differences between third-generation cephalosporin-resistant (3GCR) and CR *Klebsiella pneumoniae* bacteremia in terms of outcomes.

METHODS: This was a retrospective, cohort study. Patients were identified via the microbiology laboratory's electronic record system and included if they had a positive blood culture for *K. pneumoniae* and were > 18 years old. Patients without clinical evidence of infection were excluded. Data on baseline characteristics, clinical and microbiologic success, and mortality was collected.

RESULTS: A total of 464 patients were identified with blood cultures positive for *K. pneumoniae* from 2006–2011. 111 patients were included in the 3GCR arm and 44 in the CR arm.

	3GCR (n=111)	CR (n=44)	P value
Age, median (range)	56 (19-98)	57.5 (22-80)	0.915
Gender; Men (%)	60 (54)	20 (45)	0.4309
ICU Admissions, n (%)	65 (58.6)	34 (77)	0.0454
Presence of comorbidities, n (%)	89 (90)	40 (90)	0.168
Length of stay in days, median (range)	47 (7-416)	44 (4-153)	0.25
APACHE II, median (range)	16 (4-35)	11 (2-26)	<0.0001
Charlson index, median (range)	5 (0-14)	2 (0-11)	<0.0001
ID Consult obtained n (%)	57 (51.4)	38 (86)	0.0001
Hospital Day of first (+) BCx, median (range)	21 (1-205)	29.5 (1-181)	0.59
Microbiologic success, n (%)	101 (90.9)	27 (61)	<0.0001
Clinical Success, n (%)	61 (55)	9 (20.5)	0.0002
Mortality at the end of therapy, n (%)	31 (27.9)	24 (55)	0.0033

CONCLUSIONS: CR *K. pneumoniae* bacteremia patients had worse outcomes than those with 3GCR *K. pneumoniae* bacteremia, though baseline characteristics seemed to indicate that they were less-ill. More investigation is required to determine why this is the case.

130. Mitochondrial toxicity with caspofungin. *Kayla R. Stover, Pharm.D., BCPS*[1], Jonathan P. Hosler, Ph.D.[2], John D. Cleary, Pharm.D.[2]; (1)The University of Mississippi School of Pharmacy, Jackson, MS; (2)University of Mississippi Medical Center, Jackson, MS

PURPOSE: The echinocandins are a relatively new class of antifungal agents. In previous *ex vivo* live-heart studies, caspofungin (CASP) was found to cause cardiac toxicity. Subsequent tissue evaluation by transmission electron microscope demonstrated possible changes in the mitochondria and muscle tissue. The purpose of this study was to determine if CASP affects oxidative phosphorylation in mitochondria.

METHODS: Isolated mitochondria studies were performed using liver tissue from Harlan Sprague-Dawley Rats. Liver tissue (1 g) was homogenized and centrifuged with a sucrose mitochondrial extraction buffer. Mitochondrial respiration was measured as O_2 consumption using a Clark-type electrode in a 1.5 mL stirred vessel maintained at 25ºC, using 1 M glutamate/0.5 M malate or 0.5 M succinate as substrates (S1). ADP (60 mM) or FCCP (75 uM) and valinomycin (3 mM) (S2) were used to measure the states of respiration. After substrate baseline, CASP was added in exposure concentrations ranging from 4.9 to 70.94 ug/mL.

RESULTS: At concentrations < 10 ug/mL, CASP increased oxygen consumption from S1 baseline by 242.5 ± 13.5%. No change in oxygen consumption (3.1 ± 4.1%) was seen compared to S2 baseline. At concentrations > 10 ug/mL, decreases in oxygen consumption of 75.8 ± 10.6% and 19.7 ± 35.1% were seen compared to S1 and S2 baselines, respectively.

CONCLUSION: CASP inhibits mitochondrial oxidative phosphorylation. The inhibition of Complex I, Complex II, Complex IV, ATP synthase, the ATP-ADP translocase, and the transport of glutamate, malate and succinate cannot be the sole source of the inhibition. CASP may act to inhibit Complex III, the import of phosphate, or it may act as an inhibitor at multiple sites. Further studies are necessary to test these and other possibilities.

131. A retrospective comparison of daptomycin thrice-weekly versus Q48H dosing in hemodialysis patients with vancomycin-resistant enterococcus or methicillin-resistant *Staphylococcus aureus* bacteremia. *Katie L. Axford, Pharm.D.*, Dane L. Shiltz, Pharm.D., BCPS; Indiana University Health and Butler University, Indianapolis, IN

PURPOSE: This study retrospectively assessed clinical and microbiological outcomes in hemodialysis patients with vancomycin-resistant enterococcus (VRE) or methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia treated with daptomycin thrice-weekly compared to traditional Q48H dosing.

METHODS: All patients with positive blood cultures who received at least one dose of daptomycin between January 1st 2009 and December 31st 2010 at Indiana University Health Methodist and University Hospitals were identified. Subjects age ≥ 18 years with end-stage renal disease on a stable thrice-weekly hemodialysis regimen, confirmed VRE or MRSA bacteremia, and at least three doses of inpatient daptomycin therapy on one of the study schedules were enrolled in the study. Data were obtained through a retrospective review of electronic medical records. Microbiologic cure was assessed using time to clearance of blood cultures. Clinical indicators of infection, including daily maximum temperature (Tmax) and WBC count, were used to assess clinical cure.

RESULTS: Twelve patients were identified who met criteria for inclusion in this study. Nine received daptomycin every 48 hours for the treatment of bacteremia, and three received daptomycin thrice-weekly after dialysis. There was no difference in time to clearance of blood cultures between the Q48H and thrice-weekly groups (2.11±2.15 days vs 4.33±4.16 days; p=0.241). No patients were febrile upon initiation of daptomycin, and only three patients in the Q48H group had a clinically significant white blood cell count on initiation of daptomycin. Length of hospital stay was not statistically significantly different between the two treatment regimens (22.8 days vs 14.9 days; p=0.065).

CONCLUSION: Thrice-weekly dosing of daptomycin may be effective for the treatment of bacteremia in hemodialysis patients. Further research is needed to support the non-inferiority of this regimen compared to Q48H dosing.

132. Assessment of fluoroquinolone-resistant urinary pathogens in patients admitted to an acute care hospital from a nursing home. *Brian R. Lohr, Pharm.D.*; University of Pittsburgh Medical Center, Pittsburgh, PA

PURPOSE: This study was conducted in order to measure rates of fluoroquinolone resistance and determine empiric antibiotic therapy for nursing home patients admitted to an acute care setting diagnosed with a urinary tract infection (UTI). Initiating appropriate antibiotic treatment for nursing home patients is essential to improve clinical outcomes.

METHODS: Medical records of 105 nursing home patients admitted through the emergency department were retrospectively reviewed from April 2009 to December 2009. Diagnostic codes were used to determine the presence of UTIs during their hospitalizations. Urine cultures with corresponding susceptibilities to ciprofloxacin were evaluated and data was collected for 159 total urinary isolates. Susceptibility results were recorded as susceptible, intermediate, or resistant. Choice of empiric antibiotic therapy was also recorded for fluoroquinolone-resistant pathogens.

RESULTS: Of the 159 urinary pathogens reported, 60% were susceptible, 1% intermediate, and 39% resistant to ciprofloxacin. *E.coli* susceptibility to ciprofloxacin was 54.1% in this study. In contrast, *E.coli* susceptibility to ciprofloxacin for all patients at our institution was 73%, as documented by an antibiogram during a similar time period. Appropriate antibiotic therapy was delayed an average of 47.3 hours in 9 nursing home patients; these patients were initiated on a fluoroquinolone while infected with a fluoroquinolone-resistant urinary pathogen.

CONCLUSION: Due to the resistance rates observed in this study, antibiotics other than fluoroquinolones, such as cephalosporins and sulfamethoxazole-trimethoprim, should be considered for the empiric treatment of UTIs in nursing home patients. Clinical judgment and local susceptibility rates should also play a role when initiating antibiotic therapy for these patients.

133. Evaluation of antibiotic prescribing patterns in patients

receiving sustained low-efficiency dialysis. Laura E. Harris, Pharm.D.[1], Anne Reaves, Pharm.D.[1], Amy Krauss, Pharm.D.[1], Justin Griner, BS[2], *Joanna Q. Hudson, Pharm.D.*[2]; (1)Methodist University Hospital, Memphis, TN; (2)The University of Tennessee College of Pharmacy, Memphis, TN

PURPOSE: Sustained low-efficiency dialysis (SLED) is a new "hybrid" form of continuous renal replacement therapy that is becoming increasingly popular; however, there is very limited information on drug disposition during this procedure. The purpose of this study was to evaluate prescribing patterns for specified antibiotics for patients requiring SLED at our institution.

METHODS: A retrospective review was performed for patients who received concurrent SLED and antibiotic therapy from January 2009–January 2011. Demographic data, prescribed antibiotic dosing regimens, and doses delivered as prescribed were determined. Antibiotics of interest included cefepime (C), daptomycin (Da), doripenem (D), gentamicin (G), Imipenem-cilastatin (I), linezolid (L), meropenem (M), piperacillin-tazobactam (P), tobramycin (T), and vancomycin (V). Dosing regimens were compared to recommendations from the literature when available. The incidence of clinical and microbiologic cure was also evaluated.

RESULTS: 87 patients met inclusion criteria: mean age 54±14 yrs, 60% male, 58% Caucasian. The total number of orders for each antibiotic was: C (n=14), (n=27), D (n=35), G (n=0), I (n=18), L (n=34), M (n=27), P (n=71), T (n=0), V (n=27). Antibiotic prescriptions were evidence-based for 37% of , 3% of L, 14% of M, and 7% of V. The majority of discrepancies were due to doses lower than recommended. On average 13% of antibiotic doses were missed: 11% of C, 12% of , 10% of D, 12% of I, 6% of L, 8% of M, 14% of P, and 28% of V orders. Of the 13 patients who met inclusion criteria to evaluate clinical and microbiologic cure, 10 had a microbiologic cure and no patient achieved clinical cure.

CONCLUSIONS: Prescribed antibiotic dosing regimens varied substantially and under-dosing was common. There is a need to further evaluate antibiotic prescribing in the SLED population to ensure appropriate therapy.

134. Identifying an optimal dose of vancomycin in morbidly obese patients. *Gary N. Elsasser, Pharm.D.*[1], Phillip S. Lorhan, Pharm.D.[2], Christopher J. Destache, Pharm.D., FCCP[1]; (1)Creighton University School of Pharmacy and Health Professions, Omaha, NE; (2)Creighton University Medical Center, Omaha, NE

PURPOSE: To determine the dose (mg/kg) of vancomycin necessary to achieve a therapeutic trough concentration (10-20 mcg/ml) in morbidly obese patients and whether differences exist in non-obese, overweight, obese and morbidly obese patients.

METHODS: We retrospectively reviewed the electronic records of all adult (≥19 years) patients admitted to our hospital between January 1, 2007 and December 31, 2010 and prescribed vancomycin for a minimum of 24 hours. Non-pregnant patients with at least one vancomycin trough concentration obtained at steady state, a creatinine clearance of ≥ 60 ml/min and a stable serum creatinine were included for analysis. Patients were then subdivided into one of four groups relative to their body mass index (BMI); Group I – BMI = 18.5–24.9, Group II – BMI 25–29.9, Group III – BMI 30–39 and Group IV ≥ 40. Each group was compared using ANOVA for continuous variables with Bonferroni post-hoc testing for continuous data. An *a priori* level of significance was set at a p value of ≤ .05.

RESULTS: Of 1709 patients screened, 141 were included in the analysis (27, 38, 47, 29; Groups I–IV, respectively). There were no statistically significant differences with respect to age, gender, height, creatinine clearance, or length of hospital stay between the four groups. Mean (± S.D.) vancomycin dose producing a therapeutic trough was significantly less in Group IV (12.4 mg/kg ± 2.38, p=0.002) versus all other groups (14.8 ± 2.76, 14.4 ± 2.1, 14.1 ± 2.48, groups I-III, respectively).

CONCLUSION: Morbidly obese patients with normal renal function required a significantly less mg/kg dose of vancomycin to produce a similar therapeutic trough concentration as compared to their obese and non-obese counterparts.

135. *Pseudomonas aeruginosa* (PSA) combination antibiogram: incorporating pharmacodynamic breakpoints (PDB) to identify most appropriate empiric regimens. Kathy Zhang, Pharm.D., Candidate, Gregory A. Eschenauer, Pharm.D., *Brian A. Potoski, Pharm.D.*; University of Pittsburgh Medical Center, Pittsburgh, PA

PURPOSE: Inappropriate empirical antibiotic therapy for PSA infections has been shown to result in increased mortality. Combination antibiograms for PSA have been shown to be helpful in identifying the most appropriate empirical therapy regimen. However, such studies have not yet incorporated minimum inhibitory concentrations (MICs) in their analyses. Inclusion of such data may result in more robust recommendations, given data showing decreased efficacy of certain antibiotics as MICs increase. As appropriateness for some agents may depend on the MIC even when in the susceptible range, we devised a combination antibiogram which incorporates PDB.

METHODS: A query of the hospital microbiology database was made for PSA isolates identified from blood or respiratory tract sites in three intensive care units between 1/1/2009 and 12/31/2010. Duplicates, defined as isolates from the same source within 7 days of the index culture, were excluded. Susceptibilities and MICs were recorded. PDB, i.e., MICs above which outcomes may be expected to suboptimal, were defined as follows: cefepime (CPM) 4 μg/mL; piperacillin/tazobactam (P/T) 16 μg/mL; meropenem (M) 2 μg/mL, ciprofloxacin (C) 0.25 μg/mL; amikacin (A) 4 μg/mL; and gentamicin/tobramycin (G/T) 2 μg/mL.

RESULTS: 376 isolates were included. Incorporation of PDB into the antibiogram resulted in substantial changes in likelihood of appropriate therapy:

Likelihood of Appropriate Empiric PSA Therapy (%)

	PDB Not Incorporated	PDB Incorporated
Single Agents		
CPM	70	38
M	68	63
P/T	67	58
C	71	51
T Combinations		
CPM+T	91	77
M+T	90	82
P/T+T	92	84
C+T	91	80
C Combinations		
CPM+C	84	57
M+C	82	71
P/T+C	85	70

CONCLUSION: At our institution, incorporation of PDB resulted in dramatic changes in CPM susceptibility, such that non-standard PD-based dosing is now being evaluated for empiric use. Incorporation of PDB is necessary to properly inform choices of empiric antibiotic combinations targeting PSA.

136. The impact of a gentamicin-citrate catheter lock intervention on outpatient hemodialysis catheter-associated bloodstream infections. *Christine Hamby, Pharm.D.*[1], Kristen Buczynski, Pharm.D., Candidate[1], Michelle Vignari, RN, CIC., A.A.S.[1], Miyako Newell, B.S.N.[1], Donna Farnsworth, R.N., M.H.A., C.I.C.[2], Stephen Silver, M.D.[1], Edward Walsh, M.D.[1], Alexandra Yamshchikov, M.D.[1]; (1)Rochester General Hospital, Rochester, NY; (2)Unity Health System, Rochester, NY

PURPOSE: Central line associated blood stream infection (CLABSI) is a major contributor to morbidity and mortality in patients dialyzed via a central venous catheter (CVC). Short-term studies using antimicrobial-anticoagulant lock solutions have demonstrated reductions in CLABSI. We investigated the impact of a GC (1 mg/ml Gentamicin + 4% Citrate) lock to reduce CLABSI rates over 2-years, and its effects on access function and patterns of bacterial resistance.

METHODS: Intradialytic locking of dialysis catheters with GC solution replaced heparin for all RGHS patients receiving dialysis via CVCs from January 2009 to January 2011. CLABSI rates, alteplase use to maintain CVC patency, and incidence of gentamicin resistant bacteremias were compared for 24 months pre and post intervention using unpaired t-test.

RESULTS: During the 2-year intervention period, a quarterly average of 326 + 22 dialysis patients with CVCs were treated with the GC lock. There was a 77% reduction in CLABSI rates compared to

baseline (0.5 + 0.2 infections/1000 catheter days vs. 2.1 + 0.5 infections/1000 catheter days, $p < 0.0005$). No change in access-associated bacteremia was observed for patients dialyzed via fistulae or grafts. Alteplase use did not change significantly during the intervention (27 + 5.7 treatments/ 1000 catheter days vs. 30.2 + 5.5 treatments/1000 catheter days). Gram positive bacteria caused 71/152 (47%) CLABSI during the pre-GC period and 40/41 (98%) post-GC. Although no significant increase in enterococcal CLABSI was noted during the intervention period (14.6% vs. 16%) a significant increase in gentamicin resistance of enterococcal CLABSI isolates was observed post intervention (83% vs. 12% resistance at baseline).
CONCLUSION: Introduction of a GC intradialytic lock has resulted in a 77% reduction in CLABSI rates for patients dialyzed via a CVC. Although no significant impact on catheter function was observed, emergence of gentamicin resistance in enterococcal CLABSI isolates does merit further study.

137E. Impact of NXL104 on ceftaroline MICs for bacteria producing extended-spectrum, AmpC, or KPC β-lactamases. Robert E. Badal, B.S.[1], Samuel Bouchillon, M.D.[1], Meredith Hackel, Ph.D.[1], Daryl Hoban, Ph.D.[1], Christine Lascols, M.S.[1], Stephen Hawser, Ph.D.[2], *Gregory Williams, Ph.D.*[3]; (1)International Health Management Associates, Inc, Schaumburg, IL; (2)IHMA Europe Sárl, Epalinges, Switzerland; (3)Cerexa, Inc. (a wholly owned subsidiary of Forest Laboratories, Inc., New York, NY), Oakland, CA
PURPOSE: Ceftaroline (CPT) is a broad-spectrum cephalosporin with activity against resistant gram-positive and common gram-negative pathogens. Like other cephalosporins, its activity is significantly reduced by extended-spectrum β-lactamases (ESBL), AmpC enzymes, or KPCs. NXL104 (NXL) is a non-β-lactam β-lactamase inhibitor that enables *in vitro* activity of many β-lactams against these β-lactam-resistant isolates. We evaluated MICs of CPT with and without NXL against a collection of molecularly-characterized β-lactamase-producing *Enterobacteriaceae* (ENT).
METHODS: Susceptibility of 816 recent clinical ENT isolates previously shown to produce ESBL enzymes (including 6 TEM, 14 SHV, and 20 CTX-M variants), AmpC (10 variants), or KPC (4 variants) to CPT and CPT + NXL (CXL) was determined using broth microdilution panels in accordance with CLSI guidelines. MICs of CPT were compared to those of CXL and the magnitude of MIC reduction was calculated.
RESULTS: See table.

Enzyme Profile (N)	CPT $MIC_{50/90}$	CXL $MIC_{50/90}$	Reduction in CPT MIC_{90}
CTX-M (538)	>32/>32	≤0.06/0.25	≥256-fold
KPC (118)	>32/>32	1/2	≥32-fold
SHV (50)	>32/>32	≤0.06/0.5	≥64-fold
AmpC + CTX-M (43)	>32/>32	0.25/2	≥32-fold
SHV + CTX-M (28)	>32/>32	≤0.06/0.25	≥256-fold
SHV + KPC (18)	>32/>32	1/4	≥16-fold
TEM (7*)	[4->32]	[≤0.06-0.5]	*
TEM + CTX-M (6*)	[>32]	[≤0.06-0.5]	*
AmpC + SHV (5*)	[4->32]	[≤0.06-0.5]	*
SHV + TEM (1*)	[32]	[0.12]	*
AmpC + TEM (1*)	[>32]	[0.5]	*
AmpC + SHV + CTX-M (1*)	[>32]	[0.5]	*

*$MIC_{50/90}$ not calculated if N<10; instead, MIC range is shown in brackets.
CONCLUSIONS: NXL lowered CPT MIC_{90}s from ≥16 to ≥256-fold for all variants and combinations of β-lactamases, and lowered MICs by a minimum of 16-fold against KPC-producing isolates. CXL, the combination of NXL with CPT, promises to expand the spectrum of activity of CPT to include β-lactamase-producing ENT.
Presented at Presented at the 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, Boston, MA, September 12–15, 2010.

138. New dosing recommendations for vancomycin in premature infants. *Eric B. Hoie, Pharm.D.*, Justin Tolman, Pharm.D., Ph.D.; Creighton University School of Pharmacy and Health Professions, Omaha, NE
PURPOSE: Vancomycin is a commonly used antibiotic in premature infants for suspected or proven Staphylococcal infections. Current dosing guidelines are generally insufficient if trough concentrations of 15 mg/L are desired. New dosing recommendations are needed to achieve trough concentrations of 15 mg/L
METHODS: Using previously published pharmacokinetic parameters, dosing guidelines for vancomycin needed to achieve trough concentrations of 15 mg/L will be determined for two groups of premature infants; infants less than 36 weeks post-conceptual age (group 1) and infants greater than or equal to 36 weeks post-conceptual age (group 2). These dosing guidelines will be applied to estimate peak and trough concentrations in premature infants at our institution who have received a minimum of three vancomycin doses and had pharmacokinetic parameters calculated using peak and trough concentrations.
RESULTS: Nine infants, four in group 1 and five in group 2, had peak and trough concentrations measured on twelve courses of vancomycin. The mean trough concentrations were 8.05 and 8.97 mg/L in groups 1 and 2 respectively.
CONCLUSION: Current dosing recommendations for vancomycin in premature infants do not produce the recommended trough concentrations of 15 mg/L. New dosing recommendations will be provided to achieve this recommended trough.

139E. Spectrum of activity of ceftaroline/NXL104 and β-lactam comparator agents tested against methicillin-resistant *Staphylococcus aureus* carrying different SCC*mec* types and gram-negative bacilli with well-characterized resistance mechanisms. David J. Farrell, Ph.D.[1], Rodrigo E. Mendes, Ph.D.[1], *Gregory Williams, Ph.D.*[2], Ian Critchley, Ph.D.[2], Ronald N. Jones, M.D.[1], Helio S. Sader, M.D., Ph.D.[1]; (1)JMI Laboratories, North Liberty, IA; (2)Cerexa, Inc. (a wholly owned subsidiary of Forest Laboratories, Inc., New York, NY), Oakland, CA
PURPOSE: To determine the spectrum of activity and potency of ceftaroline combined with NXL104 (fixed 4 mg/L; CPT104) and comparators against selected MRSA (different types) and Gram-negative strains harbouring different β-lactamase (BL)-encoding genesCeftaroline is a broad-spectrum cephalosporin with activity against resistant Gram-positive and common Gram-negative organisms and limited activity against extended-spectrum β-lactamase (ESBL)- and -producing strainsNXL104 is a novel non-β-lactam BL inhibitor that inhibits Ambler class A, C, and D enzymes.
METHODS: Susceptibility testing was performed by CLSI broth microdilution on 250 strains as follows: MRSA (100 subcategorized by type; E-ESBL (50 Enterobacteriaceae [ENT] with); E-

Antimicrobial	MIC_{50}/MIC_{90} (mg/L) E-ESBL	E-AMPC	E-CARB
Ceftaroline	>64/>64	32/>64	>64/>64
CPT104[a]	0.06/0.25	0.12/0.5	0.5/2
Ceftazidime	>16/>16	>16/>16	>16/>16
P/T	32/>64	32/>64	>64/>64
Imipenem	0.12/0.5	0.5/1	8/>8

reported refer to CPT concentration.
RESULTS: All MRSA, except one, were inhibited at ≤2/4 mg/L of CPT104CPT104 was also very active against the variety of ENT (E-ESBL, E-AMPC, and E-CARB; highest MIC, 4 mg/L)Although CPT104 demonstrated activity against wild-type ACB and PSA, activity was low against BL-producing strainsCeftazidime and piperacillin/tazobactam (P/T) were inactive against all categoriesImipenem had activity against E-ESBL and E-AMPC but limited or no activity against other categories.
CONCLUSIONS: CPT104 was very active against MRSA regardless of type/subtype and ENT regardless of BL type, but had limited intrinsic activity against ACB and PSA expressing . CPT104 had a wider spectrum of activity against these resistant Gram-positive and -negative categories than the comparatorsCPT104 represents a potential therapeutic option for empiric therapy in settings where MRSA and BL-positive ENT predominate.
Presented at Presented at the 20th Annual European Congress of Clinical Microbiology & Infectious Diseases, Vienna, Austria, April 10–13, 2010.

140E. Antimicrobial activity of ceftaroline combined with NXL104 tested against a collection of organisms expressing multiple β-

lactamases. Helio S. Sader, M.D., Ph.D.[1], *Gregory Williams, Ph.D.*[2], Gary J. Moet, B.S.[1], Mariana Castanheira, Ph.D.[1], Ian Critchley, Ph.D.[2], Ronald N. Jones, M.D.[1]; (1)JMI Laboratories, North Liberty, IA; (2)Cerexa, Inc. (a wholly owned subsidiary of Forest Laboratories, Inc., New York, NY), Oakland, CA

PURPOSE: To evaluate the activity of ceftaroline combined with NXL104 (fixed 4 mg/L; CPT104) against Enterobacteriaceae (ENT) with various types of β-lactamases (BL). Ceftaroline is a broad-spectrum cephalosporin with activity against resistant Gram-positive and common Gram-negative organisms and limited activity against extended-spectrum β-lactamase (ESBL)- and AmpC-producing strains. NXL104 is a novel non-β-lactam BL inhibitor that inhibits Ambler class A, C, and D enzymes.

METHODS: CPT104 and comparators were tested for susceptibility (S) by CLSI broth microdilution against 148 clinical strains of ENT producing KPC + AmpC (n=26), ESBL + AmpC (n=27), KPC + ESBL (n=7), multiple ESBLs (n=37), SME or NMC-A carbapenemases (n=7), KPC (n=12), CTX-M (n=9), plasmidic AmpC (n=15), and metallo-BL (MBL; n=8). Isolates were collected from global surveillance programs (1998-2008).

RESULTS: CPT104 exhibited potent inhibitory effects against all BL types except MBLs; all isolates were inhibited at MICs ≤4 mg/L except MBL-producing strains. CPT104 was highly active against ENT producing KPC (MIC_{90}, 0.5 mg/L), KPC + AmpC (MIC_{90}, 2 mg/L), and KPC + ESBL (MIC_{100}, 1 mg/L). CPT104 was more active than meropenem (MIC_{90}, >8 mg/L) against these 3 groups. ENT-producing CTX-M (highest CPT104 MIC, 0.5 mg/L) and those producing more than one ESBL type (MIC_{90}, 1 mg/L) were also very S to CPT104. The highest CPT104 MIC observed among plasmidic AmpC was 0.5 mg/L. All strains producing SME or NMC-A were also inhibited at ≤0.5 mg/L of CPT104. CPT104 and all β-lactams tested showed limited activity against MBL-producing ENT.

CONCLUSIONS: NXL104, combined with ceftaroline, lowers ceftaroline MIC for ENT that produce the most clinically significant BLs, except MBLs. CPT104 was active against ENT producing KPC, various ESBL types, and AmpC, as well as those producing more than one of these BL types. CPT104 represents a promising therapeutic option for infections caused by multidrug-resistant ENT.

Presented at Presented at the 20th Annual European Congress of Clinical Microbiology & Infectious Diseases, Vienna, Austria, April 10–13, 2010.

141E. Ertapenem monotherapy versus cefotetan/metronidazole combination therapy in colorectal surgery patients. *Noreen H. Chan-Tompkins, Pharm.D.*, Valerie Vuylsteke, Pharm.D., Sunil Bhat, M.D., David Medich, M.D.; Allegheny General Hospital, Pittsburgh, PA

PURPOSE: Cefotetan, cefoxitin, or ertapenem are considerations for colorectal surgical prophylaxis. The primary objective was to compare the efficacy of combination therapy (cefotetan [or cefoxitin] and metronidazole) versus monotherapy (ertapenem) for surgical prophylaxis in patients undergoing colorectal surgery. The secondary objective was to compare post-surgical infection outcomes stratified by body mass index (BMI).

METHODS: The institutional review board approved this retrospective cohort study for colorectal surgeries between 7/1/07–6/30/09. Additional inclusion criteria: ages 18–89 years, prophylaxis with combination or monotherapy. Exclusion criteria: pregnancy, rectal only surgery, perforation/leak during surgery, post-operative antibiotics for other infections. Post-operative infection incidence was compared using logistic regression model.

RESULTS: Of 260 patients screened, 110 patients met criteria (combination, n=52 vs. monotherapy, n=58). For the combination and monotherapy group respectively, baseline characteristics: mean age was 58.5+16.5 vs. 56.4+18.1 years; male 54% vs. 57%; mean BMI 27.3+5.0 vs. 26.4+6.3; cardiovascular disease 48% vs. 45%; malignancy 17% vs. 29%; diabetes 11% vs. 10%; albumin<3.5 g/dL 8% vs. 9%; chronic corticosteroid therapy 2% vs. 9%; mean length of hospital stay 6.6+2.3 days vs. 6.7+2.5 days (p>0.05 for baseline characteristics). Post-operative prophylactic antibiotics were given in 19% of patients in both groups. In the combination vs. monotherapy group respectively, prophylaxis success (defined as no surgical drainage at 30+7 days post-colorectal surgery) was 80% vs. 89% (p=0.693); surgical site drainage (drainage from surgical incision at 30+7 days post-colorectal surgery) was 20% vs. 11% (p=0.639); surgical site infection was 9% vs. 7% (p=0.8836). For combination and monotherapy respectively, prophylaxis success stratified by BMI <30 was 83% vs. 87% (p=0.3752); BMI > 30 was 73% vs. 91% (p=0.9178).

CONCLUSION: The incidence of post-operative infections was lower in the ertapenem monotherapy compared to combination therapy (cefotetan [or cefoxitin] and metronidazole), regardless of BMI, although statistical significance was not noted. Larger prospective studies are warranted.

Presented at Presented as poster presentation at the American Society of Health-System Pharmacists Midyear Clinical Meeting, Anaheim, CA, December 5–9, 2010.

142. Treatment of urinary tract infections: are cephalosporins associated with failure?

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PURPOSE: Urinary tract infections (UTI) are a frequent cause of morbidity in the United States, resulting in millions of office visits and thousands of hospitalizations each year. The objective of this study was to compare retreatment rates of urinary tract infections treated with cephalosporins versus non-β-lactam (NBL) antibiotics.

METHODS: Restrospective cohort study including patients diagnosed and treated for an uncomplicated UTI, complicated UTI, or pyelonephritis between July 31, 2010 and October 31, 2010. Outcomes were evaluated if patients were treated for a gram-negative UTI meeting prespecified diagnostic criteria and received either a cephalosporin or a NBL such as trimethoprim/ sulfamethoxazole or a fluoroquinolone. Other data collected included patient demographics, antibiotic regimen and duration, and comorbid conditions.

RESULTS: 87 patients were included. Patients receiving cephalosporins were numerically more likely to be older (78 yr vs 55 yr median age), male (42% vs 14%), have pyelonephritis (22% vs 12%) or a complicated UTI (47% vs 25%) than uncomplicated UTI (31% vs 64%) compared to those receiving NBL. Organisms isolated: *E. coli* (61/87; 70%), *P. mirabilis* (9/87; 10%), *Enterobacter* spp. (8/87; 9%) and other (9/87; 10%). Retreatment for urinary tract infection within 30 days:

	Cephalosporins n=36	NBL n=51	p-value
Retreatment, overall	0/36 (0%)	3/51 (5.9%)	p=0.264
Retreatment, susceptible organism	0/35 (0%)	1/48 (2.1%)	p=1.000

CONCLUSIONS: Treatment with cephalosporin agents was not associated with a higher proportion of therapeutic failure when treating urinary tract infections. Treatment of urinary tract infections with cephalosporin agents may be appropriate when supported by local resistance patterns.

143. Pharmacokinetics and pharmacodynamics of piperacillin/tazobactam administered by prolonged infusion in morbidly obese, hospitalized patients. S. Christian Cheatham, Pharm.D.[1], Megan R. Fleming, Pharm.D.[1], Daniel P. Healy, Pharm.D.[2], Christina E. K. Chung, Pharm.D.[3], Katherine M. Shea, Pharm.D.[4], Melissa L. Humphrey, Pharm.D. Candidate[5], *Michael B. Kays, Pharm.D.*[3]; (1)St. Francis Hospitals and Health Centers, Beech Grove, IN; (2)James Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH; (3)Purdue University College of Pharmacy, Indianapolis, IN; (4)University Medical Center at Brackenridge, Austin, TX; (5)Purdue University College of Pharmacy, West Lafayette, IN

PURPOSE: To evaluate the PK/PD of piperacillin/tazobactam (PIP/TAZ) when administered by prolonged infusion (PI) in morbidly obese patients.

METHODS: Hospitalized patients with a BMI > 40 kg/m^2 received PIP/TAZ 6.75 g q8h (n=10) or 4.5 g q8h (n=2), infused over 4 h. Serial blood samples were collected at steady-state, and PIP/TAZ concentrations were determined by HPLC. PK parameters were estimated, and 5,000-patient Monte Carlo simulations were performed to estimate PIP PK profiles for 4 PI regimens: 3.375 g q8h, 4.5 g q8h,

6.75 g q8h, and 9.0 g q8h. Probability of target attainment (PTA) for ≥ 50% 64

RESULTS: Patient demographics were (mean ± SD): age 48 ± 11 years; weight 168 ± 26 kg; BMI 57.4 ± 15.1 kg/m^2. For PIP and TAZ, mean ± SD elimination rate was 0.424 ± 0.186 h^{-1} and 0.302 ± 0.114 h^{-1}, mg/ml. Only 9.0 g q8h achieved a PTA > 90% at an MIC of 32 mg/ml.

CONCLUSIONS: PIP and TAZ pharmacokinetics are altered in morbidly obese patients when compared to non-obese patients. Therefore, larger doses are required in morbid obesity to achieve similar exposures to non-obese patients. PI doses of 4.5 g and 6.75 g q8h in morbidly obese patients provides comparable PD exposures to 3.375 g and 4.5 g q8h, respectively, in non-obese patients.

144. Influence of Serum and Albumin on Echinocandin Pharmacodynamics. *Aasya S. Nasar, Pharm.D.*, Nathan P. Wiederhold, Pharm.D.; University of Texas at Austin College of Pharmacy, San Antonio, TX

PURPOSE: The Clinical Laboratory and Standards Institute (CLSI) has proposed lowering echinocandin *Candida* breakpoints. An alternative to this change that has been proposed is the addition of either human serum or albumin to the growth medium due to the extensive protein binding observed with these antifungals. Our objective was to evaluate and compare the in vitro pharmacodynamics of the clinically available echinocandins in the presence and absence of these biological matrices against a panel of *C. albicans* isolates with reduced echinocandin susceptibility.

METHODS: The in vitro pharmacodynamics of caspofungin, micafungin, and anidulafungin were determined against 12 *C. albicans* clinical isolates, including 11 for which the FKS1 point mutations were determined. Pharmacodynamic analysis was performed using the XTT viability assay at echinocandin concentrations ranging from 0–32 μg/mL. This was done in duplicate in RPMI, 5% human serum (HS), and 5% bovine serum albumin (BSA) as previously described (Meletiadis et al. J. Clin. Micro. 2001;39:3402). IC50 values were calculated by fitting the data to a four-parameter logistic model (Hill equation).

RESULTS: The addition of BSA significantly increased the IC50 values (mean increase 9-25-fold) of each echinocandin compared to RPMI ($p<0.001$) and HS ($P<0.01$). Although the addition of HS did increase IC50 values compared to RPMI (3–5 fold) the fold-changes were lower than observed with BSA. The changes in IC50 values were independent of the specific FKS1 mutations. The IC50 values for the wild-type isolate (ATCC 90028) did increase with the addition of HS and BSA, but remained < 1 μg/mL for each echinocandin.

CONCLUSIONS: The addition of HS and BSA significantly influenced the pharmacodynamics of the echinocandins, but to different degrees. Further work is needed to evaluate these matrices for in vitro pharmacodynamics testing and standardize echinocandin testing in their presence.

145. Simultaneous versus sequential combination therapy with vancomycin plus rifampin for *Staphylococcus aureus* biofilm infections. *Scott J. Bergman, Pharm.D., BCPS*[1], Jennifer Cho, Pharm.D.[2], Vidya Sundareshan, M.D.[3]; (1)Southern Illinois University Edwardsville, Springfield, IL; (2)Southern Illinois University Edwardsville, Edwardsville, IL; (3)Southern Illinois University School of Medicine, Springfield, IL

PURPOSE: *Staphylococcus aureus* is commonly associated with implant-related infections due to its ability to adhere to medical devices and form biofilms. Controversy exists on when to initiate combination therapy with vancomycin and rifampin. The purpose of this study was to determine if the *in vitro* effects of vancomycin and rifampin on *S. aureus* biofilms differed when initiated in combination simultaneously versus sequentially.

METHODS: Thirteen rifampin-susceptible *S. aureus* isolates from patients with prosthetic joint infections were grown as biofilms on transferable solid phase 96-pin lids (Nunc-TSP) incubated overnight rocking in tryptic soy broth with 1% dextrose. Minimum inhibitory concentration (MIC) testing was performed by microtiter broth dilution for each drug alone and in a checkerboard combination in the presence of the pin lid. A fractional inhibitory concentration index (FICI) was calculated for each isolate to determine if combination therapy provided synergy (≤0.5), indifference (>0.5–≤4), or antagonism (>4). This was compared after two days of exposure to vancomycin plus rifampin, together on each day (simultaneous) or vancomycin alone on day one and then combination therapy on day two (sequential).

RESULTS: Vancomycin MICs ranged from 2-8 mcg/mL alone while rifampin MICs were 0.0015–0.0625 μg/mL. Combination therapy resulted in indifference for all isolates when exposed simultaneously (mean FICI=1.24) or sequentially (mean FICI=0.86) except for one isolate that demonstrated synergy in the sequential arm.

CONCLUSION: Most MICs for *S. aureus* grown in biofilm were outside the traditional range of susceptibility when vancomycin was used alone, but consistently very low for rifampin. No antagonism was present in either arm. Although FICI values were lower for the sequential combination, timing of rifampin initiation on day 1 or 2 had little impact on results. Further research will need to be completed to determine if sequential use of combination therapy is significantly better then simultaneous exposure for biofilm infections.

146E. CANVAS 1 and 2: Analysis of clinical response at Day 3 from 2 phase III trials of ceftaroline fosamil vs vancomycin plus aztreonam in the treatment of complicated skin and skin structure infections. Tanya Baculik, M.D.[1], Paul B. Eckburg, M.D.[1], H. David Friedland, M.D.[1], Lily Llorens, Ph.D.[1], *Charles C. Schraa, Pharm.D.*[2], Alena Jandourek, M.D.[1], Gary Witherell, Ph.D.[1], Dirk Thye, M.D.[1]; (1)Cerexa, Inc. (a wholly owned subsidiary of Forest Laboratories, Inc., New York, NY), Oakland, CA; (2)Forest Research Institute, Mechanicsville, VA

PURPOSE: There is growing interest in assessment of antimicrobial noninferiority trials by using different endpoints as predictors of response to provide greater sensitivity to detect possible differences between comparators. Ceftaroline (CPT) fosamil (prodrug of CPT) was previously shown to be efficacious in 2 global, double-blind, randomized trials (CANVAS 1 and 2) that used clinical cure rates at the test-of-cure visit as the primary endpoint. We conducted a secondary analysis to assess CANVAS 1 and 2 results based on clinical response (CR) at Day 3.

METHODS: Hospitalized subjects with complicated skin and skin structure infections (cSSSI) were randomized to intravenous CPT fosamil 600 mg q12h vs vancomycin/aztreonam (V/A) 1 g/1 g q12h for 5–14 days. Analyses of CR at Day 3 were conducted in the exploratory modified intent-to-treat (MITT) population, who received study drug, had lesion size ≥75 cm^2, and either an infected surgical or traumatic wound, major abscess with erythema ≥5 cm, deep/extensive cellulitis, infected arthropod bite, or lower extremity abscess or cellulitis with diabetes mellitus or peripheral vascular disease. CR was achieved if subjects had cessation of infection spread, were afebrile at Day 3, and were not considered clinical failures by the investigator on Day 3.

RESULTS: CR rates at Day 3 were 74.0% (296/400) for CPT fosamil and 66.2% (263/397) for V/A in the combined analysis (exploratory MITT population; 95% CI: 1.3%, 14.0%). In the individual studies, absolute treatment differences of 9.4% (CANVAS 1) and 5.9% (CANVAS 2) favoring CPT fosamil were observed.

CONCLUSIONS: The CR rate from the combined CANVAS trials at Day 3 was higher for patients receiving CPT fosamil versus V/A (lower limit of 95% CI>0). CPT fosamil appears to provide benefit over V/A at Day 3, in terms of cessation of lesion spread and resolution of fever.

Presented at Presented at the 31st Annual Meeting of the Surgical Infection Society, Palm Beach, FL, May 11–14, 2011.

147E. FOCUS 1 and 2: Analysis of clinical response at Day 4 from 2 phase III trials of ceftaroline fosamil vs ceftriaxone in the treatment of community-acquired pneumonia. Paul B. Eckburg, M.D.[1], H. David Friedland, M.D.[1], Lily Llorens, Ph.D.[1], *Charles C. Schraa, Pharm.D.*[2], Alena Jandourek, M.D.[1], Gary Witherell, Ph.D.[1], Dirk Thye, M.D.[1]; (1)Cerexa, Inc. (a wholly owned subsidiary of Forest Laboratories, Inc., New York, NY), Oakland, CA; (2)Forest Research Institute, Mechanicsville, VA

PURPOSE: There is growing interest in assessment of antimicrobial

METHODS: Hospitalized subjects with moderate-to-severe CAP were randomized to receive intravenous CPT fosamil 600 mg q12h or

ceftriaxone (CRO) 1 g q24h for 5–7 days
RESULTS: CR rates at Day 4 were 69.5% (107/154) for CPT fosamil and 59.4% (92/155) for CRO in the combined analysis (exploratory
CONCLUSIONS: CR rates (clinical stability + symptom improvement) from the combined FOCUS trials at Day 4 were higher for patients receiving CPT fosamil versus those receiving CROCPT appears to provide benefit over CRO at Day 4.
Presented at Presented at the 48th Annual Meeting of the Infectious Diseases Society of America, Vancouver, Canada, October 21–24, 2010.

148E. Viridans group streptococci treatment with daptomycin: multinational experience. *Kenneth C. Lamp, Pharm.D.*[1], MinJung Yoon, M.P.H.[1], Ricardo L. Chaves, M.D., Ph.D.[2]; (1)Cubist Pharmaceuticals, Lexington, MA; (2)Novartis Pharma AG, Basel, Switzerland
PURPOSE: Viridans group streptococci (VGS) are a common cause of bacteremia and endocarditis. The objective of this study was to describe the use of daptomycin (DAP) in pts with VGS infections.
METHODS: All pts with a culture positive for VGS were studied from the CORE (US, 2005-2009) and EU-CORE (EU and countries worldwide, 2006-2010) retrospective registries. Investigators assessed outcome (cure, improved, failure, nonevaluable) at the end of DAP therapy.
RESULTS: Of 9105 pts, 99 (1.1%) pts had VGS infections, 52 (53%) were aged ≥ 51 years and 22% received DAP in an ICU. Underlying diseases included cancer (19%) and immunosuppression (10%). Of all pts, 58 (59%) had bacteremia; 23 (23%) pts had endocarditis. DAP was used as first line therapy in 21 (21%) and 22/78 (28%) of the second line use came after prior antibiotic failure. Most frequent prior antibiotics were β-lactams n=52 (53%) or vancomycin/teicoplanin n=35 (35%). Concomitant antibiotics were administered with DAP in 66 (67%) pts. The most frequent concomitant antibiotics were beta-lactams, n=44 (44%). The median initial DAP dose was 6 (min 3.3, max 8.3) mg/kg. The median DAP duration was 11 (min 1, max 56) days. Clinical outcomes (success, defined as cured or improved, failed, and nonevaluable) were (78%, 6% and 16%) overall; 81%, 7% and 12% for those (n=58) with positive blood cultures; 83%, 4%, and 13% for endocarditis (n=23); and 73%, 3% and 24% for those (n=33) on DAP monotherapy. Two pts had a DAP resistant pathogen (both failed); *Corynebacterium* sp. (DAP MIC > 256 mg/L) and VGS (DAP MIC > 2 mg/L. Adverse events leading to discontinuation were reported in 4% of pts. Serious AEs were reported in 6% of pts.
CONCLUSION: The clinical response and safety of DAP were similar to other pathogens reported from this registry. These data require confirmation via prospective clinical trials.
Presented at Presented at the 51st Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, American Society for Microbiology, Chicago, IL, Sep. 17–20, 2011

149. Characteristics of patients with de-escalated antibiotics based on culture and sensitivity data: impact on hospital re-admittance. *Kimberly Halton, Pharm.D.*, Jennifer Ng, Pharm.D., BCPS, Anthony Lucchi, Pharm.D., BCPS, Thara Damodaran, M.D.; Mercy Gilbert Medical Center, Gilbert, AZ
PURPOSE: De-escalation, the concept of targeting antibiotics by using microbiology results to narrow spectrum or discontinuing antibiotic use, is one way to use antibiotics judiciously. Antibiotic de-escalations have been tracked by Mercy Gilbert Medical Center's Antimicrobial Stewardship Program since September 2010. The purpose of this study was to determine 1) infection markers of patients with de-escalated antibiotic therapy and 2) the impact of de-escalation on hospital length of stay (LOS) and re-admittance.
METHODS: Retrospective review of all patients with a de-escalation recommendation by a pharmacist from September 2010 to March 2011. Patients <18 years old and immunocompromised patients were excluded. Data collected include temperature and white blood cell count (WBC) at time of recommendation, patient demographics, microbiology results, and antibiotic information.
RESULTS: One hundred ten patients were identified with an accepted de-escalation recommendation; 7 of 110 (6%) patients had their treatment escalated after de-escalation was made. Sixty-five of 103 (63%) recommendations were to discontinue an antibiotic class (e.g., Gram-positive). Thirty-nine of 103 (38%) recommendations were to de-escalate therapy. Thirty-seven of 103 (36%) patients had therapy changed with a WBC $>10x10^3/\mu L$. Ten patients of 103 (9%) were febrile (99–101°F) at time of recommendation; 2 patients had both an elevated WBC and were febrile. The average hospital LOS was 8.6 days. Fifteen of 103 (15%) patients were re-admitted within 30 days following hospital discharge; 3 were re-admitted due to infectious disease etiology. Two patients required surgical debridement and one patient was discharged on an antibiotic resistant to bacteria grown on culture (not recommended by pharmacist).
CONCLUSION: The most commonly accepted recommendation was to discontinue an antibiotic. There did not seem to be a correlation between patient outcome and infection markers at time of de-escalation. De-escalation of antibiotics was not associated with any patients being re-admitted to the hospital.

150. Assessment of antibiogram use in patients with sepsis transferred to a tertiary care facility. *Meredith Jernigan, Pharm.D.*[1], Bonnie A. Falcione, Pharm.D., BCPS[2]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Sepsis is a life threatening condition associated with high mortality, but the use of appropriate antibiotics early in the treatment course improves survival. Guidelines advocate the use of local antibiograms to select empiric regimens, however, it's unclear if these are used in practice, especially when patients are transferred to tertiary care facilities (TCF). This study evaluated prescriber reported frequency and perceived importance of outside hospital (OSH) antibiogram utilization when treating septic patients transferred to TCF.
METHODS: The study was conducted with an anonymous electronic survey of physicians at seven community and tertiary hospitals within a large health-system. The 25-question survey included Likert-scale, open-ended and multiple-choice formats, and was distributed via an electronic database three times over four weeks . Respondent demographics, and reported frequency, perceived importance and barriers for antibiogram use were collected. Ability to use an antibiogram was also evaluated. Descriptive statistics were used to analyze demographic data and responses. Comparisons were evaluated with χ^2 or Fisher's Exact tests.
RESULTS: The survey was distributed to 3397 physicians and completed by 269 (8%). Of these, 167(62%) reported they care for septic patients in a TCF and 113 (68%) reported they never use the OSH antibiogram. Use of OSH antibiograms for transferred septic patients was described as moderately-very important by 135 (80%) of these physicians. The most common reported barrier to using OSH antibiograms was information not being available. When tested on the ability to use an antibiogram, 214 (80%) used it correctly.
CONCLUSION: The majority of surveyed physicians treating septic patients transferred to TCF perceive antibiogram use as important and demonstrated correct use. However, most of these physicians never use the OSH antibiogram, primarily due to lack of availability. Lack of antibiogram use may place this group of patients at risk for inappropriate therapy and suggests OSH antibiograms should be readily available.

151E. Experience with daptomycin for coagulase-negative staphylococcal bacteremia with elevated vancomycin MICs. *Kenneth C. Lamp, Pharm.D.*, Elizabeth D. Hermsen, Pharm.D., M.B.A., BCPS, (AQ-ID), Charu Gupta, MSc, MinJung Yoon, M.P.H.; Cubist Pharmaceuticals, Lexington, MA
PURPOSE: Coagulase-negative staphylococci (CoNS) are a frequent cause of bacteremia. The purpose of this study is to evaluate DAP outcomes and safety for treatment of CoNS bacteremia with elevated vancomycin MICs.
METHODS: All pts with CoNS bacteremia were identified in CORE 2010, a retrospective, multicenter, observational registry of staphylococcal bacteremia pts with VAN MICs ≥ 1.5 mg/L. Investigators assessed pt outcome (cured, improved, failed, NE-nonevaluable) at the end or at last contact during DAP therapy. The efficacy population was the resulting cured, improved and failed pts. Pt characteristics are based on the efficacy population. All pts were included in the safety analysis.

RESULTS: There were 24 pts evaluable for DAP outcome; median 55 yrs; 38% received DAP in an ICU; 13% hemodialysis and 63% had severe sepsis. Underlying diseases included diabetes (38%) and cancer (29%). Twelve (50%) pts had catheter-related bacteremia (CRB); 4 (17%) pts had endocarditis. DAP median (min, max) initial dose, AR-LOS, and total treatment duration were 6 mg/kg (5, 8.3), 8.5 days (4, 31) and 12.5 days (5, 73). Prior antibiotic therapy was utilized in 21 pts (88%); most commonly vancomycin (90%). Six (32%) pts failed prior vancomycin therapy. DAP success was documented in 22 pts (92%; cured 58%, improved 33%), 100% (4/4) in endocarditis, 92% (11/12) in CRB and 100% (6/6) in pts who failed prior vancomycin. 25 pts were available for safety analysis. Adverse events (AE) occurred in 15 pts (60%); 1 discontinued DAP due to an AE and 4 pts had AE possibly related to DAP. The all-cause mortality rate to 30 days after stopping DAP was 12% (n=3).
CONCLUSION: DAP appeared to provide effective and well tolerated therapy for treatment of CoNS bacteremia with elevated VAN MICs, although these data are non-comparative and include a small sample size.
Presented at Presented at the 51st Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, American Society for Microbiology, Chicago, IL, Sep. 17–20, 2011

152. Daptomycin use in neutropenic patients with documented MRSA bacteremia with high vancomycin MICs. John A. Segreti, M.D.[1], *Dina Besece, Pharm.D.*[2], Hurdle Anderson, Pharm.D.[2], Charu Gupta, MSc[2]; (1)Rush University Medical Center, Chicago, IL; (2)Cubist, Lexington, MA
PURPOSE: This report describes utilizing DAP as an alternative to VAN in neutropenic pts with MRSA bacteremia and an elevated VAN MIC.
METHODS: All pts with neutropenia (≤ 1000 cells/m^3) and MRSA bacteremia with VAN MICs of ≥ 1.5 μg/mL were identified in CORE 2010, a retrospective, multicenter, observational registry of pts treated with DAP. Investigators assessed pt outcome (cured, improved, failed, NE-nonevaluable) at the end or at last contact during DAP therapy. Pt. characteristics are based on the efficacy population. All pts were included in the safety analysis.
RESULTS: 10 pts with MRSA bacteremia, neutropenia, and VAN MICs ≥ 1.5 μg/mL were identified and evaluable for outcome. Baseline characteristics included: 5 male, 5 ≥ 65 years of age, 3 with initial CrCl < 30 mL/min (2 on Hemodialysis), and 2 received DAP in an ICU. 6 pts had a history of cancer or transplant. 9 pts had a VAN MIC = 2 μg/mL (Vitek ½ N=8, unk N=1) and 1 VAN MIC = 1.5 (E-test). All pts had DAP MIC ≤ 1 μg/mL and all pts received VAN prior to DAP. The median (min,max) duration of VAN therapy was 4.5 (1,16) days . The median (min, max) initial DAP dose was 6 mg/kg (5.7,8) The median (min,max) duration of therapy was 15.5 (4,46) days. Success occurred in 80% of pts (3/3 WBC ≤ 100/mm^3 and 5/7 WBC 101-499/mm^3). 1 pt (assessed as DAP failure) was readmitted within 60 days of completing DAP therapy for an infection related event. 4 pts experienced a serious AE resulting in 2 deaths, none were possibly related to DAP.
CONCLUSION: DAP was effective and well tolerated in neutropenic pts with MRSA bacteremia and elevated VAN MICs. Further clinical trials are warranted.

153E. Improving prescribing and documentation of immunization and education in patients who undergo emergency splenectomy. *Bonnie A. Falcione, Pharm.D., BCPS*[1], Elisabeth L. George, Ph.D.[2], Richard D. Day, Ph.D.[3], Susan J. Skledar, B.S., M.P.H.[1]; (1)University of Pittsburgh School of Pharmacy, Department of Pharmacy and Therapeutics; UPMC Presbyterian Hospital, Pittsburgh, PA; (2)University of Pittsburgh School of Nursing, UPMC Presbyterian Hospital, Pittsburgh, PA; (3)University of Pittsburgh Graduate School of Public Health, Department of Biostatistics, Pittsburgh, PA
PURPOSE: Patients undergoing emergency splenectomy are candidates for immunization to prevent overwhelming post-splenectomy sepsis. Due to the multiple vaccines needed, and the urgent care setting, the immunization process is error-prone. A quality improvement audit at our institution showed errors in vaccine prescribing, dispensing, administration, and documentation.
METHODS: After a phased implementation of a customized physician order set with corresponding dispensing and documentation procedure, an IRB-approved retrospective review of medical records for patients who underwent an emergent splenectomy between January 1, 2008 and December 31, 2009, to evaluate prescribing and required documentation of vaccine administration and patient education compared to our historical baseline, was performed. Statistical analysis was performed with χ^2 and Fisher's Exact tests.
RESULTS: We found 76, 110, and 108 patients underwent splenectomy at our institution in 2007, 2008 and 2009 with 56, 44 and 46 evaluable medical records for diagnosis confirmed emergent splenectomy, respectively. Prescribing and documentation of vaccine administration for > 1 of the required vaccines increased compared to 2007 historical baseline in 2008 after implementing a pre-printed physician order set (100% vs. 88.6%; p=0.025 and 100% vs. 77.8%; p=0.004, respectively), and in 2009 after implementing a computerized physician order set (100% vs. 88.6%; p=0.022 and 100% vs. 77.8%; p=0.001, respectively). All required elements of vaccine administration documentation (site, lot number, expiration date and manufacturer increased between 2007 and 2009 (54.5% vs. 97.8%, p<0.001; 31.6% vs. 77.8%, p<0.001; 31.6% vs. 57.8%, p=0.009; 7% vs. 26.7%, p=0.01; respectively). Patient education documentation (not evaluable in 2008) increased in 2009, significantly during the six months compared to baseline (17.1% vs. 46.4%; p=0.004).
CONCLUSION: These results suggest that implementation of a customized physician order set (pre-printed or computerized), and corresponding dispensing and documentation procedure may reduce errors and omission of required documentation, including education, in patients who undergo emergency splenectomy.
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154. Evaluation of clinical outcomes and adverse events when administering alternative doses of linezolid to obese patients. Megan R. Fleming, Pharm.D.[1], S. Christian Cheatham, Pharm.D.[1], *Michael B. Kays, Pharm.D.*[2]; (1)St. Francis Hospitals and Health Centers, Beech Grove, IN; (2)Purdue University College of Pharmacy, Indianapolis, IN
PURPOSE: The WHO recognizes obesity as a global pandemic. With the increasing prevalence of obesity, it becomes paramount to explore optimal antimicrobial dosing regimens for treating infections in obese patients. The maximum FDA-approved dose of linezolid is 600 mg IV/PO q12h for adults; however, previous PK/PD analyses suggest larger linezolid doses may be needed to achieve adequate exposures in obese patients. The purpose of this study was to evaluate clinical outcomes and adverse events in obese patients receiving larger linezolid doses.
METHODS: Data were collected by retrospective chart review. Patients included in the analysis weighed > 120 kg and were treated with alternative doses of linezolid from January 2004 to December 2010. The dosing regimen, duration of therapy, patient outcomes, and adverse events were assessed. Outcome was determined at the end of hospital stay and defined as cure, improved, or failure.
RESULTS: Thirty-five patients received larger doses of linezolid and were evaluated. Mean ± SD weight and body mass index were 153.7 ± 32.5 kg and 51.4 ± 9.4, respectively. The most common linezolid dosing regimen (n=21) was 600 mg IV/PO q8h. Overall, the success rate (cure + improved) was 71.4%. Twenty-three patients (65.7%) did not experience any documented adverse events on therapy. The most frequent adverse event was thrombocytopenia, which developed in 8 patients (22.9%). After excluding confounding factors, thrombocytopenia developed in 3 patients (8.6%). The onset of thrombocytopenia in these two groups was 6.7 days and 9 days, respectively. The overall duration of therapy was 7.7 ± 4.9 days.
CONCLUSIONS: Similar clinical outcomes were observed in this obese population as previously reported in clinical trials with linezolid. These findings may suggest that empiric dose optimization is needed when treating obese patients with linezolid. Increased incidence of thrombocytopenia may be related to severity of illness and/or other confounding factors.

155. Tigecycline use and selection of *Pseudomonas aeruginosa*. *Scott J. Bergman, Pharm.D., BCPS*[1], Bart A. Smith, Pharm.D.[2], Vidya Sundareshan, M.D.[3], Janak Koirala, M.D.[3]; (1)Southern Illinois

University Edwardsville, Springfield, IL; (2)Southern Illinois University Edwardsville, Benton, IL; (3)Southern Illinois University School of Medicine, Springfield, IL

PURPOSE: Tigecycline is one of the broadest spectrum antibacterial agents available, but it does not have activity against *Pseudomonas aeruginosa*. The purpose of this study was to determine if patients being treated with tigecycline grew *P. aeruginosa* from their cultures more often than those being treated with tigecycline plus an antipseudomonal antibiotic.

METHODS: Patients were included if they received tigecycline for > 48 hours while hospitalized anytime during 2009. Patients were excluded if cultures grew *P. aeruginosa* prior to tigecycline initiation during that admission or in the first 48 hours of therapy. Included patients were split into two arms: those that received concurrent antipseudomonal antibiotics (i.e., aminoglycosides, aztreonam, certain β-lactams & fluoroquinolones) while on tigecycline and those that did not. Patients were counted as positive if they grew *P. aeruginosa* on therapy or within 10 days after discontinuation.

RESULTS: Charts were reviewed for all 260 patients receiving tigecycline and data collected for those 194 meeting inclusion criteria. A majority were excluded for not being on tigecycline the required 48 hours. Of the 85 patients receiving tigecycline without concurrent antipseudomonal therapy, seven (8.24%) had positive cultures for *P. aeruginosa* compared to nine out of 109 (8.26%) patients on tigecyline plus antipseudomonal therapy. Sites of positive cultures were similar in both groups (tigecycline, combination) and included urine (3,3), wound (3,3) sputum (1,3), bone (0,2) and catheter (2,0). Patients with diabetes were more likely to be treated with antipseudomonal antibiotics (24.7% vs. 45.8%, $p<0.05$), but were also more likely to develop positive cultures compared to non-diabetics (2.4% vs 18.3%, $p<0.05$).

CONCLUSION: Patients treated with tigecycline were no more likely to grow *P. aeruginosa* than patients on combination therapy with an antipseudomonal antibiotic. Patients with diabetes may still need to receive antipseudomonal antibiotics along with tigecycline because of their high-risk of *P. aeruginosa*.

156. Empiric anti-MRSA antibiotics for MRSA pneumonia in a community hospital. *Paul Juang, Pharm.D.*, Jennifer S. Hardesty, Pharm.D.; St. Louis College of Pharmacy, St. Louis, MO

PURPOSE: With recent increases in the rates of methicillin-resistant *Staphylococcus aureus* (MRSA) pneumonia, multiple groups have recommended the addition of anti-MRSA antibiotics in the empiric treatment of suspected pneumonia in patients with MRSA risk factors due to the clinical implications associated with inadequate initial empiric therapy. The purpose of this study is to examine the appropriate empiric treatment of MRSA pneumonia and the rate of modification of antibiotic therapy.

METHODS: A retrospective data analysis was conducted using an electronic data repository to identify patients 18 years of age or older with ICD-9 codes for pneumonia. Pregnant patients, patients with hospital-acquired or ventilator-associated pneumonia and patients not started on antibiotics within 24 hours of admission were excluded. The primary results were the rate of appropriate empiric anti-MRSA antibiotic usage in patients with culture-positive MRSA pneumonia and the rate of de-escalation based on available microbiological results. Secondary results included length of antibiotic usage, length of hospital stay and discharge disposition. Descriptive statistics were utilized where appropriate.

RESULTS: From January 1 to December 31, 2010, 2521 patients were admitted with suspected pneumonia, of which 423 patients received vancomycin while only 29 patients had positive sputum cultures for MRSA. In patients with positive MRSA sputum cultures, 24 patients were identified as having healthcare-associated pneumonia and 5 patients with community-acquired pneumonia with 20 patients started on appropriate anti-MRSA regimen empirically. Only 6/29 patients had their antibiotic regimen deescalated based on culture results. The average length of stay was 10 ± 7 days and 18/29 of the patients were discharged to home.

CONCLUSION: Our study suggests a need for a different approach to adhering to guidelines for empiric coverage in patients admitted for MRSA pneumonia. These results have encouraged the institution to revise the pneumonia order set and examine the utilization of anti-MRSA antibiotics.

157. Analysis of outcomes and risk factors associated with extended-spectrum β-lactamase-production in bloodstream infections. *S. Travis King, Pharm.D.*, Laleh Azari, Pharm.D., Jennifer D. Twilla, Pharm.D., BCPS, Justin B. Usery, Pharm.D., BCPS; Methodist University Hospital, Memphis, TN

PURPOSE: Infections with multidrug-resistant *Enterobacteriaceae* are increasing. A major mechanism of resistance within this family is production of extended-spectrum β-lactamases (ESβLs), which confer resistance to cephalosporins, penicillins, and monobactams. Our study sought to determine the clinical and microbiologic outcomes and risk factors associated with ESβL(+) infections.

METHODS: We conducted a retrospective analysis of patients with *Klebsiella pneumoniae*, *K. oxytoca*, or *Escherichia coli* bacteremia. Cultures were identified using a microbiology laboratory report and stratified based on ESβL production. All ESβL(+) organisms were screened for inclusion. Three non-ESβL isolates were randomly selected for each ESβL(+) isolate. Included patients were at least 18 years of age with 1 or more positive blood culture(s); polymicrobial cultures and patients with less than 48 hours of data were excluded.

RESULTS: Eighty-eight patients were included (22 ESβL and 66 non-ESβL). Demographics were similar between groups. Clinical cure (59.1 vs. 65.2%, p=0.6), microbiologic cure (100 vs. 91.8%, p=0.5), and mortality (22.7 vs. 18.2%, p=0.7) did not differ between ESβL(+) and non-ESβL groups, respectively. Presence of an ESβL(+) infection was associated with a longer length of stay, presence of an invasive device at admission, antibiotic exposure in the prior 30 days, and hospitalization in the prior 90 days ($p<0.05$ for all). Patients with ESβL(+) strains were more likely to receive inadequate initial antimicrobial therapy (27.3 vs. 4.6%, $p<0.007$). Of ESβL(+) patients treated with piperacillin/tazobactam (n =8), 75% achieved clinical cure and 100% of those with repeat cultures (n=6) achieved microbiologic cure.

CONCLUSION: ESβL status did not significantly affect rates of clinical or microbiologic cure or mortality. Significantly more patients with ESβL(+) infections were inadequately treated empirically. ESβL(+) infections were associated with risk factors indicative of prior healthcare exposure. Results of this study should be interpreted carefully given the limited sample size and should be assessed in prospective studies.

158. Pharmacokinetics and pharmacodynamics of meropenem in morbidly obese, hospitalized patients. S. Christian Cheatham, Pharm.D.[1], Megan R. Fleming, Pharm.D.[1], Daniel P. Healy, Pharm.D.[2], Christina E. K. Chung, Pharm.D.[3], *Michael B. Kays, Pharm.D.*[3]; (1)St. Francis Hospitals and Health Centers, Beech Grove, IN; (2)James Winkle College of Pharmacy, University of Cincinnati, Cincinnati, OH; (3)Purdue University College of Pharmacy, Indianapolis, IN

PURPOSE: Obesity is a major healthcare crisis worldwide, but only limited data are available regarding antimicrobial pharmacokinetics and appropriate dosing in morbid obesity. The purpose of this study was to evaluate the steady-state pharmacokinetics and pharmacodynamics of meropenem in patients who are morbidly obese.

METHODS: Hospitalized patients with a BMI > 40 kg/m^2 were enrolled. Patients received meropenem 1000 mg q6h (n=8) or 500 mg q6h (n=2), infused over 30 minutes. Serial blood samples were collected at steady-state, and meropenem concentrations were determined by HPLC. Meropenem PK parameters were estimated by

RESULTS: Four men and 6 women were studied. Patient demographics were (mean ± SD): age 56 ± 10 years; weight 163 ± 22 kg; BMI 60.6 ± 8.2 kg/m^2, creatinine clearance 73 ± 26 ml/minute. Mean ± SD elimination rate, half-life, β

CONCLUSIONS: Despite changes in β

159. Pharmacokinetic and safety analysis of high-dose moxifloxacin in a morbidly obese individual. *S. Travis King, Pharm.D.*[1], Ngan H. Vo, Pharm.D., BCPS[1], Andrew C. Faust, Pharm.D., BCPS[1], Dipen Kadaria, M.D.[2], John W. Thompson, M.D.[2], Matthew W. Mabie, M.D.[3]; (1)Methodist University Hospital, Memphis, TN; (2)University of Tennessee Health Science Center, Memphis, TN; (3)Mid-South Pulmonary Specialists, Memphis, TN

PURPOSE: Antimicrobial dosing in the obese population remains imprecise. A 340 kg female with past medical history of chronic obstructive pulmonary disease and penicillin allergy presented to our institution in respiratory distress. Within 24 hours of intubation, she developed a pulmonary infiltrate and was initiated on antibiotic therapy with moxifloxacin 400 mg IV daily plus vancomycin 1 gram IV every 6 hours for suspected community-acquired pneumonia; moxifloxacin was increased to 800 mg IV daily after 48 hours of therapy. Herein, we present the results of a pharmacokinetic and safety analysis of high-dose intravenous (IV) moxifloxacin in this morbidly obese individual.
METHODS: Baseline and serial electrocardiogram (EKG), liver function tests, blood glucose measurements, and neurologic assessments were ordered to assess safety. Five moxifloxacin serum concentrations were measured following the third dose of 800 mg at hours 3, 7, 11, 19, and 24. Area under the concentration-time curve (AUC) was calculated using Simpson's rule. A deep tracheal aspirate was obtained for microbial identification.
RESULTS: Pharmacokinetic assessment revealed a moxifloxacin AUC of 38.05 mg•h/L, CL of 9.9 L/hr, half-life of 17.3 hrs, and Vd of 0.7 L/kg. This is comparable to a steady-state AUC of 38 +/- 4.7 mg•h/L following multiple daily doses of moxifloxacin 400 mg IV in healthy adults. No changes were seen in the corrected QT interval. AST and ALT remained within normal range. Blood glucoses ranged from 124–183 mg/dL, with no increases in insulin requirements. The patient's neurologic status remained stable, with no evidence of seizure activity. Culture results demonstrated 2+ *Streptococcus pneumoniae* with a moxifloxacin MIC = 3 (via E-test).
CONCLUSION: Moxifloxacin 800 mg IV daily appears safe and achieved an AUC comparable to those achieved in healthy patients receiving standard dose therapy. AUC/MIC assessment in this patient is limited due to moxifloxacin resistance.

160. Efficacy and safety of six months of low- vs. high-dose valganciclovir for prevention of Cytomegalovirus disease in high-risk renal transplant recipients. *Steven Gabardi, Pharm.D., BCPS*[1], Lisa M. McDevitt, Pharm.D., BCPS[2], Christin Rogers, Pharm.D.[3], Eric Tichy, Pharm.D., BCPS[4], Renee Weng, Pharm.D.[5], Ruth-Ann M. Lee, Pharm.D.[6]; (1)Department of Pharmacy & Renal Divison, Brigham & Women's Hospital; Department of Medicine, Harvard Medical School, Boston, MA; (2)Tufts Medical Center, Boston, MA; (3)Beth Israel Deaconess Medical Center, Boston, MA; (4)Yale-New Haven Hospital, New Haven, CT; (5)UC-Irvine, Orange, CA; (6)Massachusetts General Hospital, Boston, MA
PURPOSE: Prolonged (200 days) cytomegalovirus (CMV) prophylaxis using valganciclovir (VGC) 900 mg/day has proven efficacy, yet some centers continue to utilize 450 mg/day due to its reported success and potential cost savings. This study compared the efficacy and safety of 6 months of low-dose vs high-dose VGC prophylaxis in high-risk renal transplant recipients (RTR).
METHODS: A multicenter, retrospective analysis evaluated 183 adult RTR between 8/1/2001 and 12/31/2009. Group 1 (n=106) received VGC 450 mg/day and Group 2 (n=77) received VGC 900 mg/day. VGC was started post-operatively and dose adjusted for renal function with goal duration of 6 months. The primary endpoint was CMV disease prevalence at 1 year. The rates of breakthrough CMV, resistant CMV, AR, graft loss, opportunistic infections (OI), new-onset diabetes after transplant (NODAT) and early VGC discontinuation (DC), as well as, renal function (RF) and hematologic lab values were also evaluated.
RESULTS: Patient demographics and transplant characteristics were comparable. All patients received antithymocyte globulin induction therapy and maintenance immunosuppression was similar throughout the study, with the exception of complete steroid withdrawal occurring more in Group 2 (37.7% vs 74%; p<0.0001).

12 Month Efficacy Analysis	Group 1	Group 2	P-value
CMV disease	16 (15.1%)	21 (27.3%)	0.061
- Breakthrough Disease	3 (18.8%)	3 (14.3%)	1.000
- Resistant Disease	0 (0%)	4 (19%)	0.118
AR	16 (15.1%)	10 (13%)	0.831
RF (ml/min/1.73m^2)	46.4 + 18.1	45.4 + 15.5	0.696
Graft Loss	1 (0.9%)	2 (2.6%)	0.574
OI	23 (21.7%)	12 (15.6%)	0.345
NODAT	9 (8.5%)	2 (2.6%)	0.123

The safety analysis showed similar results. The rate of early VGC DC due to myelosuppression was similar in each group.
CONCLUSION: Both regimens provide similar efficacy in prevention of CMV disease in high-risk RTR. The need for early VGC DC secondary to hematologic adverse events was comparable.

161. Effect of implementing an electronic order menu for trimethoprim-sulfamethoxazole on changing prescriber ordering behavior and decreasing adverse events in elderly outpatient veterans. *Tina M. Khadem, Pharm.D*, Kimberly MacKay, Pharm.D, Ronald Brown, R.Ph; Portland VA Medical Center, Portland, OR
PURPOSE: In September of 2009, the Portland VA Medical Center implemented an electronic order menu for trimethoprim-sulfamethoxazole (TMP-SMX). This retrospective chart review examined the effect of this on prescriber ordering behavior by comparing the change in the percentage of patients prescribed therapy in the presence of contraindications, precautions, and missing lab values. Additionally, this study evaluated the change in the number of adverse events.
METHODS: Medical records of 248 veterans who received outpatient prescriptions for at least 5 days of therapy between September 1, 2008 to August 31, 2008 and January 1, 2010 to December 31, 2010 were reviewed. Patient demographics, laboratory data, concomitant medications, comorbidities, TMP-SMX data, adverse events and hospitalizations for hyperkalemia and acute renal insufficiency were documented.
RESULTS: Before the order menu was implemented, two patients were prescribed TMP-SMX in the presence of contraindications while none were prescribed the drug after order menu implementation (1.6% vs. 0.0%, p=0.471). The percentage of patients prescribed therapy in the presence of 3 or 4 precautions also decreased (11.4% vs. 10.4% and 2.4% vs. 1.6% respectively, p=0.714). The percentage of patients prescribed therapy in the presence of 2 precautions and in the presence of missing lab values increased (45.5% vs. 48.8%, p=0.814; 11.4% vs. 17.6%, p=0.226). A greater proportion of patients experienced adverse events before the order menu was implemented. In the patients who received TMP-SMX before order menu implementation, baseline average serum creatinine was higher and the estimated glomerular filtration rate was lower (1.2 mg/dL vs. 1.0 mg/dL, p=0.012; and 73 ml/min vs. 82 ml/min, p=0.002).
CONCLUSIONS: Implementation of the TMP-SMX electronic order menu did not significantly change prescriber ordering behavior. However, a beneficial effect of the order menu may be seen when comparing baseline average serum creatinine and estimated glomerular filtration rates before and after the order menu.

162. Evaluation of colistimethate use in the Shock Trauma Center at the University of Maryland Medical Center. *Jennifer L. Bailey, Pharm.D.,* Mehrnaz Pajoumand, Pharm.D., Sai-Ho Jason Chui, Pharm.D., Ellis Caplan, M.D.; University of Maryland Medical Center, Baltimore, MD
PURPOSE: Colistimethate (CMS) has recently become the preferred formulary polymyxin at the University of Maryland Medical Center; however, concerns with dosing inconsistency and failure to utilize ideal body weight (IBW) as well as nephrotoxicity risk exist. Given the limited preexisting literature in trauma patients, a medication utilization evaluation was performed to 1) describe the prescribing trends of CMS and 2) assess the incidence of CMS nephrotoxicity at the Shock Trauma Center (STC).
METHODS: A retrospective chart review was performed on patients (N=46) admitted to the STC who received ≥ 1 dose of CMS between 2008 and 2010. Renal function, dosing regimen, previous and concomitant nephrotoxic agent administration, nephrotoxicity (using RIFLE criteria), and need for new renal replacement therapy (RRT) was collected. Descriptive statistics were performed as appropriate.
RESULTS: Nine patients received multiple CMS courses, resulting in 57 courses analyzed. The mean daily dose (using IBW) prescribed was 4.3 mg/kg/day, (range 0.9–9 mg/kg/day) and a mean of 9 days of therapy was received. Eighteen patients required RRT at baseline. Of the remaining population, 16 patients (57%) met nephrotoxicity criteria (R=5 patients, I=7 patients, F=4 patients); however, 15

received additional nephrotoxic agents and 7 had baseline SCr levels ≤0.5 mg/dL. Of 8 patients who required new RRT, 7 recovered renal function by discharge and 1 patient expired.
CONCLUSIONS: A wide range of CMS dosing was observed, creating potential for under- and overdosing and serves as an area for future pharmacist intervention. While nephrotoxicity criteria were met in over one-half of eligible patients, there was not a need for RRT beyond hospitalization in this population.

163E. Isoniazid blood levels in patients with pulmonary tuberculosis at a tuberculosis referral center. *Fanak Fahimi, Pharm.D.*[1], Shadi Baniasadi, Pharm.D., Ph.D.[2], Farzad Kobarfard, Pharm.D., Ph.D.[3], Payam Tabarsi, M.D.[4], Shabnam Hemmati, Pharm.D.[5], Jamshid Salamzadeh, Pharm.D., Ph.D.[6]; (1)Pharmaceutical Care Department, Chronic Respiratory Disease Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti, Tehran, Iran; (2)Pharmaceutical Care Department, Virology Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University., Tehran, Iran; (3)Medicinal Chemistry Department, School of Pharmacy, Shahid Beheshti University. M.C., Tehran, Iran, Tehran, Iran; (4)Chronic Respiratory Disease Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University. M.C., Tehran, Iran; (5)Clinical Pharmacy Department, School of Pharmacy, Shahid Beheshti University. M.C., Tehran, Iran; (6)Clinical Pharmacy Department, School of Pharmacy, Shahid Beheshti University of Medical Sciences Tehran, Tehran, Iran
PURPOSE: To evaluate the serum concentration of isoniazid (INH) in Iranian patients and to determine the factors correlated to the plasma INH level.
METHODS: Blood samples were obtained 2 hours post ingestion of 5 mg/kg INH in 82 patients (one sample per patient) who were in days 3–15 of treatment. Investigated variables were INH plasma level, duration of therapy, age, sex, weight, dose of administered drug, and smoking status.
RESULTS: The average±SD age and weight of patients were 60.68 ± 18.53 years and 74.96 ± 7.15 kg respectively. Prevalence of low and high concentration of INH was 14.63% and 23.17% respectively where reference ranges was 3-5 mcg/ml. Days of INH administration showed statistical correlation with plasma INH level (Kendall's rank correlation, r=0.66, p <0.001). INH plasma level was not correlated with other variables.
CONCLUSION: Based on the result of this study plasma concentrations of INH were not in therapeutic ranges for 37.80% of patients on conventional therapy. Therapeutic drug monitoring (TDM) may be needed to optimize INH dose, especially in patients with inadequate clinical response or toxicity to INH. Key words: Blood level, Isoniazid, Tuberculosis, Monitoring
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Managed Care

164E. The first pharmacist based warfarin monitoring service in Iran. *Fanak Fahimi, Pharm.D.*[1], Shadi Baniasadi, Pharm.D., Ph.D.[2], Babak Sharif-Kashani, M.D.[3], Zargham Hossein Ahmadi, M.D.[4], Jamshid Salamzadeh, Pharm.D., Ph.D.[5], Rocsanna Namdar, Pharm.D.[6], Sara Mousavi, Pharm.D., Ph.D.[7], Shadi Ziaie, Pharm.D., Ph.D.[5], Leila Ghazi –Tabatabei, Pharm.D.[8], Golnar Radmand, M.S.[9], Mohammad Reza Masjedi, M.D.[10]; (1)Pharmaceutical Care Department, Chronic Respiratory Disease Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti, Tehran, Iran; (2)Pharmaceutical Care Department, Virology Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University., Tehran, Iran; (3)Tobacco Prevention and Control Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University of Medical Scie, Tehran, Iran; (4)Lung Transplantation Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehr, Tehran, Iran; (5)Clinical Pharmacy Department, School of Pharmacy, Shahid Beheshti University, M.C., Tehran, Iran; (6)University of Colorado Anschutz Medical Campus, Aurora, CO; (7)Clinical Pharmacy Department, School of Pharmacy, Tehran University of Medical Science, Tehran, Iran; (8)Pharmaceutical Care Department, Chronic Respiratory Disease Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Behesh, Tehran, Iran; (9)Epidemiology and Biostatistics Center , NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences,Te, Tehran, Iran; (10)Chronic Respiratory Disease Research Center, NRITLD, Masih Daneshvari Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
PURPOSE: This paper evaluates the adequacy of anticoagulation care and determines the effects of consultation services in the first pharmacist-based anticoagulation clinic in Iran.
METHODS: The anticoagulation clinic of Masih Daneshvari Hospital was established by a clinical pharmacist. In a prospective cohort study, all patients on warfarin therapy who were referred to this clinic were followed during a 4 month period. Patients were monitored and consulted based on a predetermined guideline. The primary desired outcome was the control of INR per therapeutic range. Data was gathered on the indication of warfarin therapy, the pharmacist's interventions, and the adverse drug effects experienced by the participants. Descriptive statistics and logistic regression model were used to present the results.
RESULTS: A total of 76 patients were included out of which 42.1% were male. The mean age (±SD) of the participants was 50 (±17). The main indications for warfarin prescription were treatment of Deep Vein Thrombosis or Pulmonary Emboli (46.1%) and Mechanical Valve Replacement (23.7%). The primary reason for referral of patients to the clinic was routine monitoring (32.9%) and INR control (31.3%). The most common intervention by the pharmacist was increasing the dose (31.6%). Of the referred patients, 47.7% reached the target INR on follow up visits while the INR in 11.8% of them was not within the desired range. None of the clinical interventions performed by the responsible physicians for the management of bleeding was compatible with our guidelines. There was a trend between the proper use of warfarin and reaching the target goal of the INR (OR: 2.97, P: 0.09)
CONCLUSION: The results demonstrate that an anticoagulation clinic managed by a clinical pharmacist offers not only a safe and effective treatment but also a better care with respect to anticoagulation control.
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Medication Safety

165. Implementation of medication reconciliation by a pharmacist in patients with human immunodeficiency virus or acquired immune deficiency syndrome on highly active antiretroviral therapy. *Courtney L. Tam, Pharm.D.*[1], Tomasz Z. Jodlowski, Pharm.D., BCPS, (AQ-ID)[2]; (1)Beth Israel Medical Center - Petrie Campus, New York, NY; (2)St. John's University College of Pharmacy and Allied Health Professions, Queens, NY
PURPOSE: Obtaining accurate and complete medication history remains a problem at many hospitals. Following the Joint Commission's National Patient Safety Goals, this quality improvement project (QIP) evaluated the effectiveness of medication reconciliation conducted by a pharmacist, in patients with human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) on Highly Active Antiretroviral Therapy (HAART), a high risk group for medication errors.
METHODS: This was a prospective QIP that took place between December 2010 and February 2011; IRB exemption was obtained. A list of patients with HIV on HAART was accessed and eligible patients identified using predetermined inclusion/exclusion criteria. A pharmacist performed medication reconciliation within forty eight hours of admission using the following methods and compared the results to the current standard (current medication reconciliation process by a physician or nurse). Medication reconciliation included the use of a structured patient questionnaire, review of documents in the chart, and contact with an outpatient pharmacy and/or primary care provider. Discrepancies were communicated to the primary team for implementation when appropriate.
RESULTS: A total of 18 patients were included in this QIP; mostly from the medicine units. The medication history was completed by a pharmacist in approximately 30 minutes. The pharmacist identified more medications than the current standard (16.4 versus 10.7, p <0.05). Interventions were suggested (89%; 16 out of 18 patients) to

the primary team and most were accepted (78%; 34 out of 43 interventions). There were discrepancies in HAART or opportunistic infection regimens (42%; 18 out of 43 interventions) and other disease state medications (58%; 25 out of 43 interventions).
CONCLUSION: Obvious differences were identified between the mediation reconciliation performed by a pharmacist versus the current standard. This project demonstrates a potential benefit in the use of pharmacists, medication experts, in obtaining more complete medication reconciliation in patients with HIV/AIDS on HAART.

166. Apixaban and rivaroxaban safety after hip and knee arthroplasty: a meta-analysis. Carlos Alves, Pharm.D.[1], Ana F. Macedo, Pharm.D., Ph.D.[2], *Francisco Batel-Marques, Pharm.D., Ph.D.*[3]; (1)CICS – Health Sciences Research Centre, University of Beira Interior; School of Pharmacy, University of Coimbra, Coimbra, Portugal; (2)Central Portugal Regional Pharmacovigilance Unit - AIBILI; CICS - Health Sciences Research Centre, University of Beira Interior, Covilhã, Portugal; (3)Central Portugal Regional Pharmacovigilance Unit - AIBILI; School of Pharmacy, University of Coimbra, Coimbra, Portugal
PURPOSE: Safety of Xa coagulation factor direct inhibitors holding a European market authorization, apixaban and rivaroxaban, have never been evaluated by direct comparisons in randomized controlled trials. Approved therapeutic indications for both drugs are thromboprophylaxis after hip or knee arthroplasty. This study aims at evaluating available published data to further compare drugs safety profiles.
METHODS: A meta-analysis was carried out pooling data from studies identified on a Medline and Cochrane Library search. Abstracts from scientific meetings were also searched from 2003 to 2011. Primary and secondary outcome measures were major bleeding and total bleeding, respectively. Relative risks (RR) were estimated using random-effects models and statistical heterogeneity was estimated with I^2 statistics.
RESULTS: Of the 160 screened publications twelve clinical trials were included in which enoxaparin was the active control. For knee arthroplasty, apixaban was associated with significantly fewer major bleeding events (6496 patients, RR 0.56, 95% CI 0.32–0.96) and fewer total bleeding events (6496 patients, RR 0.81, 95% CI 0.67–0.97). There were no significant differences in the incidence of major bleeding events (5699 patients, RR 1.40, 95% CI 0.56–3.52) or in the incidence of total bleeding events for rivaroxaban (5699 patients, RR 1.09, 95% CI 0.91–1.30). No differences were found when thromboprophylaxis after hip replacement was the case.
CONCLUSION: Apixaban compared to rivaroxaban seems to be associated with a lower risk of the incidence of hemorrhagic events after total knee arthroplasty. For hip arthroplasty no safety differences were found.

167. The role of computerized clinical decision support in reducing Inappropriate medication administration during epidural therapy. *Jonathon Pouliot, M.S., Pharm.D.*, Erin Neal, Pharm.D., BCPS; Vanderbilt University Medical Center, Nashville, TN
PURPOSE: Continuous epidural anesthesia therapy is commonly used for pain management, particularly during the peri-operative and post-operative periods. Epidural administration of drugs puts patients at risk for complications, the most serious being bleeding complications which could cause irreversible neurologic damage. A major risk factor for complications is administration of contraindicated or high risk anticoagulants, antiplatelets, thrombolytics, and sedative medications. In order to decrease the administration of contraindicated and inappropriate medications and standardize epidural ordering facility-wide, an electronic epidural ordering advisor has been implemented into the computerized physician order entry (CPOE) system at Vanderbilt University Medical Center. The purpose of this study is to evaluate the effectiveness of this advisor at reducing occurrences of inappropriate medication administration as well as reducing complications of therapy.
METHODS: This study examined the incidence of high risk medication administration before and after CPOE advisor implementation in 404 adult patients receiving epidural anesthesia therapy between July 2010 and January 2011. This study also evaluated some common adverse events and complications of epidural therapy before and after intervention.
RESULTS: In the period prior to implementation, inappropriate medications were administered in 12.8% of cases compared to 11.4% of cases after advisor implementation (p=0.67.) Promethazine and enoxaparin were the most commonly administered inappropriate medications. There were no statistically significant differences between groups for complications including hypotensive events, respiratory depression, naloxone administration or rapid responses/codes.
CONCLUSION: Based on the results of this study, the implementation of an epidural ordering advisor did not result in fewer inappropriate medications administered to patients receiving epidural therapy. It is possible that the functionality of this advisor intervention was not optimized and could have resulted in lack of effectiveness. The results of this study emphasize the importance of proper utilization of our informatics and technology tools in order to best impact patient safety and care.

168. Compliance with NASPE monitoring guidelines for amiodarone. *Prudence Hofmann, Pharm.D.*[1], Ola O. Oyetayo, Pharm.D.[2], Carrie Rogers, Pharm.D.[1], Phillip Lubanski, Pharm.D.[1], Cheryl Holt, Pharm.D.[1], Tera Moore, Pharm.D.[1]; (1)South Texas Veterans Health Care System, San Antonio, TX; (2)Univeristy of Texas at Austin/ Univeristy of Texas Health Science Center at San Antonio, San Antonio, TX
PURPOSE: To determine the rates of compliance with North American Society of Pacing and Electrophysiology (NASPE) recommended monitoring for patients receiving chronic amiodarone therapy at the South Texas Veterans Health Care System (STVHCS). Given the potential adverse effects of amiodarone, a strict monitoring regimen is essential to the safe use of amiodarone.
METHODS: Retrospective chart review of patients receiving amiodarone for > 6 months at STVHCS between January 1, 2002 and March 31, 2010. Compliance with NASPE monitoring guidelines were recorded at baseline, 6 months, and 12 months for the following parameters: chest radiography (CXR), pulmonary function test (PFT) with D_LCO, liver function test (LFT), thyroid function test (TFT), electrocardiogram (ECG) and eye exam.
RESULTS: A random sample of 251 patients was selected out of 827 patients who met the inclusion criteria. Compliance rates in patients varied according to test. At baseline, it ranged from 6% for a D_LCO test to 63% for a LFT test (CXR – 29%, PFT – 7%, TFT – 35%, ECG – 36% and eye exam- 10%). At 6 months, recommended TFT and LFT monitoring were completed in 26% and 49% of patients respectively. At 12 months, compliance rates for CXR, TFT, LFT and ECG monitoring were 12%, 30%, 53% and 15% respectively. The rate of compliance was greater at baseline in patients initiated at STVHCS compared to an outside facility. CXR was completed in 80% vs. 13%, PFT 25% vs. 1%, TFT 53% vs. 30%; LFT 90% vs. 54%; and ECG 85% vs. 20% (all comparisons $p<0.001$). Comparisons at 6 months and 12 months remained statistically significant for all parameters.
CONCLUSION: Overall compliance with NASPE monitoring parameters for amiodarone was suboptimal. There is a need to provide additional education and perhaps a clinical reminder within the electronic medical record to ensure the safe use of amiodarone therapy.

169. Medication reconciliation: comparing a customized medication history form to a standard medication form. (CAMPII 2). *Gina J. Ryan, Pharm.D.*[1], Jane M. Caudle, MLn[2], Mary Rhee, M.D.[2], Jamye M. Hickman, Ph.D.[3], Circe W. Tsui, M.S.[2], Catherine S Barnes, Ph.D.[2], Jia Haomia, Ph.D.[4], David C Ziemer, M.D., M.P.H.[2]; (1)Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (2)Emory University School of Medicine, Atlanta, GA; (3)Southern Polytechnic State University, Marietta, GA; (4)Columbia School of Nursing, New York, NY
PURPOSE: Investigators compared the accuracy of an APhA fill-in-the-blank medication history form (STANDARD) to a customized form (CUSTOM) that contained a checklist of the clinic's most frequently prescribed medications (CORE) and a fill-in-the-blank section for those medications not on the checklist.
METHODS: CUSTOM was designed by a diabetes clinic

committee: endocrinologists, clinical pharmacist, certified diabetes educator, human factor engineer, and program manager. The content of both forms was compared to a "gold standard" medication list compiled by a clinical pharmacist using a thorough medication history, reviews of the pharmacy profiles and medical charts. Accuracy was defined as complete (name, dose, and frequency) and correct relative to the gold standard.

RESULTS: Diabetic subjects (N=77) completed CUSTOM and STANDARD; 52 (68%) were female, average age was 55.4 ± 11.6, and took 8.6 ± 3.3 number of medications. When looking at all medications, having a list or medications bottles improved recall with STANDARD (P=0.03) in a regression analysis. Age decreased accuracy when looking at only CORE medications with both forms (P<0.03).

	CUSTOM	STANDARD
Minutes to Complete	8.9 ±5.9	8.0 ±5.5
Subjects N(%) with:		
All Meds Completely Accurate	5 (6.4%)	8 (10.4%)
Subjects with All Names Accurate	16 (20.8%)	10 (13.0%)
Extra Drug Names	10(13.0%)	5 (6.4%)
CORE Meds*	18 (23.4%)	15 (19.4%)
Preferred By**	66%	33%

*P=0.0043 Adjusted for number of medications. **P<0.007

CONCLUSION: Medication self-report is very poor. However, a customized list improves accuracy by about 20%. Subjects preferred CUSTOM over STANDARD. Clinics considering using a customized checklist to collect medication histories from patients should know that it provides modest benefits for the medications on the checklist.

170. Medication errors reported by US clinical pharmacists: the ACCP PBRN MEDAP study. *Grace M. Kuo, Pharm.D., M.P.H., Ph.D.*[1], Daniel Touchette, Pharm.D., M.A.[2], Jacqueline S. Marinac, Pharm.D.[3]; (1)UCSD, La Jolla, CA; (2)University of Illinois at Chicago, Chicago, IL; (3)ACCP Research Institute, Lenexa, KS

PURPOSE: Clinical pharmacists perform a variety of tasks related to medication error (ME) detection, amelioration, and prevention. However, a national study that systematically describes these interventions has not been reported. One of our study objectives was to describe MEs and clinical pharmacist interventions within a national clinical pharmacist practice based research network (PBRN).

METHODS: Clinical pharmacists were recruited from the ACCP PBRN to report their interventions to detect, ameliorate, and prevent MEs over a 14-consecutive day period in 2010. Participating pharmacists viewed online training materials about reporting MEs and the data collection tool. IRB approval was obtained from AAFP first then local institutions as needed.

RESULTS: A total of 71 individual pharmacists submitted 924 reports; however, only 782 reports had complete ME data. MEs occurred in the inpatient (61%), outpatient (29%), home (7%), and other (3%) settings. Therapeutic categories associated with MEs frequently reported were systemic anti-infective (25%), hematologic (21%), and cardiovascular (19%) medications. The top 5 frequently reported medications were antibiotics (n=172), oral anticoagulants (n=76), injectable anticoagulants (n=68), beta-blockers (n=37), and insulin (n=29). Most MEs (95%) did not result in patient harm; however, MEs resulted in temporary harm (n=33), permanent harm (n=6), requiring interventions to sustain life (n=2), and death (n=1). The reported MEs were due to prescribing (54%), dispensing (10%), administering (13%), monitoring (13%), documenting (7%), and miscellaneous (3%) errors. Pharmacist interventions included communication (54%), medication change (35%), and monitoring (9%). Approximately 82% of pharmacist recommendations were accepted by prescribers (4% with modifications, 52% without modifications, and 26% due to pharmacist prescriptive authority).

CONCLUSION: Most MEs reported by US clinical pharmacists did not result in patient harm; however, there were reports of severe harm and death. Half of the MEs detected were prescribing errors. The majority of pharmacist recommendations to prevent or ameliorate MEs were accepted by prescribers.

171. Identifying and removing usage barriers of infusion smart pumps. *Holly Herring, Pharm.D.*, Toni Ripley, Pharm.D., Kevin Farmer, Ph.D.; The University of Oklahoma College of Pharmacy, Oklahoma City, OK

PURPOSE: Manual programming is a common cause of medication errors with infusion pumps. This can lead to patients receiving the incorrect dose or drug. Infusion smart pumps have safety features that have been shown to decrease the incidence of medication errors compared to manual programming. However, bypassing the smart pump safety feature is possible; studies suggest this safety feature is bypassed frequently. Obstacles to safety feature utilization have been described, but no evidence for improving utilization rates exist. We sought to quantify obstacles to utilizing this important technology and investigating the effectiveness of interventions to address the obstacles.

METHODS: A comparison of smart pump safety feature utilization on the cardiovascular service (CVS) before and after pharmacist education was conducted. The primary endpoint was change in 30-day usage rate after pharmacist education. A 10-question paper survey was distributed to all part- and full-time nurses on the CVS by nursing administration that targeted three domains that were potential limitations to using the technology (education/training, content, and burden of use). After baseline usage and survey data was obtained, targeted education was directed towards the obstacles cited from the nurses over a 4–6 week period. A repeat 30-day usage report was obtained after intervention.

RESULTS: Approximately 50–60 nurses were given the survey; 36 were returned. Primary obstacles to using technology were comfort with technology, motivation, and experience. After targeted education and training, utilization rates of the smart pump safety feature increased 5.5 times from baseline (5.4% versus 30.5%, P<0.000001).

CONCLUSIONS: Targeting education and training to nurses' perceived barriers of smart pump technology is an effective way to improve smart pump safety feature use, though overall utilization can still be improved. Additional obstacles to safety feature use needs to be investigated, including perceived time constraints and administrative issues, such as nursing orientation and turn-over.

172E. Evaluation of risk factors for warfarin resistance following administration of vitamin K. Sheri J. VanOsdol, Pharm.D., *Heather J. Ipema, Pharm.D.*, Edith A. Nutescu, Pharm.D.; University of Illinois at Chicago College of Pharmacy, Chicago, IL

PURPOSE: This study was conducted to evaluate the time to return of therapeutic International Normalized Ratio (INR) following warfarin reinitiation in patients who received vitamin K for reversal of excessive anticoagulation and to identify factors associated with prolonged time to therapeutic INR.

METHODS: Electronic medical records of adult patients who received any dose or route of vitamin K from April 23, 2008 to October 23, 2009 were retrospectively analyzed. This subgroup analysis was part of a larger project examining evidence-based use of vitamin K for warfarin reversal at our institution.

RESULTS: Of the 184 patients who received vitamin K during the study period, 42 patients were reinitiated on warfarin after receipt of vitamin K (median age 63 years, 69% female, 66.7% African American). Only 8 (19%) of these patients received doses/routes of vitamin K adherent with the 2008 ACCP guidelines. The median time between vitamin K receipt and reinitiation of warfarin was 68.5 hours; the median time between warfarin reinitiation and therapeutic INR was 109.5 hours. A trend was noted between higher INR at time of warfarin reinitiation and shorter time to therapeutic INR. Statistical analysis did not reveal any correlations between patient- or medication-related factors and time to therapeutic INR.

CONCLUSION: Over-correction of supratherapeutic INR with vitamin K, indicated by a sub-therapeutic INR at the time of warfarin initiation, may increase the time to therapeutic anticoagulation, compared to those with therapeutic or near-therapeutic INR at time of reinitiation. Adequately-powered studies are needed to identify factors associated with a prolonged time to therapeutic INR.

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173. Evaluation of pharmacist decision making and opinions involving prescriptions with a high probability of causing patient harm. *Colleen S. Kann, Pharm.D.*[1], James D. Hoehns, Pharm.D., FCCP, BCPS[1], John E. Sutherland, M.D.[2], James J. Poock, M.D.[2];

(1)NEIMEF/University of Iowa College of Pharmacy, Waterloo, IA; (2)NEIFPC, Waterloo, IA

PURPOSE: Adverse drug events related to medication dosage errors can result in catastrophic patient outcomes. Little is known about pharmacist decision making when they are presented with prescriptions which contain an apparent overdosage. The objective was to evaluate if pharmacists would fill a prescription which contains an excessive dosage, even if the physician verified and approved the prescription.

METHODS: A survey was sent electronically to pharmacists in Iowa. The survey presented prescription scenarios containing intentional errors in dosage or instruction. Examples included digoxin 0.25mg three tablets daily, methotrexate 7.5 mg daily for rheumatoid arthritis, and transdermal fentanyl 100mcg in a patient with limited prior opioid usage. Pharmacists were instructed that the prescribing physician was directly contacted about each prescription and that the physician approved the prescription as written.

RESULTS: There were 599 evaluable surveys completed. The frequency of pharmacists who reported they would fill the prescriptions were: digoxin 18.5%, methotrexate 16.8%, and fentanyl 37.9%. Hospital pharmacists were less likely to fill the prescriptions than community pharmacists. Nearly half of respondents felt they were inadequately trained in their pharmacy education on how to deal with prescriptions which they felt had significant potential for patient harm.

CONCLUSION: Despite significant limitations to our survey, pharmacists often reported they would fill a prescription that would commonly be viewed as highly inappropriate, provided that the prescriber verified the dosage as written. Pharmacy education curriculums should consider new strategies to educate pharmacists about minimizing harm to patients when they are presented with high risk prescriptions.

Nephrology

174. Impact of pharmacist-managed erythropoiesis-stimulating agents clinics for non-dialysis chronic kidney disease patients. *Leah Flowers, Pharm.D.*[1], Sherrie Aspinall, Pharm.D., MSc[2], Fran Cunningham, Pharm.D.[3], Xinhua Zhao, Ph.D.[4], Kenneth Smith, M.D., M.S.[5], Roslyn Stone, Ph.D.[5], Chester Good, M.D., M.P.H.[4], ESA Clinic Study Group, -[6]; (1)G.V. (Sonny) Montgomery VA Medical Center, Jackson, MS; (2)VA Center for Medication Safety, Pittsburgh, PA; (3)VA Center for Medication Safety, Hines, IL; (4)VA Pittsburgh Healthcare System, Pittsburgh, PA; (5)University of Pittsburgh, Pittsburgh, PA; (6)VA Pharmacists, -

PURPOSE: Veterans Affairs (VA) Medical Centers established pharmacist-managed ESA clinics to improve the use of erythropoiesis-stimulating agents (ESAs). To evaluate the effectiveness of these clinics, we compared the quality of care provided by pharmacist-managed ESA clinics versus usual care in patients with non-dialysis chronic kidney disease (ND-CKD).

METHODS: Outpatients who were receiving ESAs for ND-CKD at ten VA Medical Centers with a pharmacist-managed ESA clinic (n=314) and at six sites with physician-based care (i.e., usual care; n=167) on January 1, 2009 were followed for 6 months. The primary outcome measures were patient-days in the hemoglobin target range of 10–12 g/dl, ESA dose and frequency of hemoglobin monitoring. We identified factors associated with hemoglobin values below and above target range using multinomial logistic regression, adjusted for clustering at the patient level.

RESULTS: More patient-days were in the target hemoglobin range in the pharmacist-managed clinic (75.8% versus 59.3% for usual care; p<0.0001). The median 30-day dose of darbepoetin was 107 mcg in the pharmacist-managed group versus 136 mcg in usual care (p=0.02); the corresponding medians for epoetin were 29643 IU versus 42857 IU (p=0.27). Veterans in the pharmacist-managed group had more hemoglobin measurements on average (5.8 versus 3.6 in usual care; p<0.0001). In the multinomial model, glomerular filtration rate <15 ml/min/1.73m^2 was associated with increased odds of a hemoglobin value below target (reference 30–60 ml/min/1.73m^2; AOR 1.81; 95%CI 1.07, 3.15); usual care was associated with increased odds of a hemoglobin above target (AOR 2.48; 95%CI 1.52, 4.06), and heart failure was associated with decreased risk of values below and above target (AOR 0.76; 95%CI 0.58–0.99).

CONCLUSIONS: Relative to usual care, pharmacist-managed ESA clinics provided improved quality of care for Veterans with ND-CKD (i.e., more time in the target hemoglobin range, lower ESA doses and more frequent hemoglobin monitoring).

175. Effects of dual blockade of the renin angiotensin system in diabetic kidney disease: a systematic review and meta-analysis. *Jacqueline T. Pham, Pharm.D.*, David J. Leehey, M.D., Brian P. Schmitt, M.D., M.P.H.; Edward Hines JR VA Medical Center, Hines, IL

PURPOSE: There is much evidence to support a renoprotective effect of inhibitors of the renin- angiotensin system in diabetic kidney disease. However, it remains unclear whether dual renin- angiotensin system blockade has additional benefits in this population and whether any benefits outweigh the risks.

METHODS: *Study Design:* Systematic review and meta-analysis *Setting and Population:* Diabetic patients with overt proteinuria *Selection Criteria for Studies:* Randomized, controlled, parallel or crossover design studies *Intervention:* Combination renin-angiotensin system blockade vs. monotherapy *Outcomes:* The primary outcome measure was the post-treatment difference in proteinuria with combination therapy versus monotherapy. Secondary outcomes included percent change in proteinuria, changes in systolic blood pressure, glomerular filtration rate, and serum potassium, and incidence of hyperkalemia. Sensitivity analyses that evaluated differences in outcome based on study quality (assessed by Jadad scores), baseline systolic blood pressure, and drug types and doses were conducted.

RESULTS: There was significantly less proteinuria (by 334 mg/24 hr) after treatment with combination therapy vs. monotherapy. Systolic blood pressure (BP) after treatment with combination therapy vs. monotherapy was significantly lower (by 4.1 mmHg). However, clinically significant hyperkalemia was 3.5-fold more common with dual blockade. Sensitivity analyses did not identify subgroup differences that altered these findings.

CONCLUSIONS: Dual renin-angiotensin system blockade in patients with diabetic kidney disease reduces proteinuria and BP but is associated with a higher incidence of clinically significant hyperkalemia. Further studies assessing long-term outcomes are needed to weigh the benefits versus risks of combination renin-angiotensin system inhibitor therapy.

176E. Evaluation of the MDRD and Cockroft-Gault equations for sitagliptin dosing. *Joanna Q. Hudson, Pharm.D.*[1], M. Shawn McFarland, Pharm.D.[2], Brandon M. Markley, Pharm.D.[3], Paul Patel, M.D.[4]; (1)University of Tennessee Dept of Clinical Pharmacy, Memphis, TN; (2)Alvin C. York Veterans Administration, Murfreesboro, TN; (3)University Medical Center of Southern Nevada, Las Vegas, NV; (4)Murfreesboro Medical Clinic, Murfreesboro, TN

PURPOSE: The MDRD equation is now advocated along with the Cockcroft-Gault (CG) equation for drug dosing. Currently dose recommendations by manufacturers are based on estimated creatinine clearance (eCrCl) determined by CG. Few studies have evaluated differences in dosing using MDRD and CG. Sitagliptin is a dipeptidyl peptidase IV used for type 2 diabetes mellitus (T2DM) with dose adjustments based on eCrCl. We assessed discordance rates in initial sitagliptin doses recommended using MDRD and CG.

METHODS: Adult patients with T2DM prescribed sitagliptin in the outpatient clinic Oct 2006-June 2009 were included. Estimated GFR (eGFR) and eCrCl were calculated by the 4-variable MDRD and CG equations, respectively. Sitagliptin dose based on manufacturer's labeling was determined. Discordance in doses recommended using MDRD and CG estimates were compared overall and by subgroup based on eCrCl category (eCrCl >50, 30–50, and <30 mL/min).

RESULTS: A total of 121 patients were included; 52% male; 90% Caucasian; mean age 61±12 yrs; weight 93±19 kg; ideal body weight 61±10 kg; BSA 2.0±0.22 m^2. Mean eGFR was 76±19 mL/min and eCrCl was 68±17 mL/min. Discordance in sitagliptin dose was observed in 11 patients (9%) with MDRD compared to CG. Discordance by subgroup was as follows: 1/2 (50%) for eCrCl < 30; 8/10 (80%) for eCrCl 30-50, and 2/109 (2%) for eCrCl > 50 mL/min. All patients with eCrCl < 50 would have received a higher dose using MDRD while

patients with eCrCl > 50 would have received a lower dose.
CONCLUSION: Overall there was agreement in initial sitagliptin dose using MDRD and CG. Discrepancies resulted in underestimation of sitagliptin dose at eClCr above 50 mL/min and overestimation at lower eClCr. Clinical implications are the potential for excessive dosing for individuals with kidney dysfunction. Since many agents have similar dosing stratification by eCrCl, this pattern is likely for other renally eliminated agents.
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177E. Effects of α-lipoic acid on oxidative stress in ESRD patients receiving IV iron. Arif Showkat, M.D., FASN[1], *Joanna Q. Hudson, Pharm.D., FASN*[2], William Bastnagel, M.D.[1]; (1)University of TN College of Medicine, Memphis, TN; (2)University of Tennessee College of Pharmacy, Memphis, TN
PURPOSE: Oxidative stress is associated with increased risk of cardiovascular disease in ESRD patients. Intravenous (IV) iron increases oxidative stress in this population. The purpose of the study was to evaluate changes in oxidative stress markers following administration of IV sodium ferric
METHODS: ESRD patients who met inclusion were enrolled in this open-label, crossover study. During a control (C) and intervention (I) visit 125 mg IV SFG was administered over 10 minutes. During

RESULTS: Ten African-American ESRD subjects were enrolled; 5 males; mean age 45±9 yrs; mean Hb13±1 g/

Table 1: % Change in Markers

Time (min)	60	90	120	180
MDA-C	21.7±26.5	19.4±30.5	22.3±38.7	19.6±39.0
MDA-I	72.1±96.3*	66.7±70.6*	60.6±60**	65.9±69.3**
FIP-C	13.8±20.7	19.5±17.5	7.7±21.1	10.8±15.9
FIP-I	56.8±32.4**	37.6±28.7	38.9±40.4**	19.9±34.0
LHP-C	23.5±13.2	16.2±10.0	9.4±10.4	5.1±6.1
LHP-I	37.4±18.0**	28.7±15.3**	23.1±13.1**	14.8±8.4**

Mean ± SD. MDA & LHP: μmol/L, FIP: pg/mL *$P \leq 0.01$, ** $0.01 > P \leq 0.05$ compared to C group.
CONCLUSION: Administration of IV SFG is associated with an acute rise in oxidative stress. In contrast to previous studies, administration of an antioxidant was associated with a greater increase in oxidative stress.
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Neurology

178E. Rasagiline and antidepressant use in patients with Parkinson's Disease: assessing the occurrence of serotonin toxicity. *Jack J. Chen, Pharm.D.*[1], Michel Panisett, M.D.[2], Sean Rhyee, M.D., M.P.H.[3]; (1)Loma Linda University, Loma Linda, CA; (2)Notre-Dame Hospital-CHUM, Montréal, QC, Canada; (3)University of Massachusetts Medical School, Worcester, MA
PURPOSE: Use of nonselective monoamine oxidase (MAO) inhibitors concomitantly with antidepressants has been associated with serotonin toxicity (ST), a potentially life-threatening syndrome characterized by clonus and autonomic dysfunction and requires immediate medical attention. Although rasagiline is a selective MAO-B inhibitor, the prescribing information for rasagiline contains a warning about the risk of ST with concomitant antidepressants. This study assesses the occurrence of ST in patients with Parkinson disease (PD) treated with antidepressants and rasagiline.
METHODS: Multicenter, retrospective study of PD patients who began receiving rasagiline with antidepressants (R+AD), rasagiline without antidepressants (R), or antidepressants with dopaminergic therapy not including rasagiline or selegiline (AD) between 9/1/2006 and 12/31/2008. After collection of information on patient demographic characteristics, treatment history, and hospitalizations/emergency room (ER) visits, attempts were made to obtain hospital records for patients with ≥1 hospitalization/ER visit. Records were sent to an independent adjudication committee consisting of an emergency medicine physician, a clinical pharmacist/pharmacologist, and a movement disorders specialist. The committee used published criteria to review records for the occurrence of ST only in patients for whom full records were obtained for each hospitalization/ER visit.
RESULTS: Among 37 US sites, records of 1507 patients (R+AD, 471; R, 511; AD, 525) were identified. Mean (SD) age was 67 (11) years; mean (SD) time from PD diagnosis was 5.1 (5.8) years. Among the 195 patients (13%) who had ≥1 hospitalization/ER visit, 145 patients had complete hospital records available. Hospitalizations/ER visits for these 145 patients totaled 60 for R+AD, 50 for R, and 184 for AD. No occurrences of ST were found in any group.
CONCLUSION: No instances of ST among patients with complete records for each hospitalization/ER visit were found by an independent adjudication committee. Thus, the combined use of rasagiline and antidepressants was not associated with ST in this multicenter retrospective study.
Published in Published in Neurology 2011;76(suppl4):A539.

179. Increased frequency and duration of elevated blood pressure measurements after IV thrombolytics for ischemic stroke is not associated with increased risk of symptomatic intracerebral hemorrhage. *Meghan E. Groth, Pharm.D.*, Ashis H. Tayal, M.D., Melissa Tian, RN, Jillian M. Szczesiul, Pharm.D.; Allegheny General Hospital, Pittsburgh, PA
PURPOSE: Acute ischemic stroke (AIS) guidelines include specific recommendations for managing blood pressure (BP) in patients treated with IV thrombolytics and subsequently aim to reduce hemorrhagic complications. However, data assessing the relationship between BP management surrounding IV thrombolytic therapy and the risk of hemorrhage is limited. We hypothesized that an increase in frequency or duration of elevated BP after IV thrombolytics would be associated with an increased risk of symptomatic intracerebral hemorrhage (sICH).
METHODS: Patients treated with IV tissue plasminogen activator (tPA) at our institution over a three year period were reviewed for elevated BP measurements recorded during the 24 hours following therapy. Measurement of sICH was determined by the neurologist's interpretation of head computed tomography findings. Patients were excluded if they were > 89 years of age, received tPA intra-arterially, or under a violation of institutional protocol. Ordinal logistic regression and χ^2 methodology were used for primary objective analysis.
RESULTS: A total of 144 patients were included; 112 patients did not have a documented bleed while 32 patients had a documented bleed (5 were classified as sICH). An increased frequency of elevated BP measurements was not associated with an increased risk of sICH (χ^2= 7.378, p=0.061 for SBP; χ^2 = 1.088, p=0.780 for DBP). Similarly, an increased duration of elevated BP measurements was not associated with an increased risk of sICH (χ^2 = 8.066, p=0.153 for SBP; χ^2 = 1.088, p=0.896 for DBP). Overall frequency and duration of elevated BP was low, and the majority of patients (83%) did not require anti-hypertensive medications to lower baseline BP.
CONCLUSION: Neither frequency nor duration of elevated BP measurements was associated with an increased risk of sICH. These results should be confirmed in a prospective manner among a larger patient population.

Oncology

180. Impact of antiemetic regimens adherence on nausea and vomiting control among Asian breast cancer patients receiving anthracycline-based chemotherapy. *Alexandre Chan, Pharm.D., M.P.H.*[1], Rachel Ong, BSc(Pharm)Hon[1], Xiu Hui Low, BSc(Hon)[1], Kevin Yap, Ph.D.[2]; (1)National University of Singapore, Singapore, Singapore; (2)University of Warwick, Coventry, United Kingdom
PURPOSE: This study was conducted to evaluate the impact of adherence to delayed antiemetic regimens on chemotherapy induced nausea and vomiting (CINV) control in breast cancer patients, and to identify patient characteristics that may be associated with non-adherence to antiemetic regimens.
METHODS: This was a prospective, observational study conducted at the largest ambulatory cancer center in Singapore from December 2006 to January 2011. All breast cancer patients receiving

anthracycline-based chemotherapy and standardized outpatient antiemetic regimens were recruited. On the day of chemotherapy, patients were given a standardized 5-day diary to document their emesis events and their demographics obtained via interview. Pearson's χ^2 test and multiple logistic regression were performed to analyze the impact of adherence on CINV control.
RESULTS: 361 eligible patients were included in the final analysis (mean=50.0±8.9 years). Majority of the patients were Chinese (80.1%) and diagnosed with Stage 2 and above breast cancer (88.1%). Almost half of the patients (42.1%) were non-adherent to their prescribed delayed antiemetics regimens, with dexamethasone usage being the least adhered to (non-adherence: 37.4%). After adjusting for potential confounders (ethnicity, education level and stage of disease), patients who were adherent to antiemetics were more likely to achieve complete CINV control (defined as no emetic episodes, no nausea, and no rescue therapy required) than patients who were non-adherent (NNT=9.6; Adjusted OR=1.74, 95% CI: 1.01–3.01). In addition, young women aged between 21–40 years old, pursued higher education, and diagnosed with Stage 1 breast cancer were associated with non-adherence to antiemetics (p<0.05).
CONCLUSION: This is the largest study to date to evaluate the prevalence of non-adherence to delayed antiemetics among Asian breast cancer patients. Our findings indicate that a substantial amount of Asian breast cancer patients (42.1%) were not adherent to their antiemetic regimens, which have resulted into poor control of CINV.

181. Characteristics and clinical course of pediatric patients admitted with chemotherapy-related febrile neutropenia. *Suha M. Al-Omar, Pharm.D.*, Lama H. Nazer, Pharm.D., BCPS; King Hussein Cancer Center, Amman, Jordan
PURPOSE: To describe the characteristics and clinical course of pediatric patients admitted with febrile neutropenia (FN) related to chemotherapy.
METHODS: This was a 6-month prospective observational study conducted between October, 2010 and March, 2011 at a comprehensive academic cancer center. Patients admitted to the pediatric medical ward with FN were included. Patient demographics, duration since last chemotherapy, use of granulocyte colony stimulating factor (G-CSF), presence of an indwelling central venous catheter (CVC), transfer to the intensive care unit (ICU), length of stay, and mortality were recorded. In addition, the results of all cultures obtained were reviewed.
RESULTS: During the study period, 117 cases were included: 78 patients (66.7%) had hematological malignancies, while the remaining had solid tumors. Of the patients enrolled, 62 (53%) were females and the average age was 7.1± 5.06 (SD) (range 1–19) years. The mean duration since last chemotherapy was 7.78 ±7.56 (SD) days, the mean duration of hospital stay was 9.38 ±9.6 (SD) days, and transfer to the ICU was required for 12 (10.3%) patients but there were no reported deaths. Positive cultures were reported in 23 (19.7%) patients. The pathogens isolated were gram-positive organisms (n=12; 52.2%) which were mainly coagulase-negative staphylococcus species, gram-negative organisms (n=5; 21.7%), viral (n=5; 21.7%) and fungal (n=1; 4.3%). The presence of CVC was significantly more in patients with documented infections compared to patients with fever of unknown origin (FUO): 52.2% versus 29.8%, respectively (P= 0.04). There were no significant differences between patients with positive cultures and those with FUO in the age, presence of G-CSF, length of hospital stay, and transfer to the ICU.
CONCLUSION: About 80% of the pediatric patients admitted with FN had FUO. Developing risk-stratified management of FN may reduce unnecessary admissions. The pathogens reported in this patient population differ from those reported in previous studies.

182E. ENESTnd 24-month follow-up of nilotinib versus imatinib in patients with newly diagnosed chronic myeloid leukemia in chronic phase. *Gerry Gorospe, III, RN, BSN, PHN, MSN*[1], Hagop M. Kantarjian, M.D.[2], Andreas Hochhaus, M.D.[3], Richard A. Larson, M.D.[4], Giuseppe Saglio, M.D.[5], Timothy P. Hughes, M.D.[6]; (1)City of Hope, Duarte, CA; (2)University of Texas MD Anderson Cancer Center, Houston, TX; (3)Hamatologie und internistische Onkologie, Universitatsklinikum Jena, Jena, Germany; (4)University of Chicago Medical Center, Chicago, IL; (5)University of Turin, Ospedale San Luigi Gonzaga, Orbassano-Turin, Italy; (6)Royal Adelaide Hospital, Adelaide, SA, Australia
PURPOSE: This analysis evaluated 24-month follow-up outcome data of nilotinib versus imatinib from ENESTnd in patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic-phase (CML-CP).
METHODS: In ENESTnd, 846 CML-CP patients were randomized to nilotinib 300 mg twice daily (BID; n = 282), nilotinib 400 mg BID (n = 281), or imatinib 400 mg once daily (n = 283). We report minimum 24-month major molecular response (MMR; ≤0.1% BCR-ABL^{IS}), overall best molecular response, complete molecular response (CMR^4 [≤0.01% IS]) and CMR$^{4.5}$ [≤0.0032% IS]), progression to accelerated phase (AP)/blast crisis (BC), progression-free survival (PFS), and overall survival (OS).
RESULTS: With minimum 24-month follow-up, MMR rates were significantly superior with nilotinib 300 mg BID (71%) and 400 mg BID (67%) versus imatinib (44%; both P<0.0001) across all Sokal risk groups. Compared with imatinib, nilotinib 300 mg and 400 mg BID achieved significantly higher CMR^4 (44%, 36% vs 20%; both P<0.0001) and CMR$^{4.5}$ rates (26%, 21% vs 10%; both P≤0.0004). There were significantly fewer progressions to AP/BC (including clonal evolution) on nilotinib 300 mg BID (P=0.0003) and 400 mg BID (P=0.0089) compared with imatinib. At 24 months, PFS was superior with nilotinib 400 mg BID versus imatinib (P=0.0437). OS was similar in all groups, but there were fewer CML-related deaths on both nilotinib 300 mg BID (n = 5) and 400 mg BID (n = 3) versus imatinib (n = 10). The OS rate (CML-related death) was superior with nilotinib 400 mg BID versus imatinib (P=0.0485). Both drugs were well tolerated with comparable rates of discontinuation due to adverse events/lab abnormalities for nilotinib 300 mg and 400 mg BID versus imatinib (9%, 13%, and 10%, respectively).
CONCLUSION: Nilotinib demonstrated superior efficacy with significantly improved disease control vs imatinib in newly diagnosed CML-CP patients.
Presented at the 2011 American Society of Clinical Oncology Annual Meeting, June 3–7, 2011 (ASCO 2011), Chicago, Illinois, USA; abstract 6511

183E. Deeper responses achieved with switch to nilotinib in patients with Philadelphia-positive chronic myeloid leukemia in chronic phase with suboptimal molecular response to imatinib. *Susan Strauch, R.Ph., BCOP*[1], Carole Miller, M.D.[1], Sikander Ailawadhi, M.D.[2], Anand Jillella, M.D.[3], Jerald Radich, M.D.[4], Daniel DeAngelo, M.D.[5], Stuart Goldberg, M.D.[6], Solveig Ericson, M.D.[7], Felice Lin, Pharm.D.[7], Luke Akard, M.D.[8]; (1)Saint Agnes Hospital, Baltimore, MD; (2)USC/Norris Comprehensive Cancer Center, Los Angeles, CA; (3)Medical College of Georgia, Augusta, GA; (4)Fred Hutchinson Cancer Research Center, Seattle, WA; (5)Dana-Farber Cancer Institute, Boston, MA; (6)John Theurer Cancer Center, Hackensack, NJ; (7)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (8)Indiana Blood and Marrow Transplantation, Beech Grove, IN
PURPOSE: Treatment response in chronic myeloid leukemia (CML) is assessed by cytogenetics and molecular monitoring; achievement of complete cytogenetic response (CCyR) and major molecular response (MMR) are favorable prognostic factors. The purpose of this study is to evaluate the impact of nilotinib on change in BCR-ABL levels and rate of MMR in patients with suboptimal molecular response to imatinib.
METHODS: In this ongoing open-label study, CML patients in chronic phase (CML-CP) are included if they achieved CCyR but not MMR and received imatinib >1 year, or experienced >1-log increase in BCR-ABL levels from best response regardless of imatinib treatment duration. All patients receive nilotinib 300 mg twice daily with dose adjustments per protocol. MMR is measured by quantitative reverse transcriptase polymerase chain reaction analysis (RQ-PCR).
RESULTS: Fourteen patients were enrolled as of June 30, 2010; 86% of evaluable patients achieved MMR at any time on study and 71% after 1 year on study. The median BCR-ABL log reduction for patients who reached 12 months on study was 3.66 from the standardized baseline (BCR-ABL = 0.022% International Standard). Nilotinib was well tolerated; most adverse events were adequately managed by dose interruptions.

CONCLUSION: These results of this ongoing study suggest that changing treatment to nilotinib results in an improvement of molecular response and is generally well tolerated in CML-CP patients with suboptimal response to imatinib.
Presented at This study was previously presented at the 52nd American Society of Hematology Annual Meeting, Orlando, Florida, December 6, 2010 (ASH 2010); Abstract 2301

184E. Association Between Chronic Myeloid Leukemia Treatment Responses and Patient Satisfaction, Functioning, and Quality of Life: Patient Survey Results. Stuart Goldberg, M.D.[1], Vamsi Bollu, Ph.D.[2], Robert Morlock, Ph.D.[3], Aleksandr Niyazov, Pharm.D.[2], *Amy Guo, Ph.D.*[2], Elias Jabbour, M.D.[4]; (1)John Theurer Cancer Center, Hackensack, NJ; (2)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (3)i3 Innovus, Eden Prairie, MN; (4)The University of Texas MD Anderson Cancer Center, Houston, TX
PURPOSE: To assess awareness of the chronic myeloid leukemia (CML) patient of treatment response categorizations and the association between treatment responses and satisfaction, functioning, and quality of life (QOL)
METHODS: CML patients participated in an online survey (Association for Cancer Online Resources) consisting of questions on patient demographics, CML disease history, and awareness of treatment responses. Current health status information was collected using a 5-item Likert scale question and a health status thermometer. Statistical comparisons were made by means of Chi-square, Fisher's test, and multivariate regressions.
RESULTS: Overall, 123 patients responded to the survey. The mean age of respondents was 63 years (range 20–86), 49% were male, and 96% had some level of college experience. The median duration of CML diagnosis was 8 years. Nearly all respondents reported being currently in complete hematological response, 71% in complete cytogenetic response (CCyR) and 68% in major molecular response (MMR). In this educated population, 90% of respondents were aware of different CML treatment response categories. However, 71.5% believed CML patients need more information on the types of responses; respondents believed information should come from their physicians (67%) versus other staff (28%) or pamphlets (24%). According to respondents, achieving MMR generates the greatest improvement in daily functioning (86%), satisfaction with medication (87%), satisfaction with physician (79%), and outlook on life (86%). Patients achieving MMR had a significantly higher overall self-reported health status versus patients in CCyR (P=0.032).
CONCLUSION: From a patient's perspective, achieving MMR is an important milestone associated with improved satisfaction with their physician, medication, daily functioning, and outlook on life. Higher overall self-reported health status was reported by respondents in MMR than CCyR.
Presented at Presented at the 2011 American Society of Clinical Oncology Annual Meeting, June 3–7, 2011 (ASCO 2011), Chicago, Illinois, USA; abstract 6614

185E. Adherence patterns and dose adjustments with second-line nilotinib and dasatinib in patients with chronic myeloid leukemia: evaluation in a real-world setting. *Annie Guerin, MSc*[1], Vamsi Bollu, Ph.D.[2], Amy Guo, Ph.D.[2], James D. Griffin, M.D.[3], Andrew P. Yu, Ph.D.[1], Eric Wu, Ph.D.[1]; (1)Analysis Group, Boston, MA; (2)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (3)Dana-Farber Cancer Institute, Boston, MA
PURPOSE: To compare adherence, dose adjustments, and treatment interruptions associated with second-line nilotinib and dasatinib in a real-world setting.
METHODS: Adult patients with chronic myeloid leukemia (CML) receiving second-line nilotinib or dasatinib were identified from medical and pharmacy records (MarketScan and Ingenix Impact). Patients receiving ≥1 prescription and enrolled in their health plan throughout the 6-month study period were eligible. Adherence was measured by the proportion of days covered (PDC) based on prescriptions filled. Medication possession ratios (MPRs) and discontinuation rates were also evaluated. Dosage characteristics, including dose changes, were calculated.
RESULTS: Adherence and dose adjustments were determined for patients receiving dasatinib (452 and 447 patients, respectively) or nilotinib (69 and 67 patients, respectively). The mean PDC for dasatinib was lower compared with nilotinib (0.69 vs 0.79, respectively). After adjusting for confounding factors (eg, age, gender, CML disease complexity), the dasatinib group had a significantly lower PDC (approximately 13%) compared with the nilotinib group (P=0.0086). MPRs were also significantly lower with the dasatinib group versus the nilotinib group (0.75 vs 0.85, P=0.029). More dasatinib-treated patients had at least 1 dose reduction ≥15% compared with nilotinib-treated patients (19.9% vs 6.0%; P=0.0057). Overall, dose decreases occurred within 30 days of a hematological or non-hematological event in 49.5% of patients.
CONCLUSION: In this analysis, CML patients treated with nilotinib for second-line treatment were significantly more adherent to therapy and required fewer dose reductions than did patients receiving dasatinib.
Presented at Presented at the 15th Annual International Congress on Hematologic Malignancies (ICHM 2011); Whistler, British Columbia, Canada; February 17–20, 2011; poster #6

186E. A survey of current practices in the management of chronic myeloid leukemia. Michael Mauro, M.D.[1], Jorge Cortes, M.D.[2], Richard A. Larson, M.D.[3], Peter M. Herout, Pharm.D.[4], Vamsi Bollu, Ph.D.[5], Aleksandr Niyazov, Pharm.D.[5], *Amy Guo, Ph.D.*[5], Hagop M. Kantarjian, M.D.[6]; (1)Knight Cancer Institute at Oregon Health & Science University, Portland, OR; (2)The University of Texas MD Anderson Cancer Center, Houston, TX; (3)University of Chicago Medical Center, Chicago, IL; (4)EPI-Q, Inc., Oak Brook, IL; (5)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (6)University of Texas MD Anderson Cancer Center, Houston, TX
PURPOSE: This analysis evaluated physician self-reported practice patterns in the management of chronic myeloid leukemia-chronic phase (CML-CP).
METHODS: We conducted a US-based survey via an online questionnaire consisting of items updated to reflect changes in clinical practice, tyrosine kinase inhibitor (TKI) therapy, and current guidelines.
RESULTS: 507 board-certified medical oncologists/hematologists responded to the survey; 72% were in private practice. For initial therapy, nearly 60% of respondents chose various doses of imatinib; 40% chose nilotinib or dasatinib. Respondents believed achieving complete cytogenetic response (CCyR) at 6 or 12 months (32.5%) or both CCyR and major molecular response (MMR) at 12 months (23.3%) was indicative of effective initial TKI therapy. Complete molecular response (CMR; 44%) and MMR (27%) were considered primary treatment goals. Marrow-based tests were used by <50% of respondents for initial monitoring; nearly 50% cited uncertainty or unfamiliarity with international scale (IS) reporting of qPCR. Regarding suboptimal response, 26% of respondents would maintain imatinib 400 mg daily in a patient achieving CCyR but not MMR after 2 years of therapy; 34% would switch to nilotinib/dasatinib, and 52% would increase imatinib dose. Respondents were more likely to change from imatinib to nilotinib/dasatinib for failure to achieve MMR after imatinib for 2 years, or perceived treatment failure on imatinib. For a patient not in CCyR, 74% would monitor response by cytogenetic studies every 3–6 months. For a patient in CCyR, 85% would monitor response by molecular studies every 3–6 months. A slight majority (54%) would assess for BCR-ABL mutations if MMR is not achieved after 2 years of TKI; up to 30% of respondents use mutation analysis with initial diagnostic studies.
CONCLUSION: Achieving at least MMR is the predominant treatment goal in CML-CP; most respondents would adjust imatinib dose or change therapy to nilotinib or dasatinib to achieve MMR even after CCyR.
Presented at Presented at the 2011 American Society of Clinical Oncology Annual Meeting, June 3–7, 2011 (ASCO 2011), Chicago, Illinois, USA; abstract 6513

187. Evaluation of gemcitabine modulation of multidrug resistance in cisplatin resistant human ovarian cancer cell line. *Judith A. Smith, Pharm.D., BCOP, FCCP, FISOPP*[1], Anjali Gaikwad, M.S[2], Amanda Hanks, B.S[3], Robert Coleman, M.D.[4]; (1)UT M. D. Anderson Cancer Center, Houston, TX; (2)The UT MD Anderson Cancer Center, Houston, TX; (3)The UT Health Science Center at

Houton Graduate School of Biomedical Sciences, Houston, TX; (4)The University of Texas, M.D. Anderson Cancer Center, Houston, TX

PURPOSE: To evaluate the gemcitabine modulation of multidrug resistance in cisplatin resistant human ovarian cancer cell line TOV-112D-CR.

METHODS: TOV-112D was developed into a cisplatin resistant cell line (TOV-112D-CR) through sequential exposure to increasing concentrations of cisplatin. Markers of multi-drug resistance (MDR) were evaluated in both cell lines including SXR, GST-1, P-GP, MDR, p53 and Bcl-2 by Western Blot. MDR was confirmed by *in vitro* growth inhibition assays conducted in cisplatin sensitive and resistant cell lines with selected chemotherapy agents. Gemcitabine modulation of MDR was evaluated with sequential combination growth inhibition assays conducted in both cell lines.

RESULTS: Induced cisplatin resistance was confirmed by a 13-fold increase in the IC_{50} (4.2μg/mL vs. 0.32 μg/mL, p<0.001). Cross resistance to other chemotherapy agents was confirmed by a 1.5–3 fold increase in the IC_{50}. The combination growth inhibition assays with gemcitabine confirmed the role of gemcitabine in reversing resistance to cisplatin, doxorubicin and topotecan. No improvement was observed with gemcitabine plus paclitaxel or docetaxel. Furthermore, sequential for 72 hour treatment with gemcitabine followed by other selected chemotherapy demonstrated modulation of drug resistance improved by mean of 60% (28.4–95.3%), (p<0.01) compared to combination treatment. The treatment of TOV-112D-CR with gemcitabine also showed a time dependent down regulation of MDR1 and GST-1 and up regulation of wild type p53, associated with increase in drug sensitivity.

CONCLUSION: These data suggest a positive correlation between cisplatin resistance and MDR in human ovarian cancer cell line. Gemcitabine modulation of MDR was demonstrated in these in vitro studies by the reversal of the resistance with four chemotherapy agents. The potential benefits of incorporating gemcitabine in combination with selected chemotherapy agents into the treatment of recurrent MDR ovarian cancer will be pursued with confirmatory in vivo studies.

188. Evaluation of adverse drug events associated with liposomal doxorubicin in patients with renal insufficiency treated for gynecologic malignancies. *Justin Julius, Pharm.D.*[1], Graciela Nogueras-Gonzalez, M.P.H.[1], Judith K. Wolf, M.D.[2], Judith A. Smith, Pharm.D., BCOP, FCCP, FISOPP[3]; (1)The UT MD Anderson Cancer Center, Houston, TX; (2)The University of Texas, M.D. Anderson Cancer Center-Dept of Gynecologic Oncology, Houston, TX; (3)UT M. D. Anderson Cancer Center, Houston, TX

PURPOSE: Determine the impact of renal insufficiency on the incidence of adverse drug effects (ADEs) in patients receiving pegylated liposomal doxorubicin (PLD) for treatment of gynecologic malignancies.

METHODS: A retrospective chart review was conducted from a database of women with gynecologic malignancies treated with PLD between 1996 and 2006. Data collected included patient demographics, PLD dosing, ADEs, serum creatinine, disease progression and survival. Renal insufficiency was defined as an estimated creatinine clearance < 60 mL/min. Logistical regression analysis was used to identify patient characteristics associated with higher incidence of ADE and which influenced survival.

RESULTS: A total of 467 patients were identified that received PLD for gynecologic malignancies between 1996 and 2006. The mean number of PLD cycles received was 4.2 (range 1–29). 187 (40%) patients had an estimated creatinine clearance of < 60 mL/min. The most commonly reported adverse effects include nausea (32.8%), vomiting (16.7%), mucositis (20.1%), neutropenia (19.5%), palmar-plantar erythrodysesthesia (PPE) (31.5%), peripheral neuropathy (22.7%), and muscle pain and weakness (13.7% and 19.1%). Of the ADEs listed vomiting was more common in patients with renal insufficiency (21.7%) versus those with normal renal function (13.3%, p=0.017). In the logistic regression an odds ratio of 1.80 (1.11–2.94 p=0.018) was observed for the association between vomiting and CrCl < 60mL/min. A decrease in peripheral neuropathy was observed in patients with renal insufficiency with an odds ratio of 0.59 (0.37, 0.94 p=0.027). There was no difference in time to progression (TTP) or overall survival (OS) based on dose level of PLD between 25 mg/m^2 and 50 mg/m^2 received.

CONCLUSIONS: PLD is associated with increased ADEs in patients with poor renal function. Dose adjustments may be warranted in patients with renal insufficiency being treated for recurrent gynecologic cancers to decrease risk of toxicity. Dose level did not alter potential efficacy based on TTP/OS.

189. Thiopurine-associated tumorigenesis: using thiopurine methyltransferase to identify important thioguanine-induced phenotypes in astroglial cells. Amira Ahmed-Hosni, B.S.[1], Robert Rooney, Ph.D.[2], Joseph Barnes, M.S.[3], Jim Wan, Ph.D.[4], *Terreia Jones, Pharm.D.*[5]; (1)University of Tennessee, Memphis; (2)Genome Explorations, Memphis, TN; (3)University of Tennessee Health Science Center, Memphis, TN; (4)University of Tennessee Health Sciences Center, Memphis, TN; (5)University of Tennessee, Memphis, TN

PURPOSE: Thiopurines [i.e., thioguanine (TG), mercaptopurine] are antimetabolite drugs commonly used as anticancer and immunosuppressive agents. Thiopurine methyltransferase (Tpmt) is the primary enzyme responsible for deactivating thiopurine drugs and is subject to inter-patient variations in the level of protein expressed. Chronic thiopurine therapy has been linked to brain cancer development and Tpmt status has been associated with this risk. Thiopurine drug-induced DNA lesions and inadequate DNA repair processing have been implicated in tumorigenesis.

METHODS: We investigated whether TG-induced cytotoxicity and the extent of DNA damage in the form of single and double strand breaks (SSBs, DSBs) could be predicted by Tpmt expression in astroglial cells. Additionally, we compared gene expression patterns of candidate genes involved in DNA damage repair between primary astrocytes of each Tpmt genotype.

RESULTS: We found that astroglial cells with low Tpmt activity (*Tpmt* $^{+/-}$ and *Tpmt* $^{-/-}$ astrocytes and A172) predicted a significantly lower IC_{50} than did astrocytes with high Tpmt activity (*Tpmt* $^{+/+}$ astrocytes and T98). We also found that TG exposure induced significantly more DNA damage in the form of SSBs in astroglial cells with low Tpmt than in cells with high Tpmt. Interestingly, we found that *Tpmt* $^{+/-}$ had the highest degree of cytotoxicity and genotoxicity after TG exposure compared to *Tpmt* $^{+/+}$ and *Tpmt* $^{-/-}$ astrocytes. Expression studies revealed that several genes involved in the base excision and mismatch repair pathways had lower levels of expression in *Tpmt* $^{+/-}$ and *Tpmt* $^{-/-}$ as compared to *Tpmt* $^{+/+}$. Additionally, TG treatment induced the expression of some DNA repair genes in *Tpmt* $^{+/+}$ and *Tpmt* $^{-/-}$ but not in *Tpmt* $^{+/-}$ astrocytes.

CONCLUSION: The results show that low Tpmt can lead to high TG-induced toxicity in astroglial cells. Our findings also suggest that *Tpmt* genotype may influence the DNA damage response after TG exposure.

Other

190. Qatar pharmacists' understanding, attitudes, practice and perceived barriers related to providing pharmaceutical care. *Maguy S. El Hajj, Pharm.D.*, Hassna S. Al Saeed, BSPharm, Maryam A. Khaja, BSPharm; Qatar University College of Pharmacy, Doha, Qatar

PURPOSE: Pharmaceutical care (PC) is the philosophy of practice that includes identifying, preventing and resolving medication therapy problems to improve patient outcomes. The study objectives were to examine the extent of PC practice and the barriers to PC provision as perceived by Qatar pharmacists and to assess their level of understanding of PC and their attitudes about PC provision.

METHODS: A cross sectional survey of Qatar pharmacists was made. All pharmacists in Qatar were phone called and requested to participate. Consenting pharmacists were given the option to complete the survey either online using an online survey software or as paper based using fax. Data was descriptively analyzed using the Statistical Package of Social Sciences version 19.

RESULTS: Over 8 weeks, 274 surveys were collected (34% response rate). More than 70% of respondents had correct understanding of the goal and use of PC and of the pharmacist role in PC. However, only 35% understood the patient role in PC and only 17% were aware of

when to provide PC. Yet, more than 80% believed that they could be advocates when it comes to patients' medications and health matters and that they were ready to make the commitment required to improve patients' outcomes. Concerning their PC practice, respondents reported spending little time on PC activities. Offering feedback to the physician about the patient progress and documenting PC activities were always or most of the time performed by less than 25% of respondents. The top perceived barriers for PC provision included inconvenient access to patient medical information (78% of respondents) and lack of staff and time (77% and 74% respectively).
CONCLUSION: Although PC is not incorporated into pharmacy practice, Qatar pharmacists showed good attitudes toward PC provision. Efforts should be exerted to improve their understanding of PC and to overcome all perceived barriers.

191. Endocrine and Metabolism PRN updates and report of the benefit with an online journal club. Amy C. Donihi, Pharm.D.[1], Rohit Moghe, Pharm.D.[2], Emily Vescovi, Pharm.D.[3], *Jennifer N. Clements, Pharm.D.*[3], Rick Hess, Pharm.D.[4], Craig Logemann, Pharm.D.[5], Kent Porter, Pharm.D.[6]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)Thomas Jefferson University Hospital, Philadelphia, PA; (3)Bernard J. Dunn School of Pharmacy, Shenandoah University, Winchester, VA; (4)Bill Gatton College of Pharmacy, Johnson City, TN; (5)Iowa Health, Des Moines, IA; (6)Sanofi-Aventis, Lantana, TX
PURPOSE: The purpose is to describe current activities of the Endocrine and Metabolism (Endo-PRN) and member opinions on a recently initiated online journal club.
METHODS: A five-question questionnaire was created using SurveyMonkeyTM and the link to complete it was distributed to members of Endo-PRN via the PRN e-mail list-serve on December 3, 2010 and was available for completion through December 15, 2010. A reminder email was sent via the PRN e-mail list-serve on December 13, 2010.
RESULTS: Of 224 active Endo-PRN members, 22 (10%) responded to the questionnaire. One hundred percent agreed or strongly agreed that the journal club includes worthwhile topics of interest, 86% that quantity of journal club submissions per month is sufficient, and 71% that two journal club articles per week are sufficient. Journal club is read often or always by 50%, sometimes by 41%, and never by 9%. The majority (73%) reported that they have never submitted an article for the journal club. Open-ended comments were positive and suggested improvements such as increasing participation from other Endo-PRN members and possibly reducing the number of articles posted each week. There was a low response rate to the survey; therefore, results may not fully represent the PRN membership.
CONCLUSION: Based on the findings, the journal club has been well received, but all members do not contribute. A repeat survey will be done in Fall 2011. For the Endo-PRN, other activities have included its first opinion paper discussing cancer risk with insulin glargine, growth in membership, and updated policies and procedures for future projects.

192. Factors that influence board certification among pharmacy practice faculty in the US. *Kristin Watson, Pharm.D., BCPS*[1], Kimberly A. Toussaint, Pharm.D.[2], Joel C. Marrs, Pharm.D., BCPS[3], Deborah A. Sturpe, Pharm.D., BCPS[1], Sarah L. Anderson, Pharm.D., BCPS[3], Stuart T. Haines, Pharm.D., BCPS[1]; (1)University of Maryland School of Pharmacy, Baltimore, MD; (2)University of Maryland Medical Center, Baltimore, MD; (3)University of Colorado School of Pharmacy, Aurora, CO
PURPOSE: Accreditation Council for Pharmacy Education Standards state that pharmacy practice faculty should have or be working towards credentials related to their area of practice/expertise, including certification through the Board of Pharmacy Specialties (BPS). This study was conducted to determine the motivators and barriers to board certification among pharmacy practice faculty.
METHODS: Pharmacy practice faculty identified through the American Association of Colleges of Pharmacy membership directory were randomized in blocks based on faculty rank to receive an invitation to complete an online survey regarding board certification.
RESULTS: Of 900 faculty invited, 322 completed the survey (response rate 36%); of these, 308 considered themselves pharmacy practice faculty and were included in the analysis. Current BPS certification was reported by 163 respondents (52.9%). Fourteen (4.5%) were previously certified. Among all survey respondents, the most common perceived reason why pharmacy practice faculty become board certified is the desire to be recognized as an expert in the field (71.5%) followed by personal growth (38.1%). In contrast, among those who are currently board certified, the most common stated reason for seeking board certification was personal growth (60.5%, $p<0.05$) versus recognition as an expert (53.1%). Those previously certified cited no perceived benefit as the most common reason for not re-certifying (71.4%). Amongst those never board certified, no perceived need (52.0%) and no perceived benefit (44.8%) were the most common reasons for not becoming certified. A majority of those never certified (68%) stated they would consider certification if there was no associated cost and they were confident that they would pass.
CONCLUSION: Recognition by others and personal growth are the most common reasons why pharmacy practice faculty seek board certification. Although non-certified faculty indicated there is no perceived need or benefit, most would seek certification if it were free and they were guaranteed to pass.

193E. Bromfenac Ophthalmic Solution for Treating the Signs of Dry Eye Disease. Simon P. Chandler, Ph.D.[1], Sheri Rowen, M.D.[2], Neal A. Sher, M.D.[3], *James A. Gow, M.D.*[1], Timothy R. McNamara, Pharm.D.[1]; (1)ISTA Pharmaceuticals, Inc., Irvine, CA; (2)Mercy Medical Center, Baltimore, MD; (3)Eye Care Associates, Minneapolis, MN
PURPOSE: To evaluate the efficacy of bromfenac ophthalmic solution (bromfenac) using lissamine green staining in subjects with Dry Eye Disease (DED).
METHODS: On Day –14 and Day 0, subjects were diagnosed with mild or moderate DED with a mean National Eye Institute lissamine green staining grade of ≥1 in the same eye, with a minimum of 1/6 regions graded ≥ 2 in the same eye. The same region must have retained that grade on Days -14 and 0 in the same eye. During the 14 screening days, eligible subjects received only Refresh Plus® eye drops OU qid. From Day 0 - 42, subjects dosed bromfenac OU bid and Refresh Plus prn (≤qid). Subjects returned on Days 14±2, 28±2, and 42±2 for safety and efficacy assessments. During a 10-day follow-up, Refresh Plus was dosed prn (≤qid), followed by a visit on Day 52±4.
RESULTS: A total of 38 subjects were enrolled and analyzed for safety, 38 were analyzed for efficacy in ITT population, and 31 subjects were analyzed for efficacy in PP population. There was a significant improvement from baseline in the mean lissamine green staining at Day 42. Mean corneal staining also showed a significant improvement from baseline. No deaths, SAEs, or discontinuations due to AEs and 9 subjects (23.7%) experienced 18 AEs. Most AEs were either mild (6/9 subjects, 66.7%) or moderate (2/9 subjects, 22.2%); 1/9 subjects (11.1%) had a severe AE (sinusitis) considered not treatment related. Two subjects had AEs (eye discharge and eye pain) considered possibly related to treatment. One subject had a mild AE of foreign body sensation in eyes during the follow-up. Visual acuity and IOP had no significant changes from baseline.
CONCLUSION: The efficacy of bromfenac for DED subjects was robust and consistent in showing improvement in signs of DED for 42 days and 10 days follow-up when treatment was discontinued.
Presented at 6th International Conference on the Tear Film & Ocular Surface Basic Science and Clinical Relevance, Florence, Italy, September 22–25, 2010.

194E. Integrated phase 3 clinical trials of bromfenac sodium ophthalmic solution dosed once daily for ocular surgery. Simon P. Chandler, Ph.D.[1], Bonnie A. Henderson, M.D.[2], Johnny L. Gayton, M.D.[3], *James A. Gow, M.D.*[4], Timothy R. McNamara, Pharm.D.[4]; (1)ISTA Pharmaceuticals, Irvine, CA; (2)Boston Eye Surgery & Laser Center, Boston, MA; (3)Eyesight Associates of Middle Georgia, Warner Robins, GA; (4)ISTA Pharmaceuticals, Inc., Irvine, CA
PURPOSE: To evaluate the efficacy and safety of bromfenac dosed QD for ocular surgery.
METHODS: Subjects were assigned to receive either bromfenac (n=584) or placebo (n=288) dosed QD. Dosing began 1 day before cataract surgery and continued through post-surgery day 14. Primary

efficacy endpoint was ocular inflammation by day 15; secondary efficacy endpoint was number of subjects pain-free at day 1.
RESULTS: : Bromfenac was superior to placebo (P≤0.0001) in achieving the primary and the secondary efficacy endpoint. Compared to placebo, bromfenac dosed QD had a lower overall incidence of ocular adverse events.
CONCLUSION: Bromfenac sodium ophthalmic solution dosed QD is safe and effective for the treatment of inflammation and pain associated with ocular surgery.
Presented at the 114th Annual Meeting of the American Academy of Ophthalmology and Joint Meeting of the Middle East Africa Council of Ophthalmology, Chicago, IL, October 16–19, 2010.

195E. The ocular comfort of bepotastine besilate ophthalmic solution 1.5% in a safety clinical trial. Jon I. Williams, Ph.D.[1], Stacey Ackerman, M.D.[2], Jung T. Dao, M.D.[3], Tushina A. Reddy, M.D.[4], Timothy R. McNamara, Pharm.D.[1], *James A. Gow, M.D.*[1]; (1)ISTA Pharmaceuticals, Inc., Irvine, CA; (2)Philadelphia Eye Associates, Philadelphia, PA; (3)Cornea Consultants of Arizona, Phoenix, AZ; (4)Shepherd Eye Center, Las Vegas, NV
PURPOSE: To evaluate the ocular comfort of bepotastine besilate ophthalmic solution 1.5%, a dual-acting histamine H_1 receptor antagonist and mast cell stabilizer, after 6 weeks of twice daily ophthalmic dosing.
METHODS: This was a multi-center, randomized, masked, placebo-controlled, parallel-group, 6-week safety clinical trial of bepotastine besilate ophthalmic solution 1.5% and placebo with 861 healthy pediatric and adult subjects evaluated at 4 study visits. At Visits 2 and 3, subjects scored ocular comfort immediately and 5 minutes post-instillation with a 4-point grading scale (0=comfortable, 3=severely uncomfortable), 0.5-unit increments permitted. A clinically significant difference in group mean comfort scores was >1.0 unit.
RESULTS: Bepotastine besilate ophthalmic solution 1.5% subjects showed no statistically or clinically significant differences in ocular comfort compared to placebo at any study visit when evaluated. No bepotastine-related early withdrawals were due to ocular discomfort or severe adverse events.
CONCLUSION: Bepotastine besilate ophthalmic solution 1.5% was comfortable with no significant differences compared to placebo.
Presented at the 88th Annual Meeting of The American Academy of Optometry,San Francisco, CA, November 17–20, 2010.

196E. Bepotastine besilate ophthalmic solution 1.5% rapidly demonstrated near clearance of ocular itch in the conjunctival allergen challenge model of allergic conjunctivitis. Julie C. Clark, M.D.[1], Gordon L. Schooley, Ph.D.[2], Jon I. Williams, Ph.D.[1], *James A. Gow, M.D.*[1], Timothy R. McNamara, Pharm.D.[1]; (1)ISTA Pharmaceuticals, Inc., Irvine, CA; (2)Advanced Analytics and Informatics, LLC, Rancho Santa Fe, CA
PURPOSE: To assess the efficacy of bepotastine besilate ophthalmic solution (BBOS) 1.5% compared with placebo in near clearance of ocular itch using the conjunctival allergen challenge (CAC) model of allergic conjunctivitis at an onset of action CAC test.
METHODS: Two multicenter, double-masked, randomized, placebo controlled, 7 week clinical trials using the CAC model of allergic conjunctivitis. Eligible subjects were assigned randomly to either BBOS 1.5% (n=156 eyes) or placebo (n=158 eyes). Ocular itching was graded on a 0-4 unit scale and 0.5 unit increments were allowed. All patients had to achieve a score ≥2 to qualify for randomization. More severely allergic subjects were those defined as those reporting a score of 3 or greater in any eye at any time point during screening (BBOS 1.5% n=118 eyes, placebo n=108 eyes). Near clearance of itching was determined as a grade of 0 (no itch) or 0.5 units (intermittent itch sensation without rubbing) at a majority of observation time points (i.e., 3, 5 and 7 minutes following an allergen challenge) for a CAC test at 15 minutes after application of BBOS 1.5% or placebo bilaterally.
RESULTS: When measured at 3 minutes post-challenge, 75.0% (117/156) of subjects receiving BBOS 1.5% reported near clearance of ocular itch compared to 18.4% (29/158) of subjects receiving placebo. In more severely allergic subjects, the results were essentially the same: BBOS 1.5% provided near clearance in 75.4% (89/118) of eyes compared to 17.6% (19/108) with placebo (P≤0.001).
CONCLUSION: BBOS 1.5% was substantially superior to placebo in providing rapid and substantial relief of ocular itch, even in subjects with more severe itching symptoms at screening.
Presented at the 27th Annual Aspen Allergy Conference, Aspen, CO, July 27-31, 2010.

197E. Bepreve (Bepotastine Besilate Ophthalmic Solution) 1.5% improves reflective ocular itching scores in a placebo-controlled natural exposure study of subjects with a demonstrated history of seasonal allergic rhinoconjunctivitis (SAR). Jon I. Williams, Ph.D.[1], Gary D. Berman, M.D.[2], Ronald H. Saff, M.D.[3], Allan Stillerman, M.D.[4], *James A. Gow, M.D.*[1], Timothy R. McNamara, Pharm.D.[1]; (1)ISTA Pharmaceuticals, Inc., Irvine, CA; (2)Allergy & Asthma Specialists, Minneapolis, MN; (3)Allergy & Asthma Diagnostic Treatment Center, PA, Tallahassee, FL; (4)Allergy & Asthma Specialists, PA, Minneapolis, MN
PURPOSE: To establish the degree of ocular symptom improvement in a randomized, double-masked, placebo-controlled clinical study for subjects with active rhinoconjunctivitis and a history of SAR in a 2-week natural exposure study following treatment with Bepreve® 1.5% twice daily.
METHODS: Eligible subjects had to display evidence of active ocular and nasal allergic symptoms in order to be enrolled. Following randomization, 245 subjects at 12 clinical sites were assigned to placebo or Bepreve 1.5% eyedrops and self-dosed twice daily (AM and PM) during active allergy season for 14 days. Among efficacy endpoints, reflective ocular itching symptoms were each graded by subjects on a 0-3 unit scale (0 = none, 1 = mild symptoms, 2 = moderate symptoms, 3 = severe symptoms).
RESULTS: Statistically significant reductions were seen in reflective mean ocular itching scores for Bepreve 1.5% (N = 109) compared to placebo (N = 108) in the Per Protocol population. Reduction in reflective ocular symptom scores was significantly better with Bepreve 1.5% by ANCOVA analysis over the 2-week treatment period (P=0.025) and was evident within about 6 days of subject enrollment. Once significance was achieved for the ocular itching endpoint, it generally persisted through the end of the 2-week study period. Rating of a beneficial global therapeutic response at the end of the treatment period by study investigators was statistically superior (P=0.024) for Bepreve 1.5% treatment compared to placebo.
CONCLUSION: Bepreve 1.5% reduced reflective ocular itching symptom scores when compared to placebo in a 2-week natural exposure study, achieving statistical significance for reduced ocular itching that was independently supported by determination of an objective clinical response as judged by study investigators.
Presented at the 83rd Annual Meeting of The Association for Research in Vision and Ophthalmology, Inc., Ft. Lauderdale, FL, May 1–5, 2011.

Pain Management/Analgesia

198. Bupivacaine extended release liposome injection (DepoFoam® bupivacaine) vs. bupivacaine HCl: A meta-analysis of multimodal trials of doses up to and including 300 mg. *Joseph Dasta, M.S.*[1], Sonia Ramamoorthy, M.D.[2], Gary Patou, M.D.[3], Raymond Sinatra, M.D., Ph.D.[4]; (1)The University of Texas College of Pharmacy, Austin, TX; (2)University of California at San Diego, San Diego, CA; (3)Pacira Pharmaceuticals, Parsippany, NJ; (4)Yale-New Haven Hospital, New Haven, CT
PURPOSE: bupivacaine (DB) is an investigational formulation of bupivacaine which allows for release over 72 hours. Studies comparing the use of DB at doses up to 300 mg bupivacaine at doses up to 200 mg were evaluated for several key endpoints.
METHODS: Five active-control, double-blind, randomized, parallel-group trials in > 700 patients receiving doses up to and including 300 mg were reviewed. All studies had a multi-modal setting (scheduled NSAID and/or acetaminophen plus rescue opioids as needed). Surgical models included , total knee , and hernia repair. Endpoints included the area under the curve (AUC) analysis through 72 hours of the numeric rating scale scores for pain, the median time to first opioid (TTFO) , the total amount of morphine equivalents consumed over 72 hours (adjusted geometric mean), and the mean number of opioid-related adverse events (ORAE) per patient.

RESULTS: Results demonstrated that DB was statistically superior to bupivacaine

	DB (75–300 mg)	Bupivacaine HCl (75-200 mg)	p-value
AUC 0–72 hr	315	427	p<0.0001
Median TTFO	9.9 hours	2.7 hours	p<0.0001
Morphine per pt	7.9 mg 0.25	15.8 mg 0.46	p<0.0001

The adverse event profiles of the compounds were comparable; the most common treatment emergent adverse events reported across the entirety of the DB clinical program were nausea, constipation, and vomiting.
CONCLUSIONS: DB appears to offer clinically meaningful advantages over bupivacaine in multi-modal trials for postsurgical analgesia.

199. Off-label, low-dose ketamine as an effective adjunctive therapy for postoperative analgesia. *Colleen M. Culley, Pharm.D., BCPS*[1], Susan J. Skledar, B.S., M.P.H.[1], Tara Pummer, Pharm.D.[1], Lois Pizzi, BSN, RN-BC[2]; (1)University of Pittsburgh School of Pharmacy, Department of Pharmacy and Therapeutics, Pittsburgh, PA; (2)University of Pittsburgh Medical Center Shadyside Campus, Inpatient Pain Management Coordinator, Pittsburgh, PA
PURPOSE: Evaluate the safety and effectiveness of ketamine, an FDA-approved anesthetic agent, administered off-label in sub-anesthetic doses as an adjuvant analgesic, in terms of dosing, opioid consumption, pain scores, and adverse events. Additionally, compliance with process measures such as use of electronic care set, proper labeling, pump administration, and specialist prescribing was assessed.
METHODS: A prospective evaluation was conducted for the patients in the initial pilot of postoperative ketamine at two institutions in our health system between May 14 and Sept 1, 2011. Ketamine was administered via continuous infusion through a secure patient-controlled analgesia (PCA) device, to patients already receiving PCA opioid and peripheral nerve block. Patient demographics, duration, dose, time to initiation of ketamine, pain scores and adverse events were collected.
RESULTS: Twenty patients received ketamine in the pilot on general postoperative units. Median rate was 5 mg/hr (range 4–10) with a mean dose of 100.4 mg/day. Mean time to initiation of ketamine after surgery end time was 22:16 hours (range 00:49–76:18) and mean duration of 51:23 hours (range 6:09–97:45). Mean PCA opioid dose per day was 14.2 mg pre-, 21.9 mg during and 17.9 mg post-ketamine. Pain score was significantly improved from median 7 initial to 3.5 at ketamine infusion end (p<0.0001). Adverse events included urinary retention (n = 1) and hallucinations (n = 2). There was 100% compliance with involvement of pain service specialists, use of electronic order set, proper PCA cartridge labeling, pump administration and nursing verification of competency.
CONCLUSION: Sub-anesthetic doses of ketamine were effective in decreasing pain scores for postoperative patients in conjunction with opioids and peripheral nerve blocks. Ketamine was able to be administered safely and met regulatory requirements leading to approval for expansion of use. The protocol was changed to include an automatic 48-hour stop on ketamine orders based on use.

200. DepoFoam® Bupivacaine (DB; EXPAREL™; Bupivacaine Extended Release Multivesicular Liposome Injection) exhibits pharmacokinetic properties consistent with sustained release characteristics. *Deedee Hu, Pharm.D.*[1], Erol Onel, M.D.[2], Neil K. Singla, M.D.[3], Lakshmanasamy Somasundaram, M.D.[4], Jeff Gadsden, M.D.[4], William G. Kramer, Ph.D.[5], Admir Hadzic, M.D., Ph.D.[1]; (1)Memorial Hermann Memorial City Medical Center, Houston, TX; (2)Pacira Pharmaceuticals, Inc., Ridgefield, CT; (3)Lotus Clinical Research, Inc., Pasadena, CA; (4)St. Luke's Roosevelt Hospital, New York, NY; (5)Kramer Consulting LLC, North Potomac, MD
PURPOSE: Liposomal drug containing formulations are designed to provide slow release of drug over an extended period of time, thus extending duration while diminishing high plasma levels. We conducted a cross-study analysis of the pharmacokinetic properties of DB, an extended release multivesicular liposomal formulation of bupivacaine in DepoFoam, given as a single injection.
METHODS: Pooled data from 446 individuals (age 18–85; 63% male) from eleven Phase 1–3 studies who received either DB or bupivacaine HCl were analyzed for pharmacokinetic parameters including T_{max}, $t_{1/2}$, and C_{max}. Routes of administration included wound infiltration, subcutaneous, epidural, and nerve block. Surgical models included hemorrhoidectomy, herniorraphy, bunionectomy, and total knee arthroplasty. Doses ranged from 75mg-750mg.
RESULTS: DB demonstrated bimodal peak concentrations at 0.25–2 hours (likely due to the small amount of extraliposomal bupivacaine present in the formulation) and at 12–24 hours after injection (resulting from the slow and prolonged release of bupivacaine from the DepoFoam). In contrast, bupivacaine HCl peaked once at 0.25–2 hours with a rapid decline towards zero. After wound infiltration, DB exhibited a $t_{1/2}$ of 34.1 hours and a highest mean plasma C_{max} of 935 ng/ml (2–4 fold below bupivacaine's minimal toxicity thresholds), obtained after local administration of 600 mg DB.
CONCLUSION: DepoFoam bupivacaine exhibited pharmacokinetic properties consistent with a sustained release formulation after a single injection. Plasma concentration remained well below bupivacaine's reported toxic levels, even with doses of DB up to 600 mg.

201E. A post-hoc pooled data analysis to evaluate the gastrointestinal tolerability profile of tapentadol extended release (ER) versus oxycodone controlled release (CR) in patients ≥75 years of age. *David Biondi, D.O.*[1], Jim Xiang, Ph.D.[1], Mila Etropolski, M.D.[2], Bruce Moskovitz, M.D.[1]; (1)Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, NJ; (2)Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Titusville, NJ
PURPOSE: To evaluate analgesic efficacy and tolerability of tapentadol ER (100-250 mg bid) versus oxycodone HCl CR (20–50 mg bid) in patients ≥75 years of age.
METHODS: This post-hoc analysis used pooled data from 3 similarly-designed 15-week, randomized, double-blind, placebo- and active-controlled, phase 3 studies of tapentadol ER for moderate-to-severe chronic osteoarthritis knee (NCT00421928, NCT00486811) or low back (NCT00449176) pain. Analgesic efficacy was determined by the change in pain intensity (11-point numerical rating scale). Times to initial onset of gastrointestinal TEAEs and time to study discontinuation due to these TEAEs were estimated using Kaplan-Meier plots.
RESULTS: Similar numbers of subjects were in each treatment arm (tapentadol ER, n=72; oxycodone CR, n=78). No significant between-treatment difference in the least-squares mean (SEM) change in pain intensity from baseline to Week 15 was observed (tapentadol ER, –3.66[0.44]; oxycodone CR,–4.02[0.54];*P*=0.604). Significantly lower percentages of patients who received tapentadol ER versus oxycodone CR reported gastrointestinal TEAEs (51.4% vs 71.8%;*P*=0.0119) and study discontinuations due to gastrointestinal TEAEs (16.7% vs 42.3%;*P*=0.0007). Times to initial onsets of nausea, vomiting, and constipation and times to study discontinuation due to nausea and vomiting occurred later with tapentadol ER versus oxycodone CR (all $P \leq 0.0388$; time to discontinuation due to constipation, *P*=0.4685). Patients experienced the following common opioid-related gastrointestinal TEAEs for lower mean percentages of study days with tapentadol ER versus oxycodone CR, respectively: nausea, 10.2% versus 20.2%, *P*=0.0621; vomiting, 1.6% versus 9.1%, *P*=0.0008; constipation, 12.0% versus 24.8%, *P*=0.1144. Severity ratings of the common opioid-related gastrointestinal TEAEs (nausea, vomiting, constipation, and nausea and/or vomiting) were generally lower with tapentadol ER versus oxycodone CR.
CONCLUSION: Tapentadol ER (100–250 mg bid) was associated with comparable analgesia and better gastrointestinal tolerability than oxycodone HCl CR (20–50 mg bid), including lower incidences of gastrointestinal TEAEs and study discontinuation due to gastrointestinal TEAEs, in patients ≥75 years of age.
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202E. A post-hoc pooled data analysis to evaluate blood pressure (BP) and heart rate (HR) measurements in patients with a current or prior history of hypertension who received tapentadol ER, oxycodone CR, or placebo in chronic pain studies. *David Biondi, D.O.*[1], Jim Xiang, Ph.D.[1], Mila Etropolski, M.D.[2], Bruce Moskovitz,

M.D.[1]; (1)Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, NJ; (2)Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Titusville, NJ

PURPOSE: Tapentadol is a centrally-acting analgesic with μ-opioid receptor agonist and norepinephrine reuptake inhibitor activity. An analysis of pooled data from 3 similarly-designed 15-week, randomized, double-blind, placebo- and active-controlled, phase 3 studies of tapentadol ER for moderate-to-severe chronic osteoarthritis knee pain (NCT00421928, NCT00486811) or low back pain (NCT00449176) found no clinically relevant changes in mean BP or HR measurements with placebo (n=946), tapentadol ER (100–250mg bid; n=920), or oxycodone HCl CR (20–50mg bid; n=831).

METHODS: This post-hoc analysis of those pooled data evaluated systolic BP (SBP), diastolic BP (DBP), and HR in 2 cohorts—patients with a medical history of hypertension and patients with a concomitant anti-hypertensive medication.

RESULTS: In patients with a history of hypertension, the least squares mean (LSM [SE]) change from baseline to endpoint in BP and HR with placebo (n=459), tapentadol ER (n=462), and oxycodone CR (n=413), respectively, was SBP, -2.4 (0.64), -2.7 (0.64), and -3.7 (0.67) mmHg; DBP, -1.0 (0.39), -1.3 (0.39), and -2.3 (0.41) mmHg; HR, -0.7 (0.44), 0.2 (0.43), and -0.9 (0.45) beats-per-minute (bpm). In patients with a concomitant anti-hypertensive medication, the LSM (SE) change from baseline to endpoint in BP and HR with placebo (n=429), tapentadol ER (n=434), and oxycodone CR (n=387), respectively, was SBP, –1.8 (0.66), -3.3 (0.65), and -3.7 (0.69) mmHg; DBP, -0.7 (0.40), -1.4 (0.40), and -2.3 (0.42) mmHg; HR, -0.6 (0.45), 0.1 (0.44), and -0.7 (0.47) bpm. There were no significant differences between tapentadol ER and placebo or oxycodone CR in the LSM changes from baseline to endpoint in SBP, DBP, or HR.

CONCLUSION: These results showed no clinically relevant changes in BP or HR with tapentadol ER (100-250mg bid) or oxycodone HCl CR (20–50 mg bid) and suggest that tapentadol ER is a reasonable treatment option for chronic pain management in patients with hypertension.

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203. Pharmacists perceptions and knowledge regarding opioid risk evaluation and mitigation strategies (REMS) in community and ambulatory practice. *Karen Marlowe, Pharm.D., BCPS, DAAPM*, Emily McCoy, Pharm.D.; Auburn University/Univ. of S. AL, Fairhope, AL

PURPOSE: The purpose of the study is to assess ambulatory care pharmacist's perceptions and knowledge regarding opioid risk evaluation and mitigation strategies in community and ambulatory practice.

METHODS: This study was approved by the Institutional Review Board at Auburn University. A link to a 40 question survey was distributed via email to pharmacists who subscribe to an ambulatory care list-serve. The survey was completed anonymously using the Qualitrics® survey software. The survey asked demographic questions regarding educational background, length of time in practice, and amount of practice devoted to pain management, as well as approximately 4 questions concerning the pharmacists' current knowledge of REMS for opioid use, 5 questions concerning the pharmacists' methods for implementing REMS in their practice sites, and 20 questions concerning the pharmacists' opinion of REMS. Prevalence of individual practice strategies including treatment agreements, opioid informed consents, treatment monitoring with drug testing, and patient educations strategies will be assessed.

RESULTS: 79 pharmacists responded to the survey, with 69 completing all questions. 67% of the respondents had heard of REMS for opioids, and only 19% had formal policies in place to address REMS for opioids when this survey was done in March 2011. The most popular tools in use for increasing patient adherence to therapy were treatment agreements (84%) and urine drug screens (51%). Approximately half of those surveyed did not feel opioid REMS would improve the situation with opioid use in their clinic.

CONCLUSION: Ambulatory care pharmacists are in a unique position to care for patients in chronic pain and will be required to utilize mandated REMS procedures for opioids products. Current knowledge and utilization of REMS appears to be an area for targeted education.

204. Meta-analysis of the tolerability of tapentadol. Vanessa White, Pharm.D., *Stephanie L. Ballard, Pharm.D.*; Nova Southeastern University, Palm Beach Gardens, FL

PURPOSE: Tapentadol is an oral analgesic which agonizes mu-opioid receptors and inhibits norepinephrine synaptic uptake. Our objective was to systematically identify and synthesize available data on adverse events associated with use of the new analgesic tapentadol compared with placebo and oxycodone.

METHODS: We performed a database search for "tapentadol" in Medline, Embase, International Pharmaceutical Abstracts, ClinicalTrials.gov, and Google Scholar. Our search was augmented by citation tracking and package insert information. Randomized, controlled trials evaluating the safety or tolerability of tapentadol in English were included. Two independent investigators extracted study data, which was pooled and analyzed using a Mantel-Haenszel random effects model.

RESULTS: Ten studies met inclusion criteria, including 8 randomized, placebo-controlled trials (n=3,800), and 8 papers with an oxycodone active control (n=5,310). Indications for pain control included post-surgical and chronic pain due to osteoporosis and diabetic peripheral neuropathy. Studies used total daily doses of tapentadol immediate release (IR) and extended release (ER) ranging from 25–600 mg and 200–600 mg, respectively, as well as oxycodone IR and CR, dosed from 20–90 mg and 40–100 mg daily, respectively. Compared to placebo, patients receiving tapentadol were found to be statistically significantly more likely to experience nausea, dizziness, somnolence, constipation, pruritis, fatigue, vomiting, hyperhidrosis and dry mouth. The relative risk (RR) for any adverse event was significantly lower with tapentadol than oxycodone (RR 0.78; 95% confidence interval 0.68-0.87). When compared to oxycodone, patients receiving tapentadol were more likely to experience dry mouth (RR 1.6; 1.31–2.63), and less likely to report nausea (RR 0.62; 0.56–0.69), dizziness (RR 0.86; 0.75–0.96), vomiting (RR 0.40; 0.26–0.61), pruritis (RR 0.50; 0.39–0.64), and constipation (RR 0.47; 0.56–0.69).

CONCLUSION: Treatment of moderate to severe pain with tapentadol was associated with fewer adverse events than oxycodone therapy, with the exception of dry mouth.

Pediatrics

205. Pharmacokinetics of mycophenolic acid and glucuronidated metabolites following mycophenolate mofetil and mycophenolate sodium dosing in pediatric renal transplant recipients. Tony K.L. Kiang, Ph.D.[1], Mina Matsuda-Abedini, MDCM[2], *Mary H.H. Ensom, Pharm.D.*[1]; (1)Faculty of Pharmaceutical Sciences, The University of British Columbia & Child and Family Research Institute, Vancouver, BC, Canada; (2)Department of Pediatrics, Division of Nephrology, BC Children's Hospital, Vancouver, BC, Canada

PURPOSE: To characterize and compare the pharmacokinetics (PK) of mycophenolic acid (MPA) and its glucuronidated metabolites, MPAG (phenolic-glucuronide) and AcMPAG (acyl-glucuronide), following steady-state (equimolar) doses of mycophenolate mofetil (MMF) and enteric-coated mycophenolate sodium (EC-MPS) in stable pediatric renal transplant recipients.

METHODS: Following written informed consent and upon administration of a steady-state morning MMF dose, blood samples were collected at pre-dose (0 h) and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, and 8 hours. The sampling schedule was repeated in 3 months, after patients were converted to EC-MPS. Total MPA, MPAG, and AcMPAG concentrations were measured by a validated high-performance liquid chromatography-ultraviolet method and PK parameters calculated by non-compartmental analysis.

RESULTS: Patients were: 2 males and 2 females, (median[interquartile range]) 33.0 [3.2–65.5] month post-transplant, age 12.0 [9.8–14.3] yrs and weight 38.4 [28.9–50.6] kg, with serum creatinines 87.5 [69.0–129.8] (MMF visit) and 109.0 [89.0–222.5] µmol/L (EC-MPS visit). All were on prednisone and tacrolimus. Dose-normalized PK parameters of MPA from steady-state doses of MMF and EC-MPS were: (median[interquartile range]) area-under-the-curve (AUC) 19.9 [15.9–32.1] vs. 21.5 [12.2-32.3] µg×h/mL/g; maximal

concentration (C_{max}) 12.5[5.8–22.2] vs. 9.5[7.8–9.7] μg/mL/g; and minimum concentration (C_{min}) 0.7 [0.4–1.2] vs.0.8 [0.5–1.4] μg/mL/g ($p>0.05$ for all MMF vs. EC-MPS comparisons). The AUCs of MPAG (217.6 [157.8–368.1] vs. 265.6 [194.3–367.0] μg×h/mL/g; MMF vs. EC-MPS) and AcMPAG (1.8 [0.9–3.5] vs. 1. 5[0.9–2.7] μg×h/mL/g); AUC-ratios of MPAG/MPA (14.5 [10.4–15.6] vs 12.6 [7.2–18.8]) and AcMPAG/MPA (0.1 [0.1–0.1] vs. 0.1 [0.0–0.1]) were also similar when comparing MMF and EC-MPS.
CONCLUSION: Similar PK parameters of MPA and its metabolites following steady-state MMF and EC-MPS doses were observed in this pilot crossover study. This may be due to the small sample size and/or wide inter-individual variability (as has been observed in other populations). These preliminary data suggest that equimolar doses of MMF and EC-MPS yield comparable exposure to MPA and its glucuronidated metabolites in pediatric renal transplant recipients and warrant confirmation in a larger population.

206. Peroxisome proliferator-activated receptor α activity is altered by omega-3 polyunsaturated long-chain fatty acids in a cholestatic liver disease model. *Emma M. Tillman, Pharm.D.*, Richard A. Helms, Pharm.D., Dennis D. Black, M.D.; University of Tennessee Health Science Center, Memphis, TN
PURPOSE: Parenteral nutrition (PN)-associated liver disease (PNALD) occurs in children receiving long-term PN. Studies have demonstrated improvement of PNALD with omega-3 long-chain polyunsaturated fatty acids (ω3PUFA) containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are ligands for the nuclear receptor transcription factor, peroxisome proliferator-activated receptor-α (PPARα), that has anti-inflammatory and anti-apoptotic properties. Studies in cystic fibrosis transmembrane conductance regulator (CFTR) knockout mice with bile duct injury showed a defect in PPARα expression, which was reversed by DHA treatment *(Pall H et al.J Pediatr Gastroenterol Nutr.* 2006;42:275–81). The aim of this study was to determine if PPARα activity is altered with ω3PUFA treatment in a model of PNALD.
METHODS: Activation of PPARα in HepG2 cells was evaluated by isolation of nuclear protein after 4-hr treatment with the lipophilic bile acid, chenodeoxycholic acid (CDCA) 200μM ± ω3PUFA (EPA 5μM+DHA 5μM). PPARα activity was measured by assessing transcription factor activity in a non-radioactive, sensitive ELISA method for detecting PPARα DNA binding activity in nuclear extracts.
RESULTS: Treatment of HepG2 cells with ω3PUFA alone resulted in PPARα activity equal to that observed with recombinant PPARα and DNA binding of PPARα was decreased by 70% in the presence of CDCA ($p<0.001$). Treatment with CDCA and ω3PUFA resulted in less reduction of PPARα activity as compared to controls. Although this was not significantly different from that of CDCA alone, there was a trend to restoration of PPARα activity with the addition of ω3PUFA.
CONCLUSION: Activity of PPARα was reduced by treatment with lipophilic bile acid and increased in the presence of ω3PUFA. These results are similar to studies in CFTR knockout mice and suggest that PPARα activation may be a promising mechanism by which ω3PUFA attenuate the bile acid-induced hepatocellular injury that occurs in cholestasis, such as that seen in PNALD.

207. Gentamicin pharmacokinetics in neonates undergoing therapeutic hypothermia. *Liana Mark, Pharm.D.*[1], Addishiwot Solomon, Pharm.D.[2], Frances J. Northington, M.D.[3], Carlton K.K. Lee, Pharm.D., M.P.H.[4]; (1)The Johns Hopkins Hospital, Baltimore, MD; (2)University of Maryland School of Pharmacy, Baltimore, MD; (3)Department of Pediatrics, Neuro-Intensive Care Nursery, Johns Hopkins University, Baltimore, MD; (4)Department of Pediatrics, Johns Hopkins University & Department of Pharmacy, The Johns Hopkins Hospital, Baltimore, MD
PURPOSE: This study evaluated the effects of whole body therapeutic hypothermia in newborns with hypoxic ischemic encephalopathy (HIE) on gentamicin pharmacokinetics. These results were compared to newborns with HIE receiving gentamicin who eligible for, but did not receive, therapeutic hypothermia.
METHODS: Subjects with HIE who received therapeutic hypothermia were identified via a database maintained by The Johns Hopkins Hospital Neonatal Intensive Care Unit from January 1, 2007 through July 31, 2010. Eligible neonates were those who received intravenous gentamicin during the period of cooling and whose serum sampling occurred around or after the third continuous dose. Individual pharmacokinetic parameters were characterized according to standard first order pharmacokinetic equations and compared to an age-matched control group consisting of neonates with HIE who received gentamicin antibiotic therapy and who were not cooled but who met criteria for therapeutic hypothermia. Control subjects were identified via an International Classification of Diseases, 9th Revision (ICD-9) code for HIE from a hospital billing database.
RESULTS: Sixteen neonates who received therapeutic hypothermia and seven neonates who did not receive therapeutic hypothermia met our inclusion criteria. Significant differences in gentamicin pharmacokinetics were noted between the therapeutic hypothermia group and the comparator group in elimination rate constant (0.08 + 0.02 vs. 0.11 + 0.03 h-1 , $p<0.01$), elimination half-life (9.16 + 2.08 vs. 6.56 + 1.81 h, $p<0.01$), and clearance (0.04 + 0.01 vs. 0.05 + 0.01 L/h, $p<0.01$), respectively. Neonates who received therapeutic hypothermia had higher trough serum concentrations (1.68 + 0.69 vs. 0.77 + 0.53, $p<0.01$). No difference was seen in volume of distribution or peak concentrations between the groups.
CONCLUSION: Therapeutic hypothermia is associated with alterations in gentamicin pharmacokinetics, reducing gentamicin clearance by 25.5% in neonates with HIE, which may result in increased trough serum concentrations.

208. Comparison of pediatric versus adult safety studies for drug approval of antiviral and antipsychotic agents. *Gilbert J. Burckart, Pharm.D.*[1], Theresa Yoon, B.S.[2], Xiaomei Liu, M.S.,[3], Allen Rudman, Ph.D.[4]; (1)Office of Clinical Pharmacology, CDER, FDA, Silver Spring, MD; (2)Fletcher Allen Health Care, Burlington, VT; (3)University of Minnesota School of Pharmacy, Duluth, MN; (4)U.S. Food and Drug Administration, CDER, Office of Clinical Pharmacology, Silver Spring, MD
PURPOSE: This study was conducted to determine the comparability of safety studies conducted in pediatric and adult patients. The antiviral and antipsychotic agents were chosen for this review.
METHODS: A retrospective investigation of adverse events (AEs) in clinical studies submitted to the FDA was performed in the two therapeutic areas. Seventeen antiviral drugs and eleven antipsychotic drugs were reviewed, and only drugs in which both pediatric and adult clinical data were available were evaluated for these studies. All of the studies were clinical trials conducted for submission to the FDA for drug approval. The AE and safety terminology was based on nomenclature described in the specific submission and were not further standardized.
RESULTS: Eleven of the 17 antiviral drugs had both pediatric and adult safety information available. For the 11 antiviral agents, 1534 pediatric patients were included in the safety studies versus 4188 adult patients. Only 3 of the 11 antipsychotic agents had both pediatric and adult safety information. Those 3 safety studies were conducted in 1045 pediatric patients and 2831 adult patients. Complete agreement of the AE profile between the pediatric and adult patients was found for 0/11 antiviral agents and 0/3 antipsychotic agents. Differences between pediatric and adult studies were observed in both incidence of an AE and the type of AE, and in AE terminology.
CONCLUSION: Safety studies in pediatric patients are conducted in smaller patient populations than adult safety studies for drug approval. The AE profiles for adult versus pediatric patients were very different for these two drug classes. The implications of these findings are that: (1) novel methods of conducting pediatric safety studies for new drugs should be sought, and (2) consistent methods of classifying and identifying AEs should be applied whenever possible in pediatric and adult safety studies.

209E. An NIH sponsored pharmacist curriculum on interventions for Sudden Infant Death Syndrome (SIDS) risk reduction. *Hanan Kallash, M.S.*; Eunice Kennedy Shriver National Institute of Child Health and Development, Baltimore, MD
PURPOSE: Research indicates that pharmacists can benefit from a continuing education program on Sudden Infant Death Syndrome as the role of the pharmacist continues to expand. Alldrege and Koda-Kimble published an opinion piece in the American Journal of Pharmaceutical Education which stated that pharmacist roles of

prescribing, educating and monitoring patients leads to job satisfaction. They recommend pharmacists take a larger role in patient care(Douglas, 2007, Boardman et al 2005). Several studies indicate that patients are willing and open to receiving information from their pharmacists regarding issues related to health promotion(Chen 2000, Iverson 2001).Patients surveyed indicated that there was a positive attitude towards expanding the pharmacist role to include healthy living advice, health screening activity and general practitioner support. This seems to be especially pertinent for mothers of young children according to a study conducted by Hodgson and Wong which found that 61 percent of the mothers they surveyed were visiting the pharmacist at least once a month, 22 percent stated they received advice and of that 87 percent reported the suggestions to be helpful or very helpful.

METHODS: A CE program was created in partnership with 6 national pharmacist groups. Focus groups were conducted in 3 demographically diverse states, The CE is in Active Learning Tool format with cases and problem solving on caregiver/parent culturally competent education. Pre and post test are administered to measure knowledge base. Letters were sent to pharmacy associations and specific SOP to recruit participants.

RESULTS: 360 Pharmacists and 118 students have completed the program with average increase in assessment scores of 26–34%.

CONCLUSION: This program significantly increases pharmacists ability to: Define SIDS, list critical SIDS risk-reduction messages for parents/caregivers, list four barriers to back sleeping for parents/caregivers, and increase pharmacists competency as educators to parents/caregivers and peers about SIDS in a culturally appropriate manner.

Presented at American Pharmacy Association Annual conference, Washington DC, March 25–29, 2011.

210. Evaluation of vancomycin use for pediatric Staphylococcal infections. *Rebecca F. Chhim, Pharm.D.*[1], Sandra Arnold, M.D., FRCPC[1], Kelley Lee, Pharm.D., BCPS[2]; (1)University of Tennessee and Le Bonheur Children's Hospital, Memphis, TN; (2)Le Bonheur Children's Hospital and University of Tennessee, Memphis, TN

PURPOSE: Due to concern related to increasing vancomycin minimal inhibitory concentrations (MIC) for methicillin-resistant *Staphylococcus aureus* (MRSA), recent guidelines have recommended more aggressive dosing (60 mg/kg/day) and higher trough concentrations (15 – 20 mcg/ml) than traditionally used in pediatrics. The objective of this study was to evaluate our dose/trough relationship and determine if treatment failures were occurring with traditional dosing in pediatric patients with invasive staphylococcal infections.

METHODS: This was a retrospective cohort study including patients receiving vancomycin for suspected invasive gram-positive infection. Patients were excluded for age less than two months, baseline renal dysfunction, non-weight based dosing, treatment for skin or soft tissue infection, no trough concentration, or inappropriately drawn trough. Clinical outcomes were evaluated in patients who had positive cultures for *S. aureus*. MICs were measured using broth microdilution. Troughs ≥ 10 mcg/ml were considered therapeutic.

RESULTS: Dose and trough correlations were evaluated in 254 patients. Fifty-eight patients had a positive staphylococcus culture. Of those receiving 40 mg/kg/day for confirmed staphylococcal infection, 26% had undetectable trough concentrations and 70% had concentrations < 10 μg/ml. In patients receiving 60 mg/kg/day, 42% had trough concentrations < 10 μg/ml. Only 5% of MRSA isolates had MICs ≥ 2. By the end of treatment, 76% of patients with positive cultures were receiving 60 mg/kg/day or higher. In these patients, 12% had trough concentrations > 20 μg/ml. Treatment failure resulting in a change in antibiotics was only observed in one patient.

CONCLUSION: Traditional vancomycin dosing regimens did not result in recommended trough concentrations in the majority of patients. Dose escalation was performed to obtain therapeutic (≥ 10 μg/mL) trough concentrations although treatment failure for invasive staphylococcal infections was rare. Supratherapeutic concentrations were not commonly observed with higher dosing. At least 60 mg/kg/day appears to be necessary to routinely produce recommended vancomycin trough concentrations in patients with invasive infections.

211. Characterization of cannabinoid usage in a pediatric oncology population. *Joshua J. Elder, Pharm.D.*[1], Holly M. Knoderer, M.D.[2]; (1)Indiana University Health, Indianapolis, IN; (2)Indiana Univerisity School of Medicine, Indianapolis, IN

PURPOSE: Chemotherapy-induced nausea and vomiting (CINV) remains an important side effect associated with the administration of chemotherapy in pediatrics. The aim of this study is to retrospectively study dronabinol use in an academic pediatric cancer center with the intent of characterizing its use and identifying trends such as age, gender, diagnosis, and chemotherapy that describe where dronabinol may be best appropriate as an adjuvant antiemetic.

METHODS: Patients receiving dronabinol at Riley Hospital for Children between 2000 and 2010 were identified. Eligible patients were those with malignancy ≤ 18 years old who received at least one dose of dronabinol for CINV during admission. The following parameters were collected: demographics, chemotherapy regimen, dronabinol dosing and frequency, emetic events, repeat courses of dronabinol, and outpatient prescriptions for dronabinol.

RESULTS: The mean age was 13.9 years. Leukemia and sarcomas were the most common diagnoses, comprising 36% of the population respectively. Ninety five percent of patients received moderate or highly emetogenic chemotherapy. When examining dronabinol dosing, 95% received lower doses than referenced guidelines, 55% received dronabinol as a scheduled medication, and 23% received dronabinol 1–3 hours prior to chemotherapy. Overall, 60% of patients had a defined good response to dronabinol. Sixty five percent of patients received repeat courses of dronabinol and 62% received outpatient prescriptions for dronabinol.

CONCLUSIONS: Dronabinol appears to be a viable option as an adjuvant antiemetic in pediatric CINV, but a prospective trial using patients as their own controls would be appropriate to truly dronabinol's place in therapy.

212. Comparison of single dose arginine hydrochloride to multiple doses of acetazolamide to correct metabolic alkalosis in pediatric patients. *Alex Oschman, Pharm.D.*, Daniel Heble Jr., Pharm.D., Tracy Sandritter, Pharm.D.; Children's Mercy Hospital, Kansas City, MO

PURPOSE: To determine if a course of arginine hydrochloride or acetazolamide was more effective in correcting metabolic alkalosis within a 24-hour period in pediatric patients.

METHODS: Institutional Review Board approval was obtained for this retrospective comparative study. Inclusion criteria: PICU or NICU patients who received a course of acetazolamide or arginine hydrochloride (defined as 3–4 doses of acetazolamide or 66–100% of the full calculated dose of arginine hydrochloride) for metabolic alkalosis, and had a repeat metabolic panel 18–30 hours after treatment initiation. Exclusion criteria: Previous treatment with either drug within 24 hours of the study period or a documented metabolic disorder. Primary endpoints: Mean change in serum CO_2 and Cl concentrations and percent achieving metabolic alkalosis correction (serum CO_2 < 30 mmol/L and Cl^- >96 mmol/L). A subgroup analysis was conducted on patients who received concomitant therapy with acetazolamide and arginine.

RESULTS: Forty-four patients met inclusion criteria; nine patients received both agents concurrently and were evaluated as a subgroup. Treatment success was higher in the acetazolamide group (37% vs 6%, p=0.047). The acetazolamide and arginine groups had a similar correction of serum Cl^- concentration (63% vs 31%, p=0.092) with the acetazolamide group experiencing a higher rate of serum CO_2 correction (42% vs 6%, p=0.002). Both groups had a similar increase in mean serum Cl^- (5.7± 5.3 vs 5.1± 5.1 mmol/L, p=0.76). Mean serum CO_2 (5.6±5.2 vs 3.7±5.7, mmol/L, p=0.30) decreased similarily. In the subgroup analysis, treatment success was equivalent between acetazolamide monotherapy and concomitant therapy (37% vs 44%, p=1.0). Arginine monotherapy was less successful than concomitant therapy (6% vs 44%, p=0.040).

CONCLUSION: A course of acetazolamide or arginine hydrochloride appears to be safe and effective options for resolution of metabolic alkalosis in pediatric patients.

Pharmacoeconomics/Outcomes

213E. Evaluation of the hospital resource utilization associated with tolvaptan usage among heart failure patients with hyponatremia from the Everest trial. *Joseph Dasta, M.S., R.Ph.*[1], Jun Chiong, M.D., M.P.H.[2], Sonnie Kim, Pharm.D.[3], Jay Lin, Ph.D.[4]; (1)College of Pharmacy, The Ohio State University, Columbus, OH; (2)Advanced Heart Failure Program, Loma Linda University, Loma Linda, CA; (3)Otsuka America Pharmaceutical, Inc., Princeton, NJ; (4)Novosys Health, Flemington, NJ

PURPOSE: Tolvaptan is an orally administered selective vasopressin V2-receptor antagonist for hyponatremia treatment. The Efficacy of Vasopressin Antagonism in Heart Failure Outcome Study with Tolvaptan (EVEREST) trial showed that tolvaptan, combined with standard therapy, improved many heart failure signs and symptoms without serious adverse events. This study evaluated the hospital resource utilization associated with tolvaptan usage among heart failure (HF) patients with hyponatremia based on the EVEREST trial.

METHODS: A cost offset model was constructed to evaluate the impact of tolvaptan on hospital resource utilization among HF patients. The Healthcare Cost and Utilization Project (HCUP) 2008 Nationwide Inpatient Sample (NIS) database was used to estimate hospitalization length of stay (LOS) and hospital cost, for HF-associated diagnosis related group hospitalizations (DRG) of adult patients (age ≥18 years). EVEREST trial data for patients with hyponatremia were used to estimate the reduction of LOS associated with tolvaptan vs. placebo.

RESULTS: Among EVEREST trial HF patients with hyponatremia (<135 mEq/L), tolvaptan patients had a shorter hospitalization LOS than placebo patients (9.72 vs. 11.44 days, respectively), with a relative LOS reduction of 15%. 933,189 HF-associated DRG hospitalizations were identified from the HCUP NIS database. The mean LOS was 4.8 days with mean total hospital costs of $7,545, and mean daily hospital costs of $1,562. Using an inpatient tolvaptan treatment duration of 3 days with a daily wholesale acquisition cost of $250, the cost offset model estimated a LOS reduction among US HF hospitalizations of 0.73 days with a hospital cost reduction averaging $1,134 per HF admission. The cost neutral breakeven mean duration of tolvaptan inpatient therapy is 4.54 days.

CONCLUSION: Based on the EVEREST trial, tolvaptan is associated with a shorter hospitalization LOS than placebo among hyponatremic HF patients, resulting in an estimated mean hospital cost reduction of $1,134 per admission in the US.

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214. The impact of possible undiagnosed heavy menstrual bleeding (HMB) on presenteeism and activities outside of work. *Mark McCoy, Pharm.D., MBA*[1], Nathalie Horowicz-Mehler, M.S., M.P.H.[2], Amy W. Law, Pharm.D., MS[1]; (1)Bayer HealthCare Pharmaceuticals, Wayne, NJ; (2)Quintiles, Hawthorne, NY

PURPOSE: The study measured the impact of possible undiagnosed heavy menstrual bleeding on presenteeism and regular activities.

METHODS: A sample of 122,525 US women ages 18–54 from an online patient community were invited to complete a survey about their menstrual bleeding. A subset of women with possible undiagnosed or no HMB completed an additional questionnaire on the number of work hours missed due to menstrual bleeding (i.e., absenteeism) and the impact of menstrual bleeding on productivity while working (i.e., presenteeism) or regular activities outside of work from the modified Work Productivity and Activity Impairment (mWPAI) questionnaire. Responses to the impact questions were measured with Likert scales ranging from 0 to 10. Chi-square and t-test were used to determine statistical significance.

RESULTS: 2,062 (1.7%) women responded to the survey, of which 251 women (163 possible undiagnosed HMB, 88 no HMB) who completed the mWPAI questionnaire. Compared to women with no HMB, the possible undiagnosed HMB group reported a significantly greater impairment in regular activities (55% vs. 29%, p<0.0001) and presenteeism (45% vs. 21%, p<0.0001) during their menstrual periods. No significant difference was found for absenteeism.

CONCLUSION: In this limited sample, women with possible undiagnosed HMB exhibited higher presenteeism and greater impairment in non-work activities than women with no HMB. Further research is needed to validate these results in a broader population and quantify the indirect costs associated with these effects.

mWPAI Results

Measure	"no HMB" Mean ± SD	"Undiagnosed HMB" Mean ± SD	Difference in Impairment
Work Hours Missed	1.8 ± 5.9 (n=60)	3.4 ± 6.0 (n=95)	1.6[1] 16%
Productivity Impairment at Work (Presenteeism)	2.1 ± 2.4 (n=60)	4.5 ± 2.7 (n=95)	2.4[2] 24%
Actvity Impairment	2.9 ± 2.7 (n=88)	5.5 ± 2.5 (n=163)	2.6[2] 26%

[1]p=0.09; [2]p<0.0001

215. Title: West Michigan Glycemic Collaborative (WMGC): Improving inpatient glycemic control and transition of care through interdisciplinary, inter-institutional collaboration. Jodie L. Elder, Pharm.D., BCPS[1], *Larry Custer, R.Ph.*[2], Mary Wilson, NP, CDE[3], Robert Rood, M.D.[3], Adam Wolfe, D.O.[2]; (1)Ferris State University College of Pharmacy, Grand Rapids, MI; (2)Metro Health Hospital, Wyoming, MI; (3)St. Mary's Health System, Grand Rapids, MI

PURPOSE: Although there are some interactions between health systems in the state of Michigan, there has been no formal, independent forum for collaboration and the development of joint patient care initiatives. In this report, we describe the implementation of diabetes collaborative between 3 competing hospitals in West Michigan. The collaborative aspires to systematically improve member hospitals patient outcomes and work toward consensual agreement as they focus on aspects of care having the greatest collective impact.

METHODS: The West Michigan Glycemic Collaborative was established in 2008 and its members include Metro Health Hospital, Saint Mary's Health Care. Representatives from each of the hospital's medical and clinical staff including pharmacists, nurses and physicians meet monthly to discuss inpatient diabetes care initiatives and transition of care. Joint leadership was established, with one the tri-chairs being a pharmacist. Glucometrics shared between institutions included established measurements of hypoglycemia and hyperglycemia.

RESULTS: Since the formation of the collaborative in 2008, the three institutions eliminated sliding scale insulin and implemented basal-bolus protocols. A letter describing the purpose of the collaborative was developed and sent to the physician community to improve physician acceptance of protocols. Perio-operative glycemic management protocols have been developed and implemented, resulting in reductions in hospital acquired infection and length of stay. Improvements in outpatient and in-patient provider and patient education care have been seen at all three institutions.

CONCLUSION: The West Michigan Glycemic collaborative has demonstrated benefits that include: increased patient safety, implementation of evidence-based guidelines and decreases in deviation from protocols. Each hospital and respective medical staff have become better positioned to improve individual patient care as well as each hospital's individual and collective result.

Pharmacoepidemiology

216. Prevalence of the co-prescription of interacting drug combinations in cancer patients in Singapore. *Alexandre Chan, Pharm.D., M.P.H., BCPS, BCOP*, Yu Ko, Ph.D., Judith Kurniawan, M.D.; National University of Singapore, Department of Pharmacy, Singapore, Singapore

PURPOSE: This study aims to examine the prevalence of the potentially interacting drug combinations involving oral anticancer agents (OAAs) that were prescribed and dispensed from two national cancer centers in Singapore.

METHODS: Sixty clinically important and potentially interacting drug combinations involving an OAA and a non-anticancer drug were identified through predetermined criteria. The prevalence of the co-prescription of these drug combinations between January 1st, 2007 and December 31st, 2009 was assessed by a retrospective analysis of the pharmacy electronic records databases of National Cancer Center

and National University Hospital, where 85% of all cancer patients in Singapore are treated. Unique drug identifier numbers were used to query the electronic database to identify patients who were prescribed at least one of the OAAs under examination. A co-prescription was defined as either the concurrent prescription of the drug pairs (i.e., on the same prescription) or one drug whose drug supply overlapped with another drug with which it may have interacted (i.e., on separate prescriptions).
RESULTS: A total of 43,680 prescriptions of OAAs for 8,150 patients were reviewed and 637 prescriptions involving a co-prescription (1.46%) were detected in 213 patients (26 per 1,000 persons). Approximately half (47.7%) of the interacting combinations were prescribed on the same prescription. The most commonly dispensed interacting cytotoxic drug combination was methotrexate with amoxicillin (84 per 1,000 persons), while the most commonly dispensed interacting targeted therapy combination was imatinib and simvastatin (92 per 1,000 persons).
CONCLUSION: The findings of this study shed light on the existence and extent of DDI prescribing in oncology practice in Singapore. Future research is needed to determine how often these interactions actually caused clinically important adverse effects and their economic impact.

217. Can the risk of ovarian cancer be reduced by the use of aspirin, mon-aspirin nonsteroidal anti-inflammatory drugs, or acetaminophen? A large population-based case-control study. *Wei-Hsuan Lo-Ciganic, M.S.*[1], Roberta B. Ness, M.D., M.P.H.[2], Clareann H. Bunker, Ph.D.[1], Janice Zgibor, R.Ph., Ph.D[1]; (1)Department of Epidemiology, GSPH, University of Pittsburgh, Pittsburgh, PA; (2)The University of Texas School of Public Health, Houston, TX
PURPOSE: To evaluate the association between the use of aspirin, non-aspirin nonsteroidal anti-inflammatory drugs (NA-NSAIDs) and acetaminophen, and the risk of ovarian cancer (OVCA).
METHODS: In a population-based, case-control study in Western Pennsylvania, Northern Ohio, and South Western New York State, 902 women with incident epithelial OVCA who were diagnosed between 02/01/2003–11/31/2008 and 1,802 matched controls were included. Regular use (≥ 2 tablets/week for ≥ 6 months) of aspirin, NA-NSAIDs, and acetaminophen before the reference date (9 months before interview date) was assessed by in-person interview. Dose-response was evaluated by converting dosages into standardized daily doses (SDD) (low: <0.5 SDD, moderate: 0.5–1 SDD, high: >1 SDD). Duration of use was assigned into three categories: continuous, current, and past users. Logistic regression was used to calculate adjusted odds ratio (OR) and 95% confidence interval (CI).
RESULTS: Overall, 489 cases and 1,015 controls reported having used one or more of aspirin, NA-NSAIDs, or acetaminophen on a regular basis. The OR for aspirin use was 0.81 (95% CI: 0.63, 1.03, p=0.09). Decreased risks were significant among those who used aspirin continuously (OR: 0.71, 95% CI: 0.54, 0.94, p=0.02), at low-SDD (OR: 0.72, 95% CI: 0.53, 0.97, p=0.03), for prevention of cardiovascular disease (0.72, 95% CI: 0.57, 0.97, p=0.01), used aspirin recently, or used cycloxygenase-2 (COX-2) inhibitors (OR: 0.60, 95% CI: 0.39, 0.94, p=0.03). Non-significant results were found among non-selective NA-NSAIDs and acetaminophen users.
CONCLUSION: Risk reductions of OVCA were observed when women used aspirin or COX-2 inhibitors. The use of other analgesics is unlikely to be related to the risk of ovarian cancer. Given the inconsistent results and inherent study limitations and biases from observational studies, it is too early to suggest that aspirin or COX-2 inhibitor use could prevent OVCA as a public-health recommendation.

Pharmacogenomics/Pharmacogenetics

218. Risks, rewards and the double-edged sword: pharmacogenetic testing and research in the Alaska Native/American Indian community. Jennifer Shaw, M.A.[1], *Renee Robinson, Pharm.D., M.P.H.*[1], Helene Starks, Ph.D., M.P.H.[2], Wylie Burke, M.D., Ph.D.[2], Denise Dillard, Ph.D.[1]; (1)Southcentral Foundation, Anchorage, AK; (2)University of Washington, Seattle, WA
PURPOSE: Pharmacogenetics is the study of how variations in the human genome affect medication response. Pharmacogenetic testing (PGX) can increase safety and efficacy of drug treatment. However, little is known about how Alaska Native and American Indian people (AN/AI) view PGX and pharmacogenetic research (PGR). This study explored the views of the AN/AI community on PGX and PGR to understand how these views could inform future research and clinical practice.
METHODS: We conducted four focus groups with AN/AI adults to elicit views about using PGX in several clinical scenarios and views on participating in PGR. Focus groups were stratified by age (<40 years of age and ≥ 40 years of age), transcribed, coded and analyzed using thematic analysis.
RESULTS: Three key themes emerged from the data: risks of PGX, rewards of PGX and the "double-edged sword" of balancing risks and rewards for optimal benefit to the individual, community and healthcare institutions. Most participants support use of PGX and PGR if contingencies are met, such as: protection of participant confidentiality, respectful communication, appropriate consent procedures and inclusion of AN/AI people in the development and implementation of research.
CONCLUSIONS: AN/AI adults in our sample mostly support using PGX and pharmacogenetic research in their communities for the potential rewards of optimized pharmacotherapy, reduced side effects, improved health outcomes, medical advancement and community development. These perceived rewards are balanced by contingencies that protections be in place to mitigate potential risks. Concerns are grounded in awareness of the potential misuse of data and historical distrust of non-community-based, non-participatory research methods. Understanding perceived risks and rewards of PGX and PGR is essential to the effective application and utilization of these technologies in AN/AI communities.

219. Association of the γ-glutamyl carboxylase (CAA)16/17 repeat polymorphism with higher warfarin dose requirements African Americans. *Larisa H. Cavallari, Pharm.D.*[1], Minoli Perera, Pharm.D., Ph.D.[2], Gelson Taube, Pharm.D.[1], Shitalben R. Patel, M.S.[1], Keston Aquino-Michaels, B.A.[2], Marlos A.G. Viana, Ph.D.[1], Nancy L. Shapiro, Pharm.D.[1], Edith A. Nutescu, Pharm.D.[1]; (1)University of Illinois at Chicago, Chicago, IL; (2)University of Chicago, Chicago, IL
PURPOSE: Little is known about genetic variants contributing to higher than usual warfarin dose requirements, particularly for African Americans. We assessed the hypothesis that the gamma-glutamyl carboxylase (*GGCX*) genotype contributes to warfarin dose requirements >7.5 mg/day in African Americans.
METHODS: A total of 338 African Americans on a stable dose of warfarin were genotyped for the *GGCX* rs10654848 (CAA)n; *VKORC1* c.-1639G>A; and *CYP2C9**2, *3, *5, *8, and *11 genotypes, and 211 of these patients were genotyped for *GGCX* rs12714145 (G>A) and rs699664 (p.R325Q). The *GGCX* variants were tested for their association with dose requirements >7.5 mg/day alone and in the context of other variables known to influence dose requirements.
RESULTS: The *GGCX* rs10654848 (CAA) 16 or 17 repeat occurred in 5% of African Americans and was overrepresented among patients requiring >7.5mg/day (n=86) versus those who required lower doses (12% vs 3%, p=0.003; OR 4.0, 95% CI, 1.5–10.5). The *GGCX* rs10654848 genotype remained associated with dose requirements >7.5 mg/day on regression analysis including age, body size, and *VKORC1* genotype (p=0.008). Neither the rs12714145 nor rs699664 variant was associated with warfarin dose.
CONCLUSION: The *GGCX* rs10654848 (CAA) 16 or 17 repeat is predictive of warfarin dose requirements >7.5 mg/day in African Americans. This variant may be useful in identifying warfarin candidates who will require higher than usual warfarin doses.

220. Endothelial nitric oxide synthase polymorphisms and endothelial function in coronary artery disease patients. *Savanna Steele, Pharm.D.*[1], Bryant Tran, Pharm.D., M.S.[1], Kyle J. Ellis, Pharm.D.[1], Almasa Bass, Pharm.D.[1], Robert N. Schuck, Pharm.D.[1], Melissa Caughey, RVT., M.P.H.[2], George A. Stouffer, M.D.[2], Alan L. Hinderliter, M.D.[2], Craig R. Lee, Pharm.D., Ph.D.[1]; (1)Eshelman School of Pharmacy, University of North Carolina, Chapel Hill, NC; (2)Division of Cardiology; School of Medicine, University of North

Carolina, Chapel Hill, NC
PURPOSE: Impaired nitric oxide-mediated vasodilation (endothelial dysfunction) is predictive of prognosis in coronary artery disease (CAD) patients. Since identifying individuals predisposed to endothelial dysfunction could help guide therapy, we sought to characterize the relationship between genetic variants in endothelial nitric oxide synthase (eNOS:*-786T>C*, Glu298Asp) and digital peripheral arterial tonometry (PAT), an emerging method to assess endothelial function.
METHODS: Using a cross-sectional design, we studied 110 patients with established CAD (≥50% stenosis in ≥1 major coronary artery) 59±34 () days following cardiac catheterization after fasting overnight and withholding morning medications. After induction of reactive hyperemia by suprasystolic forearm cuff occlusion for 5 minutes, digital PAT was measured using the EndoPAT2000 device and expressed relative to baseline (PAT-ratio). Associations between PAT-ratio (log-transformed) and genotype were evaluated by regression.
RESULTS: Subjects were 60±9 years old, 69% male, and 19% African-American (AA); 57%, 82% and 93% were receiving ACE inhibitors, beta-blockers and statins, respectively. Racial differences in minor allele frequency were observed for *-786T>C* (AA: 0.125; non-AA: 0.328) and Glu298Asp (AA: 0.075; non-AA: 0.339). PAT-ratio was lower in variant *-786C* allele compared to wild-type, respectively [0.29±0.13 (n=55) vs. 0.34±0.13 (n=55), p=0.051; non-AA only: 0.29±0.13 (n=50) vs. 0.35±0.13 (n=40), p=0.037]. No association with Glu298Asp was observed (All: p=0.334; non-AA only: p=0.301). After stratifying by race, we assessed the additive contribution of each polymorphism by comparing PAT-ratio in non-AA's carrying 0 [wild-type for both; 0.33±0.11 (n=23)], 1 [0.36±0.15 (n=29)], 2 [0.28±0.12 (n=26)], 3 [0.28±0.13 (n=9)] and 4 [homozygous for both; 0.23±0.043 (n=3)] variant alleles (p for trend=0.076). Non-AA subjects carrying 2–4 variant alleles had significantly lower PAT-ratio compared to those carrying 0-1 [0.27±0.12 vs. 0.35±0.13, respectively; p=0.005].
CONCLUSION: The eNOS *-786T>C* and Glu298Asp polymorphisms appear to additively impair endothelial function in CAD patients. Validation of associations between eNOS genotype, digital PAT-ratio and outcomes remains necessary.

Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

221E. Population probability of target attainment of Telavancin at different levels of renal function against methicillin resistant *Staphylococcus aureus* in US medical centers. *Andras Farkas, Pharm.D.*, Catherine Hoffman, MT, ASCP; Nyack Hospital, Nyack, NY
PURPOSE: Telavancin (TLV) is a first in its class bactericidal lipoglycopeptide antibiotic with excellent susceptibility profile against *Staphylococcus aureus*. The aim of our study was to describe the Cumulative Fraction of Response (CFR) achieved by TLV package insert (PI) recommendations and alternative dosing regimens against a population of MRSA isolates in US Medical Centers.
METHODS: Pharmacokinetic data in patients with renal dysfunction (ECCMID 2004, Poster #1028, n=29) and MIC data of 2500 MRSA isolates for TLV (AAC 2010, June) was used in this analysis. Probability of Target Attainment (PTA) at different levels of renal function was established with Monte Carlo Simulation (MCS, n=5000) for MIC ranges of 0.125 to 2 mg/L. Then, CFR was calculated targeting a $fAUC/MIC$ ratio of at least 50 for PI recommendations. Additionally, lower doses of 5 mg/kg and 7.5 mg/kg were evaluated at 24 and 48 hours intervals to assess their population probability of target attainment for recently documented MRSA MIC distribution.
RESULTS: PI recommended TLV dosing regimens are expected to achieve the CFR of > 95% at all renal function categories from 20–120 ml/min. The MCS also showed that CFRs similar to that achieved by PI recommendations can be reached when using lower daily doses of TLV: 7.5 mg/kg q48h for creatinine clearance of 20–40 ml/min, 5 mg/kg q24h for 41–80 ml/min, and 7.5 mg/kg q24h for 81–120 ml/min.
CONCLUSION: We conclude that for the treatment of MRSA infections to achieve the bactericidal effect of 3 $\log_{10}$ reduction in CFU, the approved dosing regimens provide excellent coverage. Moreover, current activity of TLV against MRSA in the US would allow the use of lower daily doses without compromising the chance of clinical success
Presented at 51st Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL.

222. Drug-drug interaction of Eslicarbazepine Acetate with antiepileptic drugs. *Gary Maier, Ph.D.*[1], Mark Versavel, M.D., Ph.D., MBA[1], Jacqueline Zummo, M.S., M.P.H., MBA[1], David Blum, M.D.[1], Jahnavi Kharidia, Ph.D.[1], Patricio Soares-da-Silva, M.D., Ph.D.[2]; (1)Sunovion Pharmaceuticals, Inc., Marlborough, MA; (2)BIAL - Portela & Ca, SA, Mamede do Coronado, Portugal
PURPOSE: Eslicarbazepine acetate (ESL) is a novel antiepileptic drug (AED) administered once-daily (QD) in clinical development in the U.S. To evaluate Drug-Drug Interactions (DDIs) of ESL with concurrent AEDs.
METHODS: DDIs of AEDs were evaluated in Phase I studies of ESL 1200 mg QD coadministered with lamotrigine (150 mg), topiramate (200 mg), and phenytoin (300 mg). In addition, DDIs of coadministered ESL 1200 mg QD with carbamazepine (1200 mg), phenobarbital (150 mg), levetiracetam (750–4000 mg), gabapentin (800–3600 mg), or valproate (250–2000 mg) were evaluated by performing population pharmacokinetic analyses on data obtained from two Phase III trials in adults with partial onset-seizures.
RESULTS: In Phase I studies, coadministration of ESL decreased the exposure of lamotrigine (14%) and topiramate (18%); and increased the exposure of phenytoin (12–35%). In the same subjects, lamotrigine, topiramate and phenytoin decreased the exposure of ESL by 4%, 7%, and 33%, respectively. In the population pharmacokinetic analysis, coadministration of ESL resulted in a decrease in exposure of levetiracetam (14%) and carbamazepine (4–11%); and the exposure of ESL was decreased with carbamazepine (10–24%) and phenobarbital (21%); and increased with valproate (9–29%). No clinically relevant change in exposure was seen in the remaining AED studied.
CONCLUSION: In these studies, no clinically relevant DDIs were observed when eslicarbazepine acetate was coadministered with levetiracetam, gabapentin, lamotrigine, topiramate, or valproate. Based on these results, no dose adjustment of any of these AEDs or ESL is anticipated. In contrast, coadministration of carbamazepine, phenytoin and phenobarbital led to potentially clinically meaningful reductions in ESL exposure. Therefore the dose of ESL may need to be increased and should be guided by both pharmacokinetic and clinical response considerations. Alterations in exposure to phenytoin suggest that monitoring of phenytoin plasma concentrations may be warranted.

223. Exposure-response analysis of Eslicarbazepine Acetate adjunctive treatment of patients with partial-onset seizures. *Jahnavi Kharidia, Ph.D.*[1], Julie Passarell, M.A.[2], Gary Maier, Ph.D.[1], Jacqueline Zummo, M.S., M.P.H., MBA[1], Elizabeth Ludwig, Pharm.D.[2], Ted Grasela, Pharm.D., Ph.D.[2], Jill Fiedler-Kelly, M.S.[2]; (1)Sunovion Pharmaceuticals, Inc., Marlborough, MA; (2)Cognigen Corporation, Buffalo, NY
PURPOSE: Eslicarbazepine acetate(ESL) is a novel antiepileptic drug (AED) under clinical development in the U.S. for adjunctive therapy in adults with partial-onset seizures. Exposure-response (ER) models were developed to quantify the relationships between exposure to the active metabolite (eslicarbazepine) and seizure frequency (SF), as well as the probability of response (PR).
METHODS: Data from 628 patients providing 1253 weekly SFs were pooled from two Phase 3 trials (8-week baseline, 2-week titration, 12-week maintenance) of adjunct once-daily ESL 400, 800, 1200 mg or placebo. SF was described as the sum of baseline, placebo, and drug effects expressed as a saturable E_{max} function of average steady-state concentration ($C_{av\text{-}ss}$). Using logistic regression, PR (> 50% reduction in standardized SF/28 days from baseline to maintenance) was described as the sum of a constant placebo effect and a drug effect expressed as a linear function of $C_{av\text{-}ss}$. Drug exposures were estimated using a previously validated population PK model.
RESULTS: Estimated SF was 8.7 seizures/28 days in the placebo group, and 7.3, 6.7, and 6.6 seizures/28 days in the ESL 400, 800, and 1200 mg groups, respectively. The maximal drug effect was predicted to be related to the baseline SF; a higher maximum drug effect is

expected with higher baseline SF. Half of the maximum effect is predicted with eslicarbazepine $C_{av\text{-}ss}$ of 1970 ng/mL (less than the median value associated with the lowest dose of 400 mg). Estimated PR was 0.19 for patients receiving placebo and 0.28, 0.33, and 0.38 for patients with the median values of $C_{av\text{-}ss}$ associated with the ESL 400, 800, and 1200 mg dose groups, respectively.
CONCLUSION: Overall, these ER models support an ESL maintenance dose of 800-1200 mg QD. Based on this analysis and the shallow ER relationship, and the safety profile of ESL observed in its clinical development program to date, plasma concentration monitoring is not required to guide therapeutic dosing.

224. Population pharmacokinetics of Eslicarbazepine Acetate in patients with partial-onset seizures. *Jahnavi Kharidia, Ph.D.*[1], Mark Versavel, M.D., Ph.D.[1], Qiang Lu, Ph.D.[2], Jacqueline Zummo, M.S., M.P.H., MBA[1], Elizabeth Ludwig, Pharm.D.[2], Ted Grasela, Pharm.D., Ph.D.[2], Jill Fiedler-Kelly, M.S.[2], Gary Maier, Ph.D.[1]; (1)Sunovion Pharmaceuticals, Inc., Marlborough, MA; (2)Cognigen Corporation, Buffalo, NY
PURPOSE: Eslicarbazepine acetate (ESL) is a novel antiepileptic drug (AED) under clinical development in the U.S. for adjunctive therapy in adults with partial-onset seizures. A population pharmacokinetic (PK) model for eslicarbazepine (the active metabolite) was developed and the influence of selected covariates was investigated.
METHODS: Full profile and sparse data from 517 subjects in two Phase 3 studies (1484 concentrations) at once-daily doses of ESL 400–1200 mg were available. A 1-compartment model with first-order absorption and elimination was developed to describe eslicarbazepine PK.
RESULTS: The apparent oral clearance (CL/F) and volume of distribution (V/F) were modeled as allometric functions of weight: $CL/F \times wt^{0.75}$ and $V/F \times wt^{1}$. Estimated basal CL/F was 3.66 L/h, with an increase to 4.75 L/h with concurrent phenobarbital or phenobarbital-like metabolic inducers (phenytoin, primidone). CL/F was increased by 11.2–33.7% in patients administered concurrent carbamazepine (at daily dose of 400–1200 mg) compared to patients only receiving ESL. In contrast, CL/F was decreased by 6.9–19.3% in patients administered concurrent sodium valproate [for the median (49.8 µg/mL) to maximum (140 µg/mL) observed valproate concentration] compared to patients administered ESL alone. Tissue distribution of eslicarbazepine is extensive, with the typical V/F estimated to be 81.7 L. A visual predictive check indicated no apparent biases in the overall model fit.
CONCLUSION: The development of this population PK model for eslicarbazepine supported individual subject exposure estimation for the Phase 3 population PK/PD efficacy analyses.

225. Drug monitoring system in interstitial fluid: feasibility studies of valproic acid, methotrexate, gentamicin, and theophylline. Tony KL Kiang, Ph.D.[1], Urs O. Häfeli, Ph.D.[2], Boris Stoeber, Ph.D.[3], Beverly Chua, DVM[4], Morris Pudek, Ph.D.[5], *Mary H.H. Ensom, Pharm.D.*[1]; (1)Faculty of Pharmaceutical Sciences, The University of British Columbia & Child and Family Research Institute, Vancouver, BC, Canada; (2)Faculty of Pharmaceutical Sciences, The University of British Columbia, Vancouver, BC, Canada; (3)Departments of Mechanical and Electrical & Computer Engineering, The University of British Columbia, Vancouver, BC, Canada; (4)Animal Care Centre, The University of British Columbia, Vancouver, BC, Canada; (5)Vancouver General Hospital, Vancouver, BC, Canada
PURPOSE: Using an established rabbit model, this study compared drug concentration-time profiles of valproic acid, methotrexate, gentamicin, and theophylline in interstitial fluid (ISF) and serum, in order to assess the feasibility of therapeutic drug monitoring (TDM) in ISF and to design future alternative sampling methods for patients.
METHODS: An ultrafiltration probe (UF-3-12, Bioanalytical Systems Inc) for ISF collection was implanted subcutaneously between the shoulders of rabbits (n = 6/group). On day 3 post-implantation, an intravenous bolus of valproic acid (50 mg/kg) and methotrexate (15 mg/kg) or gentamicin (50 mg/kg) and theophylline (12 mg/kg) were administered into the ear vein. Serial (0 up to 24 h post-dose) ISF and serum concentrations were measured by fluorescence polarization immunoassay (valproic acid and methotrexate) and particle enhanced turbidimetric inhibition immunoassay (gentamicin and theophylline). Area-under-the curves (AUCs) were generated using noncompartmental pharmacokinetic modeling.
RESULTS: Of the 4 drugs tested, only methotrexate (mean±SD, 27.3±6.7 vs. 29.5±3.7 µmol×h/L) and gentamicin (176.4±54.2 vs. 145.7±40.7 µgxh/mL) had comparable AUCs in ISF and serum, respectively. The AUCs of valproic acid and theophylline were both lower in ISF. A reduced Cmax and increased Tmax in ISF were evident for all 4 drugs, but their concentration-time profiles were approximately proportional in the two matrices, except for gentamicin (that exhibited apparently different concentration profiles in ISF and serum, despite similar AUCs).
CONCLUSION: Our novel findings demonstrate feasibility of quantifying methotrexate levels in ISF. A limitation is the apparent measurement delay, which can be corrected with pharmacokinetic modeling. Experiments are ongoing with other drugs that warrant TDM in the rabbit model, and clinical studies examining feasibility of methotrexate ISF monitoring are being planned in pediatric patients. The ultimate goal is to eliminate the need for blood sampling for patients with fragile/"bad" veins, neonates, infants and children for whom blood sampling is difficult.

226. Drug monitoring system in interstitial fluid: a preliminary study of vancomycin and tacrolimus drug concentrations. Tony KL Kiang, Ph.D.[1], Urs O. Häfeli, Ph.D.[2], Boris Stoeber, Ph.D.[3], Beverly Chua, DVM[4], Morris Pudek, Ph.D.[5], *Mary H.H. Ensom, Pharm.D.*[1]; (1)Faculty of Pharmaceutical Sciences, The University of British Columbia & Child and Family Research Institute, Vancouver, BC, Canada; (2)Faculty of Pharmaceutical Sciences, The University of British Columbia, Vancouver, BC, Canada; (3)Departments of Mechanical and Electrical & Computer Engineering, The University of British Columbia, Vancouver, BC, Canada; (4)Animal Care Centre, The University of British Columbia, Vancouver, BC, Canada; (5)Vancouver General Hospital, Vancouver, BC, Canada
PURPOSE: Using a rabbit model and vancomycin and tacrolimus as probes, the purpose of this study was to compare drug concentration-time profiles in interstitial fluid (ISF) and blood, in order to design future alternative sampling methods for therapeutic drug monitoring in patients.
METHODS: An ultrafiltration probe (UF-3-12, Bioanalytical Systems Inc) for ISF collection was implanted subcutaneously between the shoulders of two rabbits. On day 3 post-implantation, an intravenous bolus of vancomycin (20 mg/kg) and tacrolimus (0.1 mg/kg) was administered into the ear vein. Serial (0 to 8 h post-dose) ISF and blood concentrations were measured by fluorescence polarization immunoassay (vancomycin) and liquid chromatography-mass spectrometry (tacrolimus), and area-under-the curve (AUC) generated by non-compartmental analysis. Glucose concentrations, known to equilibrate between ISF and blood, served as the positive control.
RESULTS: Glucose concentrations (ISF and blood) were superimposable, confirming the suitability of this rabbit model. Mean±SD vancomycin AUCs (µg×h/mL) in ISF (99.2±6.9) and blood (102.2±3.9) were similar, but a measurement delay was clearly apparent, as indicated by the time to maximal concentration in ISF of ~ 90 minutes. In contrast, ISF tacrolimus concentrations were undetectable, despite readily detectable levels in the blood.
CONCLUSION: Our novel findings demonstrate feasibility of quantifying vancomycin levels in ISF. A limitation is the apparent measurement delay, which can be corrected with pharmacokinetic modeling. However, physiochemical properties of a drug may limit the utility of ISF sampling, as evidenced by tacrolimus (i.e., likely trapped in the blood due to binding to proteins and red blood cells). Further studies with select drugs are ongoing in the rabbit model and planned in patients. The ultimate goal is to eliminate the need for blood sampling for patients with fragile/"bad" veins, neonates, infants and children for whom blood sampling is difficult.

227E. Bioequivalence of immediate-release oxycodone with Aversion® Technology (IRO-A), IRO-A with niacin, and a commercially available oxycodone. *Mark T. Leibowitz, M.D.*[1], Cynthia A. Zamora, M.D., FCCP[1], Albert W. Brzeczko, Ph.D.[2], Jeffrey

G. Stark, Ph.D.[3]; (1)Worldwide Clinical Trials Drug Development Solutions, Clinical Research Services, San Antonio, TX; (2)Acura Pharmaceuticals Inc., Technical Affairs, Palatine, IL; (3)Worldwide Clinical Trials Drug Development Solutions, Pharmacokinetics, Austin, TX

PURPOSE: To evaluate bioequivalence by comparing the pharmacokinetic characteristics of an immediate-release oxycodone tablet formulated with Aversion® Technology (IRO-A) (Acura Pharmaceuticals, Inc.) with those of branded immediate-release (IRO) (®, Pharmaceuticals, Inc.) and IRO-A with niacin, a similar product containing niacin as an aversive agent.

METHODS: A phase 1 single-dose, open-label, randomized, 3-period, 3-treatment crossover study involving 40 healthy adult subjects who received single 15-mg doses of IRO-A, IRO (the reference listed drug), or IRO-A with niacin after fasting overnight. Subjects were male (n=26) or female (n=14) and aged 18–55 years with a body mass index 18–30 kg/m^2 and a minimum weight of 110 lb. was administered to diminish opioid effects. Plasma samples were analyzed using liquid chromatography with tandem mass spectrometry.

RESULTS:

Parameter	IRO-A	IRO	IRO-A with niacin
T_{max}, h, mean (SD)	1.18 (0.57)	0.98 (0.40)	1.46 (0.44)
C_{max}, ng/mL, mean (SD)	34.5 (7.83)	36.5 (8.78)	32.2 (6.02)
AUC_{∞}, h•ng/mL, mean (SD)	168.9 (37.53)	163.4 (42.08)	167.0 (37.23)

For the log-transformed exposure parameters Adverse events were mild to moderate in intensity and typical of opioid therapy. Flushing, which occurred in the IRO-A with niacin group, is a

CONCLUSIONS: IRO-A was bioequivalent to IRO, as well as IRO-A with niacin. Because of Aversion Technology, IRO-A provides an alternative to conventional oxycodone therapy that may reduce potential intranasal and intravenous abuse.

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228. ADME properties of [^{14}C]-ACU-4429 following a single oral dose in healthy volunteers. *Suliman Al-Fayoumi, Ph.D., MBA*[1], John W. Chandler, M.D.[1], Suresh Mallikaarjun, Ph.D.[2], Shiva Patil, Ph.D.[2], Ryo Kubota, M.D., Ph.D.[1]; (1)Acucela Inc., Seattle, WA; (2)Otsuka Pharmaceutical Development & Commercialization, Inc., Rockville, MD

PURPOSE: ACU-4429, a visual cycle modulator, is an oral drug in early stage clinical development for the treatment of dry age-related macular degeneration (AMD). ACU-4429 has been shown to inhibit isomerase (RPE65) activity in pre-clinical studies and is designed to decrease levels of toxic by-products linked to the progression of dry AMD.

METHODS: A single 40 mg oral dose of [^{14}C]-ACU-4429 was administered to 8 fasted healthy male subjects. Pharmacokinetic parameters for [^{14}C]-ACU-4429 and its metabolites were assayed in plasma, urine, and feces. Samples at selected intervals/time points were analyzed for total radioactivity via accelerator mass spectrometry (AMS). Plasma concentrations of ACU-4429 and the metabolites were determined using HPLC-AMS.

RESULTS: Following administration, ACU-4429 was readily absorbed and eliminated from plasma (t_{max} 6.0 hours, $t_{1/2}$ 6.1 hours). ACU-4429 and total radioactivity were eliminated from plasma at a similar rate. $AUC_{0\text{-}t}$, $AUC_{0\text{-}inf}$, and C_{max} values were 57-, 56-, and 62-fold higher, respectively, for total radioactivity in plasma than for ACU-4429 in plasma, suggesting that the majority of circulating total radioactivity was associated with ACU-4429 metabolites. Mean C_{max} and $AUC_{0\text{-}t}$ for total radioactivity in whole blood were 76% and 74% of those for total radioactivity in plasma, respectively, indicating the majority of the total radioactivity is not preferentially bound to RBCs. Recovery of total radioactivity in urine and feces was approximately 95% by 168 hours postdose (91.3% in urine, 4.03% in feces). Elimination was primarily via renal excretion. Mean recovery of ACU-4429 in urine was 0.229% of the dose administered; mean renal clearance of ACU-4429 was 1.23 L/hr.

CONCLUSION: Three major circulating metabolites of the parent compound ACU-4429 were identified, accounting for approximately 29%, 11%, and 11% of the total AUC of circulating radioactivity following administration of [^{14}C]-ACU-4429. Only mild to moderate visual AEs were observed and all resolved by the end of the study.

229. Lurasidone pharmacokinetics: assessment of the potential for drug-drug interactions. *Antony Loebel, M.D.*[1], Sheldon Preskorn, M.D.[2], Yu-Yuan Chiu, Ph.D.[1], Donald Sarubbi, Ph.D.[2], Masaaki Ogasa, M.S.[2], Josephine Cucchiaro, Ph.D.[1]; (1)Sunovion Pharmaceuticals, Inc., Ft. Lee, NJ; (2)Clinical Research Institute, Wichita, KS

PURPOSE: The aim of the studies summarized here was to evaluate the potential risk for drug-drug interactions with lurasidone, a new psychotropic agent approved for the treatment of schizophrenia.

METHODS: Seven studies were conducted in subjects to evaluate potential pharmacokinetic (PK) interactions with single or multiple-dose lurasidone. The PK of lurasidone was evaluated when co-administered with potent or moderate CYP3A4 inhibitors (ketoconazole or diltiazem); with the CYP3A4 inducer rifampin; and with lithium. Plasma concentration changes in midazolam, a CYP3A4 substrate and in an oral contraceptive (Ortho Tri-Cyclen) were evaluated in the presence of lurasidone. The effect of lurasidone on digoxin, a P-gp substrate was also investigated.

RESULTS: Concomitant administration of lurasidone and ketoconazole, a potent CYP3A4 inhibitor, resulted in increased lurasidone $AUC_{0\text{–}72}$ (9.3-fold) and C_{max} (6.8-fold). Coadministration of lurasidone and diltiazem, a moderate CYP3A4 inhibitor, resulted in increased lurasidone AUC (2-fold) and C_{max} (2.1-fold). Concomitant administration of rifampin, a strong CYP3A4 inducer, resulted in decreased AUC (19%) and C_{max} (15%). Lurasidone at steady state exhibited weak CYP3A4 inhibition on the CYP3A4 substrate midazolam, while single-dose lurasidone exhibited no meaningful CYP3A4 inhibition. No PK interaction was observed after concomitant administration of lithium 600 mg BID and steady state dosing of lurasidone compared to lurasidone alone. Concomitant administration of lurasidone had no effect on digoxin (a P-gp substrate) suggesting that lurasidone is not associated with P-gp inhibition. Concomitant administration of lurasidone and Ortho Tri-Cyclen® resulted in equivalent $AUC_{0\text{–}\tau}$ and C_{max} of ethinyl estradiol and norelgestromin relative to Ortho Tri-Cyclen® administered alone.

CONCLUSION: Lurasidone exposure significantly increased when co-administered with the potent inhibitor of cytochrome P450 3A4, ketoconazole and decreased when co-administrated with the strong CYP3A4 inducer, rifampin. Conversely, lurasidone did not inhibit either CYP3A4 or P-gp to a clinically significant degree. No interaction was observed between lithium and lurasidone.

230. Compatibility of adenosine with iodinated contrast agents. Sulayma Naser Agha, B.S., *Nicholas B. Norgard, Pharm.D.*, Edward M Bednarczyk, Pharm.D.; University at Buffalo- School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY

PURPOSE: Little data exist on the compatibility of iodinated contrast agents with other IV materials. Manufacturers currently do not recommend mixing any drugs with intravascular contrast agents, partly due to the lack of compatibility data. While concurrent administration can often be avoided, at times it may be desirable or critical. This study evaluated the physical compatibility of adenosine with two intravascular contrast agents, iodixanol and iohexol.

METHODS: Adenosine was diluted in both iodixanol and iohexol in five ratios for compatibility testing (0 mg adenosine in 10 ml contrast, 3 mg adenosine in 9 ml contrast, 9 mg adenosine in 5 ml contrast, 15 mg adenosine in 7 ml contrast, 24 mg adenosine in 2 ml contrast). Visual signs of incompatibility, turbidity (measured as spectrophotometric absorbance), and pH were evaluated initially and at 10 minutes, 30 minutes and 1, 2, 4, 6, 24, and 48 hours, and 1 week after preparation. All measures were done at room temperature, with 6 fold replication.

RESULTS: No visual evidence of precipitation or color change was observed. The pH did not differ between contrast alone and mixtures with increasing adenosine concentrations ($p = 0.45$). No significant changes in pH were observed at any time point at any adenosine concentration. The addition of increasing amounts of adenosine did not result in significant changes in spectrophotometric absorbance ($p = 0.06$). Spectrophotometric absorbance was not significantly changed

at any time point at any adenosine concentration.
CONCLUSION: No evidence of incompatibility was observed when adenosine was mixed either iodixanol or iohexol for up to one week.

231. Relative bioavailability of oral fosphenytoin sodium injection in healthy volunteers. *Kevin Kaucher, Pharm.D.*[1], Curtis E. Haas, Pharm.D.[2], Nicole M. Acquisto, Pharm.D.[2], Jeff Huntress, Pharm.D.[3], David C. Kaufman, M.D.[4]; (1)Denver Health Medical Center, Denver, CO; (2)University of Rochester Medical Center, Rochester, NY; (3)University of Rochester Medical Center - Highland Hospital, Rochester, NY; (4)University of Rochester, School of Medicine and Dentistry, Rochester, NY
PURPOSE: Phenytoin (PHT) sodium injection has been given enterally to manage the PHT-tube feeding interaction. Fosphenytoin (FPHT) sodium injection is more commonly available in hospitals today. The oral bioavailability of FPHT sodium in humans is unknown. The primary objective of this study was to describe the pharmacokinetics of oral FPHT sodium and determine the relative oral bioavailability (F_{PO}) of FPHT sodium injection compared to PHT sodium injection in healthy volunteers.
METHODS: Open-label, randomized, single-dose, two-period, two-sequence crossover study with a minimum 7 day washout involving 10 healthy volunteers. Both drugs were administered orally at a dose equivalent to 400 mg of PHT acid. Blood samples were collected at baseline, 0.5, 1, 2, 4, 6, 12, 24, 48, and 72 hours after dosing. Serum PHT concentrations were determined by fluorescence polarization immunoassay. For preliminary analysis, $AUC_{0\text{-}72h}$ and $AUC_{0\text{-}Inf}$ were determined by trapezoidal rule and extrapolation of the final serum concentration. C_{max} and T_{max} were determined from the observed data. F_{PO} was calculated based on relative areas. The results were compared using a Wilcoxon Signed Rank test.
RESULTS: The study subjects were 8 females and 2 males with an average age of 37.1 ± 16.3 years, weight of 91.8 ± 38.9 kg, and height of 144.3 ± 45.8 cm. Median (range) $AUC_{0\text{-}72h}$ [298 (260–565) vs. 227 (176–332) mg/L·h (p=0.002)], $AUC_{0\text{-}Inf}$ [386 (323–1027) vs. 329 (196–685) mg/L·h (p=0.01)], and C_{max} [10.7 (9.0–19.4) vs. 5.0 (3.2–8.9) mg/L (p=0.002)] were all significantly greater for FPHT. Median T_{max} [1 (0.5–2) vs. 6 (2–24) h (p=0.008)] was significantly less for FPHT. Median F_{PO} for FPHT was 115% (92–260%).
CONCLUSION: FPHT sodium injection was absorbed more rapidly and to a greater extent following oral administration than PHT sodium injection. Further comparison in the presence of continuous enteral feeding is warranted.

232. Vascular protection with candesartan: beyond blood pressure reduction. *Ahmed Alhusban, Pharm.D.*, Anna Kozak, M.S., Susan C. Fagan, Pharm.D.; Program in Clinical and Experimental Therapeutics University of Georgia College of Pharmacy;Charlie Norwood VA Medical Center, Augusta, GA
PURPOSE: Hypertension is a major risk factor of stroke and it's management has been associated with reduced stroke incidence and recurrence. ARBs are one of the antihypertensive classes that have demonstrated particular benefit on stroke in both clinical and experimental settings. Despite the many hypotheses that have been suggested to explain the mechanistic pathways by which hypertension and ARBs affect stroke, there are still many uncertainties to be addressed. In this study we investigated the interaction between hypertension, ARBs and brain derived neurotrophic factor (BDNF); a protein that has angiogenic and neurogenic effects and have been shown to positively affect stroke outcome.
METHODS: We used human brain microvascular cells and spontaneously hypertensive rats (SHR) to assess the interaction between hypertension, candesartan treatment and BDNF at both the molecular and functional levels.
RESULTS: Hypertension reduced the expression of the BDNF receptor while candesartan treatment significantly increased the expression of BDNF in the brain of SHR a ($p<0.05$). Candesartan significantly increased the proliferation and viability of endothelial cells treated with angiotensin II (10^{-9} μg/ml) (p=0.0031, 0.0001 respectively) while ablating the effects of BDNF using a neutralizing antibody significantly reduced the effect of candesartan on cell viability (p=0.0001). Similarly, neutralizing the effects of BDNF significantly reduced the ability of candesartan treated cells to migrate—an initial step for angiogenesis—(p=0.0001). In cells treated with very high dose of angiotensin II (1μg/ml) candesartan treatment significantly increased the migration ability of endothelial cells (p=0.0001).
CONCLUSION: Hypertension reduced the expression of BDNF and its receptor. The beneficial effects of candesartan may be at least partially related to increasing the availability of functioning BDNF.

233. Nephrotoxicity associated with weight based vancomycin dosing. *Megan Brockman, Pharm.D.*[1], A. Shaun Rowe, Pharm.D., BCPS[2]; (1)The Univeristy of Tennessee Medical Center, Knoxville, TN; (2)The University of Tennessee College of Pharmacy, Knoxville Campus, Knoxville, TN
PURPOSE: To determine if > 30 mg/kg/day of vancomycin increases the risk of nephrotoxicity compared to ≤ 30 mg/kg/day, using linezolid as a comparator.
METHODS: This was a retrospective cohort analysis comparing patients who received vancomycin doses of > 30 mg/kg/day, ≤ 30 mg/kg/day or those who received linezolid. Patients were included in the study if they received at least 2 doses of vancomycin or linezolid, were greater than 18 years of age and resided on a general medicine floor during the study period. The primary outcome was nephrotoxicity (increase in serum creatinine of 0.5 mg/dL or 50% above baseline). Secondary objectives included: effect of the cumulative vancomycin dose on nephrotoxicity, time to nephrotoxicity and predictors of nephrotoxicity.
RESULTS: A total of 500 patients were included (>30 mg/kg/day group [n=189], ≤ 30 mg/kg/day group [n=211] and linezolid group [n=100]). Thirty patients experienced nephrotoxicity; 13 (6.9%) who received > 30 mg/kg/day of vancomycin, 9 (4.3%) who received ≤ 30 mg/kg/day of vancomycin, and 8 (8%) who received linezolid. No significant difference was found between any of the groups [> 30 mg/kg/day vs. linezolid OR = 0.85; 95% CI (0.34–2.12); ≤ 30 mg/kg/day vs. linezolid OR = 0.51; 95% CI (0.19–1.38); > 30 mg/kg/day vs. ≤ 30 mg/kg/day OR = 1.65; 95% CI (0.69–3.97)]. Cumulative vancomycin dose and time to nephrotoxicity was not significantly different between groups. The initial trough level was significantly higher in patients who experienced nephrotoxicity (14 vs. 10.1, respectively; p=0.016) and was the only predictor for nephrotoxicity.
CONCLUSION: Patients who received > 30 mg/kg/day of vancomycin did not have an increased risk of nephrotoxicity compared to those who received ≤ 30 mg/kg/day. Patients experiencing nephrotoxicity had higher initial trough levels than those that did not.

234. Candesartan for prostate cancer: A dose or a class effect?. *Ahmed Alhusban, Pharm.D.*, Ahmad Al-azayzih, Pharm.D., Diana Houng, Pharm.D., Susan C. Fagan, Pharm.D., Somanath P.R Shenoy, Ph.D.; Program in Clinical and Experimental Therapeutics University of Georgia College of Pharmacy;Charlie Norwood VA Medical Center, Augusta, GA
PURPOSE: Prostate cancer is the second leading cause of cancer related death among men in the United States. Therapeutic modalities for prostate cancer ranging from careful monitoring to chemotherapy is suggested based on patient's age, Gleason score and serum PSA levels. Recent reports have presented conflicting results with regard to the association between ARBs and the incidence of cancer; accordingly we have investigated the effect of candesartan treatment on the proliferation of prostate cancer cells at cellular and molecular levels.
METHODS: Using two metastatic prostate cancer cell lines (PC3 and LNCaP C4-2), we performed cell migration employing a monolayer scratch assay, colony formation assay, viability and proliferation assays in vitro in the presence or absence of various doses of candesartan (0–250 μM) and at doses within the therapeutic concentration of losartan (0–0.2 μM). Concomitantly these studies were also compared with western analyses for changes in major intracellular survival pathways with the different doses of candesartan. Experiments were performed in triplicates and data analyses done using student t-test and one way ANOVA.
RESULTS: Candesartan modulated the migration and colony formation ability of prostate cancer cells in a dose dependent manner

(p<0.0001 in both assays), where doses producing concentrations near the therapeutic concentration has promoted the progression of cancer cells whereas higher doses have inhibited the progression. Similarly losartan had a dose dependent modulation of prostate cancer cells progression within the therapeutic concentration. In addition candesartan has modulated the viability of prostate cancer cells in a dose dependent manner with maximum reduction in viability being at 10υM (p<0.001). Findings at the cellular levels were reproduced at the molecular level analysis of survival pathways.
CONCLUSION: We conclude that candesartan and losartan have a dose dependent modulatory effect on the progression of metastatic prostate cancer cells.

235. Dexamethasone systemic exposure is associated with hyperlipidemia in children with acute lymphoblastic leukemia. *Jitesh D. Kawedia, DPh, Ph.D.*, Wenjian Yang, Ph.D., Deqing Pei, M.S., John C. Panetta, Ph.D., Xiangjun Cai, Ph.D., Cheng Cheng, Ph.D., Chengcheng Liu, B.S., Scott C. Howard, M.D., William E. Evans, Pharm.D., Ching-Hon Pui, M.D., Mary V. Relling, Pharm.D.; St. Jude Children's Research Hospital, Memphis, TN
PURPOSE: Glucocorticoids are essential drugs for the treatment of acute lymphoblastic leukemia (ALL). Intensive treatment with glucocorticoids, particularly dexamethasone, has contributed to improved cure rates. The major dose-limiting adverse effect in current ALL clinical trials is glucocorticoid-induced osteonecrosis. We recently found that high cholesterol concentration, increased dexamethasone exposure and lower serum albumin concentration are independent risk factors for osteonecrosis, and serum albumin level is inversely related to dexamethasone plasma exposure. Asparaginase and glucocorticoids can cause hyperlipidemia but there are few data on the extent of and risk factors for hyperlipidemia during ALL therapy.
METHODS: We investigated the association of dexamethasone plasma exposure with serum lipids measured during the first re-induction phase of therapy, and changes compared to baseline levels during consolidation phase, in 266 children treated on a front-line clinical trial (St. Jude Total XV) for ALL. Patients on the standard/high risk-arm were exposed to more asparaginase than those on the low risk-arm. We performed multivariate analyses, adjusting for standard clinical features and serum albumin as covariates.
RESULTS: Mean levels of cholesterol (p=0.0009) and triglycerides ($p=1x10^{-6}$) increased while HDL (p=0.004) and LDL ($p=1x10^{-5}$) levels decreased after dexamethasone treatment (during re-induction) compared to baseline (consolidation). Multivariate analysis revealed that plasma dexamethasone exposure was associated with higher cholesterol (p=0.001) and triglycerides levels (p=0.0002), but was not associated with LDL and HDL levels. Lower serum albumin (a marker of asparaginase treatment) was also associated with higher cholesterol (p=0.008) and triglycerides (p=0.004), and with lower HDL levels ($p=2x10^{-5}$). In addition, patients in the standard/high risk-arm were at higher risk for elevated cholesterol (p=0.003), triglyceride levels (p=0.03) and LDL (p=0.01) compared to those in the low risk-arm.
CONCLUSION: Dexamethasone systemic exposure and treatment on the standard-/high-risk arm, (with more intensive asparaginase therapy) are risk factors for hypercholesterolemia and hypertriglyceridemia during ALL therapy.

236E. Pharmacokinetic interactions of roflumilast with medications commonly prescribed for COPD patients. *Phillip Jennings, Pharm.D.*[1], Gezim Lahu, M.S.[2], Abhijeet Jakate, Ph.D.[1], Andreas Hunnemeyer, M.D., M.S.[2], Nassr Nassr, M.D.[2]; (1)Forest Research Institute, Jersey City, NJ; (2)Nycomed GmbH, Konstanz, Germany, Konstanz, Germany
PURPOSE: With increasing age, patients often require treatment with multiple medications and drug interactions may affect efficacy or tolerability. Roflumilast is an oral, once-daily, selective, phosphodiesterase-4 inhibitor, metabolized by CYP1A2 and 3A4 to its active metabolite roflumilast N-oxide (RNO), which accounts for >90% of total phosphodiesterase-4 inhibitory activity (tPDE4i). RNO is cleared by CYP3A4, with a minor contribution from CYP2C19.
METHODS: Potential pharmacokinetic interactions and the safety of co-administration of a single 500μg roflumilast dose with antibiotics, bronchodilators, inhaled corticosteroids, and other typical representatives of drug classes commonly used by COPD patients or involved in drug interactions was evaluated in healthy volunteers. Increases in tPDE4i of >2-fold (>100%) may decrease tolerability and alterations of <2-fold (<100%) are not expected to result in changes in roflumilast safety and tolerability.
RESULTS: No clinically relevant interactions were observed for roflumilast and RNO with erythromycin, enoxacin, albuterol, formoterol, montelukast, budesonide, warfarin, midazolam, digoxin, sildenafil, Maalox, theophylline, and ketoconazole. Rifampin reduced tPDE4i by 58% and so may reduce the therapeutic efficacy of roflumilast. Fluvoxamine (50mg) or cimetidine (400mg) co-administration resulted in 59% or 47% increases in tPDE4i, respectively. Higher doses may alter the tPDE4i in a clinically relevant manner, but have not been investigated to date. Roflumilast appeared to have no significant pharmacokinetic influence on co-administered drugs. No safety concerns were revealed and roflumilast co-administration was generally well tolerated with each drug class.
CONCLUSION: Roflumilast was generally well tolerated and did not show clinically relevant interactions in healthy volunteers when co-administered with medications likely to be prescribed to COPD patients.
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237. The effects of repeat doses of albiglutide on the pharmacokinetics and pharmacodynamics of a low-dose oral contraceptive containing norethindrone and ethinyl estradiol. *Mark Bush, Ph.D.*[1], Rhona Scott, Ph.D.[2], Hui Zhi, Ph.D.[3], Prapoch (Keng) Watanalumlerd, Ph.D.[4], Eric Lewis, M.D.[1]; (1)GlaxoSmithKline, Research Triangle Park, NC; (2)GlaxoSmithKline, Middlesex UB11 IBT, United Kingdom; (3)GlaxoSmithKline, Reasearch Triangle Park, NC; (4)PPD, Richmond, VA
PURPOSE: Albiglutide (ALBI) is a long-acting GLP-1 agonist in phase 3 development. Potential for pharmacokinetic (PK) and pharmacodynamic interactions between ALBI and low-dose oral contraceptive (OC) containing norethindrone (NE) and ethinyl estradiol (EE) were investigated.
METHODS: Healthy female subjects (n=23 enrolled; n=18 completed; 20–40 y; BMI: 20–30 kg/m^2) received OC (0.5 mg NE, 0.035mg EE) for 21 days, then inactive tablet for 7 days in periods 1 (p1) and 2 (p2). Subjects received ALBI (50 mg) on day 26 of p1 and days 5, 12, 19 of p2. Serial blood samples for NE and EE PK were collected. Samples for luteinizing hormone (LH), follicle stimulating hormone (FSH) and progesterone were collected.
RESULTS: Exposures ($AUC_{(0\text{-}24h)}$) of NE and EE were comparable when administered alone or with ALBI. A small non-clinically relevant increase in NE C_{max} was observed during OC+ALBI administration. No clinically relevant effects on LH, FSH, or progesterone were apparent.

	Geometric LS Means		Ratio of Geometric LS Means
	OC (n=21)	OC+ALBI (n=18)	(90% CI)
EE $AUC_{(0\text{-}24h)}$, pg•h/mL	1318	1313	1.00 (0.96–1.04)
EE C_{max}, pg/mL	155	161	1.04 (0.98–1.10)
NE $AUC_{(0\text{-}24h)}$, ng•h/mL	131	144	1.09 (1.06–1.14)
NE C_{max}, ng/mL	15.8	18.9	1.20 (1.11–1.29)

	Mean (SD)	
	OC (n=21)	OC+ALBI
Maximum LH, mIU/mL	8.55 (3.56)	8.50 (4.49); n=19
Maximum FSH, mIU/mL	3.96 (1.24)	3.75 (1.50); n=19
Progesterone day 1, ng/mL	0.79 (0.21)	0.87 (0.25); n=21
Progesterone day 21, ng/mL	0.71 (0.23)	0.77 (0.17); n=18

OC was safe and well-tolerated when coadministered with ALBI. Adverse events (AEs) occurred in 5/23 subjects (21.7%) in p1 and in 10/21 subjects (47.6%) in p2. In p2, nausea and vomiting occurred in 5/21 subjects (23.8%) and 4/21 (19.0%) subjects, respectively. All other AEs occurred in 1-2 subjects.
CONCLUSION: The combination of OC+ALBI was well-tolerated. No dose adjustment for OC is required during co-administration with ALBI. Submit to: Original Research, PK/PD/pharmacometrics/metabolism

238. Inadequate empirical vancomycin dose in non-elderly neurosurgical patients by conventional dosing regimen. *Ming-Fang Wen, M.S.*[1], Ting-Ya Yang, M.S.[2], Fe-Lin Lin Wu, Ph.D.[2], Li-Jiuan Shen, Ph.D[2]; (1)Department of Pharmacy, National Taiwan University Hospital, Taipei, Taiwan; (2)Graudate Institute of Clinical Pharmacy, College of Medicine, National Taiwan University, Taipei, Taiwan

PURPOSE: Inadequate vancomycin peak/trough concentrations were observed in neurosurgical patients using conventional vancomycin dosage. The aim of the study was to characterize the pharmacokinetic properties of vancomycin for non-elderly neurosurgical patients.

METHODS: Retrospective analysis of vancomycin pharmacokinetic parameters was performed for 18-64 year-old neurosurgical patients from routine therapeutic drug monitoring data in a medical center during 2009-2010. Patients were excluded if they were with renal failure, unstable renal function, obesity, shock, and third space fluid accumulation. Patients' demographic characteristics, mannitol use, cerebrospinal fluid (CSF) drainage, and urine output were recorded as candidate covariates. Pearson's and Spearman's correlation tests followed by multiple linear regression analysis were used to assess the contribution of patients' covariates.

RESULTS: Seventy-two sets of peak/trough serum concentrations obtained from 53 patients were analyzed. The mean vancomycin clearance (Clv) and volume of distribution (Vd) were 1.83 ± 0.65 mL/min/kg (1.29 ± 0.39 folds of creatinine clearance, Clcr) and 0.92 ± 0.27 L/kg in the neurosurgical patients. In subgroup analysis, a significantly higher ratio of Clv/Clcr was observed in ICU patients than that in general ward patients, 1.57 ± 0.34 vs. 1.14 ± 0.33 in each group (p<0.05). No difference was observed in the Vd between ICU and general ward patients. Multiple linear regression of vancomycin clearance in the ICU subpopulation showed that CSF drainage and urine output were positively associated with Clv. Urine output was the second most significant variable for Clv following Clcr, which increased the adjusted R^2 of the regression model from 0.70 to 0.76.

CONCLUSION: In critically ill non-elderly neurosurgical patients, Clv is significantly elevated when adjusted by individual Clcr. The equation newly generated in our study may provide a more appropriate model in these patients. Further studies are necessary to validate the equation and investigate the mechanism of this phenomenon.

239E. Pharmacokinetics, cord blood concentrations, and tolerability of boosted fosamprenavir in pregnancy. Michelle S. Cespedes, M.D.[1], Susan L. Ford, Pharm.D.[2], *Gary E. Pakes, Pharm.D.*[2], Luis Vargas, B.S.[1], Eleanor M. De Candia, RN[1], Judith A. Aberg, M.D.[1]; (1)New York University School of Medicine, New York, NY; (2)GlaxoSmithKline, Research Triangle Park, NC

PURPOSE: Little is known about the pharmacokinetics of the protease inhibitor fosamprenavir (FPV) in pregnancy and of the concentrations of its active metabolite, amprenavir (APV), that are achieved in infant cord blood.

METHODS: A phase I, open-label, single-center study was conducted to evaluate APV pharmacokinetics following twice-daily FPV 700 mg boosted by ritonavir 100 mg in pregnant HIV-infected women. Steady-state PK was assessed in the second and/or third trimesters and at 4–12 weeks postpartum. Maternal serum and cord blood samples were obtained at the time of delivery. Plasma APV concentrations were measured by LC-MS/MS, and PK were determined using WinNonlin.

RESULTS: Pharmacokinetic data were obtained from 10 women (5 African-Americans/5 Hispanics; median age 28.6 years). The most common backbone regimen was tenofovir/emtricitabine. FPV was well tolerated, with no hepatic, renal, or adverse events attributed to antiretroviral therapy. At delivery, all women had viral loads <400 c/mL, with 9 undetectable (<50 c/mL). The median (range) AUC (in µg*h/mL), C_{max} (in µg/mL), and C_{12h} (in µg/mL) were 26.80 (18.49–40.72), 4.32 (3.07–5.87), and 1.35 (0.88–1.67) during the second trimester (n=6); 32.77 (17.05–66.42), 5.75 (3.26–10.98), and 1.46 (0.66–2.33) during the third trimester (n=9); and 41.73 (28.86–79.66), 6.92 (3.56–9.97), and 2.24 (1.17–5.32) postpartum (n=9). Overall, APV AUC was 22-34% lower, C_{max} 9-41% lower, and C_{12h} 27–28% lower during pregnancy than postpartum. Median gestational age of infants was 37.9 weeks, and birth weight was 2909 g. All infants were HIV PCR-negative. No growth abnormalities were observed. Cord blood was obtained from six deliveries; the median ratio of cord blood/maternal APV level was 0.27.

CONCLUSION: FPV use during pregnancy was well tolerated. Although APV C_{12h} was 27–28% lower in pregnancy, HIV was well suppressed for all subjects at delivery. Maternal and cord blood concentrations were above the mean protein binding-adjusted IC_{50} (0.146 μg/mL) for wild-type virus.

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240. Evaluation of newer equations for estimation of renal function for utility in drug dosing using an aminoglycoside pharmacokinetic model. *Jeremy Fox, Pharm.D., BCPS*, Charles H. Rawls III, Pharm.D.; Shenandoah University, Winchester, VA

PURPOSE: Several equations exist for estimation of renal function. This study compares estimated renal function to pharmacokinetic data to evaluate the utility of the Cockcroft-Gault (C-G), Modification of Diet in Renal Disease (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations for drug dosing.

METHODS: Medical records of patients who received aminoglycoside therapy from January 1, 2008 to December 31, 2009 were reviewed. Selected patients received gentamicin or tobramycin, had appropriately drawn peak and trough levels, and had adequate data to estimate renal function for the three test equations. Pharmacokinetic data were used to calculate a patient?s estimated true renal function (CrClKe).

RESULTS: Of 1000 records reviewed, 37 patients met inclusion criteria. The most common reason for exclusion was inadequate or inappropriately drawn pharmacokinetic data. The mean deviation of the C-G estimation of renal function was 7.4 ml/min below the CrClke and the mean deviation of the MDRD and CKD-EPI estimations of renal function were 0.5 ml/min and 0.7 ml/min above the CrClke, respectively. Using linear regression to predict CrClke, the C-G, MDRD, and CKD-EPI equations produced r2 values of 0.225 (p=0.002), 0.224 (p=0.002), and 0.305 (p<0.001) respectively. While not statistically significant (p=0.062), the C-G equation consistently overestimated renal function in males by 3 ml/min and underestimated renal function in females by 13 ml/min. The MDRD and CKD-EPI also overestimated renal function in males by 4.7 ml/min and 4.6 ml/min and underestimated renal function in females by 2 ml/min and 1.7 ml/min respectively (p=0.52 and 0.5).

CONCLUSION: Utility of the MDRD and CKD-EPI equations to estimate renal function for dosing gentamicin and tobramycin is feasible as an alternative to the Cockcroft-Gault equation. A prospective study comparing dosing via the MDRD and CKD-EPI methods should be performed. Further analysis of the differences in estimation of renal function in males and females should be studied in larger sample sizes.

241E. Clinical pharmacokinetics of low-dose cidofovir without and with concomitant probenecid used for the treatment of persistent BK viremia in renal transplant recipients. *Jeremiah D. Momper, Pharm.D.*, Yang Zhao, Ph.D., Ron Shapiro, M.D., Parmjeet Randhawa, M.D., Kristine Schonder, Pharm.D., Raman Venkataramanan, Ph.D.; University of PIttsburgh, Pittsburgh, PA

PURPOSE: Cidofovir, an antiviral nucleotide analog that is FDA-approved for the treatment of CMV infections, is used off-label for the treatment of BK virus in kidney transplant patients. However, an optimal dosage regimen has yet to be elucidated for this indication. Therefore, in order to establish the relationship between cidofovir exposure and response, we first investigated the disposition of cidofovir in kidney transplant recipients and assessed the contribution of renal secretion to the overall clearance of cidofovir by evaluating the effect of oral on cidofovir pharmacokinetics.

METHODS: Kidney transplant patients between 18–70 years with persistent BK viremia were enrolled in this study (n=10). Cidofovir doses ranged from 0.25–0.6 mg/kg weekly. A crossover study design was employed and the pharmacokinetics of cidofovir

RESULTS: The pharmacokinetic parameters of low-dose cidofovir in kidney transplant recipients are displayed below. A linear relationship was observed between cidofovir clearance and

	Cidofovir	Cidofovir + probenecid

	(mean ± SD)	(mean ± SD)
Dose-adjusted	36.2 ± 3.4	36.7 ± 2.0
Dose-adjusted AUC $_{0-\infty}$	(251.2 ± 63.8	258.4 ± 55.3
Clearance (mL/min)	83.6 ± 12.4	76.81 ± 10.3
Renal clearance (mL/min)	62.1 ± 9.14	57.5 ± 9.78
(L)	30.9 ± 19.4	31.7 ± 24.6
$_{1/2\ (h)}$	5.5 ± 1.5	5.9 ± 1.2

CONCLUSIONS: Cidofovir exhibited dose-independent pharmacokinetics and clearance was linearly related to

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242. Progesterone, a female sex hormone, inhibits CYP3A-mediated metabolism of 17-alpha hydroxyprogesterone caproate, an agent that prevents preterm birth. *Yang Zhao, Ph.D*[1], Courtney Cuppett, M.D.[2], WenChen Zhao, M.S.[1], Shimin Zhang, M.S.[1], Steve Caritis, M.D.[2], Raman Venkataramanan, Ph.D[1]; (1)University of PIttsburgh, Pittsburgh, PA; (2)Magee-Womens Hospital, Pittsburgh, PA

PURPOSE: In a clinical pharmacokinetic study of 17alpha hydroxyprogesterone caproate (17-OHPC) in pregnant women, we observed a large variation in the pharmacokinetics, and a positive correlation between the plasma concentration of 17-OHPC and progesterone. The objective of this study was to determine the effect of progesterone on the metabolism of 17-OHPC, using human liver microsomes (HLMs).

METHODS: Metabolism of 17-OHPC (concentration range from 1.2 to 768 μM) was evaluated in pooled human liver microsomes, in the presence and in the absence of various female sex hormones, progesterone, 17alpha hydroxyprogesterone, estrone, 17beta estradiol, and estriol. High performance liquid chromatography and liquid chromatography-mass spectrometry were utilized to analyze 17-OHPC and its metabolites, respectively.

RESULTS: 17-OHPC was rapidly metabolized by the HLMs with formation of two major mono-hydroxylated metabolites as well as four minor di- and tri-hydroxylated metabolites. The apparent in vitro half-life was 49±4 min. A combination of all the hormones, and progesterone by itself significantly inhibited the hydroxylation of 17-OHPC, whereas the other hormones tested alone had essentially no effect. Upon 60-min incubation in HLMs, in presence of hormone combination or progesterone alone, the depletion of substrate was 51% or 46% less, and the generation of two major mono-hydroxylated metabolites was 21–35% or 23–46% less, than control group without any hormones. The effect of progesterone was best described by a competitive inhibition and the inhibition rate constant (K(i)) was 52 μm using a substrate-depletion approach. Inhibitor of CYP3A4, ketoconazole, inhibited 17-OHPC hydroxylation in HLMs mainly through a competitive manner with K(i) 0.7 μM.

CONCLUSION: These observations suggest that progesterone has the capacity to alter the metabolism of 17-OHPC and that variable concentrations of progesterone in pregnant subjects may contribute to the observed variability in the pharmacokinetics of 17-OHPC.

243. PK/PD modeling and simulations support development of MN-221, a novel,hHighly-selective β2-adrenergic agonist for treatment of acute asthma. Kirk Johnson, Ph.D.[1], *James R. Bosley, Ph.D.*[2], Ron Beaver, Ph.D.[2]; (1)MediciNova, Inc., San Diego, CA; (2)Rosa & Co. LLC, San Carlos, CA

PURPOSE: Asthma causes 2 million annual emergency room visits in US, 500,000 of which result in hospitalizations with an average stay of 3 days. The present modeling study aimed to evaluate the efficacy of MN-221, a novel β2 agonist in asthma patients in addition to the standard of care (SOC).

METHODS: Data from three clinical trials, including a total of 40 mild to moderate asthma patients in clinic, and 33 acute patients in the emergency department, were used in the modeling process. In the ED, subjects received the SOC (inhaled albuterol, as needed). Serial blood samples were collected to determine the plasma concentrations of MN-221 and albuterol. FEV1 and heart rate, and (in the ED) QTc were monitored during each subjects' study period. A mixed-effect modeling approach was used to evaluate the PK and PD of MN-221.

RESULTS: A 3-compartment model was fitted to the MN-221 plasma concentration data with typical values for CL and MN-221 steady state volume of distribution of 27 L/h and 17.9 L, respectively. A mixture model represented distributions of and differentiated between responder and non-responder subjects. The estimatate Emax estimated from clinical data is 20% FEV1, and observed FEV1 improvement is clinically and statistically significant. A synergistic model of MN-221 and albuterol levels described the observed increase in FEV1 well.

CONCLUSION: Addition of MN-221 demonstrated a clear improvement in FEV1 over SOC alone in treating acute asthma exacerbations in responder subjects. PK/PD modeling: 1) enabled prediction the effect of MN-221 in acute patients, 2) supported dosing decisions, 3) predicted the impact of non-responders on trial outcome, and 4) suggested improved timing of FEV1 measurements. Based on the proposed PK/PD model, further development of MN-221 as a new treatment for acute exacerbations of asthma is warranted.

Psychiatry

244E. Risperidone-associated prolactin elevation and markers of bone turnover during acute treatment. *Jeffrey R. Bishop, Pharm.D., M.S., BCPP*[1], Leah H. Rubin, Ph.D.[2], James L. Reilly, Ph.D.[2], Mani N. Pavuluri, M.D., Ph.D.[2], John A. Sweeney, Ph.D.[2]; (1)University of Illinois at Chicago College of Pharmacy, Chicago, IL; (2)University of Illinois at Chicago Center for Cognitive Medicine, Chicago, IL

PURPOSE: To study the acute effects of prolactin elevation on serum markers of bone formation and resorption in patients treated with the antipsychotic risperidone.

METHODS: Thirty participants (63% male, 24±7 years of age) meeting DSM-IV criteria for schizophrenia (n=23), major depressive disorder with psychotic features (n=4), or bipolar disorder with psychosis (n=3) were enrolled. At baseline, subjects were antipsychotic free for at least four half-lives of any prior medication, with 19/33 having no prior exposure to antipsychotic medications. Subjects were evaluated before and after 4 weeks of risperidone treatment (median daily dose = 3mg/d, range 0.5-6mg/d). Assessments included symptom ratings, and a.m. blood draws to assess testosterone, estradiol, leptin, prolactin, osteocalcin (marker of bone formation), and n-telopeptide crosslinks (NTx marker of bone resorption). Primary analysis examined the impact of risperidone treatment on change on the bone markers and hormone levels from pre- to post-treatment. All analyses controlled for age, sex, and risperidone dose.

RESULTS: Prolactin levels increased significantly from pre- to post-treatment ($p<0.001$). Increases in prolactin after risperidone treatment were significantly associated with increases in NTx markers of bone resorption (OR 5.13, 95%CI 1.31–20.13). Subjects with the largest increases in prolactin after risperidone treatment had the greatest increases (worsening) in their NTx markers of bone resorption.

CONCLUSION: Study findings suggest that prolactin elevation is associated with changes in bone physiology very early in the course of treatment with risperidone. Higher levels of bone resorption occurred in patients with the greatest increases in prolactin. Interestingly, during the acute treatment phase, both increases and decreases in bone resorption were observed which may have important implications for prolactin monitoring or the periodic assessment of osteoporosis-related outcomes in patients requiring extended treatment.

Presented at Presented at the American College of Neuropsychopharmacology Annual Meeting, Miami, FL, Dec 9, 2010

245. Antipsychotic adherence and discontinuation outcomes in schizophrenia patients with metabolic comorbidities: Analysis of 24 state Medicaid programs. Iftekhar Kalsekar, Ph.D.[1], Raymond Mankoski, M.D., Ph.D.[2], Dana Goldman, Ph.D.[3], Darius Lakdawalla, Ph.D.[3], Seth Seabury, PhD[4], *Diane Ammerman, Pharm.D.*[5], Zia Rahman, Ph.D., MBA[2], Robert Forbes, Ph.D.[6]; (1)Health Services, US Medical, Bristol-Myers Squibb, Plainsboro, NJ; (2)Bristol-Myers Squibb, Plainsboro, NJ; (3)Schaeffer Center for Health Policy and Economics, Los Angeles, CA; (4)RAND Corporation, Santa Monica, CA; (5)Bristol-Myers Squibb, Cranberry Twp, PA; (6)Otsuka Pharmaceutical Development and Commercialization Inc., Princeton, NJ

PURPOSE: To compare discontinuation and adherence rates to second-generation antipsychotics (SGAs) in patients with

schizophrenia and comorbid metabolic abnormalities.
METHODS: A retrospective cohort analysis of claims data from 24 state Medicaid programs (2001–2005) was conducted. The cohort consisted of schizophrenia patients who were new users of SGA therapy and were diagnosed with metabolic syndrome, dyslipidemia, diabetes mellitus, or obesity at baseline. The index date was the fill date of the earliest SGA adopted. SGAs were categorized as high (olanzapine), discrepant (quetiapine and risperidone), or low (aripiprazole and ziprasidone) metabolic risk based on the American Diabetes Association/American Psychiatric Association consensus guidelines. Adherence was defined as a medication possession ratio (MPR) of >80% between first and last prescription fill of the index SGA. Discontinuation was defined as a gap in therapy of more than 60 days. The outcomes were evaluated in the 12-month period after the index date. Logistic regression was used to assess the impact of metabolic risk of SGA on adherence and discontinuation rates after controlling for demographics, comorbidity, and baseline psychiatric characteristics.
RESULTS: A total of 21,857 patients meeting the study criteria were identified. The mean age of the sample was 46.1 (±10.2) years and the majority of the patients were female (56.6%) and non-white (63.8%). Logistic regression results demonstrated that patients prescribed high metabolic risk SGAs were 38% less likely to be adherent ($p<0.001$) and patients prescribed discrepant metabolic risk SGAs were 21% less likely to be adherent ($p=0.006$) relative to patients prescribed low metabolic risk SGAs. Patients prescribed high or discrepant metabolic risk SGA had higher odds of discontinuation (Odds Ratios of 2.29 ($p=0.006$) and 1.18 ($p<0.001$), respectively).
CONCLUSIONS: Use of discrepant or high metabolic risk SGAs is associated with poorer adherence and higher rates of discontinuation in schizophrenia patients with comorbid metabolic conditions.

246E. Determining rates of metabolic monitoring in clozapine-treated outpatients: evaluating the need for a collaborative metabolic monitoring service. *Ted J. Turner, Pharm.D.*[1], Jamie L. Montgomery, R.Ph., BCPP[1], Melissa S. McGivney, Pharm.D., FCCP[2], Kim C. Coley, Pharm.D., FCCP[2], Tanya J. Fabian, Pharm.D., Ph.D., BCPP[1]; (1)Western Psychiatric Institute and Clinic, University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: The risk of metabolic syndrome and premature mortality is high in patients with serious mental illness. Atypical antipsychotics can cause weight gain, hyperglycemia and hyperlipidemia. Among the available atypical antipsychotics, clozapine is reserved for treatment resistant patients and is associated with the highest risk of metabolic syndrome. The purpose of the present project was to determine metabolic monitoring rates compared to the 2004 American Diabetes Association (ADA) recommended guidelines in at an outpatient clozapine clinic.
METHODS: Electronic medical records of patients enrolled in an outpatient clozapine management clinic were retrospectively reviewed between January 2005 and December 2010, and the following data elements were extracted: (1) date of clozapine initiation, (2) date and value of metabolic parameters including blood pressure, weight, waist circumference, fasting lipid and glucose levels, and (3) diagnosis and pharmacological treatment of hypertension, diabetes, obesity or dyslipidemia.
RESULTS: A total of 127 patients (mean age: 47.7 years) were included in the analyses. Of the 34 who initiated clozapine treatment between 2005 and 2010, baseline evaluations (±14 days from initiation) were: weight 70.6% (24/34), waist circumference 0% (0/34), blood pressure 52.9% (18/34), fasting lipid and glucose levels 11.8% (4/34). Within 3 months of initiating clozapine (15–98 days), blood pressure was reevaluated in 80.6% (25/31) of patients; fasting lipids and glucose levels had only been reassessed in 29.0% (9/31) of patients. Most patients who were diagnosed with diabetes (26.8%), hypertension (32.3%) or dyslipidemia (55.9%) were being treated pharmacologically for their condition(s).
CONCLUSION: Monitoring of clozapine-induced metabolic disturbances in this high-risk patient population was not consistent with ADA recommended guidelines. Additional effort is needed to improve metabolic monitoring in this high risk population. Pharmacists who oversee hematologic monitoring through the clozapine management clinic are well positioned to establish a metabolic monitoring clinic in collaboration with the clinical treatment team.
Presented at Presented at the American Pharmacist Association 2011 Annual Meeting in Seattle, WA. March 26th 2011

247. Impact of a Pharmacist on Length of Stay and Readmission Rate at an Academic Inpatient Psychiatric Unit. *Kimberly Tallian, Pharm.D., BCPP, FCCP, FASHP*[1], Gwendolyn Le, Pharm.D., Candidate[2], Duy Q. Tran, Pharm.D., Candidate[2], Sohil N. Rai, Pharm.D., Candidate[2]; (1)Scripps Memorial Hospital, La Jolla, San Diego, CA; (2)University of California, San Diego, San Diego, CA
PURPOSE: To determine the impact of a psychiatric pharmacist on acute psychiatric patient's clinical outcomes in an academic medical center including adherence to medications, length of stay, cost-effective pharmacotherapy, and readmission rate. Our secondary objective was to determine the influence of a pharmacist guided pharmacotherapy treatment plan on hospital readmission based on the patient's preferences and ability to pay for outpatient medications.
METHODS: A retrospective study compared all patients admitted to an academic, inpatient psychiatric unit between January 2006 through June 2006 (pre-intervention group without direct pharmacist involvement) and January 2010 through June 2010 (post-intervention group with direct psychiatric pharmacist involvement utilizing direct formulary and clinical services). Data was obtained from a computerized charting system, pharmacist computerized documentation system, and discharge pharmacy electronic records. Each patient's ability to access discharge medications was determined by discharge prescription records pre and post interventions groups.
RESULTS: A 25% reduction in pharmaceutical cost per patient and a reduction in length of stay by two days ($P=0.04$) was found in the post ($N=405$) versus the pre intervention ($N=314$) group despite no difference in patient severity upon admitted based on global assessment of functioning scores ($p=1.0$). Additional cost saving included formulary conversion to enhance medication adherence; generic anticonvulsant conversion; therapeutic drug monitoring; and pharmacist driven formulary to reduce the average medication cost per patient and readmission rate. Despite improved drug adherence during admission, there was no significant difference in discharge prescription compliance between the two groups ($p>0.05$), but fewer patients were readmitted in the post-intervention versus the pre-intervention group ($p<0.05$).
CONCLUSION: Provision of clinical pharmacy services influenced hospital-based medication adherence rates resulting in reduced length of stay, but its impact on hospital readmission rates remains unclear.

248. Effect of pharmacy team interventions on monitoring rates for second-generation antipsychotics in a correctional setting. *Philip J. Wenger, Pharm.D., BCPS*, Kyle R. Mays, Pharm.D.; St. Louis College of Pharmacy, Saint Louis, MO
PURPOSE: This study was conducted to assess the change in monitoring rates for second-generation antipsychotics (SGAs) at the Buzz Westfall Justice Center (BWJC) following interventions made by the clinical pharmacist and students. The interventions included development of a written protocol that outlines the necessary monitoring parameters and frequency for SGAs and a weekly clinic for the administration of the Abnormal Involuntary Movement Scale (AIMS) to patients referred by mental health providers.
METHODS: A retrospective chart review was conducted for BWJC patients receiving SGAs for the six months from 12-01-2008 to 5-31-2009. The review identified several categories below facility goal rates of greater than or equal to 80%. The clinical pharmacist and students provided education on the recommended monitoring parameters and frequencies to the providers at BWJC and instituted a weekly referral clinic for the administration of the AIMS test. A follow-up chart review was conducted to collect the monitoring rates from 12-01-2009 to 5-31-2010. The monitoring rates for each parameter post-intervention were compared to the pre-intervention rates using a chi-squared test with a significance level of 0.05. Parameters monitored were body mass index (BMI), fasting plasma glucose (FPG), fasting lipid profile (FLP), AIMS test, liver function tests (LFTs), and complete blood count (CBC).
RESULTS: Overall rates for BMI, AIMS, and LFTs were statistically

significantly improved after the pharmacy intervention. Only the rates for BMI improved to above the goal rate. No statistically significant differences were seen in the overall rates for FPG, FLP, or CBC.
CONCLUSION: The initiation of the AIMS clinic has been a positive improvement and will continue to be offered. Potential future changes for improving monitor rates of lab tests include education of all new psychiatry residents by the pharmacist or routine assessment and laboratory ordering by pharmacy for all patients taking SGAs.

Pulmonary

249. Appropriateness of chronic obstructive pulmonary disease (COPD) management per global initiative for chronic obstructive lung disease (GOLD) guidelines at a family medicine practice. *C. Brock Woodis, Pharm.D.*[1], Amber N. McLendon, Pharm.D.[2], Cheryl Van Horn, RN[3], Dallas Brooks, Pharm.D., Candidate[2], Caroline Ferguson, Pharm.D., Candidate[2], Justin Spivey, Pharm.D., Candidate[2]; (1)Campbell University College of Pharmacy and Health Sciences and Duke University Department of Community and Family Medicine, Durham, NC; (2)Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC; (3)Duke University Department of Community and Family Medicine, Durham, NC
PURPOSE: This retrospective study evaluated the appropriateness of COPD management per GOLD guidelines at a family medicine practice associated with a major academic medical center. Areas identified for improvement may be targeted by a pharmacist-managed clinic within the family medicine practice.
METHODS: Individuals who were patients of the family medicine center and had been assigned an ICD-9 diagnosis of COPD were identified by querying the practice's electronic medical records. In order to be included, patients must have been ≥ 42 years of age as of 12/31/09, seen 3 times in the past 3 years and once during measurement period (5/1/10–4/30/11) by a provider of the family medicine center, and had documented COPD staging. Age, race, pulmonary function tests (if available), and current medications for COPD were recorded.
RESULTS: Of the 78 patients reviewed, 71 were included for analysis. Per GOLD guidelines, 50.7% (36/71) received appropriate medication management (i.e., bronchodilators and corticosteroids) based on documented COPD stage. Of those who did receive appropriate management, 11.1% (4/36) received inadequate dosing of COPD medications.
CONCLUSION: Appropriately staging COPD, as well as reassessing currently prescribed medications, inhaler technique, and adherence at follow-up visits, are vital to patient care. Pharmacists are uniquely positioned to maximize COPD outcomes. A pharmacist-managed clinic may be of benefit to the multidisciplinary care of COPD patients and aid in exceeding national measurements. In addition, documentation of COPD management at this particular practice may be improved.

250. Cost-effectiveness analysis of roflumilast/tiotropium combination therapy vs. tiotropium monotherapy in patients with severe to very severe COPD. Andrew P. Yu, Ph.D.[1], *Shawn Sun, Ph.D.*[2], Maryna Marynchenko, MBA[1], Ritesh Banerjee, Ph.D.[1], Michelle Mocarski, M.P.H.[2], Donald Yin, Ph.D.[2], Eric Wu, Ph.D.[1]; (1)Analysis Group, Boston, MA; (2)Forest Research Institute, Jersey City, NJ
PURPOSE: Roflumilast, a once-daily oral selective phosphodiesterase-4 inhibitor recently approved by the FDA, reduces the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and history of exacerbations. The objective of this presentation is to conduct a cost-effectiveness analysis comparing the combination therapy of roflumilast and tiotropium versus tiotropium monotherapy in severe-to-very severe COPD patients.
METHODS: The economic evaluation applied a disease-based Markov cohort model with five health states: 1) severe COPD, 2) severe COPD with a history of severe exacerbation, 3) very severe COPD, 4) very severe COPD with a history of severe exacerbation, and 5) death. Within a given health state, a patient may have a mild/moderate or severe exacerbation or die. The probability of each event depends on the severity of COPD. Evidence from roflumilast clinical trials was used to estimate the relative risk of having an exacerbation and the change in lung function in patients treated with roflumilast. Data from published literature were used to populate other model parameters. The model calculated health outcomes and costs for roflumilast/tiotropium combination therapy versus tiotropium monotherapy over a 5-year horizon. Incremental cost and benefits were then calculated, and expressed as cost-effectiveness ratios, including cost per exacerbation avoided and cost per quality adjusted life year ($/QALY).
RESULTS: Over a 5 year horizon, the estimated incremental costs per exacerbation avoided and per severe exacerbation avoided with the addition of roflumilast to tiotropium are $589 and $5,869, respectively, and the incremental cost per QALY is $15,815. One-way sensitivity analyses varying key parameters produced an incremental cost per QALY ranging from $1,963 to $32,773. The cost-effectiveness ratio was sensitive to the relative risk reduction of exacerbations from adding roflumilast to tiotropium.
CONCLUSION: The addition of roflumilast to tiotropium may be cost-effective for the treatment of severe-to-very severe COPD patients.

251. The safety and efficacy of roflumilast: a new treatment to reduce exacerbation risk in severe COPD patients. Nicola A. Hanania, M.D., M.S., FCCP, FRCP(C), FACP[1], Mark T. Dransfield, M.D.[2], Udo-Michael Goehring, M.D.[3], Hans Mosberg, M.D.[3], *Phillip Jennings, Pharm.D.*[4]; (1)Baylor College of Medicine, Houston, TX; (2)University of Alabama, Birmingham, AL; (3)Department of Medical Scientific Strategy/Respiratory, Nycomed, GmbH, Konstanz, Germany; (4)Forest Research Institute, Jersey City, NJ
PURPOSE: COPD is a leading cause of mortality in the US and COPD exacerbations accelerate disease progression and increase mortality risk. Treatments that reduce exacerbation rates are therefore beneficial. Roflumilast, an oral, once-daily, selective phosphodiesterase-4 inhibitor recently approved for patients with severe COPD, reduces the rate of COPD exacerbations in patients with chronic bronchitis and a history of exacerbations. Here, data are presented from key trials evaluating the efficacy and safety of roflumilast 500μg for COPD treatment.
METHODS: Six phase 3 trials (3 pairs of similar studies) were used to evaluate change in exacerbation rates and lung function in COPD patients. M2-111/M2-112: 1-year trials in severe-to-very severe patients allowing concomitant ICS use; M2-124/M2-125: 1-year trials in severe-to-very severe patients with a history of exacerbations and chronic bronchitis allowing concomitant LABA use; M2-127/M2-128: 6-month studies in moderate-to-severe patients treated concomitantly with salmeterol or tiotropium, respectively. Fourteen phase 2-3 trials (n=5766 roflumilast; n=5491 placebo) evaluated adverse event (AE) frequency.
RESULTS: In M2-111/M2-112 (n=1327 roflumilast; n=1359 placebo), the moderate/severe exacerbation rate was 14.3% lower with roflumilast versus placebo (P=0.026); in M2-124/M2-125 (n=1537 roflumilast; n=1554 placebo) the rate was 16.9% lower (P=0.0003) and median time to first exacerbation was prolonged by 67 days versus placebo. Prebronchodilator FEV1 increased with roflumilast over placebo by 49mL (P<0.0001) in M2-127 (n=466 roflumilast; n=467 placebo), and 80mL (P<0.0001) in M2-128 (n=371 roflumilast; n=372 placebo). The most commonly reported AEs with roflumilast (≥2% and >placebo) were diarrhea, weight loss, nausea, headache, back pain, influenza, insomnia, dizziness and decreased appetite.
CONCLUSION: The safety and efficacy of roflumilast has been shown in a variety of phase 3 COPD studies, independent of concomitant therapy with either ICS or LABAs or LAMAs. Roflumilast is a beneficial treatment for patients with severe COPD taking concomitant COPD medications as patients may experience fewer exacerbations.

252E. An evaluation of the management of non-life threatening COPD exacerbations in hospitalized patients. *J. Andrew Woods, Pharm.D., BCPS*[1], Christopher K. Finch, Pharm, D., BCPS[2], Justin B. Usery, Pharm.D., BCPS[2], Timothy H. Self, Pharm.D.[2]; (1)Wingate University, School of Pharmacy, Wingate, NC; (2)Methodist University Hospital and University of Tennessee, Memphis, TN
PURPOSE: COPD is an increasing cause of morbidity, mortality and economic burden on our healthcare system, while exacerbations

continue to be among the top 10 causes of hospitalization in adults. Previous literature has demonstrated that only 66% of patients receive "recommended" care during an acute exacerbation of COPD. The objective of this study was to evaluate adherence to GOLD guidelines for treatment of severe, non-life threatening COPD exacerbations at a university teaching hospital.
METHODS: This study was a retrospective chart review of all patients admitted from January 2007 to June 2008 with a primary diagnosis of severe, non-life threatening COPD exacerbation (ICD-9 code 491.21). Each patient's COPD treatment regimen was assessed and compared to GOLD guideline recommendations.
RESULTS: Two hundred fifty-nine patients met inclusion criteria. The majority of patients were African-American and female with a mean age of 69 years. GOLD guidelines were met in 212 patients (81.9%). Length of stay was numerically higher in our patients versus the national average, 5.3 days vs. 4.8 days (p=NS), respectively. Approximately 66% of the patients in our study received antibiotics with 71% being unwarranted per GOLD guidelines. Systemic corticosteroids were not administered to 11% of patients
CONCLUSION: The potential to improve patient care through adherence to GOLD guidelines exists as evidenced by 18% of patients not receiving therapy per GOLD recommendations, including the administration of unnecessary antibiotics. In addition, systemic corticosteroids were not prescribed in all patients with a non-life threatening COPD exacerbation. The management of non-life threatening COPD exacerbations in hospitalized patients needs improvement and should be in accordance with well-accepted international guidelines. Efforts should be undertaken to develop a treatment algorithm or protocol to be initiated upon admission to the hospital for such an exacerbation to optimize therapy and patient outcomes while potentially reducing hospital length of stay.
Presented at Presented at the American College of Chest Physicians Meeting, Vancouver, BC, Nov 1–4, 2010

253E. An evaluation of inhaled bronchodilator therapy in patients hospitalized for non-life-threatening COPD exacerbations. *J. Andrew Woods, Pharm.D., BCPS*[1], Timothy H. Self, Pharm.D.[2], Shaunta' M. Ray, Pharm.D., BCPS[3], Justin B. Usery, Pharm.D., BCPS[2], Christopher K. Finch, Pharm, D., BCPS[2]; (1)Wingate University, School of Pharmacy, Wingate, NC; (2)Methodist University Hospital and University of Tennessee, Memphis, TN; (3)The University of Tennessee College of Pharmacy, Knoxville, TN
PURPOSE: COPD afflicts 24 million people and is the fourth leading cause of death in the United States. For this patient population, overuse and misallocation of respiratory care services is a common finding. In fact, nebulized bronchodilator therapy is commonly prescribed in excess to hospitalized patients despite the equivalent efficacy of metered dose inhalers with valved holding chambers. The objective of this study was to evaluate the current practice in the management of severe, non-life threatening COPD exacerbations and determine the number of missed nebulized respiratory treatments.
METHODS: This study was a retrospective chart review of all patients admitted from January 2007 to June 2008 at two academic medical centers with a primary diagnosis of severe, non-life threatening COPD exacerbation (ICD 9 code 491.21). Each patient's COPD treatment regimen was evaluated and the potential for nebulization to metered-dose inhaler (MDI) with valved holding chamber (VHC) conversion was assessed. The number of missed nebulized respiratory treatments was also identified.
RESULTS: Two hundred fifty-nine patients met inclusion criteria. Two hundred thirty-five (90.7%) patients received nebulized bronchodilators in the treatment of COPD exacerbations; 81.1% of these patients could have potentially utilized MDI with VHC. During this time, 11,422 nebulized medication doses were scheduled; however, 2,775 (24.3%) were omitted. Patients missed 23% and 26% of scheduled, nebulized albuterol and ipratropium doses, respectively. Even the long acting beta-agonist arformoterol was omitted 21.3% of the time.
CONCLUSION: The management of non-life threatening COPD exacerbations in hospitalized patients needs significant improvement. The number of missed doses of inhaled therapies is unacceptable and could potentially be reduced by more patients receiving respiratory treatments administered via MDI-VHC. Conversion to MDI-VHC could have significant impact on patient outcomes, length of stay, and medication cost. The development of a respiratory therapist driven conversion protocol should be implemented.
Presented at Presented at the American College of Chest Physicians Meeting, Vancouver, BC, Nov 1–4, 2010

Rheumatology

254E. Febuxostat (FEB) vs. Allopurinol (ALLO) in treating the hyperuricemia of gout in diabetic patients. *Michael A. Becker, M.D.*[1], Patricia MacDonald, NP[2], Barbara Hunt, M.S.[2], Robert L. Jackson, M.D.[2]; (1)University of Chicago, Pritzker School of Medicine, Chicago, IL; (2)Takeda Global Research & Development Center, Inc., Deerfield, IL
PURPOSE: Gout is commonly associated with cardiovascular, renal, and metabolic comorbidities, including diabetes mellitus. We report on baseline subject demographics and the efficacy and safety of urate-lowering (UL) therapy in diabetic gout subjects.
METHODS: In the 6-month CONFIRMS trial comparing UL with FEB vs ALLO, 312 of 2269 gouty subjects were diabetic by history (72% receiving either insulin or oral hypoglycemic agents). Subjects (baseline sUA >8.0 mg/dL) were randomized to daily FEB 40 mg or 80 mg (in subjects with eCLcr ≥30ml/min) or ALLO (300 mg if eCLcr ≥60 ml/min, 200 mg if eCLcr 30–59 ml/min). Safety was evaluated by physical/lab examination and reported adverse events (AEs).
RESULTS: Comorbidities were common among diabetic gouty subjects: CVD (86%, including: hypertension [83%], coronary artery disease [22%], arrhythmias [18%] and MI [10%]); impaired renal function (eCLcr <90 ml/min 79%, <59 ml/min 36%); hyperlipidemia (65%); and mean BMI of 36 kg/m^2. Years with gout (mean 13), sUA levels (mean 9.6 mg/dL), and tophi (18%) were similar across treatment groups. UL efficacy among diabetic subjects (final visit sUA <6.0 mg/dL) was 38% for FEB 40mg and 32% for ALLO; FEB 80 mg (75%) was superior to both (p<0.001), a finding also seen in mild and moderate CKD. Higher sUA and the presence of tophi at baseline were associated with lower UL efficacy. Non-fasting blood glucose levels remained stable during UL therapy. At least 1 AE was reported in 46%, 62%, and 66% of FEB 40 mg-, FEB 80 mg-, and ALLO-treated diabetic gouty subjects. Self-limiting diarrhea and upper respiratory infections were the most common. Serious AEs occurred in 1, 8, and 8 subjects in FEB 40 mg, FEB 80 mg, and ALLO groups, respectively.
CONCLUSION: Despite high rates of serious co-morbidities, diabetic gouty subjects tolerated UL therapy with either FEB or ALLO, but FEB 80 mg achieved goal range sUA significantly more often than ALLO at commonly utilized doses.
Presented at Presented at the European League Against Rheumatism (EULAR) 2011 Annual European Congress of Rheumatology. London, UK, May 25–28, 2011.

255E. Pharmacokinetics and pharmacodynamics of tocilizumab in systemic juvenile idiopathic arthritis. *Xiaoping Zhang, Ph.D.*[1], Peter N. Morcos, Pharm.D.[1], Fabrizio De Benedetti, M.D., Ph.D.[2], Hermine Brunner, M.D., M.S.[3], Nicolino Ruperto, M.D., M.P.H.[4], Felicity Schaefer, M.S.[1], Stephanie Roseti, RN, MSN, APN-BC[1], Andy Kenwright, B.S.[5], Alberto Martini, M.D.[4], Daniel Lovell, M.D., M.P.H.[3]; (1)Roche, Nutley, NJ; (2)IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy; (3)Pediatric Rheumatology Collaborative Study Group, Cincinnati, OH; (4)PRINTO-IRCCS Giannina Gaslini, Genova, Italy; (5)Roche, Welwyn, United Kingdom
PURPOSE: Tocilizumab (TCZ) is a humanized IgG1 monoclonal antibody against interleukin-6 receptor (IL-6R). TENDER is a phase 3 study evaluating efficacy, safety, PK, and PD of TCZ in systemic juvenile idiopathic arthritis (sJIA). PK, PD, and exposure-response relationships are reported for 1-year data.
METHODS: Patients received TCZ 8 mg/kg (body weight [BW] ≥30 kg; TCZ8) or 12 mg/kg (BW<30 kg; TCZ12) intravenous infusion every 2 weeks. Samples were collected for 12 weeks pre- and post-infusion for population PK analysis. Predose PK and PD samples were collected for 52 weeks. Area under curve (AUC_{2wk}) and maximum concentration (C_{max}) at week 12 dosing interval were estimated.
RESULTS: Among 52 TCZ8 and 50 TCZ12 patients, mean±SD age was 13.4±2.8 and 5.9±2.8 y; BW was 49.2±18.5 and 18.9±5.4 kg, respectively. For TCZ8 and TCZ12, mean±SD AUC_{2wk}, C_{min}, and

C_{max} at week 12 were 1337±409 and 1346±426 µg·d/mL, 69±25 and 71±31 µg/mL, and 226±55 and 263±54 µg/mL, respectively. Week 52 observed C_{min} was 65±31 and 77±28 µg/mL for TCZ8 and TCZ12. Predose TCZ and sIL-6R concentrations stabilized after week 12 (Table). Mean CRP and ESR levels decreased rapidly after the first dose, remaining low through week 52. Adverse events did not increase with greater TCZ exposure. Proportions of patients achieving ACR30/50/70/90 were similar across TCZ AUC_{2wk} or C_{min} exposure quartiles.

CONCLUSION: Similar PK and PD profiles confirmed two BW-based dosing regimens in sJIA patients.

Mean±SD sIL-6R, ESR, and CRP at Baseline and Weeks 2, 12, and 52

	sIL-6R, ng/mL	ESR, mm/h	CRP, mg/L
TCZ 8 mg/kg, BW ≥30 kg			
Baseline	43.0±12.9	54.0±36.9	194.37±456.23
Week 2	482.0±138.2	11.0±12.8	30.15±41.27
Week 12	752.0±214.9	4.0±3.8	0.70±1.26
Week 52	860.0±185.9	4.0±3.1	2.36±11.72
TCZ 12 mg/kg, BW <30 kg			
Baseline	42.0±11.0	60±31.3	148.24±237.18
Week 2	515.0±135.4	9.0±11.9	19.87±26.08
Week 12	771.0±247.0	3.0±2.5	2.90±18.09
Week 52	881.0±124.6	3.0±2.7	0.18±0.14

Presented at (1) EULAR (European League Against Rheumatism) Annual European Congress of Rheumatology; May 25–28, 2011; London, United Kingdom (2) American Society for Clinical Pharmacology and Therapeutics; March 2–5, 2011; Dallas, Texas

256E. Long-Term Safety of Tocilizumab in Rheumatoid Arthritis Clinical Trials. *Mark C. Genovese, M.D.*[1], Anthony Sebba, M.D.[2], Andrea Rubbert-Roth, M.D.[3], Juan J. Scali, M.D.[4], Moshe Zilberstein, M.D.[5], Liz Thompson, B.S.[6], Ronald F. van Vollenhoven, M.D.[7]; (1)Stanford University Medical Center, Stanford, CA; (2)University of South Florida, Palm Harbor, FL; (3)University of Cologne, Cologne, Germany; (4)Durand Hospital, Buenos Aires, Argentina; (5)Roche, Nutley, NJ; (6)Roche, Welwyn, United Kingdom; (7)Karolinska Institute, Stockholm, Sweden

PURPOSE: Assess long-term safety of TCZ in RA patients.

METHODS: Data from patients receiving ≥1 TCZ dose from initial exposure through 2/17/10 and pooled data from controlled trials and long-term extension studies.

RESULTS: Patients (N=4009) received TCZ (median[mean]) duration–3.6 (3.1) years; total observation time–12,293 patient-years (PY). Rates of SAEs, serious infections (SIs), MI, and stroke remained stable over time (Table) and are consistent with RA population reports. Overall AEs–314.6/100 PY(95% CI:311.5, 317.7); infections were most frequent AE(103.7/100 PY, 95%CI:101.9, 105.5). Rate of AEs leading to withdrawal was 5.2/100 PY; most common AEs leading to withdrawal–laboratory abnormalities (1.1/100 PY), infections/infestations (1.0/100 PY), and neoplasms (0.7/100 PY). Overall SAEs–14.7/100 PY (95%CI:14.0, 15.4); infections were most frequent SAE (4.6/100 PY; 95%CI:4.3, 5.0). Rate of GI perforations–0.24/100 PY (95%CI:0.17, 0.37) is consistent with previous reports. MI and stroke rates were, respectively, 0.3/100 PY (95%CI:0.2, 0.4) and 0.2 (95%CI:0.1, 0.3), stable over time and did not exceed expected rates (MI, 0.4-0.8/100 PY; stroke, 0.5–0.9/100 PY).[3-5] Eight patients withdrew due to anaphylactic reactions.

CONCLUSION: Rates of SAEs, SIs, and cardiovascular events remained stable with continued TCZ exposure in long-term OL clinical trials. These results demonstrate that the safety profile of TCZ does not change with longer exposure.

Event Rate/100 PY (95% CI) Over 12-Month Periods

	0–12	13–24	25–36	37–48
AEs	418.4	297.9	273.3	251.4
	(411.6, 425.2)	(291.8, 304.1)	(267.1, 279.6)	(244.8, 258.0)
SAEs	15.7	13.9	15.2	14.4
	(14.4, 17.1)	(12.6, 15.2)	(13.7, 16.7)	(12.8, 16.0)
SIs	4.6	3.9	5.2	4.9
	(3.9, 5.4)	(3.2, 4.7)	(4.3, 6.1)	(4.0, 5.9)
MI	0.3	0.2	0.3	0.5
	(0.1, 0.5)	(0.1, 0.4)	(0.1, 0.6)	(0.3, 0.9)
Stroke	0.3	0.1	0.2	0.1
	(0.1, 0.5)	(0.0, 0.3)	(0.1, 0.4)	(0.0, 0.3)

Substance Abuse/Toxicology

257. Synuclein Gene Microsatellite Length Associated with Alcohol and Cocaine Addiction. Vanessa L. Herring, B.S.[1], Wesley M. Pitts Jr., M.D.[2], *S. Casey Laizure, Pharm.D.*[1]; (1)University of Tennessee, Dept of Clinical Pharmacy, Memphis, TN; (2)Veteran Affairs Medical Center, Memphis, TN

PURPOSE: Alpha- is a highly expressed presynaptic protein that acts as a negative modulator of dopamine activity in the central nervous system. An allele-length variation in a microsatellite (NACP-Rep1) of the alpha- gene has been previously reported to be associated with alcoholism. Since dopamine is the primary neurotransmitter of the reward pathway that underlies all addictions, we hypothesized that other addiction disorders would show genetic variation in the NACP-Rep1 microsatellite consistent with alcoholism.

METHODS: This hypothesis was tested by comparing the NACP-Rep1 microsatellite allele lengths in three groups: 1 with alcoholism, 2)cocaine addicted patients, and 3)a control group without evidence of addiction. All subjects (n=61) were male, African-American patients from a Veteran Affairs Medical Center. Subjects underwent an interview to assess drug use, evaluation of their medical records, completion of an AUDIT (Alcohol Use Disorders Identification Test), and blood sample collection. Subject DNA was isolated from blood, NACP-Rep1 sequence amplified, and allele-length determined by electrophoresis.

RESULTS: The table summarizes NACP-Rep1 base pair () allele lengths by group.

			269-Containing Pairs	Major Pair Frequency		
Group	n	Age (yrs)	At least one 269 bp	267/269 bp	267/273 bp	AUDIT
Alcohol	25	55±8.7	56 %	30 %	0 %	28.6±6.4
Cocaine	18	55±6.2	61 %	22 %	6 %	8.2±9.2
Control	18	48±11.3	22 %	0 %	22 %	3.8±3.5

The probability of being a carrier of at least one 269bp allele-length was greater in the alcohol and cocaine groups when compared to the control group (p=0.036; χ^2 distribution). Also notable was the striking difference in the major pair frequency between the alcohol and control groups.

CONCLUSION: The NACP-Rep1 allele length of 269 is associated with alcohol and cocaine addiction; a finding that is consistent with in vitro alpha- expression studies and the dopamine deficiency hypothesis of addiction.

Transplant/Immunology

258. Evaluation of a pre-emptive strategy for CMV disease prevention in cardiac transplant patients. *Edward T. Horn, Pharm.D., BCPS*[1], Dana K. Reither, Pharm.D.[2], Lauren King, Pharm.D.[3], Stephen H. Bailey, M.D.[1], Walter E. McGregor, M.D.[1], Robert J. Moraca, M.D.[1], George G. Sokos, D.O.[1], Raymond L. Benza, M.D.[1], Srinivas Murali, M.D.[1]; (1)Allegheny General Hospital, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (3)Mylan School of Pharmacy Duquesne University, Pittsburgh, PA

PURPOSE: To determine the rate of cytomegalovirus (CMV) infection, based on serology, utilizing a modified pre-emptive antiviral strategy. ISHLT guidelines recommend valganciclovir (VGC) for 3 months in either D+/R- or D+/R+ patients.

METHODS: Retrospective analysis of 39 OHTx patients from February 2008-July 2010 given either acyclovir (ACV) or VGC based upon donor (D) and recipient (R) serology for 3 months post OHTx. CMV viremia was determined by polymerase chain reaction (PCR) with any value > 600 copies/ml deemed positive. CMV syndrome was defined as CMV viremia by PCR combined with fever, malaise, leukopenia, and/or thrombocytopenia. CMV tissue invasive disease was defined as end-organ infection with tissue diagnosis. Rejection was defined as any biopsy > ISHLT grade 2R. Standard immunosuppression included basiliximab, tacrolimus, mycophenolate, and steroids. Logistic regression and χ^2 tests were used to determine associations between risk factors and CMV disease occurance. Pre-Emptive CMV Prophylaxis Strategy (all therapy given for 3 months)

D+/R- VGC 900mg Daily
D+/R+ ACV 400mg BID
D-/R+ ACV 400mg BID
D-/R- ACV 400mg BID

RESULTS: Of 39 OHTx, 37 had at least 30 days of follow-up. 11/37 patients (29.7%) developed 12 cases of CMV viremia. Viremia frequency rates were: CMV D+/R- 6/15 (40%); D+/R+ 3/12 (25%); D-/R+ 1/6; D-/R- 1/4. 83% of CMV D+/R- patients developed CMV viremia after prophylaxis expired. CMV viremia did not appear to impact rejection rates between groups. Of the 12 cases of CMV viremia, 9 were asymptomatic (75%). 25% had CMV syndrome. No cases of tissue invasive disease were reported. The only significant correlation was that VGC was shown by logistic regression to prolong the time to viremia by 3 months (p=0.01).

CONCLUSIONS: We feel that a pre-emptive strategy is effective to prevent CMV disease in OHTx patients. VGC could be extended to 6 months in CMV D+/R- group. The use of VGC in other groups should be researched further.

259. Corticosteroid withdrawal in renal transplant recipients: an analysis of the Mycophenolic Acid Observational Renal Transplant Registry. *Kimi Ueda Stevenson, Pharm.D., BCPS*[1], Anne Wiland, Pharm.D., BCPS[2], V. Ram Peddi, M.D.[1]; (1)California Pacific Medical Center, San Francisco, CA; (2)Novartis Pharmaceutical Corporation, East Hanover, NJ

PURPOSE: Corticosteroid withdrawal (CSW) protocols are desired by renal transplant recipients to potentially reduce adverse effects (AEs). This analysis compared outcomes in patients who received CS to those who did not.

METHODS: Using data from the Mycophenolic Acid Observational Renal Transplant registry, a prospective study of patients receiving mycophenolate (MPA) either as enteric-coated mycophenolate sodium (EC-MPS) or mycophenolate mofetil (MMF), 12-month CSW protocol outcomes were analyzed. CSW was defined as withdrawal of steroids by 3-months post-transplant.

RESULTS: A total of 847 tacrolimus-treated patients (352 CSW, 495 CS) were included. Demographics were similar. More patients in the CSW group received depleting antibody induction (85.8%/ 63.3%). Tacrolimus trough levels were similar. Biopsy-proven acute rejections (BPAR) were low (9.6% CS/7.4% CSW, p=0.20). Interim results at 1, 3, 6 and 12 months showed that significantly (p≤0.01) more of the CS patients were maintained on full dose MPA (CS/CSW: 83.0/68.5%; 73.1/52.6%; 58.4/37.6%; 51.3/36.1%). A significantly higher percentage of CS patients treated with EC-MPS were maintained on full MPA doses compared to MMF-treated patients. This was not observed in the CSW group. There was a statistically significant difference in graft survival (99.4/97.4%, p=0.02) favoring the CSW group. Patient survival was similar. The CS patients had a higher mean serum creatinine (CS 1.53/CSW 1.40 mg/dL, p=0.02) and there were no differences in reported infections (including CMV and BK), bone disease, diabetes, malignancies, cardiovascular or GI events. More reported GI AEs occurred in the MMF-treated CSW patients (73.6% MMF/ 66.1% EC-MPS, p=0.15) and more hematological AEs in the CSW patients (61.4%/28.5%, p≤0.01), mainly driven by leukopenia.

CONCLUSIONS: CS allowed for better tolerance of full dose MPA, however, there was no difference in BPAR. Graft survival was better in the CSW group at 1 year, however, longer follow-up is needed to assess long-term outcomes of CSW.

260. Early analyses of renal transplant recipients who received expanded criteria donor kidneys from the Mycophenolic Acid Observational Renal Transplant Registry. *Kimi Ueda Stevenson, Pharm.D., BCPS*[1], Anne Wiland, Pharm.D., BCPS[2], V. Ram Peddi, M.D.[1]; (1)California Pacific Medical Center, San Francisco, CA; (2)Novartis Pharmaceutical Corporation, East Hanover, NJ

PURPOSE: The Mycophenolic Acid Observational Renal Transplant Registry, a prospective study of patients receiving mycophenolic acid (MPA) therapy, is designed to determine effectiveness, tolerability and safety of enteric-coated mycophenolate sodium (EC-MPS) versus mycophenolate mofetil (MMF) regimens. The objective of this analysis was to compare 12-month outcomes in patients who received expanded criteria donor (ECD) kidneys to those who did not.

METHODS: Based on local practices at 40 US sites, outcomes analyzed included: graft survival, patient survival, first biopsy-proven acute rejection (BPAR), adverse events (AEs), serum creatinine and proportion of patients maintained on full MPA dose (1.44/2.0 g/day, EC-MPS/MMF). A total of 102 ECD (73 EC-MPS/29 MMF) and 832 non-ECD (557 EC-MPS/275 MMF) patients were included.

RESULTS: Donors (60.7/39.0 yrs, p≤0.01) and recipients (61.6/50.1 yrs, p=0.03) were older in the ECD group. More African American patients received ECD kidneys (32.3/ 23.6%, p=0.07). The majority of patients received induction therapy (99% ECD, 97% non-ECD), tacrolimus (97% ECD, 96% non-ECD) and steroids (69% ECD, 66% non-ECD) for maintenance therapy. At 1, 3, 6 and 12 months, more non-ECD patients received full MPA doses (non-ECD/ ECD: 78.2/ 71.0%, p=0.12; 67.4/ 53.6%, p=0.01; 51.9/ 42.3%, p=0.14; 45.7/41.0%, p=0.50). Comparable 12-month effectiveness, tolerability and safety outcomes were achieved in both groups whether they received EC-MPS or MMF. Comparing 12-month outcomes in ECD to non-ECD patients regardless of MPA type, BPAR (10.0/9.1%, p=0.91) and graft survival (94.5/97.5%, p=0.08) were similar whereas mean serum creatinine (1.75/1.46 mg/dL, p≤0.01) was higher in the ECD group. Patient survival was 98.8% in the ECD and 98.9% in the non-ECD patients. There were no differences in AEs (infections, diabetes, gastrointestinal, neoplasms, hematological) between the groups.

CONCLUSION: Graft survival and BPAR were similar between ECD and non-ECD patients. However, as expected, patients who received ECD kidneys exhibited higher mean serum creatinines.

261. Comparisons of enteric-coated mycophenolate sodium and mycophenolate mofetil outcomes from the Mycophenolic Acid Observational Renal Transplant Registry. *Ali Olyaei, Pharm.D., BCPS*[1], Anne Wiland, Pharm.D., BCPS[2], Lonnie Smith, Pharm.D.[3]; (1)Oregon State University/Oregon Health and Sciences University, Portland, OR; (2)Novartis Pharmaceutical Corporation, East Hanover, NJ; (3)University of Utah Hospitals and Clinics, Salt Lake City, UT

PURPOSE: The Mycophenolic Acid Observational Renal Transplant Registry is a prospective study of de novo renal transplant patients receiving mycophenolic acid (MPA) therapy designed to determine effectiveness, tolerability and safety of enteric-coated mycophenolate sodium (EC-MPS) versus mycophenolate mofetil (MMF)-based immunosuppressive regimens.

METHODS: Based on standard-of-care at 40 centers, outcomes analyzed included: graft survival, patient survival, first biopsy-proven acute rejection (BPAR), mean serum creatinine, adverse event (AE) rates, and percentages of patients maintained on full MPA dose (1440 or 2000 mg/day, EC-MPS or MMF respectively). Preliminary data from 901 patients (age 51.5, 64% male, 43% living donor transplant recipients) receiving tacrolimus were analyzed.

RESULTS: Interim results at 1, 3, 6 and 12 months from 613 EC-MPS and 288 MMF patients showed that more EC-MPS patients were maintained on full doses of MPA (ECMPS/MMF: 79.2/71.2%, p=0.01; 68.6/55.6%, p<0.01; 52.7/43.0%, p=0.02; 47.3/39.4%, p=0.08). Actual mean MPA doses (SD) standardized to MMF dosing for EC-MPS/MMF were: 1853 (378) mg v. 1789 (441) mg, p=0.04; 1753 (465) mg v. 1648 (493) mg, p<0.01; 1590 (521) mg v. 1494 (529) mg, p=0.03; and 1532 (511) mg v. 1453 (522) mg, p=0.08 at months 1, 3, 6 and 12 post-transplant. Comparable 12-month clinical outcomes were achieved for effectiveness outcomes, tolerability and safety for both EC-MPS and MMF. There were no significant differences between EC-MPS and MMF-treated renal transplant recipients in graft survival (96.9/97.6%, p=0.48), patient survival (99.3/98.4%, p=0.31), BPAR (9.6/8.0%, p=0.30), mean serum creatinine (1.49/1.49 mg/dL, p=0.97) or cumulative incidence of early AEs by organ system, infections or neoplasia.

CONCLUSION: These results show that the majority of renal transplant recipients who received tacrolimus as maintenance immunosuppression are maintained on full doses of MPA early post-transplant. Early significant dosing differences are seen between EC-MPS and MMF which may impact outcomes at later time points in this study.

262. African American renal transplant one year outcomes from the Mycophenolic Acid Observational Renal Transplant Registry. *Lonnie Smith, Pharm.D.*[1], Anne Wiland, Pharm.D., BCPS[2], Ali Olyaei, Pharm.D., BCPS[3]; (1)University of Utah Hospitals and Clinics, Salt

Lake City, UT; (2)Novartis Pharmaceutical Corporation, East Hanover, NJ; (3)Oregon State University/Oregon Health and Sciences University, Portland, OR

PURPOSE: The Mycophenolic Acid Observational Renal Transplant (MORE) Registry, a prospective study of renal transplant recipients receiving mycophenolic acid (MPA) therapy, is designed to determine effectiveness, tolerability and safety of enteric-coated mycophenolate sodium (EC-MPS) vs mycophenolate mofetil (MMF) regimens. This analysis of the MORE registry compares outcomes of African American (AA) to non-AA patients.

METHODS: Based on local practices at 40 centers, outcomes analyzed included: graft survival, patient survival, first biopsy-proven acute rejection (BPAR), adverse events (AEs), serum creatinine and proportion of patients maintained on full MPA dose (1.44/2.0 g/day, EC-MPS/MMF). A total of 217 AA (149 EC-MPS/68 MMF) and 684 non-AA (464 EC-MPS/220 MMF) tacrolimus-treated patients were included.

RESULTS: AAs were less likely to receive a living donor (24/49%) and more likely to experience delayed graft function (21/14%) than non-AAs. At 1, 3, 6 and 12 months, more AA EC-MPS patients received full MPA dose (EC-MPS/MMF: 82.2/70.8%, p=0.07; 65.0/54.8%, p=0.21; 55.2/36.0%, p=0.05; 45.0/41.5%, p=0.71). Comparable 12-month effectiveness, tolerability and safety outcomes were achieved in both groups. Comparing EC-MPS to MMF in the AAs, there was similar graft survival (94.5/97.9%, p=0.58), BPAR (14.5/13.1%, p=0.75), mean serum creatinine (1.67/1.74 mg/dL, p=0.77) and reported AEs by organ system, infections or neoplasia. Patient survival (99.2/96.5%, p=0.04) was higher in the AA EC-MPS group. Similar outcomes were observed between EC-MPS and MMF in the non-AAs. Comparing 12-month outcomes in AA to non-AA patients regardless of MPA type, BPAR (14.1/7.5%, p=0.01), graft survival (95.5/97.7%, p=0.07) and serum creatinine (1.67/1.43 mg/dL, p<0.01) were worse in the AA patients whereas patient survival (98.3/99.2%, p=0.69) was similar.

CONCLUSION: More AA patients treated with EC-MPS were maintained on full doses of MPA. Despite this, AAs exhibited higher BPAR, serum creatinine and worse graft survival than non-AAs which may impact clinical outcomes at later timepoints in this study.

263E. Steroid-free, calcineurin inhibitor minimizing regimen with long-term mycophenolate mofetil monotherapy for HLA identical living donor kidney transplantation: long-term outcomes. *Adele R. Shields, Pharm.D.*[1], Rita R. Alloway, Pharm.D.[1], Amit Govil, M.D.[1], Gautham Mogilishetty, M.D.[1], Michael Cardi, M.D.[2], Shahzad Safdar, M.D.[2], Shaoming Huang, M.D.[2], E. Steve Woodle, M.D.[1]; (1)University of Cincinnati, Cincinnati, OH; (2)The Christ Hospital, Cincinnati, OH

PURPOSE: This study evaluated a corticosteroid-free, calcineurin inhibitor (CNI) minimizing, short-term SRL (SRL) regimen with long-term mycophenolate mofetil (MMF) monotherapy in HLA-identical living donor kidney transplant patients.

METHODS: Data from 36 HLA-identical transplant patients from 2002–2010 was prospectively collected. 2 consectutive patient cohorts were evaluated. 20 patients received tacrolimus (TAC) (target trough 4–8 ng/ml), SRL (target trough 6-10 ng/ml), and MMF (2 gm/day) started 2 days pretransplant. The next 16 patients received MMF starting 1 week pretransplant, SRL on day of transplant and TAC posttransplant day (PTD) 1. If no acute rejection (AR) from PTD 60–90, TAC dose was reduced 50% and discontinued by PTD 90–120. Corticosteroids were not given. If no AR by PTD 300, SRL was tapered off over 2 months leaving MMF monotherapy. AR diagnosed by Banff97 biopsy criteria.

RESULTS: Demographics and outcomes are in the table. 100% of patients (12/12) who reached 5 years posttransplant were maintained on MMF monotherapy. Primary reason for not being withdrawn from TAC was SRL or MMF intolerability. 4 patients (11%) required premature SRL discontinuation due to intolerability. There was no CMV disease, PTLD, malignancy, or BK nephropathy. Overall pt and death-censored graft survival are 94.4%. 2 graft losses (5.6%) were due to AR and chronic allograft nephropathy (CAN). One death was West-Nile viral meningoencephalitis on PTD 261 and one death was unexplained sudden death on PTD 163.

Demographics and Outcomes	
Median Follow-up(days)	1738 (153-3197)
Mean Age(years)	45.1 ± 9.8
Female	36%
Repeat transplant	3%
Pretxp DM	39%
Mean Class 1 Peak PRA%	11.8 ± 25.5
Mean Class 2 Peak PRA%	9.5 ±22.1
Mean Time to DC-Graft Loss(days)	660.5 ± 95.5
CMV Viremia	3.8%
CAN	5.6%
CNI toxicity	5.6%

CONCLUSION: A corticosteroid-free, CNI-sparing immunosuppressive regimen with eventual weaning to MMF monotherapy provides excellent patient survival, graft survival, and renal function with minimal posttransplant complications in HLA-identical kidney transplant recipients.

Presented at The American Transplant Congress, Philadelphia, Pennsylvania, May 1–4, 2011.

264. A prospective, single center, pilot study of pretransplant thymoglobulin administration and early corticosteroid withdrawal in living donor renal transplant recipients. *Adele R. Shields, Pharm.D.*[1], Rita R. Alloway, Pharm.D.[1], Michael Cardi, M.D.[2], Shahzad Safdar, M.D.[2], Shaoming Huang, M.D.[2], Paul Brailey, Ph.D.[1], Alin Girnita, Ph.D.[1], Rino Munda, M.D.[1], Tonya Dorst, M.A.[1], E. Steve Woodle, M.D.[1]; (1)University of Cincinnati, Cincinnati, OH; (2)The Christ Hospital, Cincinnati, OH

PURPOSE: Rabbit anti-thymocyte globulin (rATG), is widely used in renal transplant patients for induction. However, its use in a pretransplant regimen has not been evaluated. The purpose was to evaluate safety and effectiveness of rATG starting 4 days prior to transplant.

METHODS: This was an IRB approved, prospective, pilot feasibility study. Patients were eligible if they received a primary non-HLA identical living donor transpalnt. Patients received tacrolimus (10–15 ng/mL) and MMF at time of transplant. Methylprednisolone was given as premedication (500 mg with 1st dose, 250 mg with subsequent 2 doses, 125 mg with 4th dose). Group 1 received 4 doses at 1.5 mg/kg/day on Days -4, -2, 0, and 2. Group 2 received 3 doses at 1.5 mg/kg/day on Days -4 and -2, and 3 mg/kg on Day 0.

RESULTS: 11 patients were enrolled. Demographics and outcomes are in Table 1. Infusion-related toxicities are in Table 2. Patient and graft survival are 100% at 6 months and 1 year. 2 patients had an acute rejection.

	Demographics/Outcomes		
	Group 1 (n=6)	Group 2 (n=5)	p
Mean # rATG	4 ± 0	3.2 ± 0.4	NS
Mean mg/kg rATG	5.8 ±0.7	5.6 ±0.9	NS
Age	50.1 ±17.1	36.1 ±12.5	NS
Female	16.7%	40%	NS
AA	0	40%	NS
Acute Rejection	16.7%	20%	NS
Mean Scr Day30	1.6 ±0.6	1.5 ±0.7	NS
Day180	1.5 ±0.7	1.7 ±0.3	NS
Mean CD3 Day -4	1063.5 ±754.5	942.5 ±181.6	NS
Day -2	51.2 ±79	143 ±130.1	NS
Day 0	18.2 ±29.7	113 ±95.1	0.04
Day 1	2 ±1.0	4.3 ±4.2	NS
Day 2	4.5 ±5.2	8.3 ±11	NS
Day 3	3 ±0	44 ±69.3	NS
Day 4	4.8 ±3.8	43.3 ±72	NS

Toxicities	
Fever/Chills	64%
HTN	18%
Admit Observation	18%
Body-aches	18%
Nausea/vomiting	9%
WBC < 2000 cells	0
PLT < 100,000 cells	18%

CONCLUSION: rATG administration prior to txp is well tolerated and effective. These preliminary results support further study of pretxp rATG in a larger population.

265. Pepper mould contamination risk to immunocompromised. *John D. Cleary, Pharm.D.*[1], Jessica Robinson, Pharm.D.[2]; (1)University of Mississippi Medical Center, Jackson, MS; (2)University of Charleston School of Pharmacy, Charleston, WV
PURPOSE: Aeresolization of pepper in an immunocompromised patient's inhalation space could increase risk for mould infection. Our purpose was to assess potential infection risk from contamination of this food product.
METHODS: Pepper samples were purchased from retail settings over a 3 year period. Pre-culture preparation included: weighing 1 g pepper; normal saline suspension 5mL containing penicillin/streptomycin and vancomycin; 30 second vortexing; then 30 minute gravity separation. Culture Preparation involved preparing 3 serial 1:10 dilutions, plating 0.1 mL supernatant on a Sabhi agar dish in duplicate. These studies were performed in triplicate. Cultures were incubated at 30°C for up to 14 days with daily monitoring. Cultures were identified & counted using routine staining under microscopy. Galactomannan testing was performed on samples using the Platelia™ Aspergillus EIA test.
RESULTS: A total of 95 black pepper samples were collected from 23 states and 33 cities across the United States and 6 non-US sites. Samples included ground pepper and/or peppercorn. Positive samples (N=18; 20.9% of total) were more frequent in samples from Southern (61.1% of positives) compared to Western (22.2%), Midwestern (11.1%), & Northern (5.6%) states. International (N=9) was observed to have 33% positive. Analysis of positive samples by manufactures revealed that national brand name products (26.7%) were less common compared to local brands (58.6%). Sterilization (ethylene oxide) processes were used more frequently in national brands (86.7%) compared to local brands (3.4%) in positive samples. Organisms isolated include Aspergillus and Rhizopus species. All culture positive samples identifiable via galactomannan testing.
CONCLUSION: Patients receiving immune modulators (i.e., TNF inhibitors) and common immune-suppressants are not routinely warned of this risk and should be educated by the pharmacist to avoid pepper. Our plan is to genotype fungal isolates and compare with isolates identified in patients with invasive disease in attempts to further elucidate infection risk.

266. Use of HMG-CoA reductase inhibitors in liver transplant patients with recurrent Hepatitis C Virus. *Sarah E. Yost, Pharm.D.*[1], Heather J. Johnson, Pharm.D.[2], Kristine S. Schonder, Pharm.D.[3], Michael DeVera, M.D.[4], Kapil B. Chopra, M.D.[5]; (1)University Medical Center, Tucson, AZ; (2)UPMC Department of Pharmacy and Therapeutics, Pittsburgh, PA; (3)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (4)Loma Linda University Transplantation Institute, Loma Linda, CA; (5)University of Pittsburgh Medical Center, Division of Gastroenterology, Hepatology, and Nutrition, Pittsburgh, PA
PURPOSE: The aim of this study was to evaluate the antiviral suppressing effects and safety of statins in patients with Hepatitis C Virus (HCV) recurrence after liver transplantation.
METHODS: A retrospective cohort study of patients with HCV that received a liver transplant and statin therapy following documented HCV recurrence were included. The area under the HCV viral load curve (AUC) was determined. Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin were evaluated at the time of statin initiation and 3, 6, and 12 months post statin initiation.
RESULTS: Twenty nine patients with HCV recurrence after liver transplantation were started on statin therapy after HCV recurrence. Of these patients, only ten patients were included for AUC analysis. The mean atorvastatin equivalent dose was 15.4 mg ± 9.2 mg. The mean time from transplant to start of statin therapy was 1316.2 days ± 1029.3 days (range 162 to 3824 days). The majority of patients (92%) were at goal at statin initiation, with a total cholesterol less than 200 mg/dl. The majority of the AUC HCV viral load per time in days remained at baseline or decreased over time. No significant changes from baseline in aminotransaminases and total bilirubin were seen post statin initiation.
CONCLUSION: Use of statins in liver transplant patients with HCV recurrence did not appear to negatively affect the HCV viral load. Statins did not appear to significantly increase aminotransaminases and total bilirubin and can be used safely in liver transplant patients with HCV recurrence.

267. Impact of rituximab on donor specific antibody burden in solid organ transplant recipients. Dina Benani, Pharm.D., Angela Bingham, Pharm.D., Rachel Kruer, Pharm.D., *Liana Mark, Pharm.D.*, Laura Lees, Pharm.D., Kenneth Shermock, Pharm.D., Ph.D., Lindsey Lombardi Thomas, Pharm.D., Christopher R. Ensor, Pharm.D.; The Johns Hopkins Hospital, Baltimore, MD
PURPOSE: Rituximab results in the selective depletion of circulating, non-splenically-sequestered, CD-20 expressing B-lymphocytes (CD20BL) and has been associated with down-regulation of donor-specific antibody (DSA) burden in solid organ transplant recipients (SOTR). Thus, we performed a retrospective single-center study to characterize the impact of rituximab on DSA burden in SOTRs.
METHODS: Medical records of 104 adult SOTRs who received rituximab from January 1, 2005 to February 28, 2010 were reviewed. We assessed the percentage of circulating CD20BLs at day three post-rituximab and absolute lymphocyte count (ALC) for seven post-dose days. DSA mean fluorescent intensity by solid phase assay was evaluated and characterized qualitatively based on its propensity to yield a positive crossmatch either by flow cytometry or complement-dependent cytotoxicity immediately prior to rituximab administration, within the first 14 post-dose days, and at post-dose days 30, 60, 90, 120, and 180.
RESULTS: Recipients of kidney (n=99), lung (n=4), and heart (n=1) transplants were included. Mean age was 44 (SD 14) years, 61% male; many patients received concomitant intravenous-immunoglobulins (70%) or plasmapheresis (79%). 138 dose-occurrences of rituximab 375mg/m^2 were administered to 104 patients; for which 117 occurrences had DSA data available. CD20BL depletion to <1% occurred after 94% of occurrences, and median ALC fell from 605 (IQR 200-1405)/mm^3 to 200 (IQR 69-510)/mm^3. In occurrences where the baseline crossmatch was positive (n=91/117), 28% (n=26/91) experienced substantial DSA depletion to yield a negative crossmatch. Of these, 19% (n=5/26) later developed recurrent positivity. In occurrences where the baseline crossmatch was negative (n=26/117), 89% (n=23/26) remained persistently negative, while 11% (n=3/26) developed positivity.
CONCLUSIONS: Rituximab effectively depleted CD20BLs and ALCs in study SOTRs. Despite this, only 28% developed therapeutic DSA depletion. Conversion from a negative to positive crossmatch was suppressed in 89% of occurrences after rituximab. We believe prospective evaluation of rituximab use in SOTRs is warranted.

268E. Comparison of calcineurin inhibitor administration post-heart transplantation. *Cory Blacksmith, Pharm.D.*, Jodie M. Fink, Pharm.D., BCPS; Cleveland Clinic Foundation, Cleveland, OH
PURPOSE: The Cleveland Clinic heart transplant protocol was recently revised to recommend oral, rather than intravenous, calcineurin inhibitor (CNI) therapy in adult heart transplant recipients post-operatively. The protocol was changed in January 2010 due to a concern that intravenous administration of CNIs may contribute to post-operative nephrotoxicity. Thus, the evaluation of the safety and efficacy of the revised protocol comparing the immediate post-operative administration of oral vs. intravenous CNIs in adult heart transplant recipients was performed.
METHODS: A non-interventional, retrospective medical record review to evaluate adult (≥18 years old) heart transplant recipients receiving CNI therapy immediately post-operative from January 1, 2008 to February 28, 2011 for the median change in serum creatinine (SCr) post-transplantation. Secondary endpoints include time (days) to reach target trough level, episodes of rejection within the first three months of transplant, and time (days) CNI therapy was held. Heart transplant recipients who received induction therapy (i.e., thymoglobulin or basiliximab) or everolimus will be excluded. Data describing demographics, renal function, rejection episodes, and immunosuppression dosing and monitoring will be collected.
RESULTS: Fifty-one patients were enrolled in the intravenous group and 22 patients in the oral group. No difference in baseline demographics was noted. Median change in SCr post-transplantation was 0.39 mg/dL vs. 0.44 mg/dL, percentage of patients and median

time CNI therapy held post-operatively was 22% (1.75 days) vs. 27% (1.25 days), median time to reach target trough level was 9.5 days vs. 9.5 days, and percentage of patients with episodes of rejection was 27.4% vs. 19.0% in the intravenous and oral groups, respectively.
CONCLUSION: A similar safety and efficacy profile was seen between the post-operative administration of oral vs. intravenous CNI therapy. Based on these results, the protocol revisions will continued to be used due to the ease of administration.
Presented at Spring 2011 Pharmacotherapy Update of the Ohio College of Clinical Pharmacy, Warrensville Heights, OH, May 23, 2011.

269. Cardiovascular events and CV-related mortality after renal transplantation: effect of maintenance steroid therapy and preexisting coronary artery disease. *Adele R. Shields, Pharm.D.*[1], Nicole M. Schmidt, Pharm.D.[1], Rita R. Alloway, Pharm.D.[1], Michael Cardi, M.D.[2], Amit Govil, M.D.[3], Dennis Hanseman, M.S.[1], E. Steve Woodle, M.D.[1]; (1)University of Cincinnati, Cincinnati, OH; (2)The Christ Hospital, Cincinnati, OH; (3)The Health Alliance, Cincinnati, OH
PURPOSE: Early corticosteroid withdrawal (ECSWD) reduces cardiovascular (CV) risk, however long term studies translating CV risk reduction into CV events (CVE) have not been conducted. The purpose of this study was to compare actual CVE for ECSWD and chronic corticosteroid (CCS) maintenance therapy, as well as determining the impact of preexisting coronary artery disease (CAD).
METHODS: Prospective CVE data was collected and entered into an electronic database in 1004 renal transplant patients. 714 patients received ECSWD and 290 patients received CCS regimens from 1998-2010. CVE were defined as sudden death/CV-related death, myocardial infarction, angina/unstable angina, CVA/TIA, or CV procedure. Statistical analyses included Chi square, student t-test, and Kaplan-Meier (KM) using log rank.
RESULTS: Demographics and patient outcomes are in the table. 267 CVE occurred in 171 patients [100 ECSWD patients (14%) vs 71 CCS patients (24.5%), p=0.0001]. Mean corticosteroid dose in the CCS group was 6.9±5.5mg at 1 year and 5±1.6mg at 4 years. KM analysis demonstrated lower CVE rates with ECSWD (p<0.02). CV-related mortality (p=0.78) and overall pt mortality (p=0.54) however were not different. Additional KM analysis showed that the difference in CVE rates between ECSWD and CCS was primarily observed in patients without preexisting CAD (p=0.004).

	ECSWD (n=714)	CCS (n=290)	p
Mean follow-up (days)	1560.3 ± 1007.9	2217.4 ± 1465.6	<0.0001
Mean age (years)	49.3 ± 13.4	47.5 ± 12.4	0.05
Female	272 (38.1%)	133 (45.9%)	0.02
African American	146 (20.4%)	81 (27.9%)	0.01
Repeat transplant	68 (9.5%)	42 (14.5%)	0.02
Pre-transplant DM	216 (30.3%)	76 (26.2%)	0.19
Pre-transplant CAD	112 (15.7%)	33 (11.4%)	0.08

CONCLUSION: Kidney transplant patients who undergo ECSWD have a significantly higher CVE-free survival by KM despite having more CAD pretransplant. The benefit in CVE reduction seen with ECSWD is primarily in patients without pre-existing CAD. The decrease in CVE does not become apparent until 3 to 4 years posttransplant.

270. Impact of immunosuppressant regimen on the onset of hyperlipidemia in kidney transplant recipients. Shelby L. Corman, Pharm.D., M.S., BCPS, *Kristine S. Schonder, Pharm.D.*; University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Various immunosuppressive agents have been associated with hyperlipidemia. We sought to explore whether steroid-free tacrolimus-based regimens affect the time to development of hyperlipidemia after kidney transplant.
METHODS: This retrospective cohort study included patients who underwent a first kidney transplant between January 1996 and December 2009. Patients who had hyperlipidemia or were taking cholesterol-lowering medications at baseline were excluded. Patients were separated into four groups according to their baseline immunosuppressant regimen: tacrolimus monotherapy (group 1), dual therapy with tacrolimus and mycophenolate mofetil (group 2), triple therapy with tacrolimus, mycophenolate mofetil, and prednisone (group 3), and dual therapy with tacrolimus and prednisone (group 4). Patients receiving other regimens were excluded. The primary outcome was the time to development of hyperlipidemia, defined as a total cholesterol ≥200 mg/dl, low-density lipoprotein (LDL) ≥130 mg/dl (≥100 mg/dl for patients with diabetes), or triglycerides ≥150 mg/dl and/or initiation of cholesterol-lowering medications.
RESULTS: A total of 1912 patients received a kidney transplant during the study period. Of these, 919 were excluded due to baseline use of cholesterol-lowering medications (n=491), baseline hyperlipidemia (n=192), previous transplant (n=107), use of other immunosuppressant regimens (n=79), or missing laboratory or medication records (n=50). A Kaplan-Meier analysis showed that time to hyperlipidemia did not differ significantly between the groups (p=0.193).

Group	n	Days to hyperlipidemia
1	631	33.3
2	178	36.0
3	104	40.4
4	80	50.3

A Cox proportional hazards model including study group, age, sex, race, and diagnosis of diabetes as covariates showed that only female sex (HR=1.27; p<0.001) and white race (HR=1.30; p=0.003) were significant predictors of hyperlipidemia.
CONCLUSION: Steroid-free immunosuppressive regimens did not reduce the time to onset of hyperlipidemia after kidney transplant.

271. A single center experience with conversion between two generic tacrolimus formulations. *Eric Tichy, Pharm.D., BCPS*[1], Lisa M. McDevitt, Pharm.D., BCPS[2]; (1)Yale-New Haven Hospital, New Haven, CT; (2)Massachusetts College of Pharmacy and Health Sciences, Boston, MA
PURPOSE: The first generic tacrolimus product gained Food and Drug Administration (FDA) approval in August 2009 and as of June 2011 there are four generic formulations available in the US market. Reports of conversion between brand tacrolimus and Sandoz™ generic tacrolimus have previously demonstrated the safety of brand to Sandoz™ generic conversion. This prospective, observational trial sought to determine the need for dose titrations upon conversion between two generic tacrolimus formulations.
METHODS: Transplant recipients on stable tacrolimus doses were converted from Sandoz™ tacrolimus to Mylan™ tacrolimus on a mg:mg basis. Data were collected at the time of conversion (study arm) and at a time point exactly 6 months prior to conversion (control arm) for all subjects.
RESULTS: Ten conversions from a single center are reported. Subjects were a mean of 37.1 months post kidney (n=9) or liver (n=1) transplant. In the study arm, mean tacrolimus doses were 6.8 mg/day and 6.8 mg/day (p=NS) and mean tacrolimus trough concentrations were 5.9 and 5.1 ng/ml (p=0.24) before and after conversion, respectively. In the control arm, mean tacrolimus doses were 7 and 6.8 mg/day (p=0.34) and mean tacrolimus trough concentrations were 6.3 and 6.4 ng/ml (p=0.8) before and after the control time point, respectively. Dose titrations occurred in 1 patient (10%) in the control arm and 0 patients in the study arm.
CONCLUSION: These data show that dose requirements and trough levels are similar between two generic tacrolimus formulations. However, the strength of these conclusions are limited by the small sample size.

272. Is valganciclovir a viable option for cytomegalovirus (CMV) prophylaxis in liver transplantation?
Gregory Smallwood, B.S., Pharm.D.; PCOM School of Pharmacy, Suwanee, GA
PURPOSE: Currently valganciclovir is approved for CMV prevention in both cardiac and kidney transplantation. In the pivotal PV16000 registration trial, liver transplant recipients had an increase in tissue invasive CMV disease and did not receive FDA approval. However, many liver transplant centers use valganciclovir for CMV prophylaxis. The aim of the project is to compare the frequency of CMV viremia as determined by polymerase chain reaction(PCR) between liver transplant patients being followed with a preemptive strategy and treatment compared to patients taking valganciclovir for 100 days as prophylaxis.

METHODS: This is an IRB approved review of patients being followed for CMV. Patients were routinely followed by weekly, serial blood draws for CMV by polymerase chain reaction (PCR). Based on time transplanted, patients received valganciclovir prophylaxis of 900mg daily or monitored by PCR as a preemptive approach. The prophylaxis group(Pro) was compared to the pre-emptive(Pre) group for outcomes as determined by CMV viremia.
RESULTS: From Jan. 1, 2003, 309 consecutive liver transplant recipients were followed for CMV viremia. The two groups were similar in respect to demographics and primary disease(p=0.742). Seroconversion was documented in 108 (34.9%) by PCR for CMV with similar conversion rates by group(36.4% vs. 33%; p=0.562). The Pre group had higher rate of CMV at 3 months when compared to the Pro group[28/150(28.9%) vs. 6/150(4%): p=0.001]. The Pre group had shorter time to CMV(66 days vs. 158 days; p=0.001) but similar rates of rejections(p=0.899) and difference in MELD scores(21 vs. 23; p=0.002). CMV Disease free survival were similar between groups at 1 year (68.5% vs. 61.6%; p=0.936). There were slightly more mismatched organs in the Pro group (11/159 vs. 33/150; p=0.005).
CONCLUSION: Valganciclovir prophylaxis in liver transplant does not prevent CMV viremia(p=0.562), only the time to viremia(p=0.001). Continued work in CMV is required to prevent CMV viremia in liver transplantation.

Women's Health

273. Low molecular weight heparin use in the pregnant population. Kylie N. Barnes, Pharm.D.[1], *Alicia B. Forinash, Pharm.D., BCPS*[2], Laurie Niewoehner, Pharm.D.[3], Jeffrey Greenspoon, M.D.[4]; (1)St Louis College of Pharmacy, St Louis, MO; (2)St. Louis College of Pharmacy, Saint Louis, MO; (3)St. Mary's Health Center, St Louis, MO; (4)Saint Louis University, St Louis, MO
PURPOSE: Low molecular weight heparin (LMWH) is dosed based upon two determining factors: patient's weight and renal function. During pregnancy, both renal function and weight increase throughout all three trimesters, which indicatess a need for anti-Xa levels to be checked throughout the pregnancy to ensure levels are dosed high enough to accommodate for these changes. The CHEST guidelines indicate LMWH is appropriate for anticoagulation management during pregnancy and recommend LMWH doses be adjusted to achieve a therapeutic anti-Xa level (0.5–1.2 units/mL). However, the CHEST guidelines do not indicate a clear method or time frame for checking anti-Xa levels during pregnancy. The purpose of this study is to determine if pregnant patients in the high-risk OB/GYN (HROB) clinic at St. Mary's Outpatient clinic are receiving therapeutic starting doses of LMWH based on anti-Xa levels.
METHODS: Retrospective data collection through chart review using applicable ICD-9 codes identified patients receiving enoxaparin during pregnancy. Demographic information, indication for LMWH, enoxaparin dose, and frequency, anti-Xa levels, therapeutic changes based on levels, time to receive lab results, and time from receiving lab to changes were analyzed.
RESULTS: A total of 12 pregnant women were included in the study and were treated with LMWH at therapeutic doses. Only five patients had an anti-Xa level checked during their pregnancy; two of the patients' initial levels were therapeutic, and the other three were subtherapeutic. Time to first anti-Xa lab had a wide range (1 day to never checked). Initial dosing was 0.8–1.2 mg/kg/d divided for the majority of patients.
CONCLUSIONS: Significant gaps were identified in the current process of LMWH dosing in the pregnant population at St. Mary's HROB clinic. Increased education is needed to improve awareness and overall patient care. A need for pharmacy intervention with monitoring and proactive treatment approach was identified and is being addressed.

CLINICAL PHARMACY FORUM

Adult Medicine

274. Evaluation of medication reconciliation for inpatients with uncontrolled diabetes: preimplementation study. *Charlene A. Hope, Pharm.D., BCPS*; Norwegian American Hospital, Chicago, IL
PURPOSE: To evaluate accuracy of medication reconciliation of the diabetic regimens of patient admitted to adult medical-surgical nursing units. To identify drug-related problems associated with the regimen and potential for advancing patient's therapeutic regimen to goal (for example: titrating to max doses of oral therapy and/or initiating home insulin regimen).
METHODS: A retrospective chart review over a three month period was performed. Adult patients admitted to a medical-surgical nursing with a documented Hemoglobin A1C > 9 were classified as having uncontrolled diabetes and charts were selected for review. Admission Medication Reconciliation forms were reviewed and patient's home diabetes therapeutic regimens were documented and reviewed for potential drug related problems and opportunities to adjust their therapeutic regimen to achieve target A1C levels. Data collected from this study will be used as baseline data prior to implementation of a multi-disciplinary Diabetes Care Team.
RESULTS: A total of 34 medical charts were reviewed. Three (3) charts did not have discharge medication reconciliation forms and could not be utilized. Twenty-six (26) % (8/31) of the patient diabetes regimens reviewed revealed that there was no change in their regimen while admitted as an inpatient. Twelve (39%) did reveal a change in the patients drug regimen; such changes included increasing the insulin dosages or changing from a mixed-insulin to a basal-bolus insulin regimen. A little over 1/3 of the patients did not know their diabetes medication regimen or did had no medications documented on their medication reconciliation form. The average A1C of the study group was 11.3 (9.3–14).
CONCLUSION: There are several opportunities for clinical pharmacist to get involved to improve patient outcomes for this patient population. There were two that could have the most impact on improving quality of care include: 1) Participating in obtaining medication histories for these patients on admission. 2) Providing therapeutic recommendations to physicians to advance drug therapy to maximize A1C lowering.

275. Evaluation of a diabetic ketoacidosis protocol to improve quality and cost of care. *Nishil P. Patel, Pharm.D., BCPS*, Suma Dronavalli, M.D., Ishaq Lat, Pharm.D., BCPS; University of Chicago Medical Center, Chicago, IL
PURPOSE: This retrospective review was conducted to identify areas for improvement in the treatment of diabetic ketoacidosis.
METHODS: A drug utilization report was used to identify patients admitted with diabetic ketoacidosis (DKA) during January 2011. Fifteen patients were identified and retrospectively evaluated to assess the utilization and adherence to the hospital's DKA protocol. Additional data collected to determine quality and cost of care included: hypoglycemic events, total hours of insulin infusion, insulin infusion titration, reinitiation of insulin infusion, transition from intravenous to subcutaneous (SC) insulin, and serum ketones.
RESULTS: Of the 15 encounters, 10 (66%) patients were initiated on the correct protocol, but there was 0% adherence to the insulin infusion titration protocol. A total of 54 hypoglycemic events (blood glucose < 70 mg/dl) were documented, and 66% of the patients reviewed had at least one hypoglycemic event. The average time a patient remained on an insulin infusion varied by nursing unit; patients in the ED remained on insulin infusion for a mean time of 12.2 ± 8.8 hours compared to a mean of 20.75 ± 17.2 hours for patients on a medicine unit. Additionally, 46% of patients met the criteria for resolution of DKA at the cessation of insulin infusion, but only 25% of patients were properly overlapped with SC insulin. Six (40%) of the cases reviewed had insulin infusion therapy re-initiated. Lastly, 10 of 16 (62.5%) patients had a high frequency of serial serum ketones ordered which contributed to additional and unnecessary lab costs.
CONCLUSION: Retrospective analysis easily identified specific areas of quality and practice improvement.

276. Argatroban dosing evaluation amongst medical patients in a community hospital. *Janene L. Marshall, Pharm.D.*[1], Jorge Berrios, Pharm.D.[2], Rita Magnuson, Pharm.D.[3]; (1)Chicago State University College of Pharmacy, Chicago, IL; (2)Cardinal Health, Houston, TX; (3)Little Company of Mary Hospital and Health Care Centers, Evergreen Park, IL
PURPOSE: To compare patients that received argatroban dosed either by the physician or by pharmacy protocol with patients receiving

argatroban dosed with a revised protocol in order to determine if the time to achieve a therapeutic activated partial thromboplastin time (aPTT) and conversion to warfarin therapy could be decreased.
METHODS: A retrospective chart review was performed from July-December 2009 of all adult inpatients that received argatroban therapy for heparin induced thrombocytopenia (HIT) or heparin induced thrombocytopenia thrombosis syndrome (HITTS). The diagnoses, medical histories, laboratory values, and medication administration record data were documented. After evaluation, the argatroban pharmacy dosing protocol was revised. A prospective chart review was performed from September 2010-Feburary 2011.
RESULTS: In the retrospective chart review, patients achieved a mean therapeutic aPTT (SD) in 16.2 (26.2) hours and received a mean duration of 6.7 (6.4) days of therapy. Ten patients (66.7%) were converted to warfarin with 30% achieving a therapeutic INR in a mean of 5.3 (2.1) days. Two patients (13.3%) had a significant adverse drug reaction requiring a blood transfusion. In the prospective review, patients achieved a therapeutic aPTT in 6.7(4.1) hours and received a mean duration of 2.5 (1.1) days of therapy. Eight (50%) patients were converted to warfarin with 62.5% achieving a therapeutic INR in a mean of 2.4 (0.9) days. Four patients (25%) percent had a significant adverse drug reaction requiring a blood transfusion.
CONCLUSION: Upon retrospective review of argatroban dosing, it was found that a therapeutic aPTT was achieved in 16 hours for treatment of HIT or HITTS. Further review revealed deficiencies in process and outcomes. The argatroban dosing protocol was revised and the pharmacists received education regarding argatroban dosing. As a result, the time to achieve a therapeutic aPTT decreased and more patients achieved a therapeutic INR prior to discharge.

277. Tranexamic acid and decreased blood utilization. *Tracy S. Elliott, Pharm.D.*; Cleveland Clinic-Fairview Hospital, Cleveland, OH
PURPOSE: To determine if tranexamic acid use can decrease blood transfusion requirements and have an effect on hemoglobin levels.
METHODS: One hundred eleven patients underwent either total knee or total hip replacement surgery. Twenty-eight patients were given tranexamic acid 15 mg/kg prior to surgery. The units of blood transfused, percent of patients transfused, and average change in hemoglobin were assessed.
RESULTS: 0.1 units of blood per case were used in both the control group and tranexamic acid group for patients who underwent total knee surgery. Percent of patients transfused in the control group was 9% and tranexamic acid group was 6%. Average change in hemoglobin was 4.4 g/dL and 4.2 g/dL for the control and tranexamic acid groups respectively. 0.4 units of blood/case were used in the control group and were used in the tranexamic acid group for patients who underwent total hip surgery. Percent of patients transfused in the control group was 24% and the tranexamic acid group was 10%. Average change in hemoglobin in the control group was 5.2 g/dL and 4.4 g/dL for the tranexamic acid group.
CONCLUSIONS: For patients who underwent total knee surgery, tranexamic acid did not appear to affect the overall amount of units of blood transfused but did appear to have a significant effect on the overall percent of patients transfused. The increase in hemoglobin between the knee surgery test groups was of questionable significance. For patients who underwent total hip surgery, tranexamic acid appeared to have a highly significant effect on the overall amount of units of blood transfused decreasing the overall blood use by 75%. Tranexamic acid appeared to have a highly significant effect on the overall percentage of patients transfused. Tranexamic acid appeared to have a significant positive effect on the post-operative hemoglobin in these cases.

278. Impact of hospital-based pharmacist advocates in care transitions: identification and description of medication related interventions after patient discharge from hospital to home. *Rima A. Mohammad, Pharm.D.*[1], Jenny J. Kim, Pharm.D.[2], Amy C. Donihi, Pharm.D.[1], Kim Coley, Pharm.D.[1]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)University of Pittsburgh Medical Center, Pittsburgh, PA
PURPOSE: Adverse drug events, medication discrepancies and lack of patient understanding of the treatment plan are problems that often occur after hospital discharge. The primary objective was to describe medication related interventions conducted by hospital-based transition of care pharmacists following hospital discharge.
METHODS: Inpatient pharmacists conducted a standardized telephone medication evaluation within 72 hours of their patients' discharge to home. Pharmacists resolved identified medication-related problems by counseling the patient and contacting the patient's physician, pharmacy, and/or health plan, as needed. All interventions were documented in the patient's outpatient electronic medical record. Interventions were classified into four categories: (1) therapeutic drug monitoring, (2) resolution of medication discrepancies (3) medication and adherence counseling, and (4) identification and prevention of adverse drug events (ADEs).
RESULTS: Of 58 patients discharged to home, 45 (77.6%) were successfully contacted and evaluated. The mean number of scheduled and "as needed" medications at discharge was 9 (range 2–22) and 2 (range 0–7), respectively. Pharmacists made 86 medication-related interventions in 43 patients (1.9 ± 1.2 interventions per patient). Thirty (34.9%) interventions were resolution of medication discrepancies, including 13 medications incorrectly omitted by the patient, 8 prescribing errors at discharge, 5 financial-related issues, and 4 incorrect doses or medications taken by the patient. In addition, 29 interventions (33.7%) were therapeutic drug monitoring, 16 (18.6%) were medication and adherence counseling, and 11 (12.8%) were ADE-related. Medications most commonly intervened on were gastrointestinal agents and antibiotics. On average, pharmacists spent 23 (range 5–120) minutes on each patient follow-up.
CONCLUSION: Most patients experience at least one medication-related problem after hospital discharge. Hospital-based pharmacists can positively impact their patients' care during the transition from hospital to home by resolving important medication-related problems and needs.

279. Impact of inappropriate vitamin K use for management of elevated international normalized ratios on hospital length of stay. *Denise M. Kolanczyk, Pharm.D., BCPS*, Alexander J. Ansara, Pharm.D., BCPS; Indiana University Health Methodist Hospital, Indianapolis, IN
PURPOSE: The *CHEST* guidelines provide recommendations for the management of a supratherapeutic international normalized ratio (INR) regardless of bleeding. Currently there is no literature describing the impact of inappropriate vitamin K use on hospital length of stay (LOS). The primary objective is to determine if the inappropriate use of vitamin K for the reversal of supratherapeutic INR prolongs LOS. Secondary objectives include the assessment of adherence to the *CHEST* guidelines for vitamin K prescribing and to evaluate the time to achieve a therapeutic INR when re-initiating warfarin.
METHODS: Retrospective chart review of 300 patients with a supratherapeutic INR admitted to Methodist Hospital between July 1, 2008 and October 31, 2010. Therapy for reversal of a supratherapeutic INR was defined as discontinuation of warfarin or administration of vitamin K.
RESULTS: Vitamin K was administered to 150 (50%) of 300 patients. 81 out of 300 patients were inappropriately managed for a supratherapeutic INR. There was no statistical difference among LOS among patients who were inappropriately managed (12.45 days versus 12.43 days; p=0.46). Adherence to the *CHEST* guidelines was assessed in 219 patients (73%). The time it took to achieve a therapeutic INR after warfarin initiation did not differ among treatment groups (p=0.41). However, patients who received vitamin K inappropriately may have prolonged LOS.
CONCLUSION: Inappropriate management of a supratherapeutic INR did not prolong LOS, but patients who received vitamin K inappropriately may have a prolonged LOS.

Ambulatory Care

280. Results of a pharmacist-managed Cardiovascular Risk Reduction Clinic at a Veterans Affairs Medical Center. Chabely Rufin, Pharm.D., Elizabeth C. Hamilton, Pharm.D., *Crystal J. Wink, Pharm.D.*; Ralph H. Johnson VA Medical Center, Charleston, SC
PURPOSE: Describe the clinical effectiveness of a pharmacist-managed Cardiovascular Risk Reduction Clinic (CRRC) in attaining

blood pressure goals.
METHODS: The study population was defined as patients followed in the CRRC for hypertension between June 1, 2007 and September 30, 2010 with at least two clinic visits. The percent of patients attaining goal systolic and diastolic blood pressure values upon discharge from the clinic or end of study period (whichever occurred first), based on both the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) guidelines and performance measure goals were determined. The number of clinic visits required to attain JNC 7 blood pressure goals were measured. The cumulative results of the CRRC were compared to the annual performance of the facility as a whole, in meeting predetermined blood pressure performance goals.
RESULTS: The CRRC assisted in reaching the JNC 7 blood pressure goal in 89% of patients with HTN and no compelling indication and 77% of patients with hypertension and diabetes and/or chronic kidney disease. JNC 7 blood pressure goals were achieved in a mean of 2.85 and 3.47 visits for patients without and with compelling indications, respectively. The CRRC assisted in reaching the blood pressure performance goal in 89% of patients with HTN and no compelling indication (vs. facility achievement in 71-80% depending on year reviewed), and in 91% of patients with hypertension and diabetes (vs. facility achievement in 70–84% depending on year reviewed).
CONCLUSION: The pharmacist-run CRRC was successful in reaching both JNC 7 and facility performance measure blood pressure goals in a timely manner, and overall exceeded the annual performance of the facility. Implementation of a CRRC may assist in reaching performance measure goals and reduce the risk of cardiovascular events.

281. Impact of a pharmacist-managed diabetes clinic on glycemic control using concentrated U-500 regular insulin. *Tzu-Ying (Yasmina) Lee, Pharm.D., BCPS*, Anthony Firek, M.D.; VA Loma Linda Healthcare System, Loma Linda, CA
PURPOSE: Diabetic patients with severe insulin resistance are a growing challenge for practitioners. Many of these patients continue to have inadequate glycemic control despite large dose of insulin. Case reports and retrospective studies have demonstrated that concentrated U-500 regular insulin (U-500) is effective at lowering A1c in these patients. We developed a pharmacist-managed diabetes clinic focusing on patients with A1c values of > 9% at Loma Linda VA Healthcare System. These patients are at higher risk for complications and are a high resource utilization group. Many of these patients were using over 200 units of conventional insulin U-100 and are therefore candidates to use U-500. This study evaluated the effectiveness of a U-500 intervention program to improve diabetes control.
METHODS: This is a retrospective chart review of patients seen in the pharmacist-managed diabetes clinic who were initiated on U-500. Patients were included if they have been on U-500 for at least 2 months with follow-up A1c 2-6 months after initiation of U-500. A1c, body mass index (BMI), and total daily dose of insulin (TDDI) were collected at initiation and 2-6 months after initiation of U-500.
RESULTS: Of the 100 patients followed by pharmacist-managed diabetes clinic since its establishment, 7 patients met the inclusion criteria. All patients were male with mean age of 63±9.85 years, mean baseline A1c of 10.5±1.04%, mean baseline BMI of 36.69±4.76, and mean TDDI of 249.57±17.88 units. The mean reduction in A1c from baseline following 2–6 months of U-500 therapy was -2.2%±1.0%. The mean increase in BMI was +1.05±1.61 and the mean increase in TDDI was +86.86±122.27 units.
CONCLUSION: A pharmacist-managed diabetes clinic demonstrated short term but clinically significant improvement in glycemic control in poorly controlled insulin resistant patients using U-500.

282. A pharmacist-run collaborative care program in a free urban primary care clinic. *Lauren J. Jonkman, Pharm.D., BCPS*[1], Sharon E. Connor, Pharm.D.[1], Mary I. Herbert, M.S., M.P.H.[2], Sara Mrvos, Pharm.D., Candidate, 2014[3]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)UPMC Department of General Internal Medicine, Pittsburgh, PA; (3)Duquesne University Mylan School of Pharmacy, Pittsburgh, PA
PURPOSE: Pittsburgh's Birmingham Free Clinic (BFC) serves a growing population of patients with chronic diseases. BFC's walk-in model requires patients to return monthly, which works to provide access for new patients, but is less-than-ideal for patients needing continuing care. With limited volunteer physician staffing and thus, physician continuity, BFC developed a pharmacist-run appointment-based collaborative care program to provide on-going care and medication refills to patients with chronic diseases. In this assessment we investigate drug-related problems (DRPs), interventions, and clinical outcomes for program participants.
METHODS: This retrospective review included all patients with at least one pharmacist visit since program initiation (June 2009–May 2011). We recorded demographics, number of pharmacist visits, clinical data, DRPs, and interventions. The University of Pittsburgh Medical Center's quality improvement committee approved this project.
RESULTS: Sixty-four patients had at least one pharmacist visit in the period assessed with a total of 251 visits. The majority of patients were middle-aged (49.5 years), male (54.9%), black (51.6%), low-income ($640/month), and housed (59.3%). 115 DRPs were identified (average 1.8/patient; 0.46/visit), most common being "dose too low" (34.6%) and "non-compliance "(23.4%). 590 interventions were made (average 9.2/patient; 2.35/visit), most common being "education provided" (67.7%) and "referred to lab" (13.7%). Of those with diabetes (45.3%), baseline A1C was 8.0% (5.6–11.6%), blood pressure 134.6/85 mmHg (108–180/64–110 mmHg), and LDL 89.1 mg/dL (45–136 mg/dL). No statistically significant changes were seen for A1C or blood pressure; LDL decreased 10.2 mg/dL (p=0.033). However, 83.3% with A1C > 9% at baseline (6 patients) saw an A1C reduction.
CONCLUSION: While we did not find significant clinical improvements, most had reasonable disease control at baseline. Improvements are complicated by patient social situations and timely access to laboratory services for disease monitoring. This project highlights the potential role for pharmacists in resource-poor settings to provide chronic care that extends the traditional primary care infrastructure.

283. Highlighting the work of the Ambulatory Care PRN in 2011. *Marissa E. Quinones, Pharm.D.*[1], Renee Koski, Pharm.D., CACP[2], Lea E. dela Pena, Pharm.D., BCPS[3], Matthew Pitlick, Pharm.D., BCPS[4], Sarah M. Westberg, Pharm.D., BCPS[5]; (1)Parkland, Dallas, TX; (2)Ferris State University College of Pharmacy, Marquette, MI; (3)Midwestern University Chicago College of Pharmacy, Downers Grove, IL; (4)St. Louis College of Pharmacy, St. Louis, MO; (5)University of Minnesota College of Pharmacy, Minneapolis, MN
PURPOSE: To highlight the Ambulatory Care PRN in 2011.
METHODS: The Ambulatory Care PRN is composed of a large group of clinical pharmacists practicing in a variety of ambulatory care settings, including resident and student members. As of April 2011, we have a total of 1308 members in the PRN. This year the PRN offered free memberships for PGY2 ambulatory care residents and so far we have had an increase from 7 in 2009–2010 to 19 participants during 2010–2011.
RESULTS: There are a total of 8 committees in the ambulatory care PRN. Each committee has been charged with several tasks this year, including working on the FIT scholarship applications form, working on budget/request for funds process, and working on ways to increase resident/student membership. The resident/student committee has been working on increasing contributions to the ACCP Resident and Student Travel Awards from 2 to 4, organizing a PRN roundtable discussion and informal resident/student lunch during the ACCP meeting. The communication committee continues to monitor the ambulatory list serve to ensure members are following proper posting polices/procedures and has been working on updating the Survival guide with hopes to publish a new edition in 2013. The PRN is dedicated to supporting and advancing high level research among it's members and will continue to seek applications in the future for FIT and nurture young faculty and residents with the Seed Grant. The education committee finalized the annual meeting topics regarding new developments in hypertension and dyslipidemia.
CONCLUSION: Overall, the Ambulatory Care PRN has worked very hard and continues to grow each year, offering its members numerous opportunities for professional development.

284. Role of a pharmacist in a patient-centered medical home for university employees. *Erica F. Pearce, Pharm.D.*[1], William T. Manard, M.D[2], Gillian S. Stephens, M.D.[2]; (1)St. Louis College of Pharmacy, Saint Louis, MO; (2)Saint Louis University, Saint Louis, MO

PURPOSE: The patient-centered medical home (PCMH) has been increasingly endorsed both by consumer groups and medical organizations as an appropriate model upon which to build a reformed primary care delivery system in the United States. Despite the role of medications in the care of patients with acute and chronic disease, the incorporation of pharmacists' medication therapy services within the PCMH is still in its infancy. The objective of this project is to discuss the integration of a clinical pharmacist in the Saint Louis University PCMH.

METHODS: The Saint Louis University PCMH is a family medicine clinic that combines a multidisciplinary team of health care professionals that provides care for Saint Louis University employees and their families. A part-time clinical pharmacist provides services that incorporate the following five components: 1) medication therapy management (MTM); 2) disease state management (DSM); 3) health education; 4) drug information; and 5) interprofessional integration and coordination of care.

RESULTS: The development phase included identifying disease states most in need of additional management, establishing a referral process, investigating the process for billing and reimbursement for services, and educating referring providers about the services provided by the clinical pharmacist. The multidisciplinary team of the Saint Louis University PCMH has enthusiastically endorsed the incorporation of clinical pharmacy services. The clinical pharmacist is expanding access to medication therapy services to two additional clinic locations.

CONCLUSION: Pharmacists can play a fundamental role in PCMH and make significant contributions to patient care across health care settings. Such innovations in the primary care setting create a unique niche for pharmacists to use their skills. The clinical pharmacy services in the Saint Louis University PCMH will serve as a model to objectively assess the therapeutic outcomes, safety, and cost-effectiveness of incorporating a pharmacist into the PCMH.

285. Reimbursed medication therapy management services in a community health center for a Medicare population. *Rebekah E. Sherman, Pharm.D., CDE*, Leslie A. Vitin, Pharm.D., CDE; Northeastern University, Boston, MA

PURPOSE: To describe medication therapy management (MTM) services provided at a community health center (CHC) for purposes of demonstrating a successful model for pharmacy intervention and direct payer reimbursement.

METHODS: A retrospective analysis of pharmacy interventions completed during MTM visits over a seven month period from April 2010 to October 2011 was performed. The database included only MTM services reimbursed through Outcomes Pharmaceutical Health Care in coordination with the primary insurer, Senior Whole Health. MTM services were conducted face to face solely with the pharmacy team.

RESULTS: Within the seven month period, 22 patients out of over 200 eligible patients were provided MTM services for a total of 34 interventions including comprehensive medication reviews, patient consultations, and prescriber consultations. Ten different types of drug therapy problems (DTPs) were identified. Interventions to resolve DTPs ranged from patient consultations for medication non-adherence (n=7) to prescriber consultations for changes in therapy (n=15). Ninety three percent of all patient and prescriber consultations were accepted without revision. The average time spent on a single intervention was 38 minutes, and the average reimbursement was $29.47 per intervention. The average number of interventions per patient was one and a half. MTM fees reimbursed by Outcomes Pharmaceutical Health Care amounted to approximately $1002.00 for 34 interventions in comparison to the total estimated cost avoidance (ECA) which reached $51,219.25

CONCLUSION: There is a clearly demonstrated need for the provision of MTM services based on the significant number of interventions made in a small sample population. The cost of MTM services to insurers is justified in the ECA associated with pharmacy interventions.

286. Pharmacist-managed diabetes service in a rural free clinic. *Katherine R. Gerrald, Pharm.D., BCPS*, Julie M. Sease, Pharm.D., BCPS, Meg A. Franklin, Pharm.D., Ph.D.; Presbyterian College School of Pharmacy, Clinton, SC

PURPOSE: To determine the impact of pharmacist education, monitoring, and management of patients with type 2 diabetes mellitus (DM) enrolled in a free clinic that serves a rural indigent population.

METHODS: Data from 81 patients continuously enrolled in a newly established pharmacist service were analyzed over 18 months. Patients were ≥18 years of age, qualified for free care based on income and/or insurance status, and had a diagnosis of type 2 DM. Under a collaborative agreement, pharmacists educated patients on DM, counseled patients on lifestyle modifications, assessed appropriateness of drug therapy, and managed drug therapy for DM and associated co-morbid conditions. Clinical impact was measured by changes from baseline in hemoglobin A1c (A1c) levels, blood pressure, and lipid levels. Economic impact was calculated based upon expected savings per 1% decrease in A1c levels.

RESULTS: Mean A1c levels were 10.7% at baseline (SD ±2.4%). At 18 months, A1c levels decreased an average of 2.1% (P<0.001), and 28.4% of patients had an A1c ≤7%. Significant decreases in mean values were also noted for systolic blood pressure (SBP) (P=0.0023), LDL cholesterol (P <0.001), and triglycerides (P=0.003). Compared to baseline, a significant number of patients achieved A1c goal (P<0.001), SBP goal ≤130 mmHg (P=0.023), LDL ≤100 mg/dL (P<0.0007), and triglycerides ≤150 mg/dL (P<0.0018) by 18 months. A significant number of patients reached a total of 842 interventions were documented, of which 76.8% involved therapy modification. Over 50% of the modifications were increases to current doses, and 30.3% were initiating new therapy. Based on an expected savings of $1,118 per 1% decrease in A1c levels, the average savings per patient was $2,382, for a total savings potential of $192,167.

CONCLUSION: Pharmacist management of patients with type 2 DM has the potential to significantly impact clinical outcomes and improve costs of care for patients in underserved rural areas.

287. Collaborative health risk assessment and management program between the university pharmacy clinic and city employees. *Krista D. Capehart, Pharm.D., M.S.Pharm.*, Michael O'Neil, Pharm.D., Michael Bottorff, Pharm.D., FCCP; University of Charleston School of Pharmacy, Charleston, WV

PURPOSE: The purpose of the collaboration is to provide medication therapy management services to Charleston, West Virginia city employees in conjunction with the City's Employee Health Risk Management Program.

METHODS: All city employees and dependents were required to complete a comprehensive health risk assessment (HRA) in the fall of 2010. The collaborative program with the City was created based on the HRA results. Patients may self-refer to the pharmacy clinic or be referred by the City's free physician assistant-run health clinic. Services provided include medication therapy management, chronic disease management for diabetes, cholesterol, hypertension, heart failure, asthma, COPD, smoking cessation, pain management, and substance abuse prevention. The City will reimburse the PharmUC Patient Care Clinic on a fee-for-service basis. The services are free to the employee and dependents and can be utilized while at work without taking paid or unpaid time off. Adherent participants to the Health Risk Management Program receive a discount on their health premiums.

RESULTS: An agreement was reached with the City of Charleston for the PharmUC Patient Care Clinic to be a part of the City's Employee Health Risk Management Program. Utilizing the appropriate national Guidelines and/or quality indicators for each condition will be examined at six and twelve months. Also, work productivity indicators and overall healthcare savings will be evaluated. Employee satisfaction with the health plan before and after Program implementation will be assessed.

CONCLUSIONS: Opportunities exist for pharmacy-based clinics to contract with insurers, particularly self-insured companies, to facilitate improvement in the management of health risks. The City of Charleston is taking a proactive step to improve the health of its employees and beneficiaries by recognizing the benefits that clinical pharmacy can offer and incorporating these services into their health plan.

288. Development of an automated tool to document clinic-based pharmacists' activities. *Stephen F. Eckel, Pharm.D., MHA, BCPS*, Lindsey B. Poppe, Pharm.D., M.S., BCPS, Sarah K. Ford, Pharm.D., BCPS, CPP, Caron P. Misita, Pharm.D., BCPS, CPP, Lauren B. McKnight, Pharm.D., CPP, Sujing Yang, B.S., Ian R. Willoughby, Pharm.D.; University of North Carolina Hospitals, Chapel Hill, NC

PURPOSE: The University of North Carolina Hospitals (UNC) has been rapidly increasing the number of pharmacists practicing in the clinic setting. Over the past 3 years, UNC has added 8 pharmacist positions, representing nearly a 200% growth. North Carolina has a unique advanced pharmacy practice model, allowing clinical pharmacist practitioners to independently evaluate patients and prescribe under protocol. With the diversity of clinics represented and their increasing distance from the hospital, an automated tool needed to be developed to document each pharmacist's activity within the clinic setting.

METHODS: A series of meetings occurred with the clinic-based pharmacists to understand their individual involvement in patient care. Specifically, the goal was to determine activities documented in the electronic health record (EHR) that are a part of caring for ambulatory patients. Information technology was consulted to determine if this data could be automatically collected from the EHR and compiled into a routine report. After comparison of manually collected data to the generated report and correction of any discrepancies, the report is now generated automatically on a biweekly basis.

RESULTS: The following parameters were determined to be markers of clinic-based pharmacists' activity: medications updated, medication profiles reviewed, clinic notes prepared, allergies updated, interdisciplinary communications and patient phone calls addressed, and electronic prescriptions transmitted. These parameters have been developed into a dashboard to summarize each pharmacist's activity in the clinic setting.

CONCLUSION: This tool has been a means of measuring pharmacist activity in the clinic setting. As UNC recruits additional pharmacists, their documented interactions with patients will be incorporated into this tool. Further research is needed to correlate these activity measurements with clinic-based pharmacists' impact on patient care.

289. Implementation of a pharmacist-led medication reconciliation service in a federally qualified health center. *Marissa C. Salvo, Pharm.D.*; University of Connecticut - School of Pharmacy, Storrs, CT

PURPOSE: Patient appointments following hospital discharge require the primary care provider (PCP) to coordinate a variety of services, including but not limited to medication reconciliation, laboratory monitoring, and referrals. Utilizing a pharmacist to complete medication reconciliation and communicate identified discrepancies with possible resolution to the PCP prior to the patient's visit allows the provider additional time to focus on patient care.

METHODS: Following patient discharge, the PCP receives hospital discharge documents through the electronic medical record (EMR) and determines if the patient requires medication reconciliation, based on polypharmacy or concomitant medical conditions. The PCP electronically sends the documents to the pharmacist who reviews the discharge medication list with respect to the patient's outpatient EMR medication list. The pharmacist then calls the patient to determine actual medication use. Following reconciliation, the pharmacist updates the patient's EMR medication list and notifies the PCP of medication discrepancies and potential resolutions through the EMR. In addition, the pharmacist evaluates therapy to recommend medication therapy modifications, laboratory monitoring, or additional disease state management. All recommendations are recorded in the EMR.

RESULTS: The pharmacist identified numerous discrepancies among the discharge documents, outpatient medication list, and patient-reported medication use. A variety of recommendations were proposed to the PCP, including medication adjustment, laboratory monitoring, and preventative care measures.

CONCLUSION: The ambulatory care pharmacist is ideally positioned to perform medication reconciliation following patient discharge. In a federally qualified health center with an EMR, the pharmacist has the luxury of access to the discharge medication list, outpatient medication list, patient, and PCP. In addition, the pharmacist applies clinical knowledge to identify and resolve medication discrepancies and recommend therapy modification to maximize medication use and patient outcomes.

290. Incorporating a clinical pharmacist on a medical team serving the homeless. *Marissa C. Salvo, Pharm.D.*; University of Connecticut - School of Pharmacy, Storrs, CT

PURPOSE: Clinical pharmacists are active participants on medical teams in a variety of settings, including acute and outpatient care; their role and contributions have been described in numerous pieces of literature. However, the clinical pharmacist's role on a medical team comprised of a nurse practitioner (NP), nurse, and care coordinator serving the homeless is limited.

METHODS: A residency trained pharmacist clinician-educator spends one-half day per week with a medical team associated with a federally qualified health center providing care within a homeless shelter. The pharmacist identifies patients with diabetes or hypertension in order to provide medication therapy management, which includes a medication review, assessment of preventative care, and medication and disease state education. The pharmacist recommends therapy and laboratory monitoring to the NP as necessary and documents interventions and recommendations in the electronic medical record (EMR). In addition, the pharmacist meets with new patients to complete a medication, medical, social, and family history profile. Recommendations for comprehensive care are then made as necessary. Patients who are current smokers are also encouraged to talk with the pharmacist for smoking cessation counseling.

RESULTS: Incorporation of the clinical pharmacist on the medical team serving the homeless began in November 2010. All pharmacist-patient encounters and pharmacist recommendations were documented within the patient's EMR. Members of the medical team were supportive of the pharmacist's role and impact on patient care.

CONCLUSION: The clinical pharmacy service impacts patient care within a homeless population. Pharmacists should consider sharing their expertise with a medical team in providing services to a population that faces many barriers in the receipt of adequate medical care.

291. Development of a medication therapy management service at a free clinic. *Catherine A. Bourg, Pharm.D., BCPS*[1], Lisa J. Moherman, Pharm.D., CACP[2], Tara Whetsel, Pharm.D.[3]; (1)University of Georgia College of Pharmacy, Athens, GA; (2)West Virginia University Hospitals, Morgantown, WV; (3)West Virginia University School of Pharmacy, Morgantown, WV

PURPOSE: Medication non-adherence and poor disease outcomes are common among the indigent population. These patients have great potential benefits from medication therapy management (MTM) services. However, data describing MTM in the indigent population are lacking. The purpose of this project was to determine the process by which sustainable MTM services could be implemented at a free clinic.

METHODS: Milan Puskar Health Right, an indigent clinic located in Morgantown, West Virginia, was targeted for development of MTM services due to its closed circuit model. This ensured that participating patients used Health Right exclusively for primary care and prescriptions. The clinic offers primary and specialty care as well as pharmacy services to low-income, uninsured residents of the state. Recruitment for the MTM service was initially based on provider referral. The electronic medical record was used to identify patients taking five or more medications, with three or more chronic disease states.

RESULTS: Patient referrals from primary care providers took place from January 2010 to June 2010. Strategies employed to increase awareness included personalized memos, flyers, and reminder tags in clinic workrooms for providers and flyers in prescription bags for patients. Each patient completed a survey to evaluate their medication knowledge and adherence and received a personal medication record from the MTM pharmacist. Barriers to patient recruitment and participation in the service included provider availability, project timeframe, and appointment cancellations.

CONCLUSION: An MTM service utilizing third-year pharmacy students and faculty preceptors was initiated in September 2010 based on experience from this project. Despite limitations, a process for

MTM was implemented and sustainability of pharmacy services was achieved at Health Right.

Cardiovascular

292E. Evaluation of pharmacist-run anticoagulation management service of ventricular assist device (VAD) patients. *Paula Horn, Pharm.D., BCPS, CACP*, Laura Krumenacker, Pharm.D., Edward T. Horn, Pharm.D., BCPS, Robert J. Moraca, M.D., Walter E. McGregor, M.D., Srinivas Murali, M.D., George G. Sokos, D.O., Raymond L. Benza, M.D., Stephen H. Bailey, M.D.; Allegheny General Hospital, Pittsburgh, PA

PURPOSE: To determine the time in therapeutic range, as well as the type and frequency of adverse events related to anticoagulation in ventricular assist device (VAD) patients managed by a pharmacy-run anticoagulation (AC) service.

METHODS: A retrospective review was conducted of all VAD patients managed by the AC service from March 1, 2010 to December 15, 2010 utilizing medical records, physician order entry system, and clinic documentation.

RESULTS: A total of 28 patients were followed by the AC service with 552 INR results followed. The percent of INRs in target range was 62%. When this was expanded to + 0.2 of the prescribed therapeutic range, the percentage increased to 78%. Three of the 522 INR results were above 5 during the follow-up period (0.54%). One dose of oral vitamin K was administered. With respect to clinical events, 7 patients (25%) experienced 10 bleeding events. The predominant event type was gastrointestinal bleed (GIB) (70%). One patient had a fatal hemorrhagic stroke. The mean INR at event diagnosis was 2.6; median 2.5. One patient had a fatal ischemic stroke, with an INR of 1.1 at event diagnosis.

CONCLUSIONS: This data shows that a pharmacist-run AC service maintains VAD patients' anticoagulation therapy within therapeutic targets similar to those reported in the literature. This study demonstrates that pharmacist-run AC services can achieve tight control of anticoagulation management in a high-risk patient population.

Presented at Anticoagulation Forum, Boston, MA, May 5–7, 2011.

293. Opportunities for clinical pharmacist intervention in the pharmacotherapy of patients with left-ventricular assist devices. *Douglas L. Jennings, Pharm.D., BCPS, (AQ-CV)*, Cheryl Smith, RN, Robert Brewer, M.D., Celeste Williams, M.D.; Henry Ford Hospital, Detroit, MI

PURPOSE: Left-ventricular assist devices (LVADs) represent a life-saving modality for patients with advanced heart failure. Given the complex pharmacotherapy requirements of these patients, the potential for medication error is high. The purpose of this project was to determine the opportunity for participation of the clinical pharmacist in the multidisciplinary care of patients with LVADs.

METHODS: A retrospective review was conducted for patients admitted to the Cardiothoracic Surgery (CTS) service at our institution and implanted with the LVAD from July 1st, 2009 to June 30th, 2010. Ambulatory LVAD patients who were readmitted to the Advanced Heart Failure (AHF) service during the same time period were also included. Data collection included demographics, past medical history, and prescribed medications. The primary endpoint was the number of documented interventions by the clinical pharmacist during the study period. Pharmacist interventions were categorized according to class of medication (i.e., antibiotic, anticoagulant, etc.) and type of intervention (dose correction, discontinue uneeded therapy, etc).

RESULTS: A total of 30 patients had a LVAD implanted and were admitted to the CTS service, while 32 ambulatory LVAD patients were readmitted to the AHF service (71% male, 58% Caucasian, 98% HeartMate II®). The clinical pharmacist was responsible for 400 interventions in LVAD patients during the study period. Newly-implanted LVADs admitted to the CTS service had 262 interventions (average of 8.7 interventions per patient), while those readmitted to the AHF service received 138 interventions (average of 1.8 interventions per patient). Overall the most common type of pharmacist intervention was change in dose/route/frequency (33%), while the most common reason for pharmacist intervention was treatment of a disease not controlled on present therapy (36%). Most of the interventions were with antimicrobial (43%) or cardiovascular (26%) agents.

CONCLUSION: Clinical pharmacists have significant opportunity for participation in the multidisciplinary care of patients with LVADs.

294. Frequency of aminophylline use for reversal of dipyridamole and regadenoson. *Lisa M. Perry, Pharm.D.*, Mei Tse, Pharm.D.; Portland Veterans Affairs Medical Center, Portland, OR

PURPOSE: Dipyridamole and adenosine are the common pharmacologic stress agents used to mimic the effects of exercise on coronary blood flow. Regadenoson is the newest pharmacologic stress agent indicated for stress MPI and is selective for the A_{2A} receptor. It is thought that there are more undesired symptoms and safety concerns that occur when multiple adenosine receptors are stimulated. The Portland VA Medical Center's drug of choice for reversal of these pharmacologic agents is aminophylline. The objective of this retrospective chart review was to compare the incidence of adverse drug events associated with both dipyridamole and regadenoson and to report the frequency of use of aminophylline for reversal of these drug effects.

METHODS: The health system's electronic medical record system was used to identify 140 veterans that had received dipyridamole or regadenoson for stress MPI. A retrospective chart review was performed. Data was collected on patient demographics, concomitant medications, vitals, adverse drug events, and receipt of regadenoson or dipyridamole, and receipt of aminophylline.

RESULTS: The dipyridamole group reported a total of 52 adverse events compared to 62 adverse events reported by the regadenoson group (P=0.05). Mild dyspnea had the largest difference in reporting between the two groups with 36 patients in the regadenoson group and 4 patients in the dipyridamole group (P=0.003). A total of 63 patients in the regadenoson group and 61 patients in the dipyridamole group required reversal with aminophylline (P=0.791).

CONCLUSIONS: There was a significant trend towards lower adverse effects with dipyridamole than with regadenoson and the adverse effect with the largest difference in reporting between the two groups was mild dyspnea. There was no significant difference in the frequency of aminophylline use between the two groups.

295. The implications of clopidogrel black box warning on utilization of platelet aggregation testing in the community hospital setting. *Kathryn M. Momary, Pharm.D.*[1], Kevin Sponsel, Pharm.D., Candidate[1], Kelly Blanchfield, Pharm.D.[2]; (1)Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (2)Saint Joseph's Hospital of Atlanta, Sandy Springs, GA

PURPOSE: Patients producing less clopidogrel active metabolite, due to possession of CYP2C19 loss-of-function alleles, have decreased inhibition of platelet aggregation and are at increased risk for cardiovascular events. The FDA issued a black box warning for clopidogrel in March 2010 suggesting that clopidogrel not be used in patients with CYP2C19 loss-of-function alleles. However, at most institutions CYP2C19 genotyping is a "send-out" laboratory while platelet aggregation testing with VerifyNow can be done "in-house". VerifyNow testing has also been associated with risk of cardiovascular events with clopidogrel therapy. The objective of this study was to assess changes in utilization of the VerifyNow test before and after the clopidogrel black box warning was released, in March 2010, at a community hospital.

METHODS: We conducted a retrospective medical record review of all patients undergoing VerifyNow testing at a community hospital pre (Nov. 2009 to February 2010) and post (April 2010 to July 2010) the release of the clopidogrel black box warning. Documented indications for VerifyNow testing were categorized as related to safety(bleeding risk) or efficacy(thrombosis risk). Data were compared between the pre and post black box warning groups using Chi-squared tests.

RESULTS: Data from 151 patients undergoing VerifyNow testing were collected, 73 from before the black box warning and 78 after. The majority of tests were performed by surgery services (pre 88% vs. post 66% p=0.002) to assess bleeding risk with clopidogrel. There was a non-significant increase in VerifyNow testing to assess the efficacy of clopidogrel after the black box warning release (1.4% vs 6.5% p=0.121).

CONCLUSION: Use of VerifyNow testing to assess the efficacy of

clopidogrel did increase slightly after release of the black box warning, however this was still uncommon. The majority of VerifyNow testing at a community hospital is related to bleeding risk with surgical procedures.

Clinical Administration

296. Clinical pharmacy technicians: impact in cardiology and critical care pharmacy services. *Kena Lanham, Pharm.D.*, LaDonna S. Cangany, CPhT; Saint Vincent Hospital, Indianapolis, IN
PURPOSE: Pharmacy departments continue to struggle with balance between providing quality services while streamlining costs. Thus, pharmacy technicians have taken on roles previously done by pharmacists. Growing responsibilities to both staff and clinical pharmacists led to the development of two positions for clinical pharmacy technicians. The technicians provide both clinical and administrative support in the areas of cardiology and critical care.
METHODS: Clinical support-The cardiology clinical technician gathers laboratory data for the pharmacist to use in daily multidisplinary heart failure rounds. The critical care technician gathers both laboratory data and medication use data. Laboratory data is used to assess for dosing changes for renal impairment, parenteral nutrition, and monitorable medications. The medication use data tracks the use of continuous sedative infusions for the pharmacists to use in assessing daily sedative interruptions. Administrative support-Both technicians are involved in data collection for various projects including drug utilization evaluations, core measures adherence improvement, and medication management policy implementation.
RESULTS: Specific clinical technician responsibilities have changed with each challenge presented to the pharmacy department. To improve adherence to heart failure core measures, the cardiology clinical technician became involved in a medication reconciliation pilot to improve the discharge instructions measure. The critical care technician's work enables pharmacists to intervene on sedation and analgesia misadventures by targeting sedative infusions and ensuring a daily sedative interruption takes place. With each drug shortage, the clinical technicians have the ability to survey specific drug usage so that the clinical specialists have hard data to use to develop contingency plans.
CONCLUSION: The clinical technician position is viewed as an asset to cardiology and critical pharmacy teams. Their work allows pharmacists to practice patient focused pharmaceutical care and set priorities and goals to improve patient care.

297. Implementation of telepharmacy services in a multihospital health-system. *Matthew Jenkins, Pharm.D., M.S.*, Madalyn Bates, R.Ph., Meredith Jernigan, Pharm.D., Deborah Redmond, M.B.A., MHA; University of Pittsburgh Medical Center, Pittsburgh, PA
PURPOSE: The implementation of a telepharmacy service to provide round-the-clock medication order review by pharmacists is described.
METHODS: Three critical access hospitals (CAHs) worked collaboratively as part of a network of hospitals implementing the same electronic health record (EHR), computerized prescriber-order-entry (CPOE) system, and pharmacy information system to serve as the health information technology (HIT) backbone supporting round-the-clock medication order review by pharmacists. Collaboration permitted standardization of workflow policies and procedures. Through the HIT backbone, both onsite and remote pharmacists were given access to the medication orders, the pharmacy information system, and other patient-specific clinical data in patients' EHRs. Orders are typically reviewed within 60 minutes of when they are entered into the system. As part of the pilot, telepharmacy services were provided by three pharmacists employed by the health system. Using a virtual network or terminal server, pharmacists directly accessed hospital servers and information systems to conduct their work. Telephone calls were automatically routed to the telepharmacist so that handling of nursing and other calls would be transparent to staff. Hours of telepharmacy service were 6 p.m. to 7 a.m. Monday through Sunday evenings.
RESULTS: Order-processing time for routine orders averaged 15 minutes, while stat order processing averaged 9 minutes. For routine orders, turnaround times greater than 60 minutes became almost nonexistent after telepharmacy services were implemented. The total number of clinical interventions documented increased by 20%.
CONCLUSION: The implementation of a telepharmacy model in a multihospital health system increased access to pharmacy services, expanded hours of service, improved the processing of physician medication orders, and increased clinical pharmacy services and cost avoidance.

298. Warfarin monitoring by pharmacists versus usual standard of care in a long-term acute care hospital. *Helen Feinstein, Pharm.D., BCPS*; Kindred Hospital, Pittsburgh, PA
PURPOSE: To determine the impact of daily INR monitoring by staff pharmacists in a 72-bed long-term acute care (LTAC) hospital on the number of days with supratherapeutic INR levels and bleeding events.
METHODS: Comparison of 2 historical cohorts, one consisting of patients who received warfarin prior to implementation of anticoagulation monitoring program, and another consisting of patients with continuous warfarin monitoring matched for treatment indication was undertaken. Patients with diagnoses of deep venous thromboembolism (DVT), pulmonary embolism (PE), and atrial fibrillation hospitalized from April 2010 through March 2011 were selected from the pharmacy monitoring logs and the percentage of days above INR of 3.05 along with the incidence of bleeding was recorded. The same clinical indicators were pulled on randomly selected patients that met the criteria for diagnoses from the hospital's electronic medical records for the time period starting from April 2009 through March 2010.
RESULTS: After excluding patients, who had less than 5 consecutive INRs or artificial heart valves, 37 patients were selected for the control group and 33 patients were chosen from the pharmacist-monitored group. Prior to program implementation, patients spent on average 16.3% of days with the supratherapeutic INR, compared to 15.4% after pharmacists started monitoring the patients. Student's t-test did not show this difference to be statistically significant (p=0.40145). Four patients had bleeding episodes in the control group compared to 3 patients in the monitored group.
CONCLUSION: No improvement in patient outcomes with pharmacist warfarin monitoring was observed. However, it is also known that patients in the LTAC setting are more debilitated, present with multiple co-morbidities and require concurrent therapy with interacting drugs that may cause INR fluctuations or bleeding. It is possible that physicians may not be accepting some recommendations on dose adjustment as well. Staff pharmacists may need more training in managing anticoagulation therapy in our institution.

Community Pharmacy Practice

299. Community pharmacist clinical documentation intervention project. *Jamie L. McConaha, Pharm.D.*, Robert L. Maher, Pharm.D.; Duquesne University Mylan School of Pharmacy, Pittsburgh, PA
PURPOSE: To determine if a clinical intervention form implemented into community pharmacy workflow affected pharmacists' beliefs about clinical interventions performed, their perception on job satisfaction, and to measure ease of use of such a form in daily practice.
METHODS: Two community pharmacies and pharmacists participated in this pilot program. The clinical intervention form was a simple 7 x 4″ tear-off pad, developed by the researchers following the professional pharmacy services codes (PPS) designed by the National Council of Prescription Drug Programs (NCPDP). Form incorporation into daily workflow was studied for 3 months. Pre- and post-surveys were utilized to determine the pharmacists' attitudes and perceptions surrounding their involvement in clinical interventions in community pharmacy, job satisfaction, and the ease of using the form.
RESULTS: Results were analyzed using descriptive statistics. A total of 557 interventions were documented, the majority being patient-related issues and 31% of those due to drug-related issues. Dosage and duration issues accounted for 16% of all interventions documented. A change of mode score from a (4) agree to (5) strongly agree was shown on the post survey of pharmacist attitudes and indicated that pharmacists valued documentation. The satisfaction survey showed a mode score of (4) agree that the documentation form was helpful in identifying clinical interventions.
CONCLUSION: This pilot study on documentation of clinical

interventions in community pharmacy showed that pharmacists should be able to assess and quantify the clinical activities they perform and validated community pharmacists' beliefs that they perform clinical interventions. Implications may include development of an electronic means of documenting clinical interventions.

300. Implementation of a herpes zoster immunization service at an independent community pharmacy. *Karen M. Horbowicz, Pharm.D.*; Inman Pharmacy, Inc., Cambridge, MA
PURPOSE: New legislation that permits pharmacists to immunize patients against herpes zoster under the scope of a collaborative drug therapy management (CDTM) agreement was recently passed in the Commonwealth of Massachusetts. However, several barriers still exist that prevent patients from being appropriately immunized, including vaccine shortages, storage requirements, and third party billing to Medicare Part D. To our knowledge, there are no other community pharmacies in Massachusetts that offer herpes zoster immunizations administered by a pharmacist.
METHODS: To implement this novel service in Massachusetts, a CDTM agreement was developed to authorize three full-time, immunization-certified pharmacists to administer herpes zoster vaccinations. To participate, physicians must sign the CDTM agreement, write a prescription for the vaccine, and complete our referral form. Direct advertising was provided to both patients and local physician groups indicating that patients could come on a "walk-in" basis or schedule an appointment for the vaccination.
RESULTS: One hundred forty-eight patients were vaccinated since the implementation of this pharmacist-managed herpes zoster immunization program in January 2011. Another 142 patients completed the requisite paperwork but have not yet come into the pharmacy for the vaccination. Thirty-four CDTM agreements were established with different primary care providers. Referrals have steadily increased since implementation. The average reimbursement from ten different payers was $168.38. To date, this service has yielded $4,118.59 in profits and continues to grow.
CONCLUSIONS: Our efforts demonstrate that a herpes zoster immunization service can be successfully implemented within the current regulatory framework, improve vaccination rates, enhance public health, and remain profitable. Furthermore, the overwhelming support from participating physicians suggests there may be additional opportunities for collaboration between community pharmacists and physicians in the future.

301E. Identifying medication-related needs of HIV patients: foundation for communitypharmacist-based services. *Yardlee S. Kauffman, Pharm.D.*[1], Melissa McGivney, Pharm.D., FCCP[1], Elana Barkowitz, M.P.H.[2], Nicole Cerussi, Pharm.D., M.P.H.[3], Jan L Pringle, Ph.D.[1]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA; (3)UPMC Falk Pharmacy, Pittsburgh, PA
PURPOSE: The role of a community pharmacist managing HIV patients has not been well studied nor have these patients' perspectives about community pharmacist-based services. The purpose of this qualitative study was to identify medication-related needs of HIV-infected individuals who receive prescriptions from a community pharmacy and assess their perspectives of community pharmacist-based services.
METHODS: Individual, semi-structured interviews were conducted over a three-month period with participants living in both urban and rural areas. Participants were recruited from the Pittsburgh AIDS Center for Treatment in Pittsburgh, PA and the Ryan White Clinic in Johnstown, PA. Inclusion criteria included: HIV+ males and females at least 18 years old who currently take medications and use a community pharmacy for prescription fills. Interview questions were based on: (1) medication-related needs, (2) perceptions of the role of the pharmacist in their care, (3) perceived value of pharmacist services, and (4) preference for implementation of pharmacist-based services. All interviews were conducted by the principal investigator and continued until model saturation occurred.
RESULTS: Twenty-nine interviews were conducted: 15 participants from the PACT clinic and 14 from the Ryan White Clinic. Emerging themes, upon initial review, include: participants who have been on a medication regimen for several years state to be "self sufficient" and do not feel this service would be beneficial to them. Yet, they do feel that it may be valuable for patients who are starting new medications or changing medications. For those patients interested in the service, they have emphasized patient confidentiality as a key component of the service to increase their comfort with a pharmacist.
CONCLUSION: Results will better inform pharmacists in urban and rural settings about the needs of HIV/AIDS patients in their community and may guide the implementation or enhancement of community pharmacist-based services for HIV/AIDS patients.
Presented at Present at the American Pharmacists Association Annual Meeting, Seattle, WA March 25–28, 2011.

302. The role of a community pharmacy resident in expanding clinical pharmacy services within a traditional dispensing model. *Jamie Montgomery, RPh, BCPP*, Ted J. Turner, Pharm.D., Melanie Quinn, Pharm.D., Jessica Harms, Pharm.D., Sheila Samol, Pharm.D., Tanya Fabian, Pharm.D., Ph.D., BCPP; Western Psychiatric Institute and Clinic, University of Pittsburgh Medical Center, Pittsburgh, PA
PURPOSE: Patients with serious mental illness are at a higher risk for developing chronic medical disorders including metabolic syndrome and have significantly higher rates of premature mortality. Adherence to medications presents a special challenge for this vulnerable patient population. Community pharmacists can directly impact patient care and improve clinical outcomes through innovative dispensing models and specialized pharmacy services. We evaluated the role of a community pharmacy resident in expanding clinical pharmacy services within a traditional dispensing model.
METHODS: A total of 50 psychiatric outpatients were identified as having complex medication regimens and poor medication adherence and were enrolled in a pillbox program. Medical and psychiatric medications were dispensed in a weekly pillbox to promote adherence. Electronic medical records were reviewed to identify individuals with medical comorbidities including diabetes, hypertension or hyperlipidemia. A comprehensive medication review was conducted and medication education provided to the patient over three visits. Documentation of each visit was sent to the patient's primary care provider.
RESULTS: Of the 50 patients enrolled in the pillbox program, 27 (54%) had co-morbid medical diagnoses of diabetes, hypertension and/or hyperlipidemia. To date, one-third (9/27) have completed the medication management program. Patients were prescribed an average of 11 medications with complex dosing regimens. Eighteen drug therapy problems were identified of which 16 (89%) were resolved through pharmacy interventions with providers.
CONCLUSION: The addition of a community pharmacy resident was important to the success of this pilot project to assess feasibility of adding clinical pharmacy services to our current workflow. Although patients were enrolled in a structured dispensing program, drug therapy problems including adherence were identified. Pharmacists addressed patient specific medication issues and collaborated with providers to resolve. Incorporation of clinical pharmacy services into a traditional dispensing model can improve medication adherence, address access to care and promote health outcomes.

303E. Assessing community pharmacist impact on over-the-counter medication selection. *Jamie L. McConaha, Pharm.D.*[1], Jennifer E. Heasley, Pharm.D.[1], Thomas J. Mattei, Pharm.D.[2]; (1)Duquesne University Mylan School of Pharmacy, Pittsburgh, PA; (2)Mylan School of Pharmacy, Duquesne University, Pittsburgh, PA
PURPOSE: To evaluate the financial and clinical outcomes of an over-the-counter (OTC) medication consultation performed by pharmacists and student pharmacists in community pharmacy.
METHODS: Pharmacists in community pharmacy settings are sought after to provide recommendations on over-the-counter treatments. This occurs by several methods: (a) the patient approaches the pharmacy counter to ask about an OTC product, (b) the pharmacist is approached while out in the aisle by a patient about an OTC product, or (c) the pharmacist approaches a patient in the aisle if it appears that they need assistance. This prospective study looks to quantify the number of times these types of interactions occur in preselected community pharmacies. The impact will be evaluated in five ways: (1) evaluate the effects of pharmacist counseling on OTC medication

purchasing decisions/costs, (2) identify factors that influence purchasing decisions, (3) assess whether patients or pharmacists initiate the consultation, (4) measure prevented OTC medication-related adverse outcomes, and (5) assess patient likelihood to seek OTC counseling in the future. Three tool sets will be utilized to collect data in the study. The collects information such as the patient symptoms and healthcare need, initial and final purchase selections, and whether or not the recommendation was accepted. The collects the reasoning for recommendations. Lastly, the collects demographic information for study participants.

RESULTS: A total of 200 surveys have been collected to date. Initial results show that pharmacists initiate consultation >60% of the time, with 34% of these consultations accepted. The majority of patients (88.72%) have accepted the pharmacist's OTC recommendation, mainly dealing with cough and cold products (62). Pharmacist recommendations have resulted in an average savings of $2.95.

CONCLUSION: Pharmacist consultation has the potential to positively impact both financial and clinical outcomes associated with the use of OTC medications.

Presented at Presented at the American Pharmacists Association annual meeting, Seattle, WA, March 26, 2011.

Critical Care

304. Pseudoephedrine for neurogenic shock after acute spinal cord injury. *Jessica L. Johnson, Pharm.D.*[1], G. Christopher Wood, Pharm.D.[2], Jennifer N. Mitchell, Pharm.D.[3], Louis J. Magnotti, MD[4], Martin A. Croce, MD[5], Bradley Boucher, Pharm.D.[2], Joseph M. Swanson, Pharm.D.[2], Timothy C. Fabian, MD[5]; (1)Frederick Memorial Hospital, Frederick, MD; (2)University of Tennessee Health Science Center, Memphis, TN; (3)Veterans Affairs Medical Center, Charleston, SC; (4)University of Tennessee Health Sciences Center, Memphis, TN; (5)University of Tennessee College of Pharmacy, Memphis, TN

PURPOSE: Neurogenic shock is common after acute spinal cord injury (SCI) and may require extended catecholamine therapy. Oral/enteral pseudoephedrine (PSE) may be more convenient than IV vasopressors (VP); however, there are very few reports describing such use. This retrospective case series describes the effect of PSE for adjunctive treatment of neurogenic shock in acute SCI.

METHODS: Patients admitted to the trauma ICU between 2002–2010 with an acute SCI who received scheduled PSE for bradycardia (HR ≤ 50) and/or hypotension (MAP <65) were identified using the hospital database. Patients were classified as a treatment success if one of the following occurred within 7 days after PSE initiation: discontinuation of IV vasopressors (VP), or a positive clinical response (reduction in episodes of bradycardia and/or hypotension). The remaining patients were classified as treatment failure or inconclusive.

RESULTS: Twenty-one patients were identified. Descriptive statistics were: male sex 81%, age 40±18 yrs, high cervical SCI 71%, APACHE II score 13±5, injury severity score 39±15, ICU length of stay 42±24 days, and hospital length of stay 42±24 days. PSE was successful in 10 patients, failed in 4, and had an inconclusive effect in 7. In the success group, 5 patients had VP discontinued, 4 had a clinical response, and 1 had both. Patients were classified as inconclusive because of a short duration of PSE use (n=3), receipt of PSE prior to onset of neurogenic shock (n=3), or labile VP requirements that made classification difficult (n=1). Groups were not compared statistically because of low numbers, but there were no obvious clinical differences between groups.

CONCLUSIONS: Adjunctive use of PSE for patients with neurogenic shock appears to be beneficial for some patients. As the drug is relatively inexpensive and easily administered, a trial of PSE seems reasonable in patients who are difficult to wean from IV catecholamines.

305. Using non-bronchoscopic bronchoalveolar lavage-obtained respiratory cultures to guide antimicrobial therapy in patients with suspected pneumonia. Kay Lyn Lauer, Pharm.D.[1], John S. Rinck, RRT[1], John P. Kepros, M.D.[2], *Curtis L. Smith, Pharm.D.*[3]; (1)Sparrow Health System, Lansing, MI; (2)Michigan State University, East Lansing, MI; (3)Ferris State University College of Pharmacy, Lansing, MI

PURPOSE: The purpose of this study was to determine the influence of non-bronchoscopic, small volume bronchoalveolar lavage (mini-BAL)-obtained respiratory cultures on the selection or de-escalation of antimicrobial therapy in mechanically ventilated patients with suspected pneumonia.

METHODS: A retrospective chart review was conducted for patients who were mechanically ventilated and underwent a mini-BAL procedure between November 10, 2009 and December 10, 2010 to obtain a respiratory sample. Charts were reviewed for date of procedure, antibiotics received before the procedure, culture results, and antibiotic changes made subsequent to culture results. Changes in antibiotic therapy were assessed and a cost analysis was performed. The culture results were compared with those of samples obtained via bronchoscopic bronchoalveolar lavage (BAL).

RESULTS: Seventy-two patients accounted for 112 mini-BAL procedures. Fifteen of the 112 procedures were excluded. The incidence of normal flora, no growth, isolation of a specific organism or isolation of a predominant organism in combination with normal flora was 49.5%, 25.8%, 16.5% and 8.2%, respectively, for the mini-BAL samples and 63.3%, 16.7%, 3.3% and 16.7%, respectively, for the BAL samples. Of the 97 procedures, antimicrobial therapy was stopped in 26.8% of patients, changed based on susceptibility data in 12.4% of patients, expanded in 3.1% of patients and unchanged in 57.7% of patients. The cost savings of performing 97 mini-BAL procedures was a total of $10,980 (about $113 per patient) when the money saved from stopping or changing antibiotic therapy was taken into consideration.

CONCLUSIONS: The mini-BAL procedure is a cost-effective means of obtaining respiratory samples in mechanically ventilated patients with suspected pneumonia and is not inferior to BAL procedures for obtaining respiratory samples.

306. Optimizing heparin dosing in patients with cardiac arrest undergoing therapeutic hypothermia. *Jessica C. Carney, Pharm, D*[1], Randall Absher, Pharm D[1], Tatiana Daniels, Pharm, D[2]; (1)The Moses H. Cone Memorial Hospital, Greensboro, NC; (2)University of North Carolina, Eshelman School of Pharmacy, Chapel Hill, NC

PURPOSE: To evaluate and optimize heparin dosing in patients undergoing therapeutic hypothermia following cardiac arrest.

METHODS: A retrospective chart review was conducted between October 2010 and March 2011, on 34 patients admitted to The Moses H. Cone Memorial Hospital who survived cardiac arrest, underwent therapeutic hypothermia, and were treated with IV heparin for suspicion of myocardial infarction. Patients' baseline characteristics, heparin dosing, and anti-Xa heparin levels during hypothermia were evaluated. Data from hypothermic patients was compared to a historical database of normothermic patients treated with IV heparin for similar indications.

RESULTS: Hypothermic patients required lower heparin boluses and drip rates to reach therapeutic anti-Xa levels than normothermic patients. A multiple logistic regression model suggests that optimal heparin dosing for hypothermic patients consists of a bolus of 21 units/kg and an initial heparin drip rate of 9.2 units/kg/hr. Minor bleeding was reported in 5 of 34 patients.

CONCLUSIONS: As the popularity of therapeutic hypothermia in the post-arrest patient continues to grow, the use of anticoagulation in this population is also increasing. It appears a reduced heparin dosing strategy in hypothermic patients may be adequate to acheive anti-Xa levels in the therapeutic range.

307E. Survey of heparin-induced thrombocytopenia (HIT) laboratory testing and evaluation of a tailored HIT screening protocol based on the 4Ts scoring system. *Wesly A. Pierce, Pharm.D.*, Joseph Mazur, Pharm.D., BCPS, BCNSP, Charles S. Greenberg, MD, John Lazarchick, MD; Medical University of South Carolina, Charleston, SC

PURPOSE: Over-diagnosis of heparin-induced thrombocytopenia (HIT) results in costly and unnecessary laboratory screening and treatment with direct thrombin inhibitors. Our aim was to evaluate the utility of a modified "4-T's" scoring system in predicting HIT in ICU patients and to characterize our treatment of these cases.

METHODS: This retrospective review collected data from January

2009 through June 2010 to include patients who had a platelet factor 4 (PF4) assay and/or serotonin-release assay (SRA) drawn while in an ICU. Data collected consisted of patient demographics, PF4 assay/SRA results, platelet counts, heparin exposure and duration, clinical course, incidence of thrombosis, prescribed medications, and clinical outcome.
RESULTS: Of the 82 patients reviewed, only 12 (11.4%) were PF4-positive and of those, 1 (2.3%) was SRA-positive for HIT. Heparin was discontinued in only 63.4% of these patients. There were no significant differences in mean day of platelet fall, mean platelet nadir, and mean percent fall in platelet count between PF4-positive and negative patients (all p>0.2). There was a significant difference in the proportion of patients with an intermediate to high 4Ts score (66% vs. 30%, respectively; p=0.02). The negative predictive value of the 4Ts score relative to the PF4 and SRA was 92% and 100%, respectively. The estimated cost avoidance potential of the scoring system in this cohort was $21,450.
CONCLUSION: Our modified 4T's scoring system appears to be an effective tool for predicting HIT in the ICU and could avoid significant drug and laboratory expenditures if implemented prospectively. The clinical management of patients suspected of HIT is highly variable at our institution. Clinical protocols and education encouraging the proper identification and treatment of suspected HIT need to be established.
Presented at The Southeastern Residency Conference (SERC) of the Office of Postgraduate Continuing Education and Outreach - University of Georgia College of Pharmacy Athens, GA, April 28–29, 2011.

Drug Information

308. Carbapenems selection by means of the SOJA method. Ana Leandro, Pharm, D, *Armando Alcobia, Pharm.D.*; Hospital Garcia de Orta, Almada, Portugal
PURPOSE: The System of Objectified Judgement Analysis (SOJA) method is a model for drug decision making, for formulary purpose. In this method are defined selection criteria for a given group of drugs, each one with a relative weight depending on its importance. The extent in which each drug fulfils the requirements for every criterion is scored in terms of percentage of the criterion's weight. In 1998, a study (Janknegt R. et al. EHP 1998;4(1):5-12) was published comparing Imipenem/cilastatin and meropenem by means of the SOJA method. Since then, two more drugs have become available in Europe: ertapenem and doripenem. In our study, the selection criteria from the 1998's study were applied to the four drugs, with the purpose to evaluate the carbapenem group for a Pharmacy and Therapeutics Committee informed decision.
METHODS: The SOJA method was applied to the four available carbapenems: imipenem/cilastatin, meropenem, ertapenem and doripenem. The evaluation criteria were selected, and all information used in drug scoring was collected by literature research. The exceptions were resistance data and acquisition costs, where specific information from our hospital was used.
RESULTS: The following selection criteria and relative weight were used: number of formulations (20); number of approved indications (30); pharmacokinetics (60); antimicrobial spectra (110); efficacy (175); development of resistance (120); general side effects (100); severe side effects (100); drug interactions (75); dosage frequency (45); acquisition cost (105) and experience/documentation (60) The order obtained was: meropenem (722), doripenem (646), ertapenem (641) and imipenem/cilastatin (627).
CONCLUSION: Meropenem showed a total higher score, showing added therapeutic value within the carbapenem group. These results allow the Pharmacy and Therapeutics Committee to decide based on more consistent information.

309. Standard operating procedure to develop evidence-based information to support pharmacy and therapeutics committee decision for formulary management at a university hospital. *Ana C. Ribeiro Rama, Ph.D.*; Pharmacy Department, Coimbra University Hospitals and Center for Pharmaceutical Studies, Faculty Pharmacy, Coimbra University, Coimbra, Portugal
PURPOSE: Pharmacy and Therapeutics Committees (PTC) are responsible for the effective management of medicine's use through maintenance of Hospital Formulary. Standard operating procedures (SOP) were designed to overcome the need to develop strategies for PTC decision support, in response to technology progress along with rising costs, to make available evidence based information.
METHODS: Literature search to find guidelines on items of information needed to support PTC's decisions to develop a model for its delivery. Search to identify resources with valid and evidence based information on each needed item on new medicines and technologies, to develop the systematic strategy to look for information. SOP was tested with 25 medicines and 5 medical devices (MD).
RESULTS: Main items needed to support PTC's decision include comparative analysis, regarding pharmacodynamic/pharmacokinetic profile, efficacy, safety and economic impact. Search strategies were developed, with keywords and mesh terms, to identify primary and secondary literature on Medline/PubMed and most essential journals. Information resources identified were characterized regarding quality criteria and content. The 80 resources gathered, delivering evidence based information and quality assessment on new technologies, comprehend websites, freely available, of medicines agencies, governmental and nongovernmental organizations, databases, mainly from UK and USA. Document types include monographs, health technology assessment reports, PCT's reports and therapy/safety bulletins. Seven paid databases were tested. Response from all resources, vary according to: the item; web resource country of origin; document type; technology and accessibility type. With this procedure, PTC has evaluated 5 medicines in 2009, 13 medicines and 1 MD in 2010 and 8 medicines and 4 MD in 2011 and has supported their decision to include 12 of 25 medicines and 2 of 5 MD. From 2011, 6 medicines and 1 MD wait decision.
CONCLUSION: We have created a SOP to find information needed to support PTC decision and develop a model to deliver it.

Education/Training

310E. Assessing the effect of multiple advanced cardiac life support simulations on pharmacy student performance. Jason S. Haney, Pharm.D., BCPS[1], *Sarah P. Shrader, Pharm.D., BCPS*[2]; (1)South Carolina College of Pharmacy, Charleston, SC; (2)South Carolina College of Pharmacy/MUSC Medical Center, Charleston, SC
PURPOSE: To assess the effect of multiple advanced cardiac life support (ACLS) simulations on third-year pharmacy student performance with 1) managing adult patients with bradyarrhythmias, tachyarrhythmias, and cardiac arrest; 2) preparing medications with sterile technique for use during ACLS; and 3) calculating patient-specific vasopressor administration rates.
METHODS: The study was approved by the institutional review board of the Medical University of South Carolina. An ACLS simulation using a human patient simulator was developed for third-year pharmacy students at the South Carolina College of Pharmacy. Three days prior to the simulation, students received 2 hours of lecture reviewing the pharmacist's role and pharmacologic agents used in ACLS. Students were divided into 26 groups of 3–4 students and assigned a 45-minute session. The students identified and treated three scenarios: sinus bradycardia, ventricular fibrillation, and hypotension. Students rotated roles as team leader/administering respirations, preparing/administering medications, and performing compressions/operating the defibrillator following each scenario. An instructor supervised each session, graded clinical performance, and provided a debriefing session. Students were given a pre- and post-simulation written examination and survey. Eighteen students enrolled in the Acute Care Therapeutics (ACT) elective completed an additional simulation the following week without any additional formalized instruction. ACT students were reassessed for clinical performance and by written examination.
RESULTS: During the initial simulation, third-year pharmacy students successfully completed 77% of the ACLS clinical tasks. Performance improved in the ACT group from 71% to 95% during the first attempt and retest, respectively. The written examination class average improved from 97% on the pretest to 99% on the initial posttest. Written examination scores initially improved for the ACT group (91.7% pretest vs. 98.6% posttest), but declined during reassessment the following week (86%).

CONCLUSION: Repetitive ACLS simulation-based learning experiences improved pharmacy student clinical performance, but failed to improve knowledge retention for written examination.
Presented at the Annual Meeting of the American Association of Colleges of Pharmacy, San Antonio, TX, July 9–13, 2011.

311. Evaluation of a 20-week longitudinal student program. *Kelly M. Wright, Pharm.D.*, Amy L. Dzierba, Pharm.D.; NewYork-Presbyterian Hospital, New York, NY
PURPOSE: Schools of Pharmacy develop relationships with practice sites to provide students with advanced practice experiential rotations to assume direct patient care responsibilities. A typical student will have 7-9 rotation sites. NewYork-Presbyterian (NYP) has collaborated with Saint John's University School of Pharmacy to provide fifth-year pharmacy students with five, 4-week rotations in a longitudinal fashion. The 20-week student program at NYP is intended to expose the student to various aspects of clinical pharmacy within a largely diverse patient population under the direct guidance of a preceptor.
METHODS: In order to build more effective programs to enhance student achievement, an evaluation of the current process was implemented. Information including grade point average (GPA), professional involvement, work experience, and a 10-item evaluation of the program was collected. In addition, a one year follow-up email was sent to determine which career path the student pursued.
RESULTS: Thirteen students were consented and enrolled. According to student report, 8 and 13 received Honors and 4 and 10 were Honor Society members during high school (HS) and pharmacy school respectively. Nine students held a Professional Membership. Pharmacy GPA was >3.1 in twelve students. The majority of students worked in a retail setting and reported 2-4 years of pharmacy work experience. There were eleven responders for the 10-item survey. Ten students agreed or strongly agreed that the longitudinal program at NYP made them more likely to pursue a Pharmacy Residency. At 1-year there were nine responders, eight students had accepted a Pharmacy Residency position and one accepted a job in retail after failing to match.
CONCLUSION: All students were high professional achievers in HS and pharmacy school. It's unknown whether the student participants accurately represent the general student population; however per self-report they identified the longitudinal program as a positive influence to pursue a Pharmacy Residency.

312. Creation of a global health pharmacy residency in Kenya. *Monica L. Miller, Pharm.D., M.S.*, Rakhi Karwa, Pharm.D., Ellen M Schellhase, Pharm.D., Sonak D. Pastakia, Pharm.D., M.P.H., Imran Manji, B.Pharm.; Purdue University, Indianapolis, IN
PURPOSE: Clinical pharmacy services continue to advance in the United States and abroad. Despite these advances, a shortage of clinically trained pharmacists exists in developing countries. To address this need, Purdue University College of Pharmacy (PUCOP) through its Purdue Kenya Program (PKP) developed a pharmacy residency program in Kenya entitled the Clinical Pharmacy Residency Exchange Program (ClinPREP). Since 2004, PUCOP has collaborated with the Academic Model for Providing Access to Healthcare (AMPATH) to provide clinical pharmacy services. AMPATH and PKP are based in Eldoret, Kenya and provide care to more than 120,000 patients at more than 50 clinic locations throughout Western Kenya.
METHODS: ClinPREP is an international pharmacy residency program with a focus on training participants to be global health care practitioners who are able to provide leadership in resource-constrained settings worldwide. The residency class is comprised of Americans and Kenyans allowing for a bilateral exchange of experiences and ideas. The program's main goal is to train clinical pharmacists who can develop and deliver sustainable health care regardless of the setting. The ClinPREP framework was developed in part by using the ASHP residency standards and identifying additional global health related training needs of participants. The residents participate in a variety of established clinical services and as a group are developing a new, sustainable clinical service. In addition to developing clinical skills, residents receive didactic training in public health, research methodology, and preceptor development. Residents also strengthen their teaching skills while precepting PUCOP advanced pharmacy practice experience students and Kenyan pharmacy interns.
RESULTS: The program began in July 2011 with 4 participants. The residents are working to develop a new clinical service to augment patient care.
CONCLUSION: The ClinPREP residency program addresses a need for developing clinical pharmacy services in Kenya while training global health leaders from Kenya and America.

313. Expanding residency opportunities through school of pharmacy collaborations. *Heather J. Johnson, Pharm.D.*[1], Amy L. Seybert, Pharm.D.[2]; (1)UPMC Department of Pharmacy and Therapeutics, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: In 2011 over 1300 candidates did not match with the 2500 positions offered. Residency training as a requirement for direct patient care will likely increase the number of candidates. The demand for expansion of pharmacy residency programs and the challenge of expanding while maintaining quality is shared throughout our profession. Schools of Pharmacy can contribute to the expansion of pharmacy residency training . We describe the nature and impact of the University of Pittsburgh School of Pharmacy's collaboration with local residency programs and health systems on the growth and content of residency programs.
METHODS: Areas of contribution include development of learning opportunities, program sponsorship, and residency program collaboration.
RESULTS: Program Development: A suite of faculty-based longitudinal programs were developed for residents including a didactic and practical research series and teaching certificate program. Developed to enhance the quality of resident research and offer a structured framework, the research series is a required component for 18 residencies collaborating with the University of Pittsburgh School of Pharmacy. The elective teaching mastery program, completed by 43 residents to date, offers specialized and advanced opportunities for residents. Residency Sponsorship: Strategic planning identified key areas for development of residencies. Sponsorship from third party organizations as well as the School directly has led to the development of pharmacy residencies that are now self-sustaining. Program Collaboration: Program directors and School faculty form a Residency Council which collaborates on common issues. This group provides program directors guidance during residency development as well as peer review of new programs. This spirit of collaboration has enabled us to guide the development 5 new residencies in the last 4 years.
CONCLUSION: Schools of pharmacy can provide resources for the development of residents in various ways and should explore opportunities in their sphere of influence in order to facilitate residency growth.

314. Utilization of cloud computing to aid experiential precepting at a tertiary academic medical center. *Maria Giannakos, Pharm.D., M.B.A.*, Timothy Pasquale, Pharm.D.; Summa Health System - Akron City Hospital, Akron, OH
PURPOSE: The demand for experiential sites and preceptors has increased as a result of the growth of existing pharmacy programs and the increase in new colleges of pharmacy. Similarly, the number of graduates pursuing residency training has also impacted the need for additional residency opportunities and associated resources. Utilization of Google's cloud computing platform is one potential approach to consolidating rotation resources to maximize precepting time, further enhancing the learning experience.
METHODS: A shared website was created using Google infrastructure. General rotation information on the rotation site, expectations, and required reading assignments were posted for viewing. Prior to topic discussions, trainees performed literature searches and posted at least one article citation and/or link which the trainee found most useful. Completed assignments or drafts could be posted for the preceptor to retrieve, allowing off-campus collaboration. Additionally, a shared Google calendar was created within which both parties would add appointments and deadlines in a merged calendar. Useful web links, some institution-specific, were also incorporated to facilitate learning.
RESULTS: Two preceptors utilized the shared site for separate rotations in a similar, yet unique precepting experience. Seven

Pharm.D. candidates and three residents were granted access to the site over one year. The shared site consolidated resources and enhanced communication. An additional benefit seen was that of unlimited storage space and emailing capacity.
CONCLUSION: The utilization of cloud computing enhanced the organization of resources and augmented the precepting experience. Overall, on-demand electronic access to shared resources was beneficial to both preceptor and trainee.

315. Pharmacist-physician interdisciplinary faculty development: Get out of your silo!. *Trish Klatt, Pharm.D., BCPS*[1], Heather A. Sakely, Pharm.D., BCPS[1], Stephen A. Wilson, M.D., M.P.H., FAAFP[2]; (1)UPMC St. Margaret, Pittsburgh, PA; (2)University of Pittsburgh Family Medicine Faculty Development Fellowship UPMC St Margaret Family Medicine Residency, Pittsburgh, PA
PURPOSE: Innovative pharmacy resident curriculum is cultivated through a multidisciplinary approach to teaching.
METHODS: The Faculty Development Fellowship for family medicine physicians at UPMC St. Margaret has been established for 30 years. Eight years ago, our pharmacy residency started with 1 resident and since, the residents have participated in this fellowship, creating a novel learning experience. The curriculum consists of a summer intensive series of small group workshops, 4 half-days per week for 6 weeks. A longitudinal series then begins for one-half day per week throughout the year. The curriculum consists of 4 main topic areas: teaching and learning, leadership, research, and communication and professional writing.
RESULTS: The teaching and learning component focuses on precepting learners of all types, curriculum design, didactic teaching strategies, providing feedback to learners, and adult learning theory. Pharmacy residents and physicians work together to design and present a hands-on multidisciplinary, longitudinal curriculum to the physician and pharmacy residents throughout the year. Leadership skills are cultivated through this task, which has included themes of end of life care, new health care system, or some other facet of systems based health care. A database research study is often completed by participants and the pharmacy resident's personal research project is regularly discussed. Fellowship participants write and publish a letter to the editor, allowing an opportunity for professional writing and literature evaluation. Active discussion and feedback from another discipline helps the author to shape and design their writing. They also express themselves through 55-word stories about patient encounters, and gain skills interacting with the media and for grant writing.
CONCLUSION: Pharmacy residents and physicians in the fellowship often go on to academic positions. They are well positioned to hold leadership roles in professional organizations and serve as professional mentors.

316. Critical literature evaluation and advanced pharmacy practice experiences: student preparedness. *Kathryn M. Momary, Pharm.D.*, Lisa M. Lundquist, Pharm.D., BCPS; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA
PURPOSE: Compare students' performance and perceptions of preparedness to critically evaluate literature before and after advanced pharmacy practice experiences (APPE).
METHODS: A perception of preparedness questionnaire and a knowledge assessment were distributed to the students in the third professional year (before APPE) and in May of the fourth professional year(after APPE) for two consecutive classes. The knowledge assessment and preparedness instrument consisted of questions related to core knowledge and application of critical literature evaluation. Students were asked to rate the adequacy of their preparedness on a 4-point Likert scale with 1 = extremely unprepared, 2 = unprepared, 3 = prepared, and 4 = extremely prepared. Knowledge assessment was done via an 8-question multiple choice quiz. Data collection for this study was approved by the IRB and students signed informed consent prior to participation. Students' perceptions of preparedness and performance before and after APPE were compared with descriptive statistics and Pearson's correlation; pre- and post-APPE data were compared with paired *t*-test.
RESULTS: One hundred forty-two students (50%) consented for participation and completed all pre- and post-APPE perception of preparedness questionnaires and knowledge assessments before and after APPE. The perception of preparedness mean (SD) increased significantly from 2.2 (0.5) pre-APPE to 3.0 (0.4) post-APPE [$p<0.001$]. Knowledge assessment also increased significantly from 56.3% (19.0%) pre-APPE to 63.3% (16.6%) post-APPE [$p=0.001$]. There was a statistically significant correlation between the pre- and post-APPE knowledge assessment and perception of preparedness ($p<0.001$ and $p<0.001$, respectively).
CONCLUSION: Students' perceptions of preparedness and knowledge of critical literature evaluation statistically significantly improved after clinical experiences in APPE. However, student knowledge is still not optimal. APPE provide an invaluable opportunity to reinforce and expand knowledge of literature evaluation and its importance as a practicing pharmacist. Increased review of critical literature evaluation during APPE will likely further improve student performance.

Emergency Medicine

317. A retrospective review of medication orders entered for emergency department patients within an academic teaching medical center for quality assurance. *Jason W. Lancaster, Pharm.D., BCPS*; Northeastern University: Department of Pharmacy Practice/Lahey Clinic Medical Center, Boston, MA
PURPOSE: Currently the Joint Commission recommends that the Department of Pharmacy prospectively review all medication orders for patients within the emergency department (ED), and if not, that documentation that quality assurance measures performed and documented. At this time the Lahey Clinic Medical Center Department of Pharmacy has no baseline data surrounding the appropriateness of patient administered medications within the emergency department.
METHODS: Using a random numbers table patients were selected from the daily admissions to the emergency department during the month of December 2010. Patients were included if they were admitted to the ED, >18 years old and had at least one medication ordered.
RESULTS: A total of 128 patients were identified, and 100 were included. The mean age of those included was 56.8 years and a total of 248 orders were evaluated, providing an average of 2.5 orders per patient. Of the 248 orders evaluated 231 (93.1%) would have required no further intervention based on a retrospective pharmacists review. However, 17 orders (6.9%) would have and the reasons for intervention include subtherapeutic dosing, duplication of drug classes prescribed, or inappropriateness of route, frequency or dose.
CONCLUSION: From this review it was determined that a majority of the orders written and administered in the emergency department would have required no further pharmacist intervention and would have been entered directly into the pharmacy medication administration system. However, in approximately 7% of these orders additional pharmacist review may have led to optimization. Of these, the largest percentage involved antibiotic, pain medication and anti-emetic agents. Although the impact of pharmacist prospective review and intervention cannot be fully known from this study there were clear areas identified where a pharmacist prospective review of medication orders may have led to increased compliance to hospital protocol(s), reduction in costs and avoidance of duplicative medication classes and further evaluation is warranted.

318. Implementation and evaluation of a recombinant activated factor VII guideline for uncontrolled bleeding. *Nicole M. Acquisto, Pharm.D.*, Paul E. Bankey, MD, Ph.D., Curtis E. Haas, Pharm.D.; University of Rochester Medical Center, Rochester, NY
PURPOSE: Recombinant activated factor VII (rFVIIa) has been used for patients with uncontrolled bleeding without hemophilia. There are multiple controversies concerning indication, dose, adverse effects, and exclusion criteria. Due to cost and limited evidence of value, need for standardization of use is evident.
METHODS: An inter-professional group that included pharmacy and several surgical specialties was formed. Current literature was reviewed and peer institutions were queried for identification of best-practices. The guideline was developed and included indications for use, inclusion criteria for coagulopathic bleeding, exclusion criteria

for futility and risk of thromboembolic complications, dose, and relative contraindications. All patients receiving rFVIIa prior to guideline implementation and after were monitored.
RESULTS: Overall, 70 doses of rFVIIa were administered to 59 patients prior to protocol implementation (2005 to July 2008) and 95 doses to 68 patients following protocol implementation (August 2008 to 2010). The median dose (IQR) in the pre-protocol group was 90 μg/kg (43.75 to 93 μg/kg) and 26.25 μg/kg (20 to 40 μg/kg) in the post-protocol group, p<0.001. Although lower doses were evident following guideline implementation, there was no difference in in-hospital mortality, 49% vs. 45.6% in the pre- and post-protocol groups, respectively, p=0.55. An evaluation of guideline exclusion criteria found that a higher percentage of patients met at least one exclusion criteria in the pre-protocol group compared to the post-protocol group, 57.6% vs. 29%, respectively, p=0.001. Exclusion criteria were often a low platelet count at the time of rFVIIa administration without administration of additional platelets.
CONCLUSION: rFVIIa dose has decreased appreciably without an apparent negative effect on mortality. The proportion of patients receiving rFVIIa that have meet exclusion criteria continues to decrease following protocol implementation. This is likely a direct impact of the protocol and the result of regular feedback to the providers.

319. Benchmarking enoxaparin use in the emergency department as a quality improvement metric for clinical pharmacy services. *Matthew S. Nelson, Pharm.D.*, Natasha D. Lopez, Pharm.D., Candice R. Preslaski, Pharm.D., Elena Santayana, Pharm.D., BCPS, Ishaq Lat, Pharm.D., BCPS; University of Chicago Medical Center, Chicago, IL
PURPOSE: To determine the appropriateness of enoxaparin use in the emergency department and to quantify the financial impact of dispensing a single size of enoxaparin from the medication dispensing cabinet as an opportunity for continued quality improvement.
METHODS: A drug utilization review was conducted on patients who received enoxaparin in the emergency department during a 3-month period from April to June 2010. Each dispensing of enoxaparin was then compared to the administered dose and was evaluated for the amount of waste generated by the difference between the dispensed and administered doses. The orders were also evaluated by a pharmacist to assess the appropriateness of therapy taking into account the indication, weight, renal function, and any anti-Xa levels drawn for the patient. Appropriateness was determined as adherence to the medical center's enoxaparin policy.
RESULTS: Of the 124 enoxaparin orders during the 3-month period, thirty-two were dosed for prophylaxis and 92 were dosed for treatment. All 32 prophylaxis doses were deemed appropriate. Of the 92 treatment doses, fifty-two (56.5%) were deemed appropriate, and 40 (43.5%) were deemed inappropriate, as determined by medical center policy. The use of a single syringe size resulted in the aggregate waste of 3,569 mg of enoxaparin during this 3 month period. This correlates to an estimated cost of $1,446.39, which would translate to an annual cost of $5,785.56 from enoxaparin waste. Continued dispensing of inappropriate doses after hospital admission wasted an additional 3,060 mg of enoxaparin. This correlates to an estimated additional cost of $1,145.37 over the 3-month period, or $4,581.48 annually from enoxaparin wastage. Combined, the estimated annual cost from enoxaparin wastage was $10,367.04.
CONCLUSION: This study serves as a benchmark metric for quality improvement in the provision of emergency medicine clinical pharmacy services.

320. Evaluation of a pharmacist oversight program for medication use in the emergency department of an academic medical center. *Sally Rafie, Pharm.D.*, Theodore Chan, M.D., Edward Castillo, Ph.D., Douglas Humber, Pharm.D., Ronald Dunlay, Pharm.D.; UC San Diego Health System, San Diego, CA
PURPOSE: The objectives of this study were to assess the impact of pharmacist oversight of medication use in the ED on patient safety and staff acceptance of the new service. The pharmacist oversight program included review of all medication orders; however, the ED staff could remove medications from the automated dispensing cabinet via override.
METHODS: The study was conducted at an academic medical center with 61,000 ED visits annually. Retrospective data between April and August 2010 was reviewed. Reported medication errors and ED pharmacist interventions were analyzed for trends and pharmacist impact. To assess ED physician and nursing satisfaction with the ED pharmacist program, an anonymous survey was conducted one year after program initiation.
RESULTS: During the five month period, 361 medication errors were documented. The most common errors included overriding the automated dispensing cabinets (ADC) without a provider order (73%), wrong dose/infusion rate (18%), wrong drug (8%), and wrong patient (4%). A total of 244 pharmacist interventions documented, with an acceptance rate of 83.2%. Faculty, residents, and nurses completed the anonymous survey (n=79, 40.1% response rate). Staff agreed that the ED pharmacist was beneficial in assisting with drug information questions (95.9%), medical resuscitations/codes (93.2%), and patient education (89.0%). Only a small portion of respondents noted that all ED medication orders (17.8%), urgent orders (16.4%) or non-urgent orders (19.2%) should be reviewed; whereas the majority of respondents noted that orders for high risk medications (78.1%) and rarely used medications (72.6%) should be reviewed by a pharmacist. Respondents felt ED pharmacists being available for consult and attending resuscitations/codes maximized their contribution to medication safety.
CONCLUSION: The results suggest that pharmacist oversight of medication use in the ED reduces medication errors, reducing the risk of patient harm and increasing patient safety.

Endocrinology

321. Adjunctive sitagliptin therapy in postoperative cardiac surgery patients: a pilot study. *Marcia L. Brackbill, Pharm.D., BCPS*[1], Ateequr Rahman, Ph.D., MBA[1], Jeffrey Sandy, RN[2], M. Denton Stam, M.D.[3], Arthur F. Harralson, Pharm.D., BCPS[1]; (1)Shenandoah University, Bernard J. Dunn School of Pharmacy, Winchester, VA; (2)Winchester Medical Center, Winchester, VA; (3)Valley Health Cardiothoracic and Vascular Surgeons, Winchester, VA
PURPOSE: Adequate blood glucose control after cardiac surgery is often challenging for clinicians in the postoperative setting. Due its novel mechanism of action and its lack of serious side effects compared to other oral antihyperglycemic agents, sitagliptin is an ideal medication to evaluate in this setting as an adjunctive therapy. This study sought to determine if sitagliptin added to standard postoperative blood glucose management improved mean overall blood glucose control in the four-day period after cardiac surgery.
METHODS: A single center, prospective, randomized, double blind placebo-controlled pilot study was conducted in 62 hospitalized diabetic patients who underwent cardiac surgery. Patients received sitagliptin 100 mg once daily or a matching placebo after surgery for 4 days. The primary objective was to estimate the effect of adjunctive sitagliptin administration on overall mean blood glucose in the 4-day period after initiation of sitagliptin therapy compared to standard blood glucose management practices alone.
RESULTS: Sixty-two patients participated in the study, and were randomly assigned to the sitagliptin or placebo group (n=30 and 32, respectively). Baseline analysis revealed no statistical differences between the treatment groups and control groups in demographics and baseline parameters. The repeated measures test indicated that there was no significant difference between the two groups in the overall mean blood glucose level with a mean of 147.2±4.8 mg/dL and 153.0±4.6 mg/dL for the test and the control group, respectively (p=0.388).
CONCLUSION: Sitagliptin added to normal postoperative glucose management practices did not improve overall mean blood glucose control in diabetic patients in the postoperative cardiac surgery setting.

Family Medicine

322E. Incorporating pharmacy services within a family medicine residency home visit program. *Tanya M. Dougherty, Pharm.D., BCPS*[1], Heather A. Klusaritz, MSW[2], Peter F. Cronholm, MD, MSCE[2], Nishaminy Kasbekar, BS, Pharm.D., FASHP[3]; (1)Penn Presbyterian Medical Center, Department of Family Medicine and Community

Health, University of Pennsylvania, Philadelphia, PA; (2)Department of Family Medicine and Community Health, University of Pennsylvania, Philadelphia, PA; (3)Penn Presbyterian Medical Center, Philadelphia, PA
PURPOSE: To evaluate patient-related medication and safety outcomes associated with pharmacist and pharmacy student involvement in a family medicine residency home visit program.
METHODS: The home visit team at the University of Pennsylvania Family Medicine Residency consists of an attending, resident physician, social worker and pharmacist and/or pharmacy student. Patients are deemed appropriate home visit candidates for evaluation of: post-hospitalization/acute care follow-up, medication assessment/reconciliation, long-term care options, or environmental effect on illness. The pharmacy team evaluates medication taking habits at home, conducts medication reconciliation, provides counseling on adherence and medication use and recommends medication changes based on safety/efficacy concerns. Data on visit reason, adverse events, drug-related problems () and interventions was analyzed.
RESULTS: Out of 48 patients visited, reasons for home evaluation were medication assessment (41%), post-hospitalization (31%), environment (21%), options (6%), other (3%). The pharmacy team identified 79 (mean 1.9/patient; range 1–7), the most common being adherence issues (52%). Others included overuse, underuse, taking a medication that was stopped, taking expired medications, duplicate therapy, low health literacy, incorrect administration, taking a medication to which an allergy exists, and side effects. Of those , 13 preventable adverse events () were identified and solved with pharmacy recommendations in 12 patients (27%). The were: continuing to take medications (,) stopped due to adverse event (GI bleed, hypotension), taking lower or higher than prescribed doses (, insulin), duplication (), drug interaction necessitating change in therapy, crushing ER medications (acid,), patient allergic to sulfa recently started with new rash. A total of 30 pharmacy interventions were accepted including discontinuing medications, reducing cost of medications, delivery set-up, teaching, switching medications.
CONCLUSION: Involvement of a pharmacist and pharmacy students within a family medicine residency home visit program can reduce drug-related problems and preventable adverse drug events.
Presented at To be presented at Annual Meeting and Exposition of the the American Public Health Association, Washington, D.C, October 29–November 2, 2011.

323. COPD free medication initiative. *Jennie Broders, Pharm.D., BCPS*, Patricia Klatt, Pharm.D., BCPS, Isabel MacKinney-Smith, BSN, RN; UPMC St. Margaret, Pittsburgh, PA
PURPOSE: Financially, COPD is an extreme burden for patients seeking to pay for multiple expensive inhalers as well as the healthcare system due to hospital readmission rates. The University of Pittsburgh Medical Center (UPMC) - St. Margaret has the second highest 30-day COPD readmission rate within UPMC. In an effort to reduce readmission rates, a COPD task force has been formed. This group of nurse educators and case managers identifies COPD patients recently discharged and performs follow-up phone calls and home visits to improve patient and family education, subsequently decreasing readmission. Inability for many patients to obtain their inhaled medications for COPD has been identified by the task force as a major contributor to readmissions.
METHODS: UPMC has a charitable mission to provide medically necessary health care services to residents of Western Pennsylvania and its providers' primary service areas, regardless of their financial status and ability to pay. In accordance with this mission, UPMC St. Margaret's 3 family health centers have successfully offered a Free Medication Program to provide acute and maintenance medication to those patients who would otherwise be unable to afford them. The only COPD medications available through this program are albuterol and a steroid inhaler. Through this established Free Medication program system and network of COPD educators, UPMC St. Margaret proposes availability of COPD medications to all patients that are unable to afford them in UPMC St. Margaret Family Medicine practices. We will expand the formulary to include anticholinergic medications and long-acting beta agonists in order to optimize the treatment of COPD. Currently there are no generic inhalers indicated for the treatment of COPD, inherently incurring large costs for this type of program. However, we hypothesize that the cost of inhaler medication supply would be far less than readmission costs.

Geriatrics

324E. Characteristics associated with clinical pharmacist interventions among home based primary care veterans. *Jennifer T. Selvage, Pharm.D.*, Liancy Gomez, Pharm.D., Annette Kossifologos, Pharm.D., Tripti Kurup, Pharm.D., Kavita Palla, Pharm.D., Todd Lee, Ph.D., Pharm.D.; Edward Hines, Jr. VA Hospital, Hines, IL
PURPOSE: Determine patient characteristics associated with a high number of clinical pharmacist recommendations at home visits among home based primary care (HBPC) veterans.
METHODS: HBPC patients with a pharmacist home visit between 7/2009-10/2010 were identified. Characteristics obtained from charts were: demographics, medical conditions, medications, reason for pharmacist home visit, and use of non-VA providers. The number of pharmacist recommendations made from the following categories was determined: use of pillboxes, medication management process, medication commissions and omissions, possession or use of discontinued or expired medications, noncompliance, incorrect medication use or storage, potential drug-drug/disease interactions, and reported adverse drug reactions. Patients with a high number of recommendations (>7 recommendations) were compared to those with fewer recommendations. Bivariate comparisons were made between groups and logistic regression was used to estimate adjusted associations between patient characteristics and a high number of recommendations.
RESULTS: 62 patients had home visits. A total of 742 medication related issues were identified, resulting in 338 pharmacist recommendations. Patients with a high number of recommendations had, on average, 4 more medications than those with fewer recommendations (p=0.02). Factors associated with a high number of recommendations included use of lipid lowering medications [(OR) 7.3, 95% CI 0.9–60.2], GERD (OR 3.4, 1.1–11.3), number of medications (OR 1.1, 1.0–1.3), and medication self-management (OR 6.7, 1.7–27.0). Presence of hyponatremia and use of antiplatelet medications were perfectly predictive of a high number of recommendations. In adjusted analyses, medication self-management remained significantly associated with a 6-fold increase in the likelihood of being in the high recommendation group (Adj OR 6.0, 1.3–26.8). Of the pharmacist recommendations made, 63.6% were accepted.
CONCLUSION: Patients who self-manage medications, those with a greater number of medications, and those with lipid lowering medications, antiplatelet agents, GERD, or hyponatremia may benefit most from a pharmacist home visit.
Presented at Presented at the American Geriatric Society Annual Scientific Meeting, National Harbor, MD, May 11–14, 2011.

325. A pilot fee-for-service medication therapy management program in a geriatric primary care clinic. *Sunny A. Linnebur, Pharm.D., FCCP*[1], Joseph P. Vande Griend, Pharm.D.[1], Gina Moore, Pharm.D., MBA[1], Irene Girgis, Pharm.D.[2]; (1)University of Colorado School of Pharmacy, Aurora, CO; (2)Colorado Access, Denver, CO
PURPOSE: To describe the development and implementation of a pilot medication therapy management (MTM) program reimbursed as a fee-for-service through Medicare
METHODS: A contract was negotiated between the University of Colorado School of Pharmacy to provide MTM services as covered benefits for all of the Geriatric Primary Care Clinic patients enrolled in the Medicare Advantage HMO plan sponsored by Colorado Access, a non-profit insurance provider. Two clinical pharmacists, with an established relationship with clinic providers and full access to the electronic medical record (EMR), provided the services. Unreimbursed MTM services have been provided at the clinic for over 10 years. MTM was performed face-to-face and over the phone. The number of billable visits was not limited. To aid in the MTM visits, the clinical pharmacists were allowed access to prescription claims data by Colorado Access. Changes to the patient's pharmacotherapy regimen were made in concert with the patient's healthcare provider

and focused on: 1) medication reconciliation; 2) identification and resolution of drug-therapy problems, including non-adherence; 3) cost-saving through formulary management; and 4) patient-specific disease state and drug therapy education.
RESULTS: Cognitive services (CPT codes 99605, 99606) and facility fees (99212, 99214) were remitted for payment. MTM services were reimbursed at a flat rate based on the visit type. During 2010, the service was offered to 68 members, 42 of whom met with a clinical pharmacist for at least one MTM visit.
CONCLUSIONS: Full access to the EMR and prescription claims data allowed the pharmacists to provide high-level drug therapy recommendations. Having established relationships with clinic providers likely contributed to a high documented implementation rate for recommendations. For 2011, the contract was renegotiated for tiered reimbursement, based on the time and complexity of the visit, and was expanded to three additional clinics within the University system.

Health Services Research

326. Initial stages in the development of an antimicrobial stewardship program in a teaching hospital. *Ashley R. Hughes, Pharm.D.*[1], Michael C. Ott, Pharm.D., BCPS[2], Randy A. Gerwitz, R.Ph.[2], Joseph A. Paladino, Pharm.D.[3], Gina M. Prescott, Pharm.D., BCPS[1]; (1)University at Buffalo, Amherst, NY; (2)Erie County Medical Center, Buffalo, NY; (3)CPL Associates LLC, Buffalo, NY
PURPOSE: Literature detailing the significance of an antimicrobial stewardship program (ASP) in healthcare facilities is robust. However, descriptive plans illustrating the development of an ASP in the hospital setting is limited and will be addressed in this poster.
METHODS: Utilizing the Infectious Disease Society of America (IDSA)/Society of Healthcare Epidemiology of America (SHEA) guidelines, formulation of an ASP at Erie County Medical Center (ECMC) focused on initial development of a team, antimicrobial use, infection control and environmental services. Hospital policies and strategies such as intravenous to oral therapy conversion, antibiotic streamlining and de-escalation were then implemented. A proposal to review the impact of interventions was also designed.
RESULTS: Aspects of the ASP that have been created and put into practice as well as plans for future development of ASP at ECMC are illustrated. Specifically, successes and challenges encountered while developing the ASP, such as barriers in implementing policies as well as strategies taken to utilize existing resources at ECMC, are highlighted.
CONCLUSION: Building an ASP is a stepwise process and overtime progression can occur. These techniques presented can be utilized to assist with the growth and development of ASPs in other healthcare facilities.

Hematology/Anticoagulation

327. A comparative evaluation of single fixed-dosing and weight-based dosing of rasburicase for tumor lysis syndrome. *Sherrie Lathon, Pharm.D.*, Leigh Boehmer, Pharm.D., Sara Butler, Pharm.D., Kristan Augustin, Pharm.D., Ali McBride, Pharm.D., M.S.; Barnes-Jewish Hospital, St Louis, MO
PURPOSE: The purpose of this study was to evaluate rasburicase dosing strategies utilized at one institution to determine the minimum rasburicase dose required to manage hyperuricemia secondary to tumor lysis syndrome.
METHODS: This retrospective chart review was conducted between January 1, 2005 and February 18, 2011. Adult patients who received at least one 3 mg, 6 mg, 7.5 mg or weight-based dose were included. Tumor lysis laboratory data were recorded and monitored up to 72 hours after initial rasburicase dosing. Cancer diagnosis, concomitant medications known to increase hyperuricemia risk, and tumor lysis risk factors were collected and analyzed. Treatment success was defined as a normalized plasma uric acid level (< 7.5 mg/dL) within 24 hours after receiving rasburicase.
RESULTS: Three hundred and seventy-three patients were evaluated; 3 mg (n = 38); 6 mg (n = 99); 7.5 mg (n = 43); weight-based (n = 193). The mean weight-based dose utilized was 0.17 mg/kg. Median baseline plasma uric acid levels were 6.85 mg/dL (interquartile range 5.68–8.4), 8.80 mg/dL (7.75–10.8), 8.00 mg/dL (5.0–10.0) and 9.20 mg/dL (6.7–11.9). There were a total of 7 rasburicase treatment failures; 3 mg (n = 2); 6 mg (n = 1); 7.5 mg (n = 0); weight-based (n=4). At 24 hours post-rasburicase administration, there was no statistically significant difference between groups in achieving a normalized plasma uric acid level (92.9% vs 97.6% vs 100.0% vs 98.0%, p=0.190).
CONCLUSION: The efficacy of single fixed dosing and weight-based dosing strategies evaluated in this study appear to be comparable in normalizing plasma uric acid levels within 24 hours of rasburicase administration. Utilization of a 3 mg rasburicase dose is the most cost-effective treatment strategy in managing hyperuricemia secondary to tumor lysis syndrome. Further analysis of patient-specific factors will be conducted in those requiring repeat dosing with rasburicase.

328. Evaluation of an improved warfarin dosing guideline used by an inpatient pharmacy-managed anticoagulation service compared to physician's dosing. *Mandana Ghodrat, Pharm.D.*[1], Laleh Azari, Pharm.D.[2], Gregory Smallwood, Pharm.D.[1]; (1)Philadelphia College of Osteopathic Medicine - School of Pharmacy, Suwanee, GA; (2)Methodist University Hospital Department of Pharmacy, Memphis, TN
New models of inpatient anticoagulation services provided by pharmacists have resulted in improved patient outcome through reduction in number of adverse drug events. The success of the services depends on individualization of therapy through well designed warfarin dosing guidelines and careful monitoring of the patients. We developed an improved patient specific dosing guideline for management of patients receiving warfarin by pharmacists and then compared outcomes to physicians' management of warfarin.
PURPOSE: The objective of this study is to evaluate a patient-specific warfarin dosing guideline used by an inpatient pharmacy-managed anticoagulation service compared to physician's dosing.
METHODS: This is an IRB approved, single-center, retrospective chart review of hospitalized "warfarin-naïve" patients starting on warfarin between January 2009 and May 2009. Data collected include patient's demographics, target INR, time on service, time to INR, time therapeutic INR maintained, adverse events, drug interactions, education time, and dosing group. All data was evaluated comparing three groups; pharmacists using guideline (RPh-Pro), pharmacists not using guideline (RPh), and physicians (MD).
RESULTS: Data on 125 patients were collected [RPh-Pro(n=58), RPh (n=22), and MD (n=45)]. Demographics were similar between all groups (p=0.464) with group RPh having an older cohort (p=0.009). All 3 groups were similar in respect to INR target range (p=0.091), time on service(p=0.165), education time (p=0.318), and number of patients outside target INR by 0.5 (p=0.323) or 1 (p=0.490). Pharmacist using guidelines achieved INR quicker (3.8 vs 4.5 vs 4.4 days; p=0.05) and maintained therapeutic INR longer (2.5 vs.1.9 vs1.2 days; p=0.003) in a population having more drug-drug interactions(45% vs 36% vs 7%; p=0.001) with similar indications(p=0.091).
CONCLUSION: Pharmacists using the dosing guideline for warfarin achieved therapeutic INR within a shorter period of time (p=0.05), maintained therapeutic INR longer (p=0.003) in a difficult to anticoagulate population. Based on these results, our institution has adopted the pharmacy run warfarin dosing guideline for all patients on anticoagulation service.

329E. Evolution of an inpatient antithrombosis service including adaptation to the EPIC system and workload assessment. *William Dager, Pharm.D.*, Aaron Roberts, Pharm.D., Patricia Parker, Pharm.D., Richard White, M.D.; University of California, Davis Medical Center, Sacramento, CA
PURPOSE: To describe the evolution of an inpatient anticoagulation service (IPAS) and current paperless management approach within EPIC at UCDMC.
METHODS: The initial and current responsibilities/functions of the IPAS were explored. Time assessments were compiled randomly on selected daily activities of the service to describe a portion of the current workload after going paperless in 2010.
RESULTS: The initial responsibility of the service (1992) was to

consult on the dosing of warfarin (approximately 1500 inpatients annually, half were new to warfarin). In 2010 approximately 4700 new warfarin starts occurred with 30 to 60 patients monitored daily. Current warfarin workload analysis observed a mean time of 14±5 minutes for initial workup, 7±3 minutes for daily monitoring and documentation and 41 (range 31 to 51 minutes) for patient education. Monitoring direct thrombin inhibitors takes 12±9 minutes each day. The responsibilities and requests for assistance from the IPAS increased with advances in testing, availability of additional agents, expanded indications for anticoagulation, and desired to reduce related complications. The IPAS is also tasked with assisting and regulating the use of all parenteral anticoagulants and facilitating early home discharge on bridging therapy when feasible and provide assistance in reversal strategies, anticoagulant agent selection and management support.
CONCLUSION: The IPAS has served as a beneficial resource and has successfully been adapted to EPIC. The structure of inpatient anticoagulation care including the paperless system developed in EPIC to manage anticoagulation therapy along with the current activities and selected workload of the IPAS including unique services provided by the IPAS at UCDMC will be described.
Presented at Presented at the Anticoagulation Forum Conference, Boston, MA, May 5–7, 2011

Infectious Diseases

330. Development, implementation, and assessment of a pilot pharmacy vancomycin dosing service (PVDS). *Andrea Pallotta, Pharm.D.*, Elizabeth A. Neuner, Pharm.D., BCPS, Jennifer K. Sekeres, Pharm.D., BCPS, Jeffrey Ketz, Pharm.D., BCPS, Jason Skok, ITD, Nabin Shrestha, M.D., M.P.H., FACP, FIDSA; Cleveland Clinic, Cleveland, OH
PURPOSE: PVDS have effectively managed vancomycin (VANC) for decades. Now in the era of electronic medical records, we describe and evaluate a PVDS at a large, teaching hospital.
METHODS: A PVDS was instituted on August 17, 2010 after building an electronic consult order, real-time alerts, patient lists, and template notes. A retrospective chart review compared outcomes of the PVDS (RPh-group) to a pre-implementation control group (MD-group). Patients >18 years, on VANC and internal medicine teaching services were included. Patients in the RPh-group who received VANC but were not consulted to the PVDS were excluded. Outcomes evaluated the number of VANC levels drawn and the proportion of levels within the goal range. Timeframe was June 1 to July 31, 2010 for MD-group and September 1 to November 31, 2010 for RPh-group.
RESULTS: In the MD-group, 154 patients were enrolled and 116 patients were enrolled in the RPh-group. No differences in baseline demographics, weight, creatinine clearance. Most common indications for VANC were pneumonia, soft-tissue and bacteremia in both groups. 135 levels were drawn in MD-group versus 157 levels in RPh-group. The mean number of levels per patient was 2.11 and 2.15 in MD-group and RPh-group, respectively (p=0.88). A higher percentage of levels (including trough and random levels) were within goal range in RPh-group (64%) compared to MD-group (52%, p=0.03). Of the trough levels, 70% were within goal range in RPh-group compared to 55% in MD-group (p=0.20). Overall physician satisfaction was favorable.
CONCLUSION: Implementation of a PVDS utilizing the electronic medical record resulted in more appropriate vancomycin dosing without increasing the number of vancomycin levels/patient drawn.

331. Incidence of supratherapeutic trough concentrations in elderly patients with aggressive vancomycin dosing. *Nicole L. Metzger, Pharm.D.*, Faizan A. Mirza, Pharm.D., Kathryn M. Momary, Pharm.D.; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA
PURPOSE: There is limited data evaluating vancomycin dosing in the elderly, especially when targeting a trough concentration of 15–20mg/L. We conducted a retrospective, medical record review to evaluate the incidence of supratherapeutic trough concentrations in elderly patients who received aggressive vancomycin dosing (greater than 15 mg/kg/dose or Q12 hour dosing with CrCl less than 60 ml/min) compared to conservative dosing.
METHODS: Patients at least 65 years who received at least 3 consecutive treatment doses of intravenous vancomycin between January 1, 2009–February 28, 2011 were included. Patients on dialysis, in the ICU, or without trough concentrations were excluded. Patients were stratified by vancomycin dosing regimen. The primary outcome was the rate of supratherapeutic trough concentrations between the groups. Continuous and nominal variables were compared between groups using Student's t-test and chi squared, respectively.
RESULTS: Data from 105 patient encounters were included in the analysis. The majority of patients (69%) received aggressive dosing regimens. Mean age was similar between the groups (conservative 71.2 years vs. aggressive 78.8 years; p=0.055). As expected, the mean vancomycin dose was higher in the aggressive group (aggressive 18.3 mg/kg/dose vs. conservative 13.2 mg/kg/dose; 95% CI -6.21 to -4.00; p<0.001). The mean trough concentration was also higher in the aggressive group (aggressive 17.4mg/L vs. conservative 12.6 mg/L; 95% CI -8.12 to -1.51; p=0.005). More supratherapeutic trough concentrations occurred in the aggressive group compared to the conservative group (27.4% vs. 9.3%; p=0.031); however, the conservative group had more subtherapeutic trough concentrations (85% vs. 56.5%, p=0.023). Finally, there was no difference in the incidence of acute kidney injury (conservative 6.3% vs. aggressive 10.96%; p=0.360).
CONCLUSION: Aggressive vancomycin dosing in elderly patients resulted in more supratherapeutic trough concentrations than conservative dosing, while conservative dosing was associated with more subtherapeutic trough concentrations. A specific dosing algorithm for the elderly may need to be established.

332. Use of the clinical pulmonary infection score (CPIS) to guide duration of antibiotic therapy in medical intensive care unit (MICU) patients with healthcare-associated pneumonia (HCAP). *Jill Jessmer, Pharm.D.*, Maribeth Pauli, Pharm.D. , Marina Yazdi, Pharm.D. , Mojdeh Saba, Pharm.D. , Claire Chan, Pharm.D., Jonanthan Siner, M.D. , Jeffrey Topal, M.D. ; Yale-New Haven Hospital, New Haven, CT
PURPOSE: CPIS combines clinical, radiographic, physiologic and microbiologic data to systematically assess resolution of pneumonia. Scores of ≤ 6 on day 3 identify candidates for possible antibiotic discontinuation. This study will determine if a pharmacist-led antibiotic discontinuation policy using CPIS reduces duration of antibiotic therapy in patients with HCAP.
METHODS: Prospective data collection was performed as a baseline comparison of antibiotic duration for HCAP at Yale-New Haven Hospital. Patients ≥ 18 years of age admitted to the MICU on empiric antibiotic therapy for suspected HCAP were included. Duration of antibiotic therapy was the primary outcome. Secondary outcomes included length of hospital and ICU stay and recurrence of pneumonia. To detect a 2 day difference in treatment duration with 80% and a type I error of 0.05, 78 patients are required in the pre- and post-intervention groups.
RESULTS: Of 40 patients evaluated, the mean age was 67 years and evenly distributed with respect to gender. Mean APACHE II score and Charlson Comorbidity Index were 15 and 3, respectively. Mean ICU and hospital lengths of stay were 8 days and 28 days. The ICU mortality rate was 7.5% with recurrent pneumonia occuring in 15% of patients. The mean duration of antibiotic therapy was 7 days, ranging from 3 to 15 days. On day 3, 80% of patients in the pre-intervention group had CPIS values of less than or equal to 6 which would have identified them as candidates for antibiotic discontinuation, potentially averting 197 days of antibiotic therapy.
CONCLUSION: Antibiotic therapy for HCAP patients in MICU patients is routinely continued beyond clinical resolution. Implementation of a pharmacist-led antibiotic discontinuation policy using CPIS has the potential to reduce unnecessary antibiotic use in patients with HCAP which in turn would help to limit the development of antibiotic resistant flora in the ICU.

333. Sterol uptake in *Candida albicans*: a novel mechanism of fluconazole resistance. *Stephanie A. Flowers, Pharm., D.*[1], Sarah G. Whaley, B.S.[2], Katherine S. Barker, Ph.D.[1], P. David Rogers, Pharm.D., Ph.D.[3]; (1)University of Tennessee, Memphis, TN; (2)University of Tennessee College of Pharmacy, Memphis, TN;

(3)University of Tennessee Health Science Center, Memphis, TN
PURPOSE: Azole antifungals exert activity by inhibiting biosynthesis of the fungal membrane sterol ergosterol. In *Saccharomyces cerevisiae*, when endogenous sterol biosynthesis is limited, exogenous sterols can be used. These sterols are taken up by ABC transporters Pdr11 and Aus1, which are both under the control of transcription factor Upc2. It's unclear whether *Candida albicans* takes up exogenous sterols under conditions that limit sterol biosynthesis. The purpose of this study was to determine if *C. albicans* can be rescued from fluconazole treatment by providing exogenous sterols and to determine the process by which this occurs.
METHODS: A wild-type clinical isolate of *C. albicans* (SC5314) was subjected to susceptibility testing for fluconazole in YPD in the presence and absence of bovine serum (BS) as a source of exogenous cholesterol. Strains derived from SC5314 that were disrupted for the transcription factor gene *UPC2* or the putative sterol transporter gene *CDR11* were likewise tested for changes in susceptibility to fluconazole.
RESULTS: SC5314 exhibited a 24 hour MIC of 1μg/ml in YPD. Addition of %10 BS to YPD rescued *C. albicans* from the effects of fluconazole resulting in an MIC of 64μg/ml. The *upc2Δ/upc2Δ* strain exhibited a fluconazole MIC of <0.5 μg/ml in YPD and in YPD with 10% BS. The *cdr11Δ /cdr11Δ* strain exhibited a fluconazole MIC of 1μg/ml in YPD and 8μg/ml in YPD with 10% BS.
CONCLUSIONS: Our findings suggest that *C. albicans* can take up cholesterol from exogenous sources which can rescue it from the effects of sterol biosynthesis inhibition by fluconazole. These effects appear to depend upon the transcription factor Upc2 and partially upon the transporter Cdr11. These results represent a potentially novel mechanism of azole resistance in this pathogen and have significant implications for susceptibility testing as the medium currently used for such testing doesn't contain exogenous sterols.

334. Surveillance of antibiotic resistance at a tertiary institution in Trinidad. *Patricia I. Sealy, Pharm.D., Ph.D.*[1], Madhura Manjunath, M.D.[2]; (1)The University of the West Indies,Faculty of Medical Sciences, School of Pharmacy, Port of Spain, Trinidad and Tobago; (2)Ministry of Health, Port-of-Spain, Trinidad and Tobago
PURPOSE: Surveillance studies conducted by the Centers for Disease Control have demonstrated an alarming increase in resistance rates that impacted negatively on patient morbidity and/or mortality and limited the use of antimicrobial agents. Surveillance is not currently conducted in Trinidad and Tobago, a developing country that practices universal health care. The selection of antimicrobial agents for inclusion on the national formulary should be based not only on efficacy data, but also on the prevalence of resistance at tertiary institutions. We proposed to report the susceptibility data from a tertiary hospital for the years 2009 to 2010 in order to monitor the selection and spread of resistant organisms.
METHODS: In-patient clinical isolates (blood, respiratory, and urine cultures) that were processed between the years 2009-2010 from the tertiary hospital were reviewed. Clinical isolates were evaluated using disc diffusion method (zone sizes based on CLSI guidelines) and susceptibility results were reported as percentages.
RESULTS: Blood culture isolates: Klebsielia spp was consistently resistant (66%, 40s%) to amoxicillin-clavulanate and 3rd generation cephalosporins, respectively; Acinetobacter was resistant (50–90% and 50–70%) to 3rd generation cephalosporins and meropenem, respectively; ICU respiratory isolates: Klebsielia spp and Acinetobacter were consistently resistant (30–50% and > 50%) to 3rd generation cephalosporins, respectively. Urine cultures: Escherichia coli was consistently resistant (38%) to co-trimoxazole.
CONCLUSION: Waning susceptibility rates were observed for first line antimicrobial agents that may be empirically administered. Consequently, clinicians should rigorously monitor resistance rates and correlate observed trends with consumption patterns of antimicrobial agents at each institution to ensure that selected agents are susceptible. Appropriate recommendations (prescriber education and antibiotic cycling) can, therefore, be made to preserve the efficacy of antimicrobial agents. Policy makers can also use this information when making formulary decisions. Word Count - 282

Managed Care

335E. Improving documentation of the value of clinical pharmacy interventions in an integrated healthcare delivery system. Sheryl J. Herner, Pharm.D., BCPS[1], *Robin R. Hill, Pharm.D., BCPS*[1], Samuel G. Johnson, Pharm.D., BCPS[2], C. Ryan Lowe, Pharm.D., BCPS[2], Lea C. Price, Pharm.D., BCPS[3]; (1)Kaiser Permanente, Aurora, CO; (2)Kaiser Permanente, Denver, CO; (3)Kaiser Permanente, Lafayette, CO
PURPOSE: There is a continued challenge to document and validate the financial impact of patient care provided by clinical pharmacy specialists in ambulatory and acute care settings not directly related to medication cost-avoidance. We sought to establish the financial impact of clinical pharmacy patient care interventions based on monetary value derived from existing medication therapy management (MTM) reimbursement models, estimated cost avoidance literature, and an estimated physician-time offset model.
METHODS: A workgroup was formed within Clinical Pharmacy Services (CPS) to: (1) explore ways to capture the monetary value of patient care interventions (e.g., MTM, prevention of adverse drug reactions, outpatient clinic visits avoided, and physician time offset; (2) develop a tool to assist with documentation of these contributions; and, (3) foster accountability within 14 different specialty CPS practices by engaging in small-group bi-weekly huddles and collecting updated metrics every six weeks.
RESULTS: The workgroup created a spreadsheet tool for capturing value data within 14 specialty CPS practices. Bi-weekly huddles were employed to solicit feedback, demonstrate functionality, and foster accountability among individual CPS to document day-to-day interventions. For 2010, $6.8 million in financial value was documented by CPS. More than 85% of this documented value was from therapy cost-avoidance (decreased cost of goods); however, approximately 14% of documented value was related to interventions to prevent or mitigate drug-related problems.
CONCLUSION: Systematic documentation of patient care interventions within several unique clinical pharmacy practices was associated with meaningful financial value. Significant opportunity remains to completely document the financial impact of clinical pharmacy interventions on overall cost of care in an integrated healthcare delivery system.
Presented at American Society of Health-System Pharmacists Summer Meeting, Denver, CO, June 12–15, 2011

Medication Safety

336. Interdisciplinary approach to medication safety: Collaborative care for developmentally disabled individuals. *Philip Rolland, Pharm.D., MHA*; Mexia State Supported Living Center, Mexia, TX
Multidisciplinary Care: Collaboration and Teamwork in Medication Safety 300 Word TI> Interdisciplinary approach to medication safety: Collaborative care for developmentally disabled individuals. AU> Philip Rolland, Pharm.D., M.H.A. Director of Clinical Program Development, MSSLC.
PURPOSE: This article describes the interdisciplinary approach to collaborative care regarding medication safety for mentally challenged individuals.
METHODS: Our facility has a comprehensive, multifaceted interdisciplinary and collaborative approach to medication safety. This process includes; dietary, nursing, pharmacy, psychology, psychiatry and medicine. The system utilizes suspected adverse drug event reporting, chemical restraint clinical review, clinical communication documentation, quarterly psychotropic medication review, quarterly drug regimen review, and medication variance tracking, trending, analysis and process improvement. The QDDR is a comprehensive review based on Texas Administrative Code Title 25 Part 1 Chapter 415 Subchapter A "Prescribing Psychoactive Medications."
RESULTS: Dietary conducts monthly height, weight, BMI and nutrition analysis on each individual. Nursing performs monitoring for signs and symptoms of side effects and adverse drug reactions by observing first dose reactions and using both the monitoring of side effects scale (MOSES) and dyskinesia identification system condensed user scale (DISCUS) for psychopharmacologic and

anticholinergic medications. All departments report suspected adverse drug events. Pharmacy performs ADR analysis, chemical restraint clinical review, clinical communication documentation, medication variance tracking, trending, analysis and process improvement, clozapine monitoring, quarterly medication use evaluation and quarterly drug regimen review for each individual. The QDDR is reviewed by medicine and psychiatry with feedback to the pharmacist. The quarterly psychotropic review is conducted by nursing and psychiatry with input from psychology.
CONCLUSION: For the past month pharmacy conducted 62 quarterly drug regiment reviews, 28 suspected ADR's, 44 clinical interventions, 3 chemical restraint clinical reviews, 1 MUE and 89 medication variance reports and 12 clozaril reviews. The interdisciplinary, collaborative nature of this process provides a strong basis for medication safety.

337E. Investigation of potential neurological effects of stabilizers used in immunoglobulin products: comparison of proline and glycine. *Martin O. Spycher, Ph.D.*[1], Gerhard Dickneite, Ph.D.[2]; (1)CSL Behring AG, Switzerland; (2)CSL Behring GmbH, Marburg, Germany
PURPOSE: Intravenous immunoglobulin (IVIG, 10%) solutions formulated with glycine (GLY) are not stable for the entire shelf-life and/or extended times at room temperature. Proline (PRO; 250 mmol/L) at pH 4.8 allows room temperature storage of IVIG (10% protein) for 3 years. To assess the neurologic safety of GLY and PRO, high-dose studies were performed in rats.
METHODS: The neurobiologic state was evaluated using the Irwin test (MDS Pharma Services), which assesses autonomic and sensorimotor functions, convulsive behavior, and neurologic side effects of drug administration. Spatial learning and memory were assessed using the Morris water maze task (CSL Behring; Medimod Pharmacology Services). For the Irwin test, adult rats received intravenous infusions 7 hours daily over 5 days with either GLY or PRO, corresponding to daily doses of ≈2 and 5 g IVIG/kg bodyweight. Typical IVIG doses for antibody replacement range between 200–800 mg/kg bodyweight. For the Morris water maze task, newborn rats were injected subcutaneously with one of two dosing schemes: one simulating autoimmune disease (days 9–13 postnatal); the other, immunodeficiency (days 9, 16, and 23 postnatal). Daily doses corresponded to up to ≈14 g IVIG/kg bodyweight.
RESULTS: PRO did not significantly affect behavior or various neurologic parameters during or postinfusion. Rats infused with both GLY doses showed significantly decreased spontaneous activity, increased CNS excitability, and altered autonomic measures, but no significant effects on neuromuscular or sensorimotor function. Cumulative doses of GLY or PRO induced statistically significant body temperature increases after 5 days of infusion. All animals had unimpaired learning and memory abilities; no negative effect on search accuracy or intensity on day 60 was observed.
CONCLUSIONS: High-dose IV GLY caused some neurologic effects in the Irwin test. PRO caused no neurologic effects of toxicologic significance in rats, even at doses considerably higher than routinely used for IVIG treatment.
Presented at American Academy of Allergy, Asthma, and Immunology, 2007

338E. An analysis of medication errors associated with the use of technology. *Jennifer Phillips, Pharm.D., BCPS*[1], Bonnie Bachenheimer, Pharm.D.[2], Christopher Kutza, Pharm.D.[2]; (1)Midwestern University, Downers Grove, IL; (2)Advocate Lutheran General Hospital, Park Ridge, IL
PURPOSE: In recent years, there have been a number of advancements in the area of automation and technology in the healthcare industry. Recent literature suggests that technology may cause new types of medication-related errors. The main purpose of this observational retrospective study was to determine the technology most likely to be associated with medication errors and to characterize technology-associated errors with regard to the type of errors made (i.e., human vs. system errors) as well as the stage of the medication use process and the outcome.
METHODS: This was an IRB-approved retrospective, observational study at a 645-bed institution. All medication errors reported from January-December 2010 were de-identified and analyzed to determine if they were associated with the use of technology. If so, then the specific type of technology involved was identified and the error was further classified as a human error or a system error. The stage of the medication use process in which the error originated was recorded as well as the error outcome.
RESULTS: Medication errors associated with technology represented 50% of the 703 errors analyzed. Computerized prescriber order entry (CPOE) was the technology most likely to be involved in medication errors (31%). For technology-associated medication errors, human errors occurred more frequently than system errors (87% vs. 13%). Technology errors were more likely to occur during the prescribing (35% vs. 16%, $p<0.0001$) and documentation (17% vs. 9%, $p<0.001$) stages of the medication use process. Technology errors were more likely than non-technology errors to be near misses (59% vs. 51%, $p<0.05$).
CONCLUSION: At a large institution using many forms of technology, CPOE represented the largest percentage of technology-associated medication errors. Technology errors were less likely to reach the patient. Future plans include a more in-depth analysis of CPOE-related errors to identify trends and guide quality improvement initiatives.
Presented at Presented at the Illinois Council of Health-System Pharmacists (ICHP) - Missoursi Society of Health-Systems Pharmacists (MSHP) Spring Meeting, St. Charles, MO, April 14–16, 2011).

Oncology

339. Effects of standardization of urine alkalinization for hematology and oncology patients. *Patricia A. Jeppson, Pharm.D.*, Martha J. Glenn, M.D., Kenneth Boucher, Ph.D., J. Andrew Stuart, Pharm.D.; Huntsman Cancer Institute at the University of Utah, Salt Lake City, UT
PURPOSE: Though widely used in oncology protocols, the practice of alkalinizing urine prior to high dose methotrexate therapy is not well-documented in the literature. A urine alkalinization protocol was developed and implemented in order to 1) provide adequate hydration without interruption, 2) ensure patients were receiving appropriate monitoring, and 3) increase efficiency of compounding and administration through the use of standardized IV fluids. The purpose of this study was to determine if standardization also decreases time to target urine pH.
METHODS: A urine alkalinization protocol was developed and implemented in February 2009. Medical charts were reviewed for 77 patients to compare outcomes prior to and after implementation of the protocol. Outcomes measured included: time to urine pH ≥ 7, time to administration of methotrexate, and percent of time within target urine pH interval (≥ 7 and ≤ 8).
RESULTS: No differences existed between the control and intervention groups in time to urine pH ≥ 7 (5.4 hours vs. 5 hours, $p=0.63$) or time to administration of methotrexate (8.7 hours vs. 9 hours, $p=0.87$). The percent of time within the target pH interval was higher for the intervention group (50.8% vs. 73.2%, $p<0.005$).
CONCLUSIONS: A standardized urine alkalinization protocol did not decrease time to goal pH or methotrexate administration. However, urine pH measurements were within the target pH range a higher percentage of the time and all patients received continuous hydration throughout the course of therapy, which may result in more predictable methotrexate clearance. Further study is needed to determine if this intervention leads to decreased nephrotoxicity from high dose methotrexate.

340. Cut down chemotherapy errors by clinical pharmacist in Shanghai Cancer Center. *Bo Yu, M.S.*, Bin Zhu, Qing Zhai, M.S.; Fudan University Shanghai Cancer Center, Shanghai, China
PURPOSE: Shanghai Cancer Center, Fudan University, is one of the top cancer centers in China. During the year of 2010, the total numbers of out-patient and in-patient approached 700 and 30 thousand, respectively. Meanwhile, the number of patients receiving chemotherapy exceeded 100 thousand. These overwhelming forces drive our pharmacists executing their clinical practices mandatorily and mightily.

METHODS: To meet these objective requirements, we combined our prescription verification system with medical order system. With no exceptions, physicians and surgeons must send every prescription to the verification system and wait for pharmacists review. Duty pharmacists will review the prescription according to the corresponding medical examinations, characteristics of the drugs, incompatibilities, medication order etc. At the same time, senior pharmacists will be sent to monitor the process of administration and record the adverse drug events. Furthermore, all processes involving recombining or admixture of cytotoxic agents, antibiotics are under the supervision of pharmacists.
RESULTS: By these above mentioned means, the prescription error rates were cut down from around 10% to 6%. Among the remaining errors, about 5% were medication order errors, 80% were errors involving choices or volume of solvents. Traditional Chinese Medicine (TCM), which is proved to be effective in adjuvant chemotherapy, liver protection, nutrition support, etc., contributes to 20–30% solvents errors. Unfortunately, around 30% of solvent errors result from cytotoxic agents' prescription.
CONCLUSION: Our clinical oncology pharmacists' practices are a brand new model in China. We are seeking all kinds of assistance and cooperation to develop and improve the efficiency and effectiveness of our clinical practices. We are also setting a national wide education base for clinical oncology pharmacist all over China by hosting national wide medical continuous education and forum.

Other

341. Pharmaceutical appointment in clinical trials. Sebastião Ferreira da Silva, Pharm.D., Isabel Gomes, Pharm.D., Ana Luísa Vital, Pharm.D., Marta Nabais, Pharm.D., *José Feio, Pharm.D.*; Hospitais da Universidade de Coimbra, Coimbra, Portugal
PURPOSE: Clinical investigation demands the establishment of multidisciplinary teams. Clinical trials' credibility and reputation depends on the security, responsibility, transparency and tracing with which the clinical trial medicine and medical devices are used and conducted. Pharmaceutical appointment in clinical trials practice is a patient-centered and outcomes oriented.
METHODS: A pharmacist with advanced training in clinical trials practice and ICH-GCP guidelines is responsible to monitor pharmacy activities. The pharmacist:
- Conducts an interview and records the patient's pharmacotherapeutic information. The data collected is evaluated and appropriate information is supplied in order to ensure adherence, safety and effectiveness;
- Assures that the patient has the correct and sufficient investigational product, information and necessary knowledge to carry out the clinical trial plan;
- Reviews, monitors and explains modifications of the therapeutic plan as necessary and appropriate, in accordance with the patient and investigational team.
RESULTS: Three pharmacists are responsible for the Clinical Trials Department of the Pharmaceutical Services. During 2010, we were involved in 93 clinical trials, from which 12% were phase II, 81% phase III and 4% phase IV. These clinical trials enrolled 765 patients and were undertaken by 18 centers, with 32 sponsors and 122 different investigational products. We carried out 3251 pharmaceutical visits. These pharmaceutical consultations allowed us to achieve a medium therapeutic adhesion rate of 98.3% with 0 drop outs.
CONCLUSION: The high level of professional skills and proficiency of an experienced pharmaceutical team proved to be of extreme importance in the correct conductance of the clinical trial, as well as, the adherence and security of the patient to the investigational product and concomitant drugs under study. A relationship based upon caring, trust, open communication and cooperation between patient and pharmacist must be encouraged.

342. Analysis of pharmacist-driven medication reconciliation services on hospital readmission rates, emergency room, visits, and hospital length of stay. *Paula A. Helton, Pharm.D., BCPS, CGP*, Susan C. Woodard, Pharm.D., BCPS, CGP; VA Tennessee Valley Healthcare System, Nashville, TN
PURPOSE: Increased length of stay and preventable rehospitalization are persistent dilemmas that lead to escalating healthcare costs. This study assessed the effect of a pharmacist-driven medication reconciliation service on 1) the combined endpoint of hospital readmissions within 30 days and ER visits within 72 hours of discharge and 2) hospital length of stay.
METHODS: Patients were considered for inclusion in this retrospective observational study if taking five or more medications prior to admission and if they were admitted for greater than 36 hours. Patients seen by a medication reconciliation clinical pharmacist upon admission or discharge were assigned to the study group. The control group consisted of patients not reviewed by a medication reconciliation pharmacist.
RESULTS: A total of 474 patients were included in the study with 237 patients in the study group and 237 patients in the control group. Hospital readmissions within 30 days of hospital discharge showed statistical significance with 31 readmissions in study group vs. 56 readmissions in control group ($p = 0.0042$). Neither the rate of ER visits 72 hours post discharge (11 vs. 12 visits) nor the hospital length of stay (4.6977 vs. 5.2738 days) was statistically significant ($p=1$ and $p=0.2121$, respectively).
CONCLUSION: Our study showed that by addressing medication-related problems, pharmacist-driven medication reconciliation reduces hospital readmissions within 30 days of discharge thus providing evidence to support the importance of utilizing pharmacists to provide medication reconciliation services. Though not statistically significant, the average shortened length of hospital stay by 0.6 days may save our institution an average of $1,352 to $3,808 per patient.

Pain Management/Analgesia

343. Pharmacist-led and interdisciplinary model for management of adult cancer pain in a medical center. *Yuan-Hsun Ko, B.S.*[1], Yu-Hsuan Yen, M.S.[2], Mantzu M. Wu, Pharm.D.[3], Kuei-Ju Cheng, Pharm.D.[1], Hsiang-Yin Chen, M.S., Pharm.D.[4]; (1)Department of Pharmacy, Taipei Medical University-Wanfang Hospital, Taipei, Taiwan., Taipei, Taiwan; (2)Taipei Medical University - Wanfang Hospital, Taipei, Taiwan; (3)Taipei Medical University-Wanfang Hospital, Taipei, Taiwan; (4)Taipei Medical University-Wanfang Hospital., Taipei, Taiwan
PURPOSE: Management principles for adult cancer pain were developed and coordinated by pharmacists in a medical center in Taiwan. The aim of this study is to improve the adherence to the cancer pain guideline and analyze the opioid analgesic use.
METHODS: We describe the characteristics of the population seen and notice the guide bulletin throughout the hospital. Patient demographics were analyzed using descriptive statistics, medication used were noted, and performance of following guide were tracked in the before intervention (BI) group from January to June 2009 and in the after intervention (AI) group from January to June 2010.
RESULTS: A total of 160 patients included in the study. There was no significant difference between the two groups in the demographics. Forty-five patients (62.5%) in the AI group were fully met the guide better than 35 patients (40%) in the BI group ($p=0.004$). The percentage of patients used meperidine and propoxyphene decreased by 17% through intervention. The mean of daily meperidine dosage was dramatically decreased from 4.93 mg in the BI group to 2.45 mg in the AI group. The mean milligram of propoxyphene use per person and per day was significant decreased from 8.33 to 0.47.
CONCLUSION: We are able to demonstrate that the use of a pharmacist-led, interdisciplinary team produced a better complied with the guide and a significant decreased the usage of inappropriate medicines for adult cancer pain.

344. An interdisciplinary approach to reducing opioid analgesic misuse in patients with chronic noncancer pain in the primary care setting. *Michele L. Matthews, Pharm.D., CPE*[1], Robert N. Jamison, Ph.D.[2], Edgar Ross, M.D.[2], Elizabeth M. Scanlan, NP[2], Lori W. Tishler, M.D.[3]; (1)Massachusetts College of Pharmacy and Health Sciences, Boston, MA; (2)Brigham and Women's Hospital Pain Management Center, Chestnut Hill, MA; (3)Brigham and Women's Hospital Phyllis Jen Center for Primary Care, Boston, MA
PURPOSE: Many health care professionals are reluctant to support the use of opioid analgesics for patients with chronic noncancer pain

because of concerns regarding adverse effects, lack of efficacy, tolerance, and addiction. Within the past ten years the prescription of opioids for the treatment of chronic pain has increased exponentially, primarily for noncancer pain, and the abuse of such medications is receiving increasing notice. Chronic pain patients who show aberrant drug-related behavior are often dismissed from a primary care practice when they are nonadherent with opioid therapy, instead of being offered interventions to reduce misuse and to improve adherence. Unfortunately, there are few treatment resources for such patients. Through the implementation of an interdisciplinary approach to chronic pain management, we are seeking to remedy that deficit, with the goal of reducing the rate of prescription opioid misuse among those patients on or who are being considered for opioid therapy within the primary care setting.
METHODS: An interdisciplinary team of pain specialists consisting of a physician, clinical pharmacist, psychologist, nurse practitioner, and psychiatrist will work closely with primary care physicians to implement the following services and programs: direct clinical support through a weekly pharmacist-directed chronic pain management clinic embedded within the primary care center to provide recommendations for therapy and ensure adherence to an institution-wide opioid use policy; use of an electronic software program that conducts computerized 'live' interviews of patients and offers a provider report with a summarized pain assessment; psychiatry consult service to manage opioid abuse/addiction issues; and monthly provider educational sessions on pain assessment and management to promote proper patient selection and risk assessment.
RESULTS: This approach to the use of opioid analgesics will help to improve adherence and reduce misuse within the primary care setting.

Pharmacoeconomics/Outcomes

345. Examining knowledge and information seeking behaviors towards blood transfusion among individuals with Chronic Kidney Disease. *Ahmad Naim, M.D.*[1], D. Walls, Ph.D.[2], Jan Gollins, MBA[3], Chuck Reynolds, M.S.[4]; (1)Centocor Ortho Biotech Services, LLC, Horsham, PA; (2)BDJ Solutions, LLC, Medford, MA; (3)Delta Modelling Group, Mount Prospect, IL; (4)The Benfield Group, St. Louis, MO
PURPOSE: Examine knowledge and information seeking behaviors towards blood transfusions among individuals with Chronic Kidney Disease (CKD) currently not on dialysis.
METHODS: An online survey was conducted from a nationally representative patient panel in 1Q2011. Respondents were ≥18 years and diagnosed with CKD by a physician. Participants were asked about blood transfusion history, information seeking behaviors, and knowledge about blood transfusion.
RESULTS: Of 416 respondents, 59% (n=246) were female; 40% (n=165) were >65 years. 35% (n=144) had stage 4 and 58% (n=240) stage 3 CKD. 54% (n=226) were anemic. 43% (n=179) had received blood transfusion, whereas, 57% (n=237) had no transfusions. Top two sources of information were doctor (93.8%) and Internet (80.5%). Among those previously transfused, 62% received right amount of information, whereas, 34.6% received too little information, and 3.4% reported receiving too much information. More than 80% of transfused indicated they knew the reasons for and benefits of getting a blood transfusion. Less than two-thirds received information about effects, risks, and time it would take, and only 26% knew the costs. Over 60% said that it is extremely important to know right blood type, screening techniques and quality of blood, and risks of infections. Among previously transfused, only half (50%) agreed that they made an informed choice about receiving blood transfusions. Among the previously transfused, 77% agree that they knew the benefits compared with 49% not transfused. Similarly among previously transfused, 69% agreed that they knew the risks of blood transfusion compared to 51% with no transfusion history.
CONCLUSION: Doctor's office and Internet are primary sources of information about blood transfusions. Gaps in knowledge exist about benefits, risks, and costs of blood transfusions. A significant number feel that they need more information about blood transfusion to make an informed choice. Providers should consider adopting shared-decision making with their patients.

346. Examining the patient-centered decision making attributes towards blood transfusion among individuals with Chronic Kidney Disease (CKD). *Ahmad Naim, M.D.*[1], D. Walls, Ph.D.[2], Jan Gollins, MBA[3], Chuck Reynolds, M.S.[4]; (1)Centocor Ortho Biotech Services, LLC, Horsham, PA; (2)BDJ Solutions, LLC, Medford, MA; (3)Delta Modelling Group, Mount Prospect, IL; (4)The Benfield Group, St. Louis, MO
PURPOSE: Examine the patient engagement towards blood transfusion among individuals with Chronic Kidney Disease (CKD) currently not on dialysis.
METHODS: An online survey was conducted from a nationally representative patient panel in 1Q2011. All respondents were ≥18 years and diagnosed with CKD by a physician. Participants were asked about their blood transfusion history, information seeking behaviors, and knowledge about blood transfusion.
RESULTS: Of 416 respondents, 59% (n=246) were female; 40% (n=165) were >65 years. 35% (n=144) had stage 4 and 58% (n=240) stage 3 CKD. 54% (n=226) were anemic. 43% (n=179) had received blood transfusion, whereas, 57% (n=237) had no transfusions. Among previously transfused, only 50% indicated they shared in treatment decision with their doctor, whereas 40% indicated their doctor or someone else had made the decision for them. Among those who indicated someone else made the decision, 82% indicated that they like to make a shared decision. Among not transfused, only 40% are clear about their treatment choice for blood transfusion and over 75% would like to share decision to have blood transfusion with their doctor. Among not transfused, 30% agree that they are unsure about receiving blood transfusion and less than two-thirds (60%) are likely to stick with their decision to get a blood transfusion. About 39% of not transfused said it is hard to decide if benefits outweigh risks and 38% said that decision is hard for them to make.
CONCLUSION: There is a substantial lack of patient engagement towards shared-decision making in blood transfusion. Individuals most likely to receive blood transfusion expressed the most uncertainty about their decisions and are least informed about choices, benefits, and risks. These findings suggest that a significant portion of individuals facing a blood transfusion feel disempowered and are interested in engaging in shared-decision making with their physicians.

347. Quality of life burden in chemotherapy-naïve and chemotherapy-experienced men with metastatic prostate cancer. *Mekre Senbetta, Pharm.D.*[1], Jamie Forlenza, Pharm.D., M.S.[1], Amy Smalarz, Ph.D.[2], Kimberly Riggs, B.S.[2]; (1)Centocor Ortho Biotech Services, LLC, Horsham, PA; (2)United BioSource Corporation, Lexington, MA
PURPOSE: This study evaluated the QOL burden in metastatic prostate cancer (MPC).
METHODS: Eighty-four US adult men with self-reported MPC completed a cross-sectional survey between January-February 2011. QOL was assessed using computer-adapted versions of the Functional Assessment of Cancer Therapy (FACT)-General (G), –Prostate (P), and –Taxane scales and compared for respondents who self-reported having had chemotherapy treatment for prostate cancer (CE group) versus those without chemotherapy (CN group).
RESULTS: Average age was 63.6 years in the CN group (n=53) and 64.4 in the CE group (n=31). The CN group had numerically higher (better QOL) mean FACT-G scores versus the CE group (75.9 vs. 69.2, respectively, p=0.065). A statistically significant difference between CN and CE groups was observed for the mean physical subscale (21.6 vs. 18.0, respectively, p=0.003) and functional subscale (18.3 vs. 15.5, respectively, p=0.049). Compared to the CE group, the CN group reported statistically significantly higher total FACT-P scores (106.5 vs. 96.7, p=0.049) and numerically higher FACT-P Prostate Cancer Subscale (PCS) scores (30.6 vs. 27.5, p=0.069). The CN group reported better scores within the FACT-P PCS for questions pertaining to weight (p<0.001), present comfort level (p=0.014), and ability to feel like a man (p=0.015). There was no statistically significant difference in total FACT-Taxane scores (128.4 CN vs. 118.2 CE group, p=0.126) or FACT-Taxane subscale scores between groups (52.5 CN vs. 49.0 CE group, p=0.126); however, questions pertaining to numbness or tingling in the feet (p=0.019), feeling weak all over (*P*=0.017), and having trouble walking (p=0.004) were

statistically significant in favor of the CN group.
CONCLUSION: These results suggest that certain aspects of the general and disease-specific QOL for men with MPC may be better for the chemotherapy-naive versus chemotherapy-experienced group. Given the limited sample size of both groups, further research in large populations of men with MPC is warranted.

348. Cost-efficacy analysis of pemetrexed in first-line treatment of non-small cell lung cancer. Ana Leandro, Pharm.D., *Armando Alcobia, Pharm.D.*; Hospital Garcia de Orta, Almada, Portugal
PURPOSE: In a phase III trial, which included 1725 patients, and compared to in first-line treatment of non-small cell lung cancer (NSCLC), showed similar clinical efficacy. Nevertheless, the histology of NSCLC is known to affect the efficacy of treatments. The objective of this study was to evaluate the cost-efficacy of , in first-line treatment NSCLC patients, considering the different . This study was required in order to assess treatment options in our hospital.
METHODS: Based on the above-mentioned phase III trial, the efficacy of or , plus , in the first-line treatment of NSCLC was evaluated. We considered overall survival and cancer histology. Treatment costs were calculated based on the direct cost of the drugs in 2010. This study was conducted from an institutional perspective - the hospital perspective.
RESULTS: The overall survival, in years, of the NSCLC patients treated in first-line setting is described in the table:

Histology	Pemetrexed-cisplatin	Gemcitabine-cisplatin
	1.05	0.91
cell carcinomas	0.78	0.90
large cell carcinomas	0.87	0.56
other	0.72	0.77

In the associated costs calculation were considered: a body surface of 1.7 m^2, 5 treatment cycles and the need of granulocyte colony-stimulating factors (G-CSF), based on the frequency of described for the two therapeutic options. For and large cells carcinomas, the incremental cost-efficacy ratios (ICER) calculated for versus were 63.779€ (US$ 89.290) and 28.959€ (US$ 40.542) respectively. In the cell carcinomas and other , the option was more effective and less expensive.
CONCLUSIONS: In the of NSCLC in which was more effective, the calculated ICER was higher for , being too elevated for it to be considered a cost-effective option. In cell carcinomas and other , is the dominant option.

349. Economic impact of ambulatory clinical pharmacy services. *Daniel M. Riche, Pharm.D., BCPS, CDE*[1], Valyncia Green, Pharm.D.[2], Richard Jackson, M.D.[2], Marion Wofford, M.D., M.P.H.[2], Candice Adams, A.A.[2]; (1)University of Mississippi School of Pharmacy, Jackson, MS; (2)University of Mississippi Medical Center, Jackson, MS
PURPOSE: At the University of Mississippi Medical Center, the Cardiometabolic clinic has served as a core site for ambulatory clinical pharmacy services (CPS) for several years. Recently, a White Paper was published commenting on quality of ambulatory CPS. The economic component of the White Paper focused on patient-perspective costs. Rarely has an institutional perspective on cost been evaluated for ambulatory CPS. This quality assurance project is intended to ascertain if any difference in revenue exists between standard of care and ambulatory CPS.
METHODS: This is a retrospective review analyzing anticipated revenue for one physician (MD) in an insured population for one month. The MD covered Cardiometabolic clinic in addition to his standard General Medicine clinic. Charges for established patient billing codes were evaluated. Other billing codes were ignored (e.g., new patient, immunizations, pre-op, etc). Anticipated revenue (charges minus write-off) and relative value units (RVU) were averaged for the MD alone and MD/Pharm.D. groups. Downstream revenue was not available for evaluation. A t-test was used for continuous data, and a χ^2 was used for dichotomous data.
RESULTS: Of the patients seen by the MD, 13% were seen with Pharm.D. collaboration. For one month (n=201), the MD/Pharm.D. combination significantly increased anticipated revenue by 16.4% versus an MD alone (p=0.026). The anticipated cumulative revenue per patient seen by an MD/Pharm.D. is $97.67 versus $83.88 for MD alone. The average RVU per patient increased significantly from 1.22 to 1.50 (p<0.001). Extrapolating this data for 25 patients per week over a 40-week clinic schedule would reimburse an average pharmacist salary of $97,670 per year when a Pharm.D. is added to a standard MD General Medicine clinic.
CONCLUSION: Clinical pharmacists increased anticipated revenue and relative value when added to a physician's General Medicine clinic. The conservatively estimated increase in annual revenue at least justifies partial salary reimbursement for ambulatory CPS.

Pharmacogenomics/Pharmacogenetics

350. The quest towards personalized medicine: Overview of pharmacogenetics and safety of drug therapy. *Salah M. Blaih, Ph.D., R.Ph.*; Department of Chemistry and Biochemistry - Kent State University, Warren, OH
PURPOSE: Single gene interactions can alter drug disposition, efficacy, safety, and tolerability. Recent studies from US hospitals suggest that 6.7% (more than two million hospitalized patients) experience ADEs, causing approximately 100,000 deaths per year (4th - 6th leading cause of death). CYP enzymes are responsible for metabolizing the vast majority of prescribed drugs. CYP2C9, CYP 2C19, CYP2D6, as well as VKORC1, DPYD, TPMT, and UGT1A1, are polymorphic and responsible for a wide variety of ADEs.
METHODS: Data, statistics, and guidelines are summarized from various research articles, clinical trials, and FDA-approved drug labels.
RESULTS: The pharmacokinetics and pharmacodynamics of warfarin therapy are discussed. The most common poor metabolizers (CYP2C9*2, CYP2C9 *3, and –1639G>A nucleotide substitution of VKORC1) influence warfarin dose requirements and serve as a model of application pharmacogenetic data: one controls the metabolism of the drug; the other controls the effective concentration at the site of action. Up to 10-fold in maintenance dose reduction is recommended for patients with 2C9 *2/ *3 and VKORC1 -1639 AA variants. The effect of the nonfunctional 2C19*2 and *3 alleles on the pharmacokinetics and antiplatelet effects of the prodrug clopidogrel is presented. The FDA- approved drug label is to consider alternative treatment or treatment strategies in patients identified as CYP2C19 poor metabolizers. Published data indicate a marked reduction of pharmacokinetic parameters (Cmax) of the active metabolite as well as the antiplatelet effects, as measured by *ex vivo* platelet aggregation assays. Pharmacogenetic data related to cancer therapy are also presented. Risks of developing severe, life-threatening toxicities of thiopurine (hematopoietic/ myelosuppression, TPMT*3A/*3C variants); the topoisomerase I inhibitor irinotecan (severe/fatal neutropenia, UGT1A1*28 allele); and the BCR-ABL tyrosine kinase inhibitor Nilotinib (hyperbilirubinemia, UGT1A1*28 allele) are shown.
CONCLUSION: As a result, physicians may personalize treatment decisions, where a reduction in the starting dose in a range of 30–90% should be considered.

Psychiatry

351. Drug-related problems with antidepressants in a hospital setting in India. *Anantha Naik Nagappa, M.Pharm., Ph.D.*[1], Uday Venkat Mateti, B.Pharm., Pharm. D.[2], Tarachand Lalwani, B.Pharm., Pharm.D., P.B.[2], P. V. Bhandary, M.B.B.S., M.D.,[3], Verupaksha Devermane, M.B.B.S., M.D.[3], Rajesh Balkrishnan, B.Pharm., M.S., Ph.D.[4]; (1)Manipal College of Pharmaceutical Sciences,, Manipal, Karnataka, India, India; (2)Manipal College of Pharmacuetical Sciences, Manipal, India; (3)DR. A. V. Baliga Memorial Hospital, Udupi, India; (4)Center for Global Health and College of Pharmacy, Michigan, MI
PURPOSE: Drug-Related Problems (DRPs) occur frequently with antidepressants leading to treatment failure and increased morbidity in the depressed patient. The study was designed to collect preliminary data related to antidepressant drug related problems and treatment failure in India.
METHODS: A cross sectional observational study was carried out for a period of four months at a mental health facility in Udupi, India. All

the prescriptions of the study population were screened for Drug Related Problems (DRPs) such as ADRs and DDIs by using a computerized database system. These data were assessed for the pattern of the ADRs with respect to patient demographics, nature of the reaction, outcome of the reactions, causality, severity and preventability.
RESULTS: A total of 120 patients were enrolled in the study and 33 of them developed 50 Drug Related Problems (DRPs), in those 24 Drug-Drug Interactions (DDIs) and 26 Adverse Drug Reactions (ADRs). The overall incidence of DRPs in the present study was 27.5%. Among the 33 patients and the significant proportions of DRPs were in female with [p<0.01] than in male. Most of the patients who had developed DRPs was in the age group of 36–55 yrs [p<0.01] followed by other age. The common ADRs observed were hyponatremia and headache. Considering outcomes, 20 (76.9%) of cases recovered from ADRs and while assessing the preventability, 20 (76.9%) of the ADRs were definitely preventable. When causality assessments were conducted, we found that that majority of ADRs were probable and were found to be mild to moderately severe.
CONCLUSION: An ongoing drug monitoring program aimed at assessing common drug-related problems may be key in improving treatment effectiveness in patients with depression. The involvement of community pharmacists in a pilot psychiatric drug monitoring program in India assisted in the identification of common adverse drug related problems in these patients.

RESIDENTS AND FELLOWS RESEARCH IN PROGRESS

ADR/Drug Interactions

352. Comparing drug-drug interaction severity for clinician opinion to proprietary databases. *Michael J. Armahizer, Pharm.D.*[1], Sandra Kane-Gill, Pharm.D., M.S., FCCM[2], Pamela L. Smithburger, Pharm.D., BCPS[2], Amy L. Seybert, Pharm.D.[2]; (1)UPMC Presbyterian, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Commercial clinical decision support software (CDSS) may overestimate the severity of drug-drug interactions (DDI) because of their broad application; whereas, clinicians with knowledge of the patient should be able to better assess DDI severity. The purpose of this project was to compare DDI severity for clinician opinion in the context of the patient's clinical status to the severity of proprietary databases.
METHODS: This was a single-center, prospective evaluation of DDIs at a large, tertiary care academic medical center between October 11, 2010 and November 5, 2010 in a 10-bed cardiac intensive care unit (CCU). A pharmacist identified DDIs using two proprietary databases. The physicians (fellow and attending) and pharmacists (rounding and distribution) caring for the patients evaluated the DDIs for severity while incorporating their clinical knowledge of the patient. Severity was ranked on a scale ranging from A to D and X.
RESULTS: A total of 61 patients were included in the evaluation and experienced 769 DDIs. The most common DDIs included: aspirin/clopidogrel (n=21, 2.7%), aspirin/insulin (n=21, 2.7%) and aspirin/furosemide (n=19, 2.5%). Pharmacists ranked the DDIs identically 73.8% of the time, compared to the physicians who agreed 42.2% of the time. Pharmacists agreed with the more severe proprietary database scores for 14.8% of DDIs versus physicians at 7.3%. Among the five contraindicated DDIs, two were rated as category B (minor severity/no action needed) and three as category C (moderate severity/monitor therapy) by the majority of the reviewers. Clinicians agreed with the proprietary database 20.6% of the time while clinicians ranked the DDIs lower than the database 77.3% of the time.
CONCLUSION: Proprietary DDI databases generally label DDIs with a higher severity rating as compared to clinicians who are caring for patients. Developing a DDI knowledgebase for CDSS requires careful consideration of the source of the severity information to create clinically meaningful alerts.

Adult Medicine

353. Persistent use of against label statin-fibrate combinations from 2003 to 2009 despite FDA dose restrictions. *Julie C. Alford, Pharm.D.*, Joseph J. Saseen, Pharm.D., Richard R. Allen, M.S., Kavita V. Nair, Ph.D.; University of Colorado, School of Pharmacy, Aurora, CO
PURPOSE: Statin-fibrate combinations incur an increased risk of myopathy with lovastatin, rosuvastatin and simvastatin having FDA approved maximum dose restrictions when used with gemfibrozil since 2002. The purpose of this study was to evaluate concurrent use of HMG CoA reductase inhibitors (statins) with fibrates and assess compliance with 2010 FDA approved dose restrictions.
METHODS: This retrospective cohort study evaluated adults who were prescribed statin-fibrate combination therapy, defined as two or more concurrently filled prescriptions for a statin and a fibrate using dose-based National Drug Codes between January 1, 2003 and June 30, 2009. The Medstat Marketscan Claims Databases, representing over 100 employers, were used to identify patients. The primary objective was to describe the recent (18 month) prevalence rate of against label statin-fibrate combination therapy. The secondary objective was to describe annual prevalence rates of against label statin-fibrate prescribing from 2003–2009.
RESULTS: Within the 18 month period of January 2008 and June 2009, 116,078 patients were prescribed concurrent statin-fibrate combination therapy of which 7.9% (n=9,155) were against label combinations. Simvastatin-gemfibrozil accounted for 78.2% (n=7,156) of against label combinations; moreover, 89.8% of all simvastatin-gemfibrozil combinations (n=7,972) were against label. The annual prevalence of against label statin-fibrate combination therapy was 18.1% in 2003, 20.9% in 2004, 7.1% in 2005, 5.4% in 2006, 6.6% in 2007, 7.6% in 2008 and 8.1% in 2009.
CONCLUSION: Prescribing of against label statin-fibrate combinations occurred despite clearly established FDA dosing restrictions. Annual prevalence rates of against label statin-fibrate combination therapy varied but were still unacceptable, and nearly every time simvastatin-gemfibrozil was prescribed against label. The updated 2011 FDA labeling expands dose restrictions for simvastatin to include additional maximum dose restrictions and a new contraindication with gemfibrozil. Based on our data, proactive approaches to ensure compliance with FDA labeling that promote patient safety are needed.

Ambulatory Care

354. The role of clinical pharmacist in a HIV care team: a retrospective review. *Cathy Hau, Pharm.D.*, Kirsten Balano, Pharm.D., AAHIVE; University of California, San Francisco, San Francisco, CA
PURPOSE: The purpose of this study is to establish referral criteria for a clinical pharmacy adherence services in the HIV Clinic at the Sonoma County in California by 1) describing the clinical interventions and patient population that are being served by pharmacists in the HIV clinic, and 2) identifying a subpopulation of HIV patients whom pharmacists' intervention will be the most beneficial for their disease state management.
METHODS: The study is conducted as a non randomized, retrospective database review that utilizes the Sonoma County HIV patient database to compare baseline demographic data for HIV patients with or without pharmacists' follow up. This clinical database contains demographic and clinical information of about 500 patients and is being maintained by physicians in order to monitor patient care. In addition, medication lists and clinical pharmacy interventions are included in the database. Using data from January 2009 to December 2010, we compared clinical characteristics between patients who received pharmacists' care and those who did not. We evaluated the types of pharmacist interventions provided. Ultimately, we plan to generate a set of clinical parameters that warrant pharmacists' interventions.
RESULTS: Preliminary results suggest patients who were referred to pharmacist's care because they have history of antiretroviral resistance and have a more complex antiretroviral regimen. Pharmacy services were delivered as clinic visits and telephone follow-up at equal portion. Few categories of clinical interventions may not require the expertise of an HIV-trained pharmacist.
CONCLUSION: Preliminary results from this database review reveal

patient factors that allow pharmacist to create referral system for pharmacist adherence services. We identified the spectrum of pharmacist services and how these services were delivered. Criteria for referral to pharmacist's care will be established pending completion of database review.

Cardiovascular

355. Simvastatin amiodarone drug interaction alert: adherence to dosing recommendations before and after the implementation of a new computerized drug-drug interaction alert. *Rathasen Prom, Pharm.D.*[1], Craig Umscheid, M.D.[2], Sarah A. Spinler, Pharm.D., FCCP, BCPS[1]; (1)University of the Sciences in Philadelphia, Philadelphia, PA; (2)University of Pennsylvania, Philadelphia, PA

PURPOSE: In patients receiving amiodarone, the FDA previously recommended that daily dose not exceed 20 mg. In June 2011, the package labeling was revised with a new recommended dose of 10 mg daily when co-prescribed with amiodarone. The purpose of this study was to compare the frequency of appropriate prescribing before and after a revised computerized physician order entry (CPOE) alert at a large academic medical center.

METHODS: Medical records of consecutive patients who were admitted to a 60-bed cardiology service for a two-month time period will be reviewed and the frequency of appropriate orders in patients prescribed amiodarone will be compared to a two-month baseline period prior to the implementation of the revised CPOE alert. The primary end point is the percentage of completed orders which are appropriate. A completed order is defined as an order which was processed after the receipt of the drug interaction alert. An appropriate order is defined as an order for ≤ 20 mg/day or ≤ 10 mg/day for the old or new alert, respectively, or for an alternative non-interacting . Key secondary end points include the percentage of completed orders for > 20 mg/day (old alert) or > 10 mg/day (new alert) which were changed to ≤ 20 mg/day (old alert) or ≤ 10 mg/day (new alert) or a non-interacting .

RESULTS: In the control group (old alert), 56% (9/16) of completed orders were appropriate. Among the 44% (7/16) of inappropriate orders, 43% (3/7) were subsequently changed to an appropriate order during hospitalization. In the analysis which included all , 86% (37/43) of completed orders were appropriate. Data collection for the new alert is ongoing.

CONCLUSION: It is anticipated that the new alert will result in decreased inappropriate orders when co-prescribed with amiodarone.

356. Evaluation of bleeding risk using HAS-BLED scoring in patients with atrial fibrillation receiving enoxaparin bridging therapy. *Julia M. Underwood, Pharm.D.*[1], Kelly C. Rogers, Pharm.D.[2], Maria Pham, Pharm.D.[1], Robert Parker, Pharm.D.[2], Shannon W. Finks, Pharm.D.[2]; (1)Veterans Affairs Medical Center Memphis, Memphis, TN; (2)University of Tennessee College of Pharmacy, Memphis, TN

PURPOSE: In patients with atrial fibrillation, bridging treatment with low molecular weight heparins (LMWH) or unfractionated heparin is frequently used to reduce stroke risk during periods of subtherapeutic warfarin anticoagulation. The risk of bleeding from bridging therapy remains unclear, creating difficulty in balancing the risks and benefits of bridging therapy. The HAS-BLED criteria were developed to assess the risk for major bleeding in patients with atrial fibrillation treated with antithrombotic therapy. However, HAS-BLED criteria have not been evaluated in patients undergoing bridging therapy. The purpose of this study was to assess the utility of the HAS-BLED criteria in patients with atrial fibrillation being bridged with enoxaparin.

METHODS: A retrospective chart review was conducted of patients with atrial fibrillation receiving concomitant warfarin and enoxaparin treatment from July 1, 2007 to December 31, 2010. The following information was collected for each enoxaparin bridging episode: demographic data, warfarin and enoxaparin dosage, and $CHADS_2$ and HAS-BLED scores. Bleeding episodes were classified according to TIMI and GUSTO criteria.

RESULTS: A total of 118 patients meeting inclusion criteria have been reviewed thus far. A total of 16 patients (13.6%) experienced a clinically significant bleeding episode (TIMI major/minor or GUSTO severe/moderate). A trend toward increased bleeding (p=0.08) was present when a patient's HAS-BLED score exceed the $CHADS_2$ score. Of the 16 patients that bled, 6 (37.5%) had a HAS-BLED score greater than the $CHADS_2$ score. Of the 102 patients without bleeding, 17 (16.7%) had a HAS-BLED score greater than the $CHADS_2$ score.

CONCLUSIONS: Patients with atrial fibrillation receiving enoxaparin bridging are at risk of clinically significant bleeding. The HAS-BLED scoring system may be useful to predict bleeding risk in this cohort of patients. Analysis of additional patients is ongoing.

Critical Care

357. Incidence of hyperglycemia in at risk medical intensive care unit patients upon cessation of intravenous insulin infusions. *Erin N. Frazee, Pharm.D.*[1], Joanna L. Stollings, Pharm.D.[2], Heather A. Personett, Pharm.D.[1], Garrett E. Schramm, Pharm.D.[3], Philip J. Kuper, Pharm.D.[4]; (1)Mayo Clinic, Rochester, MN; (2)Mayo Clinic Rochester, Rochester, MN; (3)Mayo Clinic, Rochester, Rochester, MN; (4)Mayo Clinic Rochester - Mayo Foundation, Rochester MN, Rochester, MN

PURPOSE: To describe the incidence of hyperglycemia (≥ 180 mg/dL) upon cessation of continuous intravenous (IV) insulin infusions in at risk medical intensive care unit (MICU) patients

METHODS: This study was a retrospective review of 95 adult MICU patients at Mayo Clinic in Rochester, Minnesota. Included patients received ≥ 8 hours of a continuous IV insulin infusion per an existing protocol. Excluded patients expired during therapy, received insulin for a toxicologic emergency or did not consent for research. Data collected pertained to demographics, medications, nutrition, and blood glucose (BG) concentrations in the 24 hours following discontinuation of the infusion. Patients were analyzed in a-priori defined subgroups based on hyperglycemic risk including corticosteroids/diabetes (N=20), no corticosteroids/diabetes (N=42), corticosteroids/no diabetes (N=21), or neither risk factor (N=12).

RESULTS: Ninety-five patients were included, with a median number of five (range 3–24) available BG measurements. The primary endpoint of any episode of hyperglycemia within 24 hours of infusion discontinuation occurred in 63% of patients, of which 41% had ≥ 50% of reported BG ≥ 180 mg/dL. The hyperglycemia incidence among the subgroups was significantly different (steroids/diabetes 85%, no steroids/diabetes 76%, steroids/no diabetes 38%, neither risk factor 25%; p=0.0001). Transition insulin, defined as subcutaneous insulin or an insulin pump initiated prior to infusion discontinuation, was administered to 44 (46%) patients, most commonly to patients with both risk factors (60%) and isolated diabetes (60%). Subcutaneous NPH or glargine were selected in 80% of cases, but transition strategies were heterogeneous.

CONCLUSION: The incidence of hyperglycemia in MICU patients is common, particularly in those with diabetes and ongoing steroid therapy. Upon discontinuation of IV insulin infusions, transition insulin is administered inconsistently. Routine implementation of insulin transition strategies in the highest risk patients is needed to reduce the incidence of post-infusion hyperglycemia.

358. Blood pressure control in the hospitalized elderly trauma population. *Lina Saliba, Pharm.D.*, Anthony T. Gerlach, Pharm.D., BCPS, FCCM; The Ohio State University Medical Center, Columbus, OH

PURPOSE: It is well known that chronic hypertension leads to long-term complications, but there are no studies to date that directly examine the effects of inpatient hypertensive episodes in the trauma population. The purpose of this study is to determine whether in-hospital episodes of hypertension in trauma patients lead to increased morbidity including end-organ damage.

METHODS: A retrospective review of trauma patients 45–89 years who presented to The Ohio State University Medical Center between January 2008 and September 2008 was completed. Patients were classified based on whether or not they experienced in-hospital hypertension and were assessed for complications using written and electronic medical records. Hypertension was defined as any reading of systolic blood pressure (SBP) ≥ 180 and/or diastolic blood pressure (DBP) ≥ 110 mmHg or at least two readings of SBP ≥ 160 and/or DBP ≥ 100 mmHg. The primary outcome was a composite of myocardial infarction, stroke, venous thromboembolism, and acute kidney injury.

Statistical analysis was performed by Fisher's exact for nominal data, Mann-Whitney U for non-parametric data, and t-test for parametric data.
RESULTS: One-hundred seven patient charts were reviewed and 43 (40%) of patients developed at least one hypertensive episode during hospitalization. A total of 9 (8.4%) patients developed the primary outcome, 6 (14%) in the hypertensive group compared to 3 (4.7%) in the non-hypertensive group, p=0.15. More patients that developed hypertension required an ICU admission compared to the non-hypertensive patients (16 (37.2%) vs. 9 (14.1%), p=0.01). Of the five hypertensive patients that met the primary endpoint and were on home antihypertensive medications, two were not restarted on any home medications initially, two were restarted on some, and one was restarted on all.
CONCLUSION: Hypertensive episodes occurred in 43 (40%) patients. There was a trend for more complications in the hypertensive arm; however, further research is needed.

359. Evaluation of a standardized magnesium sulfate infusion protocol in aneurysmal subarachnoid hemorrhage. *A. Rebecca Bickley, Pharm.D.*, Sarah A. Young, Pharm.D., Edward C. Seidl, Pharm.D., Daniel A. Shade, M.D.; Allegheny General Hospital, Pittsburgh, PA
PURPOSE: This study evaluated a standardized magnesium sulfate ($MgSO_4$) infusion protocol for maintaining targeted magnesium serum concentrations [2.4–3 mg/dL] in patients with vasospasm versus patients without vasospasm secondary to aneurysmal subarachnoid hemorrhage (aSAH).
METHODS: Patients admitted with aSAH from 2008 to 2009 that received a standardized $MgSO_4$ protocol for at least 24 hours with 3 serum magnesium levels were included in this single-centered retrospective cohort study. The primary endpoint was to compare the percentage of levels within the targeted serum magnesium concentration for the duration of therapy in patients who developed vasospasm versus patients with no vasospasm. Secondary endpoints were to compare the magnesium concentration and the percentage of time within the targeted range in patients who experienced vasospasm versus no vasospasm. In addition, the percentage of time on the magnesium infusion and the serum magnesium concentrations 24 hours prior to vasospasm and the occurrence of adverse effects were evaluated.
RESULTS: Data on 59 patients demonstrated no difference in percentage of magnesium levels (62.8% vs 62.0%) or time within the targeted range (62.9% vs 65.3%) for the vasospasm versus non-vasospasm groups respectively. Incidence of hypotension was higher for the non-vasospasm group (21.9% vs 14.8%). The mean time on the infusion 24 hr prior to vasospasm was 21.9±3.8 hours. In patients with a mean serum magnesium level greater than 3 mg/dl, 6.3% experienced vasospasm while 14.4% did not.
CONCLUSION: The standardized $MgSO_4$ protocol demonstrated no difference in percentage of levels or time within the targeted concentrations between the vasospasm and non-vasospasm groups. The utility of $MgSO_4$ infusion protocols in aSAH needs to be further evaluated.

Education/Training

360. Teaching emphasis within pharmacy residency programs. *Ibrahim Sales, Pharm.D.*[1], Susan Meyer, Ph.D.[2], Sandra Kane-Gill, Pharm.D., M.S., FCCM[2], Denise Howrie Schiff, Pharm.D.[2]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: American Society of Health System Pharmacy (ASHP) standards for required teaching experiences do not provide guidance on implementation. Identified components of residency teaching programs are: 1) structured seminars on teaching; 2) practical teaching experiences; 3) teaching portfolio development; and 4) teaching mentorship. The purpose of this study is to determine whether these four components contribute to the development of residents' confidence in teaching.
METHODS: A 54-question survey was designed. An email was sent to the directors of all ASHP-accredited Pharmacy Practice residencies (n=546) requesting the survey link to be forwarded to the 2009 – 2010 residents (n=667). The four components were assessed for the likelihood of an association with the resident's perception of his or her confidence for teaching abilities using a univariate logistic regression analysis.
RESULTS: A 41% (276/667) response rate was obtained representing 23% of Pharmacy Practice programs. Residents who participated in structured seminars on teaching were more confident in developing instructional objectives (OR 5.69; 95% CI 1.50–21.58), assessing classroom learning (OR 3.77; 95% CI 1.48–9.60), and classroom management (OR 3.19; 95% CI 1.09–9.30). Participants in practical teaching experiences were more confident in their presentation skills (OR 6.86; 95% CI 1.36–34.58), implementing active learning strategies (OR 3.44; 95% CI 1.02–11.66), assessing classroom learning (OR 3.72; 95% CI 1.44–9.60), and precepting APPE students (OR 16.00; 95% CI 2.70–94.68). Residents who compiled teaching portfolios were more confident in developing statements of teaching philosophy (OR 10.73; 95% CI 4.36–26.40). Residents were more confident classroom management (OR 3.78; 95% CI 1.52–9.40) if they had a teaching mentor.
CONCLUSION: Structured seminars on teaching and practical teaching experiences are important components of teaching programs for pharmacy residents to enhance valuable skills and confidence.

361. Enhancing physician awareness of out-of-pocket medication costs to improve patient care. *Sheryl B. Fleisch, M.D.*, Ted J. Turner, Pharm.D., Jamie Montgomery, R.Ph., BCPP, Michelle L. Gross, Pharm.D., Tanya Fabian, Pharm.D., Ph.D., BCPP; Western Psychiatric Institute and Clinic, University of Pittsburgh Medical Center, Pittsburgh, PA
PURPOSE: Many patients discharged from psychiatric hospitals are unable to afford their psychotropic medications, resulting in medication non-adherence and subsequent relapse. The purpose of this study is to assess knowledge of out-of-pocket medication costs and attitudes toward cost effective prescribing practices among psychiatry residents at Western Psychiatric Institute and Clinic (WPIC).
METHODS: An anonymous online survey was disseminated to WPIC residents via email. Non-responders were emailed up to two additional times. Survey items included demographics and questions related to medication costs and prescribing practices.
RESULTS: A total of 67 of 78 residents (86%) completed the online survey. Out of a 5-point Likert scale, residents ranked the following categories highest: believing cost influences whether patients fill prescriptions (4.64), believing physicians should be knowledgeable about the cost of medications they are prescribing (4.48), and feeling comfortable with medications available on the $4 generic program (4.33). Residents ranked the following categories lowest: accessing drug cost information prior to writing a prescription (2.93), awareness of manufacturer-sponsored patient assistance programs (2.88) and awareness of patient copayment amounts when prescribing medications (2.78). Knowledge of specific psychotropic medications was also limited.
CONCLUSION: Resident physicians recognize the importance of being knowledgeable about the cost of medications and understand the impact of cost on prescription filling. However, they do not routinely access drug cost information for the prescriptions they write nor do they understand all factors that influence cost of prescriptions for patients. Increasing resident physician awareness of out-of-pocket psychotropic medication costs prior to prescribing may improve prescribing practices at WPIC and thus result in decreased out-of-pocket costs to patients. This may ultimately increase medication access and promote medication adherence.

362. Prevalence of board certification among pharmacy practice faculty at US schools/colleges of pharmacy. *Kimberly A. Toussaint, Pharm.D.*[1], Kristin Watson, Pharm.D., BCPS[2], Joel C. Marrs, Pharm.D., BCPS[3], Deborah A. Sturpe, Pharm.D., BCPS[2], Sarah L. Anderson, Pharm.D., BCPS[3], Stuart T. Haines, Pharm.D., BCPS[2]; (1)University of Maryland Medical Center, Baltimore, MD; (2)University of Maryland School of Pharmacy, Baltimore, MD; (3)University of Colorado School of Pharmacy, Aurora, CO
PURPOSE: Accreditation Council for Pharmacy Education Standards state that pharmacy practice faculty should have or be working towards credentials related to their area of practice/expertise,

including certification through the Board of Pharmacy Specialties (BPS). This study was conducted to determine the prevalence of board certification among pharmacy practice faculty at US schools/colleges of pharmacy.
METHODS: The primary objective was to determine the prevalence of board certification among pharmacy practice faculty at US schools/colleges of pharmacy. The secondary objectives were to determine the prevalence of board certification by faculty rank, geographic region, and in public compared to private pharmacy schools. A list of current board certified pharmacists was obtained from BPS. This list was compared to the American Association of Colleges of Pharmacy (AACP) online database of pharmacy practice faculty to create a list of currently board certified pharmacy practice faculty in the US.
RESULTS: The overall prevalence of board certification among pharmacy practice faculty at US schools/colleges of pharmacy is 37% (1063/2867). Assistant professors are slightly more likely to be board certified (39.4%) than either associate professors (38.8%; p=0.067) or full professors (30.3%; p<0.01). Instructors are the least likely to be board certified (6.2%; p<0.001). Board certification varied significant by region (p<0.05). Region 2 (schools in New Jersey, Pennsylvania, Maryland, Virginia, and West Virginia) has the highest prevalence of board certified pharmacy faculty (45.4%) and region 7 (schools in Idaho, Montana, Oregon, Utah, and Washington) has the lowest percentage (29.3%; p<0.01). Private and public pharmacy schools were found to have similar rates of board certification (36.8% vs. 37.6%, p=0.684).
CONCLUSION: The prevalence of board certification among pharmacy practice faculty at US schools/colleges of pharmacy is relatively low. The highest prevalence was found among assistant professors and the eastern regions.

363. Assessing the impact of an introductory biopharmaceutical industry elective on student rotation preferences and career choices. *Samantha R. Llanos, Pharm.D.*, Kelsey White, Pharm.D., Eleanor Yu, Pharm.D., Fae Wooding, Pharm.D.; Massachusetts College of Pharmacy and Health Sciences, Worcester, MA
PURPOSE: New developments in biotechnology have prompted many colleges of pharmacy to include biotechnology lectures and courses into their curriculum. The Introduction to Biopharmaceutical Industry elective is offered in an accelerated Doctor of Pharmacy Program to provide students with an overview of career opportunities for pharmacists in the industry. The purpose of this study is to assess student knowledge of opportunities within the biopharmaceutical industry and the impact of this elective on future experiential rotation preferences and career choices.
METHODS: A 12-item survey was created and administered to pharmacy students in their first professional year prior to the beginning of the Introduction to Biopharmaceutical Industry elective. Students responded to queries regarding demographics and perceptions of the science, business, and role of the pharmacist within the biopharmaceutical industry. Students will respond to a similar survey at the completion of the course to reassess their knowledge and evaluate the impact of the elective on their rotation preferences and career choices.
RESULTS: Final results are pending. A total of 16 students completed the initial survey. Preliminary results indicate that 9 students (56%) did not have any experience working in the biopharmaceutical industry. Students were most familiar with the areas of clinical research and drug safety within biopharmaceutical industry, 6 students (38%) and 4 students (25%), respectively. Students were undecided as to whether they would pursue a rotation (44%), fellowship (38%), or career (44%) within the biopharmaceutical industry.
CONCLUSION: Preliminary results suggest that many students are not aware of career opportunities in the biopharmaceutical industry. Ongoing data collection and analyses will provide more definitive conclusions regarding the impact of this elective.

Family Medicine

364. Use of an adherence estimator and individualized counseling for new chronic medication prescriptions. *Robert S. Helmer, Pharm.D.*[1], Sarah A. Treadway, Pharm.D.[1], Michelle Z. Farland, Pharm.D., BCPS[2], Shaunta' M. Ray, Pharm.D., BCPS[2]; (1)University of Tennessee College of Pharmacy/University of Tennessee Medical Center, Knoxville, TN; (2)University of Tennessee College of Pharmacy, Knoxville, TN
PURPOSE: Medication non-adherence has and continues to be a challenge for healthcare providers. The primary objective of this study is to assess the impact of individualized pharmacist counseling using a survey to predict the rate of initial fill of new chronic medications following hospitalization.
METHODS: This prospective study enrolled adult patients, discharged from an inpatient family medicine teaching service following receipt of a prescription for a new chronic medication. Patients were asked to complete the Adherence Estimator® (Merck & Co. Inc.) survey for each new medication prescribed. This validated, 3-item survey consists of statements that assess patient concerns regarding medication indication, adverse events, and cost. Patient responses were scored and stratified into low, medium and high risk for primary non-adherence. Pharmacists provided individualized counseling to patients based on survey results. Follow-up occurred 1-week after the initial encounter. The dispensing pharmacy was contacted to ascertain initial fill date, product dispensed, quantity, and patient payment. The primary outcome of the study was rate of initial prescription fill.
RESULTS: To date 20 patients with 31 medications have been enrolled. Over half of the medications prescribed were lipid-lowering agents or diuretics. Overall 77% of the current patients filled their prescription within one week. Based on Adherence Estimator® (Merck & Co. Inc.) score, 29% of patients were categorized as high risk for non-adherence, 29% medium risk and 42% low risk. One week fill rates for high, medium, and low risk groups were 100%, 77%, and 62%, respectively.
CONCLUSION: Enrollment is ongoing. One observed limitation is the literacy level of the survey tool is above that of our patient population. Preliminary results suggest focused, individualized patient counseling may have contributed to the increased primary adherence rate in the high risk group. However, final conclusions cannot be made until the predetermined study population has been enrolled.

365. Evaluation of an electronic health record warfarin documentation system within a family medicine residency program. *Nicole D'Antonio, Pharm.D.*, Roberta Farrah, Pharm.D., BCPS; UPMC St. Margaret Hospital, Pittsburgh, PA
PURPOSE: Use of a warfarin documentation system in an electronic health record (EHR) is valuable to managing warfarin patients and also serves as a teaching tool for family medicine residents. In practice, accurate electronic warfarin documentation is a challenge due to issues such as multiple users, irregular use, limited training, and many data entry points. Consequently, necessary information that guides anticoagulation decision-making can be absent, misinterpreted, or contradictory to office visit notes. This two-year research project aims to analyze the accuracy of an existing and alternative electronic warfarin documentation system and to determine a workflow that works best for our outpatient facilities.
METHODS: Pre- and post-surveys will be distributed to physicians, nurses, and pharmacists in order to evaluate provider perspectives about documenting anticoagulation information. A retrospective chart review will be performed on patients receiving warfarin therapy, comparing the accuracy of an existing and alternative warfarin flowsheet to office visit notes or telephone notes.
RESULTS: Pre-survey results show that 43.6% of providers were uncomfortable with the initial warfarin documentation system. Chart review of existing and alternative documentation workflows and post-survey will be completed by Fall 2011. Accuracy rates for flowsheets at the office visit level and the patient level will be calculated for the initial and alternative workflows. Common reasons for inaccuracy, provider comfort, and perception of time and difficulty involved with documentation will also be collected.
CONCLUSION: The results of this study are anticipated to develop a practice-specific workflow in order to improve accurate warfarin documentation and effective warfarin management.

Geriatrics

366. The use of valproic acid or oxcarbazepine to treat dementia-related agitation. *Rachel L. Freytag, Pharm.D.*, Jessica K. Cather, Pharm.D., BCPS, Susan M. Fosnight, R.Ph., CGP, BCPS, Dorcas J. Letting, Pharm.D., BCPS; Summa Health System, Akron, OH

Antipsychotic medications (AP) are used off-label for the treatment of dementia-related agitation (DRA). AP hold a black box warning stating that using AP for dementia-related psychosis can increase mortality in a dose related fashion. The use of valproic acid (VPA) and oxcarbazepine (OX) to treat these patients has increased since the black box warning was released; however, the efficacy and safety of these medications is uncertain.

PURPOSE: Determine the efficacy and safety of VPA or OX for the treatment of DRA.

METHODS: This retrospective case-matched chart review evaluates the use of VPA and OX use in DRA patients admitted to St. Thomas Hospital's geropsychiatric inpatient unit. Cases are patients started on VPA or OX to treat DRA and controls are patients treated with a scheduled AP. Twenty-nine cases matched with controls were found; twenty VPA and nine OX patients. The primary outcome measure is the average amount of AP per day (in haloperidol equivalents) used to treat DRA. Secondary outcomes include length of stay, readmission within 30 days, continuation of VPA or OX upon discharge, as well as the occurrence of hyponatremia, hyperammonemia, and thrombocytopenia.

RESULTS: The average daily dose of VPA and OX were 287 mg and 310 mg respectively. Baseline characteristics were similar between all groups. No outcomes were statistically significant; however, there were trends towards significance. The average daily haloperidol equivalent dose trended down for all cases vs. all controls (1.50 mg/day vs. 1.85 mg/day). VPA cases vs. VPA controls (1.64 mg/day vs. 1.92 mg/day) and OX cases vs. OX controls (1.23 mg/day vs. 1.72 mg/day) also trended towards a decrease in the amount of AP used daily.

CONCLUSION: Neither VPA nor OX were shown to significantly decrease the amount of AP used in patients treated for DRA, however, both VPA and OX had a trend towards decreasing the amount of AP used.

367. The effect of haloperidol loading dose on the duration of delirium. *Melinda D. Garner, Pharm.D.*[1], Susuan M. Fosnight, R.Ph., CGO, BCPS[1], Dorcas Letting-Mangira, Pharm.D.[1], Elizabeth E. Baum, M.D.[1], Rex D. Wilford, D.O., R.Ph.[1], Kyle A. Allen, D.O.[1], Susan Hazelett, RN[1], Lyn Benedict, RN[1], Michael Hewit, M.S.[2]; (1)Summa Health System, Akron, OH; (2)Northeastern Ohio Universities Colleges of Medicine and Pharmacy, Rootstown, OH

PURPOSE: Delirium is a common condition in hospitalized elderly patients that has been associated with poor outcomes including longer length of stay, increased nursing facility admissions, and increased mortality. There is little evidence based information to guide the pharmacological treatment of delirium. Haloperidol has become gold standard of treatment, although dosing guidelines are not currently available. Experts recommend a haloperidol loading dose, however there is no evidence based literature to support this dosing of haloperidol. The aim of this study is to compare efficacy and safety of delirium medication regimens in elderly patients that received a haloperidol loading dose versus those that did not received a haloperidol loading dose.

METHODS: This is a matched, case-control, retrospective chart review evaluating delirium treatment with and without a haloperidol loading dose in elderly patients. The primary endpoint was the time, in hours, from the initial medication administration until two consecutive negative delirium scores were recorded or until the patient was discharged. The length of stay, discharge disposition, deaths before discharge, and QTc prolongation were collected and are the secondary outcomes.

RESULTS: Data from twenty-one case-control matched pairs was collected. There was no statistically significant difference in the primary outcome between the cases and controls.

CONCLUSION: Patients who cleared delirium before discharge had a trend towards a shorter length of stay and also decreased duration of delirium if the haloperidol loading dose was administered. Patients who had a shorter duration of delirium were significantly more likely to be discharged to home (p=0.0006).

Hematology/Anticoagulation

368. Comparison of aPTT vs. anti-Xa assay for the therapeutic monitoring of unfractionated heparin. *Darko Todorov, Pharm.D.*, Michael Cunningham, Pharm.D., Suzanne Conyne-Rapin, Pharm.D.; UC Health-University Hospital, Cincinnati, OH

PURPOSE: The primary goal of the study was to compare time to therapeutic activated partial thromboplastin (aPTT) or antifactor-Xa (anti-Xa) assay for patients receiving therapeutic unfractionated heparin (UFH). The study evaluated the performance improvement initiative involving conversion from aPTT to anti-Xa assay for the therapeutic monitoring of UFH within our hospital.

METHODS: This retrospective, chart review study included patients treated according to the hospital's standard UFH protocol for deep venous thrombosis (DVT) and/or pulmonary embolism (PE). Outcomes measured included the percentage of patients with therapeutic aPTT or anti-Xa values at 6, 12, 24, 48 and 72 hours after UFH initiation, percentage of with adverse effects requiring UFH discontinuation, and evaluation of the cost associated with each assay.

RESULTS: Of the 509 patients screened, 152 were included in the aPTT (n=76) or anti-Xa group (n=76). There was no statistical difference between aPTT (61.8%) and anti-Xa (77.6%) groups (p=0.052) in percentage of cumulative patients achieving therapeutic values at 24 hours. There was no significant difference in number of adverse events, including bleeding, that led to discontinuation of UFH. Significantly fewer anti-Xa assays were performed as compared to aPTT assays (mean 4.2 vs. 6 tests respectively) to reach therapeutic levels with UFH, however it did not lead to significant laboratory cost savings.

CONCLUSION: There was no significant difference in the cumulative number of patients achieving therapeutic aPTT or anti-Xa levels at 24 hours. While fewer tests were performed in the anti-Xa group, it was not associated with laboratory cost savings due to the cost difference at baseline. A larger study is needed to assess outcome differences between aPTT and anti-Xa when used for monitoring of therapeutic UFH.

369. Evaluation of compliance to American College of Chest Physicians guidelines for warfarin reversal with vitamin K. *Giavanna M. Russo-Alvarez, Pharm.D.*[1], Stacey Miske, Pharm.D.[2], Leslie Gingo, Pharm.D.[1]; (1)University of Pittsburgh Medical Center St. Margaret, Pittsburgh, PA; (2)University of Pittsburgh Medical Center Northwest, Seneca, PA

PURPOSE: The study documented vitamin K therapy received by patients taking warfarin in order to 1) assess physician compliance with the 2008 American College of Chest Physician (ACCP) guidelines for excessive anticoagulation, 2) assess reasons for noncompliance, and 3) quantify the incidence of thromboembolism and major and minor bleeding after vitamin K administration and 30 days post-discharge; warfarin overcorrection; and warfarin resistance.

METHODS: Electronic medical records of 117 inpatients admitted from January 1, 2010 to September 30, 2010 at a community teaching hospital were reviewed. Patients were included if greater than 18 years and were receiving both warfarin and vitamin K. Patients were excluded if vitamin K was used for reversal of the international normalized ratio (INR) prior to surgery or invasive procedures; or for reasons other than to reverse the anticoagulant effect of warfarin.

RESULTS: Physician compliance to the 2008 ACCP guidelines was 27.4%. The top three reasons for noncompliance included administering vitamin K when the INR was < 5.0 and no significant bleeding (29%); subcutaneous administration of vitamin K (20%); and intravenous administration of vitamin K when oral route recommended (12%). Three patients were readmitted within 30 days post-discharge with major bleeding while zero patients were readmitted with a thromboembolism or minor bleeding. Of the 117 patient charts reviewed, 35% experienced warfarin overcorrection and 7% developed warfarin resistance.

CONCLUSIONS: Despite wide acceptance of the 2008 ACCP guidelines, physician compliance is still suboptimal. Academic detailing involving face-to-face educational sessions with physicians

or the development of a computerized physician order entry (CPOE) decision support order set may increase compliance at institutions. The clinical significance of noncompliance with the 2008 ACCP guidelines for vitamin K administrations warrants further study.

Infectious Diseases

370. Vancomycin serum levels and efficacy in methicillin resistant *Staphylococcus aureus* (MRSA) infections. *Khusbu Patel, Pharm.D.*, William Kernan, Pharm.D., BCPS; Cleveland Clinic Florida, Weston, FL

PURPOSE: The rationale of therapeutic drug monitoring is to improve clinical outcomes and minimize toxicity. Serum vancomycin trough levels are measured routinely to maximize outcomes of therapy. The objective of this study is to determine a correlation between vancomycin serum levels and efficacy in patients with MRSA infections.

METHODS: This is a retrospective, single-center, observational study conducted at CCF, a 150-bed community teaching hospital. The study includes all hospitalized patients from September 2009 to September 2010 with positive MRSA cultures that have been maintained on vancomycin for three or more days. Patient data was collected from their electronic medical records. Patients with positive outcomes will be compared to those with negative outcomes and a correlation with vancomycin serum levels will be determined.

RESULTS:

CONCLUSION:

371. Review of anidulafungin utilization in patients with hepatic dysfunction at a large academic medical center. *Heather A. Personett, Pharm.D.*[1], Erin N. Frazee, Pharm.D.[1], Garrett E. Schramm, Pharm.D.[2], Joanna L. Stollings, Pharm.D.[3], Philip J. Kuper, Pharm.D.[4]; (1)Mayo Clinic, Rochester, MN; (2)Mayo Clinic, Rochester, Rochester, MN; (3)Mayo Clinic Rochester, Rochester, MN; (4)Mayo Clinic Rochester - Mayo Foundation, Rochester MN, Rochester, MN

PURPOSE: To illustrate prescribing patterns of anidulafungin when restricted to use as an alternative to caspofungin in patients with moderate or severe hepatic dysfunction.

METHODS: Retrospective chart review of hospitalized patients at Mayo Clinic in Rochester, Minnesota between June 2010 and May 2011. Patients 18 years of age or older who received two or more doses of anidulafungin and consented for research were included. Data collected pertained to demographics and liver function. Mild elevation in liver function tests (LFTs) was defined as aspartate aminotransferase (AST) or alanine aminotransferase (ALT) 1–2 times the upper limit of normal. In the absence of definitive stratification criteria, patients without hyperbilirubinemia (bilirubin >2 mg/dL) and mild LFT elevation were considered to have mild hepatic insufficiency. Moderate to severe hepatic dysfunction was defined as LFTs >3 times the upper limit of normal or hyperbilirubinemia.

RESULTS: There were 81 episodes of anidulafungin use in 74 patients during the study period. Population median (IQR) AST, ALT and total bilirubin values were 109 (47–256) U/L, 86 (38–144) U/L, and 2.3 (0.9–8.7) mg/dL, respectively. In 12 instances (15%), patients receiving anidulafungin had normal LFTs without hyperbilirubinemia, while 17 patients (21%) had only mild hepatic insufficiency.

CONCLUSION: Anidulafungin is used as an alternative to caspofungin in patients with hepatic dysfunction due to lack of hepatic metabolism and seemingly insufficient knowledge and familiarity with caspofungin pharmacokinetics in this population. Our institutional policy reserves anidulafungin for patients with moderate or severe hepatic dysfunction. In the present investigation, 36% of its use was in patients with normal or mildly decreased hepatic function. This represents an opportunity to improve discrimination between mild and moderate or severe hepatic dysfunction. Such delineation may improve compliance to formulary restrictions where they have been implemented.

372. Does in-vitro resistance of *Streptococcus pyogenes* to erythromycin produce clindamycin resistance?

Christine M. Bridgen, Pharm.D., Harminder Sikand, Pharm.D., Daniel Keays, M.S., C.L.S.; Scripps Mercy Hospital, San Diego, CA

PURPOSE: Throughout the last decade there has been a trend of increasing macrolide resistance to *Streptococcus pyogenes* (Group A Strep), which is responsible for severe, life-threatening infections including toxic shock syndrome and necrotizing fasciitis. Recent data in 2010 from Scripps Mercy Hospital in San Diego, California showed a rate of 20% macrolide resistance to *S. pyogenes*. This data prompted further investigation, the main concern being that macrolide resistance would produce cross-resistance in clindamycin. Our primary objective was to determine the prevalence of erythromycin and clindamycin resistance among clinical isolates of *S. pyogenes* in the San Diego area and determine the mechanism of resistance, whether that be through drug inactivation, efflux pumps or methylation.

METHODS: 146 consecutive isolates of *S. pyogenes* were analyzed from five Scripps hospitals. The antimicrobial susceptibilities of the isolates were determined using double-disk diffusion testing (d-test). Analysis was performed using a two-sample test of proportions (2-tailed). A $p<0.05$ will be considered significant for all statistical analysis.

RESULTS: 146 strains of *S. pyogenes* were analyzed for both erythromycin and clindamycin susceptibility. There was no statistically significant difference between the resistance patterns of erythromycin or clindamycin to *S. pyogenes* (28 vs 27, p=0.88). Overall, there were 27 positive d-tests, demonstrating that the main mechanism of resistance produced by *S. pyogenes* in the San Diego area was through methylation which causes resistance to both erythromycin and clindamycin.

CONCLUSIONS: *S. pyogenes* is resistant to both erythromycin and clindamycin in ~20% of strains in the San Diego area. If a patient is resistant to erythromycin there is a high likelihood it will also be resistant to clindamycin. With the increasing trend of macrolide resistance in *S. pyogenes* strains, the penicillin family remains the drug of choice in these infections and macrolide use should be reserved for patients with true beta lactam allergies.

373. A matched-controlled evaluation of an antifungal bundle in the intensive care unit at a university teaching hospital. *Anthony J. Guarascio, Pharm.D.*[1], Douglas Slain, Pharm.D., BCPS[1], Arif Sarwari, M.D.[1], Richard L. McKnight, Pharm.D.[2], Karen O. Petros, Pharm.D.[2], John Parker, M.D., FACP, FCCP[2], Alison M. Wilson, M.D.[1], Maria Pompili, Pharm.D.[2], Melissa L. Rinehart, Pharm.D.[2], Carrie Defazio, Pharm.D.[2]; (1)West Virginia University, Morgantown, WV; (2)West Virginia University Hospitals, Morgantown, WV

PURPOSE: Care bundles have recently become important antimicrobial stewardship efforts. Echinocandins are expensive antifungals that are often overutilized in the ICU. We implemented an antifungal bundle to encourage appropriate use of these antifungals. The primary objective of this study is to assess the utility of an antifungal bundle that specifically targets caspofungin use in the ICU.

METHODS: This is a matched-controlled study of 75 adult patients prescribed caspofungin in the ICU. The antifungal bundle was implemented over a five-month time period in 2011. Bundle patients were compared to control patients who received treatment within a two year period prior to initiation of the bundle protocol. Patients were matched based on age, gender, ICU service, indication, and modified APACHE II score in a 1:2 ratio. Key components of the bundle include assessment of indication, dose, interval, and planned duration.

RESULTS: We found a significant difference in median days of therapy (4.5 vs. 2.0 days, p=0.005) for caspofungin use before and after bundle implementation. Most of this reduction in use was realized in the medical ICU (p=0.02) as opposed to the surgical ICU (p=0.54). Based on average wholesale price (AWP), these findings reflect a median cost savings of approximately $1,013/patient. Although adherence to bundle criteria was higher in the medical ICU compared to the surgical ICU, these differences were not statistically significant (76% vs. 50%, respectively; p=0.36). Of 25 patients receiving caspofungin during the bundle period, three were de-escalated to fluconazole and 13 had antifungal therapy discontinued within 3 days. Eleven of these patients had yeast culture growth from BAL or urine specimens. None of the patients in the bundle implementation group experienced recurrence or death from a fungal infection.

CONCLUSION: Use of an antifungal bundle approach appears to facilitate a reduction in echinocandin use in the ICU without adversely affecting patient outcomes.

374. Doripenem and colistin is synergistic and demonstrates bactericidal killing against pandrug-resistant *Klebsiella pneumonia* isolates in vitro. *Meredith Jernigan, Pharm.D.*, Minh-Hong Nguyen, M.D., Neil Clancy, M.D., Ellen Press, B.S., Ryan Shields, Pharm.D.; University of Pittsburgh Medical Center, Pittsburgh, PA

PURPOSE: Carbapenem-resistant *Klebsiella pneumonia* (KPC) is a major cause of disease at our center, and many isolates have developed resistance to salvage agents such as colistin (COL). We sought to identify the preferred antimicrobial combination for treatment of KPC disease by evaluating *in vitro* synergy.

METHODS: 11 unique KPC isolates were tested by time-kill assays using combinations of doripenem (DOR), COL, gentamicin (GEN), and doxycycline (DOX) at clinically achievable concentrations.

RESULTS: All isolates were non-susceptible to DOR. MIC_{50}/MIC_{90} for COL, DOX, and GENT were 8/64, 6/16, and 32/64 μg/mL, respectively. 9/11 (82%) were COL-resistant, 9/11 were GEN-resistant, and 7/11 (64%) were resistant to all agents. Synergy (≥ 1 log CFU/mL greater kill in combination *vs* most active single drug) was identified with DOR+COL, GEN+DOX, DOR+GEN, DOR+DOX, COL+GEN, and COL+DOX against 10/11 (91%), 4/9 (44%), 4/9 (44%), 4/11 (36%), 3/9 (33%), and 3/11 (27%), respectively. Only DOR+COL resulted in a reduction of starting inocula for all isolates (log-kill range: 0.3 – 5.8 CFU/mL) and was bactericidal (≥ 2 log cFu/mL kill) against 6/11 (55%). Among synergistic combinations, the most rapid kills were with COL+GEN and COL+DOR (mean areas under the bactericidal curve [AUBC]: 59.8 and 77.5; p=NS). Both combinations were superior to DOR+DOX (129.4; p=0.031 and 0.049, respectively). Antagonism (less kill in combination) was evident for COL+DOX and COL+GENT against 4/11 (36%) and 2/11 (18%), respectively. The *in vitro* data are consistent with our preliminary clinical experience in transplant recipients, in whom COL+carbapenem combinations are more effective than alternative combinations.

CONCLUSION: DOR+COL demonstrated excellent *in vitro* activity against pandrug-resistant KPC isolates. COL+GEN is rapidly bactericidal against some isolates, but antagonistic against others and clinically limited by additive toxicity. Following completion of this pilot study, DOR+COL has become the first-line treatment for KPC at our center and clinical outcomes are being evaluated prospectively.

Managed Care

375. Evaluation of a fluticasone/salmeterol step-down program. *Lily Phuong, Pharm.D.*, Emily Pearse, Pharm.D., Judy Pereira, Pharm.D., Fern Chau-Devera, Pharm.D.; Kaiser Permanente Medical Care Program, Vallejo, CA

PURPOSE: In 2010, the Food and Drug Administration mandated labeling changes that recommend stepping down long acting β-agonist (LABA) use in patients with well-controlled asthma due to increased risk of asthma-related death with LABA monotherapy. Primary care pharmacists collaborated with providers to develop a fluticasone/salmeterol (F/S) Step-Down Program to decrease unnecessary LABA use in patients with stable asthma. The primary endpoint is to determine the rate of change in F/S use after implementing the F/S Step-Down Program in 2010 compared to previous years. Secondary endpoints include identifying the patient populations that could most successfully step-down F/S use and reviewing barriers to the program.

METHODS: This is a retrospective study lasting from January to December 2010. Pharmacists started the outreach under the F/S step-down protocol. Patients who met inclusion and exclusion criteria were subdivided into three populations: Low, Moderate, and High F/S users. The yearly rates of F/S use from 2006 to 2010 were calculated.

RESULTS: In 2009, the number of patients on F/S normalized to per member per month per thousand (PMPMK) was 14.39. In 2010, it was 14.36, a small decrease in F/S usage by 0.2%. It was also found that Low and Moderate F/S users were more successful than High F/S users, p<0.001. No significant differences in success between Low and Moderate F/S users, p=0.08. Some barriers to the step down program included the inability to contact patients and providing outreach when their asthma was exacerbated due to allergies, cold, or flu.

CONCLUSION: After implementation of the program, F/S usage decreased for the first time in years. Low and Moderate users are more successful than High users. One solution to overcome barriers is to provide outreach to patients during the time of the year when asthma is more stable to educate on asthma management to prevent exacerbation.

Medication Safety

376. Avoidance of sulfonylureas in hospitalized patients at high risk for hypoglycemia: effectiveness of an email alert. *Ibrahim Sales, Pharm.D.*, Donihi Amy, Pharm.D., BCPS; University of Pittsburgh Medical Center, Pittsburgh, PA

PURPOSE: Patients of advanced age and those with renal insufficiency are at increased risk for hypoglycemia when using sulfonylureas. A Quality Improvement project was designed to determine if an email alert prompted discontinuation of sulfonylureas in hospitalized patients at risk for sulfonylurea-related hypoglycemia.

METHODS: The hospital's medical director sent an email alert to the attending physician of patients (n=64) ordered a sulfonylurea while hospitalized from July – September 2010. The following data were retrospectively collected from patients' medical records: patient age, serum creatinine (SCr), and incidence of hypoglycemia (glucose <70 mg/dL). The prevalence of risk factors (age ≥65 and SCr ≥2 mg/dL) in hypoglycemic patients was compared to the prevalence in patients without hypoglycemia.

RESULTS: Email alerts were sent for 22 (32%), 32 (19%), and 10 (30%) patients taking glyburide, glipizide, and glimepiride respectively. Fifty-five patients (86%) continued the sulfonylurea despite the alert, 5 patient orders (8%) were discontinued within 24 hours of the alert, 2 (3%) were discontinued after 24 hours, and 2 (3%) were discontinued prior to the alert. Seventeen patients (27%) experienced a total of 31 episodes of hypoglycemia. Of the patients with hypoglycemia, 9 (53%) were ≥65, 6 (35%) had SCr ≥2, and 10 (59%) were either of advanced age or with renal insufficiency. Of the 47 patients who did not experience hypoglycemia, 31 (66%) were ≥65, 11 (23%) had SCr ≥2, and 36 (77%) were either of advanced age or with renal insufficiency. There were no statistical differences between groups.

CONCLUSION: Use of an email alert was not effective in prompting discontinuation of sulfonylureas in the hospital. Alternative strategies for preventing sulfonylurea-related hypoglycemia are needed. In addition, proposed risk factors for hypoglycemia may not accurately identify hospitalized patients predisposed to hypoglycemia suggesting that sulfonylureas should be avoided in all patients in the hospital setting.

377. Creation of a risk score for predicting opioid harm in the inpatient setting. *Jordan R. Wong, Pharm.D.*, Nadia Z. Haque, Pharm.D., Megan Winegardner, Pharm.D., James S. Kalus, Pharm.D.; Henry Ford Hospital, Detroit, MI

PURPOSE: Opioid medications are the medication class most commonly associated with significant errors in the hospital setting. The purpose of this study was to create and validate a risk score for predicting naloxone use, a surrogate marker for serious opioid harm, for the inpatient setting.

METHODS: Medical records of 300 patients, receiving opioids and admitted to an inpatient hospital setting between July 2009 and December 2009, were abstracted to identify variables associated with naloxone use. From this evaluation, a risk score was developed to predict the use of naloxone. This risk score was based on the odds ratios derived from a multivariate analysis. One point was assigned for age > 65 years, opioid-naïve status, non-African American race, and chronic obstructive pulmonary disease. Two points were given for the presence of renal failure. The risk score was then validated in a different patient population (n = 300) receiving opioids and admitted between April 2010 – December 2010.

RESULTS: Risk for naloxone use increased with increasing risk score. Naloxone use at each risk score was: 0 = 8.7%, 1 = 11.1%, 2 = 30.3%, 3 = 38.6%, 4 = 46.8%, 5 = 59.1%, 6 = 100%. The area under the curve for the receiver operating characteristic (ROC) curve was 0.701 with 95% confidence interval of 0.640-0.762 (p<0.05). The sensitivity and specificity of a risk score greater than or equal to 3 was 72% and 57.5%, respectively. A risk score cut-point of greater than or

equal to 4 yielded a sensitivity of 45% and a specificity of 79%.
CONCLUSION: This opioid harm risk score provided moderate predictive ability for identifying patients at risk for opioid-related adverse events. This risk score could be useful as a screening tool for hospitalized inpatients receiving opioid therapy.

Nephrology

378. Daily home hemodialysis versus conventional in-center hemodialysis: evaluation of biomarkers of vascular calcification and management of mineral and bone disorder. *Magdalene M. Assimon, Pharm.D.*[1], Page V. Salenger, M.D.[2], Shari Meola, RN[2], Darius L. Mason, Pharm.D., BCPS[1]; (1)Albany College of Pharmacy & Health Sciences, Albany, NY; (2)Rubin Dialysis Center, Clifton Park, NY
PURPOSE: Hyperphosphatemia contributes to the pathogenesis of vascular calcification (VC). Daily home hemodialysis (DHHD) clears phosphorus more effectively than conventional in-center hemodialysis (IHD), resulting in reduced phosphate binder requirements and possible attenuation of VC. The aims of this study were to characterize concentrations of VC biomarkers among DHHD and IHD patients and to explore the management of mineral and bone disorder (MBD).
METHODS: Adult hemodialysis patients were included in this pilot study. For every DHHD patient enrolled, an age (±5 years), sex and dialysis vintage (±6 months) matched IHD patient was selected. Patient demographics, laboratory parameters and medication regimens were obtained. Pre-dialysis concentrations of VC biomarkers (FGF-23, fetuin A and osteoprotegrin) were determined using ELISA.
RESULTS: Forty patients were included in this analysis (20 DHHD and 20 IHD). Phosphorus (4.8±1.3 mg/dl versus 6.5±1.9 mg/dl, p=0.002) and PTH (211.2 [30.6–144] pg/ml versus 395 [141.4-1,388.6] pg/ml, p=0.034) levels were lower among DHHD patients, whereas calcium (9.2±0.5 mg/dl versus 8.9±0.6, p=0.049) concentrations were higher in the DHHD group. FGF-23 concentrations were lower among DHHD patients (397 [55.9–1,572.3] pg/ml versus 501.8 [177.3–4,775.2] pg/ml, p=0.0340), whereas fetuin A levels were higher among DHHD patients (1.57±0.44 g/L versus 1.02±0.69 g/L). No differences in osteoprotegrin concentrations were observed. A lower proportion of DHHD patients were using phosphate binders (60% versus 90%, p=0.029). Vitamin D analog and cinacalcet use was similar between groups. **CONCLUSIONS:** These data suggest superior control of serum phosphorus and MBD among DHHD patients, despite a smaller percentage of patients on phosphate binding therapy and use of similar doses of MBD medications compared to IHD patients. Additionally, lower FGF-23 and higher fetuin A concentrations observed in the DHHD group suggests a lower VC burden and warrants further investigation.

Neurology

379. Examining utilization patterns of patients receiving oral therapy for multiple sclerosis (MS) treatment. *Laura Studnicki, Pharm.D., M.B.A. Candidate*[1], Pamela H. Koerner, Pharm.D.[2], Richard T. Miller, R.Ph., M.B.A.[3]; (1)Walgreens, Co. and Duquesne University, Mylan School of Pharmacy, Pittsburgh, PA; (2)Duquesne University, Mylan School of Pharmacy, Pittsburgh, PA; (3)Walgreens, Co, Carnegie, PA
PURPOSE: With the introduction of the first oral therapeutic agent for MS treatment in late 2010, a study was initiated to evaluate MS patients receiving fingolimod therapy within Walgreens Specialty Pharmacy. With minimal published utilization data available the intent is to 1) identify demographics of the patient population currently utilizing the medication, 2) evaluate common side effects that patients are experiencing, and 3) review historical MS treatments in patients that were switched to oral therapy and the reasons why the initial therapy was altered.
METHODS: Patients receiving fingolimod therapy from any of our five Walgreens Co. specialty pharmacy locations, beginning on November 16, 2010, will be retrospectively reviewed. Initial assessments will include: age, gender, MS type, time since diagnosis and whether or not the patient was new to fingolimod therapy. Follow-up assessments, conducted monthly, identifies patient reported side effects, falls, missed doses, reasons for missing doses and if new assistive devices have been used in the past month. Medication Possession Ratio (MPR) will also be determined for these patients when on therapy for at least 6 months.
RESULTS: A total of 537 fingolimod patients are currently being analyzed. Women have a greater utilization rate (78.2%) when compared to men (21.8%). Relapsing remitting MS patients encompass 70% of the population, with secondary progressive at 2.8% and progressive relapsing at 2.2%. Twenty-five percent of cases did not report their MS type. Time since diagnosis was defined as follows: 0 to 6 months (5.9%), 7 to 11 months (1.7%), 1 to 5 years (26.3%), 6 to 10 years (20.3%), >10 years (35.4%) and uncertain (10.4%).
CONCLUSION: Based on the drug release date and the timing of the assessments to be conducted, data collection and analysis will be completed by August 2011. This data will include demographic information, adverse drug events reported and MPR.

Oncology

380. Isotope dilution mass spectrometry influence on calculating carboplatin doses. *Rachelle Whiteside, Pharm.D.*, Rickey Miller, Pharm.D., BCPS, BCOP, Kenneth Kochman, Pharm.D.; Allegheny General Hospital, Pittsburgh, PA
PURPOSE: Carboplatin dosing relies heavily on the accuracy of serum creatinine measures and its effect on calculating creatinine clearance. Allegheny General Hospital adopted the new standard of isotope dilution mass spectrometry (IDMS) for measuring serum creatinine in February 2009. Current equations for determining creatinine clearance do not take into account this standardization and an equation was developed to "correct" the serum creatinine. The purpose of this study is to determine the effect of IDMS standardization on area under the curve (AUC) dosing of carboplatin.
METHODS: Medical records of 232 patients who received carboplatin for a variety of malignancies were identified over a three year period. Patients were included if they received at least one dose of carboplatin. All doses of carboplatin received were analyzed. Patients AUC, dose, growth factor utilization, platelet transfusion requirements, platelet count, and absolute neutrophil count (ANC) were also documented.
RESULTS: The median dose without correction was 308 mg and with IDMS correction was 279 mg in the post-IDMS group resulting in a percent change in dosing of 9.2%. The patient's dose was compared to the Cancer Therapy Evaluation Program/National Cancer Institute (CTEP/NCI) maximum dosing. In patients with an AUC of 4, 50% of doses were above CTEP/NCI recommendations in the pre-IDMS group and 67% in the post-IDMS group. In patients with an AUC of 6, 5.3% of doses were above recommendations in the pre-IDMS group and 36.8% in the post-IDMS group.
CONCLUSION: There is approximately a 10% increase in carboplatin dosing depending on the AUC in post-IDMS patients if the correction factor of serum creatinine is not utilized when calculating the creatinine clearance. IDMS standardization of serum creatinine may result in an overestimation of creatinine clearance. As a result, larger doses of carboplatin may be prescribed potentially increasing the risk of developing toxicities.

Pharmacogenomics/Pharmacogenetics

381. The effect of epithelial sodium channel genotype on loop diuretic requirements in systolic heart failure; interim analysis of the first 50 subjects. *Adam P. Bress, Pharm.D.*, Vicki L. Groo, Pharm.D., Robert J. DiDomenico, Pharm.D., Thomas D. Stamos, M.D., Shital Patel, M.S., Larisa H. Cavallari, Pharm.D.; University of Illinois at Chicago, Chicago, IL
PURPOSE: Response to loop diuretics (LD) in patients with heart failure (HF) is highly variable. Variation in the *SCNN1G* and *SCNN1B* genes, which encode for the epithelial sodium channel gamma and beta subunits, respectively, have been associated with altered response to LDs in healthy subjects. The purpose of this study is to determine if the *SCNN1G* rs5729 T>A, variants influence oral LD requirements in HF patients.
METHODS: Adult patients with HF and systolic dysfunction treated with stable doses of HF medications, including oral LD, for ≥4 weeks are eligible for this prospective cohort study. Patients with significant

renal or hepatic dysfunction are excluded. Target enrollment is 100 patients. Patient characteristics and a buccal cell sample for genetic analysis are collected. Loop diuretic dose requirements will be compared between *SCNN1G* rs5729 T>A variant allele carriers and non-carriers. We will also compare the prevalence of high dose diuretic therapy, defined as requiring >80mg/day of furosemide (or equivalent doses of other LDs) or the combination of any LD and metolazone, between genotype groups.
RESULTS: A total of 50 subjects have been enrolled to date, with a mean age of 58±11 years and mean left ventricular ejection fraction of 22±7%. The majority (92%) have NYHA class II or III HF. The rs5729A allele frequency is 0.27. The median (IQR) daily LD dose (furosemide equivalents) is 80 (40-120) mg/day in variant allele carriers and 80 (40-160) mg/day in non-carriers. High dose LD was required in 10 (40%) variant carriers compared to 9 (36%) non-carriers.
CONCLUSION: Recruitment is on-going, but data to date suggest that, in contrast to data in healthy subjects, the rs5729 T>A variant makes no contribution to LD requirements in HF.

Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

382. Prospective trial of a novel vancomycin nomogram. *Amber R. Wesner, Pharm.D.*[1], Robert S. Kidd, Pharm.D., Ph.D.[2], Marcia L. Brackbill, Pharm.D., BCPS[2], Larissa Coyle, Pharm.D., BCPS[3]; (1)Shenandoah Univeristy, Bernard J. Dunn School of Pharmacy / Valley Health, Winchester Medical Center, Winchester, VA; (2)Shenandoah University, Bernard J. Dunn School of Pharmacy, Winchester, VA; (3)Valley Health, Winchester Medical Center, Winchester, VA
PURPOSE: Revised guidelines for appropriate vancomycin trough concentrations were published in 2009 defining appropriate trough concentrations from 10–20 μg/mL. Available nomograms were not designed to achieve these higher trough levels. The purpose of this study is to prospectively evaluate a novel vancomycin nomogram previously validated retrospectively at our institution.
METHODS: This was a prospective, open-label study at a 411-bed community hospital. Patients were included if they were >18 y, ≤120 kg, and had an order for pharmacy-dosed vancomycin. Patients were randomized to be dosed using the new nomogram, or to be dosed using traditional pharmacokinetic calculations. It was calculated that 414 patients would need to be enrolled. The primary objective was to compare the percentage of patients achieving an initial therapeutic vancomycin trough. Therapeutic troughs were defined as being drawn at steady state and falling between 10-15 or 15-20 mcg/mL based on the indication for therapy. Secondary objectives were to compare the absolute difference between desired and actual troughs measured and to assess pharmacist's opinions of the nomogram.
RESULTS: To date 157 patients have been enrolled and recruitment is ongoing. Preliminary results found traditional dosing achieved therapeutic troughs in 34% of patients and nomogram dosing achieved therapeutic troughs in 49% of patients (n=157; p=0.112). Nomogram dosing was superior to traditional dosing in the 15–20 μg/mL trough range (n=101; p=0.025), but was not statistically significant in the 10–15 μg/mL trough range (n=56; p=0.794). There was not a significant difference between groups for the absolute difference between trough measurements, and pharmacists' agreed that the nomogram saved them time.
CONCLUSION: Preliminary results did not find a statistically significant difference between methods in achieving initial therapeutic vancomycin troughs although results are trending towards significance. Data collection is continuing to determine if results will become significant as the required number of patients are enrolled to achieve power.

Transplant/Immunology

383. Tacrolimus trough concentrations in heart transplant recipients during episodes of acute cellular rejection. *Gretchen Kipp, Pharm.D.*[1], Michael A. Shullo, Pharm.D.[1], Heather J. Johnson, Pharm.D., BCPS[1], Shelby L. Corman, Pharm.D., BCPS[1], Jeffrey Teuteberg, M.D.[2], Ty Ridenour, Ph.D.[3], Raman Venkataramanan, Ph.D.[3]; (1)UPMC Department of Pharmacy & Therapeutics, Pittsburgh, PA; (2)UPMC Cardiovascular Institute, Pittsburgh, PA; (3)University of Pittsburgh, Pittsburgh, PA
PURPOSE: Approximately 20–40% of heart transplant recipients experience an episode of acute cellular rejection (ACR) within their first year after transplant. Pro-inflammatory cytokines involved in ACR are thought to down regulate the metabolism of tacrolimus causing clinically significant fluctuations in tacrolimus levels. Therefore, the primary aim of this research study was to describe tacrolimus whole blood trough concentrations during episodes of ACR in orthotopic heart transplant (OHT) recipients. The secondary aim was to determine whether elevated tacrolimus trough concentrations during ACR are associated with markers of tacrolimus toxicity.
METHODS: This retrospective cohort study was designed to describe tacrolimus trough concentrations before, during and after episodes of ACR. The first part of the study used an A-B-A study design to compare the mean dose-normalized tacrolimus trough concentrations in each patient before, during and after resolution of an episode of ACR. The second part of the study compared serum creatinine, blood urea nitrogen and potassium concentrations at the same time points.
RESULTS: A total of 129 heart transplant recipients experienced at least one episode of ACR within their first year post transplant but only 34 patients had complete dose-normalized tacrolimus concentrations available for the primary analysis. The dose-normalized concentrations were 0.793, 0.875 and 0.890 (ng/mL)/mg before, during and after episodes of ACR, respectively (p=0.383). Potassium concentrations were 4.41, 4.41 and 4.38 mEq/L for the respective time points (p=0.59). Serum creatinine concentrations were 1.60, 1.57 and 1.61 mg/dL (p=0.71) and BUN concentrations were 32.4, 31.1 and 33.4 mg/dL before, during and after ACR, respectively (p=0.25).
CONCLUSION: The results suggest that tacrolimus metabolism is not significantly altered during episodes of ACR in OHT recipients. Additional data collection and generalized mixed model growth curve analyses are ongoing.

384. Early Corticosteroid Withdrawal Reduces Risk for Actual Cardiovascular Events in Renal Transplant Recipients: A Multivariate Analysis. *Nicole M. Schmidt, Pharm.D.*, E. Steve Woodle, M.D., Rita R. Alloway, Pharm.D., Gautham Mogilishetty, M.D., Amit Tevar, M.D., Stefanie Young, Liz Cole, Dennis Hanseman, M.S., Adele R. Shields, Pharm.D.; University of Cincinnati, Cincinnati, OH
PURPOSE: Early corticosteroid withdrawal (ECSWD) has been shown to mitigate several known cardiovascular risk factors in prospective clinical trials. We have recently demonstrated that ECSWD also reduces cardiovascular events (CVE) in a large cohort of 1004 renal transplant recipients. This study examined risk factors for CVE, including ECSWD, in a multivariate analysis (MVA) in renal transplant recipients.
METHODS: Data was prospectively collected from 1998-2010 on CVE, cardiovascular risk factors, and transplant-related risk factors at baseline, 1, 3, 6 months, then yearly in 1004 renal transplant recipients. CVE included angina, cerebrovascular accident/transient ischemic attack, myocardial infarction, coronary heart disease/ischemic event, cardiovascular procedure, and cardiovascular death/sudden death. Statistical analyses included χ^2, student t-test, and MVA using logistic regression. Factors with a $p \leq 0.1$ in the univariate analysis (UVA) entered the final MVA model.
RESULTS: 714 patients received ECSWD and 290 patients received chronic corticosteroid regimens. 267 CVE occurred in 171 patients.

UVA of Risk Factors for CVE	p-value
Age (years)	0.0412
African American Race	0.0617
Pre-Transplant Dialysis	0.0028
Smoking	0.0044
Pre-Transplant CAD	0.0003
Pre-Transplant DM	<0.0001
Acute Rejection	0.0215
New Onset Diabetes After Transplantation	0.0688
Pre-Transplant SBP (mmHg)	0.0070
Mean Post-Transplant SBP (mmHg)	0.0074
Mean Post-Transplant # Hypertension Medications	0.0212

Mean Post-Transplant SCr (mg/dL)		0.0142
Mean Post-Transplant Total Cholesterol (mg/dL)		0.0128
Mean Post-Transplant Triglycerides (mg/dL)		0.0231
ECSWD		<0.0001
Final MVA Model	Odds Ratio	p-value
Pre-Transplant DM	2.686	<0.0001
Smoking	1.880	0.0024
Pre-Transplant CAD	1.529	0.0637
ECSWD	0.459	<0.0001

CONCLUSION: Risk factors significant for CVE in the MVA model included traditional cardiovascular risk factors of smoking, pre-transplant DM and preexisting CAD. In addition, ECSWD was found to reduce CVE risk by over 50%. In summary, this long term experience, when multiple risk factors are adjusted, provides strong evidence for a protective effect of ECSWD on CVE.

385. 10-Year Experience with Early Corticosteroid Elimination in Kidney Transplantation: Analysis of Patient and Graft Survival. *Nicole M. Schmidt, Pharm.D.*[1], Adele R. Shields, Pharm.D.[1], Rita R. Alloway, Pharm.D.[1], Gautham Mogilishetty, M.D.[1], Michael Cardi, M.D.[2], Rino Munda, M.D.[2], Amit Tevar, M.D.[1], Justin Burns, M.D.[1], Joseph Kremer, M.D.[2], Liz Cole[1], Stefanie Young[1], Dennis Hanseman, M.S.[1], Shahzad Safdar, M.D.[2], E. Steve Woodle, M.D.[1]; (1)University of Cincinnati, Cincinnati, OH; (2)The Christ Hospital, Cincinnati, OH

PURPOSE: Early corticosteroid withdrawal (ECSWD) reduces cardiovascular risk, however long term effects on patient and graft survival have not been established. The purpose of this study was to evaluate long term effects of ECSWD on patient and graft survival.

METHODS: Prospectively collected data (from 1998–2010) in 1004 renal transplant patients (714 ECSWD and 290 chronic corticosteroid (CCS) patients) was analyzed. Statistics included χ^2 test, student *t*-test, and Kaplan-Meier (KM) survival analyses using log rank.

RESULTS: Mean corticosteroid dose in the CCS group at 1 year was 6.9 ± 5.5 mg and 5 ± 1.6 mg at 4 years. Median follow-up was 1527 (1–3762) days in ECSWD and 2147 (2–4720) days in CCS. ECSWD were older, with more males, fewer African Americans, but with more preexisting coronary artery disease and diabetes. KM analyses demonstrated that ECSWD patients experienced significantly less cardiovascular events (CVE), but no difference in patient survival, cardiovascular-related death, non-cardiovascular related death, or cancer-related death compared to CCS patients. KM analysis demonstrated a trend toward less infection-related death (p=0.09) and numerically higher death-censored graft survival (p=0.06) with ECSWD patients.

10-Year Kaplan Meier Estimates	ECSWD (n=714)	CCS (n=290)	p-value
CVE Rate	24.0%	35.0%	0.02
Patient Survival	76.0%	76.0%	NS
Cardiovascular Related Death	15.0%	15.0%	NS
Non-Cardiovascular Related Death	13.0%	12.5%	NS
Infection-Related Death	0.8%	2.4%	0.09
Cancer-Related Death	5.0%	3.8%	NS
Acute Rejection	24.0%	27.0%	NS
1-Year Acute Rejection	13.2%	16.9%	NS
Antibody-Mediated Rejection	2.4%	2.8%	NS
Overall Graft Survival	60.0%	54.0%	NS
Death-Censored Graft Survival	81.0%	68.0%	0.06

CONCLUSIONS: KM 10 year data demonstrates that ECSWD patients experience lower CVE and higher death-censored graft survival rates. However, overall patient survival was similar between groups. In summary, this 10 year experience demonstrates substantial benefits for ECSWD patients with respect to CVE and death-censored graft survival.

386. Multivariate analysis of risk factors that influence graft survival following proteasome inhibitor therapy for antibody mediated rejection. *Basma Sadaka, Pharm.D.*, Rita R. Alloway, Pharm.D., Alin Girnita, M.D., Paul Brailey, Ph.D., Gautham Mogilishetty, M.D., E. Steve Woodle, M.D.; University of Cincinnati, Cincinnati, OH

PURPOSE: Antibody (Ab)-mediated rejection (AMR) with presence of DeNovo Donor Specific Ab (DSA) is associated with a 6.6-fold increase in risk for allograft loss. Recently, our center has pioneered the use of bortezomib to reduce DSA by depleting plasma cells, offering alternative treatment options. The purpose of this study was to define factors influencing graft loss in a large single center experience with proteasome inhibitor (PI) therapy for AMR.

METHODS: 42 renal transplant recipients diagnosed with AMR were treated with bortezomib 1.3 mg/m^{2}x4 doses. Immunodominant DSA (iDSA) is the HLA Ab with highest MFI value at the time of AMR diagnosis. Factors evaluated in the univariate analysis (UVA) with p-value<0.1 were incorporated in the logistic regression model.

RESULTS: Demographic, histologic, immunologic, and functional outcome data post treatment will be presented. Overall patient and graft survival were 97.6% and 73.8%, respectively. Non-significant factors in the UVA included: age>60, female gender, AA race, class I DSA and DQ iDSA specificity, and pre-treatment iDSA level. Significant factors in the UVA were analyzed in the MVA model:

	UVA		MVA	
	OR	p-value	OR	p-value
Serum Creatinine (SrCr) returned to 15% of baseline at day 14	5.464	0.0486	10.723	**0.0372**
iDSA reduction >25% at day 14	4.083	0.0582	0.234	0.1390
Histologic improvement within 7-14 days	3.719	0.0837	5.108	0.1044
Compliance	7.291	0.0103	7.113	**0.0544**

CONCLUSION: SrCr was a factor that influenced renal allograft survival following PI therapy. The positive effect of compliance also approached statistical significance. These factors may be useful for predicting long-term outcomes and determining which patients need additional or more aggressive AMR therapy.

387. Preservation of renal function with angiotensin converting enzyme inhibitor or angiotensin receptor blocker therapy early after heart transplantation. *David Johnson, Pharm.D.*, Michael A Shullo, Pharm.D., Shelby L. Corman, Pharm.D., M.S., BCPS, Jeffrey J. Teuteberg, M.D.; University of Pittsburgh, Pittsburgh, PA

PURPOSE: Nearly a third of orthotopic heart transplant (OHT) recipients develop renal failure within a year of transplantation. Post-OHT renal dysfunction secondary to calcineurin inhibitors (CNI) is a leading cause of renal impairment after transplantation. Several existing CNI minimization strategies have demonstrated protection against CNI induced nephrotoxicity; however, few preemptive, non-immune suppressive strategies exist. The aim of our study was to determine if early treatment with angiotensin-converting-enzyme-inhibitor/angiotensin-receptor-blocker (ACEi/ARB) therapy after OHT is asssociated with improved renal function in patients receiving CNI.

METHODS: Male and female patients ≥ 18 years old were retrospectively divided into two groups: patients who had initiated /ARB therapy within 90 days of transplantation or patients who did not receive /ARB within 90 days of transplantation. Patients surviving < 90 days after transplantation, receiving a second heart transplant or who had a GFR ≤ 30 ml/min/1.73m^2 within the first 90 days of transplantation were excluded from the study. The primary endpoint was the time-to a ≥30% reduction in baseline GFR. Secondary endpoints included time-to a GFR ≤ 30 ml/min/1.73m^2 and all-cause mortality.

RESULTS: A total of 315 patients were included in the study, 147 in the non ACEi/ARB group and 168 in the ACEi/ARB group. Both groups were similar, however, more patients in the ACEi/ARB group received MMF compared to the non ACEi/ARB group (p<0.001). There was no difference in the time to ≥30% reduction in GFR (p=0.385) or time to GFR ≤ 30 ml/min/1.73m^2 (p=0.957) between study groups. However, there was a mortality benefit in patients receiving ACEi/ARB therapy (p=0.045); however, after adjusting for use of MMF these was no longer signifcant, (p=0.397).

CONCLUSION: Early initiation of /ARB therapy did not demonstrate a renal benefit in OHT patients receiving CNI after transplantation. No mortality benefit was observed when the groups were adjusted for MMF use.

STUDENT SUBMISSIONS

ADR/Drug Interactions

388. A description of antibiotic-related laboratory interferences. *Thomas J. Wolfel, B.S., Pharm.D., 2012, Candidate*[1], Sandra Kane-Gill, Pharm.D., M.S., FCCM[1], Pamela Smithburger, Pharm.D.[2], Megan D. Schultz, Pharm.D., 2012, Candidate[1], Cortlynn Latsha, Pharm.D., 2012, Candidate[1], Lauren M. Fisher, Pharm.D., 2012, Candidate[1], Ashley N. Hogue, Pharm.D., 2012, Candidate[1]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)UPMC Presbyterian, Pittsburgh, PA
PURPOSE: Many medications, including antibiotics, interfere with laboratory tests resulting in false results. With the abundant use of antibiotics, there is a need to collectively evaluate the interfering antibiotics and the laboratory tests effected which is the purpose of this evaluation.
METHODS: A literature research of Medline was conducted from 1948–2009 for terms "drug," "interaction or interference," and "laboratory." A total of 75 articles pertaining to antibiotic-lab interferences were reviewed. Articles were evaluated by 5 students for the laboratory test being studied, interfering antibiotic, the interference caused, and mechanism of the interference.
RESULTS: The class of antibiotics that accounted for the majority of laboratory interferences was cephalosporins at 49.3% (37/75). Specifically, cefoxitin was the most common [16% (12/75)] antibiotic causing a laboratory interference. The mechanistic reason for this interference is the reaction between cephaloporins, especially cefoxitin, and the chemical alkaline picrate used in the Jaffe reaction, resulting in a falsely high serum creatinine. Other classes of antibiotics associated with interferences included β-lactams, macrolides, and fluoroquinolones. The laboratory test most frequently affected by antibiotic was serum creatinine. The articles evaluated indicated these were actual interferences and not due to cephalosporin induced nephrotoxicity. Other laboratory tests affected by interference included AST, ALT, serum glucose, and urine catecholamine.
CONCLUSION: Antibiotics have been shown to interfere with the results of a wide variety of commonly used laboratory tests. Health care professionals must use discretion when evaluating a patient laboratory results when a patient is prescribed an antibiotic.

Ambulatory Care

389. Assessing interest in clinical pharmacy services within a unique community setting. *Nadine H. Kazem, M.A., Pharm.D., Candidate*, Samantha Karr, Pharm.D., BCPS, Mary K. Gurney, Ph.D., R.Ph.; Midwestern University College of Pharmacy, Glendale, AZ
PURPOSE: There is currently limited data regarding pharmacists providing clinical services in community settings beyond ambulatory care or medication therapy management (MTM) clinics or in retail pharmacy settings. This study was designed to assess community residents' interest in the establishment of an academic ambulatory care site offering pharmacy clinical services within a unique community setting. **METHODS:** Focus groups representative of participants were conducted to elicit themes to include within the survey. A descriptive survey was constructed and approved by our institution's IRB Committee. Survey participants were recruited from two city-funded community centers; the Foothills Recreation and Aquatics Center, and the Glendale Public Library. Inclusion criteria included adults, regardless of age, gender, or race. An anonymous 17-question self-administered survey was made accessible to participants by: 1) mail; 2) a Qualtrics web-based survey link; and 3) a hard-copy format available at each site. Participants were asked to provide responses regarding demographic data, current chronic medical conditions, regular use of prescription and over-the-counter (OTC) products, use of home medical devices, and perceived benefit of pharmacist clinical services including drug utilization review (DUR), explanation of laboratory results, and assistance with optimizing use of home medical devices. Study participants were also asked to identify interest in additional individual or group consultation services. It is estimated that 100 respondents will be required for final analysis of survey results. **RESULTS:** Data collection and analysis are still in progress and will be completed by September 2011. **CONCLUSION:** Study conclusions will be made after final analysis of the data.

390. Identified drug therapy problems in a federally qualified health center. *Riane J. Ghamrawi, Pharm.D., Candidate*, Natalie J. Kolehmainen, Pharm.D., Candidate, Eric M. Tuttle, Pharm.D., Candidate, Magdi H. Awad, Pharm.D.; Northeast Ohio Medical University, Rootstown, OH
PURPOSE: Previous analyses of drug therapy problems (DTP), in mostly insured patient populations, identified "needs additional drug therapy" as the most common DTP followed by "dosage too low" and "non-adherence." The purpose of this study is to examine DTP identified in a federally qualified health center (FQHC).
METHODS: Retrospective chart reviews of medication therapy management encounters by a pharmacist and pharmacy externs between September 2010 and March 2011 was completed.
RESULTS: One hundred and forty patient charts were reviewed. The average number of medications and medical conditions per patient was 10.95 and 8.05, respectively. The average number of DTP was 5.16 per patient. Over one third of the patients were uninsured. "Non-adherence" (27.10%), "needs additional drug therapy" (17.03%), and "ineffective drug therapy" (17.00%) were the most DTP identified from the charts reviewed. About half of the "non-adherence" DTP was caused by the lack of patient understanding of medication related directions. Additionally, over 75% of "ineffective drug therapy" was attributed to the lack of effectiveness monitoring parameters placed in for specific medications. Out of the 723 DTPs uncovered, 35.5% were resolved by the pharmacist/pharmacy externs, and 64.45% were referred to the primary care provider with appropriate recommendations.
CONCLUSION: "Non-adherence" is a more prevalent issue in FQHC. Clinicians in similar settings need to implement effective approaches to communicate appropriate medication use to patients and to monitor efficacy parameters.

391. Patients' perception of clinical pharmacy services in a federally qualified health center. *Natalie J. Kolehmainen, Pharm.D., Candidate*, Riane J. Ghamrawi, Pharm.D., Candidate, Eric M. Tuttle, Pharm.D. Candidate, Magdi H. Awad, Pharm.D.; Northeast Ohio Medical University, Rootstown, OH
PURPOSE: To determine patients' perception of medication therapy management (MTM) services in a federally qualified health center (FQHC)
METHODS: Patient satisfaction questionnaires were available to 140 patients who received MTM services by a pharmacist and pharmacy externs between September 2010 and March 2011. Questionnaire was developed utilizing previous instruments that surveyed patients' satisfaction and attitudes toward MTM. Questionnaire was reviewed for face and content validity.
RESULTS: Questionnaires will be collected between May–July 2011. Descriptive data of the patients' perception will be presented. Elements presented will include patients' satisfaction and attitudes toward expanding the service, perceived impact on medication utilization and overall health outcomes, and an average of suggested charges for the MTM service

392. Utilization of IPADs to facilitate data collection during pediatric screening events. *Amy E. Haver, Pharm.D., Candidate*[1], Nicole Marcotullio, Pharm.D.[2], Jennifer P. Elliott, Pharm.D.[1]; (1)Duquesne University Mylan School of Pharmacy, Pittsburgh, PA; (2)Duquesne University, Mylan School of Pharmacy, Pittsburgh, PA
PURPOSE: To determine whether the use of IPADs versus paper forms during the intake process at screening events will provide a less time consuming method of collecting patient information.
METHODS: The screening events primarily focus on children ages 5 to 17 to determine if they are at risk for asthma, obesity, and hypertension which has been approved by our IRB committee. Prior to the screening events caregivers are asked to complete seven forms for each child participating and the children complete five forms. With the use of the IPADs the above documents were converted to PDF files and available for viewing through the TakeNotes Application. Through the TakeNotes program, the participants can sign forms, circle objects, and write in text boxes on the corresponding documents. Folders are created in the TakeNotes Application containing all of the paperwork for each child and caregiver and synced with notebook computers for storage and data analysis.

RESULTS: Participants were randomized to complete the intake process via IPAD or paper form. Twenty-eight participants completed the intake process with sixteen using the IPADs and twelve using paper. The average time to complete the forms for the IPADs and paper was 3 minutes and 36 seconds and 3 minutes and 54 seconds respectively. Of the twenty eight participants 64% of the children and 86% of the caregivers preferred the IPADs for the intake process. Of the twelve participants using paper initially 50% indicated that they would have preferred to use the IPADs.
CONCLUSION: This study will provide evidence of a novel method of data collection that will provide health care professionals with a less time consuming and economically acceptable way of collecting patient information, while also improving patient satisfaction and the ability provide a more mobile method of data collection and transfer.

393. Risk for medication non-adherence and other drug therapy problems among ambulatory patients in a safety-net health-system. *Amanda Skibowski, Pharm.D., Candidate, 2014*[1], Alan J. Zillich, Pharm.D.[1], Bradley N. Doebbeling, M.D., M.S.[2], Margie E. Snyder, Pharm.D., M.P.H.[1]; (1)Purdue University College of Pharmacy, West Lafayette, IN; (2)Indiana University School of Medicine, Indianapolis, IN
PURPOSE: To 1) characterize the patient population using a safety-net health system outpatient pharmacy, 2) estimate the prevalence of drug therapy problem risk factors, 3) identify patient factors associated with a high risk for nonadherence and other drug therapy problems, and 4) identify patient medication management routines and pharmacist actions as potential strategies for preventing and/or resolving drug therapy problems that should be explored further.
METHODS: Data were collected via a survey administered to a convenience sample of ambulatory patients waiting for prescriptions at a safety-net pharmacy. Eligible patients were 21 years of age or older and using at least one prescription medication regularly for a chronic condition. Surveys were distributed during various days and times. Surveys obtained information regarding participants' demographics, pertinent history for the identification of drug therapy problem risk factors, self-reported medication adherence, and open-ended responses describing participant medication management routines and interactions with pharmacists. Parametric and non-parametric statistics will be used as appropriate to analyze quantitative data. Qualitative analytic methods will be used to identify themes in medication management routines and pharmacist interactions.
RESULTS: Data collection is ongoing with 17 of a targeted 150 surveys completed. Updated results will be presented at the meeting.
CONCLUSION: We anticipate that our findings will provide insight into drug therapy problem risk factors present among medically underserved patients. This work will provide preliminary data regarding medication management routines and pharmacist actions to be examined in future investigations. This will inform the design of medication therapy management programs and other interventions intended to prevent, minimize and/or resolve drug therapy problems.

Cardiovascular

394. A comparison of survey methods on vitamin, herbal, and over-the-counter product use in patients with heart failure. *Anita Kashyap, Pharm.D., Candidate*[1], Stuart L. Burke, Pharm.D., Candidate[1], Lucas M. Boehm, Pharm.D., Candidate[1], Leah Holschbach, B.S., Pharm.D.[2], Tim M. Miller, Pharm.D.[1], Orly Vardeny, Pharm.D., M.S.[1]; (1)University of Wisconsin School of Pharmacy, Madison, WI; (2)Froedtert Hospital, Milwaukee, WI
PURPOSE: Over-the-counter (OTC) and herbal product use is increasing in patients with cardiovascular disease, and may be underreported. We hypothesize that different survey methods to collect OTC and herbal use, may result in different patient reporting of these products. This study was designed to 1.) assess the frequency of OTC and herbal consumption in heart failure (HF) patients and examine predisposing factors that may predict usage; and 2.) investigate differences in data collected from self-completed versus healthcare provider administered survey methods.
METHODS: One hundred sixty HF patients will be enrolled from the University of Wisconsin Advanced Heart Disease Clinic. Participants will complete a survey on herbal and OTC product use, reasons and sources of information for use, and reporting habits to health care providers. Eighty participants will self-complete the survey, and eighty age-matched participants will be administered the survey by pharmacists or pharmacy students. Medical records will be accessed to identify HF disease severity factors and current medications.
RESULTS: The first 80 participants (53 male, 27 female) were 56 ± 15.1 years old. Mean ejection fraction was 36.6 ± 16.5%, and NYHA functional classes were I (n=23), II (n=41), III (n=15), and IV (n=1). 91% reported using a vitamin, OTC, or herbal product. The most common vitamin, OTC, and herbal used was a multivitamin (45%), aspirin (48.8%), and fish oil (28.8%) respectively. Among users, 42.5% reported using a product that was not documented in their medical record. Survey results for the next 80 participants and comparisons with the first 80 participants will be reported.
CONCLUSION: Use of non-prescription therapy is prevalent in patients with HF, and is not always reported to health care providers. These data will give insight on the differences in methods to collect accurate information from patients who may benefit from education on safe OTC and herbal use.

395. Inpatient management of warfarin therapy by pharmacists compared to physicians. *Pio Juan Lansangan, B.S.*[1], Jin-Hee Nomura, Pharm.D.[2], Teresa Hong, Pharm.D.[2], Lynn Ishida-Kitazawa, Pharm.D.[2], Sheryl L. Chow, Pharm.D., BCPS[3]; (1)Western University of Health Sciences, Pomona, CA; (2)Centinela Hospital Medical Center, Inglewood, CA; (3)Western University of Health Sciences and LA BioMed at Harbor-UCLA, Pomona, CA
PURPOSE: Several studies have reported outcomes associated with pharmacist management of newly-initiated warfarin therapy in hospitalized patients. However, fluctuations in therapeutic ranges often occur in hospitalized patients on stable doses of warfarin therapy because of acute disease, drug-drug interactions, and changes in diet, requiring proactive anticoagulation management. The purpose of our study is to compare physician vs. pharmacist-directed management in hospitalized patients who are receiving chronic warfarin therapy in addition to those receiving first-time dosing.
METHODS: A total of 220 consecutive hospitalized patients admitted to Centinela Hospital Medical Center from January 1, 2010 to July 1, 2011 were included in this study. These patients required initiation and/or maintenance of warfarin therapy and were managed by either a physician or pharmacist (110 patients per group). Baseline parameters including drug interactions, indication, and warfarin use before admission were documented. The mean international normalized ratio (INR) at discharge and the rate of patients who were subtherapeutic (INR < 1.5), supratherapeutic (INR > 3.5), or excessively supratherapeutic (INR > 6.0) were compared between groups. The impact of anticoagulation management on patient outcomes was measured by bleeding rates, length of stay (LOS), and days to reach therapeutic INR (DTTI).
RESULTS: Preliminary data for 63 patients (28 physician-directed, 35 pharmacist-directed) has been completed. The mean INR at discharge was similar between physician and pharmacist-directed management (1.9 vs. 1.8, p=0.41). Both groups demonstrated no differences in rates of subtherapeutic, supratherapeutic, and excessively supratherapeutic INRs. Although a trend towards a reduced LOS was observed in patients treated by physicians (5.7 vs. 7.2 days, p=0.15), the DTTI was similar between groups (1.5 vs. 1.7 days, p=0.77).
CONCLUSION: Data from the remaining patients are currently being collected and the completed results and conclusion of all 220 patients will be presented.

Clinical Administration

396. Analysis of wait time disparities in the emergency department for patients reporting with a chief complaint of chest pain from 2003 to 2008. *Melissa Buchanan, B.S.*, Tina Tseng, Ph.D., M.S.P.H.; Campbell University College of Pharmacy & Health Sciences, Buies Creek, NC
PURPOSE: The purpose of this study was to evaluate disparities in chest pain complaining patients' characteristics (age, sex, race, and payment type) and wait time to see a physician in the emergency department (ED).

METHODS: The National Hospital Ambulatory Medical Care Survey – Emergency Department (NHAMCS-ED) database from 2003 to 2008 was utilized for a retrospective cross-sectional study. Patients 30 years and older, received an ECG, and listed chest pain as the primary reason for visit were included in the study. The endpoint used for all statistical analyses was wait time to see a physician. T-test analyses were performed to assess if there was a difference in wait time regarding age, sex, race, and payment type. A subset analysis was performed with significant data from previous T-test analyses to examine if a difference in wait times persisted for patients triaged as emergent.
RESULTS: There were 5,540 patients included in the analysis sample. Only 27% of patients were seen by a provider within the ACC/AHA guidelines recommended timeframe of 10 minutes. Patients that were 65 years and older ($p<0.001$), Caucasian ($p<0.001$), and had Medicare insurance ($p<0.001$) had shorter wait times to see a medical care provider. In the subset analysis of emergent chest pain complaining patients, both older ($p<0.001$) and Caucasian ($p<0.001$) patients had shorter wait times.
CONCLUSION: The majority of patients were not seen in the recommended guidelines of 10 minutes. Disparities in wait time to see a provider were observed with age and race. Older, Caucasian patients complaining of chest pain were seen in a shorter amount of time; however, they were still not seen within the suggested 10 minutes. Additional studies need to be done to further understand the etiology of these disparities and determine how incorporating a pharmacist in the ED can decrease disparities and increase patient care.

397. A mentoring program for clinical and operation supervisors. *Kayley M. Lyons, Pharm.D., Student*[1], Steve Bohn, R.Ph.[2], Ann Nadrash, Pharm.D., BCPS[2]; (1)South Dakota State University College of Pharmacy, Sioux Falls, SD; (2)Kaiser Permanente Colorado Region, Aurora, CO
PURPOSE: This study provides a description of a formalized mentoring program for operational and clinical pharmacy supervisors. The goal of the program is to foster collaboration and accelerate the supervisors' leadership development through valuable mentoring relationships.
METHODS: This program was implemented in the pharmacy department at Kaiser Permanente Colorado (KPCO). Entry level supervisors were matched with both a clinical and operation supervisor with demonstrated success. The program included a training presentation, supervisor self assessment at baseline and every 3 months, supervisor assessment from the mentor every 3 months, an introduction meeting, continuous meetings, and a program evaluation from both an online survey and telephone conversations with program directors. The program is a year in length, with a rotation of mentors after six months.

398. Developing a Sentri7®-driven inpatient clinical pharmacy service. *Jennifer Popa, Pharm.D., Candidate*, Andrew P. Smith, Pharm.D., Candidate, Christina J. Dewar, Pharm.D., BCPS; Aultman Hospital Inpatient Pharmacy, Canton, OH
PURPOSE: Sentri7® is one of several patient surveillance software programs available to assist pharmacists providing clinical pharmacy services. This study evaluated the impact and effectiveness of using Sentri7® surveillance software to provide clinical pharmacy services to hospitalist patients on a step-down unit compared to services provided by a clinical pharmacist.
METHODS: A prospective observational study was conducted over an 8-week period. Reports generated from a clinical pharmacist and from Sentri7® were used to present pharmacy interventions to a hospitalist. Time taken to generate the reports, number of patients, number of interventions, type of interventions and physician responses were tracked.
RESULTS: The first ten days of data collection have been completed. An interim total of 98 patients were seen generating 112 clinical pharmacist interventions in 21 categories and 122 Sentri7® interventions in 16 categories. Many, but not all of the interventions were recommended by both the clinical pharmacist and Sentri7®. The interim average time spent by the clinical pharmacist was six minutes per patient. The interim average time spent using Sentri7® was two minutes per patient. Data collection is expected to be completed in August, 2011 with final results to include the above analyses as well as an average of the physician acceptance rates of interventions overall and in each category.
CONCLUSION: Interim data shows that pre-rounding with Sentri7® takes roughly one-third of the time taken by a clinical pharmacist and still provides basic clinical pharmacy coverage. The time saved could allow the pharmacist to perform a wider range of tasks or provide more in-depth clinical services. It is expected that the analysis of physician acceptance rates will reveal that the clinical pharmacist makes more comprehensive recommendations but both Sentri7® and the clinical pharmacist catch basic pharmacy issues with high physician acceptance rates.

Community Pharmacy Practice

399. Improving health outcomes and continuity of care in underserved, urban populations. *Katie Park, Pharm.D., Candidate*, Jamie L. McConaha, Pharm.D.; Duquesne University Mylan School of Pharmacy, Pittsburgh, PA
PURPOSE: Heart disease is the leading killer across most ethnic minority communities in the United States, and causes the death of 50% of people with diabetes (IDF 2010). Both disease states can be effectively managed with early detection and monitoring. Limited access to health care results in undiagnosed and mistreated disease due to a lack of continuity of care. The purpose of this study is to measure the impact of pharmacist intervention, by free health screenings and patient education, on improving health outcomes and continuity of care in underserved, urban populations.
METHODS: Utilizing a grant through the Pennsylvania Department of Health, three free health screenings providing blood pressure, cholesterol, blood glucose, and body mass index screenings were held at underserved community pharmacy locations. Patient health history was input into an electronic database. Patients were then counseled by a pharmacist on medication and lifestyle changes and received educational supplemental materials. A process existed to enroll any high-risk patients into the Duquesne University Medication Therapy Management (DM^2) program, which provides free medication therapy management sessions and has a collaborating physician available. Six months after the screening events, follow-up phone calls will be made to assess any changes in patient lifestyle, medications, or disease progression. Specifically, a questionnaire will be administered to evaluate changes in health status markers, new or modified medications, and improvements in lifestyle.
RESULTS: A total of 50 patients participated and were enrolled in the study. Patient demographics revealed a mean age of 58 years, with 58% being female. Study protocol calls for follow-up interviews to be conducted six months post-screening (July 2011) to assess if any changes have occurred to the pre-established success of the project. Results will be presented at the ACCP Annual Meeting in October.
CONCLUSION: Pharmacist-provided free health screenings and interventions will positively impact health outcomes of underserved patient populations.

400. Financial impact of a community pharmacy based anticoagulation service. *Nicholas P. Mariani*; Wayne State University, Tecumseh, ON, Canada
PURPOSE: There is little published data on the financial impact of providing clinical pharmacy services in the community pharmacy setting. The purpose of this study is to analyze and define the economics of a community-pharmacy based anticoagulation service.
METHODS: Prescription and clinical records for all patients referred to Novacare Pharmacy's Anticoagulation Service from October 2009 to July 2011 will be comprehensively collected. Total revenue per patient will be calculated which will encompass all clinical billings and drug costs. Data will also be collected on pharmacist time, technician time, equipment costs and overhead cost in order to calculate the expenses to provide the anticoagulation services. Based on the data collected, three economic models will be created in order to assess the feasibility of this type of service in various pharmacy settings. These models will assess: 1) gross profit per patient based on clinical billings solely 2) prescription revenue per patient (excluding clinical billings) 3) total revenue per patient in addition to estimated gross profit per patient. Data will be collected and analyzed by the

presentation date.

Critical Care

401. Assessing an institution-specific therapeutic hypothermia protocol: outcomes and associated adverse events. *Sara Varnado, Pharm.D., candidate*, Lam Nguyen, Pharm.D., Robert MacLaren, Pharm.D.; University of Colorado School of Pharmacy, Aurora, CO

PURPOSE: To assess an institution-specific hypothermia protocol in terms of patient outcomes and the occurrence of hypothermia-related adverse events.

METHODS: A single center, retrospective chart audit was performed on 42 patients who received therapeutic hypothermia for ≥6 hours. Cerebral performance categories (CPC) scores were applied to delineate patients with neurologic recovery (CPC of 1-3) and poor neurologic outcomes (CPC of 4 or 5). These groups were compared using univariate analyses. Descriptive and repeated measures statistics characterized electrolyte, glucose, and coagulation parameters and the occurrence of shivering over time.

RESULTS: Twenty (47.6%) patients demonstrated neurologic recovery. Patient demographics were similar between groups with 29 (69.1%) males and an overall age of 52.5±15.9 years. Initial cardiac rhythm, documented time down, and the time to initiate hypothermia were similar between groups. Patients with neurologic recovery took longer to achieve hypothermic goal (5.7±2.4 hours vs. 4.2±2 hours, p=0.03) but spent longer at goal temperature (16.9±4.2 hours vs. 12.8±6.2 hours, p=0.031). Patients with neurologic recovery were less likely to require dobutamine (10% vs. 40.9%, p=0.06), epinephrine (20% vs. 54.6%, p=0.06), or norepinephrine (25% vs. 63.6%, p=0.04) infusions despite bradycardia being more common (81.8% vs. 36.4%, p=0.01). Neurologic recovery was associated with being discharged alive (95% vs. 5%, p<0.001). During hypothermia, hyperphosphatemia and hyperglycemia were more common in patients with poor neurologic recovery. Overall, 37 (88.1%), 35 (83.3%), 22 (52.3%), and 28 (66.7%) patients required supplementation with potassium, magnesium, phosphate, and insulin, respectively. Coagulation parameters during hypothermia varied minimally from baseline. All but three patients required neuromuscular blockade for shivering.

CONCLUSION: Patients with neurologic recovery differ from those with poor neurologic outcomes. Additional patient charts will be audited and multivariate analyses applied to determine predictors of recovery. The clinical application of therapeutic hypothermia is associated with electrolyte disturbances, hyperglycemia, bradycardia, and shivering; frequently necessitating therapeutic interventions.

402. Observational study of dexmedetomidine in trauma critical care patients. *Kristina Rokas, Pharm.D., Candidate*[1], April D. Miller, Pharm.D., BCPS[1], Brianne L. Dunn, Pharm.D.[1], Christopher Watson, M.D.[2]; (1)South Carolina College of Pharmacy-USC, Columbia, SC; (2)Palmetto Health Richland, Columbia, SC

PURPOSE: Dexmedetomidine is an alpha-agonist that provides sedation, anxiolysis, and analgesia without respiratory depression. These properties are beneficial in critically ill trauma patients who frequently require large doses of sedative agents and are being weaned from mechanical ventilation. There are few data on dexmedetomidine in a trauma intensive care unit (ICU) setting, and this study aims to evaluate the safety and efficacy of dexmedetomidine in this population.

METHODS: Patients admitted to the Trauma ICU without traumatic brain injury who received dexmedetomidine for ≥ 12 hours were included in the study. Medical records were reviewed to evaluate the efficacy of dexmedetomidine at producing desired sedation levels on the Richmond Agitation and Sedation Scale (RASS), doses used, and adverse events, including bradycardia (HR<60bpm) and hypotension (BP<90/60 mmHg).

RESULTS: Twenty patients met inclusion criteria, with approximately half of patients presenting with injuries to the chest or abdomen. Seven patients (35%) were female with an average age of 39.5 years old. Pertinent comorbidities were minimal with the exception of two patients with a history of cirrhosis and one patient with hepatitis C. Average length of stay and duration of mechanical ventilation was 18.3 days and 13.3 days, respectively. The marginal mean dosage received was 0.8 μg/kg/hour, and 10 patients received mean doses ≥ 0.7 μg/kg/hour, the maximum manufacturer recommended dose. Dexmedetomidine was administered for a median of 68.5 hours (range 20 to 261 hours). Most RASS scores (73.6%, 131/178 scores) were in the desired sedation range (-2 to 1). There were a total of 86 episodes of bradycardia in 6 patients. Hypotension occurred in 17 patients, with only one patient requiring treatment.

CONCLUSIONS: These results suggest that trauma ICU patients receive high doses of dexmedetomidine, spend a majority of time in the desired sedation range, and have minimal drug-related episodes of significant bradycardia or hypotension.

403. A multi-center characterization of antipsychotic use for the treatment of delirium in medical ICU patients. *Allison Meyer, Pharm.D., Candidate*[1], April D. Miller, Pharm.D., BCPS[1], Emily K. Dornblaser, Pharm.D., BCPS[2], Cassandra J. Bellamy, Pharm.D., BCPS[3], William D. Schweickert, M.D.[3], Amanda M. Ball, Pharm.D., BCPS[3]; (1)South Carolina College of Pharmacy - USC Campus, Columbia, SC; (2)University of New England, Portland, ME; (3)Hospital of the University of Pennsylvania, Philadelphia, PA

PURPOSE: The estimated incidence of delirium in ICU patients has been reported to be as high as 80% in some studies. The occurrence of delirium in critical illness has been associated with several negative outcomes including increased mortality. Although the data are not robust, the clinical use of atypical antipsychotics (AA) for ICU delirium has become an accepted practice at many institutions. The objective of this study is to characterize the use of atypical antipsychotics and haloperidol for the treatment of delirium in medical ICU (MICU) patients.

METHODS: MICU patients receiving an antipsychotic between January 2006 and January 2010 at two academic institutions were selected for study inclusion. Retrospective review was performed and indications for antipsychotic use, dosing, risk factors for delirium, and benzodiazepine and opioid use were recorded. Since QTc interval prolongation can be a side effect of antipsychotics, QTc intervals were also collected.

RESULTS: Of 172 patients screened, 101 met inclusion criteria. The average age was 57.3 years. Thirty-seven patients had renal dysfunction (serum creatinine > 1.5 mg/dL) and 7 had hepatic dysfunction (AST and/or ALT > 2 times the upper limit of normal). Twenty-nine patients (45%) received an AA for a baseline psychiatric disorder, with the remainder receiving agents for agitation/anxiety (14%) or undocumented reasons (42%). Haloperidol (54%), risperidone (25%) and quietiapine (24%) were the most frequently prescribed antipsychotic medications. Risperidone was the most frequently prescribed AA at one site (47%), while quetiapine was most common at the other (50%). Of the 81 patients with baseline EKG's present, 48 patients (59%) had QTc intervals > 450 mseconds. Twenty-four patients (44%) with prolonged QTc intervals received haloperidol.

CONCLUSION: Atypical antipsychotics are used frequently for pre-existing psychiatric conditions. The choice of AA was most often based on continuation of home medication. Haloperidol was primarily used for ICU delirium.

404. Hemodynamic targets and vasopressor use in neurogenic shock. *Maryjoy R. Lepak, Pharm.D., Candidate*[1], April D. Miller, Pharm.D., BCPS[1], Kimberly B. Clark, Pharm.D., BCPS[2]; (1)South Carolina College of Pharmacy-USC Campus, Columbia, SC; (2)Greenville Hospital System University Medical Center, Greenville, SC

PURPOSE: Hemodynamic management in patients with acute spinal cord injury (SCI) and neurogenic shock can improve outcomes. The purpose of this study is to determine which specific vasopressors are more effective at maintaining blood pressure in SCI with neurogenic shock, and whether certain agents improve outcomes.

METHODS: This multicenter, retrospective, observational study included adult patients with cervical or thoracic SCI and neurogenic shock. Two vasopressors, dopamine and phenylephrine, were compared based on blood pressure maintenance within target ranges, dosage adjustments, duration of therapy, heart rate, and outcomes based on the American Spinal Injury Association (ASIA) scale.

RESULTS: Preliminary results include evaluation of 12 patients (5

phenylephrine, 4 dopamine, and 3 combination therapy). Mean dose of phenylephrine was 0.94 μg/kg/min (range 0.30–1.58). Mean dose of dopamine was 5 μg/kg/min (range 2–9). Average number of dose adjustments per hour was similar, with 0.35 per hour with phenylephrine and 0.36 per hour with dopamine. Average duration of therapy for phenylephrine was 47 hours versus 38 hours for dopamine. Average mean arterial pressure (MAP) for phenylephrine was 81 mmHg (range 61–102) versus 73 mmHg (range 59–96) for dopamine. There were a similar number of systolic blood pressure readings ≥90mmHg (86% of phenylephrine versus 84% of dopamine). There were 57 episodes of tachycardia (HR>100) in 5 patients who received phenylephrine relative to 14 episodes in 4 patients who received dopamine. There were no differences in outcome among 7 patients with recorded ASIA scores. Complete impairment (ASIA score A) was observed in 2 phenylephrine, 1 dopamine, and 2 combination therapy patients, while incomplete impairment (ASIA score B) was observed in 1 phenylephrine and 1 dopamine patient.
CONCLUSION: In this preliminary analysis, phenylephrine was associated with a longer duration of therapy and more tachycardia, but maintained higher MAP in patients with neurogenic shock. In this small study, ASIA outcomes appear similar between groups.

405. A retrospective cohort study on the use of dexmedetomidine in patients with traumatic brain injury. *Jacquelyn E. Bryant, Pharm.D., Candidate*[1], April D. Miller, Pharm.D., BCPS[1], Brianne L. Dunn, Pharm.D.[1], Christopher M. Watson, M.D.[2]; (1)South Carolina College of Pharmacy - USC, Columbia, SC; (2)Palmetto Health Richland, Columbia, SC
PURPOSE: Dexmedetomidine is known for its unique sedative properties in critically ill patients however, its effects in patients with traumatic brain injury (TBI) are not well studied. This study was designed to characterize the safety and efficacy of dexmedetomidine use in TBI patients.
METHODS: Retrospective review of medical records for patients who received dexmedetomidine at our institution between December 1, 2008 and December 31, 2010 was conducted. Patients included in the study were adults with non-penetrating TBI and no past medical history related to any neurologic illness or impairment. Richmond Agitation Sedation Scale (RASS) score, Glasgow Coma Scale (GCS) score, heart rate, mean arterial pressure (MAP), intracranial pressure (ICP), and dexmedetomidine dose were recorded.
RESULTS: For the 27 patients included in the study, mean age was 41 years, and 24 patients were male. The average dexmedetomidine dose administered was 0.65 μg/kg/hour. Median admission GCS score was 6 with 51.9% of patients classified as minor brain injury, 14.8% as moderate, and 33.3% as severe. RASS scores were generally within target range with 276 of the 402 (68.7%) scores assessed between -2 to +1. Fifteen patients experienced 110 total episodes of bradycardia (< 60 beats per minute), and 21 patients experienced 300 total episodes of tachycardia (> 110 beats per minute). Twelve patients had a total of 17 MAP readings < 60 mmHg. ICP was monitored in two patients, both of which were controlled (ICP<20 mmHg).
CONCLUSION: Overall, the use of dexmedetomidine in this study population proved to be safe and efficacious. Episodes of bradycardia occurred less often than previously observed. Based on the limited ICP data, dexmedetomidine did not appear to adversely affect ICP in this study population.

Education/Training

406. Evaluation of an interprofessional approach to teaching medication therapy management (MTM).
Jaclyn A. Kruse, B.S., M.S., Pharm.D., Candidate[1], *Zachary N. Jenkins, Pharm.D., Candidate*[2], Austin Fredrickson, M.D., Candidate[3], Timothy R. Ulbrich, Pharm.D.[3], Stacey R. Schneider, Pharm.D.[3]; (1)Northeast Ohio Medical University, Willowick, OH; (2)Northeast Ohio Medical University, Akron, OH; (3)Northeast Ohio Medical University, OH
PURPOSE: This study evaluated the impact of an interprofessional approach to teaching Medication Therapy Management (MTM) on 1) the student's understanding of MTM and its place in patient care; 2) the ability of students to participate in an MTM session; 3) the difference in awareness, knowledge, and opinion of MTM before and after the training session; and 4) the student's perception of collaborating with other healthcare professionals to provide MTM.
METHODS: Pharmacy and medical students at Northeast Ohio Medical University were invited to voluntarily participate in two interprofessional sessions to learn about MTM. Session one involved a pre-survey, educational seminar, and a practice MTM case. Session two consisted of a mock MTM session with volunteer patients, followed by a post-survey.
RESULTS: The pre-survey included 23 student responses; 7 medical and 16 pharmacy. Fourteen participants had previous exposure to MTM. Ten pharmacy students stated that MTM is a formal part of their curriculum. The post-survey included 10 student responses; 3 medical and 7 pharmacy. All students "agreed" or "strongly agreed" that optimal MTM takes place when collaboration between multiple healthcare providers occurs. Lastly, all students noted that they would recommend or participate in an MTM session in the future.
CONCLUSIONS: Overall, utilizing an interprofessional approach to teaching MTM was received positively. Students gained experience by collaborating in mock MTM sessions. Despite the small study population, this study supported integrating MTM into the didactic curriculum at an interprofessional institution and also provided evidence to support teaching students to work in an interprofessional team at an early stage of their careers.

407. Assessing older adults' knowledge of safe medication use and practices. *Samantha M. Boudreau, Pharm.D., Candidate, 2013*, Helen Pervanas, Pharm.D.; Massachusetts College of Pharmacy and Health Sciences - Worcester/Manchester, Worcester, MA
PURPOSE: This study aimed to 1) assess the knowledge of older adults regarding the safe use of medications, and 2) examine whether their knowledge of safe medication practices improved following a student pharmacist presentation.
METHODS: Study participants at three adult senior centers located in the Southern New Hampshire area attended an educational presentation on the safe use of medications given by a student pharmacist. The American Association of Retired Persons' (AARP) "Wise up on Meds" program was used as a teaching tool and was supplemented by the student pharmacist's presentation. Participants were asked to complete a pre and post-survey which included questions regarding proper medication disposal, medication information to share with doctors/pharmacists, and the importance of consulting a pharmacist before taking over-the-counter (OTC) medications. This research was approved by the Institutional Review Board.
RESULTS: A majority of participants were Caucasian (97%) and female (93%) between the ages of 71 and 80 (41%). Participants reported that they took 5 to 7 prescription medications daily (38%), and 2 to 4 OTC medications daily (53%). When asked about the proper way of disposing expired medications 57% of participants chose the correct method of disposal and 31% reported that they flushed medications down the toilet. Following the presentation, 81% of participants selected the appropriate disposal method. Prior to the presentation, 76% reported that they informed their doctor/pharmacist about all medications including vitamins and herbal supplements versus 88% after the presentation. Additionally, when questioned about the importance of consulting a pharmacist regarding OTC medication use, 89% and 96% agreed it was important before and after the presentation respectively.
CONCLUSION: The student pharmacist presentation improved participant knowledge in key areas including proper medication disposal, important information to share with pharmacists/physicians, and the importance of consulting a pharmacist regarding the use of OTC medications.

408. Assessment of student pharmacist learning from a multidisciplinary older adult home visit. *Teresa M. Breslin, Pharm.D. Candidate*[1], Alexander J. Kulik, III, Pharm.D. Candidate[1], Carol A. Bugalski Stutrud, B.S.[1], Cassandra J. Bowers, Ph.D.[2], Geralynn B. Smith, M.S.[1], Jennifer Mendez, Ph.D.[3], Nelia M. Afonso, M.D.[4], Cheryl C. Waites, Ed.D.[2], Mary Beth O'Connell, Pharm.D.[1]; (1)Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI; (2)Wayne State University, College of Social Work, Detroit, MI; (3)Wayne State University, School of

Medicine, Detroit, MI; (4)Oakland University William Beaumont School of Medicine, Rochester, MI
PURPOSE: To assess achievement of pharmacy experiential goals designed to enhance student learning related to aging, social constructs, patient assessment, physician roles, team care, and home visits from a multidisciplinary team experience with older adults in their homes.
METHODS: 83 pairs of a third-year student pharmacist and second-year medical student assessed an older adult in his/her home. Student pharmacists performed a comprehensive medication review, identified drug-related problems, and with a pharmacy preceptor created a recommendation letter and medication calendar, which were given to the older adult. Medical students assessed fall risk and activities of daily living. Student pharmacists completed a post-visit learning survey related to curricular goals. Survey questions were analyzed utilizing descriptive statistics (SPSS v19). Open-ended questions were analyzed using qualitative research techniques, resulting in learning themes.
RESULTS: Sixty-six percent of students reported increased understanding about social influences on medication use. Students thought (> 70% responses) team care was more comprehensive, could improve patient outcomes, and would be important to their professional success. Most students (96%) believed the home visit resulted in additional information that could improve health care delivery. Based on qualitative findings, students learned that older adults were more active, independent, and knowledgeable about their health than expected. They felt the medical students were empathetic toward the older adult and demonstrated positive personality traits, professionalism, and good interviewing skills. Students described multidisciplinary team care as important and provider roles complementary. The home visits were noted to provide an environment more comfortable for the older adult as they were quite amiable, communicative, and receptive to information provided by the team. Most students (86%) indicated the project was worthwhile and would recommend it to other students.
CONCLUSION: Multidisciplinary training with older adults in a home environment was a good learning opportunity for the students.

409. North Carolina pharmacists' practices and opinions of smoking cessation counseling. *Janna L. Currie, Pharm.D./MSCR Candidate*, Nathan J. Hudson, Pharm.D./MSCR, Candidate, Wesley D. Rich, Ph.D.; Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC
PURPOSE: Every year, there are over 5 million deaths in the world due to cigarettes. In 2009, according to the Centers for Disease Control and Prevention (CDC), one in every five Americans smokes cigarettes. Of the 46.6 million people who smoke in America, 32.6 million would prefer to quit but have not been able to quit smoking. Health care professionals, including pharmacists are in a position to help those individuals quit. In order to begin this process, barriers to counseling need to be identified, as well as current habits and pharmacists' opinions on smoking cessation in general.
METHODS: A survey was sent out to all registered North Carolina pharmacists regarding smoking cessation counseling practices and opinions on tobacco sales in pharmacies. Specifically, pharmacists were asked about comfort levels with smoking cessation, opinions on the role of the pharmacist in the process, and what barriers prevent them from discussing smoking habits with patients. Additionally demographic information was gathered regarding pharmacy setting and potential ethical considerations for selling tobacco products in pharmacies. Other questions revolved around the 5 A's of smoking cessation: ask, advise, assess, assist, and arrange.
RESULTS: Results are pending.
CONCLUSION: The results of this survey will provide information about the next step for pharmacists in the role of smoking cessation. Knowing what barriers are present and how pharmacists currently practice may justify the need for pharmacist-facilitated smoking cessation programs or other methods of helping patients quit smoking.

410. Experiential value of an older adult medication assessment early in the pharmacy curriculum. *Kimberly M. Rutkowski, Pharm.D. Student*, Kirsten M. Freitel, Pharm.D. Student, Tara C. Rosenthal, Pharm.D. Student, Geralynn B. Smith, M.S., Mary Beth O'Connell, Pharm.D.; Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI
PURPOSE: To evaluate the learning and appropriateness of an older adult medication review early in the curriculum.
METHODS: Older adults visited the college to meet first-year students who would soon provide their medication review with a pharmacist. The team performed the review at the older adult's independent living residence during spring/summer year one experiential courses (IPPE). The pharmacist gave each older adult a medication calendar and list of recommendations. Three months later, the students visited their older adult to learn about recommendation implementation. After each aspect, students wrote a reflection. Students completed an anonymous learning survey after the program (39% response). Descriptive statistics (SPSS v19) were used to summarize survey data and qualitative research techniques (Atlas.ti v6.2) were used to determine learning themes from the reflections.
RESULTS: Students (≥73%) felt comfortable speaking with older adults at the social event, were confident in their duties, and thought the follow-up visit was valuable. They felt the medication review was beneficial to the older adult (70%). This experience helped develop communications skills (60%), enhanced understanding of pharmacists' roles in medication management (70%), and expanded medication knowledge (57%). Students thought this project should be continued (57%) and recommended changes. In the reflections, students described learning about older adult lifestyles, health, and medication issues. Students were able to practice and improve skills gained throughout didactic and lab courses (e.g., self-confidence, older adult interviewing). They learned how to prepare a medication calendar. Many students felt the older adults also benefited from the interaction. Drug related problems were identified and resolved throughout the project that might not have been recognized otherwise. Reflection reviews from the social event and 3 month follow-up visit are pending.
CONCLUSION: Students learned about older adult lifestyles, medication issues and assessment adjustments. The experience will be continued in the curriculum with changes.

411. Building a curriculum to combat obesity in elementary schools. *Chelsea M. Harrison, Pharm.D. Candidate*, Elizabeth J. Bunk, Pharm.D. Candidate, Ashley D. Modany, Pharm.D. Candidate, Jennifer P. Elliott, Pharm.D., Nicole Marcotullio, Pharm.D.; Duquesne University Mylan School of Pharmacy, Pittsburgh, PA
PURPOSE: The prevalence of obesity has more than tripled in children and adolescents from 1980 to 2008, with 12.5 million overweight children in the United States. Children that remain obese as they enter their teenage years have a 70% greater risk of becoming an obese adult. Currently, there are no universally accepted practice guidelines for the prevention of childhood obesity. The goal of this project is to develop an education curriculum that can be utilized in elementary schools to prevent and reduce the rate of childhood obesity, and improve childhood awareness of healthy eating habits and behaviors.
METHODS: A literature search was performed through Medline and the Internet to analyze the currently available childhood obesity prevention programs. Forty programs were identified with ten programs, the updated United States Department of Agriculture (USDA) nutrition guidelines and the American Academy of Pediatrics Bright Futures Nutrition 3rd edition chosen for further review. Select activities from these resources were adapted to develop the comprehensive educational curriculum.
RESULTS: The program is divided into three main categories: nutrition, physical activity, and healthy behaviors. These were determined to be the three most important subjects identified from the chosen resources. Each lesson is designed to incorporate active-learning strategies into 30-minute sessions to effectively engage and educate elementary school children on childhood obesity prevention.
CONCLUSION: Based on the design of the educational model, our goal is that this program can be employed in any elementary school curriculum at minimal cost. It will be piloted in an inner city elementary school in Pittsburgh, PA in January 2012. The effectiveness of this educational intervention will be assessed through the use of a pre and post knowledge test.

412. Impact of community pharmacy experience in a family medicine residency. *Sarah E. Krahe Dombrowski, B.S.*[1], Roberta Farrah, Pharm.D., BCPS[2], Stephanie Harriman McGrath, Pharm.D.[3]; (1)Univeristy of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)UPMC St. Margaret Hospital, Pittsburgh, PA; (3)Rite Aid Pharmacy, Pittsburgh, PA

PURPOSE: Current literature confirms that patient outcomes improve when pharmacy education is included in family medicine residency programs, but there has been little research to examine the direct impact of this education on the residents. We plan to evaluate the value of a hands-on community pharmacy experience for family medicine residents with the intent to create a model from which interprofesional education can be developed, ultimately enhancing collaborative relationships among health care providers.

METHODS: Through surveys and semi-structured interviews, we will assess the family medicine residents' perception of the role of the pharmacist in MTM, OTC medications, and prescription dispensing before and after a practical hands-on experience in a community pharmacy. This data will undergo qualitative analysis to identify themes and trends in the responses.

RESULTS: We plan to report the impact of the pharmacy experience on the family medicine residents. We expect that the residents will display increased knowledge of OTC medication use and safety. Additionally, we anticipate that they expand their understanding of the benefit of medication therapy management for their patients and the role pharmacists can play in patient care. Finally, it is expected that this experience will increase residents' enthusiasm for working collaboratively with pharmacists.

CONCLUSIONS: We plan to use this data to share our methods for fostering interprofessionalism and demonstrate the value of pharmacist collaboration in a family medicine residency program. This collaborative education program between family medicine and community pharmacists is unique; studying and documenting the impact of this program will lead to the development of interprofessional education in other residency programs.

413. Impact of a student-implemented patient education campaign. *Alexa M. Sevin, Pharm.D. Candidate*, Marshall D. Stewart, Pharm.D. Candidate, Kyle Hampson, Pharm.D. Candidate, Pamela H. Koerner, B.S., Pharm.D., Jennifer P. Elliot, Pharm.D.; Duquesne University, Pittsburgh, PA

PURPOSE: This study was designed to encourage student pharmacists and pharmacists alike to increase the frequency of providing education to patients through the use of an "Education Before Medication" campaign. This study documented each patient interaction to learn more about patient perceptions of engaging in medication counseling as well as feasibility of implementation in various community practice settings.

METHODS: Student pharmacists on Advanced Pharmacy Practice Experience (APPE) rotations at community sites between February 7 and March 11, 2011 were given a standardized "Education Before Medication" toolkit that included basic counseling points on seven of the most commonly prescribed medications. Students implemented the "Education Before Medication" campaign through a variety of site specific methods. Each patient encounter was documented, which included the patient response, medication counseled, and the time spent counseling.

RESULTS: Students offered medication counseling to 314 patients taking one or more of the medications included in the campaign toolkit. Of these patients, 27.4% refused counseling resulting in 228 patients receiving medication counseling through this campaign. Of those patients who did accept counseling, 92 were described as attentively listening and another 50 patients asked additional questions of their student pharmacist.

CONCLUSIONS: Through the use of a standardized counseling format, student pharmacists and pharmacists are able to provide timely medication counseling in a variety of community practice settings. This campaign is a great resource for any community practice setting as it can be implemented in numerous ways to fit the needs of each pharmacy. This campaign is also beneficial for student pharmacists, as they have the opportunity to learn about the medications and practice patient interaction skills.

414. Becoming an author during your residency: pharmacy resident publication rates and trends (2005–2010). *Ashley H. Cribb, Pharm.D. Student*, Kalen B. Manasco, Pharm.D., BCPS, AE-C; University of Georgia College of Pharmacy, Augusta, GA

PURPOSE: With over 3600 pharmacists applying for PGY1 and PGY2 residencies in 2011, it is clear that post-graduate residency training is quickly becoming the new standard of pharmacy education. During the year(s) spent as a resident, pharmacists are often provided the opportunity to serve as an author for publication in a peer-reviewed journal. The first objective of this study is to review the success rate for pharmacy resident publication beyond the scope of the required residency research project. The second goal is to establish residency publication rates specifically in pharmacy journals.

METHODS: Data is currently being collected via two methods. Journal reviews of *Annals of Pharmacotherapy, American Journal of Health-Systems Pharmacists,* and *Pharmacotherapy*, among others, are being conducted to search for publications by PGY1 and PGY2 residents during their residency year(s). Specifically, all journal issues from 2005 and 2010 are being reviewed. An electronic questionnaire will also be sent to all Residency Program Directors listed in the online ASHP residency directory asking for each program's resident publications over the years 2005–2010. Program Directors will be asked to provide information regarding both resident research projects as well as any other articles published during the residency year(s). Data is being collected on type of publication (research, letter to the editor, case report, etc.), year of publication (PGY1 or PGY2), and order of authorship (first, second, third).

RESULTS: Data analysis is currently pending and will be completed by September 2011

CONCLUSION: Conclusions will be available after data collection is complete

415. Gender disparities in authorship of original research publications in pharmacy journals. *Sloan M. Regen, Pharm.D. Candidate*[1], Susannah E. Moroney, Pharm.D., M.S.[2], Katie J. Suda, Pharm.D., M.S.[1]; (1)University of Tennessee Health Science Center, College of Pharmacy, Memphis, TN; (2)Pfizer Global Medical, Madison, WI

PURPOSE: In 2006, an article published in the suggested that women physicians have narrowed the gender gap in serving as either the first or senior author in medical journals. Since the American Association of Colleges of Pharmacy statistics suggest that females enrolling in Pharm.D. programs has ranged from 50–60% greater than male enrollment from 2000-2009, we question if increasing number of women pharmacists are contributing to the published pharmacy literature in the form of original research articles and editorials.

METHODS: The sex of first and senior authors of all original research articles and editorials for the years 1995, 2000, 2005, and 2010 were evaluated for five pharmacy journals; , , , , and . χ^2 analyses were used to compare the frequency of male and female authors in 1995, 2000, 2005, and 2010. A p-value less than 0.05 was considered statistically significant.

RESULTS: There were 384 original research articles and editorials published in 1995 compared with 438 articles in 2000, 581 articles in 2005, and 578 articles in 2010. Forty-five percent of the first authors were female in 1995 compared with 44.5% in 2000, 46.8% in 2005, and 47.5% in 2010. In 1995, 32.5% of senior authors were female compared with 32.8% in 2000, 32.2% in 2005, and 34.1% in 2010. Additional analyses within journals did not reveal any significant increases of female first or senior authors within the 15-year time period (p=NS). In 1995, had the highest percentage of female first authors (54.5%) while had the highest (52.4%) in 2000.had highest percentage of female first authors in 2005 (57.9%) and 2010 (64.2%).

CONCLUSION: Although the percentage of female pharmacists has increased over the past several years, this has not translated to pharmacy-specific research literature.

416. Student College of Clinical Pharmacy provides community service for the Akron Area Agency on Aging. *Christina McKenzie, Pharm.D. Candidate*[1], Natalie Kolehmainen, Pharm.D. Candidate[1], David Shifrin, Pharm.D.,Candidate[1], Susan M. Fosnight, R.Ph., CGP, BCPS[2], Patrick J. Gallegos, Pharm.D., BCPS[1]; (1)Northeast Ohio Medical University (formerly known as NEOUCOM), Rootstown,

OH; (2)Summa Health System, Akron, OH
PURPOSE: Care managers have the opportunity to interview patients in their home about medications. This environment provides distinctive opportunities to discover what medications a patient actually takes versus what is prescribed. This information is valuable when making care decisions. Our purpose is to explain a unique community service program provided by the Northeast Ohio Medical University (NEOMED) Student College of Clinical Pharmacy (SCCP) organization to Akron Area Agency on Aging care managers to improve their medication history taking skills and to evaluate the care manager's response to these sessions.
METHODS: The NEOMED SCCP organization provided presentations to the Akron Area Agency on Aging regarding the pearls of medication history taking. A voluntary survey is currently in progress to assess various items including, but not limited to: pertinence, level of comfort, application of covered skills, and overall perception of educational sessions.
RESULTS: Verbal responses to the program have been positive. The survey results are pending. Completed results will be presented at the American College of Clinical Pharmacy Annual Meeting.
CONCLUSION: This community service project provided a unique opportunity for students to help educate local care managers increasing their skills in medication history taking.

Emergency Medicine

417. Insulin based glucose control audit for emergency department observation unit patients. *Joo Hyun Ha, B.S., M.S.*[1], Miles Hawley, M.D.[2], Mary Beth Shirk, B.S., Pharm.D.[1]; (1)The Ohio State University Medical Center, Columbus, OH; (2)The Ohio State University, Columbus, OH
PURPOSE: To compare the efficacy and safety of continuous intravenous insulin (CIVI) and subcutaneous insulin (SCI) prescribing practices in our Emergency Department's Observation Unit (OU).
METHODS: OU patients receiving insulin between March 1 and July 23, 2010 were identified using a pharmacy database query. Only first visits were included for patients with multiple visits. All patients receiving CIVI during the study period were included (n=9). Patients receiving SCI were selected by convenience sampling (n=22). The safety (blood glucose (BG) <65 mg/dL and BG decrease ≥100 mg/dL/hr) and efficacy of insulin therapies were evaluated. Comparisons were made using the unpaired *t* and Fisher's exact tests.
RESULTS: Thirty-one patients (43.5±14.7yrs) were included. Twenty one were managed as part of the OU hyperglycemia protocol. HgbA1C (3mos) was 10.96±2.75 (n=25), with no significant difference between CIVI and SCI patients. CIVI rates were adjusted using the hospital standard titration scale. Duration of CIVI was 5:31±2:55 hrs. Seven violations of the titration protocol occurred in 5 patients. Initial glucose was 535±173 and 393±135 mg/dL for the CIVI and SCI arms, respectively (p=0.021). The mean decrease in BG was 313 mg/dL for CIVI (n=9), and 124 mg/dL for SCI (n=22, *P*=0.005). Hypoglycemic events occurred in 33% (3/9) and 4.5% (1/22) of CIVI and SCI patients, respectively (p=0.06). No hypoglycemic events were associated with documented symptoms. Of the six CIVI patients with a BG <250 mg/dL, four did not receive a D5W infusion, per protocol requirements. BG decreased ≥100 mg/dL/hr in 66% (6/9) CIVI patients. OU LOS was 23:17±8:00 hrs (CIVI), and 16:17±8.26 hrs (SCI) (*P*=0.04). One SCI patient was admitted for tight control during pregnancy.
CONCLUSION: Nonsignificant safety and significant LOS differences favoring SCI were identified in this retrospective nonrandomized trial, despite a significantly greater decrease in BG with CIVI. These findings warrant further consideration as to whether CIVI therapy can be used safely and effectively in the OU setting.

Endocrinology

418. Glucose control in cardiac surgery patients following IV insulin discontinuation. *Elyse R. Weitzman, B.S.*, Amy C. Donihi, Pharm.D.; University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Studies have demonstrated that good glycemic control using IV insulin for 3 days after cardiac surgery is associated with reduced morbidity and mortality. Our goal was to examine how effectively patients are transitioned off of IV insulin at our institution.
METHODS: We conducted a retrospective review of patients that underwent open-heart surgery at the University of Pittsburgh Medical Center between January and May 2011. Patients that died or were discharged within 72 hours post-surgery were excluded. Demographics, lab values including glucoses, and LOS were collected from electronic medical records. Incidence of hypoglycemia, hyperglycemia, and goal-range glucose values for the first 72 hours following IV insulin discontinuation were compared between patients with and without a known diagnosis of diabetes.
RESULTS: To date, 85 patients have been reviewed, 21 with diabetes and 64 without. There were no differences in age (63 vs. 60 years), BMI (30 vs. 27 kg/m^2), SCr (1.4 vs. 1.3 mg/dL), and Hct (28 vs. 28%) between patients with and without diabetes. Patients with diabetes had higher A1C (6.9 vs. 5.7%, p<0.001) and higher pre-surgery BG (130 vs. 111 mg/dL, p=0.002). There was no difference in LOS (24 vs. 17 days). During the first 72 hours following IV insulin discontinuation, patients with diabetes had more glucose values>300mg/dL (3.6 vs. 0.2%, p<0.001) and between 181-300mg/dL (34 vs. 10%, p<0.001). Patients without diabetes had more glucose values between 70-180mg/dL (62 vs. 90%, p<0.001). Neither group had a BG<40mg/dL; one patient with diabetes had a single hypoglycemic episode (BG= 56 mg/dL).
CONCLUSION: Glucose values in cardiac surgery patients following IV insulin discontinuation are generally well-controlled, with practically no incidence of hypoglycemia at our institution. Patients with known diabetes had higher incidence of hyperglycemia, and future efforts will focus on achieving better glycemic control in this population.

419. The effects of adding liraglutide to an urban type 2 diabetic population. *Milan Sharma, Pharm.D. Candidate*[1], Patrick Healy, RD, CDE, M.P.H.[2], Mark Drews, M.D.[2], Michelle Jacobs, Pharm.D., CDE[1]; (1)Northeastern University Bouve College of Health Sciences, School of Pharmacy, Boston, MA; (2)Whittier Street Health Center, Roxbury, MA
The effects of adding liraglutide to an urban type 2 diabetic population
PURPOSE: Glucagon-like peptide-1 receptor agonists are predominantly used as an adjunctive treatment for patients with uncontrolled type-2 diabetes and have been shown to accommodate weight loss in this population. This prospective observational study documented changes with the addition of liraglutide within a cohort of predominately African American patients enrolled in a diabetes education group in an ambulatory clinic in Roxbury, MA.
METHODS: Thirteen patients were enrolled in an educational diabetes group where liraglutide was added to their diabetes regimen between January and April 2011. Data collected and evaluated included A1c, weight, changes in the diabetes medication regimen, and occurrence of adverse effects. Liraglutide therapy was initiated at 0.6 mg/day and titrated up to 1.8 mg/day with a single daily SQ injection. Data was collected at 2-week intervals during the patientsÕ diabetes education group meetings.
RESULTS: Baseline characteristics included an average A1c of 8.5%, average weight of 241 pounds, 67% female, 85% African American, and the average number of medications prescribed for glycemia of 1.67. The patients attended an average of 7.6 visits (range 2-14) during the study period. At the end of the study period, the average A1c was 7.5%, average weight of 236 pounds (a 5 pound loss), and the end number of medications prescribed for glycemia of 1.58. Liraglutide was generally well tolerated with adverse effects noted in 2 of the 13 participants (diarrhea and nausea). Complete weight change information over the study period and descriptive changes to the diabetes medication regimen will be presented.
CONCLUSIONS: Adding liraglutide to a type 2 diabetic regimen in an urban population resulted in A1c improvement, small average weight loss, and reduction of medication for glycemic control with a tolerable side effect profile.

Family Medicine

420. Evaluation of statin therapy in patients over 40 years old with diabetes mellitus in a family medicine residency setting. *Samantha M. Allen, Pharm.D. Candidate, 2012*[1], Roberta Farrah, Pharm.D., BCPS[2], Sandra C. Sauereisen, M.D.[3]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)UPMC St. Margaret Hospital, PA; (3)UPMC St. Margaret's, Pittsburgh, PA

PURPOSE: To compare current prescribing practices with an ADA practice guideline recommending all diabetic patients over 40 years of age be prescribed statin therapy regardless of lipid levels if an additional cardiovascular risk factor is present and to assess educational opportunities for the family medicine residency program.

METHODS: Retrospective chart review was conducted on 68 diabetic patients >40 years old and not prescribed a statin between April and June of 2011. Patient follow-up, medical history, prescription medication history, last lipid panel, additional cardiovascular risk factors (smoking, hypertension, low LDL, early family history CVD), statin contraindications, and other documented reasons for not receiving a statin were noted. Patients were considered lost to follow-up if they had not been seen at the family health center in > 6 months or did not obtain a requested lipid panel.

RESULTS: Of 68 patients reviewed, 30 patients were lost to follow-up (44%), 14 patients had an LDL less than or within 10 points of goal <100 mg/dL (21%), 9 patients did not meet the ADA criteria for statin therapy (13%), 5 patients refused therapy (7%), 3 patients had a contraindication (4%), 3 patients were prescribed a diet/exercise regimen (4%), and 5 patients did not have a reason documented (7%).

CONCLUSION: The current diabetes practice guidelines recommend that diabetic patients ≥40 years old with additional cardiovascular risk factors receive a statin regardless of baseline lipid levels. Among patients retained for follow-up, physicians are predominantly reluctant to add an additional medication to a patient's regimen if the patient is close to or at LDL goal, suggesting an opportunity for physician education on current ADA practice guidelines.

421. Evaluation of CHF Patients Not Prescribed an ACE/ARB in a Family Medicine Residency Setting. *Anne M. Butera, B.S., Pharm.D. Candidate*[1], Roberta M. Farrah, Pharm.D.[2]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)UPMC St. Margaret Lawrenceville Family Medical Center, Pittsburgh, PA

PURPOSE: Determine causes why qualifying patients with congestive heart failure (CHF) had no prescribed angiotensin converting enzyme (ACE) or angiotensin receptor blocker (ARB) regimen. Identify strategies to improve this quality measure

METHODS: The January to March 2011 Quality Improvement (QI) report identified 56 patients with a CHF diagnosis and no prescribed ACE/ARB regimen. Retrospective chart review confirmed CHF diagnosis and analyzed current and prior medical history, medication records, allergies and laboratory test results. Patient records were sorted based on the reason stated for not prescribing an ACE/ARB regimen.

RESULTS: Most patients the report listed did not meet the QI initiative criteria. Of 56 CHF patients meeting the criteria, 44 received ACE/ARB medication and one did not have CHF. Eleven of the 56 patients had an accurate CHF diagnosis but no prescribed ACE/ARB medication. Records for three of the 11 patients contained clear documentation explaining why an ACE/ARB regimen was not advised, e.g., hyperkalemia or renal stenosis. For three patients, records suggested concern about renal function; however, information reviewed suggested a possible retrial since serum creatinine returned to baseline. ACE was discontinued for two patients due to cough; however, an ARB was not tried. ACE was discontinued for two patients with no clear reason stated. For one patient there was no documentation regarding any ACE/ARB medication.

CONCLUSION: Record review for CHF patients not prescribed an ACE/ARB regimen produced the following conclusions: For CHF patients, the study indicates need for educational intervention that supports the medical practice standards for care. Quality improvement initiated education should mandate: Continual monitoring for elevated potassium or serum creatinine to assess possible reinitiating of an ACE/ARB regimen Patient records must state clearly why an ACE/ARB regimen is not prescribed for a CHF patient

Geriatrics

422. Impact of a pharmacist as a member of an interprofessional team to identify and reduce medication related problems during transitions of care from skilled nursing facilities (SNFs) to home. *Karen Soong, Pharm.D. Candidate*[1], Daniel A. Zlokas, Pharm.D. Candidate[1], Shachi Tyagi, M.D.[2], Denise Z. Hodes, M.S.W.[2], Amelia Gennari, M.D.[2], Christine M. Ruby, Pharm.D., BCPS, FASCP[1]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)UPMC Shadyside Hospital, Pittsburgh, PA

PURPOSE: Transitions of care may involve multiple medication changes that lead to uncertainty about medication regimens and potential errors. This project addressed medication related problems identified during telephone calls to patients discharged from three SNFs.

METHODS: An interprofessional team, centered in an outpatient geriatric clinic, composed of a pharmacist, social worker, and physician collaborated with three SNFs to develop a protocol to improve continuity of care for returning clinic patients. Information from the recent hospitalization and SNF stay included: discharge medication lists/summaries and medication administration records. Within 3 business days of discharge, a pharmacist and pharmacy student contacted patients or family representatives via telephone to identify drug therapy problems, perform medication reconciliation, and update the electronic medical record (EMR). Referrals were made to the social worker if necessary. Therapeutic recommendations were documented in the EMR and communicated to the interprofessional team.

RESULTS: The pharmacy team contacted 10 patients, of which 8 had > 10 medications. All 10 patients (100%) were found to have medication related problems, with the most frequent problems being unnecessary drug therapy (50%) and adherence issues (50%). The pharmacist identified 26 medication-related problems (mean 2.6 per patient), made 17 recommendations and provided 22 counseling points. Common co-morbidities included: hypertension (70%), osteoporosis (50%), and pain (30%). Only 1 patient required hospitalization within 30 days after the encounter which was due to an infectious process unrelated to the previous admission.

CONCLUSIONS: Pharmacists have a crucial role as part of an interprofessional team to identify and reduce the number of medication related problems in geriatric patients during transitions of care.

423. Classifications of Drug Related Problems Discovered During Senior Brown Bag Medication Reviews. *Ashley M. Tocco, Pharm.D., IV, Student*[1], Feng Chang, Pharm.D.[2], Megan E. Kleinow, Pharm.D.[3], Jamie M. Hwang, Pharm.D.[4], Candice L. Garwood, Pharm.D.[1], Hanan S. Khreizat, Pharm.D.[3], Mary Beth O'Connell, Pharm.D.[1]; (1)Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI; (2)University of Waterloo, School of Pharmacy, Waterloo, ON, Canada; (3)Henry Ford Health System, Detroit, MI; (4)Henry Ford Piersen Clinic, Grosse Pointe Farms, MI

PURPOSE: To quantify and classify drug related problems (DRPs) discovered during brown bag medication reviews and determine recommendation acceptance.

METHODS: Medication reviews were conducted in senior centers and high-rises (N=9). A medication calendar and DRP recommendations were given to each senior. After 3 months, a survey was sent to seniors to capture implementation of recommendations (38 returns, 81% DRPs). After two training sessions, two pharmacists (10 coding pairs) classified each DRP using a modified PCNE Classification Scheme for Drug-Related Problems (V6.2;), Severity of Error in Medication Order (AJHP 99;56:2449), and Value of Service (AJHP 99;56:2449-50) scales. Disagreements were resolved by two additional investigators. Descriptive statistics were utilized for quantification and Kappa coefficients calculated to determine interrater reliability (classification agreements) per PCNE domains, severity and value scales, and by pairs (data not included); SPSS v19.

RESULTS: The seniors were 76.6 ± 8.5 years old. They had 3.7 ± 2.4 DRPs per patient (range 0 – 10). Problems were related to adverse reactions (30%), treatment effectiveness (28%), other (21%), treatment costs (13%), and information (8%). DRP causes were due to

drug selection (40%), dose (23%), patient issues (16%), drug use process (12%), other (7.4%), drug formulation (0.5%), and treatment duration (0.5%). Interventions required drug changes (44%), prescriber input (37%), patient counseling (18%), or other (1%). Seniors implemented 54% of the recommendations. Most DRP severities were classified as significant (59%) or minor (35%). Most recommendation values were classified as significant (50%) or somewhat significant (46%). Kappa coefficients were PCNE problem (0.573), PCNE cause (0.39), PCNE intervention (0.728), severity (0.231), and value (0.176).
CONCLUSION: Senior medication reviews identified important DRPs with about half of the recommendations implemented. Interrater reliability with the scales was quite variable, which might be corrected with more training and enhanced explanation of individual scale subdomains, especially for severity and value.

424. Evaluation of patient education on preventive health measures and poison control center awareness during senior brown bag medication reviews. *Nishi S. Gupta, Hons.B.S.*[1], Feng Chang, Pharm.D.[1], Megan E. Kleinow, Pharm.D.[2], Jamie M. Hwang, Pharm.D.[3], Candice L. Garwood, Pharm.D.[4], Hanan S. Khreizat, Pharm.D.[2], Mary Beth O'Connell, Pharm.D.[4]; (1)University of Waterloo, School of Pharmacy, Waterloo, ON, Canada; (2)Henry Ford Health System, Detroit, MI; (3)Henry Ford Piersen Clinic, Grosse Pointe Farms, MI; (4)Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI
PURPOSE: To evaluate patient education on preventive health measures and poison control center awareness achieved through brown bag medication reviews for seniors.
METHODS: Brown bag medication reviews were conducted in senior centers and high rises (N = 9). A medication calendar and list of recommendations were provided. Seniors were also educated on preventive health measures including vaccinations, calcium, vitamin D, and multivitamin supplementation. Seniors were informed about utilizing poison control center for unintended medication ingestion and provided with magnets or stickers with the center's contact number. A follow-up survey was sent 3 months after. Unreturned surveys were followed up by telephone.
RESULTS: 64 follow-up surveys were completed. Of the seniors who were previously not following preventive measures: 39.3% were willing to get the flu vaccine based on the pharmacists' recommendations; 75.6% considered getting or already got the pneumonia vaccine; 71.2% increased or wanted to increase their daily calcium intake; 67.3% were taking or considering taking vitamin D daily; and 68.8% started taking a multivitamin or were considering taking them. An appreciable 75.4% of the seniors had already discussed or were considering discussing the pharmacists' recommendations with their physicians. Prior to the brown bag medication review, 17% of the seniors did not know how to act in case of accidental medication ingestion compared to 0% in the follow-up survey. Only 14.2% of the seniors would have called a poison control center compared to 37.9% in the follow-up survey. Seniors also rated the session as being highly educational and found the poison control center stickers or magnets to be very helpful.
CONCLUSION: Brown bag medication reviews can be an effective setting to help seniors implement preventive health measures. By incorporating poison control center education into the review, seniors became more aware and more prepared to handle accidental medication ingestion.

425. Patient satisfaction and self-perceived knowledge gained during senior brown bag medication reviews. *Nishi S. Gupta, Hons.B.S.*[1], Feng Chang, Pharm.D.[1], Megan E. Kleinow, Pharm.D.[2], Jamie M. Hwang, Pharm.D.[3], Candice L. Garwood, Pharm.D.[4], Hanan S. Khreizat, Pharm.D.[2], Mary Beth O'Connell, Pharm.D.[4]; (1)University of Waterloo, School of Pharmacy, Waterloo, ON, Canada; (2)Henry Ford Health System, Detroit, MI; (3)Henry Ford Piersen Clinic, Grosse Pointe Farms, MI; (4)Wayne State University, Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI
PURPOSE: To examine patient satisfaction and self-perceived knowledge gained during brown bag medication reviews for seniors.
METHODS: Brown bag medication reviews were conducted in senior centers and high rises (N = 9) for seniors over the age of 60 and on 5 or more medications. Each appointment was scheduled for 45 – 60 minutes. A medication calendar and a list of recommendations were given. Seniors were asked to complete a 13-items satisfaction questionnaire following the session and rate the program's helpfulness again in a follow-up survey at 3 months. Each item on the satisfaction questionnaire was ranked 1–5 (strongly disagree–strongly agree). Self-perceived learning was reported using an 8-items survey. Each item was ranked 1–5 (very little–lots). Unreturned surveys were followed-up over the phone.
RESULTS: 64 seniors completed the satisfaction questionnaire. Overall, the seniors were highly satisfied with the program. All items on the survey were ranked between 4.44–4.90. The highest ranked items were: having enough time to ask questions (4.90); time and place of the review were convenient (4.83); trust in the pharmacist's answers (4.83); and better understanding of their medications (4.83). The lowest ranked item was perceived resolution of their health problem (4.44). At 3 months follow-up, 98% still ranked the brown bag medication review as helpful. Self-perceived knowledge gained was rated between 4.40–4.71. The highest ranked items were learning how to use their medications (4.71); when to correctly take the medications (4.66); and learning the purpose of their medications (4.64). Perceived knowledge gained in understanding medication side effects was rated the lowest (4.40).
CONCLUSION: Seniors were highly satisfied with the brown bag medication reviews. They felt a high degree of learning and found the program helpful. Individual items ranked demonstrated unique advantages and limitations of such programs.

Health Services Research

426. Evaluation of smoking rates and nicotine dependence within Sullivan University System. *Carrie M. Armstrong, M.B.A., Pharm.D. Candidate*[1], James D. Nash, Pharm.D., M.P.H., BCPS, CGP[1], Carolyn W. Chou, Pharm.D.[2], Megan E. Rose, Pharm.D.[1]; (1)Sullivan University College of Pharmacy, Louisville, KY; (2)Pfizer, Inc., Louisville, KY
PURPOSE: To assess and evaluate the prevalence and economic impact of smoking, the degree of nicotine dependence and determine the readiness to quit smoking among faculty and students within the Sullivan University System (SUS). SUS has campus locations in Lexington and Louisville, Kentucky.
METHODS: The population of SUS consists of all faculty, staff and students within all educational programs, ranging in age from 18 years or older (n = 5,980). All were asked to voluntarily participate in an anonymous online survey through Survey Monkey. The survey, developed by Pfizer, used the Fagerstrom test for nicotine dependence and a readiness to quit tool, created by Pro-Change Behavior Systems, Inc., to determine the prevalence of nicotine dependence. The participant's responses were measured on a 10 point scale where the larger values represent higher nicotine dependence. The readiness to quit assessment determined whether the participant was genuinely ready to quit smoking.
RESULTS: Currently undergoing analysis.
CONCLUSION: In Kentucky, the smoking rate is 27.6%. Conservatively, healthcare costs from smoking are estimated at $3,400 per person annually. Upon applying this to SUS, there are potentially 1,650 employees and students who currently smoke. If sixteen smokers (1%) quit, there is a projected annual cost savings of $56,100. This study will contribute to the development of a smoking cessation program made available to faculty and students through the InterNational Center for Advanced Pharmacy Services (INCAPS) within the SUS. This will allow patients to meet with a clinician for an individualized treatment plan that meets their needs.

Hematology/Anticoagulation

427. Identification of reasons for discontinuation of dabigatran in an outpatient cardiology office. *Ruth Seiffert, Pharm.D. Candidate*[1], Bethany E. Helms, Pharm.D.[1], Linda Snyder, M.S.N., CRNP[1], David S. Schwartzman, M.D.[2], Deanne L. Hall, Pharm.D.[3]; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh, Pittsburgh, PA; (3)University of Pittsburgh School of

Pharmacy/University of Pittsburgh Medical Center, Pittsburgh, PA
PURPOSE: To identify reasons for discontinuation of dabigatran in patients newly prescribed dabigatran or transitioned from warfarin and determine if discontinuation was due to an adverse event.
METHODS: Retrospective review of electronic medical records to identify patients with non-valvular atrial fibrillation who were prescribed dabigatran between November 1, 2010 and June 30, 2011 within the University of Pittsburgh Medical Center Cardiovascular Institute's University Center office. Progress notes, telephone communications and medication lists were reviewed to collect the start and stop date of dabigatran, and when stopped the reason for discontinuation of dabigatran. Where a specific reason was not noted, the patient's physician or nurse practitioner provided clarification.
RESULTS: Preliminary data revealed 90 patients were prescribed dabigatran during the identified time frame. Twenty-nine (32%) of patients discontinued dabigatran. Of these 29 patients, 8 discontinued dabigatran due to gastrointestinal side effects (27%). An adverse event was the reason for discontinuation in 14% of these patients (3 gastrointestinal bleed, 1 possible transient ischemic attack). Other reasons for discontinuation include cost (10%) and drug interactions (10%). One patient stopped dabigatran due to chest pain, and 2 patients no longer required anticoagulation. The reason for discontinuation in 8 patients has yet to be determined.
CONCLUSION: One-third of patients prescribed dabigatran discontinued use, with the most common reason for gastrointestinal side effects. Both bleeding and thrombotic adverse events were found. Data collection and analysis is ongoing. The findings of this evaluation may provide background for the office to conduct further analysis of the data to identify risk factors for patients that may be of high risk for adverse events with dabigatran.

Herbal/Complementary Medicine

428. Ethnopharmacology comparison Nicaragua and Peru. *Anna Bondar*; University of Pittsburgh, Pittsburgh, PA
PURPOSE: It is known that Latin Americans in the U.S. often utilize home remedies for many common ailments; however, there is a lack of research in the relationship between health care access and the prevalence of natural remedies. The purpose of this comparative study in Trujillo, Perú and León, Nicaragua was to determine the relationship between the health care system and patients' decisions to seek alternative forms of medicine in two societies, distinct in both geography and economic level.
METHODS: This exploratory research project was conducted in Nicaragua in the summer of 2010 and in Perú in May 2011. The author conducted structured interviews of both health care professionals and patients in various settings: hospitals, outpatient clinics, pharmacies, and natural medicine vendors. Qualitative research methods were utilized, and the qualitative portion will be analyzed prior to the ACCP Annual Meeting. The University of Pittsburgh's IRB approved this project.
RESULTS: A total of 29 interviews were conducted (15 in Nicaragua and 14 in Peru). Trujillo, Perú offers more public and private health services for its residents than León, Nicaragua. Sixty percent of the Nicaraguan sample size and eighty-five percent of the Peruvian sample size cited use of natural medicine. A language barrier exists more often in Perú than in Nicaragua, because of indigenous languages, so health professionals cite this is a reason for a significant portion of the use of natural remedies in Perú.
CONCLUSION: Although there is better access to western medical services in Trujillo, Perú, there is simultaneously more widespread use of natural medicine. Therefore, decreased access to medical services does not directly correlate with the use of alternative medicine. U.S. health care professionals must consider several factors, including access to healthcare, when discussing the use of western and natural medicine with Latino patients.

HIV/AIDS

429. An apparent drug interaction between warfarin and the antiretroviral TRIO regimen. *Amulya Vanguri, Pharm.D. Candidate*, Michelle D. Liedtke, Pharm.D., BCPS, R. Chris Rathbun, Pharm.D., BCPS; University of Oklahoma College of Pharmacy, Oklahoma City, OK
PURPOSE: Drug-drug interactions between warfarin and antiretrovirals have been reported in the literature, but limited information exists on the interaction potential with newer antiretroviral agents. The antiretroviral TRIO regimen consists of darunavir, ritonavir, raltegravir, and etravirine and has been demonstrated to be highly effective for HIV-infected patients with extensive drug resistance. We investigated whether weekly warfarin dose requirements were changed following the initiation of the TRIO regimen in an HIV-infected man.
METHODS: International normalized ratio (INR) results and weekly warfarin dose for a 51-year old man with AIDS and recurrent deep-vein thrombosis (DVT) were reviewed from April 2008-May 2011. Electronic medical records and hard-copy charts were reviewed and concomitant medications recorded. Weekly warfarin dose and INR results were compared using an unpaired t-test with an alpha of 0.05 to define significance.
RESULTS: A total of 39 and 43 INR values were available before and after TRIO regimen initiation, respectively. The patient's target INR goal range was 2.0–3.0. The mean weekly warfarin dose (n = 90 weeks) on emtricitabine monotherapy was 13.3 mg (95% CI: 12.7, 13.8). Following initiation of the TRIO regimen in January 2010, the mean weekly warfarin dose (n = 71 weeks) increased to 19.3 mg (95% CI: 18.5, 20.1; $p<0.001$). The patient's plasma HIV RNA level became undetectable within 12 weeks and remained suppressed throughout the remaining evaluation period, suggesting adherence with antiretroviral therapy. Target INR values were achieved upon titration to the higher weekly warfarin dose; mean INR values before and after TRIO regimen initiation were consistent (2.8 vs. 2.7, respectively; p=NS). Concomitant medications during the two periods were similar.
CONCLUSION: Interactions between warfarin and antiretrovirals are likely and vary depending on the specific agents. An increased weekly warfarin dose requirement is predicted when warfarin is used concurrently with the antiretroviral TRIO regimen.

Infectious Diseases

430. Do differences between quantitative viral plaque assays explain variability among pre-clinical respiratory syncytial virus studies in animals?
Indrani Kar, Pharm.D. Candidate, 2013, Jacob G. Orend, B.S., Kerry M. Empey, Pharm.D., Ph.D.; University of Pittsburgh School of Pharmacy, Pittsburgh, PA
PURPOSE: Respiratory syncytial virus (RSV) infects nearly all children by the age of two. To study RSV pathogenesis, RSV is quantified for use in rodent models. Plaque assays are the gold standard for RSV quantification, yet assay differences may contribute to variability in RSV inoculum quantification. We hypothesize RSV titers will vary significantly between two commonly used plaque assays, secondary to differences in permissiveness and viral growth among the two cell types used for each assay. Quantifying these differences will improve consistency among animal models and reduce variability in data among labs.
METHODS: The Hematoxylin and Eosin (H&E) and Antibody plaque assays were optimized, compared, and their linear range of quantification established using Hep-2 and Vero cells, respectively. Plaque morphology and cytopathic effect were evaluated for each cell type.
RESULTS: An acceptable variation in RSV titers from individual plaque forming units (pfu) per well is 0.5 log or a coefficient of variance less than 35% as calculated from linearity curves for both cell lines. The limit of quantification for RSV line 19 was 7 plaques per well in H&E and 15 plaques per well for antibody assay. The limit of quantification for RSV A2 was 8 plaques per well for both assays. The two plaque assays did not result in significantly different RSV titers.
CONCLUSIONS: RSV quantification variability may not result from plaque assay differences, as hypothesized. Our results suggest that counting too few plaques, which may be assay-dependent, and lack of assay optimization may introduce error among assays. Therefore, variability among animal studies may result from quantifying titers without considering these factors. Using limits of quantification and optimization (regardless of assay type) before inoculating mice to quantify precise RSV titers can minimize variability in animal models

and increase confidence in future testing of RSV therapeutics and vaccines.

431. Adverse drug events secondary to sulfamethoxazole/trimethoprim in HIV–infected hospitalized patients. *Caitlin L. Shamroe, Pharm.D. Candidate*[1], P. Brandon Bookstaver, Pharm.D., BCPS (AQ-ID), AAHIVE[1], Celeste N. Rudisill, Pharm.D.[1], Robert R. Moran, Ph.D.[2]; (1)South Carolina College of Pharmacy- USC Campus, Columbia, SC; (2)Health Sciences Research Core - University of South Carolina, Columbia, SC

PURPOSE: In the hospital setting, sulfamethoxazole-trimethoprim (SMX/TMP) is commonly used in management of *Pneumocystis jiroveci* pneumonia (PCP) in HIV-infected patients. Hyperkalemia and increased serum creatinine (SCr) are known adverse events (AE) associated with SMX/TMP therapy. The study goals are to determine the incidence of hyperkalemia and elevated SCr in HIV-infected patients receiving SMX/TMP and assess a dose-dependent relationship.

METHODS: Institutional Review Board approval was granted prior to initiation of this retrospective analysis. HIV-infected hospitalized patients receiving a minimum of 3 consecutive days of SMX/TMP were eligible for study inclusion. The primary endpoints of incidence of hyperkalemia and elevated SCr were defined as potassium greater than 5.0 mEq/L (or 6.0 mEq/L for severe hyperkalemia), and an increase of 0.5 mg/dL or a 50% increase above pre-treatment baseline, respectively. For secondary evaluation, the population was divided into two groups: "high-dose" SMX/TMP (> 10 mg/kg/day) and "low-dose" SMX/TMP (<10 mg/kg/day). χ^2 analysis was used for test of difference in nominal data.

RESULTS: Ninety patients met study inclusion criteria with an average age of 42 years. Of these, 93.3% had an indication for PCP treatment or prophylaxis. The incidence of elevated SCr, hyperkalemia and severe hyperkalemia was 25.5 %, 35.5 % and 7.7%, respectively with an average time to event of 8.7 days, 8 days and 11.9 days. In the high-dose group (n = 40) the incidence of elevated SCr was 22.5% compared to 28% in the low-dose group (p=NS). The occurrence of hyperkalemia was 50% (10% severe) in the high-dose group versus 24% (8% severe) in the low-dose group ($p<0.05$).

CONCLUSION: Results suggest a significant rate of elevated SCr and hyperkalemia in hospitalized HIV-infected patients receiving SMX/TMP. Prudent monitoring of renal function and potassium is important for HIV-infected patients receiving SMX/TMP, especially in combination with other host risk factors or agents with similar AE profiles.

432. Management of *Stenotrophomonas maltophilia* in pediatric patients: a retrospective evaluation. *Ashley E. Jones, Pharm.D., Candidate*, Kalen B. Porter, Pharm.D., BCPS, AE-C; University of Georgia College of Pharmacy, Augusta, GA

PURPOSE: *Stenotrophomonas maltophilia* is an opportunistic organism that is commonly associated with respiratory tract colonization but can become clinically significant in certain patient populations (cystic fibrosis, immunocompromised, catheterized, and mechanically ventilated). The organism is known to be highly resistant to many antimicrobials. The aim of this study was to evaluate clinical outcomes for antimicrobial treatment versus no treatment in pediatric patients with positive cultures for *Stenotrophomonas maltophilia*.

METHODS: Electronic medical records from an academic medical center were retrospectively reviewed to identify pediatric patients with a documented isolate for *Stenotrophomonas maltophilia* from January 2009 – June 2011. Clinical outcomes were evaluated to assess the impact of antimicrobial treatment versus no treatment; a positive outcome was defined as improvement or maintenance of clinical status and a negative outcome was defined as worsening of clinical status. Susceptibility data for trimethoprim-sulfamethoxazole, ceftazidime, ticarcillin-clavulanate, and chloramphenical were also obtained.

RESULTS: Results are pending, but will be completed by August 2011.

CONCLUSION: Conclusion is pending.

433. Vancomycin in combination with Naficillin demonstrates synergy against heteroresistant vancomycin-intermediate *Staphylococcus aureus* (hVISA). *Amy Suen, B.S.*, Samira M Garonzik, Pharm.D., Brian T. Tsuji, Pharm.D.; Laboratory for Antimicrobial Pharmacodynamics University at Buffalo, State University of New York, Buffalo, NY

PURPOSE: Combination agents with different mechanisms of action are a therapeutic option to overcome decreased susceptibility to glycopeptides in hVISA infections. Vancomycin and β-lactams have shown prelimary reports of synergy at sub-inhibitory concentrations. Our objective was to investigate the pharmacodynamics of vancomycin combined with naficillin to determine if synergy is present at clinically relevant concentrations.

METHODS: The killing effects of vancomycin and naficillin against hVISA PFGE type USA300 at 10^6 CFU/mL were observed in 48 hr time kill experiments. Time kill experiments were performed for vancomycin at varying concentrations (0, 0.5, 1, 2, 4, 8, 16, 32, 64, 128 mg/L) to characterize vancomycin pharmacodynamics. Time points were taken at 0, 1, 2, 4, 8, 24, 28, 32, and 48 hr. Time kills at varying concentrations of naficillin alone (0, 1, 16, 64 mg/L) and in combination with vancomycin were performed at the same time points. Changes in $\log_{10}$ CFU/mL at 48h vs. log ratio area were fit to a Hill-type mathematical model.

RESULTS: Vancomycin monotherapy against 10^6 CFU/mL at concentrations of 8mg/L to 128 mg/L showed a log decrease of 3.8 to 5.8 CFU/mL by 48 hours. At lower concentrations of vancomycin from 0 mg/L to 4 mg/L, a log increase of 2.9 CFU/mL was observed at 48 hr. Therapy with 32 mg/L vancomycin combined with 1, 16, or 64mg/L of naficillin and 128 mg/L vancomycin combined with 1, 16, or 64 mg/L showed bacterial killing effects to below detectable limit of 10^2 CFU/mL with a maximal log decrease of 4.8 CFU/mL at 24 h. The pharmacodynamics of vancomycin was E_{max}: 8.4, EC_{50}: 7.6, and H: 28 ($R^2 \geq 0.98$ for all experiments).

CONCLUSIONS: Combination therapy of vancomycin and naficillin demonstrated synergy against hVISA at high concentrations of vancomycin and improved maximal killing. To combat increasing vancomycin resistance, utilization of vancomycin with β-lactams may be used to treat recurrent hVISA infections in patients.

434. The Hsp40 co-chaperone Jjj1 is a negative regulator of fluconazole resistance in *Candida glabrata*. *Sarah G. Whaley, B.S.*, Kelly E. Caudle, Pharm.D., Ph.D., Katherine S. Barker, Ph.D., P. David Rogers, Pharm.D., Ph.D.; University of Tennessee College of Pharmacy, Memphis, TN

PURPOSE: In *Saccharomyces cerevisiae*, transcription factors Pdr1 and Pdr3 regulate expression of ABC transporters that confer azole resistance. Pdr3 is negatively regulated by the Hsp70 protein Ssa1. Hsp70s' chaperone activities are regulated by Hsp40 proteins of the DnaJ family. We observed the DnaJ protein Jjj1 to be differentially expressed in response to fluconazole in the related yeast *Candida glabrata*. The purpose of this study was to determine if Jjj1 influences fluconazole resistance and if Pdr1 and its downstream target ABC transporters, Cdr1, Pdh1 and Snq2 are involved.

METHODS: Strains of *C. glabrata* disrupted for *JJJ1* were constructed in wild-type and *pdr1*Δ strains. Fluconazole susceptibility testing was performed using CLSI methods. Gene expression of *JJJ1*, *PDR1*, *CDR1*, *PDH1*, and *SNQ2* was measured by relative qRT-PCR.

RESULTS: At 48 hours the MIC of wild-type was 8μg/mL. *Pdr1*Δ exhibited increased susceptibility with an MIC of 2μg/mL. When *JJJ1* was disrupted in the wild-type strain (*jjj1*Δ), the MIC increased to 64μg/mL, but only increased to 4μg/mL when both *PDR1* and *JJJ1* were disrupted (*pdr1*Δ*jjj1*Δ). In *jjj1Δ* the expression of *CDR1* was increased approximately 6-fold over the wild-type strain. The level of *CDR1* expression in *pdr1Δjjj1*Δ was not significantly different from *pdr1*Δ. There were no significant differences in *PDH1* and *SNQ2* expression in any of the strains tested.

CONCLUSIONS: We show here that Jjj1 is a negative regulator of fluconazole resistance, as disruption of this gene leads to decreased fluconazole susceptibility. This process appears to be mediated by the ABC transporter Cdr1, but not Pdh1 or Snq2, and likely involves Pdr1. The role of Hsp70s in this process is currently under investigation. Our findings allow for a better understanding of the regulation of fluconazole resistance in *C. glabrata* and potentially other pathogenic fungi, and may lead to novel therapeutic strategies to prevent and overcome azole resistance.

Medication Safety

435. Identifying optimal dosages of drugs requiring weight-based calculations in over and underweight populations. *Nicholas P. Wytiaz, Pharm.D., (c)*[1], Sandra L. Kane-Gill, Pharm.D., M.S., FCCM, FCCP[1], Mitchell S. Buckley, Pharm.D.[2], Lisa M Thompson, Pharm.D.[2], Kristina Muzykovsky, Pharm.D.[3], Henry Cohen, M.S., Pharm.D., FCCM, BCPP, CGP[3], Amy L. Seybert, Pharm.D.[1]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)St. Joseph's Hospital and Medical Center, Phoenix, AZ; (3)Kingsbrook Jewish Medical Center, Brooklyn, NY

PURPOSE: To identify dosage ranges of high-risk medications requiring weight-based dosing in over and underweight populations to better understand real-world dosing and help provide a foundation for standardized guidelines.

METHODS: A prospective, multi-center, observational study in which new and/or discontinued orders for target high-risk medications were evaluated in adult patients admitted to a cardiac intensive care unit at three institutions during 6-week periods. Intravenous high-risk medications were selected from the Institute for Safe Medication Practice's List. Patient data collected included sex, age, race, height, weight, serum creatinine, dialysis use, and medications received. Drug data included drug name, dose, concentration, route, frequency, and rate.

RESULTS: A total of 857 medication orders for 11 different high-risk medications were reviewed. 263 doses were evaluated for six different vasoactive medications. Across all weight categories, dose ranges greatly varied for each drug and were as follows: dobutamine 2.29-10.05 mcg/kg/min, dopamine 1.00–200.00 μg/kg/min, milrinone 0.19–1.04 μg/kg/min, nitroglycerin 0.06–0.85 μg/kg/min, norepinephrine 0.007–10.00 μg/kg/min, and phenylephrine 0.10–2.00 μg/kg/min. Highest average doses were observed in dopamine and norepinephrine for normal, phenylephrine for overweight, dobutamine for obese, and milrinone and nitroglycerin for morbidly obese. For non-vasoactive drugs, 371 doses were evaluated for five different medications in 97 unique patients. Across all weight categories, dose ranges again greatly varied for each drug and were as follows: fentanyl 0.0018–0.40 μg/kg/min, heparin 3.93–26.00 units/kg/hr, midazolam 0.02–20.00 μg/kg/min, propofol 5.00–101.70 μg/kg/min, and rocuronium 3.00–12.00 μg/kg/min. Highest average doses were observed in heparin for normal, propofol and fentanyl for overweight, and midazolam for obese.

CONCLUSION: A wide variance was seen in the doses used across weight classifications. Increases in dosing did not necessarily correlate with increases in weight. The vasoactive drugs were within the dosing range provided in the package inserts regardless of weight classification while heparin and the sedatives were typically dosed outside the recommendations.

436. Simvastatin safety pharmacist intervention study. *Katherine M. Crabb, Pharm.D. Candidate*[1], Marion Wofford, M.D., M.P.H.[2], Daniel M. Riche, Pharm.D., BCPS, CDE[3]; (1)The University of Mississippi School of Pharmacy, Jackson, MS; (2)University of Mississippi Medical Center, Jackson, MS; (3)The University of Mississippi Schools of Pharmacy and Medicine, Jackson, MS

PURPOSE: Recently, the FDA issued a drug safety notice pertaining to simvastatin. Simvastatin 80 mg per day is associated with an increased risk of myopathy and rhabdomyolysis and should not be started in new patients. Additionally, recommendations were made to reduce simvastatin doses in the presence of concomitant interacting medications. The purpose of this study is to identify patients seen in Internal Medicine university-based clinics who are at increased risk of myopathy and rhabdomyolysis according to the FDA safety alert and to intervene by alerting their primary provider and offering pharmacist intervention.

METHODS: This is a single-center, prospective cohort study of patients prescribed simvastatin in a contraindicated manner at a University Medical Center. Investigational Review Board approval is pending. A quality assurance database was used to generate a list of patients who have been prescribed simvastatin 80 mg per day, who were taking simvastatin with a contraindicated interacting medication, or who were taking simvastatin at a dose contraindicated with an interacting drug. An email will be sent to each patient's primary provider explaining the nature of the adverse medication regimen. Four response options are available for the provider: (1) No change in therapy; (2) Primary provider to adjust regimen, (3) Pharmacist to adjust regimen, and (4) Refer to a lipid clinic. The primary outcome is to evaluate the total number and results of pharmacist interventions for this patient population.

RESULTS: The quality assurance database identified 246 patients of 27 primary care providers qualifying for inclusion. Average age was 64 years with an equal balance between males and females. Of the patients prescribed simvastatin, 52% were receiving 80 mg per day. The most common interacting medications were calcium channel blockers, verapamil (4.5%), diltiazem (6.5%), and amlodipine (60%).

437. Development of a student pharmacist driven medication reconciliation discharge program. *Peter M. Sullivan, Student,* Amy Jurek, Student; Duquesne University, Mylan School of Pharmacy, Pittsburgh, PA

PURPOSE: Hospital discharge is a major risk factor for medication errors and discrepancies for patients; resulting in adverse effects and hospital readmission. Evidence based studies are largely based on the admission processes and lack discharge planning and patient education. We aim to develop a student pharmacist driven discharge medication reconciliation and education program to decrease discrepancies and increase caregiver knowledge in medication management.

METHODS: A PubMed search was performed and 15 articles were included which discussed medication reconciliation. Medication reconciliation upon admission appeared to be the focus of most programs, while discharge programs were less evident. Details from these programs were adapted and combined with current pharmacy based models to develop a student pharmacist driven medication reconciliation discharge program.

RESULTS: Most institutions rely on nurses to perform the tasks of medication reconciliation upon admission. All studies reviewed showed a decrease in medication errors and discrepancies after implementation of a formal program. The development of this program will involve student pharmacists preparing for and conducting the discharge counseling sessions, under the supervision of a preceptor. Discharge medication counseling sessions will be scheduled as 30 minute appointments, and patients will receive a medication information booklet and medication calendar. The medication booklets will include: general medication information including adverse effects and interactions to educate the patient and increase compliance.

CONCLUSION: Student pharmacists are at the best position to conduct medication reconciliation upon discharge, under the supervision of a preceptor. They are eager to counsel, have an expertise on medications, and have no associated cost when completed as a clerkship activity. Discharge is a crucial time for patients to receive counseling on their medications due to the complexity, and changes to their existing therapies.

438. Post-FDA safety statement medication use evaluation of rosiglitazone. *Keri L. Mills, Pharm.D. Candidate*[1], Marion Wofford, M.D., M.P.H.[2], Daniel M. Riche, Pharm.D., BCPS, CDE[3]; (1)University of Mississippi School of Pharmacy, Oxford, MS; (2)University of Mississippi Medical Center, Jackson, MS; (3)University of Mississippi School of Pharmacy, Jackson, MS

PURPOSE: Due to significant increase in risk of heart attack and heart-related deaths in patients taking rosiglitazone, the FDA has developed a Risk Evaluation and Mitigation Strategy (REMS) that must be implemented by November 18, 2011. The purpose of this evaluation was to determine if patients of the general medicine and hypertension outpatient clinics of the University of Mississippi Medical Center were currently being prescribed rosiglitazone or rosiglitazone-containing medications (new or continued prescriptions) and if patients had been appropriately counseled on the risks of these medications.

METHODS: A search was conducted to identify patients in the general medication and hypertension clinic who were prescribed rosiglitazone or rosiglitazone-containing product from January 2000 to February 2011. Prescription histories were reviewed and compared to the clinic notes. It was noted if the patient was: (1) Currently using

rosiglitazone; (2) Date of last known use; (3) Documentation of counseling; (4) Medication discontinuation/adjustment; (5) Reason the medication was altered; and (6) If a change was initiated by patient or physician.
RESULTS: Out of 186 patients with a history of rosiglitazone use, only 9 patients were currently taking rosiglitazone-containing medications, while 33 patients discontinued or changed rosiglitazone due to patient request or prescriber counseling. Counseling was not documented for any of the current rosiglitazone patients. In clinic notes, patients requested the change due to advertisements, articles, or advice of family. Prescribers most often cited the meta-analysis published in the 2007 NEJM. 141 patents discontinued or changed without regarding to FDA safety statements, rather citing uncontrolled glucose, adverse effects, cost, or lost-to-follow up.
CONCLUSION: While current use of rosiglitazone was small, the lack of documentation about cardiovascular risk counseling is concerning. This project will continue by sending letters to physicians suggesting therapy alteration and reinforcing documentation at all visits, including medication counseling.

Men's Health

439. Lack of association between statin therapy and testosterone deficiency. *Corey L. McEwen, Pharm.D. Candidate*[1], Marion Wofford, M.D., M.P.H.[2], Daniel M. Riche, Pharm.D., BCPS, CDE[3]; (1)The University of Mississippi School of Pharmacy, Jackson, MS; (2)University of Mississippi Medical Center, Jackson, MS; (3)University of Mississippi School of Pharmacy, Jackson, MS
PURPOSE: Recent studies evaluating the association of statin therapy and testosterone deficiency have had mixed results. Studies that have shown an association were done in male patients who already had erectile dysfunction (ED). This study was designed to examine whether statin therapy is associated testosterone deficiency in male patients with or without ED or any other confounding disease states.
METHODS: This study is a retrospective chart review including patients with a testosterone level drawn at a university-based outpatient clinic over a 12-month period between June 2010 to June 2011. Patient medical records were reviewed to determine statin use and testosterone deficiency (defined as testosterone level <280 ng/mL or presence of testosterone replacement). Demographic data was obtained for all patients including age, race, and weight. Co-morbid disease states of hypertension, diabetes, and the presence of erectile dysfunction medications was also obtained. Statin therapy was considered associated with low testosterone levels if the patient initiated any statin at least one month prior to their first recorded low testosterone level. Continuous data were evaluated using a *t*-test, while dichotomous data were evaluated via χ^2 test.
RESULTS: There were 93 patients meeting with testosterone drawn at the clinic during this 12-month period. The average age and weight of patients was 57.5 years and 230.6 pounds, respectively. There was no association between statin therapy and testosterone deficiency. Although there is a numerically lower testosterone level in patients receiving statin therapy, there was no statistically significant difference between groups (p=0.12).
CONCLUSION: There is no association between statin therapy and presence of testosterone deficiency.

Nephrology

440. Differential effect of IV iron compounds on intracellular reactive oxygen species (ROS) generation in aortic coronary endothelial cells. *Heena V. Patel, Pharm.D. Candidate*, Alex J. Prokopienko, Pharm.D. Candidate, Nancy Gertzberg, A.S., Paul Neumann, A.S., Arnie Johnson, Ph.D., Amy Barton Pai, B.S., Pharm.D., BCPS; Albany College of Pharmacy and Health Sciences, Albany, NY
PURPOSE: Cardiovascular disease is the leading cause of death for end-stage renal disease (ESRD) patients and is highest among patients with tunneled central venous catheters (TCVCs). This is likely due to oxidative stress and inflammation potentially exacerbated by IV iron administration. The available IV iron compounds have different stability profiles and we have previously shown there are significant differences in free iron appearance among the available compounds [Pai et al. Biometals 2011]. The purpose of this study was to investigate whether IV iron products induce ROS generation in coronary endothelium.
METHODS: Rat aortic coronary endothelial cells (RACEC) were cultured in 96-well plate. RACEC cells were treated with 0.05 mg/mL of iron sucrose (IS), iron dextran (ID), or ferumoxytol (FMX) for 60 min then washed and measured serially for 60 min. Cells were also treated with lipoteichoic acid (LTA, 30 μg/mL), a Gram-positive cell wall component found in TCVC biofilm for 120 min. ROS generation was probed for by fluorescence detection using dihydroethidium (DHE) (10 and 20 μM) for 15 minutes at 37ºC. DHE fluorescence values are reported as mean ± SD fluorescence intensity (MFI). All experiments are n ≥ 20.
RESULTS: Incubation of RACEC with IS induced the highest ROS generation compared to control (549 ± 71 vs. 491 ± 83 MFI, p=0.01). ROS generation by ID and FMX was not different than controls. Treatment with LTA also significantly increased intracellular ROS production on average 21% greater than controls (p <0.001).
CONCLUSION: The small molecular weight iron-carbohydrate complex IS significantly increased intracellular ROS generation, likely due to the labile nature of the complex. These data indicate that cardiac endothelial injury is induced differentially by IV iron compounds. The Gram-positive cell wall component LTA also significantly increased ROS generation. Further investigation of IV iron and LTA on endothelial toxicity is warranted.

441. Management of serum calcium and phosphorous levels for the prevention of mineral bone disease in chronic kidney disease patients on dialysis by multidisciplinary team care. *Da-Hae Jun, B.S.*[1], Na Young Han, M.S.[1], Eun Hee Ji, Ph.D.[1], Hyoyoung Park, M.S.[1], Suhnggwon Kim, M.D., Ph.D.[2], Jin Suk Han, M.D., Ph.D.[2], Curie Ahn, M.D., Ph.D.[2], Yon Su Kim, M.D., Ph.D.[2], Kwon Wook Joo, M.D., Ph.D.[2], Kook-Hwan Oh, M.D., Ph.D.[2], Dong Ki Kim, M.D.[2], HyunAh Kim, Pharm.D.[1], Wan Gyoon Shin, Pharm.D., Ph.D.[1], Hye Suk Lee, M.S.[3], Jung Mi Oh, Pharm.D.[1]; (1)College of Pharmacy, Seoul National University, Seoul, South Korea; (2)Division of Nephrology, Department of Internal Medicine, Seoul National University Hospital, Seoul, South Korea; (3)Department of Pharmacy, Seoul National University Hospital, Seoul, South Korea
PURPOSE: Although clinical pharmacists are at a unique position for patient education and chart reviews, multidisciplinary team care (MTC) involving clinical pharmacists is not widely practiced in Korea. This study evaluated the effect of MTC on the management of serum calcium and phosphorous in dialysis patients with clinical pharmacists as part of the multidisciplinary team.
METHODS: Electronic medical records and drug-related intervention records for 163 nephrology in-patients on dialysis admitted to a tertiary teaching hospital from January 2009 to December 2009 were retrospectively reviewed according to the 2009 KDIGO CKD-MBD guideline. Patients were categorized into a MTC group which involved nephrologists, clinical pharmacists, nurses and nutritionists, and a non-MTC group. Regulation of serum corrected calcium (cCa) and phosphorous (P) levels at admission/discharge and appropriate use of related medications were analyzed by appropriate statistics with PASW 18.
RESULTS: Baseline characteristics (including age, gender, etiology of CKD, type/duration of dialysis, days of admission) of the 163 patients were not significantly different between the two groups (MTC, n=100; non-MTC, n=63). The MTC group had more patients with better regulation of serum cCa and P levels during admission (MTC cCa 51.9%, P 20.9% vs. non-MTC cCa 26.1%, P 15.5%). While serum P levels remained stable in the MTC group, serum P levels increased significantly above the baseline in the non-MTC group (serum P level difference, p-value=0.799 vs. p-value=0.002, respectively). The appropriate use of non-calcium phosphate binders was significantly higher in the MTC group (MTC 66.67% vs. non-MTC 17.86%, p-value<0.001).
CONCLUSIONS: MTC involving clinical pharmacists was effective in improving the management of serum cCa and P levels in dialysis patients. Patient education on the administration of phosphate-binders, daily monitoring and interactions within the MTC team seem to be contributing factors. Better regulation of serum cCa and P levels by

MTC may lead to prevention of CKD-MBD.

442. Knowledge, perceptions and adherence of ESRD patients receiving erythropoietic therapy and anemia management: A student-pharmacist based survey in an outpatient peritoneal dialysis clinic. *Karen Nenno, Pharm.D., Candidate*[1], Shailly Shah, Pharm.D. Candidate[1], Oriyomi Alimi, Pharm.D. Candidate[1], Iris Hayes, L.S.W.[2], Carol Dacko, R.N.[2], Filitsa Bender, M.D.[3], Thomas Nolin, Pharm.D., Ph.D.[1]; (1)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2)DCI, Inc., Pittsburgh, PA; (3)University of Pittsburgh School of Medicine, Pittsburgh, PA

PURPOSE: Adherence is a vital component of anemia management in patients who self-administer erythropoietic (EPO) therapy. The purpose of this study was to assess the knowledge, perceptions and adherence of home hemo- (HD) and peritoneal dialysis (PD) patients pertaining to EPO therapy and anemia management.

METHODS: Cross-sectional surveys were administered to 28 PD and home HD patients from February-March 2011. Questions were designed to determine patients' understanding of their EPO prescription, hemoglobin (Hgb) concentrations, number of missed doses, adverse effects, symptoms of anemia, and negative perceptions surrounding EPO therapy. Survey responses were compared with each patient's medical, laboratory, and medication profile for the months of January-March 2011, and were evaluated using descriptive statistics and Fisher's exact test.

RESULTS: Nineteen patients (68%) knew their current EPO prescription. Five patients reported difficulty remembering to administer EPO, but only one patient reported missing doses. Hgb concentrations were >12.0 mg/dL and <10 mg/dL in fourteen (50%) and two patients, respectively. Patients who correctly recalled their most recent Hgb concentration (15/28; 54%) were more likely to be at Hgb goal than those that did not [10/15 (67%) vs 2/13 (15%); P=0.009]. Patients with changes to their EPO prescription (21/28; 75%) were less likely to know their regimen compared to those with unchanged prescriptions [12/21 (57%) vs 6/7 (86%); P=NS]. Patients receiving PD/HD >1.5 years (19/28) were less likely to be at Hgb goal, [7/19 (37%) vs 5/9 (56%); P=NS] and to know their EPO prescription [10/19 (53%) vs 8/9 (89%); P=NS] compared to those receiving it ≤1.5 years. The most commonly reported (9/28, 32%) negative perception was needle stick.

CONCLUSION: Our results suggest there is a relationship between a patient's knowledge surrounding Hgb results, duration of PD/HD, and attainment of Hgb goal. Continuing patient education may improve anemia management in these patients.

Neurology

443. Medications associated with delirium in hospitalized subjects. *Caroline A. Lindsay, B.S.*[1], Keiko A. Fukuda, B.A.[2], S. Andrew Josephson, M.D.[3], Vanja Douglas, M.D.[3]; (1)University of California San Francisco, School of Pharmacy, San Francisco, CA; (2)University of California San Francisco, Department of Neurology, Stroke Sciences Group, San Francisco, CA; (3)University of California San Francisco, Department of Neurology, San Francisco, CA

PURPOSE: To determine which medications are associated with the development of delirium in hospitalized subjects.

METHODS: Non-delirious subjects admitted to the medicine, cardiology, and neurology inpatient services at UCSF were prospectively enrolled in this cohort study. Subjects underwent a detailed baseline cognitive assessment within 24 hours of admission and were followed until discharge or up to 6 days to detect new onset delirium. Home medication lists were collected from admission notes, and medications taken each day during the hospitalization were abstracted from inpatient Medication Administration Records. The incidence of delirium will be compared to the number of subject-days of exposure to each medication or medication class using Chi-square testing for univariate analysis and with generalized estimating equations (GEE) for multivariate analysis. Classes of medications to be analyzed include anticholinergics, antihistamines, benzodiazepines, and opiates.

RESULTS: Preliminary data analysis included 209 subjects, with a median age of 66 years (interquartile range: 58, 77). 46% of the cohort was female. Races represented included Caucasian (74%), Black (16%), and Asian/Pacific Islander (10%); 4% were of Hispanic ethnicity. 25 subjects (12%) developed delirium while hospitalized. In a preliminary multivariate analysis adjusting for old age (≥80), sex, race, cognitive impairment (Mini Mental Status Exam (MMSE) score <24), moderate or severe illness as rated by a nurse, and presence of hearing or vision loss, the addition of 5 or more new medications on admission was associated with the development of delirium (OR = 3.78, p=0.018, 95% CI[1.26,11.3]). Other independent predictors include old age, moderate or severe illness, and cognitive impairment.

CONCLUSION: Consistent with published literature, we found the addition of 5 or more new medications on admission predicted development of delirium during the hospital stay. Future analysis, to be concluded by September 2011, will determine which classes of medication are most associated with delirium.

444. Treatment of fever during the acute stroke period at a primary stroke center. *Ashley H. Cribb, Pharm., D., student*[1], Diana K. Houng, Pharm.D.[1], Jody L. Rocker, Pharm.D.[2], Jeffrey Switzer, D.O.[2], David Hess, M.D.[2], Susan C. Fagan, Pharm.D.[3]; (1)University of Georgia College of Pharmacy, Augusta, GA; (2)Georgia Health Sciences University, Augusta, GA; (3)Program in Clinical and Experimental Therapeutics University of Georgia College of Pharmacy Charlie Norwood VA Medical Center, Augusta, GA

PURPOSE: Fever during the acute stroke period is common (40–60%) and is associated with poor neurological outcomes. However, the use of antipyretic therapy for defervescence and improvement of neurological outcomes is controversial. The objective of this study was to determine the incidence of fever in our population and to investigate the prescribing patterns of antipyretics and antibiotics.

METHODS: The study included 117 consecutive patients admitted to the Primary Stroke Center with a diagnosis of ischemic stroke or TIA between January 1st – June 30th, 2010. Data was collected on patient demographics, incidence and time of fever, and prescription of acetaminophen and antibiotics during hospital stay. Fever was defined as a temperature greater than 38°C.

RESULTS: Of the 117 charts reviewed, fifty-five patients (47%) received acetaminophen for either pain or fever. Seventeen of the 117 patients were febrile during inpatient stay (average temperature, 38.5°C), and sixteen of the febrile patients (94.1%) received acetaminophen. Thirteen (81.3%) of the febrile patients had reductions in fever occurring on average within three days of acetaminophen initiation. Of the 117 patients, microbiology cultures were drawn in thirty-six patients (30.8%). Thirteen of these were febrile patients, and eight (61.5%) febrile cultures showed growth. A total of twenty-three patients (19.7%) received antibiotic therapy. Of these, twelve were febrile patients receiving therapy for a positive culture or risk of aspiration or ventilator-associated pneumonia. Among the 117 patients, the average total acetaminophen dose administered during inpatient stay was 4.8 grams. Acetaminophen was prescribed alone in thirty-two patients (58.1%) and in combination with ibuprofen or codeine derivatives in twenty-three patients (41.9%).

CONCLUSION: Acetaminophen use is common in acute stroke patients, especially in the presence of fever. Guidelines for the use of acetaminophen in this setting are needed. Further data analysis is currently pending.

Oncology

445. Effects of mobilization regimens on the incidence of tumor cell contamination of the hematopoietic stem cells in breast cancer patients undergoing peripheral blood stem cell transplantation. *Sora Choi, B.S.*, Meghana V. Trivedi, Pharm.D., Ph.D.; University of Houston College of Pharmacy, Houston, TX

PURPOSE: Tumor cell contamination (TCC) of hematopoietic stem cells has been shown to confer poor prognosis in breast cancer (BC) patients undergoing peripheral blood stem cell transplantation (PBSCT). It is not clear what influence various stem cell mobilization regimens have on the incidence of TCC. We performed a systematic review of published data to examine the effects of mobilization regiment on TCC of hematopoietic stem cells in BC patients undergoing PBSCT.

METHODS: Inclusion criteria were prospective and retrospective

studies reporting the TCC of hematopoietic stem cells obtained from any stage or subtype of BC patients. Twenty-two articles (n= 2529) were included in the final analysis. Patients were divided into groups based on mobilization regimen (cytokines alone, cytokines + chemotherapy, chemotherapy only) and detection of TCC in any collection (yes or no) (Table-1).

RESULTS: We found that the proportion of patients with TCC of hematopoietic stem cells after receiving cytokines only (20.6%) was significantly higher (p=0.01, χ^2 test) as compared to that after receiving cytokines + chemotherapy (16.7%) or chemotherapy alone (8.5%) When studies using only G-CSF as a cytokine were considered (n = 1414), the difference was still statistically significant (p=0.01, χ^2 test).

CONCLUSION: Our results show that cytokines only (i.e., G-CSF) as a mobilization regimen may increase TCC of hematopoietic cells, possibly by stimulating the proliferation of BC stem cells and/or increasing the mobilization of tumor cells. Since TCC is linked to increased relapse, our systematic review provides correlative evidence to support the role of cytokines (G-CSF) in increasing the risk of relapse in BC patients undergoing PBSCT.

Table 1. BC patients undergoing PBSCT based on mobilization regimen and detection of TCC in the apheresis products.

	Cytokines only	Cytokines + Chemotherapy	Chemotherapy only
TCC +	329	156	8
TCC -	1267	777	86

446. Acneiform rash does not predict response to neoadjuvant lapatinib monotherapy in breast cancer patients. *Jennifer M. Parma, B.S.*[1], Anne C. Pavlick, B.S.[2], Jenny C.N. Chang, M.B.B.Ch.[2], Mothaffar F. Rimawi, M.D.[2], Meghana V. Trivedi, Pharm.D., Ph.D.[1]; (1)University of Houston College of Pharmacy, Houston, TX; (2)Baylor College of Medicine, Houston, TX

PURPOSE: rash is a common toxicity, occurring in more than 30% of patients receiving lapatinib, a dual inhibitor of EGFR and HER2, for the treatment of HER2-positive breast cancer. rash is a class adverse effect of drugs that target EGFR and has been associated with superior treatment response. However, this association between rash and response has never been shown for lapatinib in breast cancer patients. In this study, we hypothesized that breast cancer patients who develop rash on lapatinib treatment will have a better response.

METHODS: We prospectively enrolled 49 patients with locally advanced (≥ 3 cm) HER2-positive breast cancer on a clinical trial of neoadjuvant monotherapy with lapatinib (1500 mg per day for 6 weeks). Patients were followed for incidence of rash and diarrhea, which was graded using NCI CTCAE criteria. Primary endpoint of the trial was overall response rate, assessed by objective tumor measurements and defined by at least 50% reduction in the product of the largest perpendicular diameters of the breast lesion according to standard WHO criteria.

RESULTS: Forty-seven patients were evaluated and divided into four groups based on rash (Y/N) and response (Y/N) (Table 1). We found that the proportion of responders among patients with rash was not significantly different from that among patients who did not develop rash (p=0.75, Fisher's exact test) (Table 1). Similarly, the incidence of diarrhea was not significantly different in relation to the response in these patients.

CONCLUSION: In our study, incidence of rash and diarrhea did not predict clinical efficacy with neoadjuvant lapatinib monotherapy in treatment-naïve locally advanced HER2-positive breast cancer patients.

	Response (Y)	Response (N)
Rash (Y)	19 (73%)	7 (27%)
Rash (N)	14 (67%)	7 (33%)

447. Effectiveness of palonosetron compared with the other serotonin antagonists in combination with aprepitant in preventing highly emetogenic chemotherapy induced emesis. *Boyoon Choi, Ph.D. Candidate*[1], Dong Eun Lee, B.S.[1], Kyung Im Kim, Ph.D. Candidate[1], Hye Suk Lee, M.S.[2], Hyunah Kim, Pharm.D.[1], Wan Gyoon Shin, Pharm.D., Ph.D.[1], Jung Mi Oh, Pharm.D.[1]; (1)College of Pharmacy, Seoul National University, Seoul, South Korea; (2)Department of Pharmacy, Seoul National University Hospital, Seoul, South Korea

PURPOSE: Palonosetron, a 2nd generation of serotonin (5-HT_3) antagonist is known to be superior to the other 5-HT_3 antagonists in preventing delayed emesis in patients receiving moderately emetogenic chemotherapy. This study compared the effectiveness of palonosetron to the other 5-HT_3 antagonists in preventing highly emetogenic chemotherapy (HEC) induced emesis when administered with aprepitant and corticosteroids.

METHODS: This institutional review board (IRB) approved study retrospectively reviewed medical records of patients admitted to a tertiary teaching hospital and received HEC between April 2008 and February 2011. Patients' medical history, drugs administered and in-hospital course during the first day (for acute emesis analysis) and four subsequent days (for delayed emesis analysis) of chemotherapy were documented respectively. Primary endpoint was complete response (CR) rate and secondary endpoint was complete control (CC) rate, nausea and vomiting incidence, use of rescue medicine and parenteral nutrition, and time to treatment failure (TTF).

RESULTS: A total of 157 patients (87 patients in palonosetron group, 70 patients in control group) were included. Baseline characteristics in the two groups were similar. There was no significant difference between the two groups neither in CR rate (acute 89.7% vs 82.9%, p=0.214; delayed 57.5% vs 57.1%, p=0.967; total period 56.3% vs 48.6%, p=0.334) nor CC rate (acute 89.5% vs 81.2%, p=0.138; delayed 55.8% vs 55.1%, p=0.926; total period 55.3% vs 46.4%, p=0.271). The only significant difference between the two groups was in the incidence of nausea in favour of palonosetron (42.5% vs 55.6%, p=0.046).

CONCLUSION: This study results did not show a significant advantage of palonosetron versus the other 5-HT3 antagonists in preventing HEC induced emesis in combination with aprepitant. Since this was the first study comparing the effectiveness of palonosetron versus the other 5-HT3 antagonists in combination with aprepitant, further randomized prospective studies are warranted.

448. Evaluation of obesity on achieving remission following induction therapy for acute myelogenous leukemia. *Laura Leigh Stoudenmire, Pharm.D. Candidate*[1], Morgan Trepte, Pharm.D. Candidate[1], Katerina Katsanevas, Pharm.D.[1], Courtney McCracken, M.S. Candidate[2], David L. DeRemer, Pharm.D., BCOP[1]; (1)University of Georgia College of Pharmacy and Georgia Health Sciences Health System, Augusta, GA; (2)Georgia Health Sciences University Department of Statistics, Augusta, GA

PURPOSE: To evaluate efficacy and toxicity in obese and non-obese acute myelogenous leukemia (AML) patients who receive standard induction therapy. Obesity was defined using the WHO's criteria of a body mass index (BMI) ≥ 30. Further, to evaluate the outcomes of anthracycline dose capping for patients with a body surface area (BSA) > 2 m^2.

METHODS: Retrospective analysis of AML patients who received standard induction therapy at Medical College of Georgia Health between 2006 and 2011. The primary endpoint was to evaluate complete remission (CR) rates in obese and non-obese patients as defined by BMI. Secondary endpoints included evaluating differences in ejection fraction changes, hospitalization days, and neutropenic fever antibiotic duration. All statistical analyses were performed using SAS 9.2 for Windows (SAS Institute Inc., Cary, NC, 2009).

RESULTS: In this interim analysis, 70 patients were evaluated. The median BMI of study subjects was 28.6, and 41.4% had a BMI ≥ 30. No statistical association was found between BMI category and day 14 CR rates (P=0.0569), but trended to favor obese patients. Patients with younger age (P=0.05), Caucasian ethnicity (P=0.04), or favorable cytogenetics (P=0.0004) favored achieving a CR. Nineteen patients were identified with a BSA (>2 m^2); 9 of these patients received a capped dose which did not correlate to poorer outcomes (P=1.0). There was no correlation with BMI on cardiac toxicity, hospitalization days (P=0.2640), or antibiotic duration (P=0.3549).

CONCLUSIONS: Patients with BMI ≥ 30 trended to favor obtaining remission. Younger age, Caucasian ethnicity, and favorable cytogenetics demonstrated higher CR rates. Anthracycline dose capping did not influence outcomes.

Other

449. Pharmacists' role in evaluation of "as necessary" medications at a community hospital. *Christine E. Puschak, Pharm.D., Candidate*, Jill A. Rebuck, Pharm.D., FCCP, FCCM, BCPS; Lancaster General Health, Lancaster, PA

PURPOSE: As necessary (PRN) medications are frequently prescribed in the hospital setting from standard order sets based on convenience, regardless of whether they are administered. Our purpose was to characterize PRN medication ordering and administration practices.

METHODS: A one-time prospective evaluation of PRN medication orders for all patients hospitalized at a 640-bed community hospital was performed. Subsequently, pharmacists ordered an automatic discontinuation per protocol of unnecessary PRN medications meeting criteria for non-essential status from standard order sets if they were not administered in the previous 48 hours (excluded: inhalers/nebulizers, electrolyte supplementation, delirium agents, emergent/rescue therapies, or antihypertensives). Nurses were instructed to contact pharmacy to restart any discontinued medications if required for patient care needs. Any patient safety concerns were also assessed.

RESULTS: Of the 10,295 total medication entries evaluated, 1,935 PRN medications were identified, representing 18.8% of all medication orders. Focusing on PRN medications from order sets, 1,092 medications met criteria. Excluded were 844 (43.6%) individualized medication orders. An additional 394 medications (20.3%) were excluded from automatic discontinuation: emergent/rescue medication (164), medications administered within the past 48 hours (122), less than 48 hours since ordered (85), and other (23). Overall, 513 medications met criteria for automatic discontinuation, representing 116 different order sets. An average of 4 medications per order set were discontinued, with critical care and heart failure representing the most frequent order sets. The most common discontinued medications were analgesics (122), antiemetics (82), and sedatives (80). There were no patient complications or nursing requests to restart any discontinued medications.

CONCLUSION: Non-administered, non-essential PRN medications associated with standard order sets were common at our hospital. We demonstrated a successful automatic discontinuation of criteria-based PRN medications. Pharmacists are well-positioned to evaluate the necessity of multiple PRN medication orders.

450. Angiogenic and vasculoprotective potential of angiotensin receptor antagonists in the brain. *Lydia Cronic, B.S.*[1], Sahar Soliman, B.S.[2], Azza El-Remessy, Ph.D.[2], Susan C. Fagan, Pharm.D.[3]; (1)University of Georgia College of Pharmacy, Augusta, GA; (2)University of Georgia College of Pharmacy, Veteran's Affairs Medical Center, Augusta, GA; (3)Program in Clinical and Experimental Therapeutics University of Georgia College of Pharmacy Charlie Norwood VA Medical Center Au, Augusta, GA

PURPOSE: Few therapeutic agents are available to affect morbidity and mortality following stroke. Moreover, these agents are frequently underutilized due to needs for timely administration, risk of adverse events, and difficult dosing and administration. Current research has focused on vascular protection and angiogenesis as means of improving functional outcome and promoting recovery following stroke. Recent studies have shown that the angiotensin receptor blocker candesartan improves outcome after experimental stroke. This investigation was undertaken to determine: 1) whether candesartan has direct proangiogenic or vasculoprotective effects on human cerebral microvascular endothelial cells and 2) whether the direct effects are a class effect.

METHODS: Human cerebral microvascular endothelial cells (HCMECs) were grown on collagen and exposed to therapeutic concentrations of either candesartan or losartan. Angiogenic potential was measured through tube formation and wound healing (migration) assays. Vascular protection was measured through barrier function integrity using electric cell substrate impedance sensing (ECIS).

RESULTS: Candesartan 0.1 μg/mL and losartan 0.05 μg/mL directly promoted tube formation at 24 hours (7.8, 22.5, 20.25 for control, candesartan and losartan, $p<0.05$ n=5,6, 4 respectively). Similarly, Candesartan 0.1 μg/mL also increased migration at 18 and 24 hours (26.4 ± 1.3% and 39.0 ± 4.9% at 18 hours, $p<0.05$, F-ratio = 4.71; and 32.7 ± 1.1% and 45.2 ± 5.6% at 24 hours, $p<0.05$, F-ratio = 6.3). Similar effects were seen with losartan. Furthermore, ARB treatment protected against hydrogen peroxide-induced oxidative stress and preserved barrier function of the cells.

CONCLUSIONS: ARBs are proangiogenic and vascular protective in the cerebral vasculature at clinically-relevant concentrations. This may explain the ability of candesartan to promote recovery after experimental stroke.

451. Evaluation of a potassium replacement protocol in non-ICU patients at an urban safety net hospital. *Megan E. Austin, Pharm.D.,Candidate*[1], Andrew Smith, Pharm.D.[2], Tony Huke, Pharm.D.[1]; (1)Truman Medical Center, Kansas City, MO; (2)UMKC School of Pharmacy, Kansas City, MO

PURPOSE: This study is a retrospective evaluation of the effectiveness of a potassium replacement protocol in patients on medical/surgical (non-ICU) units.

METHODS: A retrospective case-control study was performed. The study population consists of 200 patients (100 cases and 100 controls) who were admitted September 1, 2010 to March 31, 2011 to our institution. Case patients were defined as having a potassium replacement protocol ordered and control patients didn't have the protocol ordered. The following information was obtained: age, sex, height and weight, serum creatinine, MDRD, race, admission diagnosis, index and repeat potassium level, potassium dose, route of administration, time from index level to replacement dose, time from index level to repeat potassium level, protocol deviation if present. Control patients were matched to cases in regards to gender, age and renal function. The primary outcome of the study was the response time to replacement of low potassium levels. Secondary endpoints include effectiveness of replacement protocol (i.e., $K+ \geq 4$mmol/L) and the ability of the staff to appropriately use the protocol. Comparison between data was made using student's *t*-test for continuous variables and χ^2 test for nominal or ordinal items. A p-value of < 0.05 was considered statically significant. Statistical analysis will be performed using SPSS version 18 (SPSS, Inc., Chicago, IL).

RESULTS: Data collection on the case patients has been completed. One hundred patients had 170 episodes of hypokalemia ($K+<3.5$mmol/L). The average replacement dose was 60 mEq and average time to replacement was 386 minutes. Data collection on the control patients is ongoing and will be completed prior to presentation.

CONCLUSION: Not determine at time of abstract submission.

452. Assessment of recommendations made by a clinical pharmacist in a palliative care setting: A retrospective cohort study. *Holly L. Tumlin, Pharm.D. Candidate*, LeAnn B. Norris, Pharm.D.; South Carolina College of Pharmacy-USC Campus, Columbia, SC

PURPOSE: Palliative care serves are aimed at helping control not only the symptoms of a disease, but also actively working to treat the patient's physiological and spiritual needs. According to the National Hospice and Palliative Care Organization (NHPCO), in 2009 over 5,000 palliative care sites were available in the United States and 1.56 million people received care. Despite the growth in sites, many palliative care services do not have a clinical pharmacist on their interdisciplinary team. Although documentation was seen as early as the 1980s for the useful services a pharmacist could bring to the palliative care team, little evidence exists of the actual benefit of having a pharmacist in this setting. The purpose of this study is to provide more data to identify the importance and benefit of including pharmacists in the management of patients receiving palliative care.

METHODS: This is a retrospective cohort study approved by the Dorn VA institutional review board upon initiation. Medical records of 200 patients who were over the age of 18 who were admitted to the hospice and palliative care unit at the WJB Dorn VA Hospital between August 2009 and May 2010 were reviewed for pharmacy interventions for inclusion in this study. A validated tool developed by Overhage and Lukes was utilized and adapted for documentation of pharmacy interventions, the value of service, and the outcome of the intervention. Two separate health care professionals completed the assessment tool and evaluated the outcome for comparison. The primary outcome of this project was to capture, describe, and assess

the interventions made by the pharmacist using a scale that evaluates the importance and relevance of the intervention. The secondary outcome was the pharmacy intervention acceptance rate. Appropriate statistical analysis will be applied to the data set.
RESULTS: Research ongoing
CONCLUSION: Research ongoing

Pediatrics

453. Buprenorphine withdrawal in an infant after cessation of breastfeeding: A case report and review of the literature. *Hani Elladki, Pharm.D., Candidate*[1], Paul Thill, Pharm.D., BCPS[2]; (1)Ferris State University, Dearborn Heights, MI; (2)Ferris State University College of Pharmacy, Saginaw, MI
PURPOSE: To report a case of buprenorphine withdrawal in an infant after an abrupt cessation of breastfeeding and to review the published literature on the topic. It is well known that exposure to buprenorphine in utero, can lead to neonatal abstinence syndrome (NAS). We report here a 4-month old infant who displayed symptoms of withdrawal approximately 2 days after the mother stopped breastfeeding. Symptoms included frequent yawning, sneezing, pupillary dilation, agitation, sweating, hyperactive Moro reflex, myoclonic jerks, tremors and insomnia. The mother stated that she was using buprenorphine throughout her pregnancy and there were no signs of NAS at birth. Upon diagnosis the infant was placed on methadone and experienced immediate improvement of her withdrawal symptoms. Patient was discharged after 3 days on a methadone taper. The Naranjo scale suggests this is a probable adverse event.
METHODS: We performed a MEDLINE search (1966–May 2011) using keywords: buprenorphine, breastfeeding and withdrawal. Review articles, case reports and primary research publications were included in this search.
RESULTS: No case reports were found describing buprenorphine withdrawal in infants secondary to cessation of lactation. One case report found insignificant levels in breast milk for a child experiencing NAS. Two studies investigated buprenorphine concentrations in breast milk and determined the concentration was unlikely to have adverse effects on lactating infants. This case report represents an issue that has not been discussed extensively or studied in the literature and it is likely healthcare providers do not consider it in the care of newborn infants or education of breastfeeding mothers on buprenorphine.
CONCLUSION: Although buprenorphine has generally been considered safe during lactation, this case report is in contrast to that assumption. Until more evidence is published, healthcare providers should specifically counsel lactating mothers taking buprenorphine to watch for signs of withdrawal and avoid rapid cessation of breastfeeding.

454. Evaluation of busulfan targeted therapy and pharmacokinetics in pediatric patients undergoing hematopoietic cell transplantation. *Shirley Yan, B.S.*, Christopher C. Dvorak, M.D., Lisa Musick, Pharm.D., Jason Law, M.D., Morton J. Cowan, M.D., Biljana Horn, M.D., Janel R. Long-Boyle, Pharm.D., Ph.D.; University of California, San Francisco, San Francisco, CA
PURPOSE: Busulfan is an alkylating agent routinely used in the conditioning regimens of pediatric hematopoietic cell transplantation (HCT). Identifying covariates that influence busulfan exposure is important for the development of better dosing strategies in HCT. This study aims to evaluate patient-specific covariates as contributors to the variability of busulfan exposure in pediatric HCT recipients using a population pharmacokinetic (PK) approach, as these remain poorly defined.
METHODS: We retrospectively collected PK data from the routine therapeutic monitoring of busulfan levels in pediatric HCT recipients at UCSF Benioff Children's Hospital between January 2007 and January 2011. Patients were included in the analysis if they had undergone a related or unrelated HCT including busulfan therapy, were between 0 to 18 years of age, and had busulfan time-concentration data available for analysis. Busulfan drug levels and potential covariates influencing drug exposure will be analyzed with standard population PK methodologies using non-linear mixed effects modeling software (NONMEM).
RESULTS: This study will utilize busulfan time-concentration data available in 52 pediatric HCT recipients (36 males/16 females) for a total of 117 individual PK profiles. Subjects range in age from 1 month to 18 years. Median weight is 20 kg (range, 3–101) and includes 10 subjects with an actual body weight less than 12kg. A total of 785 quantifiable concentrations are available for PK modeling. The range of observed busulfan concentrations is 0–3163 ng/mL. Forty-three subjects (83%) had intensive PK performed on more than one occasion.
CONCLUSION: Data collection is complete. PK analysis will be completed and results available at the time of the ACCP Annual Meeting.

455. A retrospective descriptive study of combination antifungal therapies in pediatric oncology patients. *Whitney L. Davis, Pharm.D. Candidate*, William L. Greene, Pharm.D., Jerry L. Shenep, M.D., Randal T. Hayden, M.D., Brandon M. Triplett, M.D.; St. Jude Children's Research Hospital, Memphis, TN
PURPOSE: Invasive fungal infections are a major cause of mortality and morbidity in immunocompromised patients such as those treated at St. Jude Children's Research Hospital. Though they have not been adequately evaluated in clinical trials, combination antifungal therapies are sometimes used to treat invasive fungal infections. The risk-to-benefit profile of antifungal therapies is unknown as they are more expensive than monotherapies and potentially more toxic. This study is an observational description of combination antifungal therapy administered to pediatric and adolescent oncology patients. Our goal is to identify practices which vary from currently published treatment guidelines, and to stimulate further study and performance improvement efforts involving treatment of these patients.
METHODS: We will conduct a retrospective chart review using an electronic medical record system. All medical records reflecting an admission between February 2006 and June 2011 during which a patient received concurrent therapy with two or more systemic antifungal drugs for more than 48 hours will be evaluated. Specific drug combinations, drug class combinations, dosages, routes, frequencies, durations of therapy, and serum concentrations will be described as well as perceived toxicities and breakthrough infections.
RESULTS: Initial review of the electronic medical record system shows 137 patients receiving combination antifungal therapy as it has been defined for this study. While most patients received one instance of combination antifungal therapy there are some patients that received multiple regimens involving different antifungal agents. Thorough data analysis will be completed by October 2011.
CONCLUSION: Combination antifungal therapy is utilized in clinical practice at St. Jude Children's Hospital. More definitive conclusions characterizing this practice will be available by October 2011.

456. Improved safety of intermittent infusion delivery in the neonatal intensive care unit: establishing a need for the standardization of medication administration. *Amy Mitchell, Pharm.D., Candidate*[1], Thomas Young, M.D.[2], Nancy Gary, RN[2], Angela Peake, Pharm.D.[2], Rhonda Zillmer, Pharm.D.[2], Laura Hayn, Pharm.D., BCPS[2]; (1)Campbell University College of Pharmacy and Health Sciences, Buies Creek, NC; (2)WakeMed Health and Hospitals, Raleigh, NC
PURPOSE: Variations in medication administration can result in incomplete medication delivery, inappropriately rapid infusion times, and/or administration of excessive fluid volumes. This study is an interdisciplinary quality improvement project involving pharmacy, nursing and medicine that includes standardization of the medication administration process along with infusion and flush time practice in a neonatal intensive care unit (NICU).
METHODS: This study assessed variability in practice of drug infusion times, flush infusion times, and flush infusion volumes in a NICU via a voluntary, anonymous survey of nursing staff. Three drugs that require different infusion and flush times were used in the survey: ampicillin (slow push), gentamicin (30 minutes) and vancomycin (60 minutes). The nurses listed their current practice of drug infusion times, flush infusion times, and flush infusion volumes for each drug and responses were compared.
RESULTS: Overall, 34 out of 93 nurses completed the survey. A total of 33 (97%) respondents documented appropriate medication infusion rates. Only 2 (5.9%) respondents documented an appropriate flush

time. After noting the variability of flush times, an analysis of intermittent IV drugs commonly used in the NICU (n=72) and the volume remaining in the tubing post infusion was performed. A list of safe flush times was developed.
CONCLUSION: The variability of results demonstrated a need for a standard medication administration protocol. A comprehensive chart of intermittent IV drug dosing volumes, infusion volumes, and infusion and flush times for the smallest and largest babies in the NICU was developed. The chart contributed to a standard medication administration protocol. The protocol has been written, and nursing education will take place.

Pharmacoeconomics/Outcomes

457. Promoting sustainability: advocating the implementation of a community-based, self- managed, pharmacist-led diabetes care program in a coastal community in the Philippines. *Marie Jett V. Cabrera, Student*, Carlo Antonio G. Boado, Student, Peter F. Quilala, R.Ph., M.D.; University of Santo Tomas, Manila, Philippines
PURPOSE: Diabetes mellitus is enlisted by the Department of Health as the 8th leading cause of mortality in the Philippines. At the current estimate of the population, this means 2.5 million Filipinos with diabetes, with perhaps an equal number remains undiagnosed. This study was carried out to 1.) identify patients at risk for diabetes and provide management for the disease, 2.) support the feasibility of a sustainable community-based, self- managed, pharmacist-led diabetes care program in a coastal community, 3.) teach the stakeholders the program process through mentoring strategies, and 4.) disseminate information packets and conduct classroom sessions.
METHODS: The program was divided into nine stations, namely, patient registration, medical history, medication history, vital signs, capillary blood glucose determination, visual acuity test, podiatric examination, diabetes risk calculation, and medication counseling. Themed activities were also done which included nutritional strategies and glycosylated hemoglobin determination. To promote sustainability, the second part of the project was conceptualized. It was divided into five phases. These were 1.) education about diabetes, 2.) establishment of the importance of knowing the HbA1c, 3.) institution of a medication review protocol for the community, 4.), and 5.) full view on how diabetes nutrition and physical activity seminars were administered respectively. To evaluate on the community's competence on operating the program, clinical outcomes, patient's demand for services, self-management behavior changes, and patient and provider's satisfaction were obtained and measured.
RESULTS: Among the 27 patients, 36% were at risk for pre-diabetes mellitus, while 8% have the disease. The study utilized two health surveys, SF-36 and Diabetes Related Quality of Life Survey (DRQoL). Satisfaction on 1.) Diabetes control from 16% was significantly raised to 84%, and 2.) Self-care regimen from 23% was significantly raised to 77%.
CONCLUSIONS: The patients seen by the clinical pharmacist report both excellent diabetes-related and overall quality of life.

Pharmacoepidemiology

458. Drug-induced acute renal failure using the FDA adverse event reporting system database. *Ali Alhammad, M.S.*, Abdulkhaliq J. Alsalman, M.S., Maitham A. Al Hawaj, B.S., Yousef N. Alhashem, M.S., Wally R. Smith, M.D., Spencer E. Harpe, Pharm.D., Ph.D.; Virginia Commonwealth University, Richmond, VA
PURPOSE: The incidence of acute renal failure (ARF) is increasing; A substantial proportion of these cases are due to drug-induced nephrotoxicity. Data from post-marketing surveillance programs, like the FDA Adverse Event Reporting System (AERS), can be useful in assessing the risk of an adverse drug event (ADE). Our objective is to describe reports with ARF (cases) and reports without ARF (non-cases) and outcomes resulting from ARF using the AERS database.
METHODS: Data were extracted from the AERS database from 2004–2009. All reports of cases and non-cases were described and analyzed interim of suspected drugs, health outcomes, and other characteristics. Descriptive statistics (frequencies and proportions) and χ^2 tests were used.
RESULTS: The AERS data used in this study represents 2,231,689 reports from 184 countries, of which 27,190 were reports of ARF. There was approximately a two-fold increase in the percentage of reports of ARF from 2004 to 2009 (n = 3,594; 13% to n = 6,104; 22%, respectively). Most reports were submitted by manufacturers (cases = 89%, non-cases= XX%). The majority of reports were for infants (cases = 75%, non-cases = 57%). In cases, drugs were the primary suspect, the secondary suspect and concomitant in 18%, 14% and 66% of reports, respectively. The five drugs with the highest reported frequencies of ARF were rofecoxib, valacyclovir, metformin, simvastatin, and digoxin. Unfavorable outcomes were more likely to occur in cases than non-cases (death 24% vs. 12%, life threatening condition 21% vs. 5%, initial or prolonged hospitalization 76% vs. 33%, disability 6% vs. 4% and required intervention 4% vs. 2%; p-value < 0.001, for all comparisons).
CONCLUSIONS: These preliminary findings present an overall picture of reports with ARF. These findings can be informative for regulatory authorities and healthcare professionals. Additional analyses with reporting odd ratios (ROR) are needed to support these initial findings.

Pharmacogenomics/Pharmacogenetics

459. Association between the *CYP2C98 variant and warfarin clearance in African Americans.** *Katarzyna Drozda, Pharm.D. Candidate*[1], Harumi Takahashi, Ph.D.[2], Shitalben R. Patel, M.S.[1], Nancy L. Shapiro, Pharm.D., BCPS[1], Edith A. Nutescu, Pharm.D.[1], Larisa H. Cavallari, Pharm.D.[1]; (1)University of Illinois at Chicago College of Pharmacy, Chicago, IL; (2)Meiji Pharmaceutical University, Tokyo, Japan
PURPOSE: *S*-warfarin is metabolized by the polymorphic CYP2C9 enzyme. The *CYP2C9* R150H (*8) allele is common (frequency of 0.07) and associated with lower warfarin dose requirements in African Americans. However, there are limited data on its functional effects. We sought to determine the impact of the *CYP2C9**8 allele on metabolic clearance of warfarin.
METHODS: A genetic sample and data were obtained from 38 African Americans on a stable warfarin dose. Genotype was determined by pyrosequencing or capillary sequencing. *S*- and *R*-warfarin steady-state plasma concentrations (C_{ss}); oral, unbound clearance ($Cl_{po,u}$) of *S*-warfarin; oral clearance (Cl_{po}) of *R*-warfarin; and *S*- to *R*-warfarin ratio were determined by HPLC and compared between *CYP2C9**1 homozygotes (n=26) and *8 carriers (n=12).
RESULTS: Data are shown in the table. Consistent with previous data, warfarin dose requirements are 27% lower with the *8 allele. As expected, *R*-warfarin clearance was similar between genotype groups. However, $Cl_{po,u}$ of *S*-warfarin was reduced by 30%, and *S*- to *R*-warfarin C_{ss} was increased by 31% with the *CYP2C9**8 allele versus the *CYP2C9**1/*1 genotype.
CONCLUSION: Our results support decreased *S*-warfarin clearance as the mechanism underlying lower warfarin dose requirement with *CYP2C9**8 allele.
Table 1.

	*1/*1 (n=26)	*1/*8 or *8/*8 (n=12)	p value
Warfarin (mg/d)	7.4 ± 3.2	5.4 ± 1.9	0.02
Cl_{po} (ml/min/m^2)	0.94 ± 0.27	0.90 ± 0.22	NS
$Cl_{po,u}$ (ml/min/m^2)	122 ± 66	85 ± 27	0.02
Cp 0.65 ± 0.22	0.85 ± 0.27	0.02	
Mean ± SD			

461. Breast cancer patient understanding and knowledge of pharmacogenomic testing in Lineberger Comprehensive Cancer Center trial 0801. *Andrea N. Yuen, Pharm.D. Candidate*[1], Jeffrey M. Peppercorn, M.D.[2], Lynn G. Dressler, Dr.PH.[3], Wing K. Chiu, M.S.[4], Christine M. Walko, Pharm.D.[1], Peter Rubin, M.D.[5], Oludamilola A. Olajide, M.D.[6], Rachel E. Raab, M.D.[7], Daniel Carrizosa, M.D.[8], Steven W. Corso, M.D.[9], Garry Schwartz, M.D.[10], Howard L. McLeod, Pharm.D.[3], Lisa A. Carey, M.D.[4], William J. Irvin Jr., M.D.[4]; (1)University of North Carolina (UNC) Eshelman School of Pharmacy, Chapel Hill, NC; (2)Duke University, Durham, NC; (3)UNC Institute of Pharmacogenomics and Individualized Therapy, Chapel Hill, NC; (4)UNC Lineberger Comprehensive Cancer Center (LCCC), Chapel Hill, NC; (5)Moses Cone Regional Cancer Center,

Greensboro, NC; (6)Rex Hematology/Oncology Associates, Raleigh, NC; (7)East Carolina University, Greenville, NC; (8)Carolinas Medical Center, Charlotte, NC; (9)Palmetto Hematology/Oncology, Spartanburg, SC; (10)Northeast Oncology Associates, Concord, NC

PURPOSE: As pharmacogenomic research becomes more prevalent, it is important to assess the motivation and understanding of trial participants to assess areas for improvement in informed consent. This study was conducted to examine these issues in patients participating in a pharmacogenomic trial.

METHODS: We conducted surveys described below among patients enrolled in a prospective study of CYP2D6 genotype-guided tamoxifen therapy for breast cancer. This trial evaluated changes in endoxifen concentrations among patients with dysfunctional CYP2D6 alleles who received an increased dose of tamoxifen. At the time of consent, participants completed a 25 item paper survey addressing genetic knowledge (T/F statements), the trial's purpose (5 point Likert Scale responses) and reasons for their participation (check all that apply). Descriptive statistics were provided for all responses.

RESULTS: 99% (376/382) completed the survey. The top three reasons for participating in this trial was: *to help other breast cancer patients (82%)*; *to help their physician understand the best way to treat their cancer* (80%); and *wanting a genetic test to show how their body uses tamoxifen* (71%). 85% correctly answered at least 5/8 of the genetic knowledge questions. Although 96% agreed that the trial's purpose was *to identify how different people respond to tamoxifen*, nearly 33% also believed that its' purpose was *to study the inherited nature of breast cancer*. Even though the informed consent stressed lack of direct patient benefit, 72% believed that *the trial would help them directly*.

CONCLUSION: Despite a general understanding of genetics, a substantial percentage of participants demonstrated confusion regarding the trial's purpose. Participants misunderstood the nature of the research, potential for direct personal benefit, and the role of the trial as a means to gain access to a test that was commercially available. These findings highlight considerable room for improvement in patient education in pharmacogenomic trials.

462. The association between NF-κB gene polymorphisms and allograft survival in the Hispanic kidney transplant population. *Eunah Cho, Pharm.D., Candidate*[1], David Min, Pharm.D[1], Ian V. Hutchinson, Ph.D.[2]; (1)Western University of Health Sciences, College of Pharmacy, Pomona, CA; (2)USC School of Pharmacy, Los Angeles, CA

PURPOSE: NF-κB is an essential transcription factor involved in cellular responses to stimuli such as cytokines, which play a key role in regulating the immune and inflammatory response during allograft rejection. The objectives of this study are: 1) to examine the NF-κB gene polymorphism in relation to risk of graft failure, and 2) to evaluate the risk factors of graft failure in renal allograft recipients.

METHODS: A total of 690 Hispanic patients who received kidney allograft between 2001 and 2010 at St. Vincent Medical Center were retrospectively evaluated. Graft survival time and other risk factors were obtained through TranTrak®; NF-κB polymorphism (NF-κB 1, NF-κB 2 and NF-κB inducing kinase) was genotyped using the Tag-Man-PCR method. All analyses were performed using SPSS version 14.0 (SPSS). The cumulative probability and associated factors of graft survival time, rejection, and graft failure were obtained through the Kaplan and Meier model and Cox regression analysis.

RESULTS: The primary outcome regarding NF-kB polymorphism in relation to risk of graft failure is currently being processed. The clinical data collection for the secondary outcome regarding the risk factors of graft failure has been completed. At multivariable Cox regression analysis, creatinine at one year (P<0.001; HR 3.58), cadaver donor (P<0.001; HR 1.45), diabetes (P=0.009; HR 1.48), delayed graft function (P=0.022; HR 1.43) were associated with the graft survival time, rate of rejection, and graft loss.

CONCLUSION: The associated predictors of graft survival time in the Hispanic renal allograft recipients were evaluated. However, the contribution of NF-κB polymorphisms to graft survival time along with the above risk factors is still currently being analyzed, and the conclusion of the study will be presented once completed.

463. Effects of CYP2D6*10/*10 genotype on the pharmacokinetics of metoclopramide. *Hye-In Lee, M.S.*[1], Chang-Ik Choi, M.S.[1], Jung-Woo Bae, Ph.D.[2], Choon-Gon Jang, Ph.D.[1], Seok-Yong Lee, Ph.D.[1]; (1)School of Pharmacy, Sungkyunkwan University, Suwon, Gyeonggido, South Korea; (2)College of Pharmacy, Keimyung University, Daegu, South Korea

PURPOSE: Metoclopramide, a dopamine D_2 receptor antagonist, is used as an antiemetic agent. Metoclopramide is mainly metabolized via monodeethylation, which is primarily mediated by CYP2D6 isozyme. We investigated the effects of *CYP2D6* genetic polymorphism on the pharmacokinetics of metoclopramide.

METHODS: Eighteen subjects were selected and they were divided into two different groups according to *CYP2D6* genotype, *CYP2D6*1/*1* (n=10) and *CYP2D6*10/*10* (n=8). After overnight fasting, each subject received a 10 mg oral dose of metoclopramide. Blood samples were collected up to 24 hr after drug intake, and plasma concentrations of metoclopramide were determined by validated HPLC-MS/MS method.

RESULTS: C_{max} and AUC_{inf} of metoclopramide in *CYP2D6*10/*10* were 1.5- and 2.1-fold higher than those in *CYP2D6*1/*1* ($P<0.01$ and $P<0.001$, respectively). AUC_{inf} of metoclopramide in *CYP2D6*1/*1* and *CYP2D6*10/*10* was 161.6 ± 41.1 ng·hr/mL and 341.8 ± 68.2 ng·hr/mL, respectively. Oral clearance of metoclopramide in *CYP2D6*10/*10* was 53% lower than that in *CYP2D6*1/*1* ($P<0.001$).

CONCLUSION: *CYP2D6*10* allele is found to affect the pharmacokinetics of metoclopramide.

464. CYP2D6*10/*10 genotype significantly affected the pharmacokinetics of tamsulosin. Hye-In Lee, M.S.[1], Chang-Ik Choi, M.S.[1], Jung-Woo Bae, Ph.D.[2], Choon-Gon Jang, Ph.D.[1], *Seok-Yong Lee, Ph.D.*[1]; (1)School of Pharmacy, Sungkyunkwan University, Suwon, Gyeonggido, South Korea; (2)College of Pharmacy, Keimyung University, Daegu, South Korea

PURPOSE: Tamsulosin, an antagonist of α_{1A} adrenoceptors in the prostate, is indicated for treatment of the signs and symptoms of benign prostatic hyperplasia. Tamsulosin is extensively metabolized, mainly by CYP3A4 and CYP2D6. The *CYP2D6*10* allele, leading to a very unstable enzyme with abnormal folding and reduced substrate affinity, is found with higher frequency in Asian populations. We investigated the effects of *CYP2D6*10/*10* genotype on the pharmacokinetics of tamsulosin.

METHODS: Sixteen subjects were selected and they were divided into two different groups according to *CYP2D6* genotype, *CYP2D6*1/*1* (n=8) and *CYP2D6*10/*10* (n=8). After overnight fasting, each subject received a 0.2 mg oral dose of tamsulosin. Blood samples were collected up to 48 hr after drug intake, and plasma concentrations of tamsulosin were determined by validated HPLC-MS/MS method.

RESULTS: C_{max} and AUC_{inf} of tamsulosin in *CYP2D6*10/*10* were 1.6- and 1.9-fold higher than those in *CYP2D6*1/*1* ($P<0.01$ and $P<0.001$, respectively). AUC_{inf} of tamsulosin in *CYP2D6*1/*1* and *CYP2D6*10/*10* was 43.0 ± 9.6 ng·hr/mL and 81.0 ± 12.2 ng·hr/mL, respectively. Oral clearance of tamsulosin in *CYP2D6*10/*10* was 52% lower than that in *CYP2D6*1/*1* ($P<0.001$).

CONCLUSION: *CYP2D6**10 allele has significant impact on the pharmacokinetics of tamsulosin.

465. Effect of CYP2D6*10 allele on the pharmacokinetics of propranolol in Koreans. *Hye-In Lee, M.S.*[1], Chang-Ik Choi, M.S.[1], Jung-Woo Bae, Ph.D.[2], Choon-Gon Jang, Ph.D.[1], Seok-Yong Lee, Ph.D.[1]; (1)School of Pharmacy, Sungkyunkwan University, Suwon, Gyeonggido, South Korea; (2)College of Pharmacy, Keimyung University, Daegu, South Korea

PURPOSE: Propranolol is a non-selective β-adrenergic blocking agent used in the treatment of hypertension, angina pectoris and cardiac arrhythmias. The major metabolic pathway of propranolol, 4-hydroxylation, is mediated by polymorphic CYP2D6. We studied to evaluate the effects of major polymorphism of the *CYP2D6*10* on pharmacokinetics of propranolol.

METHODS: A 40-mg oral dose of propranolol was given to Korean volunteers with different *CYP2D6* genotype. Propranolol was analyzed by HPLC-fluorescence in plasma samples collected up to 24

hour after drug intake.
RESULTS: Pharmacokinetic parameters of propranolol were significantly different between subjects with homozygous *CYP2D6*1* allele and those heterozygous for the *CYP2D6*10* and homozygous *CYP2D6*10* allele. In subjects heterozygous and homozygous for the *CYP2D6*10* allele, C_{max} and $AUC_{0-\infty}$ of propranolol were greater, oral clearance was lower than those in homozygous *CYP2D6*1* subjects.
CONCLUSION: The *CYP2D6*10* allele was shown to be associated with decreased metabolism of propranolol.

Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

466. Characterization of polymyxin B (PB) against *Acinetobacter baumannii* using pharmacokinetic and pharmacodynamic (PK/PD) approaches. *Marie San Roman, Pharm.D. Candidate*[1], Brian T. Tsuji, Pharm.D.[2]; (1)University at Buffalo, Buffalo, NY; (2)Laboratory for Antimicrobial Pharmacodynamics University at Buffalo, State University of New York, Buffalo, NY
PURPOSE: Infections caused by *A.* have become increasingly resistant to current therapeutic options, leading clinicians to utilize last line therapeutic options such as PB. The objective of this study was to characterize killing and define the PK/PD profile of PB against *A.* .
METHODS: *A.* ATCC 19606 was utilized at inoculums of 10^6 CFU/mL and 10^8 CFU/mL against varying concentrations of PB (0.5, 1, 2, 4, 8, 16, 32 and 64 mg/L) using a static time kill experiment with sampling time points at 0, 0.5, 1, 2, 4, 6, 8, 24, 26, 28, 30, 32 and 48 hour. Pharmacodynamic analysis was performed by fitting data to a Hill type mathematical model to compare pharmacodynamic parameters [Equation: E=E0-(-C^H)EC50^H+C^H)].
RESULTS: PB was rapidly bactericidal against a 10^6 inoculum of *A.* at 1mg/L to 64 mg/L, with a log decrease respectively, by 8 hr. At concentrations below 4 mg/L, there was regrowth by 48 hr versus complete bacterial eradication with concentrations above 4 mg/L. At 10^8 CFU/mL, PB killing was attenuated at concentrations below 16 mg/L, with little change seen in bacterial counts. At a concentration of 32 mg/L, an initial log decrease of 5.96 was seen in the first 8 hours, with subsequent regrowth. At a concentration of 64 mg/L, complete bacterial eradication was seen by 8 hours. A Hill type model characterized the PK/PD data well ($R^2 > 0.9$), with changes in the following parameters at $10^6/10^8$ CFU/mL: : 4.1/3.2, EC50: 5.9/21.6, H: 4.2/2.3.
CONCLUSIONS: PB killing was rapid at a lower inoculum of 10^6 over the first 8 hours, with regrowth seen in concentrations below 4 mg/L. At a higher inoculum, the killing of *A.* by PB is attenuated, with little change in bacterial count noted for most clinically relevant concentrations, which may have implications for the treatment of high density infections.

467. Attenuation of vancomycin pharmacodynamics (PD) due to dense inoculum methicillin-resistant *Staphylococcus aureus* (MRSA). *Curtis Johnston, Pharm.D. Candidate, 2012*, Brian T. Tsuji, Pharm.D.; Laboratory for Antimicrobial Pharmacodynamics University at Buffalo, State University of New York, Buffalo, NY
PURPOSE: Emergence of vancomycin heteroresistant sub-populations plays a significant role in treatment failure of
METHODS: A community acquired isolate (MRSA PFGE type USA300) was used in all experiments. Time kill experiments were conducted over 48 hr for three different inoculums (10^4, 10^6, 10^8 colony forming units (CFU)/, and using non-linear regression a four-parameter concentration-effect Hill-type model was fitted to the effect parameter using the equation: $E=E_0-[(Emax*x^H)/(EC50^H+x^H)]$.
RESULTS: At high (10^8 CFU/inoculums of MRSA, the bactericidal activity of vancomycin was significantly attenuated. Simulating clinically relevant vancomycin trough concentrations of 16 mg/L, the following log changes in bacterial counts were seen at 48 ht for the initial inoculums of $10^8/10^6/10^4$ CFU/: 0.1/-2.8/-4.2 $\log_{10}$ CFU/. Although greater reductions in bacterial counts were seen at lower starting inoculums, no killing was seen at 48 hr regardless of starting inoculum for any concentration below 16 mg/L. PK/PD analysis revealed significant differences across the following parameters representing decreases in bactericidal activity with increasing initial CFU/ml):
CONCLUSION: High initial inoculum MRSA attenuated the bactericidal activity of vancomycin. These results have significant clinical implications regarding the utility of vancomycin in high density infections: aggressive exposure (AUC/MIC) profiles may be necessary for vancomycin monotherapy or combinations/alternative agents should be considered.

Psychiatry

468. Blue genes: genetic variant of brain-derived neurotrophic factor associated with depression index in post-coronary artery bypass graft patients. *Diana N. Pinchevsky, Pharm.D.*, Indrani Halder, Ph.D., Bea Herbeck Belnap, Dr.Biol.Hum., Bruce L. Rollman, M.D., M.P.H., Robert E. Ferrell, Ph.D., Tanya J. Fabian, Pharm.D., Ph.D., BCPP; University of Pittsburgh, Pittsburgh, PA
PURPOSE: Depression and cardiovascular disease are often
METHODS: Mouthwash samples were collected from 237 of 453 depressed and non-depressed patients enrolled in the
RESULTS: Minor allele frequency of *BDNF* rs6265 was 18% and allelic distribution of *BDNF* genotypes was within Hardy-Weinberg equilibrium, $X^2 = 0.094$ p value = 0.76. The GG genotype at rs6265 was more commonly associated with depression defined by a score of >9 on the PHQ-9, $X^2 = 3.02$ p value = 0.08, especially in women, $X^2 = 4.94$ p value = 0.03. The DISH scores, used as a continuous measure of depression severity, were also associated with the GG genotype, p-value = 0.02.
CONCLUSION: In post-CABG patients, vulnerability to depression and depressive symptom severity are associated with the rs6265 GG genotype, while the A allele appears to be protective. This effect is particularly apparent in women. These findings warrant further validation and exploration of *BDNF* in relation to the disease state. Depression in cardiovascular disease is complex and genetic variability of *BDNF* may be a contributing component and a potential treatment target.

Substance Abuse/Toxicology

469. Benzodiazepine use in alcohol withdrawal syndrome at an academic medical center. *Kyle A. Amelung, Pharm.D. Candidate 2012*, Eli N. Deal, Pharm.D., BCPS; Barnes-Jewish Hospital, St. Louis, MO
PURPOSE: This retrospective review was completed to assess practices in managing alcohol withdrawal syndrome (AWS) at a 1300-bed tertiary academic medical center.
METHODS: Medical records were reviewed on 100 randomly-selected patients admitted between January 1 and June 30, 2010 with an ICD-9 code for alcohol use/abuse and an active benzodiazepine (BZD) order for at least 24 hours. Patients were excluded if BZD use was for sedation or non-alcohol withdrawal related anxiety. Documented information included demographic and admission information, past medical history, ethanol level upon admission, utilization of an AWS order set, alcohol withdrawal medication regimen (agent, route, and fixed-schedule or symptom-triggered dosing), and total amount of BZD administered over the length of stay.
RESULTS: The average patient was a 48-year old male who consumed 10.6 drinks per day. Approximately one-third of patients had a history of AWS with 15% having a noted history of seizures related to alcohol withdrawal. One-third had a measurable ethanol level upon admission with the mean being 233 mg/. The majority of patients were admitted to the medicine service (82%). An alcohol withdrawal order set was utilized in 45% of all patients. Overall, a fixed-regimen was chosen in 50% of cases and a symptom-triggered regimen was chosen in 87% of cases. The mean total amount of (lorazepam-equivalent) BZDs administered was 16.6 milligrams over an average length of stay of 5.4 days. When only fixed-schedule orders were written (n=12), the total amount of medication administered was 27.4 milligrams. When only symptom-triggered orders were written (n=50), the total amount of medication administered was 3 milligrams.
CONCLUSIONS: The BZD prescribing practices for AWS at this institution are varied. This could be due to a number of factors including extensive patient differences, the high number of prescribing physicians, and the lack of standardized assessments for symptoms of

alcohol withdrawal.

Transplant/Immunology

470. Effectiveness and safety of influenza vaccine in first six months post-lung transplant. *Kalynn A. Rohde, Student*, John J.M. Moran, B.S., Mary S. Hayney, Pharm.D., M.P.H.; University of Wisconsin School of Pharmacy, Madison, WI

PURPOSE: Clinicians may be reluctant to administer influenza vaccine to the recently transplanted because of hypothesized low immune responses and the possibility of inducing acute rejection. Because the influenza vaccine changes annually, all patients must be immunized each season. We hypothesized that individuals receiving influenza vaccine within the first six months following transplantation would have similar antibody responses and rates of acute rejection to those who had been transplanted up to 24 months ago.

METHODS: As part of a five-year study of influenza antibody response in lung transplant patients, we obtained serum prior to and 2-4 weeks following influenza immunization for each season. The recently transplanted group consisted of individuals who were immunized within six months of transplant date. The control group consisted of individuals who were immunized 6-24 months following transplantation. Influenza vaccine antibody concentrations in serum were measured using hemagglutination inhibition assays. Seroprotection (antibody titer at least 1:40) and seroconversion (four-fold increase in antibody concentration following immunization) rates between the two groups were compared. Rates of acute rejection in months following vaccination for the recently transplanted (November, December, and January) were compared to rates in months distant from vaccination for the control group (June, July, and August).

RESULTS: Seroprotection rates were similar between the two groups (Recently transplanted (n=15) vs. control (n=17) 87–93% vs. 88–94%; not significant (NS); χ^2). Seroconversion rates ranged from 7–33% in recently transplanted and 25–31% in controls (NS; Fisher's exact). Episodes of acute rejection rates were similar between the two groups (4 (27%) recently transplanted group vs. 3 (18%) control group; NS; Fisher's exact).

CONCLUSION: The rates of seroprotection, seroconversion, and acute rejection in the recently transplanted and control group are similar. Lung transplant patients should receive the influenza vaccine each season without regard to time since transplantation.

Women's Health

471. The pharmacokinetics of metoprolol during pregnancy. *Tracy Yep, B.S.*[1], Sara Eyal, Ph.D.[2], Thomas R. Easterling, M.D.[3], Danny D. Shen, Ph.D.[4], Edward J. Kelly, Ph.D.[4], Gary D.V. Hankins, M.D.[5], Steve Caritis, M.D.[6], Linda Risler, B.S.[1], Mary F. Hebert, Pharm.D., FCCP[3]; (1)University of Washington Department of Pharmacy, Seattle, WA; (2)Institute of Drug Research, Jerusalem, Israel; (3)University of Washington Departments of Pharmacy and Obstetrics & Gynecology, Seattle, WA; (4)University of Washington, Department of Pharmacy, Seattle, WA; (5)University of Texas Medical Branch Department of OB/GYN, Galveston, TX; (6)Magee-Womens Hospital, Pittsburgh, PA

PURPOSE: The objective of this study was to evaluate the steady-state pharmacokinetics of metoprolol during pregnancy.

METHODS: Plasma and urine concentrations of metoprolol and its metabolite, α-hydroxymetoprolol, were measured in twelve women treated with metoprolol (25–750 mg/day) for therapeutic reasons. Maternal and umbilical cord blood samples were obtained at delivery from 4 mothers and breast milk samples were obtained over one dosing interval in 2 mothers. Pharmacokinetic parameters were assessed by non-compartmental methods.

RESULTS: Metoprolol apparent oral clearance is higher during pregnancy (549±576 L/hr (NS; n=6) mid-pregnancy and 978±702 L/hr (P<0.05; n=9) late pregnancy) than in the non-pregnant state (249±132 L/hr (n=6) postpartum). Correspondingly, α-hydroxymetoprolol formation clearance was higher during pregnancy (82.7±122.8 L/hr (NS, n=5) mid-pregnancy and 106.0±75.4 L/hr (P<0.05, n=8) late pregnancy) than in the non-pregnant state (13.6±9.0 L/hr (n=6) postpartum). Metoprolol umbilical cord plasma concentrations ranged between non-detectable and 3.3 ng/mL. Relative infant exposure through breast milk to metoprolol and α-hydroxymetoprolol combined, was less than 2% of the mother's weight-adjusted dose.

CONCLUSION: Metoprolol pharmacokinetics change during pregnancy and the magnitude of change is highly variable. Metoprolol is readily transferred across the placenta, but exposure to metoprolol through breast milk is low. Due to the large gestational changes in metoprolol pharmacokinetics, clinicians should consider using an alternative β-blocker in this patient population.

472. Computer algorithm: a more sensitive tool than standard visual scoring for analyzing immunohistochemistry staining of the placental vasculature. *Michael P. Drozdowicz, Pharm.D., Candidate, 2012*[1], Katie Jaenecke, Pharm.D.[1], Andrew Tong, Pharm.D.[1], Albert Franco, M.D.[2], Daniel Brazeau, Ph.D.[3], Nilsa Ramirez, M.D.[4], Thomas J. Barr, B.S., MBA[4], William Beyer, BSEE, MSEE[4], Patty Fan-Havard, Pharm.D.[1]; (1)University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Amherst, NY; (2)Carolinas Medical Center, Charlotte, NC; (3)University of New England, Portland, ME; (4)The Research Institute at Nationwide Children's Hospital, Columbus, OH

PURPOSE: The gold standard for interpreting immunohistochemistry (IHC) stains relies on the subjective visual score made by an experienced pathologist. Computer analysis of IHC staining may offer greater sensitivity and reliability in detecting changes in protein expression. The aim of this study is to assess and compare these two techniques in their ability to detect differences in protein expression of β-catenin and VE-cadherin within the placental vasculature.

METHODS: Tissue-micro-arrays were created from cores of placental samples from healthy mothers (control), gestational diabetic mothers (GDM), and mothers being treated for HIV (n=68) and then IHC stained for beta-catenin or VE-cadherin. Fetal capillaries were selected and analyzed for protein staining by a pathologist's visual inspection and Aperio ImageScope positive pixel count algorithm, which respectively yielded a visual score and pixel count that were based on the following scale: 1–negative; 2–weakly positive; 3–positive; and, 4–strongly positive.

RESULTS: Using ANOVA analysis, significant correlations were found between visual score and strong positive pixel count ($p<0.05$) as well as intensity ($p<0.05$) for β-catenin and VE-cadherin. Computer-aided analysis detected significant differences in staining between GDM and control groups for both beta-catenin and VE-cadherin and between HIV and control groups for beta-catenin; visual scores failed to detect these differences.

CONCLUSION: Our preliminary data suggest that while visual scores and Aperio analysis are correlative, the computer-aided quantitative method may be more sensitive in the detection of differences between exposure groups than visual examination by a clinical pathologist.

LATE BREAKERS
ADR/Drug Interactions

473. Clindamycin induced acute kidney injury: Is this for real? *Nidhi Bansal, MBBS*, Jiwan Thapa, MBBS; SUNY Upstate Medical University, Syracuse, NY

PURPOSE: Clindamycin is commonly associated with gastrointestinal side effects. There is paucity of literature on its potential renal adverse effects.

METHODS: We report a case of 70 yo man presenting with leg cellulitis. Past medical history was significant for DM2, nephropathy, MRSA infection and left foot ulcers. He recently took oral ciprofloxacin without much response. He was allergic to penicillin and cephalosporins. Thus he was empirically started on clindamycin pending cultures. On day 3, serum creatinine rose to 1.7 mg/dl from baseline of 1.2 mg/dl. There was low grade fever, myalgias, fatigue but no rash/ joint pains and no signs/symptoms of hypovolemia/dehydration. Medications were reconciled to discontinue any offending drugs. By day 5, creatinine rose to 2.2 mg/dl. Urine analysis showed hematuria and pyuria. Differential WBC count revealed eosinophilia. Other urine, blood and radiologic investigations couldn't pinpoint underlying etiology. Repeat medication reconciliation revealed that clindamycin was the only new drug added.

We stopped clindamycin considering the possibility of clindamycin induced interstitial nephritis. AKI and symptoms resolved quite impressively over few days. Thus a diagnosis of clindamycin induced acute interstitial nephritis was made. He received IV vancomycin subsequently, tolerated it well and was discharged to home.
RESULTS: Clindamycin is commonly linked to *C. difficle* colitis and hematologic side effects. It could precipitate tubulointerstitial nephritis and AKI very rarely. Only 11 cases have been reported to FDA describing this entity. These account for 0.16% of total side effects. All cases were reported within 1 month of drug administration. Upto 50 % have been reported in > 60 years age group. Our patient`s clinical profile matched with these observations. The insult has been hypothesized to be immune complex mediated however the exact mechanism remains unknown.
CONCLUSION: Healthcare professionals should be aware of this rare, serious but potentially reversible side effect of clindamycin.

474. Adverse drug reactions in ambulatory care with an electronic medical record and electronic prescribing: Identification and characterization. *Katy E. Trinkley, Pharm.D.*, Harrison G. Weed, M.D., M.S., FACP, Stuart J. Beatty, Pharm.D., BCPS, Milap C. Nahata, Pharm.D., M.S., FCCP; Ohio State University Colleges of Pharmacy and Medicine, Columbus, OH
PURPOSE: This study was designed to characterize the types and frequency of adverse drug reactions (ADRs) that occured in a primary care setting using an electronic medical record (EMR) with electronic prescribing in order to identify features of prescribing which might avoid ADRs.
METHODS: Patients with a new prescription, defined as a new medication, a dose change, or a discontinuation who were seen at an outpatient Internal Medicine Clinic were evaluated for ADRs by EMR review and by telephone interview at 2 and 4 weeks after the new prescription. ADRs were independently assessed for causality, severity, preventability and ameliorability by a physician and a pharmacist using a grading instrument.
RESULTS: Of the 414 patients enrolled, 63 and 64% completed the 1st and 2nd telephone interviews, respectively. From the 835 new prescriptions, 29% were discontinued. Only 65% of the discontinuations were at the direction of a prescriber and 5% were due to an ADR. The 85 suspected ADRs were reviewed for causality and 42 were determined to be true ADRs. Of these, 21% were preventable, 36% ameliorable. There were 6 serious and 1 fatal or life-threatening ADRs. Preventable or ameliorable ADRs may have been avoided by better communication or prescribing practices.
CONCLUSION: ADRs continue to occur among outpatients despite use of an EMR with electronic prescribing. A substantial portion of these ADRs could be prevented with better communication and prescribing practices.

Ambulatory Care

475. Effectivenss of a pharmacist managed hypertension shared medical appointment. *Rachel N. Chandra, Pharm.D.*; Dayton Veterans Affairs Medical Center, Dayton, OH
PURPOSE: Shared medical appointments (SMA) are an alternative model for healthcare delivery in chronic diseases. In 2006 a SMA was initiated and led by a clinical pharmacist at the Dayton VAMC in an effort to optimize outcomes in high risk poorly controlled hypertensive veterans. Multiple models for SMAs have been developed. The model employed at the Dayton VAMC was a hybridized form as described by Noffsinger. This SMA model allowed for a multidisciplinary approach, improved access with reproducible methods.
METHODS: Patients were referred to the SMA by their primary care teams (PCT). The SMA entailed an estimated 90 minute session which met weekly. Interventions were based on current prescribing guidelines and recommendations from JNC-7. Nutrition and nursing services routinely participated. Patients were discharged when goal blood pressure was achieved. Groups were patients who received care from the SMA versus patients referred but declined to participate in the SMA and instead received usual care by their PCT. The variables include systolic blood pressure (SBP), admissions, clinic visits, medication classes and co morbidities. A total of 628 patients were referred, 72% (450) were seen in the SMA and 18% (178) were followed by their primary care teams.
RESULTS: The mean SMA clinic visits were 3.5. The two groups did not differ statistically with regards to age, sex, BMI, co-morbidities, and serum creatinine. Mean admissions for the two groups were 2.7 (SMA group) vs. 3.5 (comparator group). The initial mean SBP were 149.6 and 149.5 mm Hg respectively. SBP in both groups decreased however the change was larger in the SMA vs. comparator (-11.3 vs. -5.7 mmHg) ($p<0.05$).
CONCLUSION: Pharmacists led multidisciplinary SMA is an effective model in the management of hypertension among patients with multiple co morbidities.

Cardiovascular

476E. Is anemia associated with heart failure? NHANES database (2005–2006) analysis. *Abdulkhaliq J. Alsalman, M.S.*, Yousef N. Alhashem, M.S., Ali M. Alhammad, M.S., Maitham A. Al Hawaj, B.S., Mohammed A. Al Mohaini, B.S., Spencer E. Harpe, Pharm.D., Ph.D., M.P.H., Benjamin W. Van Tassell, Pharm.D., BCPS; Virginia Commonwealth University, Richmond, VA
PURPOSE: Anemia is a prevalent public health problem associated with increased risk of morbidity and mortality. It is also associated with cardiovascular disorders (CVDs) including heart failure (HF). In a large community study, 58% of HF patients had anemia. There is a wide variation in the reported prevalence of anemia among HF patients (7–50%). This community based study investigated whether anemia is associated with HF using data from National Health and Nutrition Examination Survey (NHANES) which is a national survey to assess the health and nutritional status in the United States.
METHODS: NHANES data from the 2005–2006 administration were combined and analyzed cross-sectionally. Descriptive statistics and univariate comparisons were used as appropriate. Weighted multivariable logistic regression was used to predict and compute odds ratios (OR) and 95% confidence intervals (CI) of the association between HF and anemia prevalence.
RESULTS: There were 953 respondents with anemia, and 180 respondents had HF. Among those with anemia, the proportion of African Americans was significantly higher than Caucasians (46% vs. 31%; $p<0.001$; respectively). Respondents with anemia were significantly more likely to have cancer, other CVDs status, and be pregnant than those without anemia ($p<0.001$, $p<0.001$, and $p<0.002$, respectively). In addition, prevalence of anemia was significantly higher in respondents with HF as compared to those with other CVDs (18% vs. 4%; $p<0.001$). Approximately 10% of HF respondents had anemia compared to just 2% among those without HF (OR=5.09, CI=5.08–5.11). This association remained statistically significant after adjusting for age, race, pregnancy status, cancer, smoking status, and other CVDs (OR=5.8, CI=5.54–5.96).
CONCLUSION: According to this study, the prevalence of anemia among HF patients is relatively high. African Americans and those with HF are more likely to experience anemia. The association between HF and anemia remained after controlling for confounders.
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477. Blockade of sodium entry ameliorates arrhythmias during calcium overload. *Przemyslaw Radwanski, Pharm.D., Ph.D.*, Steven Poelzing, Ph.D.; University of Utah, Salt Lake City, UT
PURPOSE: Heart failure and Andersen-Tawil syndrome Type 1 (ATS1), both linked to inward-rectifier potassium current (I_{K1}) abnormalities, are associated with ventricular arrhythmias. We previously demonstrated that a guinea pig model of drug-induced ATS1 (DI-ATS1) evidenced increased arrhythmia incidence preferentially originating from regions with increased Na^+/Ca^{2+}-exchanger (NCX) expression, suggesting a role not only for Ca^{2+} but also for Na^+ in ATS1-associated arrhythmogenesis. Therefore, we hypothesized that Na^+ channel blockade during DI-ATS1 will not only mitigate perturbations in Ca^{2+} handling but also will ameliorate arrhythmia burden.
METHODS: DI-ATS1 was induced by partial I_{K1} blockade with 10 μM $BaCl_2$ and 2mM $[K^+]_o$. Optical mapping with di-4-ANEPPS and indo-1 dyes were used to quantify ventricular conduction velocity (CV) and record Ca^{2+} transients respectively from Langendorff

perfused guinea pig ventricles.
RESULTS: Previously, the cardiac and not the tetrodotoxin (TTX)-sensitive Na^+ channels have been demonstrated to have a critical role in CV. Hence, as expected Na^+ channel blockade with 100 nM TTX during DI-ATS1 did not alter CV (n=6; p=ns). On the other hand, blockade with 1μM flecainide and 30 μM ranolazine during DI-ATS1 decreased CV by 14±5% (p<0.05). Furthermore, all modalities of Na^+ channel blockade decreased Ca^{2+} transient amplitude by 15±4% (p<0.05). Importantly, Na^+ channel blockade during DI-ATS1 either through TTX-sensitive or cardiac Na^+ channels (flecainide and ranolazine) ameliorated the arrhythmia burden relative to DI-ATS1 alone.
CONCLUSION: These data suggest that cytosolic Na^+ entry is necessary for arrhythmogenesis. Further, this is first report on ranolazine's effect on ventricular excitation suggesting similar pharmacology to flecainide**.** Na^+ influx might be necessary for propagation of changes in membrane potential secondary to spontaneous Ca^{2+} release. Alternatively, Na^+ influx can itself serve as a trigger for Ca^{2+} release. Importantly, inhibiting cytosolic Na^+ influx may offer a potential therapeutic target to alleviate arrhythmia burden during states of Ca^{2+} overload secondary to loss of I_{K1} function.

Community Pharmacy Practice

478. A community pharmacy, diabetes management program to improve biometric and cardiac risk factors. *Jamie Vortherms, Pharm.D.*, Michael Taitel, Ph.D., Leonard Fensterheim, M.P.H., Heather Kirkham, Ph.D., Ian Duncan, FSA; Walgreens, Deerfield, IL
PURPOSE: As a trusted source of healthcare information and services, pharmacists are ideally positioned to engage patients on the comprehensive topic of diabetes management. This study evaluated clinical changes in patients with diabetes who were enrolled in a pharmacy-led intervention program.
METHODS: The study period for this longitudinal cohort, pre-post research was January 1, 2010 (program inception) until April 30, 2011. Community pharmacists, who were certified in diabetes self-management, provided face-to-face, individual diabetes counseling to persons with type 2 diabetes and collected seven clinical biomarkers via portable, point-of-care testing devices: glycosylated hemoglobin (A1c), total cholesterol (TC), low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), triglycerides (TRIG), diastolic blood pressure (DBP), and systolic blood pressure (SBP). The Framingham risk score was used to estimate overall reduction in risk for cardiac complications
RESULTS: As of April 2011, 189 participants had data available from their 90-day evaluation. The average age of participants was 54 years (SD ± 9.3), and 53% (n = 100) were female. Comparing baseline to first follow-up, five of seven biomarkers—A1C, TC, HDL, TRIG, and SBP—significantly improved (p<0.05). On average, participants in the program decreased their 10-year Framingham risk score by almost 10% (p<0.01).
CONCLUSIONS: These early program results are consistent with other pharmacist-led intervention studies and suggest that pharmacists can play a crucial role in education and management of the diabetes patient. While not all metrics demonstrated significant improvement, the collective effect was statistically significant and more importantly may be clinically significant.

Education/Training

479E. The effect of integration of pharmaceutical care components in pharmacy schools curricula on medication adherence in Syria. *Anas Bahnassi, Ph.D.*; Arab International University, Damascus, Syria
PURPOSE: Understand the impact of inclusion of a modified clinical pharmacy course with a strong pharmaceutical care content on students of a Syrian university particularly to promote medication adherence among patients and its associated effects on blood pressure (BP) and low density lipoprotein cholesterol (LDL-C).
METHODS: Modifications were applied to clinical pharmacy curriculum. The passing students were asked to conduct a three phasal, prespective study, 200 community based patients aged 60 years or older taking at least 4 different maintainance medications were monitored over 12 months. Phases included; a 2-month baseline-adherence phase, a 6-month intervention phase where standardized medication education and direct pharmaceutical care have been closely carried out by students followed by a 4-month randomized observational phase where patients were randomly divided into continued pharmaceutical care group and usual care group. The primary endpoint was to measure medication adherence in the observational phase vs baseline-adherence phase, secondary endpoints included the measurement of the changes in BP and LDL-C values.
RESULTS: Among enrolled patients, CVD risk factors included 186 patients with treated hypertention and 106 patients with treated dyslipidemia. Baseline medication adherence was 41% ±[11.3], The percentage increased by the end of intervention phase to 86.7%±[9.2] (p<0.001). Four months after randomizations, patients with usual care showed a decrease in the persistance of medication adherence to 71.3%±[8.4] where as the pharmaceutical care group showed a rate of medication adherence of 85.2%±[9.4] (p<0.001) and a significant decrease in systolic BP in pharmaceutical care group vs usual care group. The changes were insignificant over the same period of time for LDL-C levels.
CONCLUSION: Pharmaceutical care inclusion in the pharmacy curriculum in Syrian universities is still limited. Pharmaceutical care practice in community pharmacies depends heavily on individual initiatives. The application of a pharmaceutical care program has achieved an increase in medication adherence, persistance, and significant reductions in clinical parameters. Interuption/discontinuation of this program is associated with decreased levels of medication adherence and direct effect on clinical parameters.
Presented at Presented at the Conference of the Arab Pharmacists Association in Damascus, Syria.

480. Evaluation of pharmacy resident perceptions, knowledge and interventions following a trauma response training program. *Stephen Rolfe, Pharm.D., BCPS*[1], Kimberly A. Pesaturo, Pharm.D., BCPS[2], Jeffrey Dandurand, Pharm.D., BCPS[3]; (1)University of New England, College of Pharmacy, Portland, ME; (2)Massachusetts College of Pharmacy and Health Sciences - Worcester/Manchester, Worcester, MA; (3)Clinical Pharmacy Associates, Laurel, MD
PURPOSE: The purpose of this study was to evaluate pharmacy resident perceptions of trauma response, perceived baseline level of trauma-related pharmacy knowledge and categorized clinical interventions over a six month period following educational and practical training.
METHODS: A pharmacy-focused trauma response training program was initiated for the PGY-1 and PGY-2 pharmacy residents in the emergency department (ED) at a large urban level-1 academic medical center. Residents completed didactic training during their initial residency orientation followed by preceptor-supported practical training. At the initiation of the training, pharmacy residents were asked to complete a survey that detailed the resident's perceived level of experience, comfort, and knowledge base for trauma response in an ED. Six months later, residents received a second survey as a follow-up measure of resident experience, comfort and knowledge. The primary and secondary outcomes of this study were the change in perception between the first and second survey and the characterization of pharmacy-related trauma interventions over the entire study period, respectively.
RESULTS: Eleven PGY-1 and PGY-2 pharmacy residents participated in the didactic training and subsequent trauma response program. A Mann-Whitney U test showed that baseline median scores related to resident comfort and perceived knowledge base significantly improved for twelve of fifteen questions at the six-month follow-up survey. Residents recorded participation in 399 traumas over six months. At least one intervention was made during 43% of traumas out of the 239 patients that received medications. The top three types of resident interventions were initiation of therapy, dosage recommendation, and drug information.
CONCLUSION: Completion of a trauma training program and subsequent preceptor-supported trauma experience allowed pharmacy residents increased comfort and perceived knowledge base with trauma response. Pharmacy residents were effective at intervening in traumas.

481. Pursuit of post-graduate training programs upon graduation. *Olga Hilas, Pharm.D., BCPS, CGP*, Sharon See, Pharm.D., BCPS; St. John's University College of Pharmacy and Allied Health Professions, Queens, NY

PURPOSE: The purpose of this study was to assess student interest in post-graduate training programs upon graduation and the attainment of post-graduate training positions.

METHODS: This study was designed to anonymously collect information from sixth-year pharmacy students (n = 238) regarding their pursuit and attainment of post-graduate residency or fellowship programs using Survey Monkey. Student participation was completely voluntary and all study materials were approved by the university's Institutional Review Board. The survey was emailed to students and weekly reminders were sent over a 4-week period. Survey questions included inquiries regarding pursuit of post-graduate training positions, cities and states of programs applied to, interviews obtained, "match" vs. "non-match" applications, academic history, extracurricular activities, professional affiliations, attainment of post-graduate positions and other plans upon graduation.

RESULTS: Fifty-eight percent of students completed the survey. Of these students, 25% sought a post-graduate pharmacy practice residency position. Of the remaining 75%, 4% sought a post-graduate fellowship program. The majority of students reported seeking positions in states along the eastern coast of the country, with only 3% applying to states in the west and midwest. Almost 50% of all students maintained cumulative grade point averages of 3.0 to 3.4, followed by 32% with averages of 3.5 to 4.0. The majority also participated in a variety of extracurricular activities, community service projects and professional organizations, while a minority participated in scholarly activities. Seventy-nine percent of student obtained interviews, but only 14 students reported obtaining positions. One student obtained a non-accredited residency position and no students obtained fellowship positions.

CONCLUSION: The results obtained from this study provide faculty members with valuable insight into student perceptions of and approach to pursuing post-graduate training programs. This information will be utilized to develop more effective educational sessions on post-graduate pharmacy training and opportunities for growth within the profession.

482. Assessment of the prevalence, structure and function of "informal" student chapters of ACCP. *Andrew Smith, Pharm.D.*; UMKC School of Pharmacy, Kansas City, MO

PURPOSE: A number of "informal" chapters of ACCP have begun to form to allow students increased opportunities to work towards the mission of ACCP on their campus. However, there is no clear understanding of the prevalence of these "informal" chapters as well as how they are structured and what functions they perform. Therefore this survey study was performed to describe the current state of 'informal' ACCP chapters at schools or colleges of pharmacy.

METHODS: A survey was designed that asked information such as size and type of institution, demographic information about the college of pharmacy liaison, utilization of ACCP student resources, the presence of and the structure and function of an 'informal' chapter of ACCP. The survey is being electronically sent to College of Pharmacy Liaisons registered with ACCP. The response period will be one month, with one reminder email after two weeks. The primary outcome of this study is a descriptive analysis of 'informal' student chapters of ACCP, to aid college of pharmacy liaisons that may be planning to start a chapter. Descriptive data will be presented using mean and standard deviation. Comparison between data will be made using student's *t*-test for continuous variables and χ^2 test for nominal or ordinal items. A p-value of < 0.05 will be considered statically significant. Statistical analysis will be performed using SPSS version 18 (SPSS, Inc., Chicago, IL).

RESULTS: Data collection will begin shortly and will be completed in August of 2011. Information presented will include demographic data, prevalence, structure and function of 'informal' chapters of ACCP. Data will be examined for predictors of the successful formation of an 'informal' student chapter.

Emergency Medicine

483. Development of a pharmacy computerized inventory program (PCIP) in an emergency department/intensive care unit, outpatient care, and a pediatric hospital in Haiti. *Michelle Holm, Pharm.D., R.Ph.*[1], John Rueter, R.Ph.[1], Maria Rudis, Pharm.D., R.Ph.[1], Chris Arendt, Pharm.D., RPh[1], Nikki Jensen,[2]; (1)Mayo Clinic, Rochester, MN; (2)PlanetJ Corporation, Escondido, CA

PURPOSE: After the 2010 earthquake in Haiti, a 220 bed comprehensive health facility developed rapidly in Port-au-Prince to care for maladies ranging from trauma to cholera. Our institution's mission at this facility was to help develop sustainable systems. Specifically, our objective was to develop a Pharmacy Computerized Inventory Program (PCIP) to monitor medication utilization and allow staff to provide sustainable patient care in 3 different hospital settings.

METHODS: A needs assessment of PCIP requirements was performed by our pharmacists with the facility's medical director. Needs included real-time data assessment of medication usage in 3 hospitals (ED/ICU, Inpatient / Ambulatory Care, and Pediatrics); simplicity and sustainability by local hospital personnel; and accommodation to further service expansion. Commercially available products did not meet identified needs. We partnered with a company tailoring web application tools and developed a PCIP that accomplished all identified needs. A plan for implementation of the PCIP included on-site and remote education of end-users.

RESULTS: A web-based PCIP was programmed in Haitian Creole and English. It encompasses all phases of the medication use process including: drug ordering, hospital drug requests, filling the drug requests, distribution and dispensing of the medications at the 3 hospitals; inventory of medications on hand and graphic charting of medication usage. The Haitian pharmacy and nursing staff were trained by 3 pharmacists from our institution (and local interpreters). Implementation including education occurred within weeks of program development and prior to completion of the medical mission.

CONCLUSION: The 3 Haitian hospitals now have the means to identify and order medications with a critically low supply as well as track usage for future medication needs. PCIP allows hospital staff to provide sustainable medication delivery and patient care with a simple, easy to use web based program customized to local needs.

Geriatrics

484. Clinical interventions of pharmacy practice residents on an acute care for elders unit. *Olga Hilas, Pharm.D., M.P.H., BCPS, CGP*; St. John's University College of Pharmacy and Allied Health Professions, Queens, NY

PURPOSE: The purpose of this study was to evaluate the clinical interventions proposed by post-graduate pharmacy practice residents during a 4-week experiential rotation on an inpatient geriatric unit.

METHODS: This study was designed to evaluate the types of clinical interventions made by pharmacy practice residents, time allotted for making and following-up on necessary recommendations and potential cost-savings associated with the interventions. Three residents documented all interventions proposed to the clinical pharmacist/preceptor and recommended to the medical team over a period of 4 weeks. Data obtained included the category of the intervention, drug(s) involved, estimated time of intervention, status of recommendation and estimated cost-savings of the intervention. All data was transferred and evaluated using the MedKeeper (RxRounds Interventions) program. The hospital Institutional Review Board reviewed and approved this study.

RESULTS: A total of 91 interventions were identified and proposed by the pharmacy practice residents during the 4-week period. More than 90% of the interventions were accepted by the medical residents and attending physicians (after consulting with the clinical pharmacist/preceptor). Approximately half of all interventions involved inappropriate drug dosing or utilization, mainly in patients with renal impairment. Other types of interventions included recommendations for appropriate drug monitoring, therapeutic necessity of certain medications, changes to standing and as needed orders, inappropriate or unnecessary therapy, and clinically significant interactions. Average time needed for an intervention and average savings per intervention varied according to category, but overall were

approximately 15 minutes and $100, respectively.
CONCLUSION: The results obtained from this study demonstrate the importance of thorough medication evaluations on a geriatric unit and the impact clinical pharmacists have on optimizing patient care. Training post-graduate pharmacy residents to identify potential therapeutic issues, formulate appropriate recommendations and follow-up on the status of those recommendations is imperative to their development into successful practitioners.

Medication Safety

485. Evaluation of infusion-related reactions with iron sucrose at a large tertiary medical center. *Diana R. Mack, Pharm.D.*[1], Leigh Anne Hylton Gravatt, Pharm.D., BCPS[2], Spencer E. Harpe, Pharm.D., Ph.D., M.P.H.[2]; (1)Virginia Commonwealth University Health System, Richmond, VA; (2)Virginia Commonwealth University School of Pharmacy, Richmond, VA
PURPOSE: This study was conducted to determine the association between intravenous iron sucrose dose and infusion rate with the development of an infusion-related reaction. Of the currently available intravenous iron preparations, iron sucrose has been associated with a more favorable safety profile thus has become the agent of choice at many institutions. Clinicians at Virginia Commonwealth University Health System (VCUHS) are prescribing high-dose iron sucrose infusions (> 300 mg) which is supported by limited data and adverse drug events associated with iron sucrose have been recorded through the institution's Patient Safety Net system.
METHODS: This retrospective case-control evaluation was conducted from September 12, 2005 through August 31, 2010. Case patients identified via adverse event reports were included if they were ≥ 18 years of age and received iron sucrose with a subsequent infusion-related reaction. Patients who received iron sucrose and did not experience an infusion-related reaction were identified as controls and matched at a 2:1 ratio to case patients.
RESULTS: A total of 9 case and 18 control patients were eligible for inclusion. Approximately 78% of all patients were female with a mean ± SD age of 36 ± 10.4 years. Thirty percent of all patients were receiving intravenous iron sucrose for anemia of chronic kidney disease. The most common signs and symptoms of an infusion-related reaction included hypotension, paresthesias, rash, and extremity swelling. In the bivariate analysis of dose compared to development of an infusion-related reaction, case patients were significantly more likely to have received a dose ≥ 400 mg of iron sucrose (OR [95% CI] = 9.16 [1.07–78.31]; p=0.043). Statistical significance was not found with regards to infusion rate.
CONCLUSION: Our findings suggest that high dose intravenous iron sucrose (≥ 400 mg) may be associated with a higher incidence of infusion-related reactions.

Psychiatry

486E. Effects of pharmacist drug regimen reviews on physicians' compliance with recommended laboratory monitoring criteria for psychotropic medications at a state supported living center. *Abimbola Farinde, Pharm.D., M.S., BCPP, CGP, FASCP, FACA*; Lufkin State Supported Living Center, Pollok, TX
PURPOSE: Many individuals that reside in state supported living centers for the developmental disabled and/or mentally impaired can be placed on a myriad of psychotropic medications to treat their disturbances. Appropriate and timely laboratory tests must be performed on all psychotropic medications to determine therapeutic levels for effectiveness and identify toxicities. It has been shown that failure to monitor drug therapy is among one of the most frequent causes of preventable adverse drug events. The errors that are associated with laboratory monitoring to generally tend to occur when there is a lack of baseline or follow-up laboratory work, or a delay in actions being taken to address abnormal lab results. The objective of this study is to determine if a pharmacist performing quarterly drug regimen reviews at a state supported living center can improve the compliance rate as it relates to meeting laboratory monitoring parameters for psychotropic medications.
METHODS: All the necessary documents/forms were submitted to the Texas Department of State Health Services Mental Health and Mental Retardation Research Administration Institutional Review Board #2 in Austin, Texas for review and approval. A retrospective chart review was performed on 50 residents at the Lufkin State Supported Living Center with an Axis I diagnosis of a psychotic disorder, bipolar disorder, or autism and Axis II diagnosis of mental retardation.
RESULTS: The performance of a quarterly drug regimen review by a pharmacist increased the likelihood of appropriate labs being done for individuals on psychotropic medications. From the fifty charts that were reviewed, residents who received the pharmacists' reviews (75%) had the recommended labs performed.
CONCLUSION: The results of this chart review will determine if a pharmacist's recommendations for appropriate laboratory monitoring of psychotropic medications can be instrumental in assessing for effectiveness of psychotropic medication therapy and minimize the development of adverse drug events or potential toxicities.
Presented at College of Neurologic and Psychiatric Pharmacy, Phoenix, Arizona, May 1-4, 2011 Texas Society of Health System Pharmacists San Antonio, Texas, April 14-17, 2011

Transplant/Immunology

487E. Impact of conversion to sirolimus-based immunosuppression on fibrosis progression in HCV+ liver transplant recipients. *Christin Rogers, Pharm.D.*[1], Daniel R. Stevens, B.S.[2], Michael Curry, M.D.[1]; (1)Beth Israel Deaconess Medical Center, Boston, MA; (2)Northeastern University, Boston, MA
PURPOSE: Hepatitis C (HCV) is the leading indication for liver transplantation. The optimal immunosuppression regimen for HCV+ liver transplant recipients remains unknown. The purpose of our study was to evaluate the impact of conversion from a calcineurin inhibitor (CNI) to sirolimus on fibrosis progression in HCV+ liver transplant (LT) recipients.
METHODS: Between May 2002 and August 2010, 115 HCV+ LT's were performed. Fifty-five patients were converted from CNI to SRL, of which 37 received SRL for ≥ 6 weeks with ≥ 100 days between first and last biopsy. Of the 60 maintained on CNI, 42 met criteria for inclusion as controls. Protocol liver biopsies assessed using the Metavir score were performed at 6 months, 12 months, annually and as clinically indicated.
RESULTS: Baseline donor and recipient demographics did not differ between the groups. Patients converted to SRL demonstrated a significantly lower median annual fibrosis progression rate than those remaining on CNI (initial to final biopsy 0.38 vs. 0.85, p=0.006). Fifty-one percent of patients discontinued sirolimus therapy. Duration of sirolimus use appeared to impact fibrosis progression rates (>2 yr (0.20) vs. 6 mos–2 yr (0.46) vs. < 6 mos (0.91), p=0.42). Kaplan Meier analysis demonstrated that a significantly lower proportion of patients converted to SRL progressed to ≥ stage 2 fibrosis at 1 (92% vs. 71%, p=0.02), 3 (74% vs. 46%, p=0.009), 5 (57% vs. 32%, p=0.01), and 7 (46% vs. 19%, p=0.008) years post transplant. A multivariate analysis identified continuation of CNI therapy as a potential predictor of "rapid fibrosis" (stage 2 or greater fibrosis at 1 year post transplant), with patients remaining on CNI being 2.8 times more likely to develop rapid fibrosis (p=0.07).
CONCLUSION: Conversion from CNI to SRL-based IS in HCV+ LT recipients may slow fibrosis progression post transplant. Large scale multicenter studies are needed to confirm this finding.
Presented at American Transplant Congress, Philadelphia, PA, April 30–May 4, 2011

PRN History Paper

488. Drug Information Practice and Research Network history: 2002–2009
Kristina E. Ward, B.S., Pharm.D., BCPS[1], Beatriz Manzor Mitrzyk, Pharm.D., BCPS[2], Philip J. Gregory, Pharm.D.[3], Andrea L. McKeever, Pharm.D., BCPS[4]; (1) University of Rhode Island, Kingston, RI; (2) Mitrzyk Medical Communications, LLC, Northville, MI; (3) Center for Drug Information and Evidence Based Practice (CDIEBP), Creighton University School of Pharmacy and Health Professions, Omaha, NE; (4) South University School of Pharmacy, Savannah, GA

PURPOSE: To commemorate the thirtieth anniversary of the American College of Clinical Pharmacy (ACCP), all Practice and Research Networks (PRN) in ACCP were encouraged to document their history.
METHODS: A volunteer working group from the DI PRN gathered information from previous PRN officers, business meeting minutes, financial records, newsletters, and emails to develop a formal document recording the history of the DI PRN through 2009.
RESULTS: The DI PRN is relatively new, recognized in late 2002. As of 2009, DI PRN has over 200 members and represents practitioners from academia, clinical practice, health-systems, pharmaceutical industry, managed care organizations, medical information publishers, and medical education providers in the United States and abroad. The DI PRN has several goals among which is the opportunity to network, problem-solve, and discuss professional challenges related to drug information and informatics. The DI PRN provides educational programming for Focus Sessions at ACCP meetings and typically offers an educational program during the DI PRN business meeting at the Annual Meeting. Since 2007, educational programs at the business meetings have been provided through administration of a DI Resident Presentation Award which aims to provide a venue for an immediate-past resident to present the results of their residency research project. The DI PRN considers supporting the Frontiers Fund a priority.
CONCLUSION: The DI PRN represents a diverse group of pharmacists who develop, write, and provide drug information and we endeavor to represent all of these practitioners. We value the opinions of our members and continuously update our PRN initiatives based on member feedback. We support ACCP-directed research and legislative initiatives, especially when related to drug information practice and seek out opportunities to collaborate with other PRNs to promote clinical pharmacy practice.

Infectious Diseases

489. Opportunities to improve fluoroquinolone prescribing: A pilot study. *Robert Eastin, Pharm.D.*, Amie Nguyen, Pharm.D., Maggie Brownell, Pharm.D., Donna Agan, Ed.D., Harminder Sikand, Pharm.D. Scripps Mercy Hospital San Diego, CA; Scripps Memorial Hospital La Jolla, CA.
BACKGROUND: Fluoroquinolones (FQ) are frequently prescribed because of their broad spectrum of activity, dosing convenience, and favorable safety profile. Overuse of these agents leads to decreased bacterial susceptibilities and therefore, decreased efficacy. At Scripps Mercy Hospital San Diego (SM) and Scripps Memorial Hospital La Jolla (SL), FQs are the most common prescribed class of antibiotics with levofloxacin (LVQ) being the highest in the class. Despite decreased susceptibilities to FQs over the past ten years, most notably in gram negative organisms, FQ utilization continues to be high. The objective of this study is to investigate the efficacy of empiric levofloxacin, based on microbiology results, at an academic (SM) and community (SL) institution within the system, and to ascertain de-escalation practices.
METHODS: A retrospective review was conducted between October 2010 and April 2011. Patients were included if they received LVQ empirically, had positive cultures, and remained hospitalized until final cultures and sensitivities (C&S) were reported.
RESULTS: A total of 2000 patients were screened and 204 patients met study criteria; 104 at SM, and 100 at SL. Based on final microbiological results, empiric FQ therapy could have been avoided in 46% of patients at SM and 39% of patients at SL (p=0.3). The percentage of patients found to have an infection resistant to levofloxacin was 28% and 17% at SM and SL, respectively (p=0.063). De-escalation occurred in 28% at SM vs. 23% at SL (p=0.42), and de-escalation opportunities were missed in 20% at SM vs. 48% at SL (p=0.00003).
CONCLUSION: At SM and SL combined, FQ therapy was not indicated in nearly half of patients. Both hospitals failed to de-escalate to narrower spectrum antimicrobial therapy when the opportunity arose at least 20% of the time. Additionally, de-escalation occurred more frequently at the academic institution.

ADR/Drug Interactions

490. Prevalence of adverse drug events in three Veterans Affairs nursing homes
Zachary A. Marcum, Pharm.D., M.S., Kelly L. Rovesti, Pharm.D., Michael C. Behrens, Pharm.D., Michael W. Logsdon, Pharm.D., Jill Myers, Pharm.D., Susan D. Francis, Pharm.D., Sean M. Jeffery, Pharm.D., Sherrie L. Aspinall, Pharm.D., M.S., Joseph T. Hanlon, Pharm.D., M.S., Steven M. Handler, M.D., Ph.D. University of Pittsburgh, Pittsburgh, PA; Veterans Affairs Pittsburgh Healthcare System, Pittsburgh, PA; Durham Veterans Affairs Medical Center, Durham, NC; Veterans Affairs Connecticut Healthcare System, West Haven, CT; Veterans Affairs Center for Medication Safety, Hines, IL
PURPOSE: To describe the one-month point prevalence of and factors associated with adverse drug events (ADEs) in three VA Nursing Homes (NHs) detected by a Trigger Tool (allows for rapid manual chart review using abnormal laboratory values and potentially associated medications).
METHODS: This cross-sectional study assessed 321 Veterans residing in one of three VA NHs (Durham, NC; Pittsburgh, PA; West Haven, CT) between 10/01/2010 and 10/31/2010. Electronic medical records were screened to identify residents with ≥1 abnormal laboratory value specified in the Trigger Tool. An ADE was defined as the administration of medication that could cause the abnormal laboratory value. Descriptive statistics and multivariable Poisson regression models were used for statistical analysis.
RESULTS: One hundred sixty-two Veterans were included (mean age, 70.6 years; mean # of regularly scheduled medications, 13.3; mean # of chronic medical conditions, 9.7). Ninety-nine ADEs involving 146 medications occurred in 20.2% (65/321) of Veterans. The most common ADEs were acute kidney injury (n=30 residents) associated with ACE inhibitors/ARBs and/or loop diuretics, hypokalemia (n=18) related to loop diuretics and/or b-lactam antimicrobials, hypoglycemia (n=13) in Veterans receiving insulin and/or b-blockers, and hyperkalemia (n=10) associated with ACE inhibitors/ARBs and/or beta-blockers. While controlling for demographic and other health status factors, the total number of regularly scheduled medications (Incidence Rate Ratio [IRR] 1.04, 95% CI 1.01–1.08) and number of chronic conditions (IRR 1.06, 95% CI 1.02–1.11) were associated with an increased risk of ADEs.
CONCLUSIONS: ADEs detected using a Trigger Tool are common in Veterans residing in NHs and are associated with the number of medications and chronic medical conditions. Future intervention trials should be conducted to assess the impact of ADE detection and management in the nursing home setting using the Trigger Tool.

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- O -

- P -

- Q, R -

- S -

- T -

- U -

- V -