

## 2012 ACCP Annual Meeting

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### ORIGINAL RESEARCH

#### ADR/Drug Interactions

**1. Observed incidence of linezolid-associated serotonin syndrome during concomitant serotonergic therapy.** *Melanie R. Woytowish, Pharm.D.<sup>1</sup>, Lena Maynor, Pharm.D.<sup>2</sup>*; (1) West Virginia University Healthcare, Morgantown, WV; (2) West Virginia University School of Pharmacy, Morgantown, WV

**PURPOSE:** While confirmed cases of serotonin syndrome have been documented with linezolid, the incidence in patients receiving linezolid in combination with other serotonergic medications is unknown. A retrospective study and a survey estimate the incidence to be somewhere between 3% and 25%. This prospective observational study was conducted to investigate the incidence of serotonin syndrome in hospitalized patients initiated on linezolid.

**METHODS:** A CPOE-based report of active linezolid orders was generated daily from March 1, 2012 to June 15, 2012. All adult patients receiving linezolid were included. Patients receiving concomitant medications with serotonergic activity were monitored daily for signs and symptoms of serotonin syndrome. The primary outcome, development of serotonin syndrome, was diagnosed either by the patient care team as definitive or through satisfying the Hunter Serotonin Toxicity Criteria (HSTC). Descriptive statistics were utilized to describe data.

**RESULTS:** Of the 130 unique courses of linezolid included in the study, 37 (28.5%) received concomitant therapy with at least one serotonergic agent. Seventy-five percent of the 37 were on a single concomitant serotonergic agent (8.3% on 2, 16.7% on 3). Median duration of linezolid therapy was 78 hours (range 12–444 hours). While serotonin syndrome was mentioned on the differential diagnosis for one patient, no patients met the HSTC. No cases of serotonin syndrome were observed in this patient population during hospitalization.

**CONCLUSION:** Linezolid-associated serotonin syndrome may be very rare in practice, despite use with multiple serotonergic agents. Further observation of the use of linezolid in patients receiving concomitant serotonergic agents is needed in order to describe the true incidence of this seemingly rare, potentially life-threatening reaction.

**2E. A comparative study of patients with acute promyelocytic leukemia receiving all-trans retinoic acid with and without voriconazole: effect on differentiation syndrome.** *Jason N. Barreto, Pharm.D., BCPS, John C. Kuth, Pharm.D., BCOP, Candy S. Peskey, Pharm.D., BCPS, Mrinal M. Patnaik, MBBS; Mayo Clinic, Rochester, MN*

**PURPOSE:** Differentiation syndrome (DS) is a potentially fatal complication related to all *trans*-retinoic acid (ATRA) use in induction chemotherapy for acute promyelocytic leukemia (APL) patients. Metabolism of ATRA occurs through cytochrome P450 (CYP) enzyme pathways, mostly CYP2C9 and CYP3A4. Voriconazole is a strong inhibitor of CYP2C9 and CYP2C19. We evaluated and contrasted the incidence and outcomes of ATRA-induced DS in APL patients.

**METHODS:** Forty-six APL patients undergoing induction-phase chemotherapy utilized ATRA at Mayo Clinic from 2000 to 2011. Comparisons between groups for categorical outcomes were made using Pearson's chi-square or Fisher's exact test. Two-sample *t*-tests or Wilcoxon rank-sum tests were used for continuous out-

comes. Cox proportional hazards model measured association of voriconazole and body mass index (BMI) with DS occurrence, where voriconazole was considered a time-dependent covariate.

**RESULTS:** Of the 46 patients, 27 were male with a median age of 56 years. Thirty-one patients received chemotherapy including ATRA with voriconazole and 15 patients underwent chemotherapy including ATRA without fungal prophylaxis. There was no difference in age, gender, Sanz risk assessment, combination chemotherapy regimen, WBC, platelet count, creatinine clearance and LDH levels amongst patients in the two groups. The only heterogeneity was BMI, which was higher in patients receiving voriconazole (HR: 1.04, CI: 1.001–1.078, *p*=0.0427). Overall incidence of DS was 35%, with patients receiving voriconazole being more likely to experience the same (HR: 2.31, CI: 0.78–6.874, *p*=0.1308). After adjusting for BMI, patients receiving voriconazole had a higher tendency to experience DS. Due to small numbers this trend was not statistically significant (HR: 1.96, CI: 0.65–5.94, *p*=0.23). Zero deaths were attributable to DS.

**CONCLUSIONS:** A trend towards increased incidence and severity of ATRA-mediated DS was seen in APL patients receiving voriconazole as fungal prophylaxis during induction therapy, contributing to morbidity. Statistical significance was not reached due to small sample size. This finding warrants larger studies. Presented at the 17th Congress of the European Hematology Association, Amsterdam, the Netherlands, June 15, 2012.

**3. Converting between glycine-stabilized intravenous immune globulin products: incidence of adverse events.** *Ginger Morris, Pharm.D., Eric M. Tichy, Pharm.D., BCPS; Yale-New Haven Hospital, New Haven, CT*

**PURPOSE:** The literature describing the incidence of ADEs when converting patients between Intravenous Immune Globulin (IVIg) products is limited. The purpose of this study is to evaluate the incidence of ADE when converting between two glycine-stabilized products, Gamunex-C and Gammagard Liquid.

**METHODS:** This prospective study included all inpatient and outpatient adult patients at our center who received Gamunex-C or Gammagard Liquid IVIg from November 2011 to April 2012. The objective was to compare the incidence and significance of ADEs in adult patients converted from Gamunex to Gammagard Liquid. Patients included received at least two pre-conversion doses of Gamunex (control) and two post-conversion doses of Gammagard (intervention). Patients served as their own control, therefore, baseline demographics were identical. ADE were considered significant if patients experienced rigors, decreased oxygen (O<sub>2</sub>) saturation >5% from baseline, or become hypotensive, defined as systolic blood pressure <90. Patients were excluded if they received IVIG by subcutaneous route.

**RESULTS:** A total of 86 patients were converted from Gamunex-C to Gammagard Liquid. The total number of infusions in each arm were 172 and 171, respectively. No Gamunex patients experienced ADEs. A total of seven patients in the Gammagard group experienced ADEs for a total of 16 ADEs (*p*<0.0001). One patient developed rigors, which was considered a significant ADE (*p*<0.0001). Seven reactions were considered minor, which were defined as pain (three patients), fever (one patient), chills (one patient), tachycardia (one patient), and an O<sub>2</sub> decrease of <5% (one patient) (*p*<0.0148). One patient who developed a reaction with the first infusion of Gammagard Liquid tolerated a second infusion, but was switched back to Gamunex based on patient preference. The percentage of significant reactions and minor reactions was 0.6% and 4.1%, respectively.

**CONCLUSION:** There is a low incidence of significant ADE when converting patients between glycine-stabilized IVIg products.

**4. Characterization of Dabigatran discontinuation in the community setting.** *Amanda Kerr, Pharm.D., Tina G. Hipp, Pharm.D., Becky J. Szymanski, Pharm.D.; Carolinas Medical Center – NorthEast, Concord, NC*

**PURPOSE:** This study documented (i) the reason for discontinuation of dabigatran therapy and (ii) the time to discontinuation of therapy.

**METHODS:** Patients were identified using adverse event reporting and by monthly hospital dispensing reports from November 2010 to February 2012. The anticoagulation clinic records of identified patients were reviewed to further distinguish the time of initiation of therapy and followed until time of discontinuation or until the end of the study.

**RESULTS:** Of the 104 patients evaluated, 24 patients (23%) discontinued dabigatran due to adverse events or side effects, 13 patients (13%) were discontinued due to no longer being a candidate, two patients (2%) discontinued due to price, and 2 (2%) patients discontinued due to unknown reasons. The 24 patients that experienced side effects or adverse events were on the medication for an average of 2.88 months, ranging from 0 to 10 months. The 13 patients that discontinued dabigatran due to no longer having an indication for its use, were on the medication for an average of 3.62 months, ranging from 0 to 13 months. The two patients that discontinued dabigatran due to unknown reasons were on the medication an average of 9.5 months, ranging from 8 to 11 months. The two patients that discontinued dabigatran due to medication cost, stopped taking the medication upon leaving the hospital (0 months). Of the 63 patients that were not discontinued, the average time of therapy was 7.2 months and ranged from 1 to 16 months.

**CONCLUSIONS:** Most patients that experienced a side effect or adverse event, discontinued dabigatran in the first 3 months. Follow-up with clinic physicians post discharge and monitoring patients closely for the first 3 months after initiation should be ensured.

## Adult Medicine

**5. Evaluation of anticoagulation overlap therapy for the treatment of venous thromboembolism at an academic medical center.** *Melissa M. Chesson, Pharm.D., BCPS<sup>1</sup>, Carissa J. Fischer, Pharm.D.<sup>1</sup>, Candace Stearns, Pharm.D., BCPS<sup>2</sup>*; (1) Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (2) Emory Healthcare, Atlanta, GA

**PURPOSE:** Meaningful use criteria are a set of metrics medical providers must comply with by 2015 to indicate the electronic medical record is being utilized as an effective tool. Included in these metrics is anticoagulation overlap therapy (VTE-3). This metric assesses the number of patients with a confirmed venous thromboembolism (VTE) who receive appropriate 5 day overlap therapy with a parenteral anticoagulant and warfarin. By 2015, hospitals should demonstrate an 80% compliance rate. The purpose of this study is to determine rates of compliance with VTE-3 at two hospitals within an academic medical center and evaluate the accuracy of computer software utilized within the medical center to assess rates of compliance with VTE-3.

**METHODS:** Electronic medical records for 817 patients with an ICD-9 code for VTE diagnosis admitted to the medical center between March 1, 2011 and August 31, 2011 were reviewed for compliance with VTE-3. Rates of metric compliance were based on total number of confirmed VTE cases and the number of cases meeting the quality metric.

**RESULTS:** A total of 111 patients, at the two hospitals, were identified as having a confirmed VTE with an overall compliance rate of 72% with VTE-3. Less than 5 days of overlap therapy was the most common reason (71%) for non-compliance with VTE-3. During the 3 month period of data captured by computer software, the rate of compliance was 48% compared to 76% by manual data collection.

**CONCLUSION:** An 80% rate of compliance was not demonstrated during the 6 months of data collection. Furthermore, the computer software designed to capture metric data was not as accurate as manual data collection. It remains questionable as to how computer software will be utilized to document compliance with VTE-3. The many complexities of anticoagulation therapy

management could adversely affect rates of compliance detected by computer software.

**6E. Dabigatran and warfarin: comparative analysis of safety and cost.** *Niyati H. Vakil, Pharm.D., Molly Leber, Pharm.D., BCPS, Gina Bliss, Pharm.D., Marina Yazdi, Pharm.D., BCPS; Yale-New Haven Hospital, New Haven, CT*

**PURPOSE:** Warfarin has long been considered the standard of care for prevention of stroke in patients with atrial fibrillation (AF) but has many disadvantages including extensive monitoring and numerous drug-drug interactions. Dabigatran is the first oral alternative approved for prevention of stroke in non-valvular AF. It does not require routine laboratory monitoring and has minimal drug-drug interactions. One of its disadvantages, however, is its cost compared to warfarin. Additionally, post-marketing surveillance has revealed severe and fatal bleeding events with no reversal agent available. The objective of this study was to determine the frequency of bleeding events and 30-day readmissions at a large, academic medical institution and to determine the cost-effectiveness of dabigatran as compared to warfarin.

**METHODS:** This was a retrospective study in which patients 18 years of age and older receiving dabigatran or warfarin for prevention of stroke in AF between July 1 and October 31, 2011 were identified. Patients receiving hemodialysis or with creatinine clearance less than 15 ml/minute were excluded. The primary outcome of this study was the rate of bleeding and 30-day readmission related to anticoagulation complications. A cost analysis was performed by comparing direct and indirect costs between the two drugs. p-Values were calculated for baseline characteristics only.

**RESULTS:** Dabigatran was associated with lower rates of bleeding and 30-day readmission than warfarin. While the direct cost of therapy for dabigatran was higher than warfarin, the cost of monitoring and readmission was lower.

**CONCLUSION:** Dabigatran appears to be a safe alternative for the prevention of stroke in patients with AF. In addition, dabigatran may be a cost-effective alternative to warfarin given the significant cost avoidance associated with lower rates of readmission. There is benefit in verifying the results of this study with a larger patient population.

Presented at Eastern States Residency Conference, Hershey, PA, May 2-4, 2012

**7. Should the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation be used to evaluate renal function in the hepatic failure patient awaiting liver transplantation?** *Gregory Smallwood, B.S., Phr., Pharm.D.; PCOM School of Pharmacy, Suwanee, GA*

**PURPOSE:** Estimation of renal clearance in patients with hepatic dysfunction is difficult, at best, to determine by mathematical equation. Currently several methods are utilized to estimate CrCl which include Cockcroft and Gault (CC&G) equation, modification of diet in renal disease (MDRD-6 and -4) equations, the Nix model, and a newly described CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) equation. The aim of this study is to compare the CKD-EPI and other methods of renal clearance estimation to actual, collected 24 hour creatinine clearance in hepatic failure patients.

**METHODS:** This IRB approved study collected 24 hour CrCl from patients awaiting liver transplant. The actual 24 hour CrCl was then compared to the CC&G, MDRD-6/-4, Nix model, and the CKD-EPI formula. Strength of correlation was then determined by the Pearson R method with good correlation being set at 0.75.

**RESULTS:** A total of 120 patients were evaluated with a mean age of 53 years, 59.2% male, and 13% African-American. Best correlation was seen with the CC&G and Nix's formula ( $r = 0.680$  versus  $r = 0.683$ ) with the MDRD-6/-4 and CKD-EPI a lower correlation ( $r = 0.563, 0.592, 0.575$ ). The mean calculated GFR from collection (99 ml/minute) was very different from calculated means (88 ml/minute (CC&G), 82.9 ml/minute [CPK-

EPI], 83.5 ml/minute [MDRD-4], 65.3 ml/minute [MDRD-6] and 86.3 ml/minute [Nix's]). For patients with MELD > 15, the Nix's formula better correlated CrCl than other methods ( $r = 0.841, 0.772$  and  $0.625$ ). Based on type of liver disease, the MDRD-6 had the best correlation for immune mediated diseases ( $r = 0.962$ ). For patients with CrCl < 60 ml/minute, correlation was low, but similar ( $r = 0.528, 0.507, 0.521, 0.531, 0.528$ ) with similar results for CrCl > 60 ml/minute ( $r = 0.557, 0.40, 0.447, 0.418, 0.539$ ).

**CONCLUSION:** The newer equations did no better than the CC&G in estimating CrCl for patients awaiting transplant. Due to lower than expected Pearson  $r$  with the new renal validated formulas, additional work should be undertaken to estimate clearance in hepatic failure patients.

**8. Evaluation of a pharmacy-driven erythropoiesis-stimulating agent utilization program.** Erin K. Hennessey, Pharm.D.<sup>1</sup>, Andrew J. Crannage, Pharm.D., BCPS<sup>1</sup>, Joy R. Abu-Shanab, Pharm.D., BCPS<sup>2</sup>, Matthew J. Korobey, Pharm.D., BCPS<sup>2</sup>, Julie A. Murphy, Pharm.D., BCPS, FASHP<sup>1</sup>; (1) St. Louis College of Pharmacy/Mercy Hospital St. Louis, St. Louis, MO; (2) Mercy Hospital St. Louis, St. Louis, MO

**PURPOSE:** On January 3, 2012, Mercy Hospital St. Louis changed its formulary erythropoiesis-stimulating agent (ESA) from epoetin alfa to darbepoetin alfa and concurrently instituted a new pharmacy-driven ESA utilization program. The objective of this study was to determine the impact of a pharmacy-driven ESA utilization program on appropriate use of ESAs.

**METHODS:** Prior to the formulary change and the initiation of the pharmacy-driven ESA utilization program, pharmacists received training on the expected monitoring and documentation process for appropriate utilization of ESAs as approved by the hospital's pharmacy and therapeutics committee. Adult patients with an indication for an ESA of anemia of chronic kidney disease with or without hemodialysis or chemotherapy induced anemia treated with epoetin alfa from January 15 through February 15, 2011 (pre-implementation) or darbepoetin alfa from January 15 through February 15, 2012 (post-implementation) were included. Data including ESA indication, dose, frequency, last dose administered, patient weight, hemoglobin, ferritin, and transferrin saturation was collected. The primary outcome was the difference in the proportion of patients appropriately administered an ESA before and after implementing a pharmacy-driven ESA utilization program.

**RESULTS:** Fifty patients were included in the pre-implementation group and 58 patients in the post-implementation group. There was no significant difference in baseline demographics between groups. Twenty-six percent of patients in the pre-implementation group were appropriately administered an ESA compared to 43% in the post-implementation group ( $p=0.0721$ ). Sub-analysis of the primary outcome showed that appropriate dose was received by 44% compared to 57% of patients ( $p=0.2468$ ), and appropriate laboratory monitoring occurred for 62% compared to 69% of patients ( $p=0.5427$ ) in the pre- and post-implementation groups, respectively.

**CONCLUSION:** Implementation of a pharmacy-driven ESA utilization program did not significantly improve appropriate utilization of ESAs at Mercy Hospital St. Louis. An approach which includes significant educational strategies regarding standards associated with ESAs is necessary to optimize patient care.

## Ambulatory Care

**9. Evaluation of missed opportunities for pharmacotherapy management of heart failure in primary care.** Kristyn Mulqueen, Pharm.D., Shawn Anderson, Pharm.D.; Department of Veterans Affairs, Gainesville, FL

**PURPOSE:** Titrating heart failure (HF) medications to target doses is a cornerstone of evidence-based HF management. Patients who are followed by a specialty HF disease management program (HFDMP) often have follow-up appointments with their

primary care providers (PCP) between HF clinic visits. We aimed to identify whether PCPs are missing opportunities for HF pharmacotherapy optimization at annual appointments.

**METHODS:** Medical records of 209 patients enrolled in the HFDMP at a large VA Medical Center were reviewed. Laboratory data, vital signs, physical exam information and patient-reported symptoms were collected and analyzed to determine whether an opportunity for HF pharmacotherapy optimization existed at the time of the patient's annual PCP appointment. Patients were included in the study if there was a clear opportunity for medication adjustment based on accepted guidelines and published literature.

**RESULTS:** We identified 50 PCP visits with clear opportunities for HF pharmacotherapy optimization, encompassing 77 potential interventions. Only 13 (17%) potential interventions were implemented. PCPs intervened to manage uncontrolled hypertension most often, in 6 of 14 (43%) opportunities. PCPs intervened to titrate beta blockers, ACE inhibitors or ARBs, and aldosterone antagonists in 0 of 13 (0%), 2 of 24 (8%), and 1 of 20 (5%) opportunities, respectively.

**CONCLUSION:** PCPs are missing opportunities to optimize HF pharmacotherapy for their patients who are enrolled in a HFDMP. HF patients may benefit from more timely HF pharmacotherapy optimization if a teamwork-based approach is established between primary care providers and specialty HF providers. Primary care clinical pharmacists can be utilized to assist PCPs with HF pharmacotherapy adjustment and monitoring.

**10E. Effect of intrathecal bupivacaine lidocaine combination on motor block and analgesia period.** Sara El-Adawy, Master & Board of Pharmacotherapy; Ain-Shams University, Faculty of Pharmacy, Cairo, Egypt

**PURPOSE:** Assessing the effect of intrathecal Bupivacaine-Lidocaine combination at different doses of Lidocaine (6 and 12 mg) on the onset & recovery of anesthesia; times to retain motor ability, postoperative analgesia, the hemodynamic side effect & neurological complications especially transient neurological symptoms (TNS).

**METHODS:** Ninety adult patients who were scheduled for elective lower abdominal, anal or Knee arthroscopy surgery under spinal anesthesia were randomly allocated into three groups (30 patients each) *Group I (control group):* (1.5 ml hyperbaric 0.5% Bupivacaine + 0.6 ml saline). *Group II:* (1.5 ml hyperbaric 0.5% Bupivacaine + 0.6 ml 1% Lidocaine [6 mg]). *Group III:* (1.5 ml hyperbaric 0.5% Bupivacaine + 0.6 ml 2% Lidocaine [12 mg]). Peak sensory block level, times to peak sensory block, times to two-segment regression, S2 regressions from peak, motor block degree at peak sensory block, motor block duration, PACU time, analgesia time, analgesia consumption, hemodynamic side effect & neurological complication were measured.

**RESULTS:** The median height of peak and the times to peak sensory block in Group III was higher than in Groups I or II. Times to two segment regressions and S2 regressions from peak, motor block duration and PACU time were significantly reduced in Group II compared to Group I & III. No patient required general anesthesia or experienced TNS.

**CONCLUSION:** We conclude that 0.6 ml 1% Lidocaine plus 1.5 ml 0.5% Bupivacaine (7.5 mg) can shorten the duration of the spinal anesthesia providing more rapid recovery.

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**11. Implications on vaccine compliance rates in an internal medicine outpatient clinic with the implementation of a pharmacist driven vaccination assessment: phase 2.** Jamie M. Pitlick, Pharm.D., BCPS<sup>1</sup>, Abigail Yancey, Pharm.D.<sup>2</sup>, Alicia B. Forinash, Pharm.D., BCPS, BCACP<sup>3</sup>; (1) St. Louis College of Pharmacy, St. Louis, MO; (2) St. Louis College of Pharmacy, St. Louis, MO; (3) St. Louis College of Pharmacy, Saint Louis, MO

**PURPOSE:** To determine if a pharmacist driven immunization assessment influences compliance with the CDC immunization recommendations for hepatitis A, hepatitis B, influenza, tetanus/diphtheria/pertussis (Tdap), human papillomavirus (HPV) and pneumococcal disease at a community teaching hospital internal medicine (IM) clinic.

**METHODS:** Phase 1 of the study included a baseline retrospective chart review of patients seen in the clinic during a 4 week period in 2009. Phase 2 of the study included an identical chart review 15 months after initiation of a pharmacist driven screening assessment. Rates were compared to determine efficacy of the assessment at increasing immunization compliance. The chart reviews included baseline demographics and patient specific indications for the various vaccines. Compliance was defined as having an indication for the vaccine and receiving at this visit or previously within the appropriate time frame.

**RESULTS:** A total of 194 and 209 IM patients were eligible to be included in phase 1 and phase 2 of the study, respectively. Overall compliance with the CDC immunization recommendations was generally low but significantly improved from 2009 compared to 2010 (21% versus 29.8%,  $p < 0.001$ ). Vaccination rates increased significantly for influenza, hepatitis B, and Tdap (Table 1). Although rates decreased slightly for pneumococcal, hepatitis A, and HPV, these differences were not significant.

Vaccine	IM 2009 (%)	IM 2010 (%)	p-Value
Influenza	21.7	44.8	<0.001
Pneumococcal	38.5	33.3	0.35
Hepatitis A	36	20.5	0.25
Hepatitis B	9.4	36.1	0.005
Tdap	5.2	14	0.004
HPV	41.7	25	0.67

**CONCLUSION:** Compliance with the CDC immunization recommendations improved with implementation of a pharmacist driven assessment; however, rates are still low signifying a need for additional pharmacist intervention.

**12. Association between venous thromboembolism and air pollution in an industrial North American city: implications for anticoagulation management.** Holly H. Chiu, Pharm.D.<sup>1</sup>, Peter Whittaker, Ph.D.<sup>2</sup>; (1) Beaumont Hospital, Royal Oak, MI; (2) Cardiovascular Research Institute and Department of Emergency Medicine, Wayne State University School of Medicine, Detroit, MI

**PURPOSE:** Emerging European evidence indicates that venous thromboembolism (VTE) occurs most often in winter. This suggests that VTE may be provoked by low temperatures or increased particulate matter (PM) pollution. In contrast to European cities, air pollution in many North American cities peaks in summer rather than winter. We hypothesized that analysis of temporal distribution of VTE in an industrial city (Detroit) with a summer pollution peak could resolve the role of these factors and offer insight into possible prothrombotic environmental effects.

**METHODS:** Using ICD-9-CM codes, we identified 3310 suspected VTEs in ambulatory patients at local emergency departments (2004–2008). VTE was confirmed by CT scan or sonography in 1907 cases; the remainder served as comparators. We recorded demographic data, divided the cases by location (Detroit versus suburban) and plotted the monthly VTE distributions. Using data from the Environmental Protection Agency, we determined the temporal distribution of different size categories of PM pollution. We compared distributions using circular statistics.

**RESULTS:** Monthly Detroit VTE cases (1490) exhibited a unimodal summer peak and differed from both a uniform distribution ( $p < 0.01$ ) and that of the 1123 non-VTE cases ( $p < 0.02$ ). Levels of 10  $\mu\text{m}$  diameter PM and 2.5–10  $\mu\text{m}$  PM exhibited summer peaks versus a winter peak for 2.5  $\mu\text{m}$  PM. Temporal distribution of Detroit VTE cases differed from that of 2.5  $\mu\text{m}$  and 2.5

–10  $\mu\text{m}$  PM ( $p < 0.001$ ), but not from 10  $\mu\text{m}$  PM ( $p > 0.50$ ). In contrast, suburban VTE cases (417) showed no monthly variation ( $p > 0.20$ ).

**CONCLUSIONS:** Our finding of a summer VTE peak in Detroit and close concordance with 10  $\mu\text{m}$  diameter PM indicates that low temperature is not a factor in VTE pathogenesis, but is consistent with a role for air pollution. Therefore, anticoagulation management should not only consider the patient, but also their environment; for example, patients living close to major roads and other PM sources may require increased surveillance.

**13. Comparison of cefpodoxime versus cefuroxime axetil for acute sinusitis.** Scot E. Walker, Pharm.D., M.S., BCPS, BCACP; Facts & Comparisons, St. Louis, MO

**PURPOSE:** This study compared treatment failure during a 30 day period after initiation of the second line antibiotics cefuroxime or cefpodoxime in acute sinusitis patients seen in primary care offices. Treatment failure was defined as an antibiotic change or healthcare visit for additional treatment during the study period.

**METHODS:** The practice management system records of a large multi-site primary care practice was searched to identify patients with an office visit for acute sinusitis who, based on claims data, were treated with cefpodoxime or cefuroxime. Hard copy patient charts along with electronic pharmacy and medical claims were searched for data collection.

**RESULTS:** A cohort of 104 patients was identified, with 52 patients receiving each treatment. There was no difference in mean age, gender or patients >18 between groups. Both groups were composed of 70% adult patients. There was no statistically significant difference found in the number of chronic sinusitis patients with an acute sinusitis exacerbation in the groups. There was no statistically significant difference in the presence of risk factors (recent viral rhinosinusitis, asthma, anatomical abnormalities, allergic rhinitis, immunosuppression, nasal intubation or packing, tooth abscess, swimming in contaminated water, and cigarette smoking) between groups. There was no difference in treatment failure at 30 days between groups. No statistically significant difference was found when acute sinusitis patients and chronic sinusitis patients were examined separately. There was no phone follow-up, so it is possible that patients could have paid for treatment at a retail clinic or acute care center. However it was felt that by reviewing the medical chart and insurance claims, visits to one of these clinics would have been identified.

**CONCLUSION:** No difference was found in treatment failure during a 30 day period after initiation of cefuroxime or cefpodoxime in treating acute sinusitis patients.

**14. Group clinic evaluation of diabetes related measures of control in veterans with poorly controlled type 2 diabetes.** Lauralee C. Gordon, Pharm.D., Melaina K. Perry, Pharm.D., Rebecca J. Cripps, Pharm.D., BCPS, Regina F. Cassidy, Pharm.D., BCPS, CDE, Amy S. Wilson, Pharm.D., M. Shawn McFarland, Pharm.D., BCPS, BC-ADM; VA Tennessee Valley Healthcare System, Nashville, TN

**PURPOSE:** Group medical clinics within the Patient Centered Medical Home (PCMH) model allow patients to support one another while also receiving focused care from multiple providers on specific disease states. At the Alvin C. York (ACY) campus of the Veterans Health Administration (VHA) Tennessee Valley Healthcare System, a diabetes group clinic is held weekly as part of the newly-implemented PCMH model. These clinics are conducted by a team that includes a clinical pharmacist (CDE/BC-ADM), a registered dietician (CDE), and a registered nurse (CDE). This study evaluated the effectiveness of diabetes group clinic attendance on glucose control and other diabetes-related measures of control by comparing lab results at inclusion and after 6 months of attendance.

**METHODS:** This was a retrospective, single center study. Records of all patients who were enrolled in the diabetes group clinic between January 1, 2009 and June 30, 2011 were evaluated. The primary objective was to assess the change from baseline in

hemoglobin A1c after 6 months of diabetes group clinic attendance. Secondary objectives were to assess the changes in blood pressure (BP) and lipid panel results as well as the number of patients meeting individual American Diabetes Association (ADA) treatment goals and VHA performance measures.

**RESULTS:** Forty-nine patients met inclusion criteria. Statistically significant changes were observed in A1c and systolic BP ( $p=0.003$  and  $0.016$ , respectively). There were also significant improvements in the number of patients meeting ADA goals for A1c and SBP ( $p=0.0057$  and  $0.0012$ , respectively) and VA performance measure for SBP ( $p=0.0051$ ).

**CONCLUSIONS:** Six months of group clinic attendance improved A1c and systolic BP in this veteran population. These results indicate that group clinic visits are an effective tool to help patients improve control of cardiovascular risk factors.

**15. Decreasing inappropriate prescribing in elderly patients.** *Regina Ginzburg, Pharm.D., Nicole Ng, Pharm.D.; St. John's University, Queens, NY*

**PURPOSE:** The geriatric population are well known to be more susceptible to adverse drug events (ADEs) than younger patients. These ADEs are associated with increased hospitalizations, morbidity and mortality, and increased health care costs. We previously conducted a retrospective analysis to determine how many geriatric patients were prescribed "high severity" Beers medications. In our follow-up study, we sought to evaluate whether the implementation of a Best Practice Alert (BPA) will reduce the prescribing of Beers medications in our geriatric patients.

**METHODS:** The BPA was developed and incorporated into the electronic health record (EHR) which appears when a "high severity" Beers medication is ordered by a provider to an IFH patient greater than 65 years old. A smartest was then linked which included a recommended alternative that was labeled a "positive" Beers Medications. A follow-up internal report on prescribing patterns was generated 6 months after implementation.

**RESULTS:** Eighteen high severity medications were prescribed by various providers within the institution. The most commonly prescribed medications were amitriptyline, cyclobenzaprine, diazepam, and fluoxetine. There were no changes in prescribing patterns pre and post intervention of the BPA.

**CONCLUSION:** The use of a BPA alert in the EHR did not appear to decrease prescribing of the high severity Beer's medications. More work needs to be done in this area to assess reasoning for no change physician's prescribing in this patient population.

**16. Comparison of vitamin D dosing regimens in non-obese and obese patients with low vitamin D levels.** *Bryan L. Schuessler, Pharm.D., M.S.<sup>1</sup>, Janelle F. Ruisinger, Pharm.D.<sup>2</sup>, Dennis W. Grauer, Ph.D.<sup>3</sup>, Patrick M. Moriarty, M.D.<sup>2</sup>, James M. Backes, Pharm.D.<sup>2</sup>; (1)The University of Kansas Hospital, Kansas City, KS; (2)Lipid, Atherosclerosis, Metabolic and LDL-Apheresis Center, University of Kansas, Kansas City, KS; (3)University of Kansas Medical Center, Kansas City, KS*

**PURPOSE:** Obese populations have demonstrated lower levels of 25-hydroxyvitamin D compared to non-obese subjects, yet it is unclear whether obese patients require greater amounts of vitamin D supplementation to achieve adequate repletion. The objective of this study was to compare the response to vitamin D supplementation between obese and non-obese patients based on 25-hydroxyvitamin D levels.

**METHODS:** Patients treated in a lipid specialty clinic who were over 18 years of age, had a documented low baseline 25-hydroxyvitamin D level, received vitamin D supplementation, and had a documented follow-up 25-hydroxyvitamin D level from January 1, 2007 to December 31, 2011 were included. Key exclusion criteria included history of osteoporosis, organ transplant/dysfunction, thyroid disorder, gastric bypass, hyperphosphatemia, and chronic kidney disease. Patients with a body mass index (BMI)  $>30$  kg/m<sup>2</sup>

were classified as obese, whereas those  $<30$  kg/m<sup>2</sup> were considered non-obese.

**RESULTS:** Data from 66 non-obese and 92 obese patients were analyzed. The groups differed significantly in regards to mean BMI (26.5 versus 34 kg/m<sup>2</sup>,  $p<0.001$ ), and those considered obese had higher rates of hypertension, diabetes, and metabolic syndrome ( $p<0.001$ ). Mean baseline 25-hydroxyvitamin D levels were similar in both groups (20 versus 18 ng/ml;  $p=0.094$ ). Groups were prescribed similar mean initial bolus (loading) dosing (48,400 versus 51,680 units/day;  $p=0.405$ ) and maintenance dosing (2707 versus 3181 units/day;  $p=0.284$ ). Duration of bolus dosing (10 versus 11 days;  $p=0.236$ ) and maintenance dosing (188 versus 168 days;  $p=0.290$ ) was similar in both groups, as was mean follow up 25-hydroxyvitamin D levels after supplementation (40.4 versus 38 ng/ml;  $p=0.290$ ).

**CONCLUSION:** Non-obese and obese patients had similar rates of vitamin D deficiency and did not require significantly different amounts or duration of vitamin D supplementation to achieve repletion. More information is required before modifying vitamin D supplementation regimens based on patient weight.

**17. Upper extremity deep vein thrombosis: a retrospective cohort evaluation at a university teaching hospital antithrombosis clinic.** *Rebecca H. Stone, Pharm.D., Edith A. Nutescu, Pharm.D., Nancy L. Shapiro, Pharm.D.; University of Illinois at Chicago College of Pharmacy, Chicago, IL*

**PURPOSE:** The purpose of this study is to identify risk factors associated with upper-extremity deep venous thrombosis (UEDVT) and to determine appropriateness of current prophylaxis strategies utilized.

**METHODS:** A retrospective cohort evaluation of patients with a confirmed UEDVT managed at the University of Illinois at Chicago (UIC) Antithrombosis Clinic between May 1, 2007 and October 1, 2011. Patients were identified by an ICD9 code for UEDVT (451.89, 453.82) in the electronic medical record. The primary outcome variables included were: patient demographics, past medical history, and details specific to UEDVT prophylaxis, location, symptoms, diagnosis, and treatment. A standardized data collection sheet was utilized and descriptive statistics were performed with Excel software.

**RESULTS:** A total of 232 out of 332 patients met criteria for study inclusion. The average patient age was  $49.7 \pm 15.2$  years, the average BMI was  $28.8 \pm 8.0$  kg/m<sup>2</sup>, and 165 (71.1%) patients were African American. The average number of UEDVT risk factors was  $5.1 \pm 1.8$ , and the most common risk factor was central venous catheter use in 175 (75.4%) patients. Of 109 patients with UEDVT diagnosed in the inpatient setting, 72 (66.1%) received documented DVT prophylaxis. Of the 182 patients receiving a long term vitamin k antagonist with four or more INR results, 36.6% of INR values were within therapeutic range. Of the 153 patients followed 3 months or longer after their UEDVT, 40 (26.1%) experienced a recurrent thrombotic event. During acute and long term treatment, 19 (8.2%) patients experienced a documented major bleeding event.

**CONCLUSION:** Patients with UEDVT had multiple risk factors for thrombosis, did not always receive DVT prophylaxis, and had a low quality of control of anticoagulation. Patients with UEDVT had a significant rate of documented recurrent thrombosis and bleeding events.

**18. Implications on vaccine compliance rates with the implementation of a pharmacist driven vaccination assessment: phase 2.** *Abigail Yancey, Pharm.D., Jamie Pitlick, Pharm.D., Alicia Forinash, Pharm.D.; St. Louis College of Pharmacy, St Louis, MO*

**PURPOSE:** To determine if a pharmacist driven immunization screening assessment influences compliance with the current CDC immunization recommendations for hepatitis A, hepatitis B, influenza, tetanus/diphtheria/pertussis (Tdap), human papillomavirus (HPV) and pneumococcal disease at a community teaching hospi-

tal internal medicine (IM) and obstetrics and gynecology (Ob/Gyn) clinic.

**METHODS:** Phase 1 of the study included a baseline retrospective chart review of IM and Ob/Gyn patients seen in the clinic during a 4 week period in 2009. Phase 2 of the study included an identical chart review 15 months after the initiation of a pharmacist driven screening assessment. Rates were compared to determine efficacy of the protocol at increasing immunization rates. The chart reviews included baseline demographics and patient specific indications for the various vaccines. Compliance was defined as having an indication for the vaccine and receiving at this visit or previously within the appropriate time frame.

**RESULTS:** A total of 311 patients were eligible to be included in phase 1 of the study and 376 patients in phase 2 of the study. Overall compliance with the CDC immunization recommendations was generally low. However, vaccination rates increased for flu (18.4% versus 41.1%;  $p < 0.001$ ), hepatitis A (25% versus 38.8%;  $p = 0.006$ ), hepatitis B (12.2% versus 39%;  $p < 0.001$ ), and TDaP (4% versus 15%;  $p < 0.001$ ) with assessment implementation. There was no significant difference in vaccination rates for HPV (8.6% versus 8.7%) or pneumococcal (28.2% versus 25.5%) vaccinations.

**CONCLUSION:** The compliance with the CDC immunization recommendations improved with the implementation of a pharmacist driven assessment; however, rates are still low signifying a need for additional pharmacist intervention.

**19. 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 sought 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 protocol outlining recommended monitoring parameters and rates for SGAs and a weekly pharmacy referral clinic for administration of the Abnormal Involuntary Movement Scale (AIMS).

**METHODS:** A retrospective chart review was conducted for BWJC patients receiving SGAs from December 1, 2008 to May 31, 2009. The review identified several categories below facility goal rates of  $\geq 80\%$ . The clinical pharmacist and students provided education on the recommended monitoring parameters and frequencies to the mental health providers at BWJC, prepared written instructions for psychiatry residents and instituted a weekly referral clinic for administration of the AIMS. A follow-up review was conducted to collect the monitoring rates from December 1, 2009 to May 31, 2010. 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 overall rates for FPG, FLP, or CBC.

**CONCLUSIONS:** 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 verbal education of all new psychiatry residents by the pharmacist or routine assessment and laboratory ordering by pharmacy for patients taking SGAs.

**20. Pharmacist interventions and health care outcomes in a novel heart failure medication adherence clinic.** *Jennifer L. Johnson, Pharm.D.<sup>1</sup>, Lynette R. Moser, Pharm.D.<sup>2</sup>, Candice L. Garwood, Pharm.D.<sup>3</sup>, Melissa Lipari, Pharm.D.<sup>4</sup>; (1) Detroit Medical Center, Harper University Hospital, Detroit, MI; (2) Wayne State University, Detroit, MI; (3) Wayne State University, Eugene*

*Applebaum College of Pharmacy and Health Sciences, Detroit, MI; (4) Harper University Hospital, Detroit, MI*

**PURPOSE:** Medication and lifestyle nonadherence is a common cause for rehospitalizations in heart failure (HF) patients. Patients who receive post-discharge education and support from a pharmacist have less re-hospitalizations and shorter lengths of stay. Our institution recently implemented a novel medication adherence clinic (MAC) aimed at improving transitions of care for HF patients. Our primary aims were to evaluate: (i) pharmacist interventions/activities (ii) patient perceptions of pharmacist guidance (iii) 30-day readmission rate.

**METHODS:** Electronic medical record documentation was retrospectively reviewed to identify drug or disease related problems (DRPs) and subsequent pharmacist interventions (classified using the PCNE V6.2 modified DRP classification tool). Patient perception of pharmacy was prospectively assessed, against a control group using a pre and post-intervention survey (Purdue Pharmacist Directive Guidance Scale). Participants were recruited via an electronic inpatient HF list. Residents of long-term care facilities, patients admitted for hospice care, and those with severe communication deficits were excluded from the prospective phase. Health care outcomes were evaluated retrospectively by comparing readmission rates of the clinic patients to control patients and historical institutional data.

**RESULTS:** We reviewed 16 MAC visits. A total of 83 DRPs were identified, (average  $5 \pm 2$  DRPs per visit). Thirty-six percent of DRPs were information/knowledge-based. Reasons for medication and diet nonadherence were multi-factorial and included poor care transitions, poor health literacy, and insufficient prescription taking skills. There were 223 interventions documented, (average  $14 \pm 2$  per visit). The majority of interventions were made in response to a patient's lack of knowledge or information (49%). The readmission rate at 30 days was 31% (intervention group) versus 50% (control group), which was higher than the 2011 hospital average (27.4%).

**CONCLUSION:** Pharmacists can make impactful interventions to improve adherence, increase disease state/medication knowledge and reduce 30 day readmission rates. Pharmacists are also poised to prevent adverse events through identification of post-discharge medication discrepancies.

**21E. Effects of a pharmacist-initiated outreach program on controller medication use and asthma control in non-adherent asthmatics.** *Kelly A. Gibas, Pharm.D., Amy M. Kramer, Pharm.D., Mary Ann Dzurec, Pharm.D., Paul R. Bandfield, Pharm.D.; Kaiser Permanente, Parma, OH*

**PURPOSE:** To evaluate the impact of a new program in which primary care clinical pharmacists (PCCPs) in an ambulatory care setting outreached to patients with persistent asthma.

**METHODS:** This retrospective chart review included non-COPD patients aged 5–65 with a diagnosis of persistent asthma who received PCCP outreach between September 12, 2011 and January 31, 2012. Inclusion criteria consisted of overutilization of albuterol; lack of/non-adherence to an inhaled corticosteroid (ICS); same-day/ER visit for asthma exacerbation in the past 3 months; or oral corticosteroid (OCS) prescription for asthma exacerbation filled in the past 3 months. To determine the outreach program's effectiveness, medication refills for albuterol and ICS 3 months before and after outreach were evaluated. Improvement in asthma control was assessed by comparing quantity of OCS prescriptions utilized for acute asthma exacerbation 3 months before and after outreach and change in Asthma Control Test (ACT) scores between initial outreach and follow-up approximately 1 month later.

**RESULTS:** A total of 266 patient charts were evaluated, of which 106 patients received PCCP outreach. Of these, 78 met inclusion criteria. Ninety days following outreach, 46% (36/78) had filled an ICS. 32% (25/78) filled an ICS who had not filled one in the last 90 days. The average ICS day supply per patient 90 days before and after outreach increased significantly from 12.69 to 39.71 days ( $p < 0.0001$ ). The number of albuterol canisters per patient 90 days before and after outreach also increased significantly from 1.37

canisters to 1.88 canisters ( $p=0.0141$ ). The average ACT score increased significantly from 15.6981 to 19.4906 ( $p<0.0001$ ). The percentage of patients with controlled asthma (ACT score  $\geq 20$ ) increased significantly from 21.67% to 68.3% ( $p<0.0001$ ).

**CONCLUSION:** Clinical pharmacist outreach not only improved ICS adherence but also led to clinically significant increases in ACT scores and the percentage of patients achieving ACT-defined asthma control. Presented at the Great Lakes Pharmacy Resident Conference, West Lafayette, IN, April 25–27, 2012.

## Cardiovascular

**22E. Impact of a high-fat meal on assessment of clopidogrel-induced platelet inhibition in healthy subjects.** Paul P. Dobesh, Pharm.D.<sup>1</sup>, Jamela Urban, Pharm.D.<sup>2</sup>, Scott Shurmur, M.D.<sup>2</sup>, Julie H. Oestreich, Pharm.D.<sup>1</sup>; (1) University of Nebraska Medical Center, Omaha, NE; (2) The Nebraska Medical Center, Omaha, NE

**PURPOSE:** We conducted this study to evaluate whether a high-fat meal impacts the ability of various platelet function tests to assess platelet reactivity for patients on clopidogrel.

**METHODS:** Healthy subjects not taking antiplatelet drugs presented after a 12 hour fast. After baseline platelet function assessment, subjects were given a 600 mg dose of clopidogrel. Four hours after the dose, maximum platelet inhibition was tested in the fasting state. Subjects were then provided a standardized high-fat meal, and platelet function was evaluated 2 hours later. Platelet function was assessed by two optically dependent assays (LTA and VerifyNow P2Y<sub>12</sub>) and two non-optically dependent assays (vasodilator-stimulated phosphoprotein (VASP) and whole blood aggregometry [WBA]). Platelet function was compared before and after the high-fat meal with the Wilcoxon matched-pair signed-rank test.

**RESULTS:** Twelve healthy adults were recruited. The mean triglyceride level increased following the high-fat meal (79 versus 132 mg/dl;  $p=0.002$ ). There was no significant change in maximal light transmission as assessed by LTA (range:  $-9\%$  to  $11\%$  with  $5 \mu\text{mol/L}$  ADP;  $p=0.15$  and  $-9\%$  to  $10\%$  with  $20 \mu\text{mol/L}$  ADP;  $p=0.07$ ). There was a significant change in the area under the curve with  $5 \mu\text{mol/L}$  ADP (range:  $-9$  to  $65$ ;  $p=0.03$ ) but not with  $20 \mu\text{mol/L}$  ADP (range:  $-41$  to  $63$ ;  $p=0.18$ ). Although there was no significant change in P2Y<sub>12</sub> Reaction Units with the VerifyNow P2Y<sub>12</sub> assay (range:  $-28$  to  $47$ ;  $p=0.16$ ), the change was correlated with the initial fasting value (Spearman's rho  $p=0.01$ ). There was minimal variability with the VASP assay (range:  $-4.4$  to  $5.4$ ;  $p=0.35$ ), and no changes were evident with WBA.

**CONCLUSION:** The intake of a high-fat meal did not significantly alter platelet function assessment of commonly used platelet function tests. There was more intra-subject variability with the optically dependent compared with non-optically dependent platelet function tests.

Presented at Dobesh PP, Urban J, Shurmur S, Oestreich J. Impact of a high-fat meal on assessment of clopidogrel-induced platelet inhibition in healthy subjects. *J Am Coll Cardiol* 2012;59 (Suppl A): A118 abstract 1160-632. Presented as a poster at the American College.

**23. Perceptions, knowledge, and patterns of use of "fish oil" products in cardiac patients.** Elizabeth B. Hawkins, Pharm.D.<sup>1</sup>, Hua Ling, Pharm.D.<sup>2</sup>, Tammy L. Burns, Pharm.D.<sup>2</sup>, Daniel E. Hilleman, Pharm.D., FCCP<sup>3</sup>; (1) Creighton University Medical Center, Omaha, NE; (2) Creighton University Cardiac Center, Creighton University School of Medicine, Omaha, NE; (3) Department of Pharmacy Practice, Creighton University School of Pharmacy and Health Professions, Omaha, NE

**PURPOSE:** To determine cardiac patients' beliefs, knowledge and patterns of use of "fish oil" products (FOP).

**METHODS:** Patients using a FOP admitted to a university-affiliated cardiology service were interviewed by pharmacy students or pharmacists. Patients were asked questions about their FOP including the following: indication, who recommended the product, place of purchase, active ingredient, brand, dose, and cost of product.

**RESULTS:** A total of 496 patients were included. Comorbidities included coronary disease (96%), dyslipidemia (72%), hypertension (70%), and coronary revascularization (45%). Sixty percent indicated they were taking FOP for a specific disease indication while 40% indicated they were taking FOP for a general health indication (heart health, brain health, general health). Only 10% indicated they were taking a FOP specifically for a lipid disorder. Only 9% ( $n=45$ ) of patients were told to take a FOP by their physician. Only 22 were given prescriptions for Lovaza<sup>®</sup>. Nine of these 22 patients were actually filling their Lovaza<sup>®</sup> prescriptions. Seventy-five percent of patients could not identify the active ingredient in their FOP. A total of 107 patients accurately identified the active ingredient in their FOP, but only 23 knew the dose they were taking. Seventy-three percent of patients indicated they purchased the same brand of FOP each time they purchased their FOP. Seventeen percent of patients purchased their FOP in a pharmacy. Ninety-eight percent of patients paid less than \$25 per month for their FOP while 47% spent less than \$15 per month. Only 2% of patients paid more than \$25 per month and all were receiving Lovaza<sup>®</sup>.

**CONCLUSION:** The results of this study indicate that the vast majority of patients are under-educated concerning their FOP. Few patients (10%) are actually taking FOP for lipid disorders, while only 9% were told to take FOP by their physicians. Pharmacists should play a greater role in educating patients about the use of FOP.

**24. Aliskiren in patients failing to achieve blood pressure targets with angiotensin converting enzyme inhibitors or angiotensin receptor blockers.** Elizabeth B. Hawkins, Pharm.D.<sup>1</sup>, Hua Ling, Pharm.D.<sup>2</sup>, Tammy L. Burns, Pharm.D.<sup>2</sup>, Aryan Mooss, M.D.<sup>2</sup>, Daniel E. Hilleman, Pharm.D., FCCP<sup>3</sup>; (1) Creighton University Medical Center, Omaha, NE; (2) Creighton University Cardiac Center, Creighton University School of Medicine, Omaha, NE; (3) Department of Pharmacy Practice, Creighton University School of Pharmacy and Health Professions, Omaha, NE

**PURPOSE:** To assess the efficacy of aliskiren in patients failing to reach blood pressure (BP) goals with either an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin receptor blocker (ARB).

**METHODS:** The study included 107 patients with hypertension that failed to reach BP goals on adequate doses and durations of therapy with an ACEI or an ARB. Patients were switched to aliskiren for a minimum of 4 weeks on its initial dose and a minimum of 4 weeks on its maximal dose (if needed). Other antihypertensive therapy was allowed as long as that therapy was not altered. Changes in BP were determined with initial ACEI and ARB therapy and after maximal aliskiren therapy. The proportion of patients who successfully achieved BP goals with aliskiren therapy was also determined.

**RESULTS:** ACEI were used in 79 patients and ARBs in 28 patients. Of these patients, only six received monotherapy (all on ACEI). The mean reduction in sBP and dBP with ACEI was  $8.5 \pm 6.3$  mmHg and  $6.0 \pm 4.7$  mmHg, respectively. The mean reduction in sBP and dBP with ARB was  $8.3 \pm 6.7$  mmHg and  $5.0 \pm 5.2$  mmHg, respectively. The mean reduction in sBP and dBP with aliskiren 150 mg/day was  $6.7 \pm 5.4$  and  $5.4 \pm 4.8$  mmHg, respectively. The mean reduction in sBP and dBP with aliskiren 300 mg/day was  $8.6 \pm 6.3$  and  $6.0 \pm 4.9$  mmHg, respectively. Only one patient achieved their BP target on aliskiren ( $<1\%$ ).

**CONCLUSION:** Aliskiren is not effective in patients failing either ACEI or ARBs therapy. Given the recent restricted use of aliskiren in combination with ACEI and ARBs, its excess cost, and the lack of outcome data, there does not appear to be a role for the use of aliskiren in clinical practice.

**25. Discordance between regression-derived and ATP III table-derived Framingham 10-year risk: A P.A.T.H. Substudy.** Steven M. Smith, Pharm.D., M.P.H.<sup>1</sup>, Nancy Borja-Hart, Pharm.D.<sup>2</sup>, Audrey Wooten, M.D.<sup>3</sup>, Benjamin J. Epstein, Pharm.D.<sup>4</sup>;

(1) University of Colorado, Aurora, CO; (2) East Coast Institute for Research, Jacksonville, FL; (3) St. Vincent's Hospital, Jacksonville, FL; (4) University of Florida, Gainesville, FL

**PURPOSE:** Current U.S. guidelines for treatment of high cholesterol (ATP III) recommend LDL goals based on individual Framingham 10-year "hard" CHD Risk (FR). ATP III guidelines provide tables for estimating FR, but these tables only approximate the risk estimated by the regression-derived coefficients from the Framingham cohort. The concordance between these estimates of FR is not well known.

**METHODS:** Medical records from 110 patients in a general Family Medicine practice were randomly selected for data abstraction in this cross-sectional analysis. For each patient, data were collected for gender, age, systolic blood pressure, presence/absence of antihypertensives, total cholesterol, HDL, and smoking status. Two FR scores were calculated per patient using the ATP III tables and a mathematical algorithm derived from the Framingham study. The difference and absolute difference in FR calculations for each patient were determined and a correlation analysis between the two FR calculations was performed.

**RESULTS:** Using the ATP III tables, the mean and median FR were calculated as 13% and 11% (IQR, 6–20%), whereas the regression-derived mean and median FR were calculated as 13.4% and 11.6% (IQR, 5.3–20.1%). Although the overall mean difference between FR calculations was small (0.34%), we found a significant mean absolute difference between FR calculations of 2.5% (IQR, 0.5–3.6%) with a range of 0.02–32.3% ( $p < 0.0001$  for the test that the mean absolute difference equaled 0). Ten percent of patients had an absolute difference between FR calculations exceeding 5%. Additionally, 24.5% of patients were categorized differently (e.g. low/moderate/high risk) depending on the FR calculation used. The FR calculations were highly correlated ( $r = 0.88$ ;  $p < 0.001$ ).

**CONCLUSION:** ATP III table calculations of FR differ significantly from the regression-derived FR in a significant proportion of patients. Additional studies will determine the impact of this discordance on prescribing patterns for cholesterol medications.

**26. Impact of safety alerts on prescribing patterns of simvastatin and atorvastatin in an outpatient cardiac specialty centre in Singapore.** *Chai Ling Ong, B.Sc.Pharm.(Hons.), Jacqueline Peck Sze Wong, B.Sc.Pharm.(Hons.), Shera See Ah Wong, B.Sc.Pharm.(Hons.), Huey Shyan Yong, B.Sc.Pharm.(Hons.), Jin Shing Hon, B.Sc.Pharm.(Hons.), Siew Chong Teo, M.Pharm.(Clin. Pharm.), Chi Keong Ching, FAMS (Cardiology); National Heart Centre Singapore, Singapore, Singapore*

**PURPOSE:** To evaluate the impact of the Food and Drug Administration (FDA) Safety Alert (June 2011) and National Heart Centre Singapore (NHCS) Pharmacy and Therapeutics (P&T) Committee Alert (September 2011) on prescribing patterns of simvastatin ( $70 \text{ mg} < X \leq 80 \text{ mg}$ ) and atorvastatin ( $30 \text{ mg} < Y \leq 40 \text{ mg}$ ) as an alternate therapy in NHCS.

**METHODS:** This is a retrospective observational study. The number of outpatient pharmacy prescriptions in the year 2011 with simvastatin and atorvastatin in the respective dosing range, was retrieved from the Enterprise Crystal Report Server of NHCS and tabulated in month. The prescribing trends were then compared before and after June and September.

**RESULTS:** There was a relative reduction of 30.0% for number of patients dispensed with simvastatin from June onwards; the average percentage of prescriptions with simvastatin filled reduced from 1.9% from January to May, to 0.8% from June onwards. However, the number of prescriptions processed for atorvastatin started to pick up in July with an average percentage of 22.9% versus 17.9% previously.

Year 2011	Proportion of prescriptions dispensed (percentage)	
	70 mg < X ≤ 80 mg	30 mg < Y ≤ 40 mg
January	66/3256 (2.0)	116/695 (16.7)
February	54/2581 (2.1)	91/554 (16.4)
March	59/3308 (1.8)	134/708 (18.9)
April	43/2552 (1.7)	101/580 (17.4)
May	58/2860 (2.0)	120/629 (19.1)
June	39/2799 (1.4)	140/735 (19.0)
July	21/2736 (0.8)	155/748 (20.7)
August	29/3036 (1.0)	182/777 (23.4)
September	20/2951 (0.7)	189/795 (23.8)
October	16/2717 (0.6)	191/792 (24.1)
November	15/2612 (0.6)	196/908 (21.6)
December	11/2753 (0.4)	178/747 (23.8)

**CONCLUSION:** The results reflected a reduction in prescriptions for simvastatin with a corresponding increase for atorvastatin, the most cost-effective alternative in the formulary. This study showed that the physicians were keeping abreast with relevant updates that affect patient care in statin therapy.

**27. Effectiveness and safety of rivaroxaban compared to enoxaparin for thromboprophylaxis in orthopedic patients.** *Vimala Sivapragasam, Pharm.D., BCPS, Teena Abraham, Pharm.D., BCPS, Nasser Saad, Pharm.D., Henry Tischler, M.D., Eric Balmir, Pharm.D.; New York Methodist Hospital, Brooklyn, NY*

**PURPOSE:** This retrospective study compared the effectiveness and safety of rivaroxaban to enoxaparin for prophylaxis against venous thromboembolism (VTE) in patients who had undergone total hip or knee arthroplasty (THA/TKA).

**METHODS:** The medical records of randomly selected patients who received either rivaroxaban or enoxaparin for VTE prophylaxis post THA or TKA between January 1, 2011 and March 31, 2012 were reviewed. Data was collected for a comparative analysis of baseline characteristics and primary outcomes. The primary effectiveness outcome was any post-surgical VTE event, defined as any deep vein thrombosis (DVT) or pulmonary embolism (PE) within 35 days post THA and 17 days post TKA. Safety outcomes included incidence of any post surgical hemorrhagic or non-hemorrhagic adverse events, and all cause mortality.

**RESULTS:** A total of 77 patients were analyzed (50 in the enoxaparin arm and 27 in the rivaroxaban arm). Baseline characteristics were similar in both groups. DVT or PE events occurred in none of the patients in the rivaroxaban arm and 8% (4/50) of the patients in the enoxaparin arm. Post-surgical hemorrhagic events were reported in 15% (4/27) of patients in the rivaroxaban arm and 6% (3/50) of patients in the enoxaparin group. Surgery related non-hemorrhagic adverse events were noted in 7% (2/27) in the rivaroxaban arm and none in the enoxaparin arm. There were no reports of mortality.

**CONCLUSIONS:** Rivaroxaban was associated with a lower incidence of VTE in patients who had undergone THA or TKA compared to enoxaparin. There was a higher rate of post-surgical hemorrhagic and non-hemorrhagic adverse events in patients on rivaroxaban compared to enoxaparin

**28. The relative bioavailability of single-dose rivaroxaban, a novel oral anticoagulant and a selective direct factor Xa inhibitor, administered orally (as a whole or crushed tablet) and via nasogastric tube (as a crushed tablet suspension).** *Kenneth T. Moore, M.S.<sup>1</sup>, Seema Vaidyanathan, M.S.<sup>1</sup>, Chandrasekharrao V. Damaraju, Ph.D.<sup>2</sup>, Larry E. Fields, M.D., MBA, FAHA, FACC<sup>3</sup>; (1) Janssen Research & Development, LLC, Titusville, NJ; (2) Janssen Research & Development, LLC, Raritan, NJ; (3) Janssen Scientific Affairs, LLC, Raritan, NJ*

**PURPOSE:** Some patients have difficulty swallowing whole tablets. Accordingly, this study compared the relative bioavailability of rivaroxaban administered as a whole tablet or in alternative formulations.

**METHODS:** This was a single-center, open-label crossover study. Healthy subjects were randomized to 1 of 6 dosing sequences, with each sequence consisting of three treatment periods that were each separated by a 6–14 day washout. On day 1, subjects received a single 20 mg oral dose of rivaroxaban as a whole tablet (Reference), a crushed tablet mixed in applesauce (Crushed-Oral) or a crushed tablet in a water-suspension administered via nasogastric tube (Crushed-NG). Dosing was followed by a 100 ml standardized liquid meal. The total administered volume was identical for each group (500 ml). Serial blood samples were collected pre-dose and over 48 hours post-dose. Plasma concentrations of rivaroxaban were measured and  $C_{max}$  and  $AUC_{\infty}$  estimated. While not a formal bioequivalence study, tablet formulations were considered bioequivalent if the ratios of geometric least squares means and associated 90% CIs were within the range of 80–125%.

**RESULTS:** Forty-four subjects completed the study and were included in the PK analysis set. Their mean age and BMI were approximately 38 years and 25 kg/m<sup>2</sup>, respectively. The geometric mean ratios for  $C_{max}$  and  $AUC_{\infty}$  were 90.0% and 95.4%, respectively, comparing Crushed-Oral to Reference; and 82.0% and 89.1% respectively, comparing Crushed-NG to Reference. The  $C_{max}$  and  $AUC_{\infty}$  were within the 80–125% range between the Crushed-Oral and Reference formulations. The  $AUC_{\infty}$  but not  $C_{max}$  (90% CI = 78.5–85.8%) was within the 80–125% range between the Crushed-NG and Reference formulations. The three tablet formulations were well tolerated.

**CONCLUSION:** Rivaroxaban tablets may be crushed and either mixed in applesauce or suspended in water and administered via an NG tube to appropriate patients who have difficulty swallowing a whole tablet.

**29. Factors influencing physicians' selection of dabigatran in non-valvular atrial fibrillation.** Cindy Huang, Pharm.D., Michele Siu, Pharm.D., Lily Vu, Pharm.D., Soo Wong, Pharm.D., Jaekyu Shin, Pharm.D.; University of California San Francisco, San Francisco, CA

**PURPOSE:** This study was designed to examine the factors that influence physicians' decision in initiating or switching from warfarin to dabigatran.

**METHODS:** A survey questionnaire was sent to 181 physicians who were most likely to prescribe dabigatran (e.g., cardiologists and general internists) at the University of California, San Francisco (UCSF) Medical Center between November 2011 and February 2012. Survey participants were asked to complete an electronic or a paper version of the questionnaire, which consisted of 17 multiple-choice questions. Fisher's exact test and Cochran-Mantel-Haenszel test were used to compare survey responses between cardiologists and general internists.

**RESULTS:** A total of 65 survey responses were received (35.9% response rate). Thirteen cardiologists and 51 general internists participated in the study. Cost (25%), renal function (21%) and CHADS2 score (18%) were the three factors physicians considered most often to determine a patient's eligibility for dabigatran in warfarin-naïve patients. On the other hand, histories of unstable INR (37%) and missed appointments (17%) along with cost (19%) were most often considered in patients on warfarin. Cardiologists had prescribed dabigatran more often and had a significantly higher level of comfort with prescribing the drug than general internists ( $p=0.003$ ; 77% versus 27%).

**CONCLUSION:** Cost was the most important factor influencing physicians' decision to prescribe dabigatran. Safety and effectiveness of dabigatran as well as patient preference were additional factors influencing their decision. General internists may be targeted for education on dabigatran because they were less comfortable with prescribing dabigatran than cardiologists.

**30. Comparison of the risk of bradycardia between two oral metoprolol formulations.** Jaekyu Shin, Pharm.D.<sup>1</sup>, Marco Gonzales, Pharm.D.<sup>2</sup>, Mark Pletcher, M.D.<sup>1</sup>; (1) University of California San Francisco, San Francisco, CA; (2) California Department of Health Care Services, Sacramento, CA

**PURPOSE:** Two oral metoprolol formulations – immediate release (IR) and slow-release (SR) – have different pharmacokinetics at the same total daily dose. We compared the incidence of emergency room visits or hospitalizations due to bradycardia between the two formulations in beneficiaries of Medi-Cal, the State of California Medicaid program.

**METHODS:** We identified adults initiating metoprolol use between May 1, 2004 and November 1, 2009 who had no pharmacy claim for a beta blocker within the previous 6 months of metoprolol initiation. We used International Classification of Diseases-9 codes to exclude those who had a primary or secondary diagnosis of bradycardia or pacemaker placement before metoprolol initiation. The primary outcome was time to first occurrence of an emergency room visit or hospitalization due to bradycardia after metoprolol initiation. Metoprolol formulation (IR versus SR) was included in a proportional hazards model, with adjustment for total daily metoprolol dose and the use of other drugs as time-varying covariates as well as demographics and co-morbidities.

**RESULTS:** A total of 31,991 subjects were included in the analysis. In the IR group, 117 had a bradycardic event (0.62%; 2.14 per 1000 person-months) whereas 49 had one in the SR group (0.37%; 1.13 per 1000 person-months). The IR formulation significantly increased the risk of a bradycardic event compared with the SR formulation (unadjusted hazard ratio (HR) 1.83, 95% confidence interval (CI) 1.31–2.55; adjusted HR: 1.64, 95% CI: 1.16–2.33). The use of a cytochrome P450 2D6 inhibitor (HR: 1.47, 95% CI: 1.07–2.01), an antiarrhythmics (HR: 2.31, 95% CI: 1.22–4.38), and an atrioventricular node-blocking agent (HR: 2.34, 95% CI: 1.67–3.30) also significantly increased risk of a bradycardic event.

**CONCLUSIONS:** Use of the IR instead of the SR formulation of metoprolol is associated with an increased risk of serious bradycardia events requiring emergency care, though the absolute risk is low.

**31. Heart failure patients demographics at an inner city safety net hospital.** Andrew Smith, Pharm.D.<sup>1</sup>, Darcy Green-Conaway, M.D.<sup>2</sup>, Mark E. Patterson, Ph.D., M.P.H.<sup>3</sup>; (1)UMKC School of Pharmacy, Kansas City, MO; (2)Truman Medical Center, Kansas City, MO; (3)University of Missouri-Kansas City School of Pharmacy, Kansas City, MO

**PURPOSE:** This study was undertaken to describe the heart failure (HF) population in an inner city, safety-net hospital and identify characteristics in this patient population that could impact pharmacotherapy.

**METHODS:** This retrospective cohort study selected HF patients discharged over a 1 year period with a primary discharge diagnosis code of ICD-9 CM 428.xx. The following information was extracted: admit and discharge dates, demographics, imaging results, etiology, diagnostic testing, discharge medications, cardiology consult, BNP level, the presence of 90 day all-cause or cardiovascular readmissions and comorbidities. Demographic items were analyzed and reported as means  $\pm$  standard deviation. Comparison between data was made using student's t-test for continuous variables and  $\chi^2$  test for nominal or ordinal items. Multivariate logistic regression was employed to identify predictors of 90 day readmission.

**RESULTS:** A total of 240 patients with 328 unique hospitalizations were examined. The sample of 240 patients had a mean age of 57.0  $\pm$  12.5 years, and were mostly female ( $n=124$ , 51.7%) and African-American (AA) ( $n=192$ , 80%). Patients averaged 1.4 hospitalizations over the 1 year study period, with an average length of stay of 3.95  $\pm$  3.27 days. Diastolic dysfunction was common in this population ( $n=114$ , 80%), etiology was mostly non-ischemic cardiomyopathy ( $n=119/217$ , 54.8%), and the average ejection fraction was 35.7  $\pm$  17.3%. Substance abuse (ICD-9 code 305.X) was a common comorbid condition ( $n=97$ , 40%). Most patients were prescribed angiotensin converting enzyme inhibitors or angiotensin receptor blockers ( $n=188$ , 81.7%), beta blockers ( $N=179$ , 77.8%), and loop diuretics ( $n=173$ , 75%) at discharge. In

contrast, most patients did not have aldosterone antagonists (n=43, 18.8%) or digoxin (n=33, 14.4%) prescribed at discharge.

**CONCLUSION:** This study illustrates patients discharged from an inner city safety-net hospital are mostly AA and have a high prevalence of non-ischemic etiology and substance abuse which should be considered when selecting pharmacotherapy.

**32. Impact of worsening renal function on resource utilization and medications after diuretic dose escalation in a chronic heart failure ambulatory population.** Vicki L. Groo, Pharm.D.<sup>1</sup>, Anita Lammers, Pharm.D.<sup>2</sup>, Daniel Touchette, Pharm.D., M.A.<sup>1</sup>, Thomas D. Stamos, M.D.<sup>1</sup>; (1)University of Illinois at Chicago, Chicago, IL; (2)Illinois Masonic Medical Center, Chicago, IL

**PURPOSE:** Heart failure (HF) patients often require diuretic (D) escalation to treat volume overload. Worsening renal function (WRF) is associated with increased length of stay, morbidity, mortality and costs in the inpatient setting. We sought to evaluate the impact of WRF after D escalation in the ambulatory setting.

**METHODS:** Retrospective chart review of ambulatory HF patients whose oral D was increased between July 1, 2007 and June 30, 2010. WRF was defined as a rise in serum creatinine >0.3 mg/dl after D therapy escalation. Unplanned visits included any phone contact, visit to the clinic, or lab for evaluation of renal function that was not scheduled at the index visit. Hospitalizations or ED visits related to HF or renal failure were also categorized as unplanned. Medications orders including orders to decrease or hold D or RAAS inhibitor were assessed. All visits and medication changes were totaled during a 3 month follow-up and analyzed using un-paired student's t test.

**RESULTS:** Eighty-six patients accounted for 121 day dose increases of which there were 48 episodes of WRF. Using only the first encounter, demographics, vitals, PMH, HF medications, diuretic regimen, ejection fraction, and BNP were similar between groups.

	WRF n=48		SRF n=73		p value
	Number	Avg/SD	Number	Avg/SD	
Creatinine change		0.71 ± 0.52		-0.034 ± 0.18	<0.001
Planned visits	68	1.41 ± 0.87	100	1.37 ± 0.77	0.76
Unplanned visits	102	2.12 ± 1.83	46	0.63 ± 1.01	<0.001
Lab	121	2.52 ± 1.52	76	1.04 ± 0.98	<0.001
Medications					
↓ or hold D	54	1.12 ± 0.89	22	0.30 ± 0.52	<0.001
↓ or hold RAAS	20	0.42 ± 0.77	3	0.04 ± 0.2	0.002

**CONCLUSION:** WRF occurs commonly in patients with D dose escalation in the ambulatory setting, leading to increased resource utilization and subsequent reductions in D and RAAS inhibitors.

**33. Baseline albumin predicts worsening renal function in acute decompensated heart failure patients receiving continuous infusion loop diuretics.** Megan M. Barnes, Pharm.D., BCPS<sup>1</sup>, Michael P. Dorsch, Pharm.D., M.S., BCPS, (AQ, CV)<sup>2</sup>, Susie Kim, Pharm.D.<sup>3</sup>, Keith Aaronson, M.D., M.S.<sup>2</sup>, Todd Koelling, M.D.<sup>2</sup>, Barry E. Bleske, Pharm.D., FCCP<sup>4</sup>; (1)Allegheny General Hospital, Pittsburgh, PA; (2)University of Michigan Hospitals and Health Centers, Ann Arbor, MI; (3)Eli Lilly & Company, Indianapolis, IN; (4)University of Michigan, Ann Arbor, MI

**PURPOSE:** Loop diuretics are a mainstay of therapy in patients hospitalized for acute decompensated heart failure (ADHF). Aggressive diuresis with loop diuretic infusions is often necessary for symptom relief. Overly aggressive diuresis can consequently lead to worsened renal function (WRF), which has been associated with increased mortality. We hypothesized that baseline clinical characteristics of ADHF patients receiving loop diuretic infusions could predict the development of WRF.

**METHODS:** A retrospective observational analysis of 177 ADHF patients receiving continuous infusion loop diuretics was performed. All patients admitted to the University of Michigan Health System with ADHF, receiving continuous loop diuretic infusions from January 2006 through June 2009 were included. Patients with incomplete medical records, <24 hours of loop diuretic infusion treatment, concurrent nephrotoxic agents (aminoglycosides, tacrolimus, cyclosporine, and sirolimus), patients transferred already given loop infusions, and those <18 years of age were excluded. The primary outcome of this study was to identify baseline predictors of time to WRF in an ADHF patient population receiving continuous infusion loop diuretics. WRF was defined as an increase in serum creatinine  $\geq$  0.3 mg/dl from baseline. Cox regression time-to-event analysis was used to determine the time to WRF based on different variables.

**RESULTS:** Mean patient age was 61 years, 37% were female, approximately 45% were classified as NYHA III, and median length of loop diuretic infusion was 4 days. Forty-eight patients (27%) experienced WRF and 34 patients (19%) died during hospitalization. Baseline albumin  $\leq$  3 g/dl was found to be the only significant predictor of WRF (HR 2.87; 95% CI (1.60 - 5.16); p=0.0004) and remained significant despite inclusion of other univariate variables.

**CONCLUSION:** Albumin  $\leq$  3 g/dl is a practical baseline characteristic to predict development of WRF in ADHF patients receiving continuous infusion loop diuretics.

**34E. Stability of levosimendan during simulated y-site administration.** Wayne S. Moore, II, Pharm.D.<sup>1</sup>, Jeffrey J. Cies, Pharm.D., BCPS<sup>2</sup>, Michael A. McCulloch, M.D.<sup>1</sup>, Deborah A. Davis, M.D.<sup>1</sup>, Robert W. Mason, Ph.D.<sup>3</sup>; (1)Alfred I. duPont Hospital for Children/Nemours Cardiac Center, Wilmington, DE; (2)St. Christopher's Hospital for Children, Philadelphia, PA; (3)Alfred I. duPont Hospital for Children/Nemours Biomedical Research, Wilmington, DE

**PURPOSE:** Limited information currently exists regarding the compatibility of the calcium sensitizer/inodilator levosimendan. The intent of this study was to evaluate the stability of levosimendan during simulated y-site administration with common infusions used in a critical care setting.

**METHODS:** Levosimendan 50 µg/ml in D5W was incubated at 25°C for 24 hours in a Waters<sup>®</sup> high performance liquid chromatography (HPLC) carousel. Samples were separated on a Novapak<sup>®</sup> C18 column and levosimendan was monitored and quantified by ultra-violet absorbance at 380 nm. Stability of levosimendan was measured after mixing with dobutamine, dopamine, epinephrine, esmolol, fentanyl, midazolam, milrinone, norepinephrine, remifentanyl, rocuronium, sodium nitroprusside/sodium thiosulfate, vasopressin, and vecuronium. Stability was defined as  $\geq$  90% of the initial drug concentration remaining in the admixtures at 24 hours. Visual inspection was performed to assess physical compatibility.

**RESULTS:** Levosimendan was stable for 24 hours with all the tested compounds. In the presence of sodium nitroprusside/sodium thiosulfate, a new peak was detected that eluted from the HPLC column prior to levosimendan. This peak increased linearly with time such that at 24 hours, ~7% of the original drug was depleted. This new peak did not appear when levosimendan was mixed with nitroprusside alone but a similar time-dependent increase was seen on incubation with thiosulfate alone. Visual inspection determined the solutions studied were physically compatible.

**CONCLUSIONS:** Levosimendan was compatible for 24 hours during simulated y-site testing with all of the drugs tested. Levosimendan does interact with sodium thiosulfate in a time-dependent manner. The new reaction product absorbs at 380 nm but the structure of the new compound has not yet been determined. Published in World Journal for Pediatric and Congenital Heart Surgery, April 2012; vol. 3, 2: pp. NP1-NP45. Presented at Cardiology 2012 16th Annual Update on

Pediatric and Congenital Cardiovascular Disease Orlando, FL, February 22–26, 2012.

### 35. The effect of continuous infusion loop diuretics in acute decompensated heart failure patients with hypoalbuminemia.

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**PURPOSE:** Hypoalbuminemia is believed to decrease diuretic effectiveness and contribute to diuretic resistance that is observed in patients with nephrotic syndrome. Hypoalbuminemia is also seen in patients with acute decompensated heart failure (ADHF). However, the role of hypoalbuminemia on the effectiveness of continuous infusion diuretics in patients with ADHF is not known.

**METHODS:** To evaluate hypoalbuminemia (albumin  $\leq 3$  g/dl) and diuretic effectiveness we performed a retrospective study in 162 patients admitted to a tertiary care center for treatment of ADHF over a 3 year period. All patients received continuous infusion diuretic for at least a 2 day time period.

**RESULTS:** A total of 33 patients were determined to have hypoalbuminemia with a mean albumin level of  $2.7 \pm 0.3$  mg/dl. In comparison, the mean albumin level of in the control group was  $3.7 \pm 0.4$  mg/dl ( $p < 0.01$ ). Average net urine output over 2 day study period were similar between patients with and without hypoalbuminemia ( $-1462 \pm 1734$  versus  $-1233 \pm 1560$  ml,  $p = 0.46$ , respectively). In addition, average diuretic dose (furosemide equivalent/24 hours) were similar between the two groups ( $681 \pm 800$  mg versus  $788 \pm 670$  mg,  $p = 0.35$ , respectively) as was baseline serum creatinine ( $1.6 \pm 0.6$  versus  $1.6 \pm 0.6$  mg/dl,  $p = 0.5$ , respectively).

**CONCLUSION:** Overall, hypoalbuminemia did not decrease diuretic effectiveness as measured by net urine output in patients receiving continuous infusion diuretics for the treatment of ADHF.

### 36. The effects of universal fibrinate discontinuation on management of dyslipidemia at the Portland Veterans Affairs Medical Center (PVAMC).

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**PURPOSE:** Recent FDA guidance regarding the use of simvastatin in combination with gemfibrozil led to the discontinuation of all fibrates in patients receiving concomitant statin therapy at PVAMC. The objective of this study was to evaluate changes in lipid levels after discontinuation of fibrates.

**METHODS:** Electronic medical records of all patients subject to the universal fibrinate discontinuation in June–July 2011 were reviewed. Patient demographics, comorbidities, and medications were extracted 2 years prior to discontinuation and 6 months after the discontinuation. Lipid levels were recorded from the last test prior to discontinuation and the first test within 8–20 weeks of discontinuation. Changes in medications and lipid levels were compared before and after discontinuation using the paired t-test and the chi-square test, where appropriate.

**RESULTS:** Of the 837 patients whose fibrates were discontinued, 398 have been screened to date and 348 met inclusion criteria. The majority of these patients had elevated triglycerides ( $>150$  mean 248 mg/dl), 68% had diabetes, 32% had CAD, and 11% had a stroke prior to discontinuation. Only 51% had follow-up lipid tests after discontinuation. Among these patients, there was a significant increase in triglycerides, decrease in HDL, and increase in total cholesterol ( $p < 0.05$  for all). There was no significant change in LDL or in prescribing rates for adjunctive therapies (i.e., niacin and omega-3 fatty acid preparations) after discontinuation. The proportion of the patients with

TG  $> 204$  mg/dl, HDL  $< 34$  mg/dl, and DM increased from 18% before discontinuation to 39% afterwards.

**CONCLUSION:** Pharmacy-implemented universal discontinuation of fibrates may place patients at increased risk of cardiovascular events. Targeted patient follow-up may be needed to reassess medication therapy, particularly for patients already at high-risk.

### 37. A pilot feasibility study to assess knowledge and behaviors related to warfarin therapy.

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**PURPOSE:** In order to effectively design studies to improve warfarin therapy, it is important to have an understanding of patients' knowledge and behaviors related to warfarin therapy. The objective of this pilot study was to characterize the results of and feasibility of administering health literacy, numeracy, nuisance bleeding and oral anticoagulation knowledge (OAK) questionnaires to patients who have recently started warfarin in two local anticoagulation clinics.

**METHODS:** Subjects were included if they started warfarin within the previous 2 months, were  $>20$  years of age, and had an INR goal of 2–3. Demographic and clinical information was collected and subjects completed the following validated questionnaires: REALM-R (health literacy, max score of 8, higher score = better literacy), Subjective Numeracy Scale (mathematical competency, max score of 8, higher score = better numeracy), Modified Bleed Score (nuisance bleeding assessment, max score of 10, higher score = more nuisance bleeding), and OAK test (20 questions, max 100%, higher score = better knowledge). Data were analyzed using descriptive statistics.

**RESULTS:** Twenty subjects provided written informed consent. Subjects were primarily Caucasian (60%),  $62 \pm 18$  (mean  $\pm$  SD) years of age and taking warfarin for atrial fibrillation or treatment of DVT or PE. The mean  $\pm$  sd REALM-R score was  $6.7 \pm 2.1$ , numeracy was  $4.0 \pm 1.0$ , nuisance bleeding was  $1.8 \pm 1.9$  and OAK was  $70 \pm 10\%$ . The administration of the questionnaires took approximately 12 minutes per patient. Questionnaires were reliably administered by both pharmacists and pharmacy students.

**CONCLUSION:** It was feasible to administer these questionnaires in an anticoagulation clinic. In addition, there was a significant amount of variability in patient responses, suggesting that some patients may require additional counseling related to behavior or knowledge. Thus, these questionnaires can potentially be used to identify patients requiring targeted behavior or warfarin knowledge counseling.

### 38. The effects of carvedilol in patients with cocaine-induced chest pain.

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**PURPOSE:** Benefits of beta-blocker therapy in acute coronary syndromes are well documented although their use in patients with cocaine-induced chest pain (CICP) remains controversial due to concerns regarding unopposed alpha-receptor vasoconstriction. Many patients presenting with CICP have compelling indications for beta-blockade, and carvedilol is often used because of its alpha-blocking properties. The purpose of this study is to determine safety and efficacy outcomes after carvedilol prescription to veterans after CICP.

**METHODS:** A retrospective analysis of patients presenting with chest pain and positive urine drug screen for cocaine over 72 months was performed. Demographic data, discharge beta-blocker prescription, concomitant diseases, emergency care, length of stay, all cause emergency department and readmission rates, recurrent MI, and mortality were evaluated. Outcomes were com-

pared between patients receiving carvedilol and those receiving no beta-blocker in this initial analysis.

**RESULTS:** A total of 909 occurrences were identified and outcomes in the first 76 cases meeting inclusion criteria are reported. Beta-blockers were prescribed at discharge in 25 (33%) cases, with carvedilol prescribed in 16 (64%). Patients discharged on carvedilol were significantly older and were more likely to have hypertension, heart failure, or coronary artery disease compared to patients receiving no beta-blocker. No significant differences in emergency care, length of stay, all cause emergency department and readmission rates, recurrent MI, and mortality were found between those receiving carvedilol compared to no beta-blocker. In patients with ejection fraction <40%, there were no differences in outcomes between patients receiving carvedilol and those prescribed no beta-blocker.

**CONCLUSION:** Patients with indications for beta-blocker therapy were more likely to be prescribed carvedilol at discharge, despite cocaine use. Prescription of carvedilol to patients after CICIP did not appear to worsen outcomes. Carvedilol use in patients with ejection fraction <40% and CICIP was safe.

### 39. Thromboxane and prostaglandin metabolite levels and inflammation phenotypes in coronary artery disease patients.

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**PURPOSE:** Inflammation plays a major role in the development of acute coronary syndrome (ACS) events in stable coronary artery disease (CAD) patients. In addition to regulating platelet activation, cyclooxygenase-derived thromboxane (TxA<sub>2</sub>) and prostacyclin (PGI<sub>2</sub>) have potent pro- and anti-inflammatory effects, respectively. Although low-dose aspirin suppresses platelet-derived TxA<sub>2</sub>, this prostanoid is synthesized by other cell types and initiates inflammatory processes that predispose CAD patients to increased risk of ACS events. Therefore, we evaluated associations between TxA<sub>2</sub>, PGI<sub>2</sub> and the TxA<sub>2</sub>/PGI<sub>2</sub> ratio and inflammation phenotypes predictive of prognosis.

**METHODS:** Using a cross-sectional design, we collected blood and urine from 123 patients with stable, angiographically-confirmed CAD after fasting, withholding morning medications, and withholding NSAID use for at least 7 days. Stable urine metabolites of thromboxane (Tx-M) and prostacyclin (PGI-M) were quantified by ELISA and normalized to creatinine. Relationships with circulating cellular adhesion molecules (CAMs: E-selectin, P-selectin), monocyte (MCP-1) and neutrophil (ENA-78) chemokines, and C-reactive protein (hs-CRP) were quantified by Spearman rank correlation ( $r_s$ ) and regression.

**RESULTS:** Subjects were 60 ± 10 years old, 70% male and 17% African-American, clinically stable, and 98% were receiving low-dose aspirin. Unadjusted correlations are reported below. Similar results were obtained when adjusting for demographic and clinical covariates, including aspirin dose (81 or 325 mg).

**CONCLUSION:** Elevated Tx-M levels are associated with activated inflammation phenotypes, suggesting TxA<sub>2</sub> biosynthesis is an important driver of inflammation in stable CAD patients on aspirin therapy. Future studies are needed to identify the origin of TxA<sub>2</sub> biosynthesis and develop interventions that attenuate inflammation in this high-risk population.

### 40. Racial differences in anticoagulation control and risk of hemorrhage among warfarin users.

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**PURPOSE:** Factors such as comorbidities, age, genetics, and concurrent medications have been shown to alter warfarin's dose, anticoagulant effect and associated hemorrhage risk. However, the influence of race on INR control and hemorrhagic risk in warfarin users is not well documented. Herein we assess whether there are differences in percent time spent in therapeutic INR range (2–3) and the risk of hemorrhagic complications in Blacks versus Whites.

**METHODS:** Patients on chronic warfarin therapy (n=1260) were prospectively followed from initiation of therapy. Detailed medical history was documented at baseline and monthly updates documented dose changes, INR control and occurrence of hemorrhagic complications. Racial differences in percent time in target range was assessed using Proc Mixed and risk of hemorrhage was assessed using Cox proportional hazards regression analysis in SAS version 9.2.

**RESULTS:** In comparison to Whites, Blacks spent less days within therapeutic INR range (51.85% versus 58.65%; p<0.0001) and more days below (49.96% versus 36.64%; p=0.0002) and above (18.92% versus 16.12%; p=0.0449) therapeutic INR range. In comparison to Whites, Blacks had a lower risk of a minor hemorrhage (HR: 0.76; CI: 0.64, 0.90; p=0.0017). For major hemorrhage, Blacks had a higher risk (HR: 1.67; CI: 1.13, 2.48; p=0.0104).

**CONCLUSION:** Blacks spent more time above recommended INR therapeutic range and had a higher risk of major hemorrhage. Factors explaining these differences could include clinical and genetic factors or differences in lifestyle, diet, medication adherence and access to care.

### 41. CHA<sub>2</sub>DS<sub>2</sub>-VASc score is associated with post-cardiothoracic surgery atrial fibrillation.

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**PURPOSE:** To evaluate whether pre-operative CHA<sub>2</sub>DS<sub>2</sub>-VASc score predicts the incidence of post-cardiothoracic surgery (CTS) atrial fibrillation (AF).

**METHODS:** Patients (n=560) undergoing coronary artery bypass grafting and/or valvular surgery from the Atrial Fibrillation Suppression Trials I, II and III were evaluated in this nested cohort study. Data on patient demographics, surgical characteristics, medication utilization and the incidence of post-CTS AF (defined as AF lasting at least 5 minutes in duration documented by telemetry) were all uniformly and prospectively collected. All variables showing a univariate association (p ≤ 0.20) with AF occurrence were entered into a backwards, stepwise multivariate logistic regression to control for potential confounders and calculate adjusted odds ratios (AOR) with 95% confidence intervals (CI).

**RESULTS:** The population was 67.8 ± 8.6 years old and 77.1% male. Thirty-four (6.1%) patients had a CHA<sub>2</sub>DS<sub>2</sub>-VASc score of 0–1 (low), 261 (46.5%) patients had a score of 2–3 (medium), and 265 (47.3%) patients had a score of >3 (high). A total of 177 (31.6%) patients had post-CTS AF event, including 27%, 23%, and 41%, of the low, medium, and high CHA<sub>2</sub>DS<sub>2</sub>-VASc groups, respectively. Patients in the high-score group had a 2.3-fold increased odds of developing post-CTS AF as patients in the medium-score group (p<0.0001). The difference between the high and medium-score groups versus the low-score group was not statistically significant. On multivariate logistic regression higher pre-operative CHA<sub>2</sub>DS<sub>2</sub>-VASc score was associated with higher adjusted odds of developing post-CTS AF (AOR 1.27, 95% CI 1.05–1.53).

**CONCLUSIONS:** Increasing CHA<sub>2</sub>DS<sub>2</sub>-VASc score was a strong independent predictor for the development of post-CTS AF with patients in the high-score group having the highest overall incidence. Practitioners may be able to more accurately predict patients at highest risk for Post-CTS AF and ensure that optimal pharmacologic prophylaxis is initiated.

## Clinical Administration

**42. Balance of academic responsibilities of clinical track pharmacy faculty in the US.** *Edith A. Nutescu, Pharm.D.*, Robert DiDomenico, Pharm.D., Sacheeta Bathija, B.S., Pharm., Shellee Grim, Pharm.D., Jeffrey Mucksavage, Pharm.D., Eljim Tesoro, Pharm.D., Kirsten Ohler, Pharm.D., James Thielke, Pharm.D., Juliana Chan, Pharm.D., Nancy Shapiro, Pharm.D., Janet Engle, Pharm.D.; Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy, Chicago, IL

**PURPOSE:** To assess the distribution of effort and balance of academic and clinical responsibilities of clinical track pharmacy faculty.

**METHODS:** A web-based, 23-item, cross-sectional survey of clinical track pharmacy faculty of select Practice and Research Networks of the American College of Clinical Pharmacy was conducted December 2011–January 2012. Responses were summarized using descriptive statistics, chi-square or Fisher's exact test for binary and nominal variables, and Wilcoxon's t-test for continuous variables.

**RESULTS:** Response rate was 38% (n=344). The majority of respondents were (clinical) assistant professor (54%), followed by associate (26%) and professor (11%). More faculty practiced in inpatient settings (52%) versus ambulatory care (33%), and affiliation with a state versus private school was 57.6% versus 42.4%. While department expectations did not significantly differ from actual % effort spent on clinical service (30% versus 31%), didactic/clinical teaching (37% versus 38%), and scholarship/research (12% versus 8%), department expectations and actual time spent on clinical service were higher in state-affiliated versus private schools (35% versus 30%, p=0.03 and 36% versus 30%, p=0.04 respectively). "Protected" time to perform academic/scholarly activities was reported by 26% of respondents. Increased teaching load, research funding, and administrative responsibilities were the most common factors cited to justify "protected" time. While 27% of clinical faculty reported tenure eligibility within their department, this number was lower in state-affiliated versus private schools (21% versus 36%, p=0.01). Seventy percentage of clinical faculty disagreed or strongly disagreed they have sufficient time to fulfill their academic and scholarly activities. This measure did not differ between state-affiliated and private schools.

**CONCLUSIONS:** Faculty in state-affiliated schools reported spending more time on clinical service compared to private schools. Availability of "protected" time and satisfaction with having sufficient time to adequately fulfill academic and scholarly responsibilities was generally low among the clinical track faculty.

## Community Pharmacy Practice

**43. Coaching to better medication adherence: the pharmacist as a health coach.** *CoraLynn B. Trewet, M.S., Pharm.D.*<sup>1</sup>, Jennifer R. Moulton, R.Ph.<sup>2</sup>; (1) University of Iowa College of Pharmacy, Des Moines, IA; (2) Collaborative Education Institute, Des Moines, IA

**PURPOSE:** The purpose of the study was to demonstrate improvements in medication adherence through a health coach intervention by a pharmacist.

**METHODS:** The study was a pre- and post-test study design over a 12-month period to evaluate the effects of an educational intervention on medication adherence. Community pharmacists (n=8) identified patients to coach to better adherence. The analysis included 36 patients with a Proportion of Days Covered (PDC) of <80%. PDC and Gap in Therapy were assessed pre- and post-pharmacist intervention.

**RESULTS:** The average PDC improved from 62.2% to 80.1% (p<0.001). There was a significant improvement in the number of patients (n=20, 56%) with a PDC > 80% at the completion of the intervention (p<0.001). The average GAP decreased from 21.4 days at the start of the study to 10.4 days (p<0.001).

**CONCLUSION:** The results of this study show that pharmacists trained as health coaches can be effective to improve medication adherence. Health coaching techniques utilized by pharmacists can significantly improve patient adherence to medication ther-

apy. Pharmacists should consider health coach technique training to enhance their practice skills and improve patient care outcomes.

## Critical Care

**44. Y-site physical compatibility of intensive care unit admixtures with cisatracurium.** *Jaime A. Foushee, Pharm.D.*, BCPS, Laura M. Fox, Ph.D., Lyndsay R. Gormley, Pharm.D.Candidate, Megan D. Sumner, Pharm.D.Candidate; Presbyterian College School of Pharmacy, Clinton, SC

**PURPOSE:** Critically ill patients often require multiple intravenous (IV) continuous infusions throughout their intensive care unit (ICU) stay, sometimes necessitating the co-administration of medications in patients with limited access. IV compatibility of these medications is lacking, with recent drug shortages requiring practitioners to utilize therapies with little to no compatibility data. This study will examine the physical compatibility of the neuromuscular blocking agent cisatracurium with selected continuous infusion therapies.

**METHODS:** Physical compatibility was checked in triplicate using visual assessment against both light and dark backgrounds and non-visual changes in turbidity with a turbidimeter. Assessments were made in 15 minutes increments up to 1 hour, to account for contact time in a simulated y-site. A measured turbidity difference of less than 0.5 NTU was considered compatible. Analysis of variance was used to determine statistical difference between the experimental groups and controls.

**RESULTS:** Calcium gluconate, diltiazem, esomeprazole, regular insulin, nicardipine, and vasopressin demonstrated no evidence of physical incompatibilities with cisatracurium after visual and turbidimetric assessment. Although the presence of particles, haze, gas formation or alteration of color were not visibly notable in admixtures of pantoprazole with cisatracurium, the turbidity of the admixtures was  $0.31 \pm 0.21$  NTU greater than controls. Although less than the 0.5 NTU benchmark, the turbidity of pantoprazole admixtures was statistically different from that of controls (p<0.001). Additionally, cisatracurium-pantoprazole admixtures demonstrated an increase in turbidity over 60 minutes of  $0.44 \pm 0.26$  NTU.

**CONCLUSIONS:** Practice guidelines require a minimum of physical compatibility to co-administer IV medication therapies. Calcium gluconate, diltiazem, esomeprazole, regular insulin, nicardipine, and vasopressin demonstrated physical compatibility with cisatracurium over a 1 hour period. Cisatracurium and pantoprazole should not be co-administered at this time due a statistical difference in compatibility between control and experimental groups.

**45. Effect of sedation medication and daily awakening on delirium in the mechanically ventilated critically ill patient: a descriptive pilot study.** *Trevor L. Perry, Pharm.D.*, Julie Moon, Pharm.D., BCPS, Harminder Sikand, Pharm.D.; Scripps Mercy Hospital, San Diego, CA

**PURPOSE:** Sedative medications appear to be the leading iatrogenic cause of delirium. Although daily awakenings are recommended in mechanically ventilated patients, evidence of delirium reduction is lacking. This study will determine if there are differences in delirium, days ventilated, and intensive care unit (ICU) length of stay (LOS) between lorazepam, propofol, dexmedetomidine, and fentanyl when concurrently receiving daily awakenings.

**METHODS:** An Institutional review board approved prospective, randomized, open-label, pilot-study. Medical ICU patients with informed consent were enrolled if mechanical ventilation was planned for over 24 hours. Patients were excluded for severe neurological deficits, alcohol dependency, chronic benzodiazepine usage, advanced airway modalities, acute myocardial infarction, heart rate under 50 beats per minute, mean arterial pressure less than 65 mmHg, or inability to be randomized within 48 hours of intubation. Subjects were randomized to lorazepam, propofol, dexmedetomidine, or fentanyl. Subjects underwent daily waken-

ings and were assessed for delirium. Primary outcomes were incidence of delirium with daily awakenings and between the four treatment arms in the setting of daily awakenings. Secondary outcomes included difference in days ventilated and ICU LOS. Scheffe post-hoc analysis of variance and one-sample T test were utilized.

**RESULTS:** Incidence of delirium was higher with propofol versus dexmedetomidine (78.5% versus 5%, p-value 0.025). Time ventilated was not different between treatment arms (p-value 0.685); nor was the ICU LOS (p-value 0.646). There was less delirium (-40.5%; 95% CI, -61.9% to -19.1%, p-value 0.001), and fewer days in the ICU (-3.11 days; 95% CI, -4.77 days to -1.46 days, p-value 0.001) with daily awakenings versus historical controls.

**CONCLUSION:** Dexmedetomidine has a lower incidence of delirium compared to propofol. However, the average times spent mechanically ventilated and in the ICU are equivalent between lorazepam, propofol, dexmedetomidine, and fentanyl with daily awakenings. The daily awakening process decreases the incidence of delirium and ICU LOS compared to historical data.

**46. Evaluation of procalcitonin (PCT) use for antibiotic discontinuation in medical intensive care patients at a community teaching hospital.** Sara E. Jordan, Pharm.D., Lauren M. Flannery, Pharm.D., Rodney K. Kusumi, M.D., Shiva D. Rahmianian, M.D., Kiran Devulapally, M.D., Bradley R. Harrold, M.D., Phillip C. Hawley, M.D., Amy Creighton, M.S., James J. Jenkins, II, Ph.D., Lauren A. DiBenedetto, B.S., Janelle Hartman, B.A., Vivek S. Trivedi, B.S.; Grant Medical Center, Columbus, OH

**PURPOSE:** The correlation of serum procalcitonin (PCT) with the clinical course of bacterial infection has sparked interest in the utility of PCT-guided treatment algorithms for determining appropriate antibiotic duration. The purpose of this study is to evaluate our institution's use of PCT-guided antibiotic discontinuation for safety, efficacy, and economic purposes.

**METHODS:** This single-center, retrospective cohort study was approved by OhioHealth's IRB and included all medical intensive care patients admitted to Grant Medical Center from March 2010 through September 2011. Patients were excluded if they were not on antibiotic therapy when the PCT was drawn, if death/discharge occurred before the PCT was reported, or if prolonged (>17-day) antibiotic courses were prescribed. Remaining patients were assigned to one of three study arms based on if and how PCT values correlated with antibiotic discontinuation during admission. Group 1 represented a control group (no PCT drawn during admission), and Groups 2 and 3 represented treatment arms differing based on if antibiotic discontinuation occurred against or in line with the currently-recommended PCT-guided algorithm. Primary outcomes included 28-day mortality and total antibiotic days, and nine secondary outcomes were also measured.

**RESULTS:** A total of 789 patients were included in the final analysis. The PCT groups may have been more clinically complicated than the control. While there was no significant difference in 28-day mortality between the three groups (p=0.200), the PCT groups saw significantly more total antibiotic days than the control (p<0.001) and poorer secondary outcomes.

**CONCLUSION:** While PCT-guided antibiotic discontinuation was associated with increased antibiotic use and worse secondary outcomes, its use may have mitigated mortality in a more complex patient population. PCT may therefore have some utility in determining antibiotic duration, though algorithmic use of this biomarker appears inadvisable and currently-recommended PCT cut-off values for critical patients should be reevaluated.

**47. Dexmedetomidine as adjunctive therapy in alcohol withdrawal syndrome patients in an intensive care unit.** Jennifer L. Grelle, Pharm.D., Shawna E. King, Pharm.D., BCPS, Krystal K. Haase, Pharm.D., FCCP, BCPS; Texas Tech University Health Sciences Center School of Pharmacy, Amarillo, TX

**PURPOSE:** To describe the use of dexmedetomidine (DEX) in combination with benzodiazepines for treatment of alcohol withdrawal symptoms and to identify factors associated with treatment success versus failure.

**METHODS:** A retrospective review of medical records was used to identify subjects admitted to Northwest Texas Hospital critical care units between October 1, 2009 and February 29, 2012 who were diagnosed with alcohol withdrawal syndrome (AWS), delirium tremens, alcohol-related seizures or hallucinations and treated with DEX. The study included patients >18 years of age with an ICU length of stay >24 hours. Subjects requiring mechanical ventilation prior to DEX infusion were excluded from the primary outcome. Treatment success with DEX was defined as avoidance of mechanical ventilation. Factors assessed were quantity of benzodiazepines before and after DEX, starting, bolus and total dose of DEX administered.

**RESULTS:** Thirty-nine subjects met inclusion criteria. Two subjects received DEX for surgical procedures only and were excluded from analysis. Subjects were primarily white (84.6%) males (84.6%) with an average age of 45.0 + 10.9 years, and median ICU length of stay of 7 days (range 1-30). Eleven subjects were intubated prior to initiation of DEX. The 28 remaining subjects were included in the primary outcome analysis. Of these, 89.2% were successfully treated with DEX and avoided mechanical ventilation. Quantity of benzodiazepines prior to initiation of DEX and method of DEX dosing varied considerably among subjects. Hypotension (SBP < 90) and bradycardia (HR < 50) were the most commonly observed adverse effects (35.9% and 12.8%, respectively). Discontinuation of DEX was required in one subject and three subjects required vasopressors after initiation of DEX.

**CONCLUSION:** Use of DEX in combination with benzodiazepines for management of AWS may help prevent mechanical ventilation. Further prospective studies with a larger sample size are needed to confirm these findings and determine optimal dosing strategies.

## Drug Information

**48. Assessment of drug information resource preferences by pharmacy students and faculty.** Sabrina W. Cole, Pharm.D., BCPS, Conor T. Hanrahan, Pharm.D.; Wingate University School of Pharmacy, Wingate, NC

**PURPOSE:** To evaluate accessibility and use of drug information (DI) resources by students and faculty.

**METHODS:** A 39-item survey instrument was distributed to faculty and students at Wingate University School of Pharmacy. The survey consisted of multiple choice and rank-based questions designed to assess usage of DI resources, as well as respondent preferences for accessing information.

**RESULTS:** Data were obtained for 80% (n=257) of students and 86% (n=32) of faculty. Although the majority of all respondents own and access electronic DI resources with a laptop/notebook computer (98%) and smartphone (62%), more faculty own and use tablet computers compared to students (30% versus 14%, respectively). Additionally, more faculty expressed interest in obtaining DI on a tablet than did students (64% versus 33%, respectively). When asked about preferences, both faculty and P2-P4 students prefer to access information via laptop/desktop computers (67% and 75%, respectively), followed by smartphones (27% and 22%, respectively) and tablets (7% and 2%, respectively). With respect to textbooks, both students and faculty prefer electronic access (66% and 61%, respectively). However, the majority of faculty (57%) prefer to print material from the electronic resource, while students (60%) prefer to read from the electronic device. In general, most students and faculty prefer using electronic instead of print resources (62% and 71%, respectively).

**CONCLUSIONS:** Use of DI resources is similar between pharmacy students and faculty, with both groups preferring electronic access. Laptop/desktop computers are the preferred platform for accessing DI compared to smartphones and tablets. These results

suggest that more library funds should be allocated to electronic resources.

## Education/Training

**49. Student performance and faculty perception after transition to team-based learning in a drug-induced disease elective.** Sarah A. Treadway, Pharm.D., BCPS<sup>1</sup>, Michelle Z. Farland, Pharm.D., BCPS<sup>2</sup>, Shaunta' Ray, Pharm.D., BCPS<sup>2</sup>; (1) Auburn University Harrison School of Pharmacy, Mobile, AL; (2) University of Tennessee College of Pharmacy, Knoxville, TN

**PURPOSE:** Compare student performance and faculty perception in a fourth year elective course following transition from lecture-based format to team-based learning (TBL).

**METHODS:** A drug-induced disease elective is offered each year as a fourth year, month-long elective course. Student performance was compared in the drug-induced disease elective course the year prior to and following implementation of TBL using a percentage of total points earned. Student grades were compared using the independent samples t-test. Faculty perception of TBL was determined from survey responses.

**RESULTS:** Twenty-two students were enrolled in the lecture-based course and 28 in the TBL course. Student performance was similar between the lecture-based and TBL courses when percentage of total points earned was compared ( $p=0.898$ ; 85.24 versus 84.46, respectively). Cumulative GPA prior to entry into the course was not statistically different between the two groups ( $p=0.579$ ; 3.48 versus 3.46, respectively). All eight faculty who taught in the TBL course had prior teaching experience in lecture-based classes, five had experience teaching class using some form of active learning, and two had no experience with active learning. All faculty perceived the most rewarding aspect of TBL to be observation of student learning through group discussion. Most faculty (75%) "agreed" that their impact on student learning was greater with TBL than lecture-based. All faculty "agreed" or "strongly agreed" they would consider implementing team-based learning into future courses.

**CONCLUSION:** Student performance in a TBL course was similar to lecture-based. Faculty found this method of teaching effective and rewarding.

**50. Use of a unified learning style model to improve student self-directed learning in pharmacy students.** Christopher A. Giuliano, Pharm.D., Jessica L. Jones, Pharm.D., Emily T. Martin, M.P.H., Ph.D., Vickie Poremba, Pharm.D. Candidate, Lynette R. Moser, Pharm.D.; Wayne State University Eugene Applebaum College of Pharmacy and Health Sciences, Detroit, MI

**PURPOSE:** Identify student learning preferences and use these preferences to enhance student life-long learning skills.

**METHODS:** P1 pharmacy students completed a survey about exposure to learning style models and subsequently participated in a learning styles workshop early in the P2 year. The workshop included a 30-minute lecture defining learning style preferences and 2 hours to determine their preferences using: student self-reporting, learning preference survey, and faculty assessment. Students completed a "learning satisfaction survey" before the workshop and at the end of the semester to assess learning satisfaction, gain, motivation, time spent studying, and effort used when studying. Faculty and student agreement of learning styles were described using kappa values. Mean scores on the pre and post "learning satisfaction survey" were compared using paired t-test. In addition, the proportion of students answering "always" were compared pre versus post using McNemar's test.

**RESULTS:** Fourteen percent of P1 students were familiar with learning style preferences. Seventy-three students completed the P2 workshop. Significant agreement ( $p<0.05$ ) was seen between faculty and student identification of visual, aural, reading, kinesthetic, active versus reflective, individual versus team, and competitive versus collaborative learning preference sub-categories. Significant agreement ( $p<0.05$ ) was seen between faculty and survey identification of visual, aural, deductive versus inductive, individual versus team, and introvert versus extrovert. No significant

changes were seen comparing mean scores on the learning satisfaction survey before and after the workshop. Increases were seen in the number of students answering "always" versus other categories in learning satisfaction (1 versus 5 students,  $p=0.05$ ) and effort used when studying (0 versus 5 students,  $p=0.03$ ).

**CONCLUSION:** The majority of students have limited exposure to learning style models. Student self-assessments and surveys could be used to determine learning styles. Educating students on their learning style preferences may improve their learning satisfaction and decrease their effort used when studying.

**51. Tracking the development of student self-efficacy to perform clinical pharmacy tasks.** Stuart T. Haines, Pharm.D., BCPS, David Roffman, Pharm.D., BCPS, Lisa Lebovitz, J.D., Deborah A. Sturpe, Pharm.D., BCPS; University of Maryland School of Pharmacy, Baltimore, MD

**PURPOSE:** Managing patient care requires self-confidence. We developed a survey to assess self-efficacy to perform common clinical pharmacy tasks and tracked student responses over time.

**METHODS:** The University of Maryland School of Pharmacy established 16 terminal performance outcome (TPO) statements describing specific abilities all graduates should possess. Several TPOs focus on optimizing drug therapy in individuals and populations. A survey tool describing three case scenarios in community, hospital, and managed care settings was administered to students at school entry (baseline) and annually in the Spring semester (P1, P2, P3). Each scenario included key tasks, anchored to TPOs, that must be performed to address the patient problems in each case. 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 using an anchored likert-scale. Changes in self-confidence over time and comparisons between tasks and practice settings were analyzed.

**RESULTS:** At baseline, most students indicated they could not perform the key tasks in any scenario "without substantial supervision" (ranging from 54% to 98% depending on task and scenario). As students progressed through the curriculum, the percentage who indicated they could perform these tasks without assistance significantly increased (range: 0–12% P1; 1–26% P2; 7–42% P3,  $p<0.001$ ). Likewise, mean scores increased for each task ( $p<0.01$ ). There were similar increases in self-efficacy in all practice settings. Student self-efficacy was highest for technology and information retrieval tasks and lowest for drug selection and therapy modification tasks.

**CONCLUSIONS:** Students in our curriculum demonstrated substantial and incremental improvement in their self-efficacy to perform key clinical pharmacy tasks over time. Tracking (individual and cohort) changes in self-efficacy may provide educators valuable insights regarding student progression toward curricular outcomes and may be a useful adjunct to other assessment methods.

**52. Academic workload: what the heck are we doing?** Kamila A. Dell, Pharm.D., BCPS, Marianne E. Koenig, Pharm.D., BCPS, Erin S. Serag, Pharm.D., Amanda M. DeBruin, Pharm.D., BCPS, CGP, Jose L. Barboza, Pharm.D., Aimon C. Miranda, Pharm.D., Shyam R. Gelot, Pharm.D., L. Douglas Ried, Ph.D.; University of South Florida College of Pharmacy, Tampa, FL

**PURPOSE:** This study describes the workload of pharmacy practice faculty at a new college of pharmacy.

**METHODS:** An Excel-based workload tracking tool was developed and revised based on the results of a pilot test. Seven faculty members have voluntarily used the workload tracking tool since fall 2011. Teaching, practice, service, scholarship, and other activities were tracked to the nearest 15 minute increments for up to 6 months. The frequency of documentation was not standardized. After the initial period, the tracking tool was revised and work activities were recorded for an additional 4 months.

**RESULTS:** The initial faculty workload distribution was 26% service, 23% teaching, 16% practice, 16% "other" activities, 14% professional development, and 5% scholarship. The "other" category included barriers to efficiency, email, travel, vacations, sick

leave, administration, and college and departmental meetings. Changes were made to provide usable information otherwise lost and to improve the consistency of responses. Due to a high percentage of time coded into the "other" activities category, vacations and sick leave were eliminated. Administration and college and departmental meetings were categorized into different sections. The "professional development" category was incorporated into teaching, practice, service, and scholarship sections. Results following the revisions were 28% service, 27% practice, 22% teaching, 14% scholarship, and 9% "other" activities.

**CONCLUSION:** The tracking tool benefits faculty with self-evaluation, time management, and workload documentation. The tool captures invisible acts in a traditional workload (e.g., emails, travel time). The revised tool may be useful for resource planning and career development for faculty at all levels. Non-standardized documentation frequency was a limitation and may have affected accuracy due to recall bias. A streamlined data entry process would lead to increased consistency and efficiency. Work activities will be tracked to determine how workload changes over time.

**53. Attitudes and perceptions of postgraduate residents and fellows in telemedicine services at the University of Illinois at Chicago College of Pharmacy.** *Melissa E. Badowski, Pharm.D., Chessa R. Nyberg, Pharm.D.; University of Illinois at Chicago, Chicago, IL*

**PURPOSE:** To assess attitudes and perceptions of postgraduate residents and fellows participating in a telemedicine clinic providing services to HIV positive inmates incarcerated within the Illinois Department of Corrections.

**METHODS:** Postgraduate residents and fellows participating in either a longitudinal or concentrated month of HIV telemedicine were asked a 15-question survey to assess perceptions of telemedicine prior to entering the telemedicine clinic. Demographics, telemedicine knowledge, and anticipated uses and concerns were evaluated at baseline. Upon completion of their rotation, an eight-question post-test survey was administered. Attitudes and concerns toward telemedicine were assessed upon completion.

**RESULTS:** The survey results (n=6) indicated that telemedicine was appropriate for providing medical care for common and chronic illnesses, as well as infectious diseases (n=6, 100%). Those participating in the survey felt the quality of medical care via telemedicine was the same as an in person visit (n=5, 83%), while 2 out of 6 participants felt that telemedicine should not replace face-to-face visits. All participants perceived telemedicine as a better health management tool for the future. All participants felt their skills as a clinical pharmacist were highly utilized (100%) with 5 out of 6 participants reporting no difficulties with communicating with the patients.

**CONCLUSION:** Those participating in post-graduate training at the University of Illinois at Chicago, College of Pharmacy, were highly satisfied with their clinical abilities to provide patient care, management, and education of HIV infection and antiretrovirals within the Illinois Department of Corrections.

**54. An evaluation of student drug literature evaluations skills by comparing student performance on journal club presentations and application based biostatistics questions.** *Jean E. Cunningham, Pharm.D., Laura Perry, Pharm.D.; The University of Findlay College of Pharmacy, Findlay, OH*

**PURPOSE:** Biostatistics is taught commonly through an applied format as student journal clubs. The aim of this project was to evaluate student performance on journal club presentations compared to student performance on objective application based biostatistics questions.

**METHODS:** Fifty students in a third professional year course were assigned to prepare three journal articles for presentation. Students collaboratively presented each journal article over 1 hour with each group member being randomly assigned to present a portion of the journal club. Prior to each journal club, an article specific, five question, open-note, biostatistics application quiz was administered. The questions were written by a drug

information specialist following the format of biostatistics questions used for the BCPS exam. A rubric tool was used to assess the student's ability to present on background, methods, results, evaluation, and clinical application (included case development). The individual journal club presentation scores will be compared to the individual biostatistics quiz scores using simple linear correlation (Pearson r). Hypothesis: It is theorized that higher scores on the verbal journal club presentation are correlated with higher quiz scores.

**RESULTS:** All 50 students had data available for analysis at the time of review. The average journal club presentation grade was a 90.28%. The average quiz score was a 63.13%. When comparing individual presentation scores with individual quiz scores the following data was calculated; Pearson  $r = 0.0912$ ,  $r^2 = 0.0083$ ,  $1 - r^2 = 0.9917$ ,  $p=0.53$ . When accounting for outliers (N=44), the following data was calculated; Pearson  $r = 0.1355$ ,  $r^2 = 0.01835$ ,  $1 - r^2 = 0.9817$ ,  $p=0.38$ .

**CONCLUSION:** Our findings show that there is no relationship between student's scores on a verbal journal club presentation and a biostatistics quiz. This information supports that the current approach of teaching biostatistics through an applied format in a journal club may not adequately measure student's understanding of biostatistics.

**55. Facebook activity and views regarding E-Professionalism: a survey of pharmacy students in Qatar.** *Maguy S. El Hajj, Pharm.D., Tasnim Abd Al Halim Massoud, B.Sc.Pharm.Candidate, Atefeh Gholamhussain Moeinzadeh, B.Sc.Pharm.Candidate; Qatar University College of Pharmacy, Doha, Qatar*

**PURPOSE:** Technology has changed the nature of social communication. One change is popularity of social media such as Facebook. The study objectives were to describe Qatar pharmacy students' Facebook activity, to assess their views regarding their professional attitudes and behavior on Facebook, to determine their attitudes toward judging their character, their professional attitudes, and their employability based on their online personas.

**METHODS:** Qatar University (QU) College of Pharmacy is the only pharmacy program in Qatar. The study objectives were addressed in a cross sectional survey of QU pharmacy students. The students completed a self-administered online anonymous survey designed based on previous surveys conducted in United States. Data was descriptively analyzed using Statistical Package for Social Sciences version 18. QU Institutional Review Board ethics exemption approval was obtained.

**RESULTS:** Over two weeks, 82 surveys were collected (82% response rate). Majority of respondents (89%) had Facebook accounts with 92% daily logging to their accounts. Mean time spent on Facebook was 35 minutes per log in. Most respondents indicated that they have never posted information that they would not want an employer, a patient, or a faculty member to view (81%, 85% and 72% respectively). Yet 63% stated that the image they portray online through Facebook does not reflect who they are as future professionals. Moreover, most respondents believed that pharmacy students should not be accountable for their unprofessional behavior on Facebook (59%), that pharmacy students should not be held to higher standards than others regarding the image they portray on Facebook (54%) and that their profile information should not be considered when hiring (72%).

**CONCLUSION:** Facebook plays an important role in Qatar pharmacy students' daily lives. The study results highlight the need for e-professionalism training aimed at increasing students' awareness of the risks of social media to professional image and privacy.

**56. Students' perceptions of the effect of pharmacotherapeutics workshops on clinical skills practiced on advanced pharmacy practice experiences.** *Jennifer J. D'Souza, Pharm.D., CDE, BC-ADM<sup>1</sup>, Kathy E. Komperda, Pharm.D., BCPS<sup>1</sup>, Jill S. Borchert, Pharm.D., BCPS, FCCP<sup>1</sup>, Jacob P. Gettig, Pharm.D., M.P.H., BCPS<sup>1</sup>, Meri Hix, Pharm.D., BCPS, CGP<sup>2</sup>, Tudy Hodgman, Pharm.*

D., BCPS, FCCM<sup>1</sup>, Timothy Todd, Pharm.D.<sup>1</sup>; (1)Midwestern University Chicago College of Pharmacy, Downers Grove, IL; (2)Texas Tech University Health Sciences Center School of Pharmacy, Abilene, TX

**PURPOSE:** A new pharmacotherapeutics course sequence with significant changes to the workshop component was implemented in Fall 2009. The redesigned workshops incorporated learning techniques focusing on the development of clinical skills rather than reapplication of lecture-based knowledge. The investigators hypothesize that the new workshops will improve the students' ability to perform these skills on advanced pharmacy practice experiences (APPEs). The aim of the current investigation is to describe graduating students' perceptions of whether workshops prepared them to perform specific pharmacy practice skills on advanced pharmacy practice experiences.

**METHODS:** Graduating pharmacy students (n=193) received an e-mailed survey with instructions to return to the Dean's office. The survey asked the students' perception on whether participation in the new pharmacotherapeutics workshops prepared them to perform specific clinical skills (n=15) on their APPEs. A 4-point Likert scale was utilized. In an open-ended question, students were asked what other skills needed for APPEs could be incorporated in workshops. Descriptive statistics were employed to summarize the data.

**RESULTS:** An 89.6% response rate was obtained. More than 80% of the respondents agreed or strongly agreed that workshops prepared them to perform 14 of the 15 pharmacy practice skills listed in the survey. The three skills that received the highest level of agreement included formulate a drug therapy plan (97.7%); evaluate a medical chart to retrieve and monitor data (94.2%); and critique a primary research article (93.6%). Only 39.3% of students agreed or strongly agreed that workshops prepared them to justify the cost of using tests/procedures ordered. Approximately one-third of respondents provided written feedback on additional skills that would be helpful on APPEs if taught in workshops.

**CONCLUSION:** Overall, the students perceive that the newly implemented pharmacotherapeutics workshops prepare them to perform a number of different pharmacy practice skills on APPEs.

**57. Evaluation of improved evidence-based patient care application during a primary care advanced practice experience.** Kelly Hester, Pharm.D., BCPS, AAHIVE<sup>1</sup>, Dana G. Carroll, BCPS, CDE<sup>2</sup>, Kristi Kelley, Pharm. D, Pharm.D.<sup>3</sup>; (1)Auburn University Harrison School of Pharmacy, Auburn, AL; (2)Auburn University Harrison School of Pharmacy, Tuscaloosa, AL; (3)Auburn University, Harrison School of Pharmacy, Birmingham, AL

**PURPOSE:** To evaluate improvement in application of critical thinking and evidence-based recommendations on case-based test responses during a primary care advanced practice experience.

**METHODS:** During a 5-week primary care advanced practice experience, three faculty members sought to deepen understanding of relevant primary literature to assist fourth-year professional students in gaining insight into patient-specific applications. Key research articles on the subjects of hypertension, dyslipidemia, and diabetes were identified to review with the students. Additionally, biomedical literature evaluation exercises and practice cases were developed for discussions to verbalize their conclusions and rationale in clinical decisions. The faculty corrected any misunderstandings and helped sharpen critical thinking abilities. An examination was prepared to assess critical thinking and student application of this biomedical literature in clinical decision making and individualized care. This examination was administered to the students during the first week of the rotation and prior to the therapeutic discussions as well as during the last week of the rotation as a portion of their rotation grade. A paired t-test was conducted to evaluate changes in pre- and post-scores on this examination as a result of the evidence-based therapeutic discussions.

**RESULTS:** Thirty students were examined and the mean change in scores was a 27.9 improvement (p<0.05). The mean prescore

was 57.7 and mean postscore was 85.5. The primary areas of improvement: defending patient-specific recommendations with detailed results from the literature and independent of pharmacologic effects (ie cardiovascular outcomes with metformin); compare and contrast therapies with and without evidence of health outcomes (reduced morbidity and mortality); identifying areas for optimization in therapy for primary or secondary prevention, and identified drug-related problems.

**CONCLUSION:** Integrating informal primary literature activities into a primary care rotation deepened understanding and improved critical thinking and patient care application of therapeutic recommendations. The teaching time dedicated to such activities was reasonable.

**58E. Evaluation of clinical skills with an objective structured clinical examination.** Elizabeth M. Urteaga, Pharm.D., Rebecca Attridge, Pharm.D., M.S., BCPS, John Tovar, Pharm.D., Amy Witte, Pharm.D.; University of the Incarnate Word Feik School of Pharmacy, San Antonio, TX

**PURPOSE:** Health professionals are expected to exhibit strong communication and clinical skills. The curriculum at pharmacy schools should prepare students not only to successfully pass licensure examinations, but also to provide excellent clinical services to patients. Unfortunately, standardized testing is a mediocre way to evaluate clinical and communication skills. Current literature supports the use of objective structured clinical examinations (OSCEs) as an effective tool to evaluate these skills. We used an OSCE to evaluate how effectively second-, third-, and fourth-year pharmacy students' and practicing pharmacists' communicate and apply knowledge to simulations of commonly encountered patient scenarios.

**METHODS:** Second-, third-, and fourth-year pharmacy students enrolled at the University of the Incarnate Word, Feik School of Pharmacy completed an OSCE as part of their required courses. Licensed pharmacists were recruited to complete the OSCE and serve as controls. Trained standardized patients graded the interaction based on a rubric that consisted of clinical skill and communication checklists.

**RESULTS:** A total of 275 pharmacy students and six licensed pharmacists completed the OSCE and consented to participate in the study. Overall, the licensed pharmacists performed better than the pharmacy students. The fourth-year students performed better than the second-year (p=0.01) and third-year pharmacy students (p≤0.0001). The pharmacists performed better than the second-year (p=0.02) and third-year (p=0.002) pharmacy students; however, there was not a statistically significant difference in performance between the fourth-year pharmacy students and pharmacists (p=0.07).

**CONCLUSION:** The results of this study provide a better understanding of the clinical and communication skills of practicing pharmacists and pharmacy students at different stages of the curriculum.

Presented at International Pharmaceutical Federation (FIP) Centennial Congress, Amsterdam, The Netherlands, October 2012.

**59. Standardized approach to patient-based pharmacotherapy notes in a therapeutics course.** 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 standardized patient-based pharmacotherapy notes, specifically the Subjective Objective Assessment Plan Education (SOAPE) note format, to improve students' knowledge and confidence in patient-based documentation in a cardiovascular therapeutics course.

**METHODS:** For two consecutive years, 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 a second patient case and submit-

ted a SOAPE note for a grade. A pre-test and post-test assessing students level of confidence and knowledge 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 Institutional Review Board and students voluntarily signed informed consent prior to participation. Scores on the pre-tests and post-tests were compared utilizing descriptive statistics and student's t-tests.

**RESULTS:** A total of 242 (88.6%) students completed both the pre-test and post-test. There was significant improvement in students' confidence in writing SOAPE notes by the end of the course, with a mean (SD) score of 2.69 (0.51) on the pre-test and 3.59 (0.36) on the post-test ( $p < 0.001$ ). Students' mean (SD) performance on the knowledge section of the pre- and post-tests were 93.7% (9.64) and 99.2% (3.99), respectively ( $p < 0.001$ ). Students with prior experience writing SOAPE notes had higher confidence and knowledge scores on the pre-test compared to those without experience, however on the post-test, there was no significant difference between both groups.

**CONCLUSION:** Utilization of a standardized approach to patient-based pharmacotherapy notes may enhance students' understanding and confidence to perform this vital task on experiential patient care rotations and in clinical practice.

#### 60. Student perceptions of team-based learning activities in a critical care elective as preparation for advanced practice pharmacy experiences. *Katie E. Ronald, Pharm.D.*; Southern Illinois University Edwardsville School of Pharmacy, Edwardsville, IL

**PURPOSE:** To evaluate student perceptions of team-based learning (TBL) activities implemented in a critical care elective as preparation for advanced pharmacy practice experiences (APPEs) and to evaluate if those perceptions change over time.

**METHODS:** Spring 2011, TBL was implemented in a critical care elective, a two credit-hour elective offered to P3 students. Group instruction feedback technique (GIFT) was completed while students were enrolled in the course. Students were then surveyed at two different time points during APPEs, after three and eight APPEs. Via survey, student perceptions of TBL activities as preparation for APPE rotations (Likert scale, 5 = strongly agree and 1 = strongly disagree) as well as ranking activities from most-to-least helpful (1 = most to 8 = least) were collected. Descriptive statistics were used to summarize results (mean for Likert scale and mode for rank).

**RESULTS:** A total of 15 students (100%) completed both the GIFT and first survey, and eight students (53%) completed the final survey. Through the GIFT, students identified reading assignments as a "burden" and not as an element that enhanced learning in the classroom. Subsequently, students acknowledged that reading assignments provide skills for APPEs (mean 4.21, 4.25) and ranked reading assignments as the most helpful activity. In-class assignments, individual- and team-readiness assessments and team case presentations were perceived as helpful throughout the study. Perceptions of team case presentations as being helpful transformed over the course of APPEs (mode 5-3). Peer and self assessments provided skills (mean 3.50, 4.00; 3.50, 4.13, respectively) but were ranked as the least helpful activities.

**CONCLUSIONS:** Reading assignments resulted in the largest conversion in student perceptions of a TBL activity, from didactic to clinical setting. Overall, student perceptions of all TBL activities were favorable with respect to providing skills that helped prepare them for APPEs. Those perceptions remained relatively constant over the course of APPEs.

#### 61. Development and evaluation of a team-taught academic advanced pharmacy practice experience (APPE). *Sandra Benavides, Pharm.D.*<sup>1</sup>, Antonia Zapantis, Pharm.D., M.S.<sup>1</sup>, Jehan Marino, Pharm.D.<sup>1</sup>, Jennifer G. Steinberg, Pharm.D.<sup>1</sup>, Elizabeth Sherman, Pharm.D.<sup>1</sup>, Angela S. Garcia, Pharm.D.<sup>1</sup>, Nancy Borja-Hart, Pharm.D.<sup>2</sup>, Joshua Caballero, Pharm.D.<sup>1</sup>; (1) Nova Southeastern

University, College of Pharmacy, Davie, FL; (2) East Coast Institute for Research, Jacksonville, FL

**PURPOSE:** A team-taught pharmacy practice academic APPE was developed to expose students to various experiences and philosophies in academia with the goal of encouraging academic career interest. The development and evaluation of this APPE is described.

**METHODS:** Pharmacy practice faculty developed a shared syllabus, educational outcomes with corresponding activities, and a structured discussion schedule for a 4-week APPE. Students participating in this academic APPE during the 2011-2012 academic year were included in the analysis. During the APPE, each student completed a pre- and post-assessment to measure knowledge in regards to academia as a profession. Students completed self-assessment evaluations at mid-point and at completion of the APPE which were compared with faculty assessments of students. An IRB-approved anonymous 17-item electronic questionnaire evaluated students' perception of the APPE and likelihood in pursuing academic careers. Descriptive and inferential statistics were used as appropriate. Significance was set at a p-value of 0.05.

**RESULTS:** Fourteen students completed the academic APPE with seven faculty members. All students completed outlined learning objectives. Prior to the rotation five students (36%) had an interest in academia versus 6 (42%) upon APPE completion. Average student scores on the pre- and post-assessments were 66.2% and 83.5% respectively, demonstrating increase knowledge base in academia ( $p = 0.0007$ ). Nine students (64%) completed the post-APPE questionnaire; all agreed or strongly agreed the teaching style of the APPE enhanced learning, weekly discussions were positive experiences, and would recommend this APPE to classmates.

**CONCLUSIONS:** A team-taught academic APPE increased student knowledge of pharmacy practice faculty responsibilities and encouraged interest in academic careers in fourth year pharmacy students.

#### 62. Impact of a Residency Interviewing Preparatory Seminar (RIPS) elective in securing post-doctoral training. *Joshua Caballero, Pharm.D.*<sup>1</sup>, Sandra Benavides, Pharm.D.<sup>1</sup>, Kevin A. Clauson, Pharm.D.<sup>2</sup>, Jennifer G. Steinberg, Pharm.D.<sup>1</sup>, Timothy P. Gauthier, Pharm.D.<sup>1</sup>, Shara Elrod, Pharm.D.<sup>1</sup>, Jehan Marino, Pharm.D.<sup>1</sup>; (1) Nova Southeastern University, College of Pharmacy, Davie, FL; (2) Nova Southeastern University, College of Pharmacy - West Palm Beach, USA, Palm Beach Gardens, FL

**PURPOSE:** In response to increased competitiveness for securing post-doctoral training, the Residency Interviewing Preparatory Seminar (RIPS) was implemented as an intensive, 8-week elective for students in their final professional year. The seminar required participants to complete a variety of preparatory and simulated residency application situations (e.g., interview, topic presentation, journal club) with immediate feedback from course faculty. The purpose of this research is to determine the impact of the RIPS in assisting students to secure post-doctoral training, specifically residency and fellowship.

**METHODS:** Fourth-year pharmacy students seeking post-doctoral training for two consecutive years were anonymously surveyed via an electronic IRB-approved questionnaire regarding demographics and attitudinal items (e.g., confidence, preparedness). Rates of obtaining post-doctoral positions of RIPS participants were compared to non-RIPS participants at our University. Significance was set at a p-value of 0.05.

**RESULTS:** Over a 2 year period, 86 students from our institution self-reported actively pursuing residencies or fellowships. Of those, 21 students participated in the RIPS elective. There was no difference between RIPS and non-RIPS participant demographics with regard to age, grade point average, number of organizational memberships, officer positions held, formal applications submitted, or interviews secured. However, RIPS participants reported feeling better prepared to interview at the ASHP Midyear meeting compared to non-RIPS participants (94% versus 31%;  $p < 0.01$ ). There was a significant difference between RIPS and non-RIPS

participants in rates of securing residencies or fellowships (81% versus 52%;  $p < 0.03$ ).

**CONCLUSIONS:** The RIPS delivered direct experience replicating interview activities for pharmacy students. The course increased RIPS students' confidence and resulted in a higher rate of securing post-doctoral positions than non-RIPS participants at our institution, despite similar demographics. With national residency matching rates dropping to approximately 60% in 2012, similarly structured courses may offer students a direct benefit in preparing for the residency and fellowship seeking process.

**63. Patient care impact and potential cost avoidance generated by student pharmacists during Advanced Pharmacy Practice Experiences.** *Adam B. Woolley, Pharm.D., BCPS, Roger A. Edwards, Sc.D., Charles A. Berds, IV, B.S., Pharm., Margarita V. DiVall, Pharm.D., BCPS; Northeastern University School of Pharmacy, Boston, MA*

**PURPOSE:** Student pharmacist contributions to patient care have been documented in the literature. However, exploration of potential cost avoidance is warranted. This investigation analyzed interventions documented by fourth-year professional (P4) Northeastern University student pharmacists during Advanced Pharmacy Practice Experience (APPEs) in outpatient and inpatient settings. We evaluated student impact on patient care and potential cost avoidance.

**METHODS:** P4 pharmacy students were trained to use a school-wide web-based intervention system (PxDx, E-value) and encouraged to document interventions throughout 36 weeks of APPEs. The database was retrospectively analyzed to review characteristics of interventions documented during the 2011–2012 APPE cycle. An evaluation was conducted to assess the potential cost avoidance associated with the interventions. Estimates of costs were derived from a comprehensive literature review and adjusted to 2011 dollars based on the consumer price index for medical care.

**RESULTS:** Eighty-seven students (71%) documented 5775 interventions (3041 inpatient and 2734 outpatient) over 36 weeks with an estimated potential total cost avoidance of \$780,876. The most common intervention categories reported were patient education (26%) and drug information (26%). Students also reported that 2082 (36%) potential adverse drug events (ADEs) were prevented. Seventy-one percent of interventions were accepted as is, 26% were informational only, and 3% of the recommendations were rejected. Students identified 93% of interventions as having a clinically significant impact on patient care. While we could not assign cost savings to each intervention, the intervention categories associated with the greatest cost avoidance were ADE prevented (\$203,742), patient education (\$148,745) drug information (\$145,201), addition of medication with clinical indication (\$84,267), and therapeutic dose adjustment (\$32,126).

**CONCLUSIONS:** P4 student pharmacists represent a valuable resource to both the inpatient and outpatient pharmacy settings. They can make a positive impact on patient care while also contributing to cost avoidance. This analysis provides the foundation for future work.

**64. Use of pre- and post-tests to assess student pharmacist effectiveness when presenting in-services to other health care professionals.** *Amber N. McLendon, Pharm.D.<sup>1</sup>, C. Brock Woodis, Pharm.D.<sup>2</sup>; (1) Campbell University College of Pharmacy and Health Sciences and Glenaire, Inc. CCRC, Buies Creek, NC; (2) Campbell University College of Pharmacy and Health Sciences and Duke University Department of Community and Family Medicine, Durham, NC*

**PURPOSE:** This study evaluated the effectiveness of student pharmacist in-service presentations to other health care professionals (HCPs) by the use of pre- and post-test evaluations.

**METHODS:** Student pharmacists present a required in-service to other HCPs during their final year of this Doctor of Pharmacy program. An opportunity to complete this competency is provided within a required geriatrics advanced practice experience at

a continuing care retirement community (CCRC). Groups of three students assigned to the CCRC work together to address questions posed by other HCPs within the CCRC. Student groups identified objectives for their topic and developed no more than 10 questions to assess the targeted audience's understanding of the objectives. These questions were given as a pre-test before the presentation and the same questions were administered after the presentation for comparison. Groups presenting for greater than 30 minutes were included in the analysis. Tests were completed by the in-service attendees and submitted anonymously. Correct answers were reviewed with the audience after the presentation was completed and the post-tests were submitted. The percentages of correct answers prior to the presentation were compared to the percentages of correct answers after the presentation.

**RESULTS:** Of the completed pre- and post-tests reviewed, 162 responses were included for analysis. The correct responses submitted for the pre-test were 43% and for the post-test were 71% ( $p < 0.05$ ).

**CONCLUSIONS:** In addition to having a significant impact on HCP understanding of presented topics, in-services provide an opportunity for student pharmacists to further develop presentation skills. Use of pre- and post-tests give student pharmacists instantaneous feedback on the effectiveness of their performance. At this clinical practice site, pre- and post- tests allow student pharmacists to develop assessment methods for their presentation objectives and focus on the most relevant material during the presentation.

**65. The impact of objective structured clinical examination on pharmacy intern training program.** *Shu-Hsien Wu, B.S., Yun-Ting Pan, B.S., Ming-Shya Wan, M.S., Shu-Hui Sun, M.S.; Department of Pharmacy, Far Eastern Memorial Hospital, New Taipei City, Taiwan*

**PURPOSE:** We used the Objective Structured Clinical Examination (OSCE) as an assessment of hospital training model for Pharmacy student's internship. It was found that these interns performed poorly in the clinical management of pediatric program, so we have reviewed the program and modified the model.

**METHODS:** After discussing with senior pharmacists, the intern-learning handbook was revised so that the content of the pediatric section could be clarified. The clinical management of pediatric care was emphasized using case-based scenarios and written questions. The OSCE scores (three-point scale) were compared and analyzed by students t-test.

**RESULTS:** A total of 17 pharmacy interns completed the OSCE assessment on December 16, 2010, March 4, 2011 and April 27, 2012. The students in the final two examinations completed the modified training program. For those students who completed the modified training program, the score is increased from 2.09 to 2.91 for communication skills, from 2.07 to 2.87 for medical knowledge, and from 1.95 to 2.96 for interpersonal skills ( $p < 0.0001$ ). In addition, pharmacy interns who participated in the first OSCE exam recommended to visit the examination room and to release the direction of exam 3 days prior to OSCE. This allows them grouping the exam situation and helps the interns to know the focus of the program.

**CONCLUSION:** OSCE is an assessment tool that not only evaluates the clinical competency of interns but also assesses the effectiveness of current training program. Our new educational intervention helped these students utilize the pediatric program more, and the learning handbook assisted mentors to teach the students. Both OSCE exam and the modified training program helped the interns apply the professional knowledge more effectively.

**66. Interventions by student pharmacists in an outpatient teaching family medicine center.** *Miranda R. Andrus, Pharm.D., BCPS, T. Lynn Stevenson, Pharm.D., BCPS, CDM; Auburn University Harrison School of Pharmacy, Auburn, AL*

**PURPOSE:** Data describing student pharmacist interventions have primarily been documented in the inpatient setting. Justifica-

tion of the value of student pharmacists in outpatient settings is needed. This study describes the clinical interventions of student pharmacists in an outpatient teaching family medicine center.

**METHODS:** All clinical interventions of fourth year student pharmacists at this school are documented in a single, commercially-available, web-based, documentation system. Reports generated in 2011 for one faculty member and corresponding students in an outpatient teaching family medicine center were analyzed. Students at this site see patients for individual appointments with the pharmacist, see patients with resident physicians, and perform medication reconciliation activities.

**RESULTS:** In 2011, 2900 clinical interventions were documented at this practice site by one clinical pharmacist and 21 student pharmacists. This included 206 individual patient appointments with the pharmacist in which a comprehensive medication history, adherence assessment, pharmacotherapy assessment, related laboratory assessment and patient counseling were performed. Outside of these scheduled visits, another 855 patient medication histories and 581 chart reviews were performed. In addition, 322 patients were counseled, 89 drug information questions answered, and 105 vaccines recommended. Drug therapy was adjusted, discontinued or initiated 254 times. Patient safety interventions (including allergies clarified, drug interactions identified, clarification of orders, ADRs prevented and therapeutic duplication avoided) were documented 83 times. Approximately 1500 hours were spent on these interventions. The clinical pharmacist documented 6% of these interventions independently from students.

**CONCLUSIONS:** Student pharmacists can have a significant impact on patient care in an outpatient teaching family medicine center. Incorporation of student pharmacists into outpatient practices is a cost-effective way to expand clinical pharmacy services, assist with teaching medical residents, and improve patient safety.

**67. Impact of a virtual patient pilot program on student pharmacists' learning outcomes.** Mark A. Douglass, Pharm.D.<sup>1</sup>, Jillian Casale, Pharm.D.Candidate<sup>2</sup>, Margarita V. DiVall, Pharm.D., BCPS<sup>2</sup>, J. Andrew Skirvin, Pharm.D., BCOP<sup>2</sup>; (1)Northeastern University Department of Pharmacy Practice/Boston Medical Center, Boston, MA; (2)Northeastern University School of Pharmacy, Boston, MA

**PURPOSE:** To assess the impact of virtual patient (VP) technology implementation on student pharmacists' medication therapy management (MTM) skills.

**METHODS:** Third professional year student pharmacists (N=135) participated in a pilot program involving a web-based, clinical practice simulator near the completion of a therapeutics course series. Ten virtual patient cases and their electronic medical records were developed. Clinical competencies were established for each case to evaluate MTM skills. Assessments included simulator competency achievement and performance on four pairs of short-answer exam questions that were mapped to four competencies (antibiotics/allergies (AA), heart failure (HF), preventative health (PH), and medication adherence (MA)) which were administered before and during the pilot. A paired t-test compared exam results. A survey was administered at the program completion to evaluate students' attitudes towards the software and its contribution to learning.

**RESULTS:** One hundred and nineteen students successfully completed eight or more cases and the average number of competencies achieved was 40 out of 55 (73%). Students' exam scores significantly improved on three of the four mapped competencies (AA, 40% versus 57.8%, p<0.001; PH, 89.1% versus 99%, p<0.001; and MA, 89.6% versus 99.6%, p<0.001) with non-significant improvements noted on HF (61.1% versus 70.6%, p=0.06). Eighty and 90% of students thought the pilot improved their chronic disease management skills and was a good summary of the course series, respectively. Commonly reported concerns involved limitations or "glitches" with the technology software.

**CONCLUSION:** Improvements in students' MTM skills were observed on three of the four mapped competencies, based on significantly higher exam scores and a high competency achievement rate. Software assessment data will be used to identify learning

gaps and make curricular improvements. Overall student perceptions of the VP technology were positive, however, the software requires further technical refinement before it can be fully integrated into the school's curriculum.

**68. Evaluation of a strategy to build competency in a drug literature evaluation course.** Shannon Reidt, Pharm.D., M.P.H., Kristin K. Janke, Ph.D., Jenifer L Morgan, Pharm.D.; University of Minnesota College of Pharmacy, Minneapolis, MN

**PURPOSE:** To implement a series of educational interventions designed to foster drug literature evaluation skills and to assess students' confidence and perception of change in skills.

**METHODS:** Pharmacy students enrolled in the Drug Literature Evaluation course participated in the following interventions: six in-class article reviews, written article review, student-led journal club, and a final written exam. Students rated their skills pre- and post-course using an End-of-Course Self Assessment (ECSA). A Journal Club Self Assessment (JCSA) was conducted after the student-led journal club. Each assessment was based on seven drug literature evaluation skills (DLES), and participants rated their skills using a five point rating system of Novice, Developing, Skilled, Facilitating/Leading, or Educating.

**RESULTS:** One hundred and sixty-six students responded to both self-assessments. In the ECSA, 46% of respondents reported describing study design as their strongest skill while 23% reported identifying ways to improve study design as their weakest skill. Determining impact on clinical practice and interpreting clinical significance were reported as skills that grew the most (22% and 21%, respectively). In the JCSA, 56% of respondents rated their ability in preparing discussion questions as "skilled" although 32% of respondents stated that formulating discussion questions was the hardest component of the journal club to complete. All seven DLES had statistically significant changes (p<0.001) pre- to post-course. However, average ratings post-course were less than "skilled" for all DLES.

**CONCLUSION:** Although statistically significant improvements in skills were made, interventions need to be incorporated across a curriculum to improve students' skills and confidence further.

**69. Teaching HIV management to pharmacy students: taking the clinic to the classroom.** Lisa Inge, Pharm.D., BCPS, BCACP, AAHIVE; University of Florida, College of Pharmacy, Jacksonville, FL

**PURPOSE:** To assess the educational impact of lectures on anti-retroviral use in multiple patient populations, along with correlating longitudinal HIV patient cases mimicking "clinic visits", on fourth year pharmacy students.

**METHODS:** In an 8 week elective students received pre-taped HIV management lectures on; the treatment of the naïve population, opportunistic infections, perinatal transmission prevention, pediatric infections, post-exposure prevention guidelines and pre-exposure prophylaxis. Correlating longitudinal cases incorporating the same two "patients" were also assigned weekly. These cases required students to apply the lecture's content throughout the course. Case answers were discussed with a facilitator during class to assess potential recommendations. At the end of these class sessions, students were required to write individual management recommendations in an assessment and plan format (problems, medications, monitoring and education). These recommendations were tracked weekly in "patient charts". Final individual summative "transfer notes" were graded. A self-administered pre-post survey measured each student's level of confidence with HIV management on a four point scale at the end of the course, in addition to standard content testing.

**RESULTS:** A Wilcoxon-Signed Rank Test was conducted to evaluate the impact of these lectures and longitudinal patient case studies on students' confidence in use of antiretroviral agents. The test revealed a statistically significant increase in students' confidence levels, z = 24.57, p<0.001, with an effect size (r = 0.85). The median score on the confidence levels increased from the pre-survey (Median=1) to post-survey (Median=3)

**CONCLUSION:** Using longitudinal patient cases as a teaching method allowed students to recognize the impact of their pharmaceutical recommendation in a classroom setting. In turn this provided them with a greater level of confidence that they could make patient specific recommendations for antiretroviral agents in multiple populations.

**70. Student use of insulin pumps as an empathy exercise.** *Ashley W. Ellis, Pharm.D., BCACP<sup>1</sup>, Matthew Strum, Pharm.D., BCACP, CDE<sup>2</sup>, Anastasia B. Jenkins, Pharm.D.<sup>3</sup>, John Bentley, B.S., M.B.A., Ph.D.<sup>2</sup>; (1) University of Mississippi, TN; (2) University of Mississippi School of Pharmacy, MS; (3) University of Mississippi, MS*

**PURPOSE:** This study assessed empathy scores before and after students were trained to use insulin pumps for 24 hours.

**METHODS:** A diabetes-care module was introduced to PY2 students in pharmacy practice skills lab. The lecture covered the use of and insulin, pen devices and insulin pumps. Students were divided into two lab sections. Students in the first section were asked to wear insulin pumps filled with normal saline for 24 hours (n=24). Students were trained regarding pump initiation, common errors, and insulin administration. Students were sent blood glucose readings via text message and asked to record their response. After returning the pumps, the Jefferson Scale of Empathy-Health Profession Student Version (JSE-HPS) was administered online. The second lab section, the control group (n=32) was given the JSE-HPS prior to lab, and participated in the same procedures for the insulin pump lab as the treatment group. The groups' JSE-HPS scores were then compared. All students were asked to record their perceptions in a journal.

**RESULTS:** The mean JSE-HPS score for the control group was 106.96 and 109.47 for the treatment group. Possible scores range from 20 to 140, with higher scores indicating higher empathy. A t-test comparing the difference in JSE-HPS means between the two groups was non-significant (p=0.46). Student perceptions recorded via journal entry were overwhelmingly positive including several mentions of increase ability to empathize with diabetic patients, particularly those using pumps.

**CONCLUSIONS:** Despite the lack of expected significance between the groups on empathy scores, student feedback of increased empathy indicates the importance of including training and personal use of insulin pumps in a skills lab curriculum.

**71. Research competencies and preparedness among hospital practicing pharmacists in Qatar.** *Ahmed Awaisu, Ph.D.<sup>1</sup>, Dana Bakdach, B.Sc.(Pharm.)<sup>1</sup>, Reem H. Elajez, B.Sc.(Pharm.)<sup>1</sup>, Manal Al Zaidan, B.Sc.(Pharm.)<sup>2</sup>; (1) College of Pharmacy, Qatar University, Doha, Qatar; (2) Heart Hospital and NCCCR, Hamad Medical Corporation, Doha, Qatar*

**PURPOSE:** Research is an important mandate of pharmacy and other health care professions. Hamad Medical Corporation (HMC), the predominant public health care organization in Qatar, in alliance with Qatar's National Vision 2030 and the National Health Strategy 2011–2016, aims to be the leading health research organization in the Middle East region. Pharmacists have a pivotal role to play in this strategy. However, there is paucity of data about pharmacists' competence and preparedness in conducting health-related research in Qatar. This study primarily aims to determine (i) the research background of hospital pharmacists in Qatar; (ii) their self-perceived preparedness, competence, and confidence in conducting research; and (iii) to examine their preferences for research capacity building.

**METHODS:** A cross-sectional survey using a validated 70-item questionnaire was conducted among randomly selected pharmacists practicing at seven HMC-managed hospitals. Constructs measuring pharmacists' competence and confidence were tested for reliability. Both descriptive and inferential analyses were applied using IBM-SPSS<sup>®</sup> version 20.

**RESULTS:** A total of 120 participants responded to the survey (66.7% response rate). Over 60% of the participants did not have any previous research experiences. Notably, at least 25% of the

respondents admitted inadequate competence/confidence in developing research protocols, critical appraisal of literature, undertaking statistical techniques, and interpreting research findings. Highest level of education along with current hospital of practice had significant effects on pharmacists' self-perceived competence (p<0.05). Overall, 85% of participants were interested in pursuing post-graduate studies or research-related training.

**CONCLUSION:** A large proportion of hospital pharmacists in Qatar admitted having deficiencies in several domains of research process or competencies, particularly in developing research protocols, critical appraisal of literature, and applying appropriate statistical techniques. These findings have important implications on developing informal research training programs and promoting pursuit of formal postgraduate programs to bridge the gaps found among hospital practicing pharmacists in Qatar.

**72. The state of nuclear pharmacy education in ACPE-accredited colleges of pharmacy.** *Edward M. Bednarczyk, Pharm.D., Samuel Miller, Pharm.D., Mark Sauberan, B.S.; University at Buffalo, Buffalo, NY*

**PURPOSE:** In addition to MRI and CT studies, approximately 17 million nuclear medicine procedures are performed annually in the US, each of which requires administration of a radiopharmaceutical. With the expansion of new schools of pharmacy, relative shortage of faculty, and economic constraints on established programs, some areas of specialty practice may be perceived as expendable, and de-emphasized or eliminated from the curriculum. A previous survey conducted in 2001 indicated a sharp reduction in this content from 1981, with the majority of pharmacy programs offering no instruction in nuclear pharmacy. This study was undertaken to assess the status of instruction in nuclear pharmacy practice in schools of pharmacy.

**METHODS:** An electronic survey was sent to the curricular chairs of 103 fully accredited ACPE schools in the U.S. and Canada. The survey consisted of 21 questions about the teaching of nuclear pharmacy practice. Schools were asked if instruction was offered, and where in the curriculum it was included.

**RESULTS:** Thirty seven (35.9%) schools responded. Of these, 21 (56.8%) offer no instruction in nuclear pharmacy in any portion of the curriculum, with 10 programs indicating an intention to add this to the curriculum. Among the 16 (43%) offering instruction, the majority offer it as an elective course or as part of an elective course. Only nine programs reported teaching nuclear pharmacy content as part of the core curriculum relevant to generalists (ie pharmacokinetic distribution or drug interactions). The current level of instruction appears to be consistent with a 2001 survey.

**CONCLUSION:** The majority of graduates from ACPE-accredited schools of pharmacy are not presented with any instruction related to this widely used class of pharmaceuticals, however this decline appears to have slowed. Lack of knowledge of these agents will continue to provide challenges to provision of comprehensive pharmaceutical care.

**73. Clinical communication skills compared with written and oral examination performance.** *Lisa M. Lundquist, Pharm.D., BCPS, Angela O. Shogbon, Pharm.D., BCPS, Kathryn M. Momary, Pharm.D., BCPS; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA*

**PURPOSE:** To compare performance on knowledge-based written and oral examinations to faculty evaluation of communication skills.

**METHODS:** For three consecutive years, a patient case-based oral examination was given to all second professional year pharmacy students enrolled in the cardiovascular therapeutics course in addition to traditional written examinations. Students were provided with a patient case 24-hours prior to the oral examination to allow adequate preparation time and the examination incorporated information also tested in written format. In addition to evaluation of pharmacotherapy knowledge on the oral examination, faculty used a standard rubric to assess students'

communication skills in the areas of rapport (confidence, non-verbal, tone of voice, eye contact) and presentation of therapeutic recommendations (concise, pronunciation, well-prepared, patient-focused). Students' performance on the written and oral examinations were compared to faculty evaluation of their communication skills using descriptive statistics, two-way ANOVA, and Pearson's correlation.

**RESULTS:** Over 3 years of this study, a total of 403 (97.8%) students provided informed consent for participation. A positive correlation was seen between performance on the oral examination and mean faculty communication evaluation scores ( $r = 0.49$ ,  $p < 0.001$ ). Little correlation was seen between written and oral exam performance ( $r = 0.19$ ,  $p < 0.001$ ) and between written exam performance and mean faculty communication scores ( $r = 0.06$ ,  $p = 0.208$ ). In addition, students who scored 90 or greater on the oral examination had higher mean (SD) faculty communication scores than those who scored  $< 90$  (3.65 [0.36] versus 3.35 [0.43], respectively,  $p < 0.001$ ).

**CONCLUSION:** Success as a pharmacist requires both therapeutics knowledge and effective communication skills. Identification of potential disparities between knowledge and communication skills may lead to a broader curricular focus on oral communication in therapeutics courses.

**74. Communication of clinical recommendations during oral examinations.** Lisa M. Lundquist, Pharm.D., BCPS, *Angela O. Shogbon, Pharm.D., BCPS*, Kathryn M. Momary, Pharm.D., BCPS; 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 three consecutive years in the Cardiovascular/Renal therapeutics course, one individual and one group patient case-based oral examination were given to all second-year student pharmacists. 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, tone of voice, eye contact) and presentation of therapeutic recommendations (concise, pronunciation, well-prepared, patient-focused). 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 Institutional Review Board 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 student's t-tests.

**RESULTS:** A total of 401 (97.3%) 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 3.16 (0.52) and 3.51 (0.42), respectively. For the group oral examination, mean (SD) student self-assessment and faculty's evaluation of communication were 3.35 (0.47) and 3.52 (0.34). Faculty evaluations in both the individual and group oral examinations were statistically significantly higher than the students' self-assessments ( $p < 0.001$ ). In addition, students' self-assessment of communication increased from the individual to the group examination ( $p < 0.001$ ).

**CONCLUSION:** Student pharmacists' self-assessment of communication skills was 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. Increased utilization of patient case-based oral examinations in therapeutic courses may help to improve student's confidence and self-assessment of their communication skills.

**75E. Evaluation of pharmacy students' clinical interventions on advanced pharmacy practice experiences at a non-teaching hospital.** *Angela O. Shogbon, Pharm.D., BCPS*, Lisa M. Lundquist, Pharm.D., BCPS; Mercer University College of Pharmacy and Health Sciences, Atlanta, GA

**PURPOSE:** To evaluate clinical interventions of pharmacy students on advanced pharmacy practice experiences (APPE) at a community non-teaching hospital by assessment of clinical interventions for estimated cost savings, intervention class, and acceptance rate.

**METHODS:** Clinical interventions of 69 fourth-year pharmacy students on Medication Safety ( $n=13$ ), Advanced Institutional ( $n=17$ ) and Internal Medicine ( $n=39$ ) APPE were collected from June 2009 to July 2011. Students documented daily clinical interventions on a data collection form. Interventions were classified into the following areas: therapeutic (antibiotic recommendations, medication initiation/discontinuation, therapeutic interchanges), safety (dose evaluations, lab evaluation, drug interactions, allergy clarification, medication order clarification), quality assurance (medication history, duplicate avoidance), intravenous to oral route conversions, and information/education (drug information, patient education). The data were entered into a pharmacy intervention database for analysis of estimated cost savings, intervention class, and acceptance rates.

**RESULTS:** A total of 1007 clinical interventions were attempted (126 from Medication Safety APPE, 141 Advanced Institutional, 740 Internal Medicine). Acceptance rate for all interventions was 96.5%. The total estimated cost savings was \$119,401. Types and estimated cost savings of accepted interventions included: therapeutic ( $n=117$ , \$18,489), safety ( $n=119$ , \$18,207), quality assurance ( $n=84$ , \$12,852), intravenous to oral ( $n=206$ , \$3451), and information/education ( $n=446$ , \$66,402). Internal medicine APPE students contributed to most of the therapeutic (96.1%), safety (94.9%) and quality assurance (96.6%) interventions.

**CONCLUSION:** Pharmacy students on APPE at a community non-teaching hospital have multiple opportunities to participate in clinical activities, interact and collaborate with other healthcare professionals, and significantly impact patient care through clinical interventions, while also contributing to pharmacy cost savings.

Presented at Presented at the American Association of Colleges of Pharmacy Annual Meeting, Kissimmee, FL, July 16, 2012.

**76. Student pharmacists' perception of a service learning experience at a charity pharmacy.** *Lauren S. Bloodworth, Pharm.D., BCPS*, Meagan Brown, Pharm.D., Courtney Davis, Pharm.D., Leigh Ann Ross, Pharm.D., BCPS; University of Mississippi School of Pharmacy, Jackson, MS

**PURPOSE:** The objective is to evaluate student pharmacists' perception of a service-learning opportunity through the Mississippi Dental Association's Mission of Mercy Pharmacy Clinic.

**METHODS:** The University of Mississippi established a charity pharmacy to support the medication needs of the patients of a temporary, free dental clinic targeted to provide dental and pharmacy services to low-income individuals of the Jackson, Mississippi, area. Current PY3 and PY4 students volunteered time to dispense and counsel patients on his/her prescribed medications. A 23-question pre-survey tool and a 32-question post-survey tool were used to assess the student pharmacists' perception of the service learning experience. The survey questions examined student demographic data, previous work history, volunteer experience, attitudes and perceptions about community service, and civic, cultural, and social issues.

**RESULTS:** Of the 22 students who completed service learning experience, 100% responded to the surveys (1 PY3 and 21 PY4). The majority of respondents perceived that he/she improved in terms of knowledge/understanding of the health care needs of the community in which he/she served (64%), the barriers to receiving health care in the community that he/she served (64%), how to work with patients who have various levels of health care knowledge (50%). One hundred percentage of the students

reported that he/she was willing or very willing to volunteer for community service post graduation.

**CONCLUSIONS:** These results suggest that participation in a service learning experience was seen as valuable and beneficial. It also offers opportunities for students to grow professionally and personally while providing much needed service to the community.

**77. Incorporation of human patient simulation into an antimicrobial stewardship based infectious diseases elective.** *Bonnie A. Falcione, Pharm.D., BCPS(AQ-ID), Susan M. Meyer, Ph.D., Amy L. Seybert, Pharm.D., FASHP, FCCP; University of Pittsburgh School of Pharmacy, Pittsburgh, PA*

**PURPOSE:** Human patient simulation (HPS) immerses students in interactive learning while avoiding patient safety risks; however the utility of teaching antimicrobial stewardship (AS) principles hasn't been demonstrated for HPS. Our goal was to incorporate HPS into an infectious diseases elective, originally developed to teach knowledge and application of AS with complex cases, without compromising student learning satisfaction. We aimed to conduct HPS cases for the learning objectives recognition and management of antimicrobial-induced adverse effects, including selection of alternative regimens.

**METHODS:** Two longitudinal HPS cases, bacterial endocarditis (BE) and cryptococcal meningitis (CM), were conducted over week-3 and 4 of a 5-week 1-credit elective with two high-fidelity mannequins during two 1-hour group sessions for 11 third (of fourth) professional year pharmacy students. Four pharmacy residents trained in conducting scripted high-fidelity HPS-sessions role-played and synchronized manifestations of antimicrobial adverse effects in response to student-groups' assessment and recommendation appropriateness, including alternative antimicrobials. Students completed individual pre- and post-HPS graded assignments, and anonymous pre- and post-course assessments (baseline AS knowledge and perceived learning satisfaction, respectively, with 5-point Likert or open-ended questions).

**RESULTS:** All 11 students completed HPS-sessions, assignments and assessments. Two (18%) had baseline AS knowledge. Nine (82%) indicated course improved application of science/practice knowledge for complex patients in AS context to very-high/high degree. Eighty-two and 73% indicated course improved BE and CM management knowledge to very high/high degree, respectively, while 82% and 91% indicated HPS added to BE and CM management knowledge to very high/high degree, respectively. Eighty-two percent of students' open-ended responses indicated HPS was the course "best part".

**CONCLUSION:** HPS was used for critical thinking and problem solving in teaching AS principles without compromising student learning satisfaction. HPS can be readily incorporated into case-based AS scenarios for learning objectives involving recognition, management and alternative agent selection for antimicrobial-induced adverse effects.

**78. SOAP note written documentation needs assessment and course methodology evaluation for on-line course.** *Ann M. Snyder, Pharm.D.; Pharmacotherapy & Translational Research, University of Florida, Gainesville, FL*

**PURPOSE:** The objective of this study was to (i) evaluate practicing pharmacist's experiences with clinical documentation experiences and (ii) evaluate the effectiveness of an online clinical documentation educational intervention.

**METHODS:** As part of an online course for first year licensed pharmacists enrolled in an online PharmD degree program, 93 individuals completed a pre-survey exploring demographics and experiences with clinical documentation and evaluated a SOAP note. Over the course of 3 weeks, individuals participated in didactic learning modules related to clinical documentation and note writing and completed practice exercises and a comprehensive self-assessment. Following the completion of the learning activities, individuals complete a post-assessment and evaluated a SOAP note.

**RESULTS:** (i) Forty-nine percentage of the 93 participants stated no prior instruction related to the documentation of patient care. Among those that reported previous instruction, 50.5% indicated that they received on-the-job training, 16.5% stated they received training during intern or externship, 15.5% reported a combination of intern / externship and job training, and 17.5% reported that they were self-learned. (ii) Post-survey results indicated on average 50% learners were able to identify 50% of the necessary components for subjective and objective information, 42% for assessment, 88% for recommendation, and 83% for monitoring plan. (iii) Eighty-two percentage used self-assessment activities to guide their learning. Twenty-two percentage of participants used that self-assessment once, 54% of participants made two to three attempts at the self-assessment activity, and 10.5% made four or more attempts (attempt range 1-9). (iv) All post-survey respondents stated the combinations of lecture examples; self-assessment, grading note exercise, and the rubric were useful for learning and practicing written documentation. (v) Student's ability to grade and assess the appropriateness of notes, evaluated pre and post completion of learning activities, improved. Students still struggle with creating assessments.

**CONCLUSION:** On-line methods can be effective for assessing and teaching basic clinical documentation skills and guiding future learning strategies.

## Emergency Medicine

**79. Etomidate versus non-etomidate induction for rapid sequence intubation in trauma.** *Elizabeth Hand, Pharm.D.<sup>1</sup>, Michael Corneille, M.D.<sup>2</sup>, Kay Green, R.Ph., BCPS<sup>1</sup>, Pam Maxwell, Pharm.D., BCPS<sup>1</sup>, Darrel W. Hughes, Pharm.D., BCPS<sup>1</sup>; (1) University Health System, San Antonio, TX; (2) UTHSCSA, San Antonio, TX*

**PURPOSE:** Etomidate is the most commonly used induction agent for rapid sequence intubation (RSI). Single-dose etomidate may inhibit cortisol production for 72 hours. The impact of etomidate-induced adrenal suppression in critically ill trauma patients has not been fully elucidated. The primary outcome was to compare in-hospital mortality for traumatically injured patients receiving etomidate versus alternative induction agents for RSI.

**METHODS:** A single-center, retrospective review was performed of medical records for 202 traumatically injured adult patients between July 2008 and March 2010. Patients were identified through an institutional trauma registry and data were collected from medical records.

**RESULTS:** The patient population was mostly male (72.8%) with a median age of 44 years. More patients were intubated in the ED than prior to arrival (56% versus 44%). Motor vehicle accident was the most frequently reported mechanism of injury (n=71). Etomidate was used in 130 cases (63%), while 72 patients received alternative sedatives including midazolam (n=45), propofol (n=8), ketamine (n=4), or no induction therapy (n=15). ISS (22 versus 26, p=0.18) and SOFA scores (6 versus 6, p=0.20) were similar at baseline between etomidate and non-etomidate groups, respectively. Intravenous fluids (4.6 versus 4.8 L, p=0.87) and units of packed red blood cells (pRBCs) received (4 versus 4, p=0.28) were similar for both etomidate and non-etomidate groups during the first 24 hours following injury. In-hospital mortality rates were similar between groups (1.5% versus 12.5%, p=0.82). ICU LOS (8.5 versus 8 days, p=0.45), hospital LOS (14.5 versus 13.5 days, p=0.68), ventilator days (6 versus 5, p=0.61), and vasopressor days (6 versus 5, p=0.60) were not significantly different.

**CONCLUSION:** Etomidate use does not appear to be associated with increased in-hospital mortality or resource utilization when used for RSI induction in traumatically injured patients.

**80. Intravenous sodium bicarbonate therapy in severely acidotic diabetic ketoacidosis.** *Bryson Duhon, Pharm.D.<sup>1</sup>, Ana Crystal Franco-Martinez, Pharm.D., BCPS<sup>1</sup>, Rebecca Attridge, Pharm.D.,*

M.S., BCPS<sup>2</sup>, Pam Maxwell, Pharm.D., BCPS<sup>1</sup>, Darrel W. Hughes, Pharm.D., BCPS<sup>1</sup>; (1) University Health System, San Antonio, TX; (2) University of the Incarnate Word Feik School of Pharmacy, San Antonio, TX

**PURPOSE:** The use of IV bicarbonate in diabetic ketoacidosis (DKA) may be considered for patients with a pH of <6.9. The impact of this therapy on resolution of acidosis in DKA patients is unclear. The primary outcome was to compare time to resolution of acidosis (pH  $\geq$  7.20) between DKA patients who received IV bicarbonate versus those who did not.

**METHODS:** This single-center, retrospective analysis included 86 adult DKA patients between January 2007 and July 2011. Patients were identified by a diagnosis code of DKA and included if they presented with a pH < 7.0.

**RESULTS:** Patients were mostly female (58%) and Hispanic (64%) with a median age of 35 (interquartile range 25–46 years). More patients had Type 1 diabetes mellitus (53%) compared with Type 2 (41%); of patients with Type 2 diabetes, 78% were insulin dependent. Average pH (6.86 versus 6.97,  $p=0.2$ ) and blood glucose level (560 versus 595 mg/dl,  $p=0.53$ ) at presentation were similar between bicarbonate and no bicarbonate groups. There was no significant difference in time to resolution of acidosis (8 versus 8 hours,  $p=0.7$ ) nor time to hospital discharge (68 versus 61 hours,  $p=0.3$ ). Insulin requirements in the first 24 hours were significantly higher in patients receiving IV bicarbonate versus those not receiving IV bicarbonate (100 versus 86 units,  $p=0.04$ ). There was no significant difference in hours on continuous insulin infusion (27 versus 26 hours,  $p=0.09$ ), or potassium requirements in the first 24 hours (135 versus 120 mEq,  $p=0.84$ ). Subgroup analyses of patients with initial pH < 6.9 showed no difference in time to resolution of acidosis (10 versus 12 hours,  $p=0.3$ ) or hospital length of stay (68 versus 70 hours,  $p=0.9$ ).

**CONCLUSION:** IV bicarbonate therapy did not decrease time to resolution of acidosis or time to hospital discharge for DKA patients with initial pH < 7.0.

**81. Heparin therapy for venous thromboembolism: are morbidly obese patients treated differently?** *Suprat Saely, Pharm.D., BCPS<sup>1</sup>, Brian Badgley, Pharm.D.<sup>1</sup>, Peter Whittaker, Ph.D.<sup>2</sup>;* (1) Detroit Receiving Hospital, Detroit, MI; (2) Cardiovascular Research Institute and Department of Emergency Medicine, Wayne State University School of Medicine, Detroit, MI

**PURPOSE:** Heparin dosing for obese patients with venous thromboembolism (VTE) poses challenges because of concern for bleeding if doses are based on body weight. The challenges and concerns are amplified in morbid obesity (body mass index (BMI) >40 kg/m<sup>2</sup>). We aimed to determine if: (i) obese and morbidly obese patients received appropriate heparin doses; (ii) the given doses were associated with delayed anticoagulation; (iii) adverse events were more frequent in obese patients.

**METHODS:** Our retrospective chart-review compared 155 non-obese (BMI < 30 kg/m<sup>2</sup>) patients with 91 obese (BMI = 30.0–39.9 kg/m<sup>2</sup>) and 31 morbidly obese patients who presented to the emergency department with confirmed VTE. We determined the proportion of patients who: (i) received the appropriate initial bolus (80 units/kg) and infusion (18 units/kg/hour) dose according to our protocol (for obese patients, we used an adjusted body weight-based nomogram), (ii) achieved aPTT > 48 seconds within 12 hours of heparin treatment, and (iii) experienced in-hospital bleeding or had VTE recurrence within 90 days.

**RESULTS:** Underdosing (defined as >10% below target) for infusions occurred more frequently for non-obese patients (31%) than either obese group (obese = 14%; morbidly obese = 19%;  $p<0.01$ ). Bolus underdosing was similarly high for non-obese (28%); but, did not differ between groups (obese = 19%; morbidly obese = 32%;  $p=0.16$ ). In contrast, failure to achieve target aPTT was highest with morbid obesity (39%; versus obese = 10%; non-obese = 19%;  $p<0.002$ ). Nevertheless, bleeding (morbidly obese = 3.2%; obese = 1.1%; non-obese = 0.6%) and VTE recurrence (3.2% versus 3.3% versus 2.6%) was similar ( $p=NS$ ).

**CONCLUSIONS:** Morbidly obese patients were not treated differently; the proportion underdosed according to the adjusted body weight-based nomogram did not differ from that of obese patients. Despite this equivalence, morbidly obese patients responded differently: exhibiting greater failure to achieve anticoagulation. Nonetheless, such delay was not associated with increased VTE recurrence. The compromised response to heparin therapy in morbid obesity warrants further investigation to determine its clinical and practical significance.

**82. Hypotension associated with propofol in trauma patients in the emergency department.** *Amanda E. Shearin, Pharm.D., Asad E. Patanwala, Pharm.D., Andrew Tang, M.D., Brian L. Erstad, Pharm.D.;* University of Arizona, Tucson, AZ

**PURPOSE:** Propofol is commonly used in mechanically ventilated trauma patients after intubation in the emergency department. The purpose of this study was to determine the incidence of hypotension and identify predictors of hypotension associated with propofol in this setting.

**METHODS:** This was a retrospective cohort study conducted between June 24, 2010 and December 1, 2011. Consecutive adult trauma patients who were initiated on a propofol infusion in the emergency department during this time frame were included. Patients were excluded if they had baseline hypotension (systolic blood pressure <90 mm Hg or on a vasopressor) prior to propofol initiation. The incidence of subsequent hypotension was determined prior to patient transfer. A multivariate logistic regression analysis was performed to identify predictors of hypotension.

**RESULTS:** A total of 200 patients were included in the final analyses. Of these, 32 (16%) developed hypotension in the emergency department. In the multivariate analysis, increasing patient age (odds ratio: 1.035, 95% CI: 1.007–1.064,  $p=0.014$ ) and weight (odds ratio: 1.026, 95% CI: 1.003–1.048,  $p=0.025$ ) were associated with more hypotension. The risk of hypotension also increased with lower baseline blood pressure (odds ratio: 0.953, 95% CI: 0.932–0.975,  $p<0.001$ ). Other variables such as sex, race propofol infusion rates, and use of analgesia was not predictive of hypotension.

**CONCLUSION:** Increasing age and weight, and lower baseline blood pressure is associated with a higher risk of hypotension in trauma patients treated with propofol infusions in the emergency department.

**83. From sunset to sunrise: the role and potential value of newly established night-shift emergency department pharmacists in a community regional medical center.** *Sandra C. Bartlett, Ph.D., Pharm.D., BCPS, Brooke M. Bitner, Pharm.D., Katherine E. Burenheide, M.S., Pharm.D., BCPS; Stormont-Vail HealthCare, Topeka, KS*

**PURPOSE:** Stormont-Vail Regional Health Center (SVHC) is a 586-bed acute care facility with an Emergency and Trauma Center expecting over 60,000 patients this year. The study objectives are: to examine the role of the night ED Clinical Pharmacy Specialists (ED-CSPEC) and determine their value in terms of cost-avoidance and potential cost-savings.

**METHODS:** This retrospective study quantifies 3 months of high-priority interventions using i-Vents generated in the Epic electronic medical record to describe the night ED-CSPEC activities. A pharmacoeconomic analysis was conducted to determine intervention value using Pharmacy OneSource standard intervention dollars. For interventions not included in the model, extrapolations were used.

**RESULTS:** During the study period, 901 interventions were documented during 78 shifts corresponding to one intervention per hour. Interventions were made on 14  $\pm$  5% of patients. Monthly interventions were not statistically different between pharmacists (181  $\pm$  61 versus 120  $\pm$  53;  $p=0.26$ ). The most frequent pharmacist interventions include: providing medication/dosing recommendations to ED providers (26%), assistance to nurses on IV drug infusion rate or compatibility (16%) and response to stroke calls (8.5%). Other interventions include participation in: rapid sequence intubation (6.5%), procedural sedation (3.4%), drug

overdose (5.5%), code blue (4.2%) and traumas (4.2%) or providing information to retail pharmacies (4.3%). Pharmacoeconomic analysis of interventions reveal a cost-avoidance of \$430,775 for the study period that translates to an annual cost-avoidance of \$1,723,102 with an annual cost-savings of \$1,497,886 to the institution.

**CONCLUSIONS:** SVHC ED-CSPECs spend the night providing medication and dosing information to ED providers and assisting nurses with medication infusion rates and IV compatibilities. In addition, they participate in rapid sequence intubations, code blues, traumas, procedural sedations and stroke calls as well as talking with retail pharmacies. These selected interventions alone have a significant positive financial impact and will provide over \$1 million dollars in annual cost-savings to the institution.

## Endocrinology

**84. Pharmacist-led diabetes chronic care management program improves glycemic control without increasing costs in patients with uncontrolled type 2 diabetes.** *Carrie McAdam-Marx, Ph.D., R. Ph.<sup>1</sup>, Brandon T. Jennings, Pharm.D.<sup>2</sup>, Arati Dahal, Ph.D.<sup>1</sup>, Karen Gunning, Pharm.D.<sup>3</sup>*; (1)University of Utah Pharmacotherapy Outcomes Research Center, Salt Lake City, UT; (2)University of Utah College of Pharmacy, Salt Lake City, UT; (3)University of Utah Departments of Pharmacotherapy & Family and Preventive Medicine, Salt Lake City, UT

**PURPOSE:** Evaluate clinical and economic outcomes in university-owned community clinic patients with uncontrolled type 2 diabetes (T2DM) referred to pharmacist-coordinated, diabetes chronic care management (DCCM).

**METHODS:** This retrospective cohort study based on medical record and administrative data from 2008 to 2010 compared patients with uncontrolled T2DM (HbA1c  $\geq 7.0\%$ ) referred to DCCM in 2009 or 2010 to a cohort of patients with uncontrolled T2DM treated by a clinic not supporting DCCM. Index date was DCCM enrollment date or for comparison patients, HbA1c reading after 12 months of EMR activity after 1/1/2008. Changes in HbA1c from baseline to 6-months ( $-90$  to  $+180$  days) and goal attainment ( $<7.0\%$  versus  $\geq 7.0\%$ ) were identified, as were changes in utilization and costs from 6-months pre- to 6-months post-index. Multivariate regression analyses were used to calculate the likelihood of attaining HbA1c goal and estimate adjusted changes in HbA1c, healthcare use, and costs.

**RESULTS:** A total of 119 DCCM and 199 comparison patients were included. Mean (SD) age was 58.7 (13.1) versus 60.9 (12.9) years ( $p>0.05$ ) for DCCM and comparison patients, respectively; 55.3% versus 42.7% were female ( $p=0.03$ ). Baseline HbA1c was higher for DCCM (10.2% [1.8]) than comparison patients (8.4% [1.5];  $p<0.001$ ). After adjusting for baseline HbA1c and other confounders, the DCCM group had a 1.3% greater reduction in HbA1c than comparison patients (coefficient:  $-1.31$ ; 95% CI:  $-1.76$ ,  $-0.86$ ) and were 2.6 times more likely to attain HbA1c goal. DCCM patients had an increase in the mean number of community clinic visits during the follow-up period than comparison patients (1.5 versus  $-0.3$  visit change;  $p=0.009$ ). When adjusting for confounders, the overall cost differences from pre- to post index date did not differ.

**CONCLUSION:** This pharmacist-led DCCM program was associated with improved glycemic control and an increase in community clinic visits without increasing costs in patients with uncontrolled T2DM.

**85E. Evaluation of the use of different insulin regimens in the treatment of type 1 and type 2 diabetes mellitus.** *Maha Mahmoud Al Hakim, Master in Clinical Pharmacy<sup>1</sup>, Abobakr Abasaed, Pharm.D.<sup>2</sup>, D. Jones Jones<sup>3</sup>*; (1)Mafrag Hospital, Inpatient Pharmacy, Drug Information Centre, Abu Dhabi, UAE; (2)Ministry of Health, Abu Dhabi, UAE; (3)Queen University, Belfast, United Kingdom

**PURPOSE:** To compare the effect of different insulin regimens and to evaluate patient satisfaction and acceptability of the regi-

mens after a consistent high quality diabetic education program through a multidisciplinary team.

**METHODS:** Design analysis of data collected from a randomized cross sectional study performed through retrospective and prospective phases. Data obtained through the qualitative and quantitative method. The data collected was analyzed using SPSS software, frequency distribution and cross tabulation. Setting: Endocrinology clinic and wards in Al Mafrag Hospital in the United Arab Emirates. The Hospital is well-equipped facility with 450 beds. Sample: 120 male/female diabetic patients consist of 37 males and 53 females aged 18 years and older. These patients were randomly selected between April 2008 and June 2009. Interventions: Implementation of multidisciplinary diabetic education program.

**RESULTS:** The analysis of data showed that the highest percentage of patients (41.6%) achieved the therapeutic goal (A1C  $< 7\%$ ) were on basal bolus insulin (MDI), and mild hypoglycemia most frequently occurred (48.2%) in patients with this regimen too. In terms of educational intervention, the data demonstrated that the highest percentage of patients achieved glycemic goal corresponded to the "very good" response to learning education program. Regarding patient satisfaction with current insulin treatment, 50% of the "very satisfied" are on basal bolus insulin analogues.

**CONCLUSION:** This study goes in accordance with clinical studies suggesting that analogue regimens can be used successfully to achieve guidelines' target and the initiation and intensification of insulin is a vital part of the care plan for many patients with diabetes. The results showed that the highest percentage of the patients achieved target glycemia where treated by basal-bolus and it is the most preferred regimen by its users. Effectively educate patients about their insulin therapy will improve glycemic control, and their compliance with insulin regimens through multidisciplinary diabetic team.

Presented at Presented at the Diabetes 2011, 13th National Conference in London, UK, 05-06 July 2011. Presented at SEHA Research Conference in Abu Dhabi, UAE, December 2010.

**86. Impact of an interdisciplinary inpatient diabetes education process on patient understanding and adherence.** *Amanda Lin, Pharm.D.<sup>1</sup>, Kim C. Coley, Pharm.D.<sup>2</sup>, Rima A. Mohammad, Pharm.D.<sup>2</sup>, Amy C. Donihi, Pharm.D.<sup>2</sup>*; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA

**PURPOSE:** Our hospital recently implemented an organized interdisciplinary education process for teaching hospitalized patients about their diabetes. This project was designed to evaluate how well patients understand and adhere to discharge insulin instructions following hospital discharge.

**METHODS:** A convenience sample of 25 adult medical inpatients with diabetes who were discharged to home with a prescription for scheduled insulin were included. A questionnaire was administered via telephone 24-48 hours following hospital discharge to test patients' knowledge and adherence to discharge insulin instructions.

**RESULTS:** Median age was 61 (range 38-89) years and 56% of patients were male. Nine (36%) of the 25 patients had diabetes teaching documented in the medical record by any healthcare professional during hospitalization, although 16 (64%) actually recalled being taught by a nurse, pharmacist or dietician. Overall, 20 (80%) patients correctly stated when they should administer their insulin(s), 19 (76%) knew how to dispose of their used syringes or pen needles, 16 (64%) knew their doses, and 21 (84%) were able to recognize the symptoms of hypoglycemia. There were no statistically significant differences in correctly answered questions between patients with documentation of teaching compared to those without documentation. Of the patients on multiple insulin products ( $n=14$ ), 85.7% could correctly identify the type of insulin (long-acting versus short-acting insulin). Of the patients who were new to insulin ( $n=5$ ), all (100%) had documentation of teaching and four (80%) were taught by a pharmacist.

**CONCLUSION:** This QI project shows that insulin education is not documented for most inpatients at our hospital. Although most patients had some knowledge of how to administer their insulin, there were still knowledge deficits, especially with respect to insulin dosing.

**87. A retrospective analysis of vitamin D practice patterns in a Veterans Affairs Medical Center.** Elizabeth A. Connolly, Pharm.D.<sup>1</sup>, Debra W. Kemp, Pharm.D., BCPS, BCACP<sup>2</sup>, Karen Barnard, M.D.<sup>3</sup>; (1) UNC Eshelman School of Pharmacy, Chapel Hill, NC; (2) UNC Eshelman School of Pharmacy/Durham VA Medical Center, Durham, NC; (3) Durham VA Medical Center, Durham, NC

**PURPOSE:** The purpose of this study was to determine the rates of vitamin D sufficiency, insufficiency, and deficiency among patients with measured 25(OH)D levels at a VA Medical Center, to assess the treatment and follow-up that occurred after patients were identified as vitamin D insufficient or deficient, and to assess the effectiveness of vitamin D regimens recommended for the treatment of vitamin D insufficiency or deficiency.

**METHODS:** The medical records of 300 patients who had an initial vitamin D level measured at between March 1, 2009 and June 30, 2009 were reviewed. The following information was recorded: race, BMI, medical history, VA medication use within previous 6 months of initial 25(OH)D, laboratory values within previous 6 months of initial 25(OH)D, type of clinic and provider ordering or treating 25(OH)D level, recommended vitamin D and calcium therapy, and information regarding first follow-up within 1 year of initial recommendation.

**RESULTS:** Vitamin D deficiency and insufficiency was identified in 49% and 26% of evaluated patients respectively. An initial vitamin D recommendation was documented for 62% of patients with vitamin D deficiency and 73% of patients with vitamin D insufficiency. Among the deficient and insufficient patients who received an initial vitamin D recommendation, 62% and 51%, respectively, were followed-up at least once within 12 months of the initial recommendation. A serum 25(OH)D level  $\geq 30$  ng/ml was achieved in 34% of the deficient patients who received follow-up and 69% of the insufficient patients who received follow-up. Prescribers recommended more than 30 different ergocalciferol regimens.

**CONCLUSION:** The treatment of suboptimal vitamin D levels at an academic VA Medical Center varies considerably among providers. The wide variety of recommended vitamin D regimens and inconsistent follow-up suggest that an institution specific protocol would be beneficial for optimal patient care.

## Gastroenterology

**88. Comparison of polyethylene glycol – electrolyte solution versus polyethylene glycol – 3350 for the treatment of fecal impaction in pediatric patients.** Erin Boles, Pharm.D.<sup>1</sup>, Emma M. Tillman, Pharm.D.<sup>2</sup>; (1) Le Bonheur Children's Hospital, Memphis, TN; (2) University of Tennessee Health Science Center, Memphis, TN

**PURPOSE:** Functional constipation is common in pediatric patients and if untreated can lead to fecal impaction. Orally administered polyethylene glycol-electrolyte solution (PEG-ES) has been studied for efficacy in treatment of fecal impaction. Although it is effective, it is difficult to administer and is associated with side effects. Polyethylene glycol-3350 (PEG-3350), is more tolerable to patients and seems to be effective in treating fecal impaction. To date, there are no studies comparing these two treatment options. The aim of this study was to compare safety and efficacy of PEG-ES versus PEG-3350 for the treatment of fecal impaction in pediatric patients.

**METHODS:** Medical records from pediatric patients who received either PEG-ES or PEG-3350 for fecal impaction were included in this retrospective observational study. Patients were excluded if they were discharged prior to resolution of symptoms, or if they were not receiving appropriate doses. Data collected included demographic data, treatment data, length of stay, time to resolution of symptoms, and side effects.

**RESULTS:** Fifty-one patients were included for evaluation, 23 patients received PEG-ES and 28 patients received PEG-3350. Gender, race, age, and weight were not statistically different between the two groups. Resolution of fecal impaction was not significantly different between PEG-ES versus PEG-3350, 87% and 86% respectively ( $p=0.87$ ). There was only one reported side effect with PEG-3350 versus 19 reported side effects with PEG-ES ( $p<0.01$ ). Eighteen patients required NG tube placement for administration of PEG-ES and zero patients required NG placement for administration of PEG-3350 ( $p<0.01$ ).

**CONCLUSION:** This is the first reported comparison of the efficacy of PEG-ES and PEG-3350 for the treatment of fecal impaction in pediatric patients. PEG-3350 is as effective as PEG-ES for the treatment of fecal impaction in pediatric patients, PEG-3350 is associated with fewer side effects compared to PEG-ES, and PEG-3350 administration is less invasive to pediatric patients.

**89E. Efficacy, safety and tolerability of HZT-501, including users of low-dose aspirin (LDA), a single-tablet combination of ibuprofen-famotidine: results of two phase 3 trials.** Michael Weinblatt, M.D.<sup>1</sup>, Mark C. Genovese, M.D.<sup>2</sup>, Alan Kivitz, M.D.<sup>3</sup>, Alfonso E. Bello, M.D.<sup>4</sup>, Amy Grahn, M.S.<sup>5</sup>, Jeffrey W. Sherman, M.D., FACP<sup>5</sup>, Michael H. Schiff, M.D.<sup>6</sup>, Merrell Magelli, Pharm.D.<sup>5</sup>; (1) Division of Rheumatology, Immunology and Allergy, Brigham and Women's Hospital, Boston, MA; (2) Stanford University Medical Center, Stanford, CA; (3) Altoona Center for Clinical Research, Duncansville, PA; (4) Illinois Bone & Joint Institute, Glenview, IL; (5) Horizon Pharma, Inc, Northbrook, IL; (6) Rheumatology Division, University of Colorado, Denver, CO

**PURPOSE:** To determine whether a combination tablet of ibuprofen (IBU) plus a high-dose H2RA will decrease ulcer disease in NSAID plus LDA users and improve compliance.

**METHODS:** Two 24-week double-blind, randomized trials of HZT-501 (DUEXIS), a single-tablet combination of ibuprofen (IBU; 800 mg) and famotidine (FAM; 26.6 mg) given three times daily were undertaken (REDUCE-1 and REDUCE-2). Patients 40–80 years expected to require daily NSAID therapy  $\geq 6$  months with no history of ulcer complications, negative *H. pylori* stool test and baseline endoscopy (EGD) showing no ulcers and  $<5$  erosions in the UGI tract were randomly assigned in a 2:1 ratio to HZT-501 or IBU 800 mg tablets. Concomitant LDA ( $\leq 325$  mg daily) and oral anticoagulants (OAC) therapies were permitted. Randomization was stratified based on LDA/OAC therapy and prior ulcer history. Study EGDs were done at 8, 16 and 24 weeks of therapy. The predefined population for primary analyses of ulcers was all patients with at least one on-study EGD. Additional safety data included treatment emergent adverse events (TEAEs), clinical laboratory assessments and physical exams.

**RESULTS:** The studies included 906 and 627 patients. Total patients were 1533, of which 1022 received HZT-501 and 511 received IBU. They included 121 of 812 and 79 of 570 LDA users in their primary analysis populations, respectively. A combined sub-group analysis of the LDA users demonstrated a reduction in UGI ulcers (HZT-501: 14.0% versus IBU: 34.5%; difference 20.5% [95% CI: 6.5, 34.6]). There were no clinically relevant differences between treatment groups in vital signs, hematology, biochemistry values or physical exams.

**CONCLUSION:** HZT-501 reduces NSAID-associated UGI ulcers overall and in the subset of NSAID users taking LDA. TEAEs were balanced across both treatment groups except dyspepsia which was statistically lower for HZT-501 versus IBU in line with known activity of FAM.

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**90. Risk factors associated with hospital-origin versus community-origin *Clostridium difficile*-associated diarrhea.** Bonnie Dean, Ph.D.<sup>1</sup>, Rebecca S. Campbell, M.D., M.P.H.<sup>1</sup>, Brian H. Nathanson, Ph.D.<sup>2</sup>, Tracy Haidar, M.S.<sup>1</sup>, Marcie E. Strauss, M.P.H.<sup>3</sup>, Sheila

Thomas, Pharm.D.<sup>3</sup>; (1)Cerner LifeSciences Consulting, Culver City, CA; (2)OptiStatim, LLC, Longmeadow, MA; (3)Optimer Pharmaceuticals, Inc., Jersey City, NJ

**PURPOSE:** The incidence of community-origin *Clostridium difficile*-associated diarrhea (CO-CDAD) is increasing. Little is known about how risk factors differ between patients with CO-CDAD versus hospital-origin (HO)-CDAD.

**METHODS:** A retrospective analysis (4/05–6/11) of the *Health Facts*<sup>®</sup> database (Cerner Corp., Kansas City, MO), containing comprehensive clinical records from 186 US hospitals, identified hospitalized patients  $\geq 18$  years with a first positive *C. difficile* toxin collected  $< 48$  hours prior to (CO-CDAD) or  $\geq 48$  hours after (HO-CDAD) admission. A multilevel mixed-effects logistic regression model was constructed; variables that were collected at baseline or soon after admission were considered. Adjusted odds ratios (ORs) predicting HO-CDAD versus CO-CDAD (referent) were reported.

**RESULTS:** A total of 4521 patients with HO-CDAD and 2851 with CO-CDAD met inclusion criteria. HO-CDAD patients were at a greater risk for heart failure (OR: 1.48,  $p < 0.001$ ), diabetes (OR: 1.15,  $p = 0.019$ ), and critical care use within 48 hours of admission (OR: 2.06,  $p < 0.001$ ). In contrast, renal impairment (OR: 0.655,  $p < 0.001$ ) and inflammatory bowel disease (IBD) (OR: 0.445,  $p < 0.001$ ) were each associated with CO-CDAD. Cancer patients were equally as likely to contract HO as CO-CDAD. Age did not differ between groups, but HO-CDAD patients were more likely to be male and of black race. The model had acceptable discriminatory power evidenced by an area under the ROC curve of 0.718; 95% CI (0.706, 0.730).

**CONCLUSION:** CO and HO-CDAD patients present with different comorbidities and demographics. HO-CDAD patients are more likely to have critical care exposure shortly after admission, which may increase their risk of developing CDAD in the hospital. Conversely, patients having underlying conditions such as renal disease and IBD may be at greater risk for hospitalization with CO-CDAD.

## Geriatrics

**91. Opportunities for quality improvement in long term care (LTC): medication related contributors to falls among older residents of a retirement community.** Carlos Rojas-Fernandez, Pharm.D.<sup>1</sup>, Susan G. Brown, M.Sc.<sup>2</sup>, Josie d'Avernas, M.Sc.<sup>2</sup>; (1)University of Waterloo School of Pharmacy/Schlegel-UW Research Institute for Aging, Kitchener, ON, Canada; (2)Schlegel-UW Research Institute for Aging, Kitchener, ON, Canada

**BACKGROUND:** Falls are common in older people. They are potentially preventable and are associated with significant morbidity and mortality. Medications represent modifiable risk factors and opportunity to lower fall risk.

**PURPOSE:** To identify medications that may have contributed to falls among older people who recently fell and investigate facility care processes to identify methods to increase awareness of medications as falls risk factors.

**METHODS:** Incident falls were identified from a registry. Medical and sociodemographic information was collected from medical charts. Male and female residents of two LTC facilities who fell between July 31, 2009 to July 31, 2010, were 65 years of age or older and whose ambulatory status was independent, with cane, or with walker were assessed by the principal investigator.

**RESULTS:** To date, data have been collected for 43 residents. Fifty-eight percentage suffered one fall, 24% two falls, 9% three falls and 9%  $> 4$  falls. Residents received an average of 8.5 medications. Antihypertensives, antidepressants, antipsychotics, hypnotic/sedatives, and antiepileptic drugs were used by 68%, 57%, 38%, 27%, and 19%. Among those who experienced  $> 1$  fall, the five most common medications taken were antidepressants (66%), antihypertensives (61%), acetaminophen (55%), furosemide (44%), and sedative hypnotics (44%). Of the medications that residents were taking which are known to be associated with falls, 55% could have been modified in order to decrease patient's fall risk. Only 44% and 38% of residents were taking vitamin D or

calcium supplements. Awareness of medications as modifiable risk factors by health providers appears inadequate, and care processes do not appear to be aligned for optimal fall risk reduction with regards to medications.

**CONCLUSIONS:** Medication contributors to falls are common in this population. Various opportunities exist to improve care processes to decrease fall risk. Work is ongoing to develop sustainable methods to heighten awareness of medication's role in falls.

**92. Psychotropic use monitoring for nursing home residents with dementia.** Kai Zhen Yap, B.Sc.(Pharm.)(Hons.)<sup>1</sup>, Joyce Y. Lee, Pharm.D.<sup>1</sup>, Ee Heok Kua, MBBS, M.D., FRCPsych, PBM<sup>2</sup>, Sui Yung Chan, B.Sc.(Pharm.)(Hons.), M.B.A., Ph.D.<sup>1</sup>; (1)National University of Singapore, Singapore, Singapore; (2)National University Health System, Singapore, Singapore

**PURPOSE:** Behavioral and psychological symptoms of dementia (BPSD) contribute significantly to disability, patient distress, and caregiver burden. In the nursing home setting, the use of psychotropic agents to manage BPSD depends heavily on nurses' observational feedback. Therefore, objective monitoring of BPSD and the associated adverse effects of psychotropic use is pivotal to ensure appropriate use of these agents. For this purpose, a Psychotropic Use Monitoring (PUM) form was developed by a multi-disciplinary team consisting of geriatricians, psychiatrists, nursing officers and clinical pharmacists. The aim of this study was to evaluate the outcomes from the implementation of PUM in a Volunteer Welfare Organization-run nursing home (NH).

**METHODS:** PUM consists of two assessments: (i) symptoms and severity of BPSD and (ii) adverse effects of psychotropics. In addition to usual care, PUM was implemented and carried out over 24 weeks among the nursing staff in the dementia ward of the participating NH. Training on PUM was provided by a clinical pharmacist. Data pertinent to the use of psychotropics before and after the implementation, particularly antipsychotics, from all residents in the ward were evaluated. Feedback on PUM was also sought from each nursing staff through face-to-face interviews.

**RESULTS:** After implementing PUM, there was a 3 mg decrease in the average daily chlorpromazine equivalent doses used among residents; and a 38% increase in the total number of antipsychotic dose adjustments made by the visiting psychiatrist. There was also a 50% reduction in the number of adverse incidents, such as falls and non-fall related injuries, reported in the dementia ward. Furthermore, the nursing staff indicated feeling more confident and less stressed when caring for the residents.

**CONCLUSION:** From the preliminary results, PUM improved the use of antipsychotics to manage BPSD in the nursing home, and reduced the prevalence of adverse incidents reported.

**93. Results of a pharmacist-managed anticoagulation service at a long-term care facility.** Haley M. Phillippe, Pharm.D.; Harrison School of Pharmacy, Brownsboro, AL

**PURPOSE:** To compare warfarin therapy managed by physicians to a pharmacist-managed anticoagulation service in a long-term care facility (LTCF). The impact of oral anticoagulation monitoring by pharmacists in a LTCF has not been studied.

**METHODS:** Patients receiving warfarin at a LTCF were identified. INRs were monitored and warfarin dosages were adjusted at the discretion of the pharmacist. After 4 years, a retrospective chart review was conducted. Patients were included if they were anticoagulated for a minimum of 1 month and had at least two INR values. Information on demographics, indication for and length of warfarin therapy, INR values, time in therapeutic range, drug interactions, and thromboembolic and bleeding events were recorded.

**RESULTS:** A total of 316 patients met our inclusion criteria. The post-pharmacist TTR was 64% compared to 29% before intervention. The extended TTR (goal INR  $\pm 0.2$ ) was 76% post-pharmacist intervention and 43% prior to the intervention. Before pharmacist intervention 47% of INRs were  $< 2$  and 2%

were >4, compared to 24% of INRs <2 and 1% >4 following intervention. No adverse events were reported.

**CONCLUSION:** Although there were limitations to this retrospective analysis, the results of this study demonstrate that a clinical pharmacist does improve the management of anticoagulation therapy by increasing the TTR and decreasing supra and subtherapeutic INRs. The clinical pharmacist provides a consistent approach to anticoagulation management, and is an asset that should be utilized in caring for patients in LTCF.

## Health Services Research

**94. Does a pharmacist care management program improve hypertension outcomes in Veterans?** Alan J. Zillich, Pharm.D.<sup>1</sup>, Heather A. Jaynes, RN, MSN<sup>1</sup>, Susan D. Bex, Pharm.D., BCPS<sup>2</sup>, Amy S. Boldt, Pharm.D.<sup>2</sup>, Darin C. Ramsey, Pharm.D.<sup>2</sup>, Cassandra M. Walston, Pharm.D.<sup>2</sup>, Dawn M. Bravata, M.D.<sup>2</sup>; (1)Purdue University College of Pharmacy, Indianapolis, IN; (2)Richard L. Roudebush VA Medical Center, Indianapolis, IN

**PURPOSE:** To evaluate a care management program for Veterans with hypertension (HTN) provided by clinical pharmacists.

**METHODS:** Using a retrospective case-control design, cases included all HTN patients referred to the care management program while controls included HTN patients who were not referred to the program during the same 1-year period. Each case was matched to a maximum of three controls on: primary care physician, age  $\pm$  5 years, diagnoses of diabetes and kidney disease, baseline systolic blood pressure (SBP)  $\pm$ 10 mmHg, and number of unique BP medications. Primary outcomes were SBP and diastolic blood pressure (DBP) at 6-, 9-, and 12-months follow-up from baseline. Multivariate regression models compared each BP endpoint between the cases and controls adjusting for age, comorbidities, baseline BP and baseline number of BP medications. Similar logistic regression models evaluated national guideline-defined BP control.

**RESULTS:** Three to one matching was achieved in 77.4%(418/540) of cases; 85%(460/540) of cases had at least one matched control. Cases and controls did not differ with respect to age, gender, or co-morbidity; baseline BP was higher (139.6/80.0 versus 136.7/78.2 mmHg) and BP control lower (35% versus 49%) in the cases compared to controls. Among cases (n=460), BP decreased from baseline by  $-5.3/-2.4$ ,  $-7.7/-3.2$ , and  $-6.6/-3.0$  mmHg at 6-, 9-, and 12-months; BP decreased among controls (n=1264) by  $-2.0/-1.0$ ,  $-1.9/-0.9$ , and  $-3.4/-1.6$  mmHg at 6-, 9-, and 12-months. Multivariate regression modeling results identified significantly lower SBP for the cases compared with controls at all time points; but for DBP, only the 9-month follow-up was significantly lower. BP control was better among cases than controls at 6-(56% versus 55%; OR = 1.8; CI: 1.3-2.4; p<0.001) and 9-months (65% versus 54%; OR = 2.3; CI: 1.7-3.0; p<0.001) but not at 12-months (57% versus 60%; OR = 1.3; CI: 0.95-1.7; p=0.11).

**CONCLUSION:** Patients referred to the pharmacist hypertension care management program had a significant improvement in most BP outcomes. This program may be an effective method of improving BP control among Veterans.

**95. Effectiveness of a pharmacy care management program for veterans with dyslipidemia.** Michael C. Smith, Pharm.D.<sup>1</sup>, Amy S. Boldt, Pharm.D.<sup>1</sup>, Cassandra M. Walston, Pharm.D.<sup>1</sup>, Alan J. Zillich, Pharm.D.<sup>2</sup>; (1)Richard L. Roudebush VA Medical Center, Indianapolis, IN; (2)Purdue University College of Pharmacy, Indianapolis, IN

**PURPOSE:** To evaluate the effectiveness of a dyslipidemia care management program provided by clinical pharmacists.

**METHODS:** A retrospective cohort design compared an intervention (IT) cohort of 213 patients referred to a clinical pharmacist for dyslipidemia management with 219 patients in a usual care (UC) cohort within two primary care clinics at a Veterans Affairs Medical Center. Using multivariate regression models to adjust for baseline characteristics, the primary analyses compared low-density lipoprotein cholesterol (LDL), total cholesterol (TC),

high-density lipoprotein cholesterol (HDL), and triglycerides (TGs) among the IT and UC cohorts at the final follow-up visits. Secondary analyses compared the change in TC, LDL, HDL and TGs, the proportion of patients achieving guideline concordant LDL goals, and the time to achieve LDL goals between the two groups.

**RESULTS:** The mean change in initial to final lipid values in the IT cohort was LDL:  $-31$  mg/dl, TC:  $-44$  mg/dl, HDL:  $-1$  mg/dl, TGs:  $-59$  mg/dl versus the UC cohort LDL:  $-22$  mg/dl, TC:  $-29$  mg/dl, HDL:  $0$  mg/dl, TGs:  $-43$  mg/dl. Compared to the UC cohort, the adjusted difference in LDL for the IT cohort was  $-10.4$  mg/dl (95% CI,  $-16.1$  to  $-4.6$ , p<0.001) mg/dl and TC was  $-12.7$  (95% CI,  $-21.3$  to  $-4.1$ , p=0.004). There was no difference in HDL and TGs. LDL was controlled in 80.3% of patients in the IT cohort and 65.3% of patients in the UC cohort (adjusted OR, 2.6; 95% CI, 1.6-4.3, p<0.001). Mean days to achieve goal LDL was  $86.6 \pm 59.3$  and  $332.2 \pm 241.0$  (p<0.001) for the IT and UC cohorts, respectively.

**CONCLUSION:** Veteran patients referred to a clinical pharmacist achieved significant reductions in TC and LDL. The time to achieve and the proportion of patients achieving target LDL goals were better in the pharmacist-managed cohort, supporting a continued role for pharmacy in dyslipidemia care management.

**96. Self-control by patients of the medication list compared to medication verification with pharmacist.** Anders Ekedahl, Ph.D.; Medical Products Agency, Uppsala, Sweden

**PURPOSE:** To investigate the effect of patients receiving the Medication List (ML) in the Electronic Medical Record before a scheduled visit to the physician with a call to control the ML and bring it to the visit compared to medication verification with a trained pharmacy student immediately before the visit.

**METHODS:** Patients with five or more prescribed current medications scheduled to visit a physician at four Health Care Centres in the Kalmar County were invited to participate, and were assigned to (i) self-control (SC) – to check the ML at home and bring the ML to the physician; or (ii) a medication verification (MV) with a pharmacy student immediately before the visit. All patients were interviewed immediately after the visit to the physician.

**RESULTS:** A total of 148 patients (90 women) with in total 1039 prescriptions in the ML were included – 93 SC-patients and 55 MV-patients. Before the visit, 73% of patients in both groups had at least one discrepancy in the ML, in total 162/1039 discrepancies (15.6%) in the ML in the SC-group compared with 95/539 (17.6%) discrepancies in the MV-group. After the visit, 60/93 (65%) patients in the SC-group had a ML without discrepancies compared with 40/55 (73%) patients without discrepancies in the MV-group (p=0.086; not significant). The total numbers of discrepancies were 63/975 (6.5%) in the SC-group compared with 26/500 (5.2%) in the MV-group (p=0.30; not significant).

**CONCLUSION:** Self-control of the medication list is a mean to empower the patient to participate in the treatment. Our study showed that self-control by patients of the medication list before a scheduled visit to the physician decreases the numbers of discrepancies and give similar outcome to medication verification with trained pharmacy students. There are virtually no costs to implement the results into daily praxis.

**97E. Characterizing financial burden of pulmonary hypertension within an integrated healthcare delivery system.** Samuel G. Johnson, Pharm.D., BCPS, (AQ, Card), Adrian Larkin, Pharm.D., Paul B. Shaw, Pharm.D., BCPS, Thomas Delate, Ph.D.; Kaiser Permanente, Aurora, CO

**PURPOSE:** The financial burden associated with providing healthcare to patients with pulmonary hypertension (PH) is not well characterized. We sought to quantify 3-year healthcare expenditures and determine whether expenditures differed between incident and prevalent PH cases.

**METHODS:** This was a retrospective cohort study involving Kaiser Permanente Colorado (KPCO) patients with a confirmed

diagnosis of PH. Included patients were followed from study entry until 3 years, death or termination of KPCO membership. All expenditures were reported in 2011 US dollars from KPCO perspective.

**RESULTS:** In total, 157 patients were included: 44 (28%) prevalent and 113 (78%) incident cases. Mean age (prevalent versus incident cases) was 61 versus 67 years and 13.6% versus 27.4% were men. Mortality was equivalent between prevalent and incident cases (34.1% versus 25.7%;  $p=0.291$ ). Significant differences between prevalent and incident cases were noted for median total emergency department (ED) expenditures (\$357 versus \$1250;  $p=0.009$ ) and median total inpatient expenditures (\$980 versus \$7313;  $p=0.028$ ). Median daily expenditures (\$54 versus \$56;  $p=0.284$ ), median total expenditures (\$37,340 versus \$55,073;  $p=0.284$ ), median pharmacy daily expenditures (\$4 versus \$5;  $p=0.867$ ), median PH specialty medication daily expenditures (\$226 versus \$223 among specialty medication users only;  $p=0.574$ ), and mean days of follow-up (843 versus 975 days;  $p=0.331$ ) were equivalent between prevalent and incident cases.

**CONCLUSION:** Healthcare expenditures related to the management of PH represent a substantial financial burden. Significant differences according to prevalent or incident case status appeared to be driven by median ED and inpatient costs; however, PH specialty medication expenditures (for those patients receiving them) represented a significant driver of costs overall. Future efforts should focus on optimizing care for patients with PH to avoid unnecessary harm or waste.

Presented at the Western States Residency Conference, Monterey, CA, May 22–25, 2012

## Hematology/Anticoagulation

**98. Quality and outcomes assessment of intravenous unfractionated heparin anticoagulation in venous thromboembolism.** *Christine P. Rash, Pharm.D.<sup>1</sup>, Ruchi Patel, Pharm.D., BCPS<sup>1</sup>, Keri Bicking, Pharm.D., BCPS, BCNSP<sup>1</sup>, Luigi Brunetti, Pharm.D., BCPS, M.P.H., CGP<sup>2</sup>, Brian Faley, Pharm.D., BCPS<sup>2</sup>, Zachariah Thomas, Pharm.D., BCPS<sup>2</sup>, Massimo Napolitano, MD<sup>1</sup>;* (1)Hackensack University Medical Center, Hackensack, NJ; (2)Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey, Piscataway, NJ

**PURPOSE:** Achieving a therapeutic activated partial thromboplastin time (aPTT) within 24 hours of intravenous unfractionated heparin (IV UH) initiation has shown a reduction in recurrence and mortality in venous thromboembolism. This study evaluated IV UH administered according to an institution-specific thromboembolic nomogram to: (i) assess the percentage of patients achieving a therapeutic aPTT within 24 and 48 hours and (ii) evaluate compliance and safety.

**METHODS:** A retrospective analysis of 300 adult patients treated with IV UH for at least 24 hours was conducted. Data abstracted from the medical record included patient demographics, IV UH dosing information and laboratory data.

**RESULTS:** A therapeutic aPTT ( $\geq 60$  seconds) was achieved in 97.3% and 98.7% of all patients within 24 and 48 hours, respectively. Use of initial bolus, increasing BMI and/or increasing body weight did not impact the percentage of patients achieving therapeutic aPTT. Eighty-one percent of patients receiving the nomogram recommended initial bolus had suprathreshold aPTTs ( $>85$  seconds) upon first draw versus 43% of patients not receiving an initial bolus. Fifty-one percent of suprathreshold aPTTs on first draw were above the upper limit of laboratory detection ( $>180$  seconds). Full compliance to the nomogram was observed in 21% of patients. Major bleeding occurred in 26.3% of patients.

**CONCLUSION:** The institution-specific IV UH nomogram is successful in rapidly achieving a therapeutic aPTT within 24 and 48 hours irrespective of BMI, weight, or bolus administration. The high rate of suprathreshold initial aPTTs observed in this study calls into question the appropriateness of the recommended initial bolus, as the majority of patients achieved the primary endpoint regardless of bolus administration. Though observed rates

of major bleeding were consistent with previous studies, future studies are needed to characterize the relationship between aPTT and bleeding risk and to further explore heparin dosing options that optimally balance efficacy and safety.

**99. Impact of platelet functional assays on the cost of treating suspected heparin induced thrombocytopenia (HIT).** *Ziad Sadik, Pharm.D., Douglas L. Jennings, Pharm.D., BCPS, (AQ-CV), Carrie W. Nemerovski, Pharm.D., BCPS, (AQ-CV), James S. Kalus, Pharm.D., BCPS, (AQ-CV); Henry Ford Hospital, Detroit, MI*

**PURPOSE:** To determine the costs associated with the treatment of suspected HIT and to investigate the potential cost savings of functional platelet assays like the serotonin release assay (SRA) in the diagnosis of this condition.

**METHODS:** We performed a retrospective cost of illness analysis of suspected HIT, which was defined as thrombocytopenia leading to heparin discontinuation, positive screen for heparin/platelet-factor 4 antibodies and treatment with a direct thrombin inhibitor (DTI). Direct medical costs were collected, including those associated with diagnostic testing, DTI treatment, and complications (bleeding and thrombosis). Patients with the SRA ordered as part of their diagnostic evaluation were compared to those who did not. The primary clinical endpoint was a composite of mortality and major bleed, defined by the International Society on Thrombosis and Haemostasis criteria.

**RESULTS:** A total of 147 patients were identified ( $61.2 \pm 15.1$  years, 49% female, 54.4% African American, 51.7% thrombosis). An SRA was ordered in 53 patients, of whom only 17% were positive. The average delay in reporting SRA results was 9 days. Overall, the use of the SRA did not reduce the total cost of treatment per patient (\$7954 versus \$7136,  $p=0.331$ ), length of stay (22 versus 22 days,  $p=0.486$ ), or the composite primary clinical endpoint (32.1% versus 33%,  $p=0.911$ ). Early ordering of the SRA (within 48 hours) was associated with shorter length of stay (20 versus 27 days,  $p=0.029$ ) and a trend toward lower DTI duration (7.5 versus 10 days,  $p=0.240$ ) and primary endpoint (20.8% versus 41.4%,  $p=0.442$ ). A negative SRA led to the discontinuation of the DTI in 77.8% of patients, and subsequently 33.3% were discharged within 48 hours.

**CONCLUSION:** The use of the SRA in the diagnosis of suspected HIT did not reduce costs or clinical outcomes in our overall analysis, however earlier availability of this test may impact therapy and reduce costs.

**100. Assessment of warfarin requirements in post-bariatric surgery patients.** *Adriane N. Irwin, M.S., Pharm.D., Kathleen H. McCool, Pharm.D., Thomas Delate, Ph.D., Daniel M. Witt, Pharm.D.; Kaiser Permanente Colorado, Aurora, CO*

**PURPOSE:** To quantify the change in weekly warfarin requirement following bariatric surgery in patients requiring chronic anticoagulation therapy.

**METHODS:** This was a retrospective matched cohort study of patients chronically anticoagulated who underwent surgery between January 1, 1996 and December 31, 2010. Bariatric surgery patients were matched to patients who underwent other abdominal procedures by date of surgery ( $\pm 2$  years), age ( $\pm 5$  years), and target INR range. The primary study endpoint was change in weekly warfarin requirement from baseline assessed post-operatively at weeks 1 through 8 and months 3 and 6.

**RESULTS:** A total of 86 patients were included – 27 (31%) in the bariatric surgery group and 59 (69%) in the control group. The bariatric patients had a statistically significant decrease in weekly warfarin requirement at all time points (week 1,  $p<0.05$ ; all others,  $p<0.001$ ), except 6 months ( $p>0.05$ ). No statistically significant decreases in warfarin requirement were detected at any time in the control group (all  $p>0.05$ ). Twenty patients (74.1%) in the bariatric surgery group experienced a  $\geq 20\%$  decrease in weekly warfarin requirement compared to 19 patients (32.2%,  $p=0.004$ ) in the control group. There were no differences in warfarin-related adverse events between groups ( $p>0.05$ ).

**CONCLUSION:** Weekly warfarin requirement dropped immediately following bariatric surgery, but returned to baseline after approximately 6 months. This pattern was absent in a control group undergoing other types of abdominal surgery. Without vigilant monitoring and warfarin dosing adjustment, anticoagulation control in patients following bariatric surgery is likely to result in over anticoagulation. Future research should attempt to develop and validate a post-bariatric surgery warfarin dosing algorithm.

**101E. Evaluating standardized weight based heparin nomogram versus patient specific dosing to achieve and maintain targeted activated partial thromboplastin time (aPTT) at a quaternary care teaching hospital.** *Leslie Varikattu, Pharm.D., Samrah Ahmad, Pharm.D., Rehana Jamali, Pharm.D.; North Shore University Hospital, Manhasset, NY*

**PURPOSE:** At North Shore University Hospital (NSUH), there are two order forms for intravenous (IV) heparin use; Standardized weight based dosing nomograms with preselected aPTT targets, doses are initiated by prescribers based on indication and may be titrated by nurses. Patient specific order form is also an option, allowing the prescriber to select aPTT targets and initial dosing; dosing titrations are made at the discretion of the physician. Primary objective was to compare these two methods of ordering heparin infusion to see which was able to achieve targeted activated partial thromboplastin time (aPTT) faster and maintain within therapeutic range longer. Secondary objectives include number of sub therapeutic and supra therapeutic aPTT levels.

**METHODS:** This was a retrospective chart review. Study population included, patients received IV continuous infusion of heparin at NSUH on or after June 1st 2011 based on either the weight based nomogram or patient specific dosing form. The first 54 patients that meet the eligibility criteria were selected. For both groups, appropriateness of aPTT monitoring, time to first therapeutic aPTT, as well as the number of sub and supra aPTT levels in each group, and time within target aPTT range was evaluated.

**RESULTS:** Time to first therapeutic aPTT was found to be not statistically significant between the two groups ( $p < 0.0502$ ). Time within therapeutic range was found to have statistical significance favoring the nomogram driven group ( $p < 0.0021$ ). Sub and supra therapeutic aPTT levels between groups were found to be not statistically significant ( $p < 0.0519$ ).

**CONCLUSION:** Patient care can be optimized by efficiently using the nomogram driven heparin dosing to maintain therapeutic aPTT levels for longer. Standardization of dosing for this high risk medication may also be explored.

Presented at Eastern States Conference, Hershey, PA, May 2-4, 2012

**102. Adverse events in patients initiated on dabigatran etexilate therapy in a pharmacist-managed anticoagulation clinic.** *Mark Donaldson, BSP, PHARM.D., FASHP, FACHE, Amber Norbeck, PHARM.D.; Kalispell Regional Medical Center, Kalispell, MT*

**PURPOSE:** Warfarin has been the treatment of choice in preventing thromboembolic events, but problems such as the need for frequent dose adjustment and monitoring of coagulation status, including multiple drug and food interactions, make its use challenging. Dabigatran etexilate is a new oral direct thrombin inhibitor, given in fixed doses not requiring routine coagulation monitoring. This study documented adverse drug events (ADEs) recorded in patients started on dabigatran etexilate therapy, including those who were previously controlled on warfarin and those who were anticoagulant naïve.

**METHODS:** A total of 222 patients were initiated on dabigatran etexilate therapy between October 15, 2010 and April 1, 2012. Forty-three percent of these patients were previously stable on warfarin therapy while 57% of these patients were anticoagulant naïve.

**RESULTS:** Fifty-four of these 222 patients (24.3%) developed an ADE while on dabigatran etexilate. The average time to event after the start of dabigatran treatment was 48.4 days (range 1-

344). Twenty-four out of the 54 patients (44.4%) experienced a major ADE requiring a hospital visit and four of these patients died; one death was directly related to dabigatran etexilate therapy. The remaining 30 patients (55.6%) experienced a clinically relevant non-major ADE. Of the 54 patients, 31 were male. The average age of the patients was 73.7 years (range 54-89) and the average patient weight was 93.2 kg (range 46.8-159.1 kg). Fifty-seven percent of those who experienced an ADE were previously controlled on warfarin therapy.

**CONCLUSIONS:** While many clinicians have been interested in utilizing the new direct thrombin inhibitor dabigatran etexilate, this new therapy is not without risks. This study documented adverse events (ADEs) recorded in 54 patients out of a total of 222 patients (24.3%) who were initiated on dabigatran etexilate therapy over an 18 month period. ADEs were most common in patients who were previously controlled on warfarin therapy.

**103. Effect of patient self-testing on chronic anticoagulation.** *Cindy Leslie A. Arocena, Pharm.D., Stacey Dean, Pharm.D., BCPS; Virginia Commonwealth University Health System, Richmond, VA*

**PURPOSE:** The primary aim of this quality improvement project is to evaluate the safety of patient self-testing (PST), with a home INR monitor, and to determine patients' satisfaction of their anticoagulation management. Based on the results of this evaluation, a protocol may be developed that will allow for identification of patients who qualify for at Virginia Commonwealth University Health System (VCUHS).

**METHODS:** This evaluation is a retrospective, electronic medical record review that includes patients enrolled in the anticoagulation clinic at VCUHS from 2008 through 2011. Subjects for this quality improvement project are patient's  $\geq 18$  years of age who were managed in the anticoagulation clinic for at least 3 months prior to being transitioned to PST. The primary outcome, or the time in therapeutic range pre- and post-transition, was compared. Secondary outcomes included the percent of time spent in therapeutic range (TTR), number of INR readings, and incidence of undercoagulation and overanticoagulation. In addition, a patient satisfaction survey, using the validated Duke Anticoagulation Satisfaction Scale (DASS), was mailed to the patients.

**RESULTS:** Medical records of 104 patients, initially managed in the anticoagulation clinic and then transitioned to PST, were identified and reviewed. Eighty patients were included in the study analysis, and 45 returned the survey questionnaire. The percent TTR of INR values obtained during PST was significantly higher than the clinic management phase, 66% versus 51%, respectively ( $p < 0.0001$ ). INR values obtained during the PST phase had a higher rate of percent under-anticoagulation compared to during the clinic phase (35% versus 23%,  $p < 0.0001$ ). No other statistically significant difference was found for any other secondary outcomes.

**CONCLUSION:** Our study demonstrated that INR values using a PST device can be a safe and efficacious alternative to anticoagulation management done in the physician or specialty anticoagulation clinics.

## HIV/AIDS

**104E. Pharmacokinetics, safety, and antiviral activity of fosamprenavir-containing twice-daily regimens in HIV-infected children 2-18 years old: report from APV29005, a 48-week prospective, open-label, multicenter cohort study.** Evgeny E. Voronin, M.D., Ph.D.<sup>1</sup>, Claudia Fortuny, M.D., Ph.D.<sup>2</sup>, Desamparados Pérez-Tamarit, M.D.<sup>3</sup>, Dan Duiculescu, M.D., Ph.D.<sup>4</sup>, Mark F. Cotton, M.D., Ph.D.<sup>5</sup>, Lisa L. Ross, M.S.<sup>6</sup>, Susan L. Ford, Pharm.D.<sup>6</sup>, Yu Lou, M.S.<sup>6</sup>, Naomi Givens, M.S.<sup>7</sup>, Katharine Cheng, M.D.<sup>7</sup>, Jörg Sievers, D.Phil.<sup>7</sup>, Gary E. Pakes, Pharm.D.<sup>6</sup>; (1) Republic Hospital of Infectious Disease, St. Petersburg, Russia; (2) Sant Joan de Déu Hospital, Barcelona, Spain; (3) Hospital Infantil La Fe, Valencia, Spain; (4) "Dr. Victor Babes" Hospital for Infectious and Tropical Diseases, Bucharest,

Romania; (5) Tygerberg Children's Hospital, Tygerberg, South Africa; (6) GlaxoSmithKline, Research Triangle Park, NC; (7) GlaxoSmithKline, Uxbridge, United Kingdom

**PURPOSE:** Amprenavir (APV) pharmacokinetics, safety and antiviral activity with unboosted fosamprenavir (FPV) and ritonavir (RTV)-boosted FPV BID were evaluated in protease inhibitor (PI)-naïve and -experienced HIV-1-infected children aged 2–18 years.

**METHODS:** Intensive pharmacokinetic sampling performed at Wk2, pre-dose samples were collected every 4–12 weeks. Safety and plasma HIV-1 RNA were monitored every 4–12 weeks.

**RESULTS:** A total of 109 HIV-1-infected children (2–5 years [n=39], 6–11 years [n=30], 12–18 years [n=40]) received  $\geq 1$  dose of FPV ( $\pm$ RTV), 88% exposed >48 weeks. Twenty PI-naïve children 2–5 years received FPV BID and 89 received FPV/RTV BID. In children aged 2–5 years administered FPV 30 mg/kg BID (n=9), geometric mean (GM;95%CI) plasma APV AUC (0–t) was 22.3 (15.3, 32.6) hour  $\mu$ g/ml,  $C_{max}$  7.15 (5.05, 10.1)  $\mu$ g/mL,  $C_t$  0.552 (0.406, 0.750)  $\mu$ g/mL (n=19), and CL/F 19.3 (13.2, 28.2) ml/minute/kg. These values were 1.27-, 1.41-, 1.90-, and 1.23-fold higher than respective historical values reported in adults administered FPV 1400 mg BID (n=189). Pharmacokinetic findings with the FPV/RTV regimen are shown in the table.

APV Parameter	FPV/RTV BID*		
	2–5 years 23/3 mg/kg BID, N=14	6–11 years 18/3 mg/kg BID, N=12	12–18 years 700/100 mg BID, N=13
AUC (0– $\tau$ ), hour $\mu$ g/ml	55.3 (37.9, 80.7)	48.4 (38.1, 61.4)	35.3 (28.2, 44.1)
$C_{max}$ , $\mu$ g/ml	8.66 (6.08, 12.3)	6.40 (5.02, 8.15)	4.93 (3.83, 6.34)
$C_t$ , $\mu$ g/ml	3.39 (2.51, 4.57) (n=16)	2.42 (1.90, 3.07) (n=23)	2.01 (1.74, 2.32) (n=40)
CL/F, ml/minute/kg	6.06 (4.12, 8.91)	5.27 (4.16, 6.68)	5.33 (4.23, 6.68)

\*GM (95% CI); PK values were within 0.876–1.72-fold range of historical values in adults treated with FPV/RTV 700/100 mg BID.

At Week 48, 60% (12/20) of the PI-naïve children on FPV and 73% (36/49) on FPV/RTV achieved HIV-1 RNA <400 c/ml, versus 48% (19/40) of PI-experienced children on FPV/RTV (intent-to-treat-exposed, snapshot analysis). Median CD4+ cell percentages increased 6–10% by Wk 48. Twenty-five children experienced analysis plan-defined virologic failure. Drug-related Gr2-4 AEs occurred in 12/109 (11%), including vomiting (3/109, 3%), diarrhea and AST increases (each 2/109, 2%). Eighteen children experienced serious AEs, nine with suspected abacavir hypersensitivity.

**CONCLUSION:** FPV-containing regimens provided APV exposures in 2-to-18-year-old children comparable to exposures reported with FPV regimens approved in adults. The safety profile was also similar. Virologic suppression was maintained over 48 weeks.

Presented at The XIX International AIDS Conference, Washington, DC, July 22–27, 2012

**105E. Steady-state pharmacokinetics and 48-week safety and antiviral activity of fosamprenavir/ritonavir twice-daily regimens in HIV-infected children 4 weeks to <2 years old: results of APV20002, a prospective, open-label, multicenter cohort study.** Mark F. Cotton, M.D., Ph.D.<sup>1</sup>, Haseena Cassim, MBCh<sup>2</sup>, Noris Pavia-Ruz, M.D.<sup>3</sup>, Lisa L. Ross, M.S.<sup>4</sup>, Susan L. Ford, Pharm.D.<sup>4</sup>, Yu Lou, M.S.<sup>4</sup>, Naomi Givens, M.S.<sup>5</sup>, Katharine Cheng, M.D.<sup>5</sup>, Jörg Sievers, D.Phil.<sup>5</sup>, Gary E. Pakes, Pharm.D.<sup>4</sup>; (1) Tygerberg Children's Hospital, Tygerberg, South Africa; (2) Perinatal HIV Research Unit, Johannesburg, South Africa; (3) Universidad Nacional Autonoma de Mexico, Facultad de Medicina, Mexico, DF, Mexico; (4) GlaxoSmithKline, Research Triangle Park, NC; (5) GlaxoSmithKline, Uxbridge, United Kingdom

**PURPOSE:** Pharmacokinetics, safety and antiviral activity of fosamprenavir/ritonavir (FPV/RTV) twice daily (BID) were evaluated in protease inhibitor (PI)-naïve and -experienced HIV-1-infected children aged 6 months to <2 years (Cohort-1) and

4 weeks to <6 months (Cohort-2) primarily from South Africa and Mexico.

**METHODS:** Intensive pharmacokinetic sampling was performed at Week 2 or 8; pre-dose samples were collected every 4–12 weeks. Safety and plasma HIV-1 RNA were monitored every 4–12 weeks.

**RESULTS:** Fifty-nine HIV-1-infected children received  $\geq 1$  dose of FPV/RTV; 54 were included in the intent-to-treat-exposed (ITT [E]) population (28 in Cohort-1, 26 in Cohort-2). Median FPV exposure was 640 days (range 8–1093 days), with 78% exposed >48 weeks. Plasma APV PK parameters, as geometric means (GM) with 95% confidence intervals and ratios of GM pediatric means to historical adult values (HAV), are shown in the table.

APV PK parameter	HAV 700/100 mg BID, N=159	6 months to <2 years (Cohort-1)/fraction of HAV	4 weeks-<6 months (Cohort-2)/fraction of HAV
		45/7 mg/kg BID, N=10	45/10 mg/kg BID, N=9
AUC (0– $\tau$ ) (h. $\mu$ g/mL)	37.0 (35.1, 38.9)	27.5 (14.5, 52.1)/0.744	26.6 (15.2, 46.8)/0.720
$C_{max}$ ( $\mu$ g/mL)	5.62 (5.35, 5.92)	5.84 (3.35, 10.2)/1.04	6.25 (3.82, 10.2)/1.11
$C_t$ ( $\mu$ g/mL)	2.17 (2.05, 2.30) (n=158)	2.17 (1.69, 2.80) (n=29)/1.00	0.860 (0.500, 1.48) (n=11)/0.397
CL/F (mL/min/kg)	3.52 (3.33, 3.71) (n=157)	22.8 (12.0, 43.1)/6.47	22.9 (12.9, 40.6)/6.51

At Week 48, 64% (18/28) of Cohort-1 and 58% (15/26) of Cohort-2 achieved HIV-1 RNA <50 copies/ml (ITT[E], Snapshot analysis). Nine children experienced analysis plan defined virologic failure. Median increase from baseline in CD4+ cell percentages at Week 48 was 5% in both cohorts. Drug-related Gr2-4 AEs occurred in 12/59 (20%) children; the most frequent were increased cholesterol (5/59, 8%) and gastroenteritis (2/59, 3%). Twenty-two children experienced serious AEs (SAEs), of which three were considered drug-related. Three children died following SAEs.

**CONCLUSION:** FPV/RTV dosing regimens provided plasma APV exposures in Cohort-1 comparable to those reported in FPV/RTV-treated adults. APV  $C_t$  was lower in Cohort-2 but clinical outcomes were comparable. The overall safety profile in children aged <2 years was similar to that observed in older children and adults.

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**106E. Prevalence of HIV-associated neurocognitive disorders (HAND) in virologically suppressed HIV-infected individuals in the ASSURE (EPZ113734) study versus non-HIV-infected control subjects.** David A. Wohl, M.D.<sup>1</sup>, Laveeza Bhatti, M.D., Ph.D.<sup>2</sup>, Paul Maruff, Ph.D.<sup>3</sup>, Kevin R. Robertson, Ph.D.<sup>4</sup>, Catherine B. Small, M.D.<sup>5</sup>, Howard E. Edelstein, M.D.<sup>6</sup>, Henry Zhao, Ph.D.<sup>7</sup>, David A. Margolis, M.D.<sup>7</sup>, Lisa L. Ross, M.S.<sup>7</sup>, Mark S. Shaefer, Pharm.D.<sup>8</sup>, Gary E. Pakes, Pharm.D.<sup>7</sup>; (1) Division of Infectious Disease, University of NC at Chapel Hill School of Medicine, Chapel Hill, NC; (2) AIDS Healthcare Foundation, Beverly Hills, CA; (3) CogState Ltd., Melbourne, Vic., Australia; (4) University of NC at Chapel Hill, AIDS Dementia Center, Chapel Hill, NC; (5) New York Medical College, Valhalla, NY; (6) Alameda County Medical Center, Oakland, CA; (7) GlaxoSmithKline, Research Triangle Park, NC; (8) ViiV Healthcare, Research Triangle Park, NC

**PURPOSE:** Cognitive impairment prevalence and potential predictive variables in HIV-infected subjects were examined; cognitive impairment prevalence was compared to uninfected controls.

**METHODS:** HIV-infected, ART-experienced subjects stably suppressed (HIV-1 RNA <75 c/ml) with  $\geq 6$  months' tenofovir/emtricitabine/atazanavir/ritonavir treatment had neurocognitive evaluations prior to clinical study randomization for ASSURE. Z

scores were obtained for four Cogstate tasks. Poor cognition = 2 of 4 component z scores  $\leq -1$  or composite score  $\leq -2$ . Forty-three baseline variables underwent univariate and multivariate analyses to identify those associated with poor cognition. Using logistic regression and analysis of variance, results were compared to data from 700 uninfected controls (data supplied by Cogstate).

**RESULTS:** A total of 293 HIV-infected subjects were evaluated. Baseline characteristics: median age 43 years (range: 21–68); 79% male; African-American/White/Other race 34%/60%/5%; Hispanic/Latina ethnicity 26%; CDC Class C 18%; median CD4 count: 492 cells/mm<sup>3</sup>; median CD4 nadir: 265 cells/mm<sup>3</sup>; median days prior antiretroviral therapy: 1000. Control group (n=700); median age: 44 years (range: 15–79); 50% male. Poor cognition was observed in 56% (164/293) of HIV-infected subjects compared to 17% (117/700) of uninfected controls (odds-ratio: 6.33 increase in risk for HIV-infected subjects). Significant differences were observed between HIV-infected subjects and uninfected controls ( $p < 0.0001$ ) and when adjusting for age ( $p < 0.001$ ) for each test component. Poor cognition was associated with increasing age for both HIV-infected subjects and uninfected controls. In HIV-infected subjects, significant associations ( $p < 0.05$ ) were observed by univariate analysis between composite score and race, gender, ethnicity and homosexual contact, but not CD4 cell count or CD4 nadir. Multivariate analysis confirmed significant associations ( $p < 0.05$ ) between poor cognition and Hispanic/Latina ethnicity and between poor cognition and African-American race.

**CONCLUSION:** The HIV-infected ASSURE population had a 3-fold higher prevalence of greater cognitive impairment compared with non-HIV-infected controls (56% versus 17%) and a sixfold higher odds ratio for developing cognitive impairment. By multivariate analyses, Hispanic/Latina ethnicity and African-American race were associated with poorer cognition.

Presented at The XIX International AIDS Conference, Washington, DC, July 22–27, 2012

**107E. HIV-1 drug resistance and mutational profile in fosamprenavir-treated HIV-infected children aged 2 months to 18 years at start of therapy.** Lisa L. Ross, M.S.<sup>1</sup>, Mark F. Cotton, M.D., Ph.D.<sup>2</sup>, Haseena Cassim, MBCh<sup>3</sup>, Evgeny E. Voronin, M.D., Ph.D.<sup>4</sup>, Naomi Givens, M.S.<sup>5</sup>, Jörg Sievers, D.Phil.<sup>5</sup>, Katharine Cheng, M.D.<sup>5</sup>, Gary E. Pakes, Pharm.D.<sup>1</sup>; (1) GlaxoSmithKline, Research Triangle Park, NC; (2) Tygerberg Children's Hospital, Tygerberg, South Africa; (3) Perinatal HIV Research Unit, Johannesburg, South Africa; (4) Republic Hospital of Infectious Disease, St. Petersburg, Russia; (5) GlaxoSmithKline, Uxbridge, United Kingdom

**PURPOSE:** The treatment-emergent HIV resistance profiles were examined for children receiving fosamprenavir (FPV)-containing regimens in Studies APV20002 (age range: 2 months to 2 years) and APV29005 (age range: 2–18 years) over 48 weeks.

**METHODS:** HIV from antiretroviral therapy (ART)-naïve and ART-experienced (ART-e) study subjects who met virologic failure (VF) criteria by either failing to suppress (HIV-1 RNA  $< 400$  copies/ml) through Wk24 or experienced confirmed rebound to  $> 400$  copies/ml through Wk 48 were analyzed for treatment-emergent mutations (TEMs) or reduced drug susceptibility (RS).

**RESULTS:** Through Week 48, 25/109 (23%) APV29005 subjects and 9/54 (17%) APV20002 subjects met VF criteria (overall VF rate, 21%). Most of these subjects (17/25 and 7/9, respectively) were ART-e. Paired HIV-1 baseline and VF results were obtained for 22 subjects (15/25 APV29005 and 7/9 APV20002), 19 of whom received FPV/ritonavir (RTV)-containing ART and three unboosted FPV. TEMs were detected in virus from 7/15 (APV29005) and 3/7 (APV20002) subjects. Major protease inhibitor (PI) TEMs at VF included mutations or mutation mixtures at codons M46, I50, I54, Q58, V82 and I84. Virus from five subjects selected the NRTI mutation M184V at VF; virus from two subjects selected minor NNRTI mutations. HIV from nine subjects (7/15 [47%] in APV29005 and 2/7 [29%] in APV20002) developed RS to any antiretroviral drug at VF. Of these, 4/9 subjects were ART-naïve. Three (of 4) ART-naïve subjects with any RS

received unboosted FPV; all developed NRTI RS, and 2 (of 3) also developed FPV RS.

**CONCLUSION:** The overall VF rate through 48 weeks was relatively low (21%), given the high proportion of ART-e children. For subjects meeting VF criteria, most of whom were previously ART-e, 45% had virus with TEMs (although some were minor PI or NNRTI TEMs only) and 41% developed RS to  $\geq 1$  drug. TEMs were generally consistent with those observed in adults meeting VF on FPV-containing regimens.

Presented at The XIX International AIDS Conference, Washington, D.C., July 22–27, 2012

**108E. Antiretroviral (ART) therapeutic drug monitoring (TDM) and virologic suppression (VS) in pediatric patients with human immunodeficiency virus.** Jomy M. George, Pharm.D., BCPS<sup>1</sup>, Tara DeCervo, Pharm.D.<sup>2</sup>, Laura L. Bio, Pharm.D., BCPS<sup>1</sup>, Lori Connelly, RN<sup>3</sup>, Laura Pontiggia, Ph.D.<sup>4</sup>; (1) Philadelphia College of Pharmacy, University of the Sciences, Philadelphia, PA;

(2) Thomas Jefferson University Hospital, Philadelphia, PA; (3) Cooper University Hospital, Camden, NJ; (4) Misher College of Arts and Sciences, University of the Sciences, Philadelphia, PA

**PURPOSE:** Optimizing therapy through TDM may assist in achieving VS in HIV infected pediatric patients; however, current guidelines do not recommend its routine use.

**METHODS:** A retrospective chart review was conducted in perinatally infected HIV patients from birth to 18 years of age between January 2002 and September 2010. The primary objective was to determine if ART serum drug concentrations could predict the probability of VS, as defined by an undetectable viral load (VL) at 6 months from a clinical intervention. The secondary objective was to assess change in virologic status (detectable VL to VS) from baseline to 6 months following a clinical intervention.

**RESULTS:** Of the 53 clinic patients screened, 29 were included in the analysis: 17 LPV/RTV, 3 ATV, 2 EFV, and 7 NFV. The sample was stratified by age:  $< 1$  year (17%), 1–5 years (17%), 6–12 years (35%), and 13–18 years (31%). Baseline demographics were similar amongst groups. The median (IQR) CD4% and VL were 24% (17.8–32.5) and 2637 copies/ml (884–20,729), respectively. Primary analysis was performed only on the LPV/RTV group who had at least two data time points (n=12). Logistic regression showed no statistically significant difference in virologic outcome based on serum LPV/RTV trough concentrations ( $p = 0.8811$ ). Of the 29 patients included, 20 (69%) had detectable VL at baseline; of which 13 (65%) achieved VS at 6 months after a clinical intervention. There was a significant shift change in virologic status after a clinical intervention ( $p = 0.0009$ ). Most common interventions included dosage adjustment and adherence counseling.

**CONCLUSION:** Serum LPV/RTV trough concentrations did not appear to have a significant effect on VS. However, there was a significant change in virologic status after a clinical intervention. Further studies are required to assess the utility of TDM in pediatric patients. Presented at the Bruce Helms Residency Showcase at the Pediatric Pharmacy Advocacy Group (PPAG) National Conference in Memphis, TN in March 2011.

## Infectious Diseases

**109. Reducing fluoroquinolone use in the adult emergency department of a community hospital.** Yesenia Camero, Pharm.D., Erika Dittmar, Pharm.D., BCPS, Radhan Gopalani, Pharm.D., BCPS, Heidi Clarke, Pharm.D.; Baptist Hospital of Miami, Miami, FL

**PURPOSE:** The widespread use of fluoroquinolone antibiotics has contributed to the emergence of bacterial resistance among gram negative bacilli. Moreover, fluoroquinolones have been associated with an increased incidence and resistance of *C. difficile* infections. At Baptist Hospital of Miami, the resistance of inpatient *E. coli* isolates is currently  $> 40\%$ . The purpose of this study was to reduce fluoroquinolone use in the adult emergency department (ED).

**METHODS:** This prospective, IRB-approved study included patients at least 18 years of age ordered levofloxacin 250 and 500 mg orally or intravenously in the adult ED. Data collection included patient demographics, diagnosis, laboratory values, and imaging studies. The primary outcome was to compare the number of levofloxacin doses dispensed during May to July 2011 (prior to the study period) with November 2011 to January 2012 (during the study period). Secondary outcomes included the number and type of pharmacist interventions and the prescribing trends for levofloxacin in the ED. Education to all ED staff, including physicians, nurses, and pharmacists, was carried out prior to initiation of this study.

**RESULTS:** The number of levofloxacin doses dispensed decreased from 871 to 248 over the study period. A total of 66 patients ordered levofloxacin were evaluated. There were 37 clinical interventions made, which primarily resulted in a change in drug or dosage. Analysis of indications for prescribing levofloxacin demonstrated a reduction in prescribing for intra-abdominal infections, an increase for respiratory infections, and no difference for urinary tract infections.

**CONCLUSION:** Pharmacist intervention in the adult ED led to a significant reduction in levofloxacin use and optimization of antimicrobial therapy.

**110E. Evaluating the use of procalcitonin as a biomarker for infection in a medical intensive care unit.** *Chung-Shien Lee, Pharm.D., Rubiya Azmiree, Pharm.D., BCPS, Rehana Jamali, Pharm.D.; North Shore University Hospital, Manhasset, NY*

**PURPOSE:** The primary objective of this study was to determine if the utilization of procalcitonin (PCT) levels resulted in decreased antibiotic usage. The secondary objectives were to determine if the utilization of PCT levels resulted in a decreased hospital and medical intensive care unit (MICU) length of stay, decreased adverse events, timely resolution of infection and any difference in mortality.

**METHODS:** This study was a retrospective chart review that compared adult patients who had a PCT level ordered versus a control group of patients, who did not have a PCT level ordered in the MICU. Patients were included into the study if they were >18 years of age who were admitted to the MICU and treated with antibiotics. Patients were excluded if they were under the age of 18, pregnant, received antifungal agents, immunocompromised, had metastatic cancer or did not have antibiotics ordered during their stay in the MICU. The following data was collected: sex, age, ICD-9 codes, PCT level, total number of days on antibiotic therapy, adverse events reported, total hospital length of stay, total MICU length of stay, mortality and time to resolution of infection.

**RESULTS:** Both groups of patients had similar age and sex ratio. Patients who had a PCT level measured had a significantly greater total number of days on antibiotics (median 9.5 versus 6.0 days;  $p < 0.0001$ ), greater total number of hospital days (median 18.5 versus 10.0;  $p < 0.0004$ ), greater total number of MICU days (median 3.0 versus 2.0;  $p < 0.003$ ) and higher incidence of adverse events (16.7% versus 4.2%;  $p < 0.042$ ) compared to patients without PCT levels measured. There was no difference shown in time to resolution of infection and mortality.

**CONCLUSION:** PCT did not decrease antibiotic usage in a MICU. Furthermore, the biomarker did not assist in decreasing the length of hospital stay or intensive care unit length of stay.

Presented at Eastern States Residency Conference 2012, Hershey, PA, May 2-4, 2012

**111. Implementing antimicrobial stewardship in a community hospital.** *Jordan Walter, Pharm.D., Radhan Gopalani, Pharm.D., BCPS, Heidi Clarke, Pharm.D.; Baptist Hospital of Miami, Miami, FL*

**PURPOSE:** Antimicrobial stewardship is defined as appropriate selection, dosing, route, and duration of antimicrobial therapy with a primary goal of optimizing clinical outcomes. A significant amount of evidence has correlated pharmacist interventions with

the appropriate use of antimicrobials. The purpose of this study was to optimize antimicrobial use via pharmacy stewardship interventions.

**METHODS:** This is an IRB approved, prospective review. Patients >18 years of age receiving IV antimicrobials for >48 hours on a medical/surgical floor were included and reviewed during the months of November 2011 to January 2012. Antimicrobial therapy was reviewed for appropriate indication, dose, route, and duration. Patients were excluded if they were immunocompromised, HIV positive, post-transplant, or pregnant. The primary objective of this study was to assess pharmacist interventions on antimicrobial utilization, including the number and type of recommendations made and accepted by physicians. The secondary objective was to assess the cost savings associated with accepted interventions.

**RESULTS:** A total of 340 patients were reviewed after screening for inclusion/exclusion criteria, 95 of these patients required therapy modification. A total of 124 recommendations were made on 95 patients, of which 59 were automatic interventions. Out of the remaining 65 recommendations made, 80% were accepted. A total of 29 antimicrobials were discontinued on the basis of no infection present, antimicrobial course of therapy completed, or therapeutic duplication. Furthermore, these interventions resulted in an estimated cost savings of \$13,526 over the study period.

**CONCLUSION:** The number of interventions made during the study period supports the impact of a pharmacist-driven antimicrobial stewardship program in a community hospital. In addition, pharmacy protocols for automatic intravenous to oral conversions and renal dose adjustments facilitate appropriate route and dosing of antibiotics.

**112. Protease inhibitors: beyond anti-viral property.** *Talia Mazidi, Pharm.D., Khandaker Anwar, M.D., Richard M. Novak, M.D., Mahmood Ghassemi, Ph.D.; University of Illinois at Chicago, Chicago, IL*

**PURPOSE:** Since Mycobacteria, both *Mycobacterium tuberculosis* (M.tb) and *Mycobacterium avium* complex (MAC), are among the most common opportunistic infections in HIV-infected patients, this study was designed to evaluate the inhibitory effect of commercially-available protease inhibitors (PIs) on MAC-induced NF- $\kappa$ B activation and consequent HIV-LTR (long terminal repeat) upregulation.

**METHODS:** The U937 cell line was used for both transient transfection with NF- $\kappa$ B/LTR Luc constructs and infection with MAC. Transfected cells and MAC-infected cells were co-cultured in the absence and presence of various concentrations of PIs for 24 hours at 37°C. Co-cultured cells were subsequently lysed, and luciferase activity was measured.

**RESULTS:** MAC-infected cells co-cultured with NF- $\kappa$ B/LTR-transfected cells exerted significant increase in luciferase activity. Of nine PIs tested, Nelfinavir (NFV), Lopinavir (LPV), Ritonavir (RTV), Saquinavir (SQV) and Tipranavir (TPV) showed dose-dependent inhibitory effect on NF $\kappa$ B activity. Among these PIs, NFV and LPV showed the most potent effect as they were effective at concentrations as low as 2.5  $\mu$ g/ml, while the inhibitory effect of RTV, SQV and TPV was present only at the highest concentration tested (20  $\mu$ g/ml). Four other PIs, Indinavir (IDV), Darunavir (DRV), APV (Amprenavir), and Atazanavir (ATV) failed to show any inhibitory effect even at the highest non-toxic concentrations.

**CONCLUSION:** To our knowledge this is the first study that compares all commercially available protease inhibitors with regard to their anti-inflammatory effect unrelated to their anti-retroviral properties. Studies of the anti-inflammatory and immunomodulatory properties of this family of drugs as well as other antiretrovirals will provide insights into alternative mechanisms of action that may be clinically important.

**113. Inhibition of mitochondrial oxidative phosphorylation with andulafungin.** *Kayla R. Stover, Pharm.D., BCPS<sup>1</sup>, Jonathan P. Hosler, Ph.D.<sup>2</sup>, John D. Cleary, Pharm.D.<sup>2</sup>; (1)The University of*

Mississippi School of Pharmacy, Jackson, MS; (2) University of Mississippi Medical Center, Jackson, MS

**PURPOSE:** In previous ex vivo live-heart studies, anidulafungin (ANID) was found to cause cardiac toxicity. Because similar chemicals are known to inhibit mitochondrial respiration, the purpose of this study was to elucidate the effect of ANID on oxidative phosphorylation in mitochondria.

**METHODS:** Liver mitochondria were isolated from Harlan Sprague-Dawley rats by homogenization of 1–2 g of tissues followed by differential centrifugation. Mitochondrial respiration was measured as O<sub>2</sub> consumption using a Clark-type electrode and initiated with 5 umol/L succinate (S), 10 umol/L glutamate/5 umol/L malate (G), or 5 umol/L pyruvate (P). After establishing the rates of state 2 and 3 (+1060 umol/L ADP) respiration, ANID was added in concentrations ranging from 0.2 to 19.9 umol/L and compared to (i) state 3 respiration (S3R) in the absence of ANID and (ii) state 4 respiration induced by oligomycin (OLIG) 4.9 umol/L, a known mitochondrial toxin, in the absence of ANID. A one-sided Student t-test was used to determine the significance of comparisons.

**RESULTS:** ANID decreased S3R by  $64.5 \pm 13.7\%$  and  $70.3 \pm 16.4\%$ ,  $65.7 \pm 15.2\%$  and  $72.6 \pm 18.9\%$ , and  $44.8 \pm 6.7\%$  and  $39.7 \pm 13.5\%$  at 0.2, 2.0, and 19.9 umol/L, respectively, with S and G-driven respiration ( $p < 0.0001$  for all). With P, ANID decreased S3R by  $11.9 \pm 0.7\%$ ,  $12.0 \pm 2.2\%$ , and  $30.8 \pm 3.2\%$ , for 0.2, 2.0, and 19.9 umol/L, respectively ( $p < 0.0001$  for all). OLIG 4.9 umol/L decreased oxygen consumption by  $51.0 \pm 21.6\%$ ,  $51.1 \pm 22.8\%$ , and  $76.2\% \pm 7.1\%$  with S, G, and P, respectively ( $p < 0.0001$  for all).

**CONCLUSION:** ANID inhibits mitochondrial oxidative phosphorylation more than OLIG with S and G. Since the respiration of substrate producing ubiquinol (S) is inhibited as much by ANID as substrates producing NADH (G, P), it seems unlikely that ANID inhibits Complex I. Studies to locate the molecular target are underway.

**114. Impact of clinical pharmacist interventions with infectious disease team.** *Eyad T. Almadhour*; Hamad Medical Corporation, Doha, Qatar

**PURPOSE:** To determine the impact and cost saving of clinical pharmacist's intervention with infectious disease team, regarding treatment selection, dosing, renal and hepatic adjustments, Therapeutic drug monitoring and patient follow up.

**METHODS:** (i) This is a prospective observational study from February 2010 to June 2012. In this study the clinical pharmacist daily rounded with infectious disease team, make and documents interventions for patients in medical, surgical and intensive care units. (ii) The Clinical pharmacist interventions includes treatment selection, appropriate dose, renal and hepatic dose adjustments, TDM and patient education and follow up for any side effects. (iii) All intervention data were entered and analyzed using SPSS program version 20.

**RESULTS:** Over more than 700 rounding days the clinical pharmacist made over than 950 interventions. 49% of interventions related to drug dosing, 16.2% of interventions dealing with determining the duration of therapy, 12.7% related to writing prescriptions and 7.5% for therapeutic drug monitoring. Some of interventions data were lost because the unavailability of SPSS program during months June, July and August 2011.

**CONCLUSION:** The clinical pharmacist has a huge impact and great role with infectious disease team leading to better patient care and optimal outcomes. Total number of intervention were more than 950 clinical interventions over 700 rounding days. This study emphasizes on the great role of clinical pharmacist with recommendation to hire more clinical pharmacists to cover other specialty teams.

**115. Retrospective review of antimicrobial selection for treatment of *Enterobacter* in a teaching hospital.** *Maria Pompili, Pharm.D., Aaron Cumpston, Pharm.D., Michael Sweet, Pharm.D., Arif Sarwari, M.D.*; West Virginia University Healthcare, Morgantown, WV

**PURPOSE:** *Enterobacter* spp. are intrinsically resistant to first and second generation cephalosporins through constitutive chromosomal AmpC beta-lactamases. Avoidance of third generation cephalosporins has been believed to be necessary due to the association of hyperproducing AmpC mutations. This retrospective review evaluated antimicrobial treatment selection in patients with *Enterobacter* spp. infections, specifically focusing on the use of third generation cephalosporins.

**METHODS:** All microbiology cultures positive for *Enterobacter* spp. were retrospectively identified from the microbiology laboratory database at West Virginia University Healthcare from January to October 2010. Electronic medical records were reviewed for site of infection, date of culture collection, date of culture results, and antimicrobial choice. Infections were divided into three categories: urine, wound, and deep-seeded (including osteomyelitis, meningitis, pneumonia, and bacteremia). Duplications of infections, determined as a recurrent positive culture within 14 days time, were removed from evaluation. The choice of antimicrobial treatments was determined at 48 hours after culture resulting. This information was further divided into antimicrobial classes.

**RESULTS:** *Enterobacter* spp. infections were identified in a total of 128 patients, 49 with urine cultures, 21 with wound cultures, and 58 with deep-seeded cultures. Cephalosporins were the chosen treatment in 28% of urine cultures, 21% of wound cultures, and 19% deep-seeded cultures in those patients that received single antimicrobial coverage.

**CONCLUSIONS:** Validating our concern, a significant number of *Enterobacter* spp infections are treated with cephalosporins at our institution. Staff awareness is pertinent at this time regarding antibiotic treatment choices. Efficacy of cephalosporin treatment for *Enterobacter* spp. needs to be validated by further evaluation to determine clinical outcomes.

**116E. Population pharmacokinetic (PPK) analysis of ceftaroline (CPT) in patients with complicated skin and skin structure infection (cSSSI) or community-acquired pneumonia (CAP).** *Scott A. Van Wart, M.S.<sup>1</sup>, Alan Forrest, Pharm.D.<sup>1</sup>, Tatiana Khariton, Ph.D.<sup>2</sup>, Christopher M. Rubino, Pharm.D., BCPS<sup>1</sup>, Sujata M. Bhavnani, Pharm.D., MS<sup>1</sup>, Todd Riccobene, Ph.D.<sup>2</sup>, Paul G. Ambrose, Pharm. D., FIDSA<sup>1</sup>*; (1) Institute for Clinical Pharmacodynamics, Latham, NY; (2) Forest Research Institute, Inc., Jersey City, NJ

**PURPOSE:** We developed a PPK model for CPT, the active form of prodrug CPT fosamil, in Phase 2/3 patients with cSSSI or CAP given intravenous (IV) or intramuscular (IM) CPT fosamil.

**METHODS:** Data from 185 Phase 1 subjects and 92 cSSSI patients were pooled to develop a PPK model. Data from 128 CAP patients were used for external validation. Phase 1 subjects received CPT fosamil 50–2000 mg IV over 1 h q12h or q24h for up to 14 days, or IM injection for up to 5 days. Patients with cSSSI or CAP received CPT fosamil 600 mg over 1 hour q12h and PK samples were collected and analyzed. Covariates were assessed using stepwise forward selection ( $\alpha = 0.01$ ) and backward elimination ( $\alpha = 0.001$ ). Monte Carlo simulation and bootstrap analyses were used for model evaluation.

**RESULTS:** A three-compartment (CMT) model with zero-order input or dual-phase first-order IM absorption and first-order elimination described the prodrug. A 2-CMT model with rapid first-order conversion of prodrug to CPT and parallel linear ( $CL_{lin} = 3.06$  L/hour) and saturable elimination ( $CL_i = 11.6$  L/hour;  $km = 9.62$  mg/L) described CPT with good agreement between observed and population ( $r^2 = 0.927$ ) and individual ( $r^2 = 0.983$ ) predictions.  $CL_i$  and  $V_c$  were higher in patients than in Phase 1 subjects. Creatinine clearance (CrCL) was the major determinant of CPT exposure; both  $CL_i$  and  $CL_{lin}$  increased with CrCL. Simulated patients with  $30 < CrCL < 50$  ml/minute/1.73 m<sup>2</sup> given 400 mg and those with  $CrCL \leq 30$  ml/minute/1.73 m<sup>2</sup> given 300 mg had comparable  $AUC_{0-12}$  relative to those with normal renal function given 600 mg IV q12h. The 90% prediction intervals captured observed CPT data in both cSSSI and CAP patients.

**CONCLUSION:** A PPK model was developed to describe the time-course of CPT in plasma and identify relevant PK covariate effects. This model evaluated adjustments for renal insufficiency and assessed pharmacokinetic-pharmacodynamic relationships in patients treated with CPT fosamil. Presented at the 51st Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, September 17–20, 2011.

**117E. A single- and multiple-dose study to determine the safety, tolerability, and pharmacokinetics (PK) of ceftaroline fosamil plus avibactam (CXL) administered by intravenous (IV) infusion to healthy subjects.** *Todd Riccobene, Ph.D.<sup>1</sup>*, Sheng Fang Su, Ph.D.<sup>1</sup>, Douglas R. Rank, M.D.<sup>2</sup>; (1) Forest Research Institute, Inc., Jersey City, NJ; (2) Cerexa, Inc. (a wholly owned subsidiary of Forest Laboratories, Inc., New York, NY), Oakland, CA

**PURPOSE:** Ceftaroline (CPT) fosamil (the prodrug of CPT) is a new broad-spectrum cephalosporin with activity against gram-positive organisms, including methicillin-resistant *Staphylococcus aureus*, as well as common gram-negative pathogens. Avibactam (AVI) is a novel non- $\beta$ -lactam  $\beta$ -lactamase inhibitor that inhibits Ambler class A and class C enzymes. This study was conducted to determine the safety, tolerability, and PK of IV doses of CXL in healthy adults.

**METHODS:** This study included two parts. In the open-label arm, 12 subjects received single IV infusions over 1 hour of 600 mg CPT fosamil, 600 mg AVI, and 600/600 mg CXL separated by a 5-day washout. In the double-blind arm, 9 active/3 placebo subjects per cohort received IV infusions of CXL 600/600 mg q12h, CXL 400/400 mg q8h, CXL 900/900 mg q12h, or CXL 600/600 mg q8h for 10 days. CPT and AVI in plasma and urine were measured.

**RESULTS:** Following single IV doses alone or coadministered with AVI, CPT fosamil was rapidly converted to CPT. There were no significant differences in systemic exposure of CPT or AVI administered alone or when coadministered. No appreciable accumulation occurred with multiple IV doses of CXL. Infusions of CPT fosamil, AVI, and CXL were well tolerated. All adverse events (AEs) were mild to moderate in severity; no serious AEs occurred. Infusion-site reactions were the most common AEs reported with multiple dosing. There were no discontinuations due to an AE in the single-dose arm and 2 (5.6%) on CXL in the multiple-dose arm.

**CONCLUSION:** There was no apparent PK interaction between CPT fosamil and AVI administered as a single dose. PK parameters for CPT and AVI were similar on Days 1 and 10 when coadministered for 10 days. Infusions of CPT fosamil, AVI, and CXL were safe and well tolerated at total daily doses up to 1800 mg. Presented at the 51st Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, September 17–20, 2011.

**118E. Efficacy and safety of tedizolid phosphate for 6 days versus linezolid for 10 days in a phase 3 study in patients with ABSSSI using the new FDA primary outcome measure.** *Carisa De Anda, Pharm.D.<sup>1</sup>*, Edward Fang, M.D.<sup>1</sup>, Purvi Mehra, M.D.<sup>2</sup>, Sinikka Green, M.D.<sup>2</sup>, Philippe Prokocimer, M.D.<sup>1</sup>; (1) Trius Therapeutics, San Diego, CA; (2) eStudySite, San Diego, CA

**PURPOSE:** The FDA is using a new primary outcome measure for acute bacterial skin and skin structure infections (ABSSSI) of cessation of spread and absence of fever at an early time point at 48–72 hours after the first dose of study medication.

**METHODS:** This was a randomized, double-blind, multicenter Phase 3 study of oral tedizolid phosphate 200 mg QD for 6 days versus oral linezolid 600 mg every 12 hours for 10 days for the treatment of ABSSSIs in adults. The primary objective was to determine the non-inferiority in the early clinical response rate of 6-day oral tedizolid phosphate compared with that of 10-day oral linezolid treatment at the 48–72 hour visit in the ITT analysis set in patients with ABSSSI. Patients were programmatically defined as a responder at the 48–72 hour Visit if there was documented cessation of spread of the primary ABSSSI and an absence of fever.

**RESULTS:** A total of 667 patients were randomized. The primary ABSSSI type enrolled was cellulitis (41%) followed by major cutaneous abscesses (30%) and infected wounds (29%). Median measurements of surface area of lesion were comparable in both treatment groups. The primary outcome results are listed in table below. The primary reason for indeterminate was out of window or missing temperature measurements.

Response	Tedizolid phosphate (N=332) n (%)	Linezolid (N=335) n (%)
Responder	264 (79.5)	266 (79.4)
Non-responder or indeterminate	68 (20.5)	69 (20.6)
Non-responder	27 (8.1)	35 (10.4)
Indeterminate	41 (12.3)	34 (10.1)

Treatment emergent adverse events were balanced overall between the two treatment groups. However there was a statistically significantly higher incidence of GI-related adverse events with linezolid.

**CONCLUSION:** The results of this study demonstrated that tedizolid phosphate QD for 6 days achieved its primary endpoint of non-inferiority versus linezolid Q12H for 10 days.

Presented at The Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, CA, September 9–12, 2012.

**119E. Effects of tedizolid phosphate and linezolid on platelet counts in a phase 3 ABSSSI study.** *Edward Fang, M.D.<sup>1</sup>*, Carisa De Anda, Pharm.D.<sup>1</sup>, Anita F. Das, Ph.D.<sup>2</sup>, Philippe Prokocimer, M.D.<sup>1</sup>; (1) Trius Therapeutics, San Diego, CA; (2) AxiStat, Inc., San Francisco, CA

**PURPOSE:** Tedizolid phosphate is a novel oxazolidinone prodrug antibiotic of the active moiety tedizolid, being developed for the treatment of acute bacterial skin and skin structure infections (ABSSSI). The only oxazolidinone currently on the market is linezolid (Zyvox) which has been associated with thrombocytopenia. Platelet counts in subjects enrolled in a phase 3 ABSSSI study comparing 6 days of oral tedizolid phosphate 200 mg qd (followed by 4 days of placebo) with 10 days of oral linezolid 600 mg bid were reviewed.

**METHODS:** A total of 666 adult subjects with ABSSSI were randomized to tedizolid phosphate or linezolid treatment and received at least one dose of study drug. Platelet counts were reviewed for worst post-baseline values and values at Study Days 11–13.

**RESULTS:** Number of subjects receiving tedizolid phosphate and linezolid with post-baseline platelet counts below the lower limit of normal (LLN) or were substantially abnormal (<75% of LLN) are presented in the table below.

Subjects groups	Tedizolid phosphate n (%)	Linezolid n (%)	p-Value
Subjects with any baseline platelet count and the worst (lowest) post-baseline value	N=304 28 (9.2) 7 (2.3)	N=308 46 (14.9) 15 (4.9)	0.035 0.127
Below LLN			
Substantially abnormal			
Excluding subjects with an abnormal or missing baseline platelet count, values at Study Days 11–13	N=259 8 (3.1) 1 (0.4)	N=247 19 (7.7) 7 (2.8)	0.0282 0.0337
Below LLN			
Substantially abnormal			
Including subjects with an abnormal baseline value and excluding subjects with a missing baseline platelet count, values at Study Days 11–13	N=268 9 (3.4) 2 (0.7)	N=266 30 (11.3) 12 (4.5)	0.0004 0.0065
Below LLN			
Substantially abnormal			

**CONCLUSION:** Subjects receiving tedizolid phosphate in this phase 3 ABSSSI trial had lower rates of abnormal platelet counts compared with linezolid, which in many cases were statistically significant.

Presented at Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, CA, September 9–12, 2012.

**120E. Favorable adverse event profile of tedizolid phosphate compared to linezolid in a phase 3 ABSSSI study.** Edward Fang, M.D.<sup>1</sup>, CarisaDe Anda, Pharm.D.<sup>1</sup>, Anita F. Das, Ph.D.<sup>2</sup>, Philippe Prokocimer, M.D.<sup>1</sup>; (1)Trius Therapeutics, San Diego, CA; (2)AxiStat, Inc., San Francisco, CA

**PURPOSE:** Tedizolid phosphate is being developed for the treatment of acute bacterial skin and skin structure infections (ABSSSI). Adverse events reported in a phase 3 ABSSSI study comparing 6 days of oral tedizolid phosphate 200 mg qd (followed by 4 days of placebo) with 10 days of oral linezolid 600 mg bid were reviewed.

**METHODS:** A total of 666 adult subjects with ABSSSI were randomized to tedizolid phosphate or linezolid therapy and received at least one dose of study drug. Treatment-emergent adverse events (TEAEs) by System Organ Class (SOC) and Preferred Terms (PT), Investigator-determined relationships and serious adverse events (SAEs) were reviewed. Coding was performed with MedDRA version 13.1.

**RESULTS:** Overall, TEAEs frequencies were similar in the tedizolid phosphate and linezolid treatment arms, 40.8% and 43.3%, respectively, though rates of Investigator-determined drug-related TEAEs were lower for tedizolid phosphate compared with linezolid, 24.2% and 31.0%, respectively. Rates of TEAEs leading to discontinuation of study drug were 0.6% in both groups, and rates of SAEs were 1.5% and 1.2%, respectively. Most TEAEs in both treatment groups were mild, with similar distribution of severity.

**CONCLUSION:** Overall, subjects receiving tedizolid phosphate and linezolid in this phase 3 ABSSSI trial had similar rates of TEAEs, SAEs, and discontinuation of study drug due to TEAEs. However, there were more Investigator-determined drug-related TEAEs in the linezolid group. Additionally, subjects receiving tedizolid phosphate had significantly better GI tolerability compared with linezolid.

Presented at Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, CA, September 9–12, 2012.

**121. Appropriate use of in vitro susceptibility testing in the selection of antifungal therapy.** Shaily Arora, Pharm.D., Rebecca Gayle, Pharm.D., B. Joseph Guglielmo, Pharm.D.; University of California San Francisco, San Francisco, CA

**PURPOSE:** Evaluate the appropriateness of use of in vitro antifungal susceptibility testing in the treatment of *Candida* infections.

**METHODS:** All in vitro antifungal susceptibility test results performed for patients with infection due to *Candida* species from 2005 to 2011 were retrospectively reviewed. Information collected from the medical record included antifungal therapy before and after availability of susceptibility test results, results of the testing, appropriateness of use, and presence of an infectious disease service consult. Definitions for appropriate and inappropriate application of the antifungal susceptibility test results were developed and applied to each case.

**RESULTS:** Of the 96 susceptibility tests performed, 64 (66.7%) were classified as “appropriate” and 32 (33.3%) as “inappropriate” in influencing prescribing decisions. The most common “appropriate” use involved a change in antifungal therapy in direct response to the susceptibility results. The primary reason for “inappropriate” use was no change in therapy despite the opportunity to refine therapy based upon the results. In those instances of inappropriate use, 28 of 32 (87.5%) were associated with an infectious disease consult, compared to 61 of 64 (95.3%) appropriate uses. The 96 susceptibility tests involved a total of 106 *Candida* infections with 113 infected sites. *Candida glabrata*

was the most common yeast, present in 53 of 106 (50%) infections, and 43 of 113 (38.1%) of *Candida*-infected sites were bloodstream-based. Of the 22 infections caused by *Candida albicans*, three were resistant to fluconazole.

**CONCLUSIONS:** In vitro antifungal susceptibility test results are not always utilized appropriately in the optimization of antifungal therapy. Infectious disease consultation does not appear to improve the appropriate use of these test results. Continued quality improvement is needed to guide the appropriate use of in vitro susceptibility testing for antifungal agents.

**122E. Comparative potency of oxazolidinones tedizolid (TR-700) and linezolid against target gram-positive pathogens in the US from 2009 to 2010.** Chris Pillar, Ph.D.<sup>1</sup>, Daniel Sahn, Ph.D.<sup>1</sup>, Ken Bartizal, Ph.D.<sup>2</sup>; (1)Eurofins Medinet, Chantilly, VA; (2)Trius Therapeutics, San Diego, CA

**PURPOSE:** Resistance and multidrug resistance among Gram-positive pathogens, in particular *Staphylococcus aureus*, has limited the utility of many common antibacterials. Decreased susceptibility to daptomycin, linezolid, and vancomycin remains infrequent, but potential for growing resistance is a significant concern. Tedizolid (TR-700), formerly known as torezolid, is an oxazolidinone with potent activity against Gram-positive pathogens currently undergoing trials for the treatment of acute bacterial skin and skin structure infections (ABSSSI). This study reports the current susceptibility of target Gram-positive pathogens from the United States, comparing the activity profiles of TR-700 and linezolid.

**METHODS:** A total of 1248 *S. aureus*, 50 *Enterococcus faecalis*, 38 *Enterococcus faecium*, 101 *Streptococcus pyogenes*, 28 *Streptococcus agalactiae*, and 29 anginosus group streptococci (AGS) clinical isolates from 93 distributed sites from 2009 to 2010 were tested by broth microdilution per Clinical and Laboratory Standards Institute (CLSI) guidelines for susceptibility to TR-700, linezolid, and comparators. Resistance to  $\geq 3$  classes of agent (excluding beta-lactams) defined multidrug resistance among *S. aureus*.

**RESULTS:** TR-700 and linezolid (LZD) activity against evaluated isolates by phenotype was documented. Based on MIC<sub>50</sub>/MIC<sub>90</sub>, TR-700 was 4- to 8-fold more potent than linezolid. The activity profiles of TR-700 and linezolid were not impacted by resistance common among the evaluated pathogens (eg, MRSA, VRE, etc), and TR-700 maintained activity against linezolid-resistant isolates. Against the only linezolid-resistant *S. aureus* and *E. faecium* [TR-700 minimum inhibitory concentrations (MICs) of 16 and 32 mg/ml, respectively], TR-700 had MICs of 1 and 4 mg/ml, respectively.

**CONCLUSION:** The activity profile of TR-700 highlights its potential for the treatment of Gram-positive infections such as ABSSSI, though emerging resistance warrants continued surveillance for all developmental and approved oxazolidinones.

Presented at Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, September 17–20, 2011.

**123. Therapeutic drug monitoring of posaconazole in adults: a retrospective analysis.** Timothy J. Jancel, Pharm.D.<sup>1</sup>, Scott R. Penzak, Pharm.D.<sup>1</sup>, Pamela A. Shaw, Ph.D.<sup>2</sup>, Claire W. Hallahan, M.S.<sup>2</sup>, Harry L. Malech, M.D.<sup>3</sup>, Alexandra F. Freeman, M.D.<sup>4</sup>, Kenneth N. Olivier, M.D.<sup>4</sup>, Steven M. Holland, M.D.<sup>4</sup>; (1)National Institutes of Health, Bethesda, MD; (2)National Institute of Allergy and Infectious Diseases (BRB), Bethesda, MD; (3)National Institute of Allergy and Infectious Diseases (LHD), Bethesda, MD; (4)National Institute of Allergy and Infectious Diseases (LCID), Bethesda, MD

**PURPOSE:** Serum posaconazole (POS) concentrations >500–700 and >1250 ng/ml are associated with successful prophylaxis and treatment of invasive fungal infections (IFIs), respectively. We investigated factors potentially contributing to inadequate serum POS concentrations.

**METHODS:** Retrospective review was performed of all NIAID patients  $\geq 18$  years who received POS at NIH (September 2006–

March 2012) and had  $\geq 1$  available serum POS concentration. ANOVA, Wilcoxon, and Fisher's exact tests were used to assess the following variables for their influence on POS concentrations: race, sex, underlying diagnosis, gastrointestinal (GI) disease (diarrhea, CGD [chronic granulomatous disease] colitis), and indication (treatment/prophylaxis).  $p < 0.05$  was accepted as statistically significant.

**RESULTS:** A total of 283 serum POS concentrations were available from 73 pts (66% male). Median (range) age and body weight were 28 (18–74) years and 60 (39–106) kg. Frequent underlying conditions were CGD (56%), Hyper-IgE syndrome (18%), and bronchiectasis (12%). POS was prescribed for prophylaxis, and treatment in 55% and 45% of patients, respectively. Median values for POS serum concentration and dose-adjusted concentration were 896 (<50–2845) ng/ml and 1.11 (0–4.74) ng/ml/mg, respectively. Failure to attain a concentration of 500, 700, and 1250 ng/ml occurred in 18%, 33%, and 81% of patients, respectively. Patients with CGD and GI disease had significantly lower POS concentrations than those who did not ( $p = 0.002$  and  $0.03$  respectively). In addition, age was positively correlated with dose-adjusted concentration ( $p < 0.001$ ) with an estimated 0.24 ng/ml/mg increase in POS concentration per 10 year age increase. Indication, race, and sex did not influence POS concentrations.

**CONCLUSION:** Achieving target POS concentrations for treatment and prophylaxis of IFIs may be impeded by CGD-related GI disease and younger age. Therapeutic drug monitoring would be particularly useful to ensure adequate POS exposure in these patient subsets, and as a test for patient adherence.

#### 124E. An evaluation of the absorption, metabolism, and excretion of orally administered [ $^{14}$ C]-TR-701 FA in healthy subjects.

Howard Dreskin, M.S., Teresa Boyea, Pharm.D., Jeff Barker, B.S., Edward Fang, M.D., Shawn Flanagan, Ph.D., Philippe Prokocimer, M.D.; Trius Therapeutics, San Diego, CA

**PURPOSE:** TR-701 free acid (FA) (tedizolid phosphate) is a novel oxazolidinone prodrug antibiotic currently in phase 3 clinical trials for the treatment of acute bacterial skin and skin structure infections (ABSSSI). Data generated with the oral formulation suggested that 200 mg QD is the lowest effective dose. The aim of the present study was to characterize the absorption, metabolism, and excretion of a single 200-mg dose of [ $^{14}$ C]-TR-701 FA in healthy male subjects to determine its metabolic fate.

**METHODS:** This was an open-label, single-dose study. TR-701 FA was administered orally in six healthy male volunteers. Subjects received a single dose of [ $^{14}$ C]-TR-701 FA administered as an oral solution. Blood, urine, and fecal samples were collected at protocol-defined time points. Assays included scintillation counting of blood, plasma, and excreta, a validated LC-MS-MS assay for quantitation of TR-700 (tedizolid) in plasma, and LC-MS and HPLC with radiochemical detection for metabolite profiling.

**RESULTS:** The majority (87.6%) of the radioactivity was recovered by 96 hours postdose, and total recovery in urine and feces combined was approximately 99.5% by 288 hours postdose. Mean recovery of total radioactivity in urine was 18.0%, with 81.5% of the radioactive dose recovered in feces. Eight metabolites were identified in plasma, urine, and feces. The only significant circulating metabolite found in plasma was the hydrolyzed alcohol product, TR-700, which constituted approximately 94.54% to 98.23% of sample radioactivity. Other than TR-700, which accounts for approximately 95% of the total radiocarbon AUC in plasma, there are no other significant circulating metabolites. The main metabolite found in feces and urine was the sulfate analog of TR-700. No TR-701 was identified in plasma.

**CONCLUSION:** TR-701 underwent rapid and extensive hydrolysis of the phosphate moiety and converted into TR-700, the microbiologically active moiety. Feces were the major elimination pathway. TR-700 was the only appreciable circulating metabolite following oral administration.

Presented at Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, IL, September 17–20, 2011.

#### 125E. Improved pharmacokinetics of the novel oxazolidinone antibiotic tedizolid phosphate compared with linezolid in healthy subjects.

Shawn Flanagan, Ph.D.<sup>1</sup>, Kelly A. Munoz, B.A., M.A.<sup>1</sup>, Sonia Minassian, Dr.P.H.<sup>1</sup>, Claudette Bethune, Ph.D.<sup>2</sup>, John Bohn, B.S.<sup>2</sup>, Robert Wright, B.S.<sup>2</sup>, Paul Bien, M.S.<sup>1</sup>, Philippe Prokocimer, M.D.<sup>1</sup>; (1) Trius Therapeutics, San Diego, CA; (2) Covance, Madison, WI

**PURPOSE:** Tedizolid phosphate disodium salt (TR-701) is a novel oxazolidinone prodrug that is rapidly converted to the microbiologically active molecule tedizolid (TR-700). TR-700 is active against gram-positive organisms. TR-701 FA (free acid) is currently in phase 3 trials for the treatment of acute bacterial skin and skin structure infections. The objective of this study was to compare the pharmacokinetics (PK) and safety of 200 mg TR-701 and the current label-approved dose of linezolid in healthy adults.

**METHODS:** This study evaluated the single and multiple dose PK of TR-700, compared with linezolid in healthy adults. Each cohort of 10 subjects (8 active and 2 placebo) received oral 200 mg TR-701 once-daily, or oral 600 mg linezolid twice-daily for 21 days. TR-700 and linezolid plasma concentrations were determined using validated tandem mass spectrometry assays and PK was determined with standard noncompartmental methods using WinNonlin.

#### RESULTS:

- Mean TR-700 half-life was approximately 2-fold longer than that of linezolid, thus supporting once-daily administration.
- The pharmacokinetics of TR-700 after a single dose of TR-701 well predicted the exposure after repeat administration (linearity ratio = 0.94).
- Day 21 pharmacokinetics of linezolid exhibited nonlinearities (linearity ratio = 1.55) following multiple twice-daily dosing.
- Moderate accumulation of TR-700 (approximately 28%) and marked accumulation of linezolid (approximately 72%) was observed after 21 days.

#### CONCLUSION:

- After 21 days of TR-701 treatment, TR-700 exhibited consistent and predictable exposure.
- Nonlinear linezolid kinetics were observed with increased exposure after repeat administration.
- Both drugs were safe and well tolerated.

Presented at European Congress of Clinical Microbiology and Infectious Diseases, Vienna, Austria, April 10–13, 2010.

#### 126. Correlation of cefpodoxime susceptibility with cephalothin, cefuroxime, and ceftriaxone for urinary tract isolates.

David A. Bookstaver, Pharm.D., Christopher M. Bland, Pharm.D., Mitchell W. Woodberry, Ph.D., Karon B. Mansell, M.T.ASCPSM; Eisenhower Army Medical Center, Fort Gordon, GA

**PURPOSE:** Current guidelines recommend that cefpodoxime susceptibility should be extrapolated from the cephalothin result for urinary tract isolates. The purpose of the study was to determine whether cefuroxime or ceftriaxone was superior to cephalothin as a surrogate marker for cefpodoxime susceptibility.

**METHODS:** Automated susceptibility testing for cephalothin, cefuroxime and ceftriaxone was conducted on consecutive urine cultures with a colony count of at least 50,000 organisms via the Microscan© system. *Pseudomonas*, *Enterococcus*, *Acinetobacter* and methicillin-resistant *Staphylococcus* isolates were excluded. Simultaneously, a manual E-test for cefpodoxime was placed on the culture plate, the minimum inhibitory concentration was determined, and susceptibility was based on the FDA-approved breakpoints. The interpretation for cefpodoxime was compared to that of the other three agents, and a correlation rate was calculated defined as the percentage of identical susceptibility interpretations. Chi-square was used for comparisons.

**RESULTS:** A total of 292 isolates were assessed. The correlation rate was 93% for ceftriaxone, 91% for cefuroxime, and 63% for cephalothin. The concordance of both ceftriaxone and cefuroxime were superior to cephalothin ( $p < 0.01$ ). Of 107 discordant isolates, 43 tested resistant and 59 were intermediate to cephalothin while testing susceptible to cefpodoxime. Thirteen isolates susceptible to cefuroxime were either resistant (9) or intermediate (4) to cefpodoxime. Conversely, 11 isolates susceptible to cefpodoxime were

either resistant (9) or intermediate (2) to cefuroxime. For ceftriaxone, 17 susceptible isolates were either resistant (13) or intermediate (4) to cefpodoxime. Three isolates were susceptible to cefpodoxime but not ceftriaxone. The likelihood of inaccurately extrapolating susceptibility was higher for ceftriaxone than cefuroxime ( $p=0.02$ ).

**CONCLUSION:** Both cefuroxime and ceftriaxone were better predictors of cefpodoxime susceptibility than cephalothin. Cefuroxime appears to be the preferred surrogate agent for interpreting cefpodoxime urinary susceptibilities.

**127. Vancomycin dosing requirements in obese patients.** Mitchell S. Buckley, Pharm.D.<sup>1</sup>, Julie A. McIndoo, Pharm.D.<sup>1</sup>, Aundrea R. Linn, Pharm.D.<sup>1</sup>, Marianna Yanashyan, Pharm.D.<sup>2</sup>, Douglas N. Fish, Pharm.D.<sup>2</sup>; (1)Banner Good Samaritan Medical Center, Phoenix, AZ; (2)University of Colorado School of Pharmacy, Aurora, CO

**PURPOSE:** Appropriate initial vancomycin dosing in obese patients remains controversial. The purpose of this study was to evaluate vancomycin dosing requirements in obese patients to achieve serum trough concentrations of 15–20 mg/L.

**METHODS:** A retrospective case-control study was conducted at two academic medical centers. Obese (total body weight [TBW]  $\geq 101$  kg) and non-obese (TBW  $< 101$  kg) patients were included based on age  $\geq 18$  years,  $\geq 48$  hours of vancomycin therapy, baseline serum creatinine  $< 2.0$  mg/dl, and  $\geq 1$  vancomycin trough level. Exclusion criteria included cystic fibrosis, unstable renal function, renal replacement therapy, or IV contrast dye within 7 days of starting vancomycin. Total daily dose (TDD) requirements were evaluated based on TBW and adjusted dosing weight (ADW), defined as ideal body weight (IBW) + 0.4 (TBW – IBW).

**RESULTS:** A total of 116 obese (mean  $\pm$  SD 122.0  $\pm$  20.1 kg, range 101.0–205.0 kg) and 115 non-obese patients (72.8  $\pm$  12.9 kg, range 44.5–99.1 kg) were evaluated. Eighty-six obese patients (74%) and 78 non-obese patients (68%) had documented steady-state trough concentrations of 15–20 mg/L (median trough concentrations 17.4 and 17.2 mg/L, respectively). Among patients achieving desired trough concentrations, median TDD in obese and non-obese patients were 3000 and 2250 mg/day, respectively. Obese and non-obese patients required means of 26.6  $\pm$  9.9 versus 34.4  $\pm$  14.4 mg/kg/day, respectively, based on TBW ( $p < 0.0001$ ). Among obese patients, mean TDD based on ADW was similar to the TBW-based dose in non-obese patients (35.6  $\pm$  12.6 versus 34.4  $\pm$  14.4 mg/kg/day, respectively;  $p=0.545$ ). However, substantial variability was observed in the TDD based on ADW in the obese group.

**CONCLUSION:** To achieve trough concentrations of 15–20 mg/L, obese patients dosed on ADW required TDD similar to non-obese patients dosed on TBW. Obese patients should be initially dosed based upon the recommended 30–40 mg/kg/day using ADW with follow-up monitoring.

**128. Vancomycin doses of  $\geq 4$  g/day are not associated with nephrotoxicity in obese patients dosed to trough concentrations of 15–20 mg/L.** Mitchell S. Buckley, Pharm.D.<sup>1</sup>, Julie A. McIndoo, Pharm.D.<sup>1</sup>, Aundrea R. Linn, Pharm.D.<sup>1</sup>, Marianna Yanashyan, Pharm.D.<sup>2</sup>, Douglas N. Fish, Pharm.D.<sup>2</sup>; (1)Banner Good Samaritan Medical Center, Phoenix, AZ; (2)University of Colorado School of Pharmacy, Aurora, CO

**PURPOSE:** Vancomycin-induced nephrotoxicity has been associated with total body weight (TBW)  $\geq 101$  kg and total daily doses (TDD)  $\geq 4$  g. We hypothesized that nephrotoxicity is not associated with TBW  $\geq 101$  kg or TDD  $\geq 4$  g when vancomycin is dosed to achieve trough concentrations of 15–20 mg/L.

**METHODS:** A retrospective case-control study was conducted at two academic medical centers. Obese (TBW  $\geq 101$  kg) and non-obese (TBW  $< 101$  kg) patients were included based on age  $\geq 18$  years,  $\geq 48$  hours of vancomycin therapy, baseline serum creatinine (SCr)  $< 2.0$  mg/dl, and  $\geq 1$  vancomycin trough level. Exclusion criteria included cystic fibrosis, unstable renal function,

renal replacement therapy, or IV contrast dye within 7 days of starting vancomycin. Nephrotoxicity was defined as SCr increased  $> 0.5$  mg/dl or  $> 50\%$  over baseline on  $\geq 2$  consecutive days after initiating vancomycin.

**RESULTS:** A total of 116 obese (mean  $\pm$  sd 122.0  $\pm$  20.1 kg, range 101.0–205.0 kg) and 115 non-obese patients (72.8  $\pm$  12.9 kg, range 44.5–99.1 kg) were evaluated. Nephrotoxicity occurred in 9% (10/116) of obese and 10% (12/115) of non-obese patients ( $p=0.661$ ; OR: 0.81; 95% CI: 0.33, 1.96). Nephrotoxicity occurred in 4/37 patients (11%) receiving TDD  $\geq 4$  g versus 18/194 (9%) in patients receiving  $< 4$  g/day ( $p=0.761$ ; OR: 0.118; 95% CI: 0.38, 3.73). Thirty-one obese patients (27%) required TDD  $\geq 4$  g to achieve troughs of 15–20 mg/L compared to six non-obese patients (5%); nephrotoxicity occurred in 3/31 (10%) and 1/6 (16%) of obese and non-obese patients, respectively ( $p=0.523$ ; OR: 0.53; 95% CI: 0.04, 6.2). Nephrotoxicity was not significantly associated with TBW ( $p=0.702$ ), TDD on Day 1 of therapy ( $p=0.738$ ), or TDD during maintenance dosing ( $p=0.765$ ).

**CONCLUSION:** Obese patients and those requiring TDD  $\geq 4$  g are not at significantly increased risk of vancomycin-induced nephrotoxicity when dosed to achieve recommended trough concentrations of 15–20 mg/L.

**130E. Clinically-derived mutations in *ERG11* caused decreased fluconazole susceptibility when expressed in a susceptible strain of *C. albicans*.** Stephanie A. Flowers, Pharm.D.<sup>1</sup>, Katherine S. Barker, Ph.D.<sup>2</sup>, P. David Rogers, Pharm.D., Ph.D.<sup>2</sup>; (1)University of Tennessee, Memphis, TN; (2)University of Tennessee College of Pharmacy, Memphis, TN

**PURPOSE:** *ERG11*, which encodes the ergosterol biosynthesis enzyme lanosterol demethylase, can contribute to fluconazole resistance by its overexpression due to GOF mutations in transcription factors like Upc2, or by *ERG11* mutations that interfere with binding of azole antifungals. Although mutations in *ERG11* are associated with azole resistance, the specific contribution of these mutations to fluconazole resistance in a *C. albicans* background has not been explored.

**METHODS:** In 29 clinical isolates with decreased fluconazole susceptibility, both alleles of *ERG11* and *UPC2* were sequenced. We selected six mutant alleles (K143R, G464S, Y132F, V488I, G488S and S405F) to express homozygously or with a wild-type allele in an azole-susceptible background strain, SC5314. For the constructed strains, we tested resulting FCZ susceptibility and *ERG11* expression by q-RT-PCR.

**RESULTS:** We found that 23 of the 29 clinical isolates carried at least one mutation in *ERG11* that resulted in an amino acid substitution in the predicted protein sequence. Mutations in *ERG11* were observed in isolates that also carried a mutation in *UPC2*. Decreased FCZ susceptibility was observed for strains expressing alleles containing the K143R, G464S, Y132F, V488I and S405F substitutions. When expressed homozygously, the K143R substitution resulted in a fourfold increase in FCZ MIC as compared to SC5314. The Y132F substitution increased FCZ MIC by twofold. Likewise, the G464S substitution, the V488I substitution and the S405F substitution each increased FCZ MIC by onefold. Interestingly, distinct mutations in *ERG11* resulted in altered *ERG11* expression in these constructed strains.

**CONCLUSION:** These findings indicate that mutations in *ERG11* are prevalent in a large group of clinical isolates and most *ERG11* mutations characterized in our study contribute to decreased fluconazole susceptibility and influence *ERG11* expression. Our sequence data show that *ERG11* mutations occur with *UPC2* mutations. We suspect that the collective result of these mutations has a significant impact on fluconazole susceptibility. Presented at ICAAC, San Francisco, CA, September 9–12, 2012

**131. Transcriptional regulation of fluconazole susceptibility in *Candida parapsilosis*.** Eileen Wanamaker, B.S.<sup>1</sup>, Minlu Zhang, Ph.D.<sup>2</sup>, Long J. Lu, Ph.D.<sup>2</sup>, Phillip J. Dexheimer, M.S.<sup>2</sup>, Kelly E. Caudle, Pharm.D., Ph.D.<sup>1</sup>; (1)James L. Winkle College of

Pharmacy, University of Cincinnati, Cincinnati, OH; (2)Cincinnati Children's Hospital Medical Center, Cincinnati, OH

**PURPOSE:** *Candida parapsilosis* is a major (yet understudied) cause of mucosal and invasive fungal infections in the United States. The development of high level azole resistance in *C. parapsilosis* has recently been reported in bloodstream isolates. The ability to develop resistance to this antifungal class during therapy or prophylaxis makes this a significant problem in the management of candidiasis.

**METHODS:** Using a new genome-wide expression study technique (RNA-Seq) and real-time RT-PCR, we identified regulatory networks involved in azole resistance in *C. parapsilosis*. We compared the changes in gene expression between clinical matched fluconazole-susceptible and -resistant *C. parapsilosis* isolates representing the development of high-level azole antifungal resistance during a course of fluconazole therapy used to treat endocarditis (isolate set 35177 (MIC < 1 µg/ml) versus 35176 (MIC > 64 µg/ml) and during routine use of fluconazole prophylaxis in a NICU (isolate set KC18 [MIC < 2 µg/ml] versus KC23 [MIC > 64 µg/ml]).

**RESULTS:** Although these isolates have similar azole susceptibility patterns, the mechanisms of resistance appear to be different. The 35176 isolate had increased expression of genes encoding proteins involved in the ergosterol biosynthesis pathway, the target of the azole antifungals. The KC23 isolate had increased expression of genes encoding major facilitator transporter proteins which are known to efflux fluconazole out of the cell in other *Candida* species.

**CONCLUSION:** The contribution of this research is detailed understanding of the molecular pathways involved in azole resistance in *C. parapsilosis* and is expected to lead to development of pharmacologic strategies that will circumvent the problem of azole resistance in all *Candida* species. As these pathways are controlled by fungal specific transcriptional regulators in other *Candida* species, further studies are being conducted to elucidate the transcriptional control of these pathways in these *C. parapsilosis* clinical isolates.

### 132. Doripenem pharmacokinetics and pharmacodynamics in obese patients hospitalized in an intensive care unit.

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**PURPOSE:** To evaluate the pharmacokinetics and pharmacodynamics of doripenem in obese patients who are hospitalized in an intensive care unit.

**METHODS:** Patients with a BMI > 40 kg/m<sup>2</sup> or who were >100 pounds over their ideal body weight and who were hospitalized in an intensive care unit were enrolled. All patients received doripenem 0.5 g IV q8h, infused over 1 h. Serial blood samples and urine were collected at steady-state, and doripenem concentrations were determined by ultraperformance liquid chromatography with tandem mass spectrometry detection. Pharmacokinetic parameters were estimated (best fit two-compartment model), and 5000-patient Monte Carlo simulations were performed to calculate the probability of target attainment (PTA) at specific MICs using a pharmacodynamic target of 40% fT > MIC. Cumulative fraction of response (CFR) was calculated using MIC data for eight gram-negative pathogens from the TRUST surveillance program (TRUST 11-13).

**RESULTS:** Ten patients were studied. Patient demographics were (mean ± SD): age 53 ± 10 years; weight 173 ± 37 kg; BMI 59.6 ± 16.8 kg/m<sup>2</sup>; measured CLcr 138 ± 42 ml/minute. Mean ± SD C<sub>max</sub>, C<sub>min</sub>, terminal elimination rate, elimination half-life, V<sub>c</sub>, V<sub>ss</sub>, CLs, and CLr were 15.4 ± 3.4 µg/ml, 1.5 ± 0.7 µg/ml, 0.24 ± 0.08/hour, 3.2 ± 1.1 hour, 24.5 ± 8.7 L (0.14 ± 0.04 L/kg), 44.6 ± 13.8 L (0.26 ± 0.06 L/kg),

13.0 ± 3.2 L/hour, and 6.7 ± 3.1 L/hour, respectively. PTA was ≥ 92% for MICs ≤ 2 mg/ml. CFR was ≥ 98% for the six enteric gram-negative pathogens, 88.1% for *P. aeruginosa*, and 64.3% for *Acinetobacter* species.

**CONCLUSIONS:** For obese patients hospitalized in an intensive care unit, doripenem 0.5 g IV q8h provides adequate pharmacodynamic exposures for bacterial pathogens with MICs ≤ 2 µg/ml. However, larger or alternative dosing regimens may be required for less susceptible pathogens.

### 133. Comparative pharmacokinetics and pharmacodynamics of doripenem and meropenem in obese patients.

*Michael B. Kays, Pharm.D.<sup>1</sup>, Megan R. Fleming, Pharm.D.<sup>2</sup>, S. Christian Cheatham, Pharm.D.<sup>3</sup>, Christina E. K. Chung, Pharm.D.<sup>1</sup>, JoEtta Juenke, B.S., C(ASCP)<sup>4</sup>; (1)Purdue University College of Pharmacy, Indianapolis, IN; (2)Methodist Dallas Medical Center, Dallas, TX; (3)Franciscan St. Francis Health - Indianapolis, Indianapolis, IN; (4)ARUP Institute for Clinical and Experimental Pathology, Salt Lake City, UT*

**PURPOSE:** To compare the pharmacokinetics and pharmacodynamics of doripenem and meropenem in obese patients.

**METHODS:** Obese patients (BMI > 40 kg/m<sup>2</sup> or >100 pounds over IBW) hospitalized on a general ward with CLcr ≥ 50 ml/minute were randomized to receive doripenem 0.5 g q8h (1-hour infusion) or meropenem 1 g q8h (0.5-hour infusion). Serial blood samples were collected at steady-state, and drug concentrations were determined by ultraperformance liquid chromatography with tandem mass spectrometry detection. Pharmacokinetic parameters were estimated, and 5000-patient Monte Carlo simulations were performed to calculate the probability of target attainment (PTA) at specific MICs using a pharmacodynamic target of 40% fT > MIC. Cumulative fraction of response (CFR) was calculated using MIC data for eight gram-negative pathogens from the TRUST surveillance program (TRUST 11-13).

**RESULTS:** Twenty patients were studied. Mean ± SD BMI was 65 ± 28 and 65 ± 17 kg/m<sup>2</sup> for doripenem and meropenem, respectively. Pharmacokinetic data are shown below. PTA was >90% for MICs ≤ 2 and ≤ 4 mg/ml for doripenem and meropenem, respectively. For both drugs, CFR was ≥ 90% for the six enteric gram-negative pathogens and *P. aeruginosa*, but only 66-71% for *Acinetobacter* species.

	Doripenem	Meropenem	p-Value
C <sub>max</sub> (µg/ml)	21.0 ± 7.4	62.6 ± 16.3	<0.0001
C <sub>min</sub> (µg/ml)	1.6 ± 1.5	4.9 ± 4.2	0.033
t <sub>1/2β</sub> (h)	2.7 ± 0.9	2.8 ± 1.4	NS
V <sub>c</sub> (L)	15.7 ± 6.7	13.1 ± 5.5	NS
V <sub>ss</sub> (L)	32.2 ± 12.2	25.1 ± 9.1	NS
CLs (L/h)	11.7 ± 4.1	8.1 ± 2.6	0.03

**CONCLUSIONS:** For obese patients hospitalized on a general ward, doripenem 0.5 g q8h and meropenem 1 g q8h provide adequate pharmacodynamic exposures for enteric gram-negative pathogens and *P. aeruginosa*. Based on these data, dose escalation of these carbapenems based solely on obesity is unnecessary.

### 134. Population pharmacokinetics and pharmacodynamics of piperacillin, administered with tazobactam by prolonged infusion, in morbidly obese and non-obese patients.

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**PURPOSE:** To evaluate the population PK/PD of piperacillin, when administered with tazobactam by prolonged infusion (PI), in morbidly obese and non-obese patients.

**METHODS:** Serial serum piperacillin concentrations (n=197) were collected at steady-state from 13 hospitalized patients with a BMI < 40 kg/m<sup>2</sup> who received piperacillin/tazobactam 4.5 g q8h and from 14 hospitalized patients with a BMI > 40 kg/m<sup>2</sup> who

received piperacillin/tazobactam 4.5 or 6.75 g q8h. All doses were infused over 4 h. Population PK/PD analyses were performed using NONMEM. A total of 5000-patient Monte Carlo simulations were performed to estimate piperacillin PK profiles for 4 PI (4-hour infusion) regimens: 3.375 g q8h, 4.5 g q8h, 6.75 g q8h, and 9.0 g q8h. Probability of target attainment (PTA) for  $\geq 50\%$   $f/T > MIC$  was calculated at MICs ranging from 1 to 64  $\mu\text{g/ml}$ .

**RESULTS:** A one-compartment model best fit the PK data. Creatinine clearance (CRCL), total body weight (TBW), and body mass index (BMI) were the most significant covariates affecting piperacillin PK. CRCL and TBW were significantly correlated with systemic clearance, and BMI was significantly correlated with volume of distribution. For patients with BMIs  $< 50 \text{ kg/m}^2$ , PTA was  $>90\%$  for regimens  $\geq 4.5 \text{ g q8h}$  at MICs  $\leq 16 \text{ mg/ml}$ , but only 9.0 g q8h achieved a PTA  $> 90\%$  at an MIC of 32 mg/ml. For patients with BMIs  $> 50 \text{ kg/m}^2$ , PTA was  $> 90\%$  for regimens  $\geq 6.75 \text{ g q8h}$  at MICs  $\leq 16 \text{ mg/ml}$ ; however, no regimen achieved a PTA  $> 90\%$  at an MIC of 32 mg/ml.

**CONCLUSIONS:** Piperacillin PK is altered in morbid obesity, and larger doses should be utilized in these patients. Based on this population PK/PD analysis, patients with a BMI  $> 50$  and  $<50 \text{ kg/m}^2$  should be treated empirically with 4-h infusions of 6.75 g and 4.5 g q8h, respectively.

**135. Evaluation of compatibility and stability of daptomycin in an antibiotic-anticoagulant lock solution.** P. Brandon Bookstaver, Pharm.D., BCPS, AQ-ID, AAHIVE, Padmavathy N. Premnath, M.Pharm., Ph.D.Candidate, Julie M. Edwards, Pharm.D. Candidate; South Carolina College of Pharmacy – USC Campus, Columbia, SC

**PURPOSE:** To evaluate the in vitro stability and compatibility of daptomycin in novel antimicrobial-anticoagulant combination lock solutions.

**METHODS:** Candidate lock solutions included daptomycin (D) 1 mg/ml in solution with different combinations of heparin (H), trisodium citrate (TSC), azithromycin (A) and/or gentamicin (G). Lactated Ringer's solution was added to provide a total volume of 5 ml. Chemical stability was assessed by a determination of degradation of the components of the admixture. Drug concentration was assessed via Waters Alliance HPLC using Phenomenex Luna C8(2), 150  $\times$  2.6 mm, 5  $\mu$  column. A gradient run was carried out for 20 minutes with 0.45% ammonium dihydrogen phosphate, pH 3.25 as eluent A and acetonitrile as eluent B at a flow rate of 1.0 ml/min. Each test solution was visually inspected for particulate matter and color change. Lock solutions were prepared in glass vials and tested in triplicate.

**RESULTS:** Table 1. Daptomycin concentrations of test solutions at 48, 72 and 96 hours.

Lock Solution	48 hours,%	72 hours,%	96 hours,%
D 1 mg/ml + H 1000 units/ml	101.18	98.33	83.99
D1 mg/ml + H 100 units/ml	101.16	99.42	82.12
D 1 mg/ml + TSC 28 mg/ml (2.8%)	102.41	101.94	93.26
D 1 mg/ml + A 5 mg/ml + H 1000 units/ml	101.79	101.84	91.45
D 1 mg/ml + A 5 mg/ml + H100 units/ml	101.54	100.33	101.36
D 1 mg/ml + A 5 mg/ml + TSC 28 mg/ml (2.8%)	101.37	101.27	103.31
D 1 mg/ml + G 3 mg/ml	97.18	91.56	78.99
D 1 mg/ml + G 3 mg/ml + TSC 28 mg/ml (2.8%)	90.66	86.69	81.55

Daptomycin concentrations were maintained  $\geq 90\%$  of baseline for all solutions at 48 hours. Gentamicin concentrations (not shown in table) remained  $\geq 95\%$  of baseline for the full 96-hour study period.

**CONCLUSION:** This study confirms the stability and compatibility of daptomycin in combination with select antimicrobials and additives in lock solutions. The extended stability of  $\geq 48$  hours

may allow for ease in preparation, longer catheter dwell times and less frequent exchanges without compromising in situ effectiveness.

**136. Recurrent *Clostridium difficile* infection (rCDI) is a risk factor for rehospitalization.** Marya D. Zilberberg, M.D., M.P.H.<sup>1</sup>, Kimberly Reske, Ph.D., M.P.H.<sup>2</sup>, Kerry Bommarito, M.D., Ph.D.<sup>2</sup>, Margaret Olsen, M.P.H.<sup>2</sup>, Yan Yan, M.D., MSPH<sup>1</sup>, Marcie E. Strauss, M.P.H.<sup>3</sup>, Erik Dubberke, M.D., M.P.H.<sup>1</sup>; (1)EviMed Research Group, LLC, Goshen, MA; (2) Washington University School of Medicine, St. Louis, MO; (3) Optimer Pharmaceuticals, Inc., Jersey City, NJ

**PURPOSE:** Hospitalization is one of the strongest drivers of healthcare costs. Recurrent *Clostridium difficile* infection (rCDI) is common and patients with rCDI are frequently rehospitalized. It is hypothesized that rCDI is an independent risk factor for a rehospitalization.

**METHODS:** This is a retrospective cohort study of all adult patients with an initial case of CDI (iCDI) at Barnes-Jewish Hospital (BJH) from January 1, 2003 to December 31, 2009. The observation period for rehospitalization was 180 days from the rCDI or end of the risk period for rCDI. An iCDI episode was defined as a positive toxin assay for *C. difficile* with no CDI in the previous 60 days. rCDI was defined as symptomatic patients with repeat positive toxin within 42 days of stopping the iCDI treatment. Patients with  $\geq 1$  rehospitalization were compared to those not rehospitalized based on their demographic characteristics, rCDI status, comorbidities, laboratory data and treatment exposures. A generalized linear model was developed to estimate the impact of rCDI on the risk of a rehospitalization.

**RESULTS:** Among the 3601 patients with iCDI, 1471 (41%) were rehospitalized. Of the 432 patients with rCDI, 362 (84%) were rehospitalized. Independent risk factors for rehospitalization on multivariate analysis included rCDI (relative risk [RR] = 2.15, 95% confidence interval [CI] = 2.01–2.30), non-white race (RR = 1.13, 95% CI = 1.04–1.22), prior admissions to the hospital before iCDI (RR = 1.24, 95% CI = 1.15–1.34), receipt of  $>10$  days of vancomycin (RR = 1.10, 95% CI = 1.00–1.24), a receipt of 5–10 days low-CDI risk antibiotics (RR = 1.14, 95% CI = 1.01–1.28), receipt of  $>10$  days low CDI risk antibiotics (marker for severity-of-illness) (RR = 1.13, 95% CI = 1.01–1.27), and 11 comorbidities (range of RR = 1.17–1.55). Age  $\geq 70$ , not receiving a fluoroquinolone or low-CDI risk antibiotic, and an elevated WBC at time of iCDI were protective against rehospitalization. Age  $\geq 70$  likely appeared protective due to competing risk of death.

**CONCLUSION:** rCDI was the risk factor most strongly associated with rehospitalization

**137E. Comparison of bacterial pneumonia etiology in dialysis versus non-dialysis patients.** Nicole C. Farrell, Pharm.D., Jason M. Cota, Pharm.D., M.S., Cheryl K. Horlen, Pharm.D., Russell T. Attridge, Pharm.D., M.S.; University of the Incarnate Word Feik School of Pharmacy, San Antonio, TX

**PURPOSE:** There are limited data to characterize pneumonia pathogens among patients on chronic hemodialysis (HD). The primary objective of this study was to compare the incidence of selected pneumonia pathogens (methicillin-resistant *Staphylococcus aureus* [MRSA], *Pseudomonas*, and *Streptococcus pneumoniae*) between chronic HD patients and non-HD patients.

**METHODS:** Data from 2009 to 2010 were collected from the U. S. CDC National Hospital Discharge Survey, an annual survey of short-stay, non-federal hospitals. Pneumonia, comorbidities, and pathogens were determined using ICD-9-CM codes. Data weights were used to provide population estimates. Pneumonia cases were required to have been admitted from a community setting and have a principal ICD-9-CM diagnosis of pneumonia or a secondary diagnosis of pneumonia if accompanied by a primary diagnosis of sepsis or respiratory failure. Cases were excluded if patient age was  $<18$  or hospital length-of-stay (LOS) was  $<1$  day. Statistical significance was defined as  $p < 0.0001$ . Dichotomous variables were compared using chi-square tests. LOS was compared using the Wilcoxon rank-sum test.

**RESULTS:** There were 2,217,040 community-dwelling pneumonia cases identified; 72,334 cases (3.3%) had end-stage renal disease requiring chronic HD. Median age was 71 (inter-quartile range 57–82). MRSA accounted for 64% of all *Staphylococcus aureus* cases. *Pseudomonas pneumonia* was more common in HD versus non-HD cases (33.6 *Pseudomonas pneumoniae* per 1000 pneumonia cases versus 16.8 per 1000 cases;  $p < 0.0001$ ), while MRSA pneumonia was increased in the non-HD cohort (32.2 per 1000 cases versus 15.5 per 1000 cases,  $p < 0.0001$ ). *S. pneumoniae* rates were lower in HD versus non-HD cases (9.6 per 1000 cases versus 33.6 per 1000 cases;  $p < 0.0001$ ). Compared to non-HD patients, HD patients had increased in-hospital mortality (9.7 versus 6.9%;  $p < 0.0001$ ) and median LOS (6 versus 5 days;  $p < 0.0001$ ).

**CONCLUSION:** Chronic HD in community-dwelling pneumonia patients is associated with an increased incidence of *Pseudomonas pneumonia* and significantly worse health outcomes versus non-HD patients.

Submitted for presentation at ID week, a joint meeting of Infectious Diseases Society of America, the Society for Healthcare Epidemiology of America, HIV Medicine Association, and Pediatric Infectious Diseases Society; San Diego, CA; October 17–21, 2012.

**138. Daptomycin outcomes by duration of methicillin-resistant *Staphylococcus aureus* bacteremia with vancomycin MIC > 1 mg/L.** Kenneth C. Lamp, Pharm.D., Maria I. Amodio-Groton, Pharm.D., Min J. Yoon, M.P.H.; Cubist Pharmaceuticals, Lexington, MA  
**PURPOSE:** *Staphylococcus aureus* bacteremia duration is often correlated with complications and outcome. Current guidelines recommend alternative treatment when MRSA have vancomycin MICs  $\geq 2$  mg/L. This analysis presents daptomycin (DAP) clinical outcomes by MRSA duration in the presence of elevated vancomycin MICs.

**METHODS:** All patients (pts) with MRSA bacteremia (MRSA-B), excluding catheter-related, were identified from a retrospective, multicenter, observational registry with a vancomycin MICs of  $\geq 1.5$  mg/L. Definition of bacteremia duration: number of days between first and last positive blood culture or time until negative culture if within 3 days of index culture, all others were classified as unknown. Pt characteristics and outcomes are based on the efficacy population. All pts were included in the safety analysis.

**RESULTS:** There were 97 pts with MRSA-B; 95 evaluable for outcomes (92/95 vancomycin MIC = 2 mg/L). Demographics: 48% male, 47%  $\geq 65$  years of age, 13% on dialysis, 22% received DAP treatment in the ICU, and 35% had severe sepsis. DAP median dose was 6 mg/kg in each MRSA-B duration group. Antibiotics prior to DAP were given in 72 pts (76%); primarily vancomycin (93%, 67/72). Concomitant antibiotics were used with DAP in 42 pts (44%) and was not different by bacteremia duration. The most frequent concurrent infections included endocarditis (13%), bone/joint infections (12%) and skin infections (11%). DAP median (min, max) duration of treatment was 11 days (2, 62). Success occurred in 88% (cured 43%, improved 45%). Success by bacteremia duration was:  $\leq 1$  day (100%, 3/3),  $>1$  to  $<3$  days (100%, 33/33),  $\geq 3$  days (92%, 11/12), and unknown (79%, 37/47). Serious adverse events were reported in 17 pts (18%); none were possibly-related to DAP. Two pts discontinued DAP due to adverse event. The overall mortality rate was 20% (19/97).

**CONCLUSION:** In this real-world population, DAP appeared to be a useful agent for MRSA with a VAN MIC  $\geq 1.5$  mg/L.

## Managed Care

**139. Assessment and evaluation efficacy of a clinical pharmacist-led inpatient warfarin knowledge education program and follow up at a Chinese tertiary referral teaching hospital.** Guy-Armel Bounda, B.Sc.(Pharm.), M.Sc.(Clin., Pharm.), Ph.D.Candidate(Clin., Pharm.)<sup>1</sup>, Cosette Ngarambe, B.Sc.(Med.)<sup>2</sup>, Wei Hong GE, B.Sc.(Pharm.), M.Sc.(Clin., Pharm.)<sup>3</sup>, Feng Yu, B.Sc.(Med.), M.Sc., Ph.D.<sup>1</sup>; (1)China Pharmaceutical University, Nanjing, China; (2)Southeast University, Nanjing, China; (3)The Affiliated Drum

Tower Hospital of Nanjing University Medical School, Nanjing, China

**PURPOSE:** This study aims to evaluate clinical pharmacist-led inpatient warfarin knowledge education program and to assess a follow up efficacy in at a Chinese tertiary referral teaching hospital.

**METHODS:** One-on-one interviews questionnaire were conducted among 47 Chinese patients who had undergone prosthetic valve replacement. Before the patient education program's implementation, at discharge time and 3, 6 and 12 months after surgery were considered as time points. A previously validated 17-item questionnaire was used to measure the patient's knowledge level of warfarin and to assess and evaluate a follow up efficacy of this patient education program run by a clinical pharmacist. Knowledge scores were compared using the Student t test or one-way analysis of variance.

**RESULTS:** Patients mean age was  $47.68 \pm 9.70$  years (range 23–67). The higher education strata had significantly higher warfarin knowledge scores ( $p < 0.05$ ; Table 2). In terms of hospital stay post-surgery, compared to others groups, patients with an average of 11–14 days, were found significantly and statically higher knowledgeable in Warfarin ( $p < 0.05$ ; Table 2). The clinical pharmacist' service was found very satisfied  $f$  (80.85%).

**CONCLUSION:** Chinese patients on warfarin therapy should benefit from periodic educational efforts reinforcing key medication safety information. Patient education is not a once-off procedure. A complete patient education program run by a clinical pharmacist in a cardio-thoracic ward can considerably improve and enhance to reduce the hospital stays and significantly enlighten the role of the patient education in adherence to therapy.

## Medication Safety

**140. Impact of a pharmacist-conducted admission medication reconciliation program on medication errors.** Mitchell S. Buckley, Pharm.D., FCCM, BCPS<sup>1</sup>, Craig A. Wesley, Pharm.D.<sup>1</sup>, Butch David, Pharm.D.<sup>1</sup>, Pamela L. Smithburger, Pharm.D., BCPS<sup>2</sup>, Sandra Kane-Gill, Pharm.D., M.S., FCCM<sup>2</sup>, Sandeep Devabhakthuni, Pharm.D.<sup>3</sup>, Earnest Alexander, Jr, Pharm.D.<sup>4</sup>, Lisa M. Harinstein, Pharm.D.<sup>5</sup>; (1)Banner Good Samaritan Medical Center, Phoenix, AZ; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (3)University of Maryland School of Pharmacy, Baltimore, MD; (4)Tampa General Hospital, Tampa, FL; (5)Cleveland Clinic, Cleveland, OH

**PURPOSE:** The purpose of this study was to (i) determine the medication error rate identified upon admission medication reconciliation; (ii) describe the error type, proximal cause, and potential severity, and; (iii) determine the time allocated in conducting medication reconciliation.

**METHODS:** This was a single-center, concurrent study conducted at a major teaching medical institution. Following IRB approval, data collection was conducted over a 4-week period (August 22, 2011 to September 16, 2011). Descriptive statistical methods were performed for all data analysis.

**RESULTS:** A total of 517 patients involving 5006 medications were included in this study. Over 25% ( $n=132$ ) of patients had  $\geq 1$  error associated with a medication prescribed upon hospital admission, which was resolved through pharmacist intervention. Pharmacists resolved a total 467 admission medication errors, which translated into  $3.5 \pm 2.3$  (mean  $\pm$  SD) medication errors per patient. The most common type of medication error resolved by the pharmacist upon hospital admission was medication omission (79.6%) followed by wrong dose (12.6%) and wrong frequency (4.3%). In regards to severity, 46% of medication errors were considered significant or serious. Overall, the mean ( $\pm$ SD) total time was  $44.4 \pm 21.8$  minutes per medication reconciliation.

**CONCLUSION:** A significant number of medication errors were identified and resolved by pharmacist intervention during the admission medication reconciliation process. Pharmacist involve-

ment in the admission medication reconciliation process demonstrated significant improvement in patient safety.

**141. Assessment of inpatient boxed warning compliance.** *Megan A. Kloet, Pharm.D.<sup>1</sup>, Pamela L. Smithburger, Pharm.D., BCPS<sup>2</sup>, Amy L. Seybert, Pharm.D., FASHP, FCCP<sup>2</sup>, Sandra L. Kane-Gill, Pharm.D., M.S., FCCM, FCCP<sup>2</sup>; (1)University of Pittsburgh Medical Center, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA*

**PURPOSE:** Boxed warnings (BW) are the most serious type of safety warning mandated by the United States Food and Drug Administration. Prescriber compliance to BWs was assessed to determine how often general medicine patients are prescribed a medication that is non-compliant to a BW, to evaluate reasons for prescriber non-compliance, and to assess the possibility of a consequential adverse drug reaction (ADR).

**METHODS:** Approval was obtained for this evaluation as a quality improvement project by the Total Quality Council at our institution. For 10 weeks, general medicine patients were evaluated for medication orders with an actionable BW, defined as a warning that allowed for intervention by a pharmacist. When BW non-compliance occurred, the physician was contacted and a reason for non-compliance was determined. Patients that received a medication non-compliant to a BW were monitored for an ADR until discharge, and causality analysis was performed with published tools to determine if a suspected reaction was related to the BW non-compliance.

**RESULTS:** A total of 224 patients were evaluated for non-compliance of 149 actionable BWs. There were 175 drugs with BWs prescribed, of which 107/175 (61%) were medications restarted from home. A total of 23 BW non-compliances occurred in 18 patients, and 13/23 (57%) occurred with home medications. Non-steroidal anti-inflammatories (NSAIDs) were the most common BW medication involved (81%), and the reasons for non-compliance were equally split between knowledge deficit and risk-to-benefit ratio. One possible ADR occurred related to a drug-drug interaction with ritonavir and antiarrhythmic co-administration.

**CONCLUSION:** This project illustrates BW non-compliance is a problem in the general medicine population, specifically in patients with high cardiovascular risk that are prescribed NSAIDs. Over half of BW non-compliance occurred in medications restarted from home, which emphasizes the need for improved transitions of care.

**142. High-risk medications on pharmacy discount program formularies; a brief report.** *Abir O. Kanaan, Pharm.D.<sup>1</sup>, Jennifer L. Donovan, Pharm.D.<sup>1</sup>, Darren M. Triller, Pharm.D.<sup>2</sup>, Shawn Gagne, B.S.<sup>3</sup>, Jennifer Tjia, M.D., MSCE<sup>3</sup>; (1)Massachusetts College of Pharmacy and Health Sciences, Worcester, MA; (2)IPRO, Albany, NY; (3)Meyers Primary Care Institute, University of Massachusetts Medical School, Worcester, MA*

**PURPOSE:** The Medicare Modernization Act provided prescription drug coverage to Medicare and Medicaid beneficiaries to improve Medicare and address drug costs faced by the elderly. Simultaneously, large chain pharmacies offered discounted generic drug programs to attract consumers. The purpose of this study was to determine the prevalence of high-risk medications on pharmacy discount formularies compared to insurer formularies.

**METHODS:** In this descriptive study, the formulary lists of the top five leading pharmacy operators in 2007 (CVS, Kroger, Rite Aid, Walgreens, and Wal-Mart) and a comparator group of tier-one prescription drug formularies of four health insurers in the United States (Community CCRx, Humana, UnitedHealthcare, and WellCare) were surveyed for the presence of two types of high-risk medications: drugs with black box warnings (BBW) or drugs on the Beers list. To identify and enumerate these drugs, an analyst programmed Microsoft Excel to match pharmacy and insurer formularies to Beers and BBW medications based on the active pharmaceutical ingredient. The number of matches was

enumerated as the percentage of formulary drugs that overlapped with the Beers and BBW lists.

**RESULTS:** Pharmacy formularies had an average of 158.4 medications (range 143–175) and tier-one insurance formularies had an average of 358 medications (range 112–476). The average number of Beers list drugs present on pharmacy formularies was 26.2 (16.5%) (range 25–30 [17.5–18.6%]) and on tier-one insurance formularies was 42 (11.7%) (range 17–54 [9.9–15.2%]). The average number of BBW drugs present on pharmacy formularies was 58.8 (37.1%) (range 55–63 [34.5–39.1%]) and on tier-one insurance formularies was 114 (31.8%) (range 52–140 [27.7–46.4%]). Common to both pharmacy and insurer formularies were nine Beers list medications and 27 BBW medications.

**CONCLUSION:** The presence of high-risk medications is common and not unique to generic pharmacy discount programs, making the potential for prescribing these drugs similar amongst both pharmacy and insurer formularies.

**143. Does interprofessional medication reconciliation from admission to discharge reduce post-discharge patient emergency department visits and hospital readmissions?** *Michelle Baker, B.Sc. Pharm.<sup>1</sup>, Chaim M. Bell, M.D., Ph.D.<sup>2</sup>, Wei Xiong, M.Sc.<sup>1</sup>, Edward Etschells, M.D., M.Sc.<sup>3</sup>, Peter Rossos, M.D., M.B.A.<sup>1</sup>, Kaveh Shojania, M.D.<sup>3</sup>, Kelly Lane, B.Sc.<sup>1</sup>, Tim Tripp, B.Sc., MLIS<sup>1</sup>, Mary Lam, B.Sc.<sup>1</sup>, Kimindra Tiwana, B.Sc.Pharm.<sup>4</sup>, Nita Dhir, M.B.A.<sup>1</sup>, Derek Leong, B.Sc.Pharm.<sup>1</sup>, Gary Wong, B.Sc.Pharm.<sup>1</sup>, Jin Huh, B.Sc. Pharm.<sup>1</sup>, Emily Musing, MHS<sup>1</sup>, Olavo Fernandes, Pharm.D.<sup>1</sup>; (1)University Health Network, Toronto, ON, Canada; (2)St. Michael's Hospital, Toronto, ON, Canada; (3)Sunnybrook Health Sciences Centre, Toronto, ON, Canada; (4)Institute for Safe Medication Practices Canada, Toronto, ON, Canada*

**PURPOSE:** To evaluate the impact of integrated interprofessional (pharmacist-prescriber) medication reconciliation on patient emergency department visits and hospital readmissions.

**METHODS:** The setting for this retrospective, observational cohort study was two tertiary-care teaching hospitals. Patient records were obtained from hospital administrative databases. All hospitalized patients who were discharged by General Internal Medicine (GIM), Cardiology, and Multi-Organ Transplant services during the selected time periods were examined. The intervention group (patients receiving interprofessional admission to discharge reconciliation supported by an electronic platform) was compared to a control group of those not receiving interprofessional discharge reconciliation. The outcome was defined as a composite of emergency department or hospital readmissions within 30 days of the index discharge. A multivariate logistic regression model was used to adjust for age, gender, number of medications, and LACE index.

**RESULTS:** From 2007 to 2011, a total of 24,524 unique patient visits (n=20,319 patients) met the criteria of the study. The main analysis of GIM patients (n=8678) did not detect a difference in outcomes between the intervention group (540/2541) and control (1423/7390) for the primary endpoint of 30 day post-discharge hospital visits. The adjusted odds ratio was 1.058 (21.25% versus 19.26%, 95% CI 0.945–1.19, p=0.326). Increasing number of medications, LACE index score, as well as male gender were independently correlated with a higher risk of hospital visits (univariate analysis). Also, subgroup analyses of high-risk groups: patients  $\geq 65$  years, LACE index  $\geq 10$ , those on high-alert medications, and  $\geq 10$  medications also did not detect a statistically significant outcome difference between groups.

**CONCLUSION:** A 5 year observational evaluation of interprofessional medication reconciliation did not detect a difference in 30 day post-discharge patient hospital visits. Future prospective studies could focus on an enhanced reconciliation intervention bundle on avoidable "medication-related" hospital admissions and post-discharge adverse drug events.

## Nephrology

**144E. Effects of the ESRD Medicare bundling rule on anemia management in private dialysis units.** *Natsuki Kubotera, B.S.*, Amy Barton Pai, B.S., Pharm.D., BCPS, Katie Cardone, Pharm.D.; Albany College of Pharmacy and Health Sciences, Albany, NY

**PURPOSE:** Reform of the CMS ESRD payment policy in January 2011 required bundled payments for previously separated billable drugs. Given the cost difference between erythropoiesis stimulating agents and IV iron, this study evaluated implications of the new bundling rule on anemia management.

**METHODS:** This was a retrospective cohort study of in-center hemodialysis (IHD), home hemodialysis (HHD) & peritoneal dialysis (PD) patients at two private, nonprofit dialysis centers in Upstate New York. Medical record & laboratory data were pooled and evaluated for time periods Jan 2010 – April 2010 (pre-bundle) and from January 2011 – April 2011 (post-bundle). All patients with available anemia medication use data were included. Monthly epoetin alfa (EPO) and IV iron sucrose (IVFe) doses were analyzed pre- and post-bundling. All available monthly [hemoglobin] for study patients were collected.

**RESULTS:** A total of 1470 patient-months were evaluated, IHD = 1061 months, HHD = 288 months, PD = 121 months. Among IHD patients receiving EPO, mean (SD) monthly doses significantly decreased after the bundle was imposed, 62,758 (69,034) versus 44,140 (45,454) units, respectively ( $p < 0.001$ ). For those on IVFe, mean monthly doses significantly increased from 306 (221) to 453 (290) mg ( $p < 0.001$ ). Mean hemoglobin concentrations were significantly lower after implementation of the bundle 11.1 (1.4) compared to 11.6 (1.4) g/dL pre-bundle ( $p < 0.001$ ). Similar drug use shifts were observed in both the HHD and PD patients. Both the HHD and PD groups had a 0.5 g/dl reduction in Hb concentrations in the post-bundle observation period ( $p < 0.001$  in both groups).

**CONCLUSIONS:** Since the revision of the ESRD Conditions for Coverage, we observed significant decreases in EPO and increases in IVFe doses. Hemoglobin concentrations were significantly reduced, but remained within target range. Given long-term safety concerns with EPO and IV iron, practice pattern changes related to the bundled drug coverage policy should continue to be closely evaluated with regard to patient outcomes.

Presented at the American Society of Nephrology Renal Week, Philadelphia, PA, November 9–13, 2011.

**145. Incidence and predictors of hepatitis B vaccine non-response among hemodialysis patients.** *Magdalene M. Assimon, Pharm.D., M.S.<sup>1</sup>*, Emily Bruni, Pharm.D. Student<sup>1</sup>, Louise-Ann McNutt, Ph.D.<sup>2</sup>, Darius L. Mason, Pharm.D., BCPS<sup>1</sup>, Nimish Patel, Pharm.D., M.S., AAHIVP<sup>1</sup>; (1) Albany College of Pharmacy & Health Sciences, Albany, NY; (2) University at Albany, School of Public Health, Rensselaer, NY

**PURPOSE:** Tremendous strides have been made to protect hemodialysis (HD) patients from bloodborne pathogen infections, including hepatitis B virus (HBV) vaccination. Despite routine immunization against HBV in the HD population, antibody response is often variable and inadequate. The objectives of this study were to quantify the incidence and identify risk factors of HBV vaccine non-response among maintenance HD patients.

**METHODS:** A retrospective cohort study was conducted at Rubin Dialysis Centers between January and June 2011. Inclusion criteria were: age  $\geq 18$  years, uninfected with HBV, received  $\geq 1$  HBV vaccine dose (Recombivax HB<sup>®</sup>) as a HD patient and availability of hepatitis B surface antibody (anti-HBs) titers to classify outcome status. Vaccine non-response was defined as an anti-HBs titer  $< 10$  mIU/ml. Due to the high proportion ( $> 10\%$ ) of patients with titers  $< 10$  mIU/ml, log-Poisson regression was used to determine factors independently associated with vaccine non-response.

**RESULTS:** During the study period 119 patients (51% female, 85% Caucasian, 40% diabetic etiology) were identified. At the time of first vaccine dose, mean  $\pm$  SD age was  $62.9 \pm 15.5$  years and median (IQR) HD vintage was 13.1 (3.1–34.4) months. Overall, 50% of patients failed to achieve anti-HBs titers  $\geq 10$  mIU/

ml after receiving the primary vaccine series. Of primary series non-responders, 17 patients received subsequent doses and only 24% ( $n=4$ ) achieved titers  $\geq 10$  mIU/ml. In multivariate analyses, age  $\geq 58$  years (RR [95% CI] = 1.65 [1.08, 2.51];  $p=0.02$ ), BMI  $\geq 36.4$  kg/m<sup>2</sup> (RR [95% CI] = 1.81 [1.08, 2.51];  $p < 0.01$ ) and receiving  $\geq 4$  vaccine doses (RR [95% CI] = 1.64 [1.22, 2.21];  $p < 0.01$ ) were independently associated with HBV vaccine non-response.

**CONCLUSION:** Older age and obesity appear to be important predictors of HBV vaccine non-response among HD patients. Attainment of protective anti-HBs titers after primary HBV vaccine series and supplemental doses was suboptimal, suggesting current HBV immunization strategies in the HD population may be ineffective and warrants further investigation.

**146. Comparison of the Chronic Kidney Disease Epidemiology Collaboration, modification of diet in renal disease, and Cockcroft-Gault equations for drug dosing in the elderly population.** *M. Shawn McFarland, Pharm.D.<sup>1</sup>*, Christina F. Burger, Pharm.D.<sup>1</sup>, Alex K. Stephens, Pharm.D.<sup>1</sup>, Joanna Q. Hudson, Pharm.D.<sup>2</sup>, Jennifer R. Bean, Pharm.D.<sup>1</sup>; (1) VA Tennessee Valley Healthcare System, Murfreesboro, TN; (2) University of Tennessee, Memphis, TN

**PURPOSE:** The Cockcroft-Gault (CG) equation provides an estimate of creatinine clearance (CrCl) and has been the standard for dosing medications based on kidney function. The Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) and Modification of Diet in Renal Disease (MDRD) equations provide an estimate of glomerular filtration rate (eGFR), are more accurate for staging CKD, and have recently been advocated for drug dosing. The primary objective of this study was to determine whether a dosing discordance exists for a selected group of renally eliminated medications in an elderly population when using CKD-EPI or MDRD to estimate kidney function versus CG.

**METHODS:** Patients  $\geq 65$  years of age were included in this retrospective, observational analysis. A theoretical dosing simulation was conducted by calculating eGFR and eCrCl to determine whether a dose adjustment was recommended per the manufacturers' labeling for the following renally eliminated medications: allopurinol, enoxaparin, gabapentin, piperacillin/tazobactam, sulfamethoxazole/trimethoprim. Data was analyzed for discordance among the three estimating equations for drug dosing.

**RESULTS:** A total of 4160 patients were included: 98% male, 79% Caucasian, mean age  $74 \pm 7.4$  years, mean eCrCl  $61 \pm 19$  ml/minute, mean eGFR/BSA (MDRD)  $75 \pm 21$  ml/minute, mean eGFR/BSA (CKD-EPI)  $75 \pm 23$  ml/minute. The observed dosing discordance was: allopurinol 0.5%, enoxaparin 2.9%, gabapentin 27.1%, piperacillin/tazobactam 9.1%, and sulfamethoxazole/trimethoprim 3.1%.

**CONCLUSION:** CG led to medication adjustments more often than CKD-EPI and MDRD. Use of eGFR as opposed to eCrCl for medication dosing resulted in higher doses being prescribed more often in the elderly population.

## Neurology

**147. ANCHOR-CD (Abobotulinumtoxin A Neurotoxin: Clinical and Health Economics Outcomes Registry in Cervical Dystonia): a multicenter, observational study of dysport in cervical dystonia: baseline data and cycle one outcomes data.** *Jack J. Chen, Pharm.D.<sup>1</sup>*, Richard M. Trosch, M.D.<sup>2</sup>, Cynthia L. Comella, M.D.<sup>3</sup>, Steven B. Hall, R.Ph.<sup>4</sup>, Yavuz Silay, M.D., M.B.A.<sup>4</sup>, Chandra M. Coleman, Ph.D.<sup>4</sup>, Stephen F. Chang, Ph.D.<sup>4</sup>, Dominic Marchese, R.Ph.<sup>4</sup>; (1) Loma Linda University, Loma Linda, CA; (2) William Beaumont School of Medicine, Oakland University, Southfield, MI; (3) Rush University Medical Center, Chicago, IL; (4) Ipsen Biopharmaceuticals, Basking Ridge, NJ

**PURPOSE:** ANCHOR-CD is a prospective, open-label, observational study of adult patients with idiopathic cervical dystonia (CD) designed to evaluate real life patient response and health

economics data from patients treated with abobotulinumtoxinA (known as Dysport®). Interim efficacy (cycle one) and patient satisfaction outcomes data are reported.

**METHODS:** Prospective, open-label, observational study of adult patients with idiopathic CD. Efficacy assessments include: the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS), Pain Numeric Rating Scale (NRS), Clinical Global Impression of Change (CGIP), Patient Global Impression of Change (PGIC), and Treatment Satisfaction Questionnaire for Medication (TSQM).

**RESULTS:** Baseline patient demographic, history, and health economic data were collected from 155 patients enrolled at 40 US clinical sites. Treated population comprised of 76% females and 24% males, mean age 58.2 years. Types of dystonic neck posturing included torticollis (81.3%), laterocollis (50.3%), retrocollis (25.8%), and anterocollis (16.1%). The median abobotulinumtoxinA dose was 500 Units. The most frequently injected muscles were the splenius capitis, levator scapulae, trapezius, semispinalis capitis, and sternocleidomastoid. Preliminary analysis included 122 patients who completed follow-up assessments for treatment cycle one. Mean (SD) TWSTRS total score was 40.3 (16.7) at baseline and 27.3 (15.5) at 4 week follow-up demonstrating -13.1 (9.2) mean change or 33% improvement compared to baseline. Mean (SD) Pain NRS score was 4.9 (3.0) at baseline and 3.6 (2.7) at 4-week follow-up demonstrating -1.4 (2.6) mean change compared to baseline. A 63.9% of physicians 40.2% of patients rated much improved and very much improved for the CGIC and PGIC, respectively.

**CONCLUSION:** Physicians and cervical dystonia patients treated with abotulinumtoxinA reported improvements in the severity, disability and pain of CD.

**148. Relationship between the metabolic syndrome and C-reactive protein with stroke prevalence.** Stacy A. Voils, Pharm.D.; Virginia Commonwealth University Health System, Richmond, VA

**PURPOSE:** Identify any relationship between metabolic syndrome and CRP concentrations with stroke prevalence.

**METHODS:** Subjects >19 years old completing the 2009–2010 National Health and Nutrition Examination Survey (NHANES), a nationally representative, complex sample combining interviews and physical examinations, were included. Metabolic syndrome was defined as having at least three of the following: hypertension, insulin resistance, hypertriglyceridemia, low HDL cholesterol, or high waist circumference. Elevated CRP was defined as >2 mg/L. Multivariate logistic regression modeling accounting for clustering and unequal probability of selection in complex samples was used to assess the relationship between CRP and metabolic syndrome with stroke prevalence. Potential interaction between CRP and metabolic syndrome was also statistically assessed.

**RESULTS:** A total of 6210 subjects met the inclusion criteria and were included in the analysis. Two-thirds of subjects were 20–55 years old, 52% were female, and the overall stroke prevalence was 2.6%. Metabolic syndrome prevalence was 29% overall, 21% in subjects 20–55 years old, and 46% in subjects >55 years old. Stroke prevalence in those without metabolic syndrome was 1.3% (% population attributable risk = 50%). Multivariate logistic regression modeling revealed a significant association between stroke prevalence and advanced age (OR: 2.1 [1.0–4.3]), African-American race (OR: 2.6 [1.2–5.7]), and metabolic syndrome (OR: 3.6 [1.5–8.3]). Smoking (OR: 0.92 [0.46–1.8]) or elevated CRP levels (OR: 1.8 [0.35–9.1]) were not associated with stroke prevalence. No evidence of interaction was found between CRP levels and metabolic syndrome.

**CONCLUSION:** Age >55 years, African-American race, and the metabolic syndrome were the most powerful predictors of stroke prevalence. Although elevated CRP has previously been shown to be associated with stroke prevalence, we did not find an association between CRP and stroke prevalence when controlling for other risk factors.

## Nutrition

**149E. Omega-3 long-chain polyunsaturated fatty acids attenuate bile acid-induced apoptosis via Fas-dependent pathways.** Emma M. Tillman, Pharm.D.<sup>1</sup>, Richard A. Helms, Pharm.D.<sup>2</sup>, Dennis D. Black, M.D.<sup>1</sup>; (1) University of Tennessee Health Science Center, Memphis, TN; (2) University of Tennessee, Memphis, TN

**PURPOSE:** Clinical studies have demonstrated improvement of parenteral nutrition (PN)-associated liver disease (PNALD) with omega-3 long chain polyunsaturated fatty acid (ω3PUFA) containing eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). One possible mechanism is attenuation of apoptosis induced by high levels retained hydrophobic bile acids (chenodeoxycholic acid [CDCA]) thereby activating death receptors. The aim of this study was to define specific apoptotic pathways through which ω3PUFA attenuate CDCA induced apoptosis.

**METHODS:** Cultured HepG2 cells were treated for 0.5 hours with 200 μmol/L CDCA in the presence and absence of ω3PUFA (5 μmol/L EPA + 5 μmol/L DHA). Eighty-four genes involved in apoptosis were evaluated using quantitative RT-PCR.

**RESULTS:** There was a 286-fold increase in Fas ligand (FasL) mRNA levels when cells were incubated with CDCA alone, compared to a 9.8-fold increase in FasL mRNA levels when incubated with CDCA with the addition of ω3PUFA (p<0.01). There was a 1.4-fold increase in Fas with CDCA alone, and a 2.0-fold decrease when treated with CDCA+ ω3PUFA. There was a 38-fold increase in Fas-associated death domain (FADD) mRNA levels when cells were incubated with CDCA alone, as compared to a 3.8-fold increase in FADD mRNA levels when incubated with CDCA and ω3PUFA (p<0.01). There was a 142-fold increase in caspase 8 (CASP8) mRNA levels when cells were incubated with CDCA alone, as compared to 45-fold increase in CASP8 mRNA levels when incubated with both CDCA and ω3PUFA (p<0.01).

**CONCLUSIONS:** Treatment with CDCA increased expression of FasL, Fas, FADD, and CASP8 genes and the addition of ω3PUFA resulted in less fold-increase in each of these mediators. This suggests attenuation of bile acid-induced apoptosis occurs via reduction of Fas ligand, thereby reducing binding to Fas and the activation of FADD and CASP8 necessary for mitochondrial amplification to trigger apoptosome formation, indicating that this pathway may have relevance to the pathophysiology and treatment of PNALD.

Presented at the American Association for Study of Liver Disease (AASLD) Annual Meeting, San Francisco, CA, November 5, 2011.

## Oncology

**150. An evaluation of the drug-drug interaction between proton-pump inhibitors and EGFR tyrosine kinase inhibitors in non-small cell lung cancer patients.** Alexandre Chan, Pharm.D., M.P.H.<sup>1</sup>, Bingrong Chen, B.Sc.Pharm.(Hon.)<sup>1</sup>, Raymond Ng, MBChB, FRACP, M.P.H.<sup>2</sup>, Wei-Peng Yong, MBChB, MRCP<sup>3</sup>, Yu Ko, Ph.D.<sup>1</sup>; (1) National University of Singapore, Singapore, Singapore; (2) National Cancer Centre Singapore, Singapore, Singapore; (3) National University Cancer Institute, Singapore, Singapore

**PURPOSE:** Pharmacokinetic studies have suggested that proton-pump inhibitors (PPI) may reduce bioavailability of epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKI). This study aims to examine the impact of the co-administration of EGFR-TKI and PPI on treatment outcomes in non-small cell lung cancer (NSCLC) patients.

**METHODS:** This was a retrospective, observational study conducted at the largest ambulatory cancer center in Singapore. All patients diagnosed with NSCLC receiving EGFR-TKI (gefitinib or erlotinib) between January 2007 to December 2010 were included in this study. All traceable baseline patient characteristics from the date of EGFR-TKI initiation to the date of death or the last follow up date, whichever occurred first, were obtained from the electronic databases and medical records. Treatment outcomes measured in this study included overall survival (OS),

progression-free survival (PFS) and tumor response (with or without disease progression). Cox regression analysis and multivariate logistic regression were conducted for data analysis.

**RESULTS:** A total of 237 eligible patients were included in the final analysis (median age = 67.0 years). Majority of the patients were female (69.2%), diagnosed with Stage 4 NSCLC (65.8%) and received gefitinib (91.6%). Two groups were formed based on PPI exposure, and PPI were concomitantly used with EGFR-TKI among 107 (45.1%) patients. Baseline characteristics were similar between these two groups. Comparing the clinical outcomes between with and without co-administration of PPI, no significant difference was observed in mean OS (13.1 versus 12.8 months;  $p=0.30$ ), mean PFS (10.1 versus 9.0 months,  $p=0.37$ ) or the proportion of patients without disease progression (24.5% versus 30.0%,  $p=0.24$ ).

**CONCLUSION:** This is the largest study to date to evaluate the interaction between PPI and EGFR-TKI among NSCLC patients. Our findings suggest that concomitant use of TKI and PPI may not compromise treatment outcomes.

**151. Correlation of EGFR (epidermal growth factor receptor) mutation status with Gefitinib response rate used as second-line therapy in patient with metastatic non-small-cell lung cancer.** *Sagar Pravinchandra Kansara, M.Pharm.*<sup>1,2</sup>, Varsha J. Galani, M.Pharm., Ph.D.<sup>1,2</sup>, Chirag J. Desai, M.D., D.M. (Oncology)<sup>1,2</sup>; (1) A.R. College of Pharmacy and Hemato-Oncology Clinic, Vedanta Institute of Medical Sciences, Ahmedabad, India; (2) A.R. College of Pharmacy at Anand, Gujarat, India

**PURPOSE:** The aim of the study was to evaluate the efficacy of gefitinib and the epidermal growth factor receptor (EGFR) mutation to gefitinib response in a series of patients with pretreated advanced non-small-cell lung cancer (NSCLC).

**METHODS:** A total of 20 patients who had failed at least one First line chemotherapy cycle received gefitinib 250 mg once daily. The mutation analysis of the EGFR kinase domain was performed for 20 patients using paraffin-embedded tumor tissue.

**RESULTS:** The response rate was 30% and the disease control rate was 75%. Objective response was correlated with Adenocarcinoma, female gender and non-smokers. The median PFS for patient with EGFR (+Ve) mutation was  $8.08 \pm 2.67$  months whereas it was  $5.25 \pm 0.707$  months for patients without the mutation. PFS for patient with EGFR (+) mutation was significant longer than patient with EGFR (-) mutation. ( $p=0.0303$ ). Active gene mutation was detected in 20 patients. Mutation rates were higher in Male patients than Female patients. There was no significant difference in smoking status, pathological features, responder and non-responder between patient with EGFR (+) mutation and patient with EGFR (-) mutation.

**CONCLUSION:** Gefitinib demonstrated significant antitumor activity with a less toxicity profile for pretreated patients with advanced NSCLC. Gefitinib prolonged progression free survival in patient with EGFR (+) mutation as compared to patient with EGFR (-) mutation. There is nosignificant relationship between EGFR mutation status and Gefitinib response rate in pretreated NSCLC patients.

**152E. Phase I results of decitabine in combination with midostaurin (PKC412) for elderly (age  $\geq 60$ ) newly diagnosed or relapsed/refractory adult patients with AML.** *Casey B. Williams, Pharm.D., BCOP*<sup>1</sup>, Suman Kambhampati, M.D.<sup>2</sup>, Siddhartha Ganguly, M.D.<sup>2</sup>, Omar Aljitiawi, M.D.<sup>2</sup>, Jo Wick, Ph.D.<sup>2</sup>, Ruben Reyes, M.D.<sup>2</sup>, Allan Fleming, M.D.<sup>2</sup>, Kapil Bhalla, M.D.<sup>2</sup>, Sunil Abhyankar, M.D.<sup>2</sup>, Joseph McGuirk, D.O.<sup>2</sup>; (1) Sanford Research/USD, Sioux Falls, SD; (2) University of Kansas Medical Center, Kansas City, KS

**PURPOSE:** To determine the maximum-tolerated dose (MTD) and recommended Phase II dose of midostaurin, a multi-targeted tyrosine kinase inhibitor with demonstrated activity in patients with AML with FLT3 mutations, combined either sequentially (days 8–21) or concurrently (days 1–28) with intravenous decitabine 20 mg/m<sup>2</sup> days 1–5 in elderly newly diagnosed or relapsed/refractory adult patients with AML.

**METHODS:** Sixteen patients (median age, 68 years) were enrolled; eight were untreated and eight had relapsed AML. Only 2 of 16 patients (13%) had FLT3 ITD mutations and no patient had KIT mutations.

**RESULTS:** The MTD and schedule of the combination that was identified in this trial was decitabine followed by sequential midostaurin (cohort 2). Three patients (from cohorts 2 and 3) developed dose limiting toxicities: two patients developed pulmonary edema requiring mechanical ventilation and one patient developed a prolonged QTc > 500 millisecond. Of the eleven patients evaluable for response, 82% achieved stable disease or better while on trial. Four of the 11 patients (36%) had a complete hematologic response (two patients had a complete cytogenetic response). Pharmacokinetic analysis revealed results that were similar to what has been previously reported for midostaurin.

**CONCLUSION:** The combination of decitabine with sequential midostaurin is possible without significant unexpected toxicity, but the concurrent administration of the combination led to pulmonary toxicity after only a few doses. On the basis of these results, additional studies exploring the combination in untreated AML in elderly patients are warranted to further evaluate this combination at the MTD. Presented in part at the 53rd Annual Meeting of the American Society of Hematology, December 9–13 2011, San Diego, CA and the 7th Annual Meeting of the Hematology/Oncology Pharmacy Association, March 23–26, 2011, Salt Lake City, UT.

**153. Efficacy of single dose rasburicase in prophylaxis and treatment of tumor lysis syndrome: a metaanalysis.** *Xiaodong Feng, Ph.D., Pharm.D.*, Kevin Dong, Pharm.D. Student, Dan Pham, Pharm.D. Student, John Inciardi, Pharm.D., D.Sci., Nilesh Bhutada, Ph.D.; California Northstate University College of Pharmacy, Rancho Cordova, CA

**PURPOSE:** This metaanalysis study evaluated the efficacy of single dose rasburicase (SDR) comparing with FDA approved daily dosing of rasburicase (DDR) for 5 days in adults with hyperuricemia or at high risk for TLS.

**METHODS:** Metaanalysis of prospective and retrospective studies were retrieved from systemic search of major electronic data sources. Studies included in the metaanalysis were those with SDR for the prophylaxis of high risk TLS or treatment of hyperuricemia in adults. The results of response rate and controlling of time dependent plasma uric acid reduction were pooled and compared with the results from patients treated with DDR for 5 days or patients treated with allopurinol.

**RESULTS:** Nine studies (seven retrospective and two prospective) evaluated the response rate and reduction of plasma uric acid level monitored over time. The pooled total number of patients treated with SDR (from 0.15 to 0.2 mg/kg) was 254. The pooled response rate of SDR was not inferior to DDR (0.2 mg/kg) for 5 days (response rate: 88.24% versus 90.18%), but much stronger than that of allopurinol (300 mg/day orally days 1–5) treatment group (response rate 88.24% versus 66%). Although pooled SDR group efficiently controlled the uric acid level below 4.5 mg/dl over 12, 24, 48 and 72 hours, its controlling of plasma uric acid was inferior to that of DDR. Furthermore, the controlling of uric acid level for pooled higher single dose treatment ( $\geq 6$  mg) was stronger than that of pooled low single dose group ( $< 6$  mg).

**CONCLUSION:** SDR for adults with hyperuricemia or at high risk for TLS demonstrated better response rate and stronger controlling of uric acid level compared to allopurinol. SDR response rate was not inferior to that of DDR. Additional randomized control studies are needed to confirm this metaanalysis study.

**154E. An evaluations of the incidence of proteinuria and hypertension in patients receiving shorter infusions of bevacizumab.** *Sachin R. Shah, Pharm.D., BCOP*<sup>1</sup>, Sarah M. Gressett Ussey, Pharm.D., BCOP<sup>2</sup>; (1) Texas Tech University Health Sciences Center School of Pharmacy/VA North Texas Health Care System, Dallas, TX; (2) Bristol Myers Squibb, Waxahachie, TX

**PURPOSE:** The FDA approved minimum duration for bevacizumab administration is a 30 minute intravenous infusion. A previous study has shown that shorter, 0.5 mg/kg/minute, bevacizumab infusions can be safely administered without increasing the risk for infusion-related hypersensitivity reactions. However, the risk of proteinuria and hypertension in patients receiving shorter infusion of bevacizumab is undetermined. Purpose of this study was to evaluate the incidence of proteinuria (primary objective) and hypertension in patients receiving shorter infusions of bevacizumab.

**METHODS:** This is a multicenter, prospective, observational study in patients receiving less than 10 mg/kg dose of bevacizumab infused over 0.5 mg/kg/minute. Patients with prior bevacizumab exposure were excluded from the study. Patients were observed on this trial until discontinuation of bevacizumab for progression of cancer or toxicity.

**RESULTS:** Sixty-three patients received a total of 392 doses of shorter bevacizumab infusions. Of these, 22 patients received bevacizumab at a dose of 5 mg/kg and 41 patients received a dose of 7.5 mg/kg. Nineteen (30.2%) patients experienced proteinuria while receiving bevacizumab. Out of 19 patients, 13 had grade 1 and 6 had grade 2 proteinuria. None of the patients experienced grade 3 or 4 proteinuria. Hypertension was reported in 32 (50.8%) patients receiving bevacizumab. Twelve (19%) patients developed grade 3 or greater hypertension on bevacizumab.

**CONCLUSION:** A shorter, 0.5 mg/kg/minute bevacizumab infusions does not increase the risk of proteinuria and hypertension. The incidences of proteinuria and hypertension are similar to that previously reported with the standard infusion rate of bevacizumab.

Presented at the Hematology Oncology Pharmacists Association (HOPA) Conference, Orlando, FL, March 21–23, 2012.

**155. Pilot study: valproic acid effectiveness in minimizing incidence of seizures in postoperative pediatric brain tumor patients.** Sherif Kamal<sup>1</sup>, Maggie M. Abbassi, Ph.D.<sup>2</sup>, Sherif Abouelnaga, Ph.D.<sup>3</sup>, Azza M. Agha, Ph.D.<sup>4</sup>; (1) Children Cancer Hospital Egypt 57357, Cairo, Egypt; (2) Faculty of Pharmacy, Cairo, Egypt; (3) Children cancer Hospital Egypt, Cairo, Egypt; (4) Faculty of Pharmacy, Cairo, Egypt

**PURPOSE:** To assess valproic acid effectiveness in postoperative seizure prophylaxis in pediatric brain tumor patients.

**METHODS:** A retrospective review of pediatric brain tumor patients was performed to evaluate the effect of VPA on postoperative seizure prophylaxis. The patients were monitored for a period of 3 months postoperatively to determine whether VPA was effective in prophylaxis from seizures. The data collected included the patients' age, sex, weight, prescribed antiepileptic drugs (AED), platelet count, albumin, liver enzymes, duration of VPA treatment, serum VPA concentration and any other medications the patients were receiving. Any clinical intervention and any drug interaction were recorded.

**RESULTS:** Sixty patients were eligible for this study, 27 patients received VPA and 33 received no AED. Seven patients from the VPA group had a history of seizures compared to two patients only in the non-VPA group. Postoperatively, a total of eight patients had seizures, one patient in the VPA group with an onset of 36 days, and six patients in the non-VPA group with an average onset of 32 days. Comparing the incidence of seizures postoperatively using Fisher's exact test, the difference between the two groups was not statistically significantly different ( $p=0.11$ ).

**CONCLUSION:** Although VPA tended to reduce the incidence of seizure events and to delay the onset of seizures postoperatively in brain tumor patients, the difference did not reach statistical significance. Further studies are needed to investigate this difference on a larger number of patients to examine whether the difference observed is real.

**156. High-dose bolus interleukin-2: correlating response rate with number of doses received.** Jolly Patel, Pharm.D., Dawn Goetz, Pharm.D., BCOP, Mayer Fishman, M.D., Ph.D., Ragini Kudchadkar, M.D.; H. Lee Moffitt Cancer Center, Tampa, FL

**PURPOSE:** The administration of high-dose interleukin-2 (IL-2) in metastatic renal cell carcinoma and metastatic melanoma has led to higher response and survival rates when compared to low dose and subcutaneous administration. In patients who achieve a response, some are complete responses, but at the expense of toxicity. It is of interest to correlate response rate with the number of doses or cumulative dose received. The primary objective of this study is to determine if there is a direct relationship with response and cumulative dose or the total number of doses received.

**METHODS:** A retrospective chart review was conducted of all patients at H. Lee Moffitt Cancer Center diagnosed with metastatic renal cell carcinoma or metastatic melanoma who received high dose IL-2 from September 30, 1999 to September 30, 2010. The cumulative dose and the number of doses of IL-2 received was recorded and associated with response (complete response, partial response, stable disease or progressive disease). Pertinent data was also collected to determine the incidence of toxicity.

**RESULTS:** In the metastatic renal cell carcinoma population, 31 out of 55 patients analyzed achieved a response to IL-2. Patients who received a higher number of doses and higher cumulative dose were more likely to respond ( $p=0.0272$  and  $p=0.0077$ , respectively). In the metastatic melanoma population, 18 out of 57 patients analyzed achieved a response. Patients who received a higher number of doses and higher cumulative dose were more likely to respond to therapy ( $p=0.0013$  and  $p=0.007$ , respectively).

**CONCLUSION:** Cumulative dose and number of doses received are associated with a statistically significant difference in response rate.

**157. Investigating the in vivo effects of dexamethasone using a human disease relevant mouse model of glioblastoma.** Amira Hosni-Ahmed, B.S.<sup>1</sup>, Ken Pitter, B.S.<sup>2</sup>, Eric Holland, M.D., Ph.D.<sup>2</sup>, Terreia Jones, Pharm.D.<sup>1</sup>; (1) University of Tennessee Health Science Center, Memphis, TN; (2) Memorial Sloan-Kettering Cancer Center, New York, NY

**PURPOSE:** Glioblastoma (GBM) is the most common and malignant primary brain tumor overall. Standard therapy includes dexamethasone for symptom management prior to surgical resection and DNA damaging therapy (temozolomide, radiation); and in many cases maintenance on dexamethasone through post-operative radiation therapy. It is not known how dexamethasone works in glioma or if it influences the response to DNA damaging therapy. The goal of our study was to investigate the effects of dexamethasone in glioma and elucidate possible mechanisms of action using a PDGF-driven mouse model of GBM.

**METHODS:** We treated glioma-bearing mice with 10 mg/kg/day of dexamethasone for 3 days and collected tissue for immunohistochemical and microarray analysis. In vitro studies were performed using primary glioma cultures to validate in vivo findings.

**RESULTS:** We found that the majority of the differentially expressed genes were down-regulated by dexamethasone and were involved in cell cycle proliferation; which was confirmed by PCNA and Ki67 immunohistochemistry. When these genes were analyzed in The Cancer Genome Atlas (TCGA) GBM data set, we found that high expression of the genes down-regulated by dexamethasone predicts a significantly longer survival compared to tumors with lower levels. Studies of glioma cultures treated in vitro suggest that dexamethasone may work indirectly through the tumor microenvironment; and microarray analysis of tumor and tumor-associated microglial cells provides insight into possible mechanisms of action.

**CONCLUSION:** Our data suggests that dexamethasone inhibits tumor cell proliferation, possibly through a tumor-microenvironment interaction. TCGA analysis suggests that down-regulation of our dexamethasone-induced gene set may have an adverse effect on survival. It is possible that a decrease in tumor cell proliferation may decrease the efficacy of antineoplastic therapy that is most toxic to proliferating cells. This study confirms the importance of defining the mechanism of how dexamethasone affects tumor and stromal cells in glioma.

**158. Obesity and carboplatin dosing in gynecologic oncology patients.** Cory R. Bivona, Pharm.D.<sup>1</sup>, Susan Klenke, R.Ph., BCO<sup>1</sup>; Gary Johnson, M.D.<sup>2</sup>, Casey B. Williams, Pharm.D., BCO<sup>3</sup>; (1)University of Kansas Hospital, Kansas City, KS; (2)University of Kansas Cancer Center, Kansas City, KS; (3)Sanford Research/USD, Sioux Falls, SD

**PURPOSE:** This retrospective study illustrates the relationship between body weight, dose of carboplatin and treatment outcomes for patients with gynecologic malignancies.

**METHODS:** A retrospective chart review of 100 patients who received carboplatin from the University of Kansas Hospital for the treatment of gynecologic malignancies between July 1, 2009 and June 30, 2011 was performed. Medical records were reviewed for indication, dosing weight, stage, performance status, dose modifications, concurrent chemotherapy, granulocyte colony stimulating factor (GCSF) use, platelet count, serum albumin, serum creatinine, cancer antigen 125 (CA-125) levels, robotic versus open surgery, and adjuvant versus neoadjuvant therapy. Outcomes were evaluated by a student t-test.

**RESULTS:** After evaluating 100 patients, a statistically significant difference in platelet response was discovered when actual versus adjusted body weight was used for carboplatin calculations (38.7% versus 44.0%;  $p=0.009$ ). When stratifying by GCSF utilization, a more robust platelet response was seen when GFR was calculated by actual body weight and GCSF was utilized (45.6% versus 40.3%;  $p=0.022$ ), but not if GCSF was excluded (41.1% versus 32.9%;  $p=0.053$ ). A significant difference was also found in patients with a serum albumin less than 3.5 g/dl (45.1% versus 40.2%,  $p=0.019$ ) and a trend was observed when comparing intensity of therapy in obese compared to non-obese patients. No difference in progression-free interval was encountered when evaluating CA-125 levels.

**CONCLUSIONS:** Using adjusted body weight when calculating the dose of carboplatin in patients with gynecologic malignancies significantly diminished platelet response in patients receiving GCSF as well as the combined group. A trend towards significance was seen in the non-GCSF group. Serum albumin concentrations and obesity also influence the extent of hematologic toxicity.

## Other

**159. Reduction in toll-like receptor-4 (tlr-4) on blood mononuclear cells after 3 weeks of rosuvastatin treatment in healthy male subjects.** Timothy R. McGuire, Pharm.D., FCCP, BCO<sup>1</sup>, Paul P. Dobesh, Pharm.D., FCCP, BCPS<sup>1</sup>, Donald G. Klepser, Ph.D.<sup>1</sup>, Andre C. Kalil, M.D.<sup>2</sup>, Keith Olsen, Pharm.D., FCCP<sup>1</sup>; (1)University of Nebraska Medical Center, Omaha, NE; (2)Internal Medicine, University of Nebraska Medical Center, Omaha, NE

**PURPOSE:** Rosuvastatin is a statin drug with major benefits in dyslipidemia. It may share many of the pleiotropic effects of this drug class one of which is a potential anti-inflammatory effect. One of the proposed anti-inflammatory mechanisms of statins is to modulate tlr-4 (LPS receptor) expression and a resulting reduction in the production of TNF-alpha and other anti-inflammatory cytokines.

**METHODS:** This study evaluated tlr-4 expression on blood mononuclear cells and plasma inflammatory cytokine concentrations before and after 3 weeks of rosuvastatin in 20 healthy male subjects. Plasma cytokine concentrations were analyzed before and after incubating blood samples with LPS. IL-8, sCD14, IL-6, IGF-1, and TNF-alpha were measured by sandwich-type ELISA (R&D Systems). The density of tlr-4 was measured using single color flow cytometry gating on mononuclear cell fraction with appropriate isotype controls.

**RESULTS:** Sixteen of 20 consented male patients between the ages of 22-38 years (avg. 27 years) were evaluable. Four subjects did not meet stringent inclusion criteria having minor elevations in bilirubin. The expression of tlr-4 on blood mononuclear cells was significantly lower after 3 weeks of rosuvastatin ( $p=0.046$ ). TNF-alpha release associated with ex-vivo treatment of blood with LPS trended lower after 3 weeks of rosuvastatin treatment ( $p=0.08$ ).

None of the other inflammatory markers (CRP, IL-8, sCD14, IL-6, and IGF-1) were modified with rosuvastatin treatment. There was a significant decline in cholesterol ( $p<0.0001$ ), LDL ( $p<0.0001$ ), and cholesterol/HDL ratio ( $p<0.0001$ ). However, there was no significant effect on triglycerides, VLDL, or HDL.

**CONCLUSION:** The decline in the percentage of blood mononuclear cells expressing tlr-4 and the near significant decline in plasma TNF levels after 3 weeks of rosuvastatin suggest a potential anti-inflammatory activity. The anti-inflammatory effect occurs on a similar timeline as its cholesterol lowering effects.

**160. Evaluation of Jamaican knowledge of diabetes and health beliefs.** Melody L. Hartzler, Pharm.D., AE-C<sup>1</sup>, Aleda M.H. Chen, Pharm.D., Ph.D.<sup>1</sup>, Bethany L. Murphy, Pharm.D.<sup>2</sup>, Sarah J. Rodewald, BSN<sup>3</sup>; (1)Cedarville University School of Pharmacy, Cedarville, OH; (2)Union University School of Pharmacy, Jackson, TN; (3)Miami Valley Hospital, Dayton, OH

**PURPOSE:** To (i) evaluate rural Jamaican patients' diabetes-related knowledge and health beliefs, (ii) determine the association between diabetes-related knowledge and health beliefs, and (iii) identify diabetes-related educational needs in rural Jamaica.

**METHODS:** Patients with diabetes were asked to voluntarily participate during a medical mission trip to the St. Elizabeth Province of Jamaica. Participants were asked to verbally complete the Spoken Knowledge in Diabetes Survey (SKILLD, 10 items) and Diabetes Health Beliefs Model Scale (DHBM, 11 items), as well as a demographics survey. Analyses were performed in SPSS v. 19.0. Frequencies were utilized for categorical variables, means for continuous, and medians for individual HBM items. Spearman or Pearson correlations were utilized to assess associations.

**RESULTS:** Participants (N=48) were mostly female (66.7%) and had completed primary school (60.4%). The average diabetes-related knowledge of participants was  $3.8 \pm 2.3$  (38% correct), with an average score of  $38.3 \pm 5.6$  (maximum score = 55, higher scores = readiness to take action) on the DHBM survey. There were no significant associations between participant knowledge and health beliefs or between health beliefs and any demographic variable. There was a statistically-significant, positive association between educational attainment and diabetes knowledge ( $r = 0.32$ ,  $p=0.03$ ). Less than 50% of participants answered questions correctly regarding signs and symptoms of high/low blood glucose, foot/eye exams, fasting blood glucose levels, and long-term complications. Only one participant gave a correct answer regarding normal hemoglobin A1c levels.

**CONCLUSIONS:** Among this population of rural Jamaican patients, general knowledge regarding diabetes remains low. Although results of this study did not find an association between disease knowledge and health beliefs, results of the DHBM survey indicate a readiness to take action regarding their diabetes. These results indicate a continued need to develop programs to provide diabetes-related education to patients living in rural Jamaica, as patients are ready to improve their management of diabetes.

**161. ACCP Ambulatory Care Practice and Research Network (PRN): recent PRN activities and assessment of membership diversity over the last decade.** Lea E. dela Pena, Pharm.D., BCPS<sup>1</sup>, Kassandra Bartelme, Pharm.D., BCACP<sup>2</sup>, Catherine A. Bourg, Pharm.D., BCPS, BCACP<sup>3</sup>, Jennifer D'Souza, Pharm.D., CDE, BC-ADM<sup>4</sup>, Katherine R. Gerrald, Pharm.D., BCPS, BCACP<sup>4</sup>, Brian K. Irons, Pharm.D., FCCP, BCACP, BCPS, BC-ADM<sup>5</sup>, Emily K. McCoy, Pharm.D., BCACP<sup>6</sup>, Daniel M. Riche, Pharm.D., BCPS, CDE<sup>7</sup>, Nicole Rockey, Pharm.D., BCACP<sup>1</sup>; (1)Midwestern University Chicago College of Pharmacy, Downers Grove, IL; (2)Concordia University Wisconsin School of Pharmacy, Mequon, WI; (3)University of Georgia, Athens, GA; (4)Presbyterian College School of Pharmacy, Clinton, SC; (5)TTUHSC School of Pharmacy, Lubbock, TX; (6)Auburn University, Harrison School of Pharmacy, Birmingham, AL; (7)University of Mississippi School of Pharmacy, Jackson, MS

**PURPOSE:** The objectives of this project are to update the ACCP membership on recent activities of the Ambulatory Care

PRN and to evaluate the diversity within the ACCP Ambulatory Care PRN by comparing 2012 survey results to similar surveys conducted as far back as 2003.

**METHODS:** Each of the PRN committee chairs were queried as to their recent activities. In addition, an internet-based questionnaire designed using SurveyMonkey™ queried the PRN members in May 2012 regarding training/degrees/certifications, practice setting, teaching and precepting responsibilities, and research. Survey results were compared to two previous and similar surveys, conducted in 2009 and 2003, to assess how the PRN's membership demographics have evolved.

**RESULTS:** Recent PRN activities include the development of a new webinar series providing up to date educational programming, a guide for new members to orient them to the PRN, and developing a resource guide of key disease state and ambulatory care issues. Results of the survey compare the basic demographics, practices, and credentials of the 2012 membership with those of the 2003 and 2009 membership surveys allowing for evaluation of key parameters of the PRN membership.

**CONCLUSIONS:** The Ambulatory Care PRN is vitally active in numerous ways providing its membership with new and exciting membership rewards. It is comprised of members with diverse job responsibilities and practice settings and continues to evolve over the last decade. Knowledge of changes in membership makeup may help the PRN plan meaningful and interesting educational programming and identify opportunities for its members to become more involved within the PRN and ACCP.

**162. Integrating clinical pharmacists and industrial engineers' perspectives to develop a codebook to characterize structure at anticoagulation clinics.** Abir O. Kanaan, Pharm.D.<sup>1</sup>, Jennifer L. Donovan, Pharm.D.<sup>1</sup>, Mustafa Ozkaynak, Ph.D.<sup>2</sup>, Sharon Johnson, Ph.D.<sup>2</sup>, Bengisu Tulu, Ph.D.<sup>2</sup>, Adam Rose, M.D.<sup>3</sup>; (1)Massachusetts College of Pharmacy and Health Sciences, Worcester, MA; (2)WPI, Worcester, MA; (3)Bedford VA Medical Center, Bedford, MA

**PURPOSE:** Health care quality is inferred from three constructs: structure, process, and outcomes. The literature on quality in anticoagulation clinics (ACCs) is focused on processes and care outcomes. Our interdisciplinary research aims to better understand the structural dimension of health care delivery in an ACC. The purpose of this study was to integrate clinical and industrial engineering perspectives to create a codebook that guides analysis of qualitative data to identify components of ACC structure that affect quality.

**METHODS:** Members from six ACCs within the Veterans Health Administration System (VHA) were interviewed to assess the quality of anticoagulation care delivery. A research team of two clinical pharmacists, three industrial engineers, and one physician was assembled to develop a codebook based on the interview data. Codes emerged from existing theory, raw data, and from our research goals and questions. Three coders (one industrial engineer and two clinical pharmacists) qualitatively analyzed interviews by inductive analysis and creative synthesis. Coders and other team members met regularly to discuss existing codes, develop new ones, clarify definitions, and share examples. Consensus was reached on all codes over a 6 month period through a multi-step sense-making process, beginning from the separate codes developed by each coder.

**RESULTS:** The codebook contains 46 codes describing components of the ACC structure and organized into nine categories: Organizational Factors, Technology, ACC Processes, Staff Related Issues, VHA Context, ACC Outcomes, Interactions with Other Clinics, Interaction with Patient, and Patient Related Factors. The codebook is an intermediate product of qualitative inquiry and also serves as a detailed description of important components related to ACC structure.

**CONCLUSION:** Clinical pharmacists and industrial engineers provided complementary perspectives for understanding the ACC structure. Such multidisciplinary collaborations can lead to unique insights with practical and theoretical implications for improving anticoagulation care.

**163. Patient satisfaction with an inpatient pharmacist-directed anticoagulation service.** Charles T. Makowski, Pharm.D.<sup>1</sup>, Carrie W. Nemerovski, Pharm.D., BCPS, (AQ-CV)<sup>2</sup>, Douglas L. Jennings, Pharm.D., BCPS, (AQ-CV)<sup>2</sup>, James S. Kalus, Pharm.D., BCPS, (AQ-CV)<sup>2</sup>; (1)Wayne State University Eugene Applebaum College of Pharmacy, Detroit, MI; (2)Henry Ford Hospital, Detroit, MI

**PURPOSE:** To describe the impact of an inpatient pharmacist-directed anticoagulation service (PDAS) on patient satisfaction.

**METHODS:** This IRB-approved study was conducted at an urban, tertiary hospital. PDAS is a clinical pharmacy service that has improved transition-of-care, safety, and efficacy involving anticoagulant usage at our institution. Patients receiving inpatient anticoagulation therapy, during February 2001–April 2007 (pre-PDAS) and December 2008–December 2010 (post-PDAS), who responded to a mail-in survey, were included. Survey items included SATISFACTION (*Overall, how satisfied were you with the medical care?*), AMTINFO (*How was the amount of information received about your medicine?*), CLARITY (*How was the clarity of the information received about your medicine?*), ANSWER (*How were the answers to your questions about your medicine?*), and SPEAK (*Did a pharmacist speak with you during your stay?*). Response options for AMTINFO, CLARITY, ANSWER, and SATISFACTION used a five-point scale, either where 1 = “very good” and 5 = “very poor” or, for SATISFACTION, 1 = “extremely satisfied” and 5 = “not at all satisfied”. Positive response = options 1–2. Negative response = options 3–5. For SPEAK, positive response = “yes” and negative response = “no”. Patient satisfaction equaled rate of positive responses. Primary analysis compared patient satisfaction between pre-PDAS and post-PDAS respondents.

**RESULTS:** Surveys were distributed to 1684 patients after discharge, with 689 (40.5%) responding. Post-PDAS respondents had improved patient satisfaction for all items (Table 1). Improvements were 72.5% for AMTINFO, 68.2% for CLARITY, 52.3% for ANSWER, 12.8% for SATISFACTION, and 149% for SPEAK.

Table 1. Positive responses, n (%).

	Pre-PDAS	Post-PDAS	p values
AMTINFO	271/528 (51.3)	138/156 (88.5)	<0.0001
CLARITY	272/527 (51.6)	138/159 (86.8)	
ANSWER	295/523 (56.4)	134/156 (85.9)	
SATISFACTION	439/528 (83.1)	149/159 (93.7)	
SPEAK	148/528 (28.6)	113/159 (71.1)	

**CONCLUSIONS:** PDAS, a focused program with a systematic approach to patient-pharmacist communication, improved patient satisfaction. Given the upcoming era of hospital value-based purchasing, the impact of this type of program on standardized hospital surveys should be further explored.

## Pain Management/Analgesia

**164. Opioid utilization patterns among cancer patients: an analysis using the chronic opioid medication use evaluation (MUE) tool.** Anisha M. Patel, M.S., Jacqueline A. Pesa, Ph.D., M.P.H., Andrew Howe, Pharm.D., Samir H. Mody, Pharm.D., M.B.A.; Janssen Scientific Affairs, LLC, Raritan, NJ

**PURPOSE:** Effective treatment with opioids for moderate-to-severe cancer pain depends on appropriate analgesic choice, dosing, monitoring, and side-effect management. This analysis aims to describe trends in real-world utilization of long acting opioids (LAOs) and chronic short acting opioids (SAOs) among cancer patients.

**METHODS:** The Chronic Opioid Medication Use Evaluation (MUE) software analyzed 2010 OptumInsight Clinformatics™ Data Mart pharmacy claims for enrollees with ≥ 1 LAO and/or chronic SAO (≥ 60 days continuous therapy) claim. Cancer cohort was identified with primary or secondary diagnosis of cancer; the reference cohort consisted of patients without a cancer diagnosis. Study measures included daily average consumption (DICON), concomitant GI medication, and acetaminophen (APAP) use.

**RESULTS:** A total of 26,732 and 78,059 unique patients comprised the cancer and reference population (mean age = 54 and 49 years), respectively. Nearly 61% of cancer and 73% of reference patients were on chronic SAOs, and <20% of these had a concurrent LAO. LAO utilization was higher in cancer than reference patients (56% versus 46%). The most commonly filled LAOs in the cancer and reference samples were: oxycodone CR (33%, 33%), fentanyl transdermal (27%, 21%), and morphine CR/ER/SR (18%, 19%), respectively, with the DACONs for morphine CR/ER/SR (2.5, 2.5) and oxycodone CR (2.7, 2.8) above the recommended range. Average APAP daily dose of 3.1–4.0 g/day and  $\geq 4.0$  g/day were observed for 5.4% and 1.5% of cancer and 5.2% and 1.2% of reference patients, respectively. About 16% of LAO and 19% of chronic SAO users in the cancer group began a GI prescription concurrently with or after starting opioid therapy, slightly higher than the reference group (11–13%).

**CONCLUSION:** Tools such as the Chronic Opioid MUE facilitate long-term monitoring of utilization and practice patterns for opioid treatment in cancer patients. This analysis identified APAP overload and chronic SAO use as potential areas of improvement for cancer and non-cancer pain patients.

**165. Assessment of impact of a pharmacist-run pain clinic on patient outcomes in hypertension, diabetes, and hyperlipidemia.** *Melissa R. Mahoney, B.S., Pharm.D., Jennifer Patton, Pharm.D.; Memphis VA Medical Center, Memphis, TN*

**PURPOSE:** This study explored whether pharmacist management of chronic pain results in subsequent improvements in markers of hypertension, hyperlipidemia and diabetes mellitus.

**METHODS:** Medical records of 66 veterans attending a pharmacist-run ambulatory pain clinic between August 1, 2010 and March 31, 2012 were reviewed. Baseline and post-pain clinic data collected included blood pressures, A1c, lipid panels, pain scores, weight, and BMI. Medication compliance was also assessed pre and post interventions by pain clinic pharmacist. Deviations from baseline values were analyzed using a student's paired t test and McNemar's test.

**RESULTS:** Reductions in systolic blood pressure ( $134 \pm 12$  versus  $130 \pm 13$ ,  $p=0.03$ ), diastolic blood pressure ( $78 \pm 8$  versus  $76 \pm 7$ ,  $p=0.04$ ), total cholesterol ( $202 \pm 53$  versus  $184 \pm 56$ ,  $p=0.009$ ), LDL cholesterol ( $122 \pm 48$  versus  $105 \pm 42$ ,  $p=0.008$ ), and pain scores ( $7.2 \pm 1.8$  versus  $6.6 \pm 2.4$ ,  $p=0.009$ ) following pain management by a clinical pharmacist were statistically significant. Reductions in A1c, triglycerides, weight, and BMI were not statistically significant nor was change in HDL cholesterol. Medication compliance increased post pain clinic, with the increases in medication compliance for hypertension (75% versus 91%,  $p=0.04$ ) and hyperlipidemia (61% versus 86%,  $p=0.001$ ) being statistically significant.

**CONCLUSIONS:** This study is one of the first to demonstrate the positive impact of pain management by a clinical pharmacist on chronic disease states. While increased medication compliance likely played a significant role in reducing blood pressure and improving cholesterol management, other contributing factors likely played a part. More studies with a larger sample size are needed to determine if pain management by a clinical pharmacist results in significant changes in A1c.

## Pediatrics

**166E. Success of a methadone treatment protocol in neonatal drug withdrawal following in-utero exposure to substances of abuse.** *Varsha Bhatt-Mehta, M.S., CRDSA, Pharm.D., FCCP, Robert E. Schumacher, M.D., Chee M. Ng, Pharm.D., Ph.D, FCP; University of Michigan, Ann Arbor, MI*

**PURPOSE:** To evaluate the effectiveness of a methadone treatment protocol for NAS.

**METHODS:** Neonates who received methadone treatment according to a preexisting treatment protocol were evaluated for treatment success defined as adherence to the methadone regimen with no residual signs of withdrawal. Data collected included:

methadone dosages, Lipsitz scores, length of methadone treatment (LOT), and total length of stay (LOS).

**RESULTS:** Sixty subjects were included. The mean gestational age (GA) and birth weight (BW) were  $36.8 \pm 3.03$  weeks and  $2.79 \pm 0.63$  kg. All exhibited NAS within 72 hours of life. 59/60 (98.3%) initiated treatment according to protocol. There was significant deviation from the protocol at 48 and 72 hours of treatment with 33% and 12% of the patients requiring more than the prescribed amount of methadone to control NAS. The mean (SD) total methadone exposure was  $1.96 \pm 1.63$  mg/kg, LOT  $11.66 \pm 9$  days and LOS  $22.4 \pm 29.3$  days suggesting significant variability in response. No significant correlation was found between BW or GA and LOT.

**CONCLUSION:** At diagnosis a protocol for treating NAS was closely followed. Despite a formal protocol there was substantial variability in total methadone exposure, LOT and LOS suggesting other contributory factors for the observed variability.

Will be presented at the Annual European Academic Societies Conference in Istanbul, Turkey September 2012 if accepted.

**167. Characterization and evaluation of clinical decision support dosing alerts for medications prescribed among pediatric patients.**

*Jeremy S. Stultz, Pharm.D.<sup>1</sup>, Karl A. Matuszewski, Pharm.D., M. S.<sup>2</sup>, Gregory H. Dorn, M.D., M.P.H.<sup>2</sup>, Milap C. Nahata, Pharm.D., M.S.<sup>1</sup>; (1) Ohio State University College of Pharmacy, Columbus, OH; (2) First Databank, Inc., South San Francisco, CA*

**PURPOSE:** Dosing range alerts are frequently used in pediatric institutions. Nationwide Children's Hospital's (NCH) dosing alert system combines rule logic created by First Databank (FDB) with NCH customization. Detailed analysis of alert appropriateness is lacking. The aims of this study were to characterize and evaluate dosing alerts occurring at NCH.

**METHODS:** This was a retrospective analysis of practitioner viewed dosing alerts during July 2011. Orders were excluded if they were outpatient or discharge prescriptions, for age  $\geq 18$  years, or part of a research protocol. For each order, patient charts were reviewed and doses were compared with Lexicomp<sup>®</sup> and hospital practices. Rule logic for each alert was analyzed. A 95% binomial confidence interval was used to describe the number of alerts for orders outside reference ranges.

**RESULTS:** Of 1936 orders that led to alerts for 701 patients (mean age 7.1 years), 58% of orders were outside of Lexicomp<sup>®</sup>, either due to different hospital practice ranges or clinical situations (e.g., titrations and pharmacokinetic adjustments). Twenty-eight percentage of orders with alerts were within Lexicomp<sup>®</sup> ranges, but the rule logic was unable to describe the dosing. Six percentage of orders with alerts used extrapolated pediatric dosing due to knowledge deficiencies. Eight percentage (155) of orders with alerts were prescribed outside of all reference ranges. FDB rule logic alerted 122 of these orders and all 155 orders were alerted by FDB rule logic with NCH customization (CI: 71–85%,  $p<0.001$ ). All 155 orders had alerts overridden by at least one practitioner and 43% (66) of the medications were administered.

**CONCLUSION:** Dosing alerts designed by FDB alerted practitioners when abnormal dosing occurred and were enhanced by NCH customization, contributing to dosing error prevention. However, many alerts for orders outside of reference ranges were overridden and doses administered. Further, 86% of alerts warned practitioners for doses within Lexicomp<sup>®</sup> or due to clinical situations.

**168. Vancomycin pharmacologic modeling in critically-ill children following modified IDSA guidelines.** *Christopher L. Shaffer, Pharm.D., MS, BCPS; University of Nebraska Medical Center, Omaha, NE*

**PURPOSE:** This study evaluated the success rates of current pediatric vancomycin dosing regimens in achieving initial serum trough concentrations  $\geq 10$  mg/L and the projected initial dosing requirements to achieve serum trough concentration 10–20 mg/L in the critically-ill child as recommended by the IDSA.

**METHODS:** A retrospective chart review of 40 pediatric patients in the PICU receiving vancomycin between May 1, 2009 through

May 1, 2010 was performed. Patient medical history, hospital course, antimicrobial therapy including resultant vancomycin serum concentrations, microbiologic results, renal function and patient outcomes were documented. Pharmacokinetic parameters were calculated using a one-compartment model.

**RESULTS:** The currently published initial dosing regimens achieved trough concentrations  $\geq 10$  mg/L in 52% of critically-ill patients. The 20 mg/kg every 8 hour regimen was mostly likely to obtain initial target trough concentrations as compared to other dosing regimens ( $p < 0.05$ ). A total of 83 vancomycin sample pairs were evaluated to determine pharmacokinetic characteristics. Mean vancomycin clearance (0.134 L/kg/hour) was similar to that seen in other pediatric patient populations. Based upon microbiologic data, a projected dose of 75–90 mg/kg/day would be needed initially to achieve an AUC/MIC ratio  $>400$  in MRSA patients with a MIC = 2.

**CONCLUSION:** The current dosing recommendations of vancomycin in pediatric dosing references do not consistently achieve serum trough concentrations  $\geq 10$  mg/L in the critically-ill child. Based upon increasing MIC's associated with *Staphylococcus aureus*, current regimens do not achieve optimal pharmacodynamic eradication of these organisms and could possibly promote resistance. A prospective study evaluating initial vancomycin doses of 75–90 mg/kg/day is warranted to assess the safety and efficacy of this higher dosing regimen in this patient population.

**169. Lack of association of late onset sepsis with ranitidine use in neonates.** Chasity M. Shelton, Pharm.D., Jasmine K. Sahni, Pharm.D., Ramsubbarreddy Dhanireddy, M.D., Michael L. Christensen, Pharm.D.; The University of Tennessee Health Science Center & Le Bonheur Children's Hospital, Memphis, TN

**PURPOSE:** The primary objective of this study was to determine if an association exists between late onset sepsis (LOS) and ranitidine exposure in critically ill neonates. Recent literature has suggested that ranitidine use in neonates increases the risk of developing LOS.

**METHODS:** Medical records of neonates,  $\leq 28$  days of life on admission, admitted to a referral, Level IIIIC, neonatal intensive care unit between January 1 and December 31, 2010 were reviewed. Patients' demographics, ranitidine use (received at least one dose), diagnosis of LOS (sepsis after 7 days of life), parenteral nutrition (PN) use, mechanical ventilation, and length of stay were recorded. T-test, Wilcoxon rank sum, and Fisher's exact test were used for data analysis. A p-value of  $<0.05$  was considered significant.

**RESULTS:** Ranitidine was used in 33% of the 276 patients evaluated. The overall incidence of LOS was 7.6%. The incidence of LOS in patients exposed to ranitidine and those not exposed to ranitidine was comparable (8.8% versus 7.0%,  $p=0.6$ ). Also, birth weight (2.48 kg versus 2.38 kg,  $p=0.4$ ) and gestational age (35.1 versus 34.5 weeks,  $p=0.4$ ) were similar in patients exposed to ranitidine and those not exposed to ranitidine, respectively. In patients exposed to ranitidine, LOS was associated with greater duration of ranitidine use (median 26 versus 9 days,  $p < 0.05$ ). LOS was associated with lower birth weight (1.43 versus 2.49 kg) and gestational age (30.1 versus 35.1 weeks), longer duration of PN (65.8 versus 13.1 days) and mechanical ventilation (19.0 versus 5.6 days), and increased length of stay (86.1 versus 24.6 days); ( $p < 0.001$ ).

**CONCLUSION:** There was no association between LOS and ranitidine exposure. In patients who received any doses of ranitidine, LOS was associated with longer exposure to ranitidine.

**170E. Don't leave without them: dispensing asthma medications to pediatric patients upon discharge is associated with decreased hospital readmissions.** Kelly J. Hiteshew, Pharm.D.<sup>1</sup>, Thaddeus Franz, Pharm.D.<sup>1</sup>, Kristen Lamberjack, Pharm.D.<sup>2</sup>, Aleda M. H. Chen, Pharm.D., Ph.D.<sup>1</sup>; (1)Cedarville University School of Pharmacy, Cedarville, OH; (2)Nationwide Children's Hospital, Columbus, OH

**PURPOSE:** The objective of this study was to determine if patients who obtain discharge medications from a pediatric insti-

tution's outpatient pharmacy after an emergency department or inpatient admission for asthma have a lower 30-day readmission rate than those who do not obtain discharge medications from the outpatient pharmacy.

**METHODS:** This multi-phase study included an initial chart review, an intervention period, and a second retrospective chart review. The chart reviews included patients age 2 years and older with a primary discharge diagnosis of asthma or wheezing. During the intervention phase, pharmacists promoted use of the outpatient pharmacy by patients admitted for these conditions using multiple methods. In each chart review, the patients readmitted for asthma or wheezing within 30 days were classified as either outpatient pharmacy users (OPP users) or non-OPP users. Differences in readmission rates between OPP users and non-OPP users, as well as differences in overall OPP utilization, were analyzed before and during the intervention phase using a Chi-square test.

**RESULTS:** The initial chart review found no significant difference in 30 day readmission rates between OPP users and non-OPP users (6.2% and 7.5%, respectively;  $p=0.283$ ). The number of OPP users increased significantly from the first chart review to the second (11.8% and 45.8%, respectively;  $p < 0.0001$ ). The second chart review revealed that OPP users had a significantly lower readmission rate than non-OPP users during the intervention phase (2.3% and 10.9%, respectively;  $p < 0.0001$ ). Post-hoc power analyses indicated that the first chart review failed to provide sufficient power to detect statistical differences while the second chart review did achieve sufficient power due to the increased utilization of the OPP.

**CONCLUSIONS:** Dispensing medications to pediatric patients upon discharge should be part of future efforts to decrease readmissions for asthma.

Presented at the Annual Conference and Trade Show of the Ohio Pharmacists Association, Columbus, OH, April 20, 2012.

**171. Effectiveness of alprostadil dose titration in neonates with congenital heart disease.** Marcia L. Buck, Pharm.D., D. Scott Lim, M.D., Joshua Attridge, M.D.; University of Virginia Children's Hospital, Charlottesville, VA

**PURPOSE:** Alprostadil maintains patency of the ductus arteriosus in neonates with congenital heart disease. At recommended doses (0.05–0.1  $\mu\text{g}/\text{kg}/\text{minute}$ ), alprostadil produces apnea in 20–30% of patients. Use of doses  $\leq 0.02$   $\mu\text{g}/\text{kg}/\text{minute}$  has been suggested to lower the incidence of apnea, but the effectiveness of this strategy has not been well studied. The purpose of this study was to evaluate the effect of alprostadil dose reduction on maintenance of ductal patency and the incidence of apnea.

**METHODS:** A single-center retrospective study was conducted in infants receiving alprostadil between 6/1/06 and 6/3/12. Demographic data, alprostadil dosing information, and apneic events were assessed. Data were analyzed with paired t-tests.

**RESULTS:** Two hundred neonates were evaluated. Mean ( $\pm$ SD) weight and gestational age were  $3.04 \pm 0.70$  kg and  $37.8 \pm 2.3$  weeks. The most frequent diagnoses were transposition of the great arteries, hypoplastic left heart syndrome, and coarctation of the aorta. Alprostadil was initiated at  $0.05 \pm 0.03$   $\mu\text{g}/\text{kg}/\text{minute}$  (range 0.01–0.2  $\mu\text{g}/\text{kg}/\text{minute}$ ). The mean treatment duration was  $10.3 \pm 17.0$  days. Ductal patency was achieved in all but one patient. The dose at discontinuation ( $0.02 \pm 0.02$   $\mu\text{g}/\text{kg}/\text{minute}$ ; range: 0.005–0.1  $\mu\text{g}/\text{kg}/\text{minute}$ ) was significantly lower than the initial dose ( $p < 0.0001$ ). Dose reduction was achieved in 140 patients (70%). Ductal patency was maintained with doses  $\leq 0.02$   $\mu\text{g}/\text{kg}/\text{minute}$  in 121 patients (61%). Twenty-five (13%) required an increase due to worsening oxygenation or ductal narrowing, but only eight remained on higher doses at the end of treatment. Fifty-nine patients (30%) developed apnea, at an average dose of  $0.08 \pm 0.12$   $\mu\text{g}/\text{kg}/\text{minute}$ . Forty-eight (81%) had a dose  $>0.02$   $\mu\text{g}/\text{kg}/\text{minute}$  at the time of their first event. Dose reduction produced resolution of apnea in 35 patients (59%).

**CONCLUSIONS:** Alprostadil can be successfully reduced to doses  $\leq 0.02$   $\mu\text{g}/\text{kg}/\text{minute}$  in most neonates while maintaining ductal patency. This strategy may be useful in minimizing alprostadil-induced apnea without reducing efficacy.

**172. The impact of a training program on pharmacists' comfort with pediatric pharmacy concepts and basic pediatric knowledge.**

*Elizabeth A. Riney, Pharm.D.<sup>1</sup>, Andrew J. Crannage, Pharm.D., BCPS<sup>1</sup>, Nausheen Hasan, Pharm.D.<sup>2</sup>, Rachel M. Tanner, Pharm.D., BCPS<sup>2</sup>, Julie A. Murphy, Pharm.D., BCPS, FASHP<sup>1</sup>; (1)St. Louis College of Pharmacy/Mercy Hospital St. Louis, St. Louis, MO; (2)Mercy Hospital St. Louis, St. Louis, MO*

**PURPOSE:** There is little data in the literature describing programs to enhance pharmacists' comfort and competency related to pediatrics. The objective of this study was to determine the impact of a training program on pharmacists' comfort with pediatric pharmacy concepts and basic pediatric knowledge.

**METHODS:** All pharmacists at Mercy Hospital St. Louis were invited to participate in the study. Pharmacists completed a baseline survey of 15 questions on basic knowledge in five pediatric topic areas (pharmacokinetics/pharmacodynamics, weight-based dosing, anticoagulation, renal dosing, common antibiotics) as well as a self-assessment for eight statements of comfort with pediatric pharmacy. Following the pre-training survey, a training program combining mandatory self-study of handouts on the five topics with optional attendance at live education sessions was completed. Pharmacists then completed a post-training survey on the five topics including a repeat comfort assessment. The primary outcome was the change in self-assigned scores on the comfort-based assessment before and after training.

**RESULTS:** Fifty-two pharmacists consented to participate. Pharmacists reported significant improvement in six of eight comfort questions post-training ( $p < 0.001$ ). On average, pharmacists rated all eight comfort statements with a level of disagreement at baseline; however, four statements transitioned to ratings of agreement post-training. Those without prior pediatric experience had lower comfort ratings at baseline than those with experience and showed significant improvement post-training for the same six questions ( $p < 0.001$ ). Those with recent pediatric experience demonstrated significant change in comfort post-training for only one question ( $p = 0.048$ ). Significant improvement in the proportion of correct answers on the knowledge assessment occurred post-training, regardless of prior experience (0.61 pre versus 0.89 post,  $p < 0.001$ ).

**CONCLUSION:** Self-study training with optional live education resulted in significant improvement in most self-reported comfort scores for pharmacists, particularly those without recent pediatric pharmacy experience. Pharmacists, regardless of experience, improved basic pediatric knowledge scores post-training.

**173. Evaluation of a trace element dosing protocol during trace element product shortages.** *Catherine M. Crill, Pharm.D., Rebecca F. Chhim, Pharm.D., Chasity M. Shelton, Pharm.D.; The University of Tennessee Health Science Center, Memphis, TN*

**PURPOSE:** Trace element supplementation in parenteral nutrition (PN) is critically important to prevent deficiency. Our institution has dosed traces individually, rather than using multitrace products, to optimize supplementation (copper, zinc, selenium), while avoiding accumulation (chromium, manganese). Due to PN product shortages, we began using a neonatal multitrace product in late 2011. Since no pediatric multitrace products contain selenium, we instituted an intermittent dosing protocol to prolong supply. The objective of this study was to evaluate trace element concentrations with this dosing protocol.

**METHODS:** Neonatal multitrace element product (chromium 0.85 µg/ml, copper 0.1 mg/ml, manganese 25 µg/ml, zinc 1.5 mg/ml) was dosed at 0.2 ml/kg/day. Additional zinc was supplemented daily via single-entity product. In patients receiving PN > 1 month, selenium was supplemented (4 µg/kg < 2.5 kg; 5 µg/kg ≥ 2.5 kg) on Monday, Wednesday, and Friday. This was a retrospective chart review of trace element concentrations in infants receiving this protocol over an 8-week period.

**RESULTS:** Seven infants (34.1 ± 3.9; range 27–38 weeks gestational age and 3.2 ± 0.8; range 2.2–4.5 kg during the evaluation period) had diagnoses of necrotizing enterocolitis (n=3), gastro-

schisis (n=3), and volvulus (n=1). Baseline selenium concentrations were assessed in five patients (25.6 ± 9.9; range 10–35 µg/L), with one having a concentration below normal limits (16–71 µg/L). All seven patients had selenium concentrations within normal limits at the end of the evaluation period (40.6 ± 14.5; range 20–45 µg/L). Copper concentrations assessed in two patients were within normal limits. Manganese concentrations, assessed at the end of the evaluation period in four patients, were all above normal threshold of 1.1 µg/L (median 3.25; range 1.7–12.8). Three of these four patients had elevated direct bilirubin (2.3 ± 0.6; 1.8–3 mg/dL).

**CONCLUSIONS:** An intermittent selenium dosing protocol resulted in maintained concentrations within normal limits. Infants receiving multitrace element products accumulate manganese and should be monitored accordingly.

**174. Evaluation of premixed parenteral nutrition solutions in children.** *Rebecca F. Chhim, Pharm.D., Ryan O'Neal, B.S., Catherine M. Crill, Pharm.D.; The University of Tennessee Health Science Center, Memphis, TN*

**PURPOSE:** In response to the intravenous amino acid shortage, our institution began using premixed parenteral nutrition (PN) solutions in 2010. Although some of these products have been marketed for use in children, safety and efficacy have not been established in this patient population. We aimed to review the use of premixed PN solutions in children, focusing on safety and the ability to meet nutritional goals.

**METHODS:** This was a retrospective review of all patients <18 years of age who received a premixed PN solution at Le Bonheur Children's Hospital between October 2010 and April 2012. Data collection included patient demographics, PN indication, duration of premixed PN use, reason for change to individualized PN (if applicable), and estimated goal and actual protein and total caloric intake.

**RESULTS:** Sixty-nine patients received 82 courses premixed PN solutions for a median duration of 3 (1–31) days. Median age and weight were 12 (1.1–18) years and 39 (8.8–118) kg, respectively. Indications for PN were critical illness (n=27), appendicitis (n=22), gastrointestinal disease (n=12), pancreatitis (n=3), seizure disorder (n=3), and inadequate enteral intake (n=2). The premixed PN regimens provided estimated protein goals in 78 of 82 (96%) PN courses and estimated caloric goals in 46 of 82 (56%) courses. Twenty-four patients (35%) required a change from premixed to individualized PN due to electrolyte abnormalities (n=17), need to increase caloric intake (n=7), and preparation for home PN (n=5).

**CONCLUSION:** Premixed PN solutions were used safely and effectively in a wide range of pediatric patients, and most patients were able to receive premixed PN for the entire course of therapy. Premixed solutions provide a potential option in pediatric patients when drug shortages limit product supply required for individualized PN. Close monitoring for electrolyte abnormalities and protein and caloric intake is recommended during therapy with premixed PN solutions in children.

**175E. Evaluation of microbial contamination associated with pharmacy preparation of intravenous fat emulsion.** *Kelly Walls, Pharm.D.<sup>1</sup>, Rebecca F. Chhim, Pharm.D.<sup>2</sup>, Catherine M. Crill, Pharm.D.<sup>2</sup>; (1)Le Bonheur Children's Hospital, Memphis, TN; (2)The University of Tennessee Health Science Center, Memphis, TN*

**PURPOSE:** Provision of intravenous fat emulsion (IVFE) is problematic in neonates and infants due to smaller volumes of IVFE utilized for daily doses, lack of commercially available IVFE units <100 ml, potential for overdose with larger volumes, and controversy over recommended IVFE infusion times. While many institutions repackage IVFE to decrease cost and waste and allow for infusion via syringe pump, repackaging has been associ-

ated with microbial contamination. Our institution utilizes drawn down IVFE, whereby the original manufacturer's containers are infused at bedside after excess volume has been removed. The objective of this study was to evaluate the potential for microbial contamination in different IVFE preparations over time.

**METHODS:** Three different IVFE preparations were evaluated: manufacturer's container spiked with IV tubing, drawn down unit spiked with IV tubing, and repackaged syringe. Samples were obtained for sterility testing from each unit at baseline, 18, and 30 hours. Since IVFE is prepared  $\pm$  6 hours prior to infusion, the 18 and 30 hour assessments simulate 12 and 24 hour infusion under actual use conditions. All IVFE preparation, tubing insertion, and sample collection occurred under USP 797 conditions by one of the investigators or an IV technician. Sterility testing by the hospital clinical microbiology laboratory consisted of incubation in blood culture bottles for 5 days. Samples with no growth were subcultured on blood agar plates with olive oil and incubated in a carbon dioxide incubator for an additional 2 days to assess for *Malassezia furfur*.

**RESULTS:** Samples from 30 manufacturer's containers, 88 drawn down units, and 89 repackaged syringes showed no bacterial or fungal growth.

**CONCLUSIONS:** In this study, contamination previously described with repackaged IVFE did not result from pharmacy preparation under USP 797 conditions. Drawn down IVFE is an alternative to repackaged IVFE that also avoids infusion-related errors in vulnerable patients.

Presented at J Pediatr Pharmacol Ther 2012 (abstracts available online). Pediatric Pharmacy Advocacy Group 21st Annual Meeting. Houston, TX. April 20, 2012. Also presented at the Mid-South Residency Conference, Memphis, TN, May 4, 2012.

## Pharmacoeconomics/Outcomes

**176. Using observational data to inform the design of a prospective effectiveness study for a novel insulin delivery device.** *Yong Chen, Ph.D.*<sup>1</sup>, Matthew Nguyen, Pharm.D.<sup>2</sup>, Michael Grabner, Ph.D.<sup>1</sup>, Ralph Quimbo, M.A.<sup>1</sup>; (1)HealthCore, Inc., Wilmington, DE; (2)Valeritas, Inc., Bridgewater, NJ

**PURPOSE:** To inform the design and assess the feasibility of a prospective effectiveness study evaluating a delivery device for insulin among patients with diabetes mellitus (DM) to be conducted within the membership of a large US commercial insurer.

**METHODS:** Providers with  $\geq 1$  prescription for insulin between 01/01/2011 and 09/30/2011 were selected from the HealthCore Integrated Research Database. Diabetes patients with encounters among these providers and continuous eligibility throughout 2011 were identified. Providers were dichotomized into high- [HVPs] and low-volume groups [LVPs] based on the median number of DM patients per provider.

**RESULTS:** We identified 15,491 HVPs and 15,200 LVPs (median number of patients = 14). Most HVPs located in the Midwest (N=6342 [40.9%]) and South (N=5146 [33.2%]), while LVPs were evenly distributed across regions. Over 80% (N=12,756) of HVPs practiced family or internal medicine, while approximately 6.5% (N=999) were endocrinologists. Metformin was the most commonly prescribed oral antidiabetic (39%  $\pm$ 13% of patients with  $\geq 1$  fill per provider). HVPs prescribed insulin to an average of 26% ( $\pm$ 14%) of their patients. Patients of HVPs (N=524,086) had similar characteristics to patients of LVPs (N=79,725), except for geographical dispersion, which followed those of providers. Approximately 66% of patients were aged 18–64 and 95% had type 2 DM. Among patients with  $\geq 1$  available HbA1C result during 2011 (N=103,961), 48% (N=50,268) had an average HbA1C  $\geq 7.0\%$ . Among these uncontrolled patients, 44% (N=22,354) received  $\geq 1$  insulin prescription.

**CONCLUSION:** The observed provider and patient populations support the feasibility of the prospective study. Sampling of patients from HVPs is efficient while minimizing bias as patients are similar in characteristics to those from LVPs. The study also

highlights unmet need for improved glycemic control since approximately half of DM patients are not on goal.

**177. Risk of venous thromboembolism complications associated with recurrent venous thromboembolism.** *Patrick Lefebvre, M.A.*<sup>1</sup>, François Laliberté, M.A.<sup>1</sup>, Edith A. Nutescu, Pharm.D.<sup>2</sup>, Mei Sheng Duh, M.P.H., ScD<sup>3</sup>, Joyce C. LaMori, MHS, M.B.A.<sup>4</sup>, Brahim Bookhart, M.B.A., M.P.H.<sup>4</sup>, William H. Olson, Ph.D.<sup>4</sup>, Katherine Dea, M.A.<sup>1</sup>, Yvonnick Hossou, B.A.<sup>1</sup>, Jeff Schein, Dr.P.H., M.P.H.<sup>4</sup>, Scott Kaatz, D.O.<sup>5</sup>; (1)Groupe d'Analyse, Ltée., Montreal, QC, Canada; (2)University of Illinois at Chicago College of Pharmacy, Chicago, IL; (3)Analysis Group, Inc., Boston, MA; (4)Janssen Scientific Affairs, LLC, Raritan, NJ; (5)Henry Ford Hospital, Detroit, MI

**PURPOSE:** Venous thromboembolism (VTE) increases the risk of developing several complications, including recurrent VTE. This study quantifies the long-term risk of complications associated with the development of an index recurrent VTE.

**METHODS:** An analysis of healthcare insurance claims from the Ingenix *IMPACT* database was conducted. Between January 2004 and September 2008, subjects aged  $\geq 18$  years on the date of first recurrent VTE diagnosis requiring hospitalization (index recurrent deep vein thrombosis [DVT], pulmonary embolism [PE], or both) with  $\geq 12$  months of baseline observation prior to the index recurrent VTE were matched 1:1 with control VTE patients without recurrence, based on exact matching factors and propensity scores. The risk of developing thrombocytopenia, superficial venous thrombosis, venous ulcer, pulmonary hypertension, stasis dermatitis, and venous insufficiency for up to 1 year after the index recurrent VTE event was compared between the recurrent VTE and the VTE control group.

**RESULTS:** The recurrent VTE and VTE cohorts (8001 subjects in each group) were well-matched with respect to age, gender, comorbidities, and VTE risk factors distributions. The absolute risks of developing thrombocytopenia, superficial venous thrombosis, venous ulcer, pulmonary hypertension, stasis dermatitis, and venous insufficiency were 7.1%, 4.4%, 1.5%, 5.3%, 1.4%, and 7.2% for the recurrent VTE group and 2.5%, 1.3%, 0.8%, 2.0%, 0.9%, and 3.8% for the VTE group, respectively. The corresponding risk ratios indicated that the risk of developing any complications was significantly higher for the recurrent VTE group compared to the VTE group (risk ratio [95% CI]: thrombocytopenia: 2.8 [2.4–3.3], superficial venous thrombosis: 3.3 [2.7–4.1], venous ulcer: 1.9 [1.4–2.6], pulmonary hypertension: 2.7 [2.2–3.2], stasis dermatitis: 1.5 [1.1–2.0], and venous insufficiency: 1.9 [1.6–2.2], all p-values  $< 0.01$ ).

**CONCLUSION:** In this large matched-cohort study, recurrent VTE patients had significantly higher risk of complications compared to VTE control patients.

**178E. Incremental economic burden of *Clostridium difficile* associated diarrhea among hospitalized patients at high risk of recurrent infection.** *Swetha Rao Palli, M.S.*<sup>1</sup>, Ralph A. Quimbo, M.A.<sup>1</sup>, Joseph R. Singer, M.D.<sup>1</sup>, Marcie E. Strauss, M.P.H.<sup>2</sup>, Sheila Thomas, Pharm.D.<sup>2</sup>; (1)HealthCore Inc., Wilmington, DE; (2)Optimer Pharmaceuticals, Inc., Jersey City, NJ

**PURPOSE:** To determine the incremental economic burden associated with *Clostridium difficile* associated diarrhea (CDAD) among patient sub-populations at elevated risk for recurrent CDAD: immunocompromised (IC), prior CDAD, concurrent antibiotic use (cABx), renally impaired (RI), inflammatory bowel disease (IBD), and age  $\geq 65$  years (elderly) patients.

**METHODS:** CDAD cases hospitalized with a diagnosis of CDI (ICD-9-CM: 008.45) having  $\geq 12$  months of prior health plan eligibility and  $\geq 18$  years of age between January 1, 2005 and October 31, 2010 were identified from the HealthCore Integrated Research Database (HIRD<sup>SM</sup>). CDAD cases within each sub-population were matched to hospitalized controls without CDAD diagnosis based on: age  $\pm 10$  years, gender, preceding/

in-hospital comorbidities (cardiovascular, pulmonary, haematopoietic, and musculoskeletal) and use of antibiotics. Incremental hospital length of stay (LOS) and hospital costs between cases and controls were assessed using multivariate generalized linear models using a Gamma distribution and logarithmic link function. Covariates were determined from post-match univariate analysis of baseline characteristics for each sub-population.

**RESULTS:** Post-match case-to-control ratios ranged from 1:1 to 1:3 for each sub-population (IC: n=3586 cases; prior CDAD: n=933 cases; cABx: n=4429 cases; RI: n=5533 cases; IBD: n=1206 cases; elderly: n=10933 cases). Post-match comparisons of baseline characteristics indicated no significant ( $p>0.05$ ) difference in targeted match criteria. Compared to controls in all sub-populations, CDAD cases had significantly greater ( $p<0.0001$ ) hospital LOS (mean incremental days [95% C.I.]; IC: 8.4 [7.9–9.0]; prior CDAD: 2.9 [2.4–3.6]; cABx: 7.8 [7.4–8.3]; RI: 17.3 [16.4–18.3]; IBD: 3.3 [2.9–3.7]; elderly: 7.8[7.5–8.1]) and hospital costs (mean incremental USD [95% C.I.]; IC: \$31.8K [28.5–35.5]; prior CDAD: \$28K [19.7–40.0]; cABx: \$36.3K [33.3–39.6]; RI: \$115.6K [105.2–127.1]; IBD: \$11.2K [9.3–13.4]; elderly: \$43.2K [40.9–45.7]).

**CONCLUSION:** This study demonstrates the significant incremental economic burden associated with CDAD both within the hospital setting and from a payer perspective. CDAD patients in each sub-population incurred significantly greater hospital LOS and corresponding hospital costs relative to matched controls. Presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 17th Annual International Meeting, Washington, DC, June 2–6, 2012.

**179E. Post-hospitalization discharge economic burden of *Clostridium difficile* associated diarrhea among high-risk patient sub-groups in a managed care setting.** Swetha Rao Palli, M.S.<sup>1</sup>, Sheila Thomas, Pharm.D.<sup>2</sup>, Ralph A. Quimbo, M.A.<sup>1</sup>, Marcie E. Strauss, M.P.H.<sup>2</sup>; (1) HealthCore Inc., Wilmington, DE; (2) Optimer Pharmaceuticals, Inc., Jersey City, NJ

**PURPOSE:** To evaluate the short- and long-term incremental economic burden following CDAD hospitalization among the following sub-populations: immunocompromised (IC), prior CDAD, concurrent antibiotic users (cABx), renally impaired (RI), inflammatory bowel disease (IBD) and elderly ( $\geq 65$ ).

**METHODS:** Patients with an inpatient CDI diagnosis (ICD-9-CM: 008.45), aged  $\geq 18$  years and  $\geq 12$  months of prior health plan eligibility between January 1, 2005 to October 31, 2010 were identified from the HealthCore Integrated Research Database (HIRD<sup>SM</sup>). Within each sub-population, cases were directly matched to controls- patients hospitalized without a CDI diagnosis. Matching criteria included sub-population defining condition(s), gender, age  $\pm 10$  years, and baseline/in-hospital comorbidities. Follow-up was the period between hospital discharge and earliest occurrence of end of continuous health plan eligibility or available data stream, or death. Incremental ( $\Delta$ ) post-discharge resource and health plan costs between cases and controls were assessed using multivariate GLMs with Poisson and Gamma distributions, respectively, adjusting for significant post-match characteristics. Short-term burden was evaluated for the post-discharge 30-day period. Long-term cost burden was assessed over the available follow-up period on a PMPM basis.

**RESULTS:** Post-match case-to-control ratios ranged from 1:1 to 1:3 in each sub-population (IC: n=3586; prior CDAD: n=933; cABx: n=4429; RI: n=5533; IBD: n=1206; elderly: n=10,933 cases respectively). Cases incurred a significantly ( $p<0.0001$ ) greater number of hospitalizations and overall health plan costs relative to controls during the 30-day (see table) post-discharge duration. Cases also had significantly greater  $\Delta$ PMPM burden with medical expenditures representing the majority of costs.

Subgroup	30-day Post-discharge mean $\Delta$ burden*		$\Delta$ PMPM (\$)*
	# Inpatient /medical encounters per 100 patients	Inpatient /medical costs (\$)	
IC	6/3	2318/3908	3033
Prior CDAD	7/47	6649/4868	4513
cABx	7/-5	2320/2574	1831
RI	9/-12	4410/5013	3851
IBD	4/-30	529/557	704
Elderly	9/-43	4149/3982	3258

\* $\Delta$  = CDAD/non-CDAD difference.

**CONCLUSION:** CDAD patients in each sub-population incurred substantial incremental PMPM and post-discharge economic burden to the health plan; they appear to be driven by a higher number of hospitalizations. Submitted to the AMCP 2012 educational conference.

**180. Use of a Medication Access and Adherence Tool (MAAT) to identify patients at high risk for medication-related problems.** Kim C. Coley, Pharm.D.<sup>1</sup>, Amy C. Donihi, Pharm.D.<sup>1</sup>, Rima A. Mohammad, Pharm.D.<sup>1</sup>, Jenny Kim, Pharm.D.<sup>2</sup>, Patricia D. Kroboth, Ph.D.<sup>1</sup>; (1) University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2) Bernard J. Dunn School of Pharmacy, Shenandoah University, Winchester, VA

**PURPOSE:** To develop and evaluate a tool that effectively identifies patients at risk for medication access and adherence problems.

**METHODS:** A five-item questionnaire (MAAT) was developed to aid clinicians in identifying patients at risk for medication access or adherence problems at home. This tool's items included beliefs about treatment (n=1), medication adherence (n=2), medication access/affordability (n=1), and adverse drug events (n=1). Inpatients on a medicine unit were administered the tool, assessed for medication access/adherence problems, and followed up within 72 hours of discharge by their hospital pharmacist. Correlations between MAAT scores and medication access/adherence problems and additional post-discharge problems were assessed.

**RESULTS:** There were 206 inpatients that completed the MAAT: median age 57 years; 53% female. MAAT items: 22% were not always certain they needed medications to treat their health problems; 10% were not always sure they could take their medications as prescribed; 35% sometimes stopped taking or skipped doses of their medications; 28% found it difficult to pay for their medications; and 35% experienced adverse effects from their medications. During the inpatient stay, pharmacists identified 71 (35%) patients with medication access/adherence problems. There was a moderate correlation ( $r^2 = 0.46$ ,  $p<0.001$ ) between MAAT score and the number of medication access/adherence problems identified. There were 149 patients who were eligible for post-discharge follow-up and 107 (72%) of these were contacted. Medication problems were identified in 66% of these patients. There were no correlations between number of post-discharge medication problems and age, number of discharge medications, or comorbidities. There was a slight correlation ( $r^2 = 0.22$ ,  $p<0.02$ ) with the MAAT score and the number of post-discharge medication problems.

**CONCLUSION:** The MAAT is an effective tool to identify patients at risk for medication access and adherence problems and can also help determine which patients would benefit most from a pharmacist intervention after hospital discharge.

**181. Evaluation of medication adherence in a medically underserved population.** Bradley M. Wright, Pharm.D., BCPS<sup>1</sup>, Karen Marlowe, Pharm.D., BCPS<sup>1</sup>, Errol Crook, M.D.<sup>2</sup>; (1) Harrison School of Pharmacy, Auburn University, Mobile, AL;

(2) Department of Internal Medicine, University of South Alabama, Mobile, AL

**PURPOSE:** The purpose of this prospective study was to describe the medication taking behaviors of a sample of patients from a teaching internal medicine clinic.

**METHODS:** Patients were included if they were >18 and taking a medication for blood pressure as well as a cholesterol medication and/or a diabetes medication. Patients completed questionnaires including demographics and medication history. A clinical pharmacist determined a total number of barriers to medication taking for each patient. Correlations were examined between education level, total barrier count, number of medications, and measures of adherence (Morisky and ASK 20).

**RESULTS:** Between May 2011 and March 2012, 66 patients were enrolled and baseline demographics were collected. Forty of the patients enrolled in the study (61%) had no insurance or state Medicaid, and only 4 (6%) patients included had private insurance. Five patients had not completed high school. Forty-eight (72%) listed their education level as completion of high school. The mean ASK20 score was  $41.9 \pm 9.9$  and Morisky score was 0.9 for their medication adherence. The average number of barriers to medication taking in this population was 4.6 ( $\pm 2.1$ ). There was a lack of correlation between the total barrier count (TBC) and the Morisky score ( $r^2 = 0.23$ ); however, there was a better correlation between the ASK 20 and the TBC ( $r^2 = 0.76$ ). During individual patient interviews, medication histories were verified. A summary of pharmacist interventions will be presented including correlations to questions in adherence questionnaires.

**CONCLUSION:** Medically underserved populations have large number of reasons for poor adherence to medications. Providers should be aware of adherence barriers. The Morisky and ASK20 may be highly variable measures of adherence in an underserved population.

**182. Economic evaluations of clinical pharmacy services: 2006–2010.** Daniel R. Touchette, Pharm.D., MA, FCCP<sup>1</sup>, Fred Doloresco, M.S., Pharm.D.<sup>2</sup>, Katie J. Suda, Pharm.D., M.S.<sup>3</sup>, Alexandra Perez, Pharm.D.<sup>4</sup>, Stuart Turner, B.Pharm., M.P.H.<sup>5</sup>, Yash J. Jalundhwal, B.Pharm., M.S.<sup>1</sup>, Maria C. Tangonan, B.S., Pharm.D.Candidate<sup>1</sup>, James M. Hoffman, Pharm.D., M.S., BCPS<sup>6</sup>;

(1) University of Illinois at Chicago, Chicago, IL; (2) SUNY: University at Buffalo, Buffalo, NY; (3) University of Tennessee Health Science Center, College of Pharmacy, Memphis, TN; (4) Nova Southeastern University, Ft. Lauderdale, FL; (5) University at Buffalo, Buffalo, NY; (6) St. Jude Children's Research Hospital, Memphis, TN

**PURPOSE:** To evaluate the costs and benefits of clinical pharmacy services (CPS) in studies published between 2006 and 2010. This report focuses on study methods, CPS setting and type, and a comparison with a previous report.

**METHODS:** Scientific literature databases (Medline, IPA, Embase, and CINAHL) for 2006–2010 were searched to identify studies describing CPS. Studies meeting inclusion criteria (original research; evaluation of CPS; economic and clinical outcomes sufficiently described) were reviewed by two investigators. Methodology employed, economic evaluation type, CPS setting and type, and clinical and economic outcome results were abstracted. Chi-square was used to compare 2006–2010 with the 2001–2005 study.

**RESULTS:** The initial search identified 3587 potential studies. Twenty-five meeting inclusion underwent full review. Common CPS settings were hospital (40.0%), community (36.0%) and clinic (28.0%). The most common CPS types were disease state management (48.0%), general pharmacotherapeutic monitoring (44.0%), patient education or cognitive service (32.0%), and target drug programs (20.0%). Two (8.0%) studies stated that the CPS was medication therapy management. Disease state management programs were evaluated more frequently in the current period (2006–2010: 48.0% versus 2001–2005: 22.6%;  $p=0.02$ ). A control was included in 84.0% (21/25) of studies from 2006 to 2010, compared with 43.0% (40/93;  $p<0.001$ ) from 2001 to 2005.

Most of the 2006–2010 studies (17/25; 68.0%) involved a full economic evaluation, compared with 48.4% (45/93) in 2001–2005.

**CONCLUSION:** Fewer studies documented the economic impact of CPS in 2006–2010 than in 2001–2005 although the quality of the studies improved, evidenced by a higher proportion involving controlled designs and full economic evaluations. A significantly greater proportion involved disease state management. A trend toward more outpatient evaluations (community and clinic) was also observed. It is unclear whether the observed reduction in published papers is due to changes in practice, research funding, reduced need for documentation of CPS, or decreased journal acceptance of such reports.

## Pharmacoepidemiology

**183. A descriptive analysis of medication adherence and mortality among elderly post-MI patients.** Tasneem Lokhandwala, M.S., Matthew Strum, Pharm.D., BCACP, CDE, Yi Yang, M.D., Ph.D., John Bentley, B.S., M.B.A., Ph.D., Benjamin Banahan, III, Ph.D.; University of Mississippi School of Pharmacy, University, MS

**PURPOSE:** To provide a descriptive analysis of adherence to secondary prevention therapies and mortality among post myocardial infarction (MI) Medicare beneficiaries.

**METHODS:** The 2006–2007 5% national sample of Medicare claims data were used. Beneficiaries  $\geq 65$  years old, hospitalized for acute MI between January 1 and December 31, 2006, were identified using a validated algorithm. Only those who survived for  $\geq 90$  days were included in analysis. Patients with ESRD and disabilities were excluded. Three classes of secondary prevention medications were examined: statins, beta-blockers, and ACEI/ARBs. Patients were classified as adherent if proportion of days covered during follow-up for a class of medication was  $\geq 0.8$ .

**RESULTS:** Of the 11,472 patients identified, 58.3% female, 87.7% white, 37.9% lived in the South, and 42.1% were 75–85 year olds. Among 5036 statin users, 34.7% were adherent; a greater proportion of the non-adherent patients were from the South (38.4% versus 36.5%;  $p=0.0069$ ) compared to adherent patients. Among beta-blocker users (6016), 38.9% were adherent; a higher proportion of the non-adherent patients were black (10.3% versus 8.1%;  $p=0.0109$ ) and from the Northeast (24.0% versus 21.0%;  $p=0.0015$ ) compared to adherent patients. Among 5327 ACEI/ARBs users, 32.4% were adherent; non-adherent patients were more likely to be black (11.1% versus 9.3%;  $p=0.0363$ ) compared to adherent patients. Overall, 16.1% of patients died within a year. Across all three classes of medications, non-adherent patients were more likely to die within a year compared to adherent patients: statins (15.8% versus 1.8%;  $p<0.0001$ ), beta-blockers (20.9% versus 2.4%;  $p<0.0001$ ), and ACEI/ARBs (18.9% versus 2.6%;  $p<0.0001$ ).

**CONCLUSION:** There are racial and geographic disparities in adherence to secondary prevention therapies among elderly post-MI patients and nonadherence is associated with a higher risk of mortality. Further research needs to identify predictors of such disparities and appropriate measures need to be designed to improve medication adherence.

**184. Identification of adverse drug events post-hospital discharge in a geriatric population.** Jennifer L. Donovan, Pharm.D.<sup>1</sup>, Abir O. Kanaan, Pharm.D.<sup>1</sup>, Jennifer Tjia, M.D., MSCE<sup>2</sup>, Terry S. Field, D. Sc.<sup>3</sup>, Shawn Gagne, B.S.<sup>2</sup>, Lawrence Garber, M.D.<sup>4</sup>, Sarah L. Cutrona, M.D., M.P.H.<sup>2</sup>, Leslie R. Harrold, M.D., M.P.H.<sup>2</sup>, Peggy Preusse, RN<sup>4</sup>, George Reed, Ph.D.<sup>5</sup>, Jerry H. Gurwitz, M.D.<sup>5</sup>;

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**PURPOSE:** Adverse drug events (ADEs), especially those that may be preventable, are among the most serious concerns regarding medication use in older persons. The purpose of this study

was to describe the incidence, severity and preventability of ADEs occurring within 45 days post hospitalization in an ambulatory geriatric population.

**METHODS:** We studied 1000 consecutive discharges of patients aged 65 and older who received medical care from a large multi-specialty medical group in Central Massachusetts. Discharges were excluded if the discharge diagnosis was psychiatric or if discharges were not to home. Two trained clinical pharmacists reviewed the ambulatory records of each discharged patient to identify drug-related incidents occurring during the 45-day period post hospital discharge, which were subsequently presented to a pair of physician-reviewers who independently classified incidents as to whether an adverse drug event was present, the severity of the event, whether the event was preventable. When the physician-reviewers disagreed on the classification of an incident, they met and reached consensus; consensus was reached in all instances where there was initial disagreement.

**RESULTS:** There were 244 ADEs identified, of which 34% (n=84) were considered preventable. Of the ADEs, 77% were categorized as less severe, 21% were serious, and 2% were life-threatening; of the serious and life-threatening events, 54% were considered preventable, compared to 21% of the less severe events. There was at least one ADE identified in 18.9% (n=189) of discharges during the 45-day period post hospitalization. There were 7.4% of discharges that had at least one ADE that was deemed preventable.

**CONCLUSION:** Adverse drug events are common and often preventable among older persons in the ambulatory setting. The substantial portion of serious events that were considered preventable suggests opportunities for improving care during the post-hospital discharge period.

**185. Cardiovascular thromboembolic events associated with use of Febuxostat: Investigation of case reports from the FDA adverse event reporting system database.** Pranav K. Gandhi, Ph.D., William M. Gentry, Pharm.D., Michael Bottorff, Pharm.D.; South College School of Pharmacy, Knoxville, TN

**PURPOSE:** Uloric (Febuxostat) has been linked with cardiovascular thromboembolic events for chronic management of hyperuricemia in gout patients (information from package insert and randomized clinical trials). However, no post-marketing data analysis has investigated these drug-associated adverse event reports. The study objective was to extract Febuxostat-associated cardiovascular thromboembolic event reports in the United States (US) using the Food and Drug Administration adverse event reporting system (AERS) database.

**METHODS:** Reports listing Uloric and Febuxostat as the suspect drug and cardiovascular thromboembolic events (combined in a single term based on adverse event reports of myocardial infarction, stroke, among others) as the adverse event were extracted from the drug's approval date (February 16, 2009) through the fourth quarter of 2011, since at the time when this study was conducted, data after the fourth quarter of 2011 were not available. Bayesian statistics within the neural network architecture were implemented to identify potential signals of Febuxostat-associated cardiovascular thromboembolic events. A potential signal for the drug-adverse event combination reports is generated when the lower limit of the 95% two-sided confidence interval of the information component (IC), denoted by  $IC_{0.25}$  is greater than zero.

**RESULTS:** A total of 86 and 3460 reports concerning Febuxostat and cardiovascular thromboembolic events, respectively, were extracted. Twenty-one combination reports of Febuxostat-associated cardiovascular thromboembolic events were identified in gout patients. The mean age of case reports for Febuxostat-associated cardiovascular thromboembolic events was 64 years. Potential signal ( $IC_{0.25} = 4.09$ ) was generated for combination reports of Febuxostat-associated cardiovascular thromboembolic events.

**CONCLUSION:** The extracted case reports from AERS indicate potential signals of Febuxostat-associated cardiovascular thromboembolic events. AERS is not capable of establishing the causal link and detecting the true frequency of an adverse event associ-

ated with a drug. The higher IC value found merits continued surveillance and assessment of the credibility of the reported adverse events associated with the drug.

**186. Identification of bleeding adverse events associated with the concurrent administration of Dabigatran and Dronedarone: investigation of case reports from the FDA adverse event reporting system database.** Pranav K. Gandhi, Ph.D., William M. Gentry, Pharm.D., Michael Bottorff, Pharm.D., FCCP, FNLA, CLS; South College School of Pharmacy, Knoxville, TN

**PURPOSE:** An increased risk of bleeding has been noted when Pradaxa® (Dabigatran) is co-administered with Multaq® (Dronedarone). To date, no post-marketing data analysis has identified bleeding adverse events associated with the co-administration of Dabigatran and Dronedarone. The study objective was to investigate potential case reports of bleeding associated with the concurrent administration of Dabigatran-Dronedarone in the United States (US) using the Food and Drug Administration adverse event reporting system (AERS) database.

**METHODS:** Reports listing the concurrent administration of Pradaxa, Dabigatran, or Dabigatran Etxilate with Multaq or Dronedarone as the suspect drug, and bleeding events (combined in a single term based on adverse event reports of haemorrhage, rectal haemorrhage, among others) as the adverse event were extracted from the drug's approval date (Dabigatran, October 19, 2010) through the fourth quarter of 2011; data subsequent to fourth quarter of 2011 were not available at the time of this study. Bayesian statistics within the neural network architecture were implemented to identify potential signals of Dabigatran-Dronedarone-associated bleeding events. A potential signal for the co-administration of two drugs-associated adverse event is generated when the lower limit of the 95% two-sided confidence interval of the information component (IC), denoted by  $IC_{0.25}$  is greater than zero.

**RESULTS:** A total of 89 Dabigatran-Dronedarone combination reports and 11,810 reports concerning bleeding events were extracted. Forty-five out of 89 combination case reports were identified to be associated with reports of bleeding. Potential signal ( $IC_{0.25} = 3.80$ ) was generated for bleeding events associated with the co-administration of Dabigatran and Dronedarone.

**CONCLUSION:** The extracted case reports and IC values indicate potential signal of bleeding events associated with the co-administration of Dabigatran-Dronedarone. AERS is not capable of establishing the causal link and detecting the true frequency of an adverse event associated with the concurrent administration of two drugs.

**187E. Clinical epidemiology of carbapenem-resistant enterobacteriaceae in community hospitals: a case-case-control study.** Grace C. Lee, Pharm.D., BCPS<sup>1</sup>, Donna R. Burgess, R.P.H.<sup>2</sup>, Kurt R. Winkler, Pharm.D., M.H.A., BCPS<sup>3</sup>, David S. Burgess, Pharm.D., FCCP<sup>1</sup>; (1) University of Texas at Austin College of Pharmacy and University of Texas Health Science Center School of Medicine, San Antonio, TX; (2) Methodist Hospital Department of Pharmacy and University of Texas at Austin College of Pharmacy, San Antonio, TX; (3) Methodist Hospital Department of Pharmacy, San Antonio, TX

**PURPOSE:** Despite the increasing rate of carbapenem-resistant *Enterobacteriaceae* (CRE), there are limited data identifying risk factors. This study evaluated risk factors associated with the acquisition of CRE among hospitalized patients.

**METHODS:** We performed a retrospective matched case-case-control study in four community hospitals from June 2007 through November 2011. Case Group (CG) 1 comprised of patients with CRE. CG 2 comprised of patients with carbapenem-susceptible *Enterobacteriaceae* (CSE). CG 2 patients were matched to CG 1 patients by site of infection and specific species of *Enterobacteriaceae*. Hospitalized controls were matched 2:1 by date of admission and hospital location to patients in CG 1. Two sets of analyses were conducted comparing demographics, comorbidities and antibiotic exposures of CG 1 and CG 2 to controls

then contrasted to identify unique risk factors associated with CRE.

**RESULTS:** Overall, 104 patients (CG 1 – 25 patients; CG 2 – 29 patients, Control Group – 50 patients) were evaluated. CRE and CSE comprised mostly of *Klebsiella species* (64%) from a urinary source (28%). In univariate analysis, renal failure ( $p < 0.001$ ), exposure to fluoroquinolones ( $p < 0.01$ ), carbapenems ( $p < 0.001$ ), aminoglycosides ( $p < 0.01$ ), poor functional status ( $p < 0.01$ ), ICU stay ( $p < 0.01$ ), cumulative number of antibiotics exposures ( $p < 0.001$ ), and cumulative number of antimicrobial days by “time at risk” ratio ( $p < 0.001$ ) were significantly higher in CG 1 than controls. In multivariable analysis, poor functional status (OR: 4.43, CI: 2.25–8.73;  $p < 0.01$ ), ICU stay (8.9, CI: 3.49–23.03  $p < 0.01$ ), and cumulative number of antibiotics exposures ( $p < 0.01$ ) were distinct independent predictors of CRE isolation whereas cumulative healthcare exposures ( $p < 0.01$ ) and vancomycin exposure (OR: 2.5, CI: 1.63–3.84;  $p < 0.01$ ) were predictors for CSE.

**CONCLUSION:** CRE should be considered in patients with poor functional status requiring ICU admission, particularly those who have received multiple antibiotics.

Presented at ID Week Conference, San Diego, CA, 2012.

### Pharmacogenomics/Pharmacogenetics

#### 188. The effect of NAD(P)H dehydrogenase, quinone 1 genotype on warfarin dose requirements in Hispanic and African Americans.

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**PURPOSE:** Warfarin is the most widely used oral anticoagulant, but its usability is limited by a narrow therapeutic index and nearly a 20-fold variation in dose requirements. The objective of this study was to determine the additional contribution of NAD (P)H dehydrogenase, quinone 1 (*NQO1*) genotype to warfarin dose requirements across two racial groups after accounting for *VKORC1*, *CYP2C9*, and *CYP4F2* genotypes.

**METHODS:** A total of 313 patients were enrolled, including 260 African Americans and 53 Hispanic Americans. After obtaining written informed consent and a genetic sample, the following factors were assessed: demographics; clinical data; *NQO1* Pro187Ser (\*1/\*2); *CYP2C9* Arg144Cys (\*2), Ile359Leu (\*3), Asp360Glu (\*5), and Arg150His (\*8); *CYP4F2* Val433Met; and *VKORC1* -1639G>A genotypes.

**RESULTS:** The *NQO1*\*2 allele frequency was higher in Hispanics compared to African Americans (0.27 versus 0.18,  $p = 0.05$ ). There was no association between *NQO1*\*2 (genotype and warfarin dose requirements in either race by bivariate analysis. However, after adjusting for associated genetic (*CYP2C9*, *CYP4F2* and *VKORC1*) and clinical (age, body size, history of hypertension or atrial fibrillation) factors, possession of the *NQO1*\*2 allele was associated with a 35% increase in warfarin maintenance dose ( $p = 0.004$ ) in Hispanics. In this population, the inclusion of *NQO1*\*2 genotype improved the dose variability explained by the model from 0.62 to 0.68 ( $p = 0.004$ ), a 10% improvement. In contrast, we found no association between *NQO1*\*2 genotype and therapeutic warfarin dose in African Americans after adjusting for known genetic and clinical predictors.

**CONCLUSION:** In our cohort of inner city U.S Hispanics, *NQO1* genotype was significantly associated with warfarin dose requirements after holding clinical and genetic predictors constant. If our findings are confirmed, they would suggest that inclusion of *NQO1*\*2 genotype in warfarin dosing algorithms may improve the predictive ability of such algorithms in Hispanics.

#### 189. Community pharmacists' attitudes towards pharmacogenetic testing. Sony Tuteja, Pharm.D., BCPS<sup>1</sup>, Kevin Haynes, Pharm.D.<sup>1</sup>, Cara Zayac, M.P.H.<sup>1</sup>, Jon E. Sprague, Ph.D.<sup>2</sup>, Barbara Bernhardt,

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**PURPOSE:** To examine community pharmacists' attitudes towards pharmacogenetic (PGx) testing including their views of the clinical utility of PGx and the ethical, social, legal, and practical implications of PGx testing.

**METHODS:** Web-based survey administered to 5600 licensed community pharmacists in the states of OH and PA.

**RESULTS:** Of 580 respondents, 52% were male, 68% >40 year old, 78% had a BS in Pharmacy degree, and 58% worked in a chain drug store. Those with the PharmD degree were fewer years from graduation than those with a BS in pharmacy ( $8 \pm 7$  versus  $27 \pm 11$  years,  $p < 0.001$ ). Of five knowledge score items, the average correct was  $2.8 \pm 0.5$ . PharmD trained pharmacists had a significantly higher knowledge score than those with a BS in pharmacy ( $3.2 \pm 0.9$  versus  $2.6 \pm 0.6$ ,  $p < 0.0001$ ). All pharmacists had positive attitudes towards PGx and most (87%) felt it would decrease the number of adverse events and optimize drug dosing. More than half (57%) of pharmacists felt it was their role to counsel patients regarding PGx information, but felt they needed more training. Many (65%) were concerned that PGx test results may be used to deny health insurance.

**CONCLUSION:** Pharmacists with PharmD training had greater knowledge regarding PGx testing. Since the PharmD trained pharmacists were fewer years from graduation, this difference in knowledge most likely reflects recent changes to the pharmacy curriculum that includes education about PGx. Regardless of type of education, all pharmacists had positive attitudes towards PGx and seemed willing to counsel patients regarding PGx test results, but needed more training in this area. There is still a concern among pharmacists that PGx test results may be used to deny health insurance and thus there is a need to educate pharmacists about legal protections prohibiting genetic discrimination.

#### 190. Association between CYP2C9 genetic polymorphism and the pharmacokinetics and pharmacodynamics of glipizide. Byung-Sung Kang, Ph.D. Candidate, Hye-In Lee, M.S., Chang-Ik Choi, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Glipizide, a second-generation sulfonylurea antidiabetic agent, is used for the treatment of type II diabetes mellitus. The metabolism of glipizide is mediated primarily by *CYP2C9*, a highly polymorphic drug-metabolizing enzyme. *CYP2C9*\*3 and *CYP2C9*\*13 alleles, reported to be associated with decreased *CYP2C9* enzyme activity, are found in Asians including Koreans. We investigated the effects of *CYP2C9* genetic polymorphism on the pharmacokinetics and pharmacodynamics of glipizide.

**METHODS:** Twenty-four healthy subjects were selected and they were divided into two different groups according to *CYP2C9* genotype, *CYP2C9*EM (*CYP2C9*\*1/\*1,  $n = 11$ ) and *CYP2C9*IM (*CYP2C9*\*1/\*3 and *CYP2C9*\*1/\*13,  $n = 13$ ). After overnight fasting, each subject received a single oral dose of 5 mg glipizide. Blood samples were collected up to 15 hours after drug intake, and the plasma concentrations of glipizide were determined by using HPLC-UV system. Pharmacodynamics of glipizide was evaluated by the measurement of plasma glucose and insulin concentration.

**RESULTS:** AUC<sub>inf</sub> of glipizide in *CYP2C9*IM was 1.5-fold higher than that in *CYP2C9*EM ( $3937.3 \pm 502.4$  ng hour/ml and  $2625.3 \pm 782.3$  ng hour/ml, respectively,  $P < 0.0001$ ). Oral clearance of glipizide in *CYP2C9*IM was 37% lower than that in *CYP2C9*EM ( $1.29 \pm 0.18$  and  $2.05 \pm 0.55$  L/hour, respectively,  $P < 0.0001$ ). However, other parameters were not significantly different between two groups. Plasma glucose and insulin concentration between two groups were also not significantly different ( $P > 0.05$ ).

**CONCLUSION:** *CYP2C9* genetic polymorphism has a significant impact on the pharmacokinetics, but not on the pharmacodynamics of glipizide.

**191. Drug-drug interaction between pramipexole and cimetidine, an OCT2 inhibitor.** *Byung-Sung Kang, Ph.D.Candidate, Hye-In Lee, M.S., Chang-Ik Choi, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea*

**PURPOSE:** Pramipexole, a non-ergoline dopamine agonist, is approved for the treatment of Parkinson's disease and restless legs syndrome (RLS). Pramipexole is well absorbed and undergoes little presystemic biotransformation. Approximately 90% was excreted in the urine as unchanged drug, with possible involvement with organic cation transporters (OCTs) in the renal tubules. We investigated the effects of cimetidine, known as an OCT2 inhibitor, on the pharmacokinetics of pramipexole.

**METHODS:** Eighteen healthy male subjects were recruited for the study. In the control phase, each subject received a single oral dose of 0.25 mg pramipexole after overnight fasting. In the cimetidine phase, the subjects were administered an oral dose of 400 mg cimetidine twice daily for 5 days. On the morning of day 6, they received a single oral dose of 0.25 mg pramipexole 2 hours later the administration of a 400 mg oral dose of cimetidine. Blood samples were collected up to 48 hours after drug intake, and the plasma concentrations of pramipexole were determined by using LC-MS/MS system.

**RESULTS:** In the cimetidine phase,  $C_{max}$  and  $AUC_{inf}$  of pramipexole was 1.2- and 1.4-fold higher than in the control phase ( $p < 0.001$  and  $p < 0.0001$ , respectively). Apparent renal clearance ( $CL/F$ ) of pramipexole in the cimetidine phase was 30% lower than in the control phase ( $p < 0.0001$ ). Elimination half-life ( $t_{1/2}$ ) of pramipexole between two phase were not significantly different.

**CONCLUSION:** OCT2 is found to be associated with the renal excretion of pramipexole in vivo. Further studies on the effects of OCT2 genetic variants on the pharmacokinetics of pramipexole will be meaningful.

**192. Effects of CYP2C9 genetic polymorphism on the pharmacokinetics of zafirlukast.** *Mi-Jung Kim, Ph.D.Candidate, Choon-Gon Jang, Ph.D., Seok-Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea*

**PURPOSE:** Zafirlukast is an oral leukotriene receptor antagonist (LTRA) for the maintenance treatment of asthma, often used in conjunction with an inhaled steroid and/or long-acting bronchodilator. A previous in vitro study showed that cytochrome P450 (CYP) 2C9 and 3A4 are the major enzymes participating in zafirlukast metabolism. It is reported that the *CYP2C9\*3* and *CYP2C9\*13* alleles are associated with decreased CYP2C9 enzyme activity. We investigated the effects of *CYP2C9* genetic variants on the pharmacokinetics of zafirlukast.

**METHODS:** Eighteen subjects were selected and they were divided into two different groups according to *CYP2C9* genotype, *CYP2C9EM* (*CYP2C9\*1\*1*,  $n=10$ ) and *CYP2C9IM* (*CYP2C9\*1\*3*,  $n=8$ ). After overnight fasting, each subject received a single oral dose of 20 mg zafirlukast. Blood samples were collected up to 12 hours after drug intake, and plasma concentrations of zafirlukast were determined by a validated LC-MS/MS analytical method.

**RESULTS:**  $C_{max}$  of zafirlukast in *CYP2C9IM* group was 1.4-fold higher than that in *CYP2C9EM* group ( $397.8 \pm 87.5$  versus  $290.7 \pm 57.6$  ng/ml,  $p < 0.01$ ).  $AUC_{inf}$  of zafirlukast in *CYP2C9IM* group was also 1.6-fold higher than that in *CYP2C9EM* group ( $1244.3 \pm 205.2$  versus  $768.1 \pm 135.2$  ng hour/mL,  $p < 0.0001$ ). Apparent oral clearance ( $CL/F$ ) of zafirlukast in *CYP2C9IM* group was 39% lower than that in *CYP2C9EM* group ( $16.5 \pm 2.9$  versus  $27.0 \pm 4.9$  L/hour,  $p < 0.0001$ ).

**CONCLUSION:** *CYP2C9* genetic polymorphism significantly affected the pharmacokinetics of zafirlukast

**193. Effects of CYP2C19 genetic polymorphism on the disposition of atomoxetine and its major metabolites.** *Mi-Jung Kim, Ph.D. Candidate, Choon-Gon Jang, Ph.D., Seok-Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea*

**PURPOSE:** Atomoxetine, a selective norepinephrine receptor inhibitor (SNRI), is used for the treatment of attention-deficit hyperactivity disorder (ADHD) in children, adolescents and adults. The metabolism of atomoxetine is primarily via the major three pathways; aromatic ring-hydroxylation, benzylic hydroxylation and *N*-demethylation. *CYP2C19*, a highly polymorphic drug metabolizing enzyme, is mainly responsible for the atomoxetine *N*-demethylation. We investigated the effects of *CYP2C19* genetic polymorphism on the pharmacokinetics of atomoxetine and its major metabolites, 4-hydroxyatomoxetine (4-HAT) and *N*-desmethyatomoxetine (N-DAT).

**METHODS:** Nineteen subjects were selected and they were divided into two different groups according to *CYP2C19* genotype, *CYP2C19EM* (*CYP2C19\*1\*1*,  $n=12$ ) and *CYP2C19PM* (*CYP2C19\*2\*2* or *CYP2C19\*2\*3*,  $n=7$ ). After overnight fasting, each subject received a single oral dose of 40 mg atomoxetine. Blood samples were collected up to 24 hours after drug intake, and plasma concentrations of atomoxetine and its metabolites were determined by a validated LC-MS/MS analytical method.

**RESULTS:**  $C_{max}$  and  $AUC_{inf}$  of NDAT in *CYP2C19PM* group were significantly lower than those in *CYP2C19EM* group (all  $p < 0.0001$ ).  $AUC_{inf}$  of NDAT in *CYP2C19EM* and *CYP2C19PM* groups were  $82.0 \pm 20.3$  and  $31.0 \pm 10.3$  ng hour/ml, respectively. Other parameters of NDAT were not significantly different between two groups. Also, there were no significant differences in the overall pharmacokinetic parameters of atomoxetine and 4-HAT between two genotype groups.

**CONCLUSION:** *CYP2C19* genetic polymorphism has an impact on the pharmacokinetics of *N*-desmethyatomoxetine, an inactive metabolite of atomoxetine. The clinical implication of these observations is likely to be little.

**194. Pharmacokinetics and pharmacodynamics of meloxicam in relation to CYP2C9 genotype.** *Mi-Jung Kim, Ph.D.Candidate, Choon-Gon Jang, Ph.D., Seok-Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea*

**PURPOSE:** Meloxicam is a nonsteroidal anti-inflammatory drugs (NSAIDs) that exhibits anti-inflammatory, analgesic and antipyretic effects via a selective inhibition of cyclooxygenase-2 (COX-2). Meloxicam is almost completely metabolized to four inactive metabolites, and *CYP2C9* plays an important role in the conversion of meloxicam into 5'-hydroxymethyl metabolite. We investigated effects of different *CYP2C9* genotypes on the pharmacokinetics and pharmacodynamics of meloxicam.

**METHODS:** Twenty-one subjects were selected and they were divided into three different groups according to *CYP2C9* genotype, *CYP2C9EM* (*CYP2C9\*1\*1*,  $n=11$ ), *CYP2C9IM* (*CYP2C9\*1\*3*,  $n=8$ ) and *CYP2C9PM* (*CYP2C9\*3\*3*,  $n=2$ ). After overnight fasting, each subject received a single oral dose of 15 mg meloxicam. Blood samples were collected up to 72 hours after drug intake, and plasma concentrations of meloxicam were determined by a validated HPLC-UV analytical method.

**RESULTS:**  $AUC_{inf}$  of meloxicam in *CYP2C9IM* group was 1.7-fold higher than that in *CYP2C9EM* group ( $74.6 \pm 16.1$  versus  $42.8 \pm 13.3$   $\mu$ g hour/ml,  $p < 0.001$ ). Apparent oral clearance ( $CL/F$ ) and elimination half-life ( $t_{1/2}$ ) of meloxicam between *CYP2C9EM* and *CYP2C9IM* groups was also significantly different ( $p < 0.01$  and  $p < 0.001$ , respectively).  $AUC_{inf}$  of meloxicam in *CYP2C9PM* group ( $341.8 \pm 37.4$   $\mu$ g hour/ml) was almost 8.0-fold higher compared with that in *CYP2C9EM* group. The rate of  $TXB_2$  production was significantly lower in the *CYP2C9IM* and *PM* groups than in the *CYP2C9EM* group.

**CONCLUSION:** *CYP2C9* genetic polymorphism seems to be associated with the pharmacokinetics and pharmacodynamics of meloxicam.

**195. CYP2C9 genetic polymorphism significantly affected the pharmacokinetics of candesartan and its metabolite.** *Ji-Yeong Byeon, B.S., Jung-In Park, B.S., Choon-Gon Jang, Ph.D., Seok-*

Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Candesartan cilexetil, a selective nonpeptide angiotensin II receptor subtype 1 antagonist, is primarily used in the treatment of hypertension. During gastrointestinal absorption, candesartan cilexetil is converted into its active metabolite, candesartan. Candesartan is further metabolized to the inactive compound MII, mediate by CYP2C9 enzymes. We investigated the effects of CYP2C9 genetic variants on the pharmacokinetics of candesartan and its metabolite.

**METHODS:** Twenty-two subjects were selected and they were divided into two different groups according to CYP2C9 genotype, CYP2C9EM (CYP2C9\*1/\*1, n=12) and CYP2C9IM (CYP2C9\*1/\*3 or CYP2C9\*1/\*13, n=10). After overnight fasting, each subject received a single oral dose of 16 mg candesartan cilexetil. Blood samples were collected up to 36 hours after drug intake, and the plasma concentrations of candesartan and its metabolites were determined by using HPLC system with fluorescence detection.

**RESULTS:** AUC<sub>inf</sub> of candesartan in CYP2C9IM group was 1.3-fold higher than that in CYP2C9EM group (p<0.01). Apparent oral clearance of candesartan in CYP2C9IM group was 27% lower than that in CYP2C9EM group (p<0.01). C<sub>max</sub> and AUC<sub>inf</sub> of MII were also significantly different between two genotype groups (all p<0.01). AUC ratio of MII over candesartan was significantly decreased in CYP2C9IM group (1.31 ± 0.26) compared to CYP2C9EM group (2.50 ± 0.53, p<0.0001).

**CONCLUSION:** CYP2C9 genetic polymorphism reduced the metabolism of candesartan into its inactive metabolite.

**196. Effects of ABCC2 C-24T genetic variant on the pharmacokinetics of valsartan in healthy Koreans.** Ji-Yeong Byeon, B.S., Jung-In Park, B.S., Choon-Gon Jang, Ph.D., Seok-Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Valsartan, a selective angiotensin II receptor type-1 (AT1) antagonist, is widely used for the treatment of essential hypertension. Valsartan is minimally metabolized in humans, and more than 80% of absorbed valsartan is excreted in feces, primarily as unchanged drug. It is reported that valsartan is a substrate of MRP2, an efflux transporter encoded by ABCC2 gene. We investigated the effects of ABCC2 C-24T genetic variant on the pharmacokinetics of valsartan.

**METHODS:** Eleven healthy volunteers were selected and they were divided into two groups according to ABCC2 C-24T genotype, -24CC type (CC type, n=6) and -24TT type (TT type, n=5). After overnight fasting, each subject received a single oral dose of 80 mg valsartan. Blood samples were collected up to 24 hours after drug intake, and the plasma concentrations of valsartan were determined by using HPLC system with fluorescence detection.

**RESULTS:** C<sub>max</sub> and AUC<sub>inf</sub> of valsartan in TT type (3.2 ± 2.0 ng/ml and 20.1 ± 13.8 ng hour/ml, respectively) were higher than those in CC type (2.2 ± 0.8 ng/ml and 11.0 ± 3.6 ng hour/ml, respectively). Oral clearance (CL/F) of valsartan in TT type was lower than that in CC type (6.4 ± 5.0 versus 8.7 ± 5.3 L/hour). However, all of these differences were not significant, maybe due to relatively small number of subjects in each group.

**CONCLUSION:** ABCC2 C-24T variant can be a possible genetic determinant that affects the disposition of valsartan. Further studies will establish more clear relationship between ABCC2 genotype and valsartan pharmacokinetics.

**197. Effects of CYP2C9\*3 and CYP2C9\*13 alleles on the pharmacokinetics of celecoxib and its carboxylic metabolite.** So-Young Park, B.S., Hye-In Lee, Ph.D. Candidate, Chang-Ik Choi, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Celecoxib is a selective cyclooxygenase 2 (COX-2) inhibitor and is used for the treatment of rheumatoid arthritis

and osteoarthritis. Celecoxib is mainly metabolized via hydroxylation pathway, which is primarily mediated by CYP2C9, and further immediately oxidized to the inactive carboxylic metabolite. We investigated effects of CYP2C9 genetic polymorphism on the pharmacokinetics of celecoxib and its metabolite in healthy Korean subjects.

**METHODS:** Twenty-six subjects were selected and they were divided into three different groups according to CYP2C9 genotype, CYP2C9EM (CYP2C9\*1/\*1, n=12), CYP2C9IM (CYP2C9\*1/\*3 and CYP2C9\*1/\*13, n=12) and CYP2C9PM (CYP2C9\*3/\*3, n=2). After overnight fasting, each subject received a single oral dose of 200 mg celecoxib. Blood samples were collected up to 48 hours after drug intake, and plasma concentrations of celecoxib and its carboxylic metabolite were determined by using LC-MS/MS system.

**RESULTS:** AUC<sub>inf</sub> of celecoxib in CYP2C9IM group was significantly higher than that in CYP2C9EM group (p<0.001). Oral clearance (CL/F) of celecoxib in CYP2C9IM group was significantly lower than that in CYP2C9EM group (p<0.01). Other parameters of celecoxib were not significantly different between two groups. All pharmacokinetic parameters of celecoxib carboxylic acid (CCA) between CYP2C9EM and CYP2C9IM groups were not statistically significant. Marked increased plasma concentrations of celecoxib and decreased concentrations of CCA were observed in CYP2C9PM group compared with those in other genotype groups.

**CONCLUSION:** CYP2C9 genetic polymorphism can affect the pharmacokinetics of celecoxib and its carboxylic metabolite.

**198. Dose adjustment of celecoxib based on CYP2C9 genotype in healthy Koreans.** So-Young Park, B.S., Hye-In Lee, Ph.D. Candidate, Chang-Ik Choi, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Celecoxib is a selective cyclooxygenase 2 (COX-2) inhibitor and is used for the treatment of rheumatoid arthritis and osteoarthritis. Celecoxib is extensively metabolized by hydroxylation, mediated by CYP2C9 and further oxidation. It is reported that CYP2C9 genetic polymorphism can affect the pharmacokinetic and pharmacodynamic changes of several NSAIDs, including celecoxib. We studied the optimal dose adjustment of celecoxib in relation to CYP2C9 genotype in healthy Koreans.

**METHODS:** After the preliminary study with 26 subjects with different CYP2C9 genotypes, verification study was performed with 31 healthy Koreans. They were divided into two groups according to CYP2C9 genotype, CYP2C9EM (CYP2C9\*1/\*1, n=17) and CYP2C9IM (CYP2C9\*1/\*3, n=14). After overnight fasting, each study group received a single oral dose of 200 and 125 mg celecoxib, respectively. Blood samples were collected up to 48 hours after drug intake, and plasma concentrations of celecoxib were determined by using LC-MS/MS system.

**RESULTS:** In the verification study, oral clearance (CL/F) of celecoxib in CYP2C9IM group was significantly lower compared to that in CYP2C9EM group (96.7 ± 31.2 versus 53.6 ± 14.8 L/hour, p<0.0001), but other pharmacokinetic parameters of celecoxib between two groups were not significantly different. AUC<sub>inf</sub> of celecoxib in CYP2C9EM and CYP2C9IM group was 2226.3 ± 573.8 ng hour/ml and 2502.3 ± 679.2 ng hour/ml, respectively.

**CONCLUSION:** Doses of celecoxib used in this study can be helpful to optimize the CYP2C9 genotype-based doses of celecoxib.

**199. CYP2C9 genotype dependent inhibition of gastric acid secretion by omeprazole.** So-Young Park, B.S.<sup>1</sup>, Chang-Ik Choi, Ph.D.<sup>1</sup>, Jung-Woo Bae, Ph.D.<sup>2</sup>; (1) School of Pharmacy, Sungkyunkwan University, Suwon, South Korea; (2) College of Pharmacy, Keimyung University, Daegu, South Korea

**PURPOSE:** Omeprazole, a proton pump inhibitor (PPI), is used for the treatment of peptic ulcer, gastroesophageal reflux disease (GERD), and the eradication of *Helicobacter pylori* with antimicrobials. The metabolism of omeprazole is primarily mediated by

CYP2C19 enzyme and a lesser extent, CYP3A4. CYP2C19 is known as one of highly polymorphic drug metabolizing enzymes, so we investigated the effect of *CYP2C19* genetic polymorphism on the pharmacokinetics and pharmacodynamics of omeprazole in healthy Koreans.

**METHODS:** Thirty-nine healthy Korean subjects were selected and they were divided into three groups according to *CYP2C19* genotype, CYP2C19EM (*CYP2C19\*1/\*1*, n=16), CYP2C19IM (*CYP2C19\*1/\*2* and *CYP2C19\*1/\*3*, n=13), and CYP2C19PM (*CYP2C19\*2/\*2*, *CYP2C19\*2/\*3*, and *CYP2C19\*3/\*3*, n=10). After overnight fasting, each subject received a single oral dose of 40 mg omeprazole. Blood samples were collected up to 12 hours after drug intake, and the plasma concentrations of omeprazole was determined by using HPLC-UV system. Pharmacodynamics of omeprazole was evaluated by the measurement of intragastric pH.

**RESULTS:**  $C_{max}$  and  $AUC_{inf}$  of omeprazole in CYP2C19PM group was significantly higher than that in CYP2C19EM and IM groups (both  $p < 0.0001$ ). Half-life ( $t_{1/2}$ ) and oral clearance (CL/F) of omeprazole were also significantly different between three genotype groups (both  $p < 0.0001$ ). The differences of mean pH, median pH and the fraction time pH > 4 in each genotype group were all statistically significant (all  $p < 0.0001$ ).

**CONCLUSION:** *CYP2C19* genetic polymorphisms affected the inhibition of gastric acid secretion by omeprazole.

**200. Dose optimization of omeprazole according to the CYP2C19 genotype.** So-Young Park, B.S.<sup>1</sup>, Jung-Woo Bae, Ph.D.<sup>2</sup>, Chang-Ik Choi, Ph.D.<sup>1</sup>; (1) School of Pharmacy, Sungkyunkwan University, Suwon, South Korea; (2) College of Pharmacy, Keimyung University, Daegu, South Korea

**PURPOSE:** Omeprazole, a proton pump inhibitor (PPI), is used for the treatment of peptic ulcer, gastroesophageal reflux disease (GERD), and the eradication of *Helicobacter pylori* with antimicrobials. Omeprazole is extensively metabolized by cytochrome P450 enzymes, and CYP2C19 is the main metabolizing enzyme which is known to be highly polymorphic. It is reported that *CYP2C19* genetic polymorphism can affect the pharmacokinetic and pharmacodynamic changes of several PPIs, including omeprazole. We studied the optimal dose adjustment of omeprazole in relation to *CYP2C19* genotype.

**METHODS:** Forty-two healthy Korean subjects were selected and they were divided into three groups according to *CYP2C19* genotype, CYP2C19EM (*CYP2C19\*1/\*1*, n=15), CYP2C19IM (*CYP2C19\*1/\*2* and *CYP2C19\*1/\*3*, n=15) and CYP2C19PM (*CYP2C19\*2/\*2*, *CYP2C19\*2/\*3* and *CYP2C19\*3/\*3*, n=12) group. After overnight fasting, each genotype group received a single oral dose of 75, 60 and 20 mg omeprazole, respectively. Blood samples were collected up to 12 hours after drug intake, and plasma concentrations of omeprazole were determined by using LC-MS/MS system.

**RESULTS:** Although the  $C_{max}$ ,  $t_{1/2}$  and CL/F were significantly different among three genotype groups ( $p < 0.01$ ,  $p < 0.0001$  and  $p < 0.0001$ , respectively),  $AUC_{inf}$  of omeprazole in each three group was not significantly different. These results indicates that overall plasma concentration of omeprazole in each group was similar.

**CONCLUSION:** Doses of omeprazole used in this study can be applied to the *CYP2C19* genotype-based omeprazole dose determination in Koreans.

**201. CYP2C19 genotype: a moving target?** Tracy N. Zembles, Pharm.D., Charles J. Marcuccilli, Ph.D., M.D., Tara L. Sander, Ph.D., Pippa Simpson, Ph.D.; Children's Hospital of Wisconsin, Milwaukee, WI

**PURPOSE:** Cytochrome *P450 2C19* metabolizes many important medications. Some variants of *CYP2C19* will result in increased or decreased metabolism. Recently, a variant allele (*CYP2C19\*17*) associated with increased gene transcription and thus ultra rapid metabolism of *CYP2C19* substrates was discovered. The aim of this study was to investigate the *CYP2C19\*17*

allelic frequency and recalculate previously reported frequencies of the *CYP2C19\*1* allele.

**METHODS:** Seventy-nine patients that had already been genotyped for *CYP2C19* participated in the study. Laboratory specimens were analyzed using the Applied Biosystems Taqman Drug Metabolism Genotyping Assays, a real-time PCR based genotyping platform which uses 5' nuclease chemistry for amplifying and detecting specific polymorphisms in purified genomic DNA samples. Prevalence of genotypes, alleles, and predicted phenotypes were determined. Distribution of observed genotypes according to ethnicity was documented. Genotypes using the expanded assay were compared to previous results.

**RESULTS:** The *CYP2C19\*17* allelic frequency was 24.7%. Genotyping *CYP2C19\*17* changed our frequency of extensive metabolizers from 74.7% (defined as *CYP2C19\*1/\*1*) to 64.6% (defined as *CYP2C19\*1/\*1* or *CYP2C19\*1/\*17*), reclassifying 10.1% as ultra rapid metabolizers (defined as *CYP2C19\*17/\*17*). Distribution of *CYP2C19\*17* alleles was consistent with known frequencies in the general population.

**CONCLUSION:** As a result of *CYP2C19* testing, individuals with genotypes associated with a higher risk of adverse events or a risk of lack of therapeutic response can be identified, and an alternative strategy can be instituted. Several studies have already reported the functional effect of *CYP2C19\*17* may be clinically important. Our study highlights the need for reassessment of *CYP2C19* allelic frequencies in view of the role *CYP2C19\*17* may have in predicting clinical outcome for drugs metabolized via this pathway.

**202. Effects of CYP3A5 genetic polymorphism on the pharmacokinetics of tamsulosin in subjects with with CYP2D6\*10/\*10.** Ji-Yeong Byeon, B.S., Choon-Gon Jang, Ph.D., Seok-Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Tamsulosin is a selective  $\alpha_1$ -adrenoceptor antagonist and is primarily used for the treatment of lower urinary tract symptoms that are suggestive of benign prostatic hyperplasia (BPH). CYP3A4 and CYP2D6 are major metabolic enzymes responsible for the biotransformation of tamsulosin. It is reported that CYP3A5, one of highly polymorphic CYP450 isozyme, is considered to have similar substrate specificity with CYP3A4. We investigated the effects of *CYP3A5* genetic polymorphism on the pharmacokinetics of tamsulosin when the CYP2D6 activity was decreased.

**METHODS:** Ten healthy subjects genotyped as homozygous for the *CYP2D6\*10* alleles were recruited and they were divided into two groups according to *CYP3A5* genotype, *CYP3A5* expressors (*CYP3A5\*1/\*1* or *CYP3A5\*1/\*3*, n=4) and *CYP3A5* non-expressors (*CYP3A5\*3/\*3*, n=6). After overnight fasting, each subject received a single oral dose of 0.2 mg tamsulosin. Blood samples were collected up to 48 hours after drug intake in each phase, and plasma concentrations of tamsulosin were determined by using LC-MS/MS system.

**RESULTS:**  $C_{max}$  and AUC values of tamsulosin in *CYP3A5* expressors and non-expressors were not significantly different.  $AUC_{inf}$  of tamsulosin in each genotype group was  $88.2 \pm 25.2$  and  $80.4 \pm 10.4$  ng hour/ml, respectively. Although 1.3-fold longer half-life ( $t_{1/2}$ ) of tamsulosin was observed in *CYP3A5* expressors compared with that in *CYP3A5* non-expressors, these difference was not also statistically significant.

**CONCLUSION:** *CYP3A5* genetic polymorphism is not likely to affect the pharmacokinetics of tamsulosin

**203. NOTCH3: a potential predictive biomarker in malignant glioma.** Mohammad A.Y. Alqudah, Pharm.D.<sup>1</sup>, Supreet Agarwal, B.Sc.<sup>1</sup>, Maha S. Al-Keilani, Pharm.D.<sup>1</sup>, Zita Sibenaller, Ph.D.<sup>2</sup>, Timothy C. Ryken, M.D.<sup>2</sup>, Mahfoud Assem, Ph.D.<sup>1</sup>; (1) Pharmaceuticals and Translational Therapeutics, University of Iowa, Iowa, IA; (2) Neurosurgery Department, University of Iowa, Iowa, IA

**PURPOSE:** Malignant gliomas have poor prognosis resulting mainly from high level of cell proliferation, invasion and angio-

genesis. This hallmark of glioma makes the surgery difficult and increase the incidence of tumor recurrence and resistance to cancer therapy. Identification of novel biomarkers that are critical elements in glioma pathogenesis may help individualize therapy and predict prognosis. NOTCH signaling pathway is commonly deregulated in glioma. Using Genome-wide exploration, we previously identified amplification at the NOTCH3 locus. This amplification was associated with high level of NOTCH3 transcripts, NOTCH3 protein content and VEGFA transcripts. In our current study, we analyzed the effect of NOTCH3 knockdown on cell proliferation, cell migration and VEGFA expression.

**METHODS:** NOTCH3 specific shRNA lentivirus was used to knockdown NOTCH3. NOTCH3 knockdown was confirmed using RT-PCR, QReal-time PCR and westernblot. The effect of knockdown on cell proliferation, cell migration and VEGFA expression was analyzed using MTT cell proliferation assay, wound healing assay and QReal-time PCR, respectively.

**RESULTS:** Notch3 locus amplification associated with worse outcome compared to tumors with non-amplified locus ( $p=0.00098$ , 10 versus 28 months median survival, log-rank test). NOTCH3 knockdown significantly reduced cell proliferation, cell migration and VEGF expression compared to the control.

**CONCLUSION:** Our results support NOTCH3 prognostic and predictive biomarker role of NOTCH3 in high grade glioma.

### Pharmacokinetics/Pharmacodynamics/ Drug Metabolism/Drug Delivery

**204. Improvement of vancomycin utilization in a community teaching hospital.** Brenda Gitman, Pharm.D., Rani Patel, Pharm.D., Joseph Gugliotta, M.D.; Hunterdon Medical Center, Flemington, NJ

**PURPOSE:** Pharmacokinetic parameters must be taken into consideration to optimize the utilization of agents such as vancomycin. Currently, at our institution, dosing and monitoring does not follow a standardized approach which may potentiate suboptimal outcomes. The objective of this study was to implement a pharmacist-driven pharmacokinetic service to improve the utilization of vancomycin.

**METHODS:** A 3 month prospective study was conducted at Hunterdon Medical Center. Quadramed Computerized Patient Record System (QCPR) was utilized to identify patients receiving at least one dose of vancomycin from January 2012 to March 2012. Patients were evaluated for appropriateness of initial dosing based on weight and renal function and pharmacokinetics were calculated for all subsequent doses. This dosing strategy was used to assess for therapeutic troughs and compare to retrospective data collected January 2011 to May 2011.

**RESULTS:** One hundred and seven patients in the Phase II portion of the study received at least one dose of vancomycin; of these 47 patients (43.9%) were able to attain a therapeutic trough as compared to the 17 out of 100 patients (17%) included in Phase I of the study ( $p=0.00010$ ). Improvements were seen when assessing the percentage of patients who were able to attain a therapeutic first trough in Phase I and II, 25% and 39.3%, respectively ( $p=0.0372$ ). In assessing composite number of troughs not drawn there were 47 patients who were not monitored with troughs in Phase I and 35 patients in Phase II who required troughs but did not have them drawn ( $p=0.1349$ ); 199 troughs were requested in Phase II. Forty-eight cost saving interventions were recommended and accepted, including dose increases/decreases, frequency increases/decreases, and discontinuation of the agent.

**CONCLUSION:** Improvement in vancomycin utilization was observed after the implementation of a pharmacist-driven pharmacokinetic service.

**205. Evaluation of digoxin pharmacokinetics in a patient undergoing continuous venovenous hemofiltration.** Scott T. Benken, Pharm.D., Bryan D. Lizza, Pharm.D.; Northwestern Memorial Hospital, Chicago, IL

**PURPOSE:** This case report highlights the use of digoxin for right ventricular (RV) support in a critically ill patient requiring continuous venovenous hemofiltration (CVVH) after left-ventricular assist device placement. Therapeutic drug monitoring was utilized in order to (i) calculate the sieving coefficient (sc) of digoxin and (ii) estimate appropriate dosing of digoxin based on extracorporeal unit clearance.

**METHODS:** Pre-filter serum, post-filter serum, and dialysate digoxin concentrations were drawn to calculate the sc. Samples were drawn 6–8 hours after digoxin administration and were collected within 5 minutes of each other. Sampling of serum and dialysate concentrations were conducted in duplicate on consecutive days in order to verify the accuracy of serum and dialysate concentrations.

**RESULTS:** The sc was calculated ( $[2 \times \text{dialysate concentration}] / [\text{pre-filter concentration} + \text{post-filter concentration}]$ ) as 0.80 and 0.76. Extracorporeal unit clearance was estimated to be ~28 ml/minute based on an ultrafiltration rate of 2.2 L/hour (calculated by the ultrafiltration rate [ml/minute]  $\times$  sieving coefficient). Therapeutic serum levels were achieved after calculation and dosing strategy implementation.

**CONCLUSIONS:** Digoxin appears to be cleared by CVVH with a sc of ~0.8. This information could be used to design a dosing regimen that may prevent drug accumulation in patients who require CVVH. Current labeling of digoxin recommends dose reductions of 25–75% or an increase in dosing interval for this calculated extracorporeal unit clearance. The patient was placed on digoxin 125  $\mu\text{g}$  every other day (50% dose reduction) which achieved therapeutic levels for RV support. Further studies are needed to evaluate and verify the pharmacokinetics of digoxin in critically ill patients undergoing CVVH.

**206. Is a standard vancomycin dosing protocol appropriate to achieve therapeutic trough levels in adult neutropenic patients?** Kellye A. Donovan, Pharm.D., Julie Sklenicka, Pharm.D.; Naval Medical Center San Diego, San Diego, CA

**PURPOSE:** Neutropenia is a condition defined as an absolute neutrophil count (ANC) less than 1000 cells/mm<sup>3</sup>, at which point a patient's risk increases for opportunistic infections. Bacteremia cases often involve drug resistant organisms, such as methicillin-resistant *Staphylococcus aureus* (MRSA). Vancomycin is used to treat MRSA infections and serum concentrations must remain above the minimum inhibitory concentration (MIC) to be effective. Improper dosing can delay therapy, which can be life-threatening in neutropenic patients. NMCS D uses a standard vancomycin protocol to target trough concentrations between 10–20  $\mu\text{g}/\text{ml}$ , which correlate to better clinical outcomes in systemic infections. This protocol doses vancomycin at 15–20 mg/kg/dose and administration times are determined by patient renal function. The aim of this study is to explore if vancomycin pharmacokinetics are altered in neutropenic adult patients.

**METHODS:** This retrospective study reviewed neutropenic, adult patients treated with vancomycin from January 2006 to August 2011. A chart review was performed and demographic information was collected. Data included initial vancomycin dosing and administration details. The primary outcome was evaluated by collecting corresponding trough concentrations and results were divided into subtherapeutic (<15  $\mu\text{g}/\text{ml}$ ), therapeutic (15–20  $\mu\text{g}/\text{ml}$ ) or supra-therapeutic (>20  $\mu\text{g}/\text{ml}$ ). Patient demographics were evaluated for effect on achieving therapeutic trough concentrations.

**RESULTS:** A total of 198 patients met inclusion criteria. A total of 107 (54%) patients followed vancomycin dosing and interval recommendations per the protocol. Across all interval groups, 25.3% ( $p<0.001$ ) of patients achieved therapeutic trough concentrations. Comparing the higher frequency group ( $n=42$ ) to the recommended frequency group ( $n=107$ ), there was no significant improvement in achieving therapeutic concentrations. Age, sex and renal function had no significant impact on the ability to achieve therapeutic concentrations.

**CONCLUSIONS:** Study confirms that vancomycin pharmacokinetics is altered in adult neutropenic patients. The pharmacy department is recommending the use of a loading dose for adult

patients with an ANC < 1000 cells/mm<sup>3</sup>. Future studies evaluating use of loading dose and clinical outcomes are needed.

**207. Pharmacokinetics of vancomycin in patients with continuous flow left-ventricular assist devices.** Charles T. Makowski, Pharm.D.<sup>1</sup>, Rachel M. Chambers, Pharm.D., BCPS, (AQ-ID)<sup>2</sup>, Douglas L. Jennings, Pharm.D., BCPS, (AQ-CV)<sup>2</sup>; (1) Eugene Applebaum College of Pharmacy, Wayne State University, Detroit, MI; (2) Henry Ford Hospital, Detroit, MI

**PURPOSE:** To describe the pharmacokinetics of vancomycin in patients with continuous flow left-ventricular assist devices (CF-LVADs).

**METHODS:** This IRB-approved retrospective, descriptive analysis was conducted at an urban, tertiary hospital. Eligible patients were ≥ 18 years old, implanted with a HeartMateII CF-LVAD during January 2008-April 2012, and treated with vancomycin ≥ 48 hours for infection. Key exclusion criteria include < 2 vancomycin levels, ≥ Stage I AKIN acute kidney injury (change in Scr ≥ 0.3 mg/dl or ≥ 1.5-baseline or urine output < 0.5 ml/kg/hour for ≥ 6 hours), acute heart failure exacerbation, hemodynamic instability, and surgery ≤ 5 days before initiating vancomycin. Methods for estimating first-order elimination rate constant (K<sub>e</sub>) (Table 1) and volume of distribution (V<sub>d</sub>) (using ideal [IBW], adjusted [AdjBW], and actual [ABW] body weights) were compared with the actual K<sub>e</sub> and V<sub>d</sub>. Actual pharmacokinetic parameters were calculated from steady-state peak and trough vancomycin levels using one-compartment model equations. Paired t-test or signed-rank test was used.

**RESULTS:** Twelve patients were included (age 44.9 ± 15 years, 91.7% male, 58.3% obese, CL<sub>Cr</sub> 79.2 ± 27 ml/minute). Common reasons for exclusion were < 2 vancomycin levels drawn (n=65) and unstable renal function or hemodynamics (n=4). Common treatment indications (n ≥ 2) were health-care associated pneumonia (41.7%), driveline infection (25%), and sepsis (16.7%). Methods CL<sub>Cr1</sub> and CL<sub>Cr2</sub> for estimating K<sub>e</sub> were highly correlated with actual K<sub>e</sub> (r = 0.78 and 0.79, respectively; p < 0.01). CL<sub>Cr3a</sub> tended to overestimate actual K<sub>e</sub> for obese patients (0.0254/hour [-0.0001 to 0.051 hour; p=0.051]). Obese patients had a lower-than-expected actual V<sub>d</sub>, which was numerically less compared with non-obese patients (0.44 ABW versus 0.57 L/kg ABW; p=0.17). Therefore, EstV<sub>d</sub>\_ABW overestimated actual V<sub>d</sub> for obese patients (23.2 L [7.5–38.9 L; p=0.028]).

**CONCLUSION:** General population methods may accurately estimate the pharmacokinetic parameters of vancomycin for stable non-obese patients with CF-LVADs. Obese patients may require use of AdjBW or IBW for an accurate prediction of V<sub>d</sub>.

Table 1. Methods for estimating K<sub>e</sub><sup>\*</sup>.

Method	ABW/IBW	Designated body weight for CL <sub>Cr</sub> equation <sup>†,‡</sup>
CL <sub>Cr1</sub> <sup>†</sup>	Any	IBW
CL <sub>Cr2</sub> <sup>†</sup>		72 kg
CL <sub>Cr3a</sub> <sup>‡</sup>	≥ 1.3	ABW
CL <sub>Cr3b</sub> <sup>‡</sup>	(obese)	AdjB

<sup>\*</sup>K<sub>e</sub> = 0.00117·CL<sub>Cr</sub> + 0.03.

<sup>†</sup>Cockcroft-Gault.

<sup>‡</sup>Salazar-Corcoran.

**208. Linagliptin fixed-dose combination with metformin is bioequivalent to free-pill combination therapy.** Susanne Buschke, Ph.D., Arne Ring, M.D., Christian Friedrich, M.D., Katrin Metzmann, M.D., Thomas Meinicke, M.D.; Boehringer Ingelheim, Biberach, Germany

**PURPOSE:** To demonstrate bioequivalence of linagliptin-metformin fixed-dose combination (FDC) tablets and the corresponding combination of individual tablets taken together, i.e. combination with free pills (FP).

**METHODS:** These studies used a prospective, open-label, randomized, two-way crossover design. After an overnight fast, healthy

volunteers received an FDC tablet once, and on a separate visit received the corresponding FP once. The two possible treatment sequences (FDC/FP and FP/FDC) were randomly allocated to the subjects. A washout period of 35 days separated the two study treatments. Three dosing combinations were evaluated: linagliptin 2.5 mg with 500, 850, or 1000 mg metformin. The primary endpoints were maximum plasma concentration (C<sub>max</sub>), area under the plasma concentration-time curve from 0–72 hours (AUC<sub>0–72</sub>) for linagliptin, and from 0-infinity (AUC<sub>0–∞</sub>) for metformin.

**RESULTS:** The 90% confidence intervals of the geometric mean ratios (GMR) of C<sub>max</sub> and AUC (calculated as FDC/FP) were within the bioequivalence acceptance limits of 0.80–1.25 (Table). The number of subjects reporting at least one adverse event (AE) in the FDC group was comparable to or less than that in the FP group. Evaluation of vital signs and clinical laboratory tests revealed no safety issues.

**CONCLUSION:** Fixed-dose combination tablets of linagliptin and metformin are bioequivalent to individual tablets of respective dose strengths taken together. Both treatments were well tolerated.

	2.5/500 mg <sup>*</sup> FDC N=94 FP N=95	2.5/850 mg <sup>*</sup> FDC N=95 FP (linagliptin) N=94	2.5/1000 mg <sup>*</sup> FDC N=96 FP N=93
Linagliptin			
AUC <sub>0–72</sub> (nmol × h/l)	1.00 (0.97–1.03)	1.04 (1.00–1.08)	1.07 (1.03–1.10)
C <sub>max</sub> (nmol/L)	0.98 (0.94–1.02)	1.06 (1.03–1.09)	1.03 (1.00–1.07)
Metformin			
AUC <sub>0–∞</sub> (ng × h/ml)	0.99 (0.96–1.02)	1.01 (0.98–1.04)	1.04 (1.00–1.07)
C <sub>max</sub> (ng/ml)	0.98 (0.94–1.02)	1.00 (0.96–1.04)	1.05 (1.00–1.09)

Data are adjusted GMR (FDC/FP) with 2-sided 90% confidence intervals.

<sup>\*</sup>Linagliptin/metformin.

**209. Drug-drug interaction between tamsulosin and diltiazem, a moderate CYP3A4 inhibitor.** Ji-Yeong Byeon, B.S., Jung-In Park, B.S., Choon-Gon Jang, Ph.D., Seok-Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Tamsulosin, a selective α<sub>1A</sub>-adrenoceptor antagonist with relatively high affinity for α<sub>1A</sub>-subtype, is primarily used for the treatment of lower urinary tract symptoms that are suggestive of benign prostatic hyperplasia (BPH). It is reported that CYP3A4 and CYP2D6 are major metabolic enzymes responsible for the biotransformation of tamsulosin. Diltiazem is known as a moderate inhibitor of CYP3A4. In this study, we investigated the effects of co-administration of diltiazem on the pharmacokinetics of tamsulosin.

**METHODS:** Ten healthy subjects genotyped as homozygous for the *CYP2D6* wild-type alleles (*CYP2D6*\*1 or \*2) were recruited for the study. In the control phase, each subject received a single oral dose of 0.2 mg tamsulosin. In the diltiazem phase, the subjects were administered an oral dose of 60 mg diltiazem three-times daily for 4 days. In the study day (day 3), they received a single oral dose of 0.2 mg tamsulosin, 1 hour after the the morning dose of diltiazem was ingested. Blood samples were collected up to 48 hours after drug intake in each phase, and plasma concentrations of tamsulosin were determined by a validated LC-MS/MS analytical method.

**RESULTS:** In the diltiazem phase, C<sub>max</sub> and AUC<sub>inf</sub> of tamsulosin were both 1.7-fold increased than those in the control phase (both p < 0.0001). AUC<sub>inf</sub> of tamsulosin in the control phase and in the diltiazem phase was 48.2 ± 14.1 and 82.2 ± 21.9 ng hour/ml, respectively. Oral clearance (CL/F) of tamsulosin in the diltiazem phase (2.6 ± 0.6 L/hour) was also significantly decreased than that in the control phase (4.4 ± 1.1 L/hour, p < 0.0001). However, half-life (t<sub>1/2</sub>) of tamsulosin between two phases were not significantly different.

**CONCLUSION:** Co-administration of diltiazem significantly decreased the plasma exposure of tamsulosin by the inhibition of CYP3A4 enzyme.

**210. Food and tablet dissolution characteristics do not affect the bioavailability of linagliptin fixed-dose combination with metformin.**

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**PURPOSE:** To investigate the effect of food and tablet-dissolution characteristics on relative bioavailability of a 2.5-mg linagliptin + 1000-mg metformin fixed-dose combination (FDC) tablet.

**METHODS:** Two open-label, randomized, two-way crossover studies enrolled healthy volunteers, who received the FDC tablet once after overnight fast, and once after a high-fat/high-calorie meal (Study-1, N=32), or who received two FDC tablets with either normal-dissolution or prolonged-dissolution behavior after overnight fast (Study-2, N=40). A 35-day washout period separated the two study conditions in each trial. Primary endpoints were  $C_{max}$  and  $AUC_{0-72}$  for linagliptin, and for metformin  $C_{max}$  and  $AUC_{0-24}$  (Study-1), and  $C_{max}$  and  $AUC_{0-tz}$  (Study-2).

**RESULTS:** The 90% confidence intervals of the geometric mean ratios (GMR) of  $C_{max}$  and  $AUC_{0-72}$  for FDC taken with/without food and FDC with normal dissolution/slow dissolution were generally within bioequivalence acceptance limits of 0.80–1.25 (Table). Eleven of 32 subjects in Study-1 and 17/40 in Study-2 reported at least one adverse event (AE) during the two treatments (none serious); no subject was discontinued due to AE. Vital signs, electrocardiography, and clinical laboratory tests revealed no safety issues.

**CONCLUSION:** A high-fat/high-calorie meal does not significantly affect bioavailability of linagliptin or metformin when taken in fixed-dose combination. Food intake reduced the rate of metformin absorption but had no influence on extent of absorption. Differences in FDC dissolution behavior are not relevant for either linagliptin or metformin. All treatments were well tolerated.

	Without food	With food	Adjusted GMR (95% CI)
Study-1			
Linagliptin			
$AUC_{0-72}$ (nmol × h/L)	163.8	161.6	0.99 (0.95–1.03)
$C_{max}$ (nmol/L)	4.99	4.56	0.91 (0.86–0.97)
Metformin			
$AUC_{0-24}$ (ng × h/mL)	12,000	11,500	0.96 (0.89–1.03)
$C_{max}$ (ng/mL)	1820	1490	0.82 (0.77–0.87)
Study-2	Normal dissolution	Slow dissolution	Adjusted GMR (90% CI)
Linagliptin			
$AUC_{0-72}$ (nmol × h/L)	179	179	1.00 (0.96–1.04)
$C_{max}$ (nmol/L)	5.36	5.39	0.99 (0.94–1.05)
Metformin			
$AUC_{0-tz}$ (ng × h/mL)	12,100	12,100	1.00 (0.96–1.05)
$C_{max}$ (ng/mL)	1790	1820	0.98 (0.93–1.04)

**211. Impact of Hispanic ethnicity on tacrolimus dosing in liver transplant patients.** *Annelise M. Nelson, Pharm.D., BCPS, Christina T. Doligalski, Pharm.D., BCPS, Angela T. Logan, Pharm.D., Andrew Silverman, Pharm.D., Angel Alsina, M.D.;* Tampa General Hospital, Tampa, FL

**PURPOSE:** To determine if Hispanic patients require higher doses of tacrolimus to maintain therapeutic concentrations compared with Caucasian patients after liver transplantation, as dose-requirement differences between other ethnic groups have been recognized.

**METHODS:** A retrospective single-center review of Hispanic and Caucasian liver recipients transplanted between January 1, 2007 to December 31, 2010 was conducted. Included patients had stable liver function and stable tacrolimus dosing (three consecutive levels on the same dose) at 3 months post-transplant. Exclusion: age less than 18, previous transplant, total bilirubin above 3 mg/dl, or survival less than 6 months. The primary endpoint was tacrolimus dose (mg/day) at 3 months post-transplant; secondary endpoints included tacrolimus dose (mg/kg/day), tacrolimus dose/concentration ratio and 6 month rejection rates.

**RESULTS:** A total of 374 charts were reviewed; 133 were included with 85 Caucasian and 48 Hispanic subjects. There were no differences in baseline characteristics between groups for age, gender, hepatitis C, or BMI. The mean tacrolimus mg/day and mg/kg/day dose at 3 months was  $7.7 \pm 3.4$  mg/day (0.092 mg/kg/day) for Caucasian patients and  $9.0 \pm 3.8$  mg/day (0.107 mg/kg/day) for Hispanic patients (mg/day  $p=0.04$ , mg/kg/day  $p=0.103$ ). The average tacrolimus trough at 3 months was  $7.1 \pm 1.9$  and  $8.7 \pm 2.8$  ng/ml in the Caucasian and Hispanic groups, respectively ( $p=0.0002$ ). There was no statistical difference in the concentration/dose ratio ([ng/ml]/[mg/kg/day]) between the groups,  $97.7 \pm 59.1$  in the Hispanic group and  $110.7 \pm 93.2$  in the Caucasian group ( $p=0.3273$ ). Rejection in the first 6 months was rare, occurring in 8 and 5 patients in the Caucasian and Hispanic groups, respectively ( $p=0.85$ ).

**CONCLUSIONS:** At 3 months post-transplant, Hispanic patients had higher tacrolimus dose requirements but achieved higher trough concentrations than Caucasian patients. No differences in rejection were seen. Future studies are needed to determine if hypermetabolism of tacrolimus in Hispanic patients exists as it does with other ethnic populations.

**212. Modeling of aceclofenac metabolism to major metabolites in healthy volunteers.** *Eunyoung Kim, Pharm.D., Ph.D.<sup>1</sup>, Wonku Kang, Ph.D.<sup>2</sup>;* (1)Chungnam National University, Daejeon, South Korea; (2)Yeungnam University, Kyoungsan, South Korea

**PURPOSE:** Aceclofenac used widely as a NSAID is converted to 4-hydroxyaceclofenac and diclofenac via cytochrome P450 2C9-mediated hydroxylation and hydrolysis, respectively. CYP2C9 also mediates the hydroxylation of diclofenac to yield 4-hydroxydiclofenac and the hydrolysis of 4-hydroxyaceclofenac to 4-hydroxydiclofenac. We analyzed the pharmacokinetics of aceclofenac and the sequential formation of its three metabolites using a compartmental modeling approach.

**METHODS:** Following an administration of aceclofenac 100 mg in healthy volunteers, blood sample was serially taken and plasma concentrations of aceclofenac and its three metabolites were measured using LC/MS/MS. Time courses of plasma concentrations of four substances were modeled by ADAPT 5.

**RESULTS:** The delay parameter ( $\tau = 0.2$  hours) shifted the plasma aceclofenac concentration–time profile to the right and provided a large improvement of fit, especially during the absorption phase and around the maximum concentration of aceclofenac. The absorption rate constant,  $k_a$ , was 0.65/hour in the absence of the time delay, and the correlation coefficient ( $r^2$ ) was 0.82. A steep absorption rate constant (0.95/hour) was obtained with  $\tau$ , and  $r^2$  increased to 0.96. Two compartments were needed to fit the aceclofenac and 4-hydroxyaceclofenac data, and one additional compartment was sufficient to describe the time courses of the generated plasma concentrations of diclofenac and 4-hydroxydiclofenac. The metabolism rate constant for 4-hydroxyaceclofenac ( $k_{m,4OH-ace}$ , 0.72/hour) was estimated to be much greater than that for diclofenac ( $k_{m,diclo}$ , 0.04/hour). In the same manner, the generation rate constant of 4-hydroxydiclofenac from diclofenac ( $k_{m,Fdiclo}$ , 0.46/hour) was greater than that of its generation from 4-hydroxyaceclofenac ( $k_{m,F4OH-ace}$ , 0.01/hour).

Aceclofenac and its metabolites were simulated following multiple administration of aceclofenac 100 mg twice daily.

**CONCLUSION:** Our model fully describes the time course of plasma aceclofenac concentration as well as the formation and disposition of its three major metabolites in healthy volunteers.

### 213. Cytochrome P450 3A4 drug interaction profile of tofacitinib.

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**PURPOSE:** Tofacitinib is an oral Janus Kinase (JAK) inhibitor currently in development for the treatment of several inflammatory conditions including rheumatoid arthritis. Tofacitinib is primarily metabolized by the cytochrome p450 3A4 system (CYP3A4). The objective of these studies is to describe the potential drug-interaction profile of tofacitinib, focusing on the CYP3A4 isoenzyme.

**METHODS:** Two separate open-label, pharmacokinetic studies were conducted in 12 healthy volunteers to determine the pharmacokinetic parameters of oral tofacitinib when administered with ketoconazole (potent CYP3A4 inhibitor), and rifampin (potent CYP3A4 inducer). In study 1, subjects received a single-dose of tofacitinib 10 mg in Period 1. In Period 2, subjects received ketoconazole 400 mg for 3 days followed by a single-dose of tofacitinib 10 mg on Day 3. In study 2, subjects received a single-dose of tofacitinib 30 mg in Period 1. In Period 2, subjects received rifampin 600 mg for 7 days followed by a single-dose of tofacitinib 30 mg on Day 8. In both studies, blood samples of tofacitinib were taken at 0, 0.5, 1, 2, 4, 6, 8, 12, 16, and 24 hours after tofacitinib dosing in Periods 1 and 2.

**RESULTS:** Coadministration with ketoconazole increased tofacitinib AUC<sub>inf</sub> and C<sub>max</sub> by 103%, (ratio: 203% [90% CI: 191–216%]) and 16% (ratio: 116% [90% CI: 105–129%]), respectively. Mean t<sub>1/2</sub> increased from 2.9 to 3.9 hours and median T<sub>max</sub> increased from 0.5 to 1.0 hours with ketoconazole administration. Coadministration of rifampin decreased mean tofacitinib AUC<sub>inf</sub> by 84% (ratio: 16% [90% CI: 14–18%]) and C<sub>max</sub> by 74% (ratio: 26% [90% CI: 23–31%]). Mean t<sub>1/2</sub> for tofacitinib decreased from 4.2 to 2.9 hours, however, median T<sub>max</sub> was similar with and without rifampin.

**CONCLUSION:** These results suggest that pharmacokinetic parameters of tofacitinib are altered when it is administered with ketoconazole (potent CYP3A4 inhibitor) or rifampin (potent CYP3A4 inducer).

### 214. Ethanol inhibits the metabolism of oseltamivir to its active metabolite.

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**PURPOSE:** Human carboxylesterase-1 (hCE1) plays an important role in the metabolism of many commonly used drugs containing ester groups. Unlike drugs metabolized by cytochrome-P450 enzymes, it remains unclear whether metabolic inhibition of hCE1 is a potential mechanism for drug-drug interactions for medications that are substrates for this enzyme. Ethanol inhibits hCE1 in-vitro and in animal models but its effects on hCE1 substrates in humans are uncertain. This study uses the ester prodrug oseltamivir (OS) as a probe in humans to determine if ethanol inhibits hCE1-mediated hydrolysis of OS to the active neuraminidase inhibitor metabolite, oseltamivir carboxylic acid (OSA).

**METHODS:** Healthy human volunteers (n=9) received 150 mg oral OS (Tamiflu™) alone and with ethanol on separate study days with blood samples collected at various times for analysis of OS and OSA by LC/MS/MS. OS and OSA pharmacokinetic parameters were estimated using standard noncompartmental analysis.

**RESULTS:** The effects of ethanol on OSA pharmacokinetics are shown in the table below. Ethanol did not affect OS C<sub>max</sub>, T<sub>max</sub>, AUC<sub>0–6 hours</sub>, or AUC<sub>inf</sub>.

OSA pharmacokinetic parameters	Oseltamivir	Oseltamivir + EtOH
C <sub>max</sub> (ng/ml)	477 ± 59	432 ± 68*
T <sub>max</sub> (hours)	4.4 ± 0.5	6.2 ± 1.2*
AUC <sub>0–6 hours</sub> (ng/ml hour)	1759 ± 379	1437 ± 368*
AUC <sub>0–6 hours</sub> Ratio (ng/ml hour)	6.9 ± 1.8	4.9 ± 1.2*
AUC <sub>0–inf</sub> (ng/ml hour)	6838 ± 593	6755 ± 840
AUC <sub>0–inf</sub> Ratio (ng/ml hour)	22.6 ± 4.6	19.3 ± 5.4*

\*p<0.05; AUC<sub>0–6</sub> ratio = OSA AUC<sub>0–6 hours</sub> / OS AUC<sub>0–6 hours</sub>; AUC<sub>inf</sub> Ratio = OSA AUC<sub>inf</sub> / OS AUC<sub>inf</sub>. Data are mean ± standard deviation.

**CONCLUSION:** Ethanol inhibits the conversion of OS to the active OSA metabolite and therefore could affect the antiviral activity of OS (Tamiflu™). Ethanol-mediated inhibition of hCE1 hydrolysis may be an important mechanism for drug-drug interactions and affect the safety and efficacy of the many medications that are substrates for this enzyme.

### 215. Three cases of iatrogenic adrenal insufficiency due to concomitant administration of posaconazole and budesonide.

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**PURPOSE:** Iatrogenic adrenal suppression and Cushing syndrome are well-described adverse events in patients receiving corticosteroids in combination with azole antifungals other than posaconazole (POS). Like other azoles, POS is an inhibitor of CYP3A4. Budesonide (BUD), a corticosteroid, is a substrate for CYP3A4. To date, no studies have assessed the influence of POS on corticosteroid pharmacokinetics (PK). Moreover, current labeling for POS does not include possible interactions with corticosteroids. The purpose of this report is to describe the interaction between POS and budesonide via retrospective analysis.

**METHODS:** Retrospective review of patients receiving concurrent POS and BUD.

**RESULTS:** Patients receiving concomitant POS and BUD.

Patient and Diagnosis [POS Dose]	BUD dose	BUD trough serum concentrations* (nmol/L)	Cortisol normal range: 5 – 25 µg/dl
29 year old male with common variable immunodeficiency enteropathy [400 mg BID]	3 mg QD	4.41	<1.0 µg/ml
7 year old male with chronic granulomatous disease colitis [300 mg TID]	3 mg QD	7.20	<1.0 µg/ml
59 year old female with celiac disease and bronchiectasis [200 mg QID]	3 mg QOD	5.81	<1.0 µg/ml
	3 mg TID	10.11	<1.0 µg/ml
	3 mg BID	9.06	<1.0 µg/ml
	3 mg QD	5.34	<1.0 µg/ml

\*Average BUD peak concentration following a 9 mg dose is ~5 nmol/L.

**CONCLUSION:** Three patients receiving concomitant BUD and POS experienced adrenal insufficiency along with BUD trough concentrations that exceeded typical peak BUD concentrations when the drug was administered without concurrent azole therapy (Table). Inhibition of budesonide metabolism via CYP3A4 by POS is the likely mechanism for this interaction. To our knowledge, this is the first report of a PK/PD interaction between POS and a corticosteroid. Accordingly, POS should be used with cau-

tion in patients receiving concurrent corticosteroids metabolized via CYP3A4. In addition, POS labeling should recognize the possibility of this interaction due to its potentially serious nature.

**216. The vasculo-protective effect of candesartan after ischemic stroke: an antioxidant.** *Ahmed Alhusban, Pharm.D.<sup>1</sup>, Anna Kozak, M.S.<sup>2</sup>, Tauheed Isharat, Ph.D.<sup>3</sup>, Bindu Pillai, M.S.<sup>3</sup>, Susan C. Fagan, Pharm.D.<sup>3</sup>;* (1) University of Georgia, Augusta, GA; (2) University of Georgia College of Pharmacy and Veteran's Affairs Medical Center, Augusta, GA; (3) Program in Clinical and Experimental Therapeutics, Charlie Norwood VA Medical Center Au, University of Georgia College of Pharmacy, Augusta, GA

**PURPOSE:** Angiotensin II receptor blockers (ARBs) have been found to have antioxidant effects and to reduce vascular injury after stroke, but whether the two are causally related is unclear.

**METHODS:** Forty hypertensive rats (SHR) were treated with either candesartan 1 mg/kg or saline after 3 hours of middle cerebral artery occlusion (MCAO) and were reperfused for 21 hours prior to sacrifice. An additional group (n=16), were treated with the SOD mimetic, tempol, for 2 weeks prior to the same procedure. After saline perfusion, brain tissue was collected for quantification of excess hemoglobin, and biochemical analyses.

**RESULTS:** Treatment with tempol and candesartan significantly reduced the blood pressure, but the effect of tempol was less pronounced than candesartan. Candesartan 1 mg/kg significantly reduced hemorrhagic transformation (HT) in SHR animals after stroke (p<0.05). Animals treated with tempol had significantly lower incidence of HT than controls and this was NOT further reduced by candesartan (p=0.01). Candesartan treatment significantly increased the expression of eNOS in stroked hemisphere (p<0.05) a response that was lost in those treated with tempol. In contrast, the p-eNOS/eNOS ratio was significantly increased in animals treated with candesartan and tempol combination, compared to either alone (p<0.5).

**CONCLUSION:** Acutely administered candesartan reduces HT in SHRs at 24 hours after MCAO by an antioxidant mechanism.

**217E. In vitro activity of colistin alone and in combination with doripenem against KPC-producing *K. pneumoniae* isolates.** *Grace C. Lee, Pharm.D., BCPS, David S. Burgess, Pharm.D., FCCP;* University of Texas at Austin College of Pharmacy and University of Texas Health Science Center School of Medicine, San Antonio, TX

**PURPOSE:** Most KPC-producing organisms have maintained susceptibility to polymyxins; however, development of resistance to polymyxins has been increasingly reported. One potential treatment modality is to optimize the use of combination therapy. Therefore, we evaluated the in vitro activity of doripenem and colistin alone and in combination against KPC-producing *K. pneumoniae*.

**METHODS:** MICs were determined for doripenem (DOR) and colistin (COL) against four non-duplicate KPC-*K. pneumoniae* isolates. All isolates carried bla<sub>KPC-3</sub> and genes encoding TEM-1 and SHV-11/36 as previously described in the clinical outcomes evaluation (J Clin Microbiol 2010;48: 623-5). Time-kill curves were performed with the following antibiotic concentration (mcg/mL) alone and in combination with DOR (6) and COL (2x MIC). Bacterial densities were determined at 0, 4, 8, 12, 24 and 48 hours. Bactericidal activity was defined as  $\geq 3\text{-log}_{10}$  CFU/ml reduction from the starting inoculum. Synergism was defined as  $\geq 2\text{-log}_{10}$  reduction with the combination when compared to the most active single agent at 24 hours.

**RESULTS:** MICs for COL ranged from 0.0625 to 0.5  $\mu\text{g/ml}$  and all isolates were resistant to DOR (MICs ranged 16-32  $\mu\text{g/ml}$ ). Monotherapy with COL displayed killing activity within 12 hours; however, significant re-growth occurred by 24 hours for COL monotherapy in all isolates. Monotherapy with DOR did not show bactericidal activity in any isolate. Synergy occurred in combination of COL with DOR against all isolates and was sustained at 48 hours. Combination of COL and DOR demonstrated rapid bactericidal activity by 4 hours in all isolates and was sustained for 24 hours.

**CONCLUSION:** Colistin in combination with doripenem may be an important treatment modality despite colistin susceptibility to reduce potential resistance when treating KPC-producing organisms.

Presented at 52nd Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco, CA, 2012.

**218. Evaluation of the maternal-fetal transfer of granisetron in an ex vivo placenta perfusion model.** *Judith A. Smith, Pharm.D., BCOP, FCCP, FISOPP<sup>1</sup>, Justin Julius, Pharm.D.<sup>2</sup>, Andrew Tindall, B.S.<sup>3</sup>, Jerrie Refuerzo, M.D.<sup>4</sup>, Pamela D. Berens, M.D.<sup>4</sup>, Kenneth Moise, M.D.<sup>4</sup>;* (1) UT M. D. Anderson Cancer Center, Houston, TX; (2) The UT MD Anderson Cancer Center, Houston, TX; (3) UT MD Anderson Cancer Center, Houston, TX; (4) University of Texas Health Sciences Center at Houston Medical School, Houston, TX

**PURPOSE:** The primary objective of this study was to determine the transfer of granisetron across the placental/trophoblastic barrier (PTB). Define the no effect dose level (NOEL) on the fetal tissues after in utero exposure to granisetron.

**METHODS:** Term human placentas (N=8) were collected immediately after delivery. A single cotyledon from each placenta was localized, perfused and stabilized with physiologic Eagles minimal essential medium containing 3% bovine albumin and heparin. Granisetron was added to the maternal medium in two concentrations to mimic systemically achieved maternal peak concentrations following IV administration (50 ng/ml) and transdermal administration (5 ng/ml). To assess transfer and accumulation, fluid aliquots from both maternal and fetal compartments were collected for an open and closed systems. In vitro exposure of fetal derived cell lines with assessment of toxicity using flow cytometry and apoptotic protein ELISA.

**RESULTS:** In the 50 ng/ml open model, maternal granisetron the mean peak concentration was  $47.4 \pm 14.8$  ng/ml and a mean trough concentration of  $27.0 \pm 8.1$  ng/ml with fetal side peak/trough concentrations of  $7.1 \pm 6.4$  and  $4.8 \pm 4.4$  ng/ml respectively. However, in the 5 ng/ml model, the maternal granisetron peak/trough concentrations were  $5.0 \pm 0.5$  and  $3.7 \pm 0.6$  ng/ml and there was no detectable drug in the fetal compartment. The mean granisetron clearance index was  $0.70 \pm 0.68$ . No significant difference was observed in apoptosis at 3 ng/ml.

**CONCLUSIONS:** Transplacental passage of granisetron was incomplete at high concentrations that would be achieved with intravenous dosing in the pregnant patient. Higher concentrations have potential to induce up to 10% apoptosis in cardiac tissue however the clinical significance needs further evaluation. At concentrations similar to those achieved with transdermal administration of granisetron there was no transplacental passage of granisetron and were below the NOEL thus would be safe during pregnancy.

## Psychiatry

**219E 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;* Clear Lake Regional Medical Center, Webster, TX

**PURPOSE:** Individuals that reside in state supported living centers for the developmental disabled and mentally impaired can be 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 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 50 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 minimizing the development of adverse drug events or potential toxicities. Presented at College of Psychiatric and Neurologic Pharmacists meeting.

#### 220E. Second generation antipsychotic prescribing patterns for veterans with posttraumatic stress disorder over a 10-year period.

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**PURPOSE:** This study examined the pattern of use of second generation antipsychotics (SGAs) in veterans with posttraumatic stress disorder (PTSD) over a 10-year period. The specific objectives were to determine the percentage of PTSD patients who were prescribed SGAs each year during the study period and to determine prescribing patterns for individual SGAs.

**METHODS:** De-identified clinical data were retrieved from the VISN-7 Data Warehouse (includes eight VA Medical Centers in Alabama, Georgia, and South Carolina). Patients with an ICD-9 code for PTSD (excluding bipolar, psychotic, and dementia diagnoses) in fiscal years 1999–2008 were selected for inclusion, and the electronic pharmacy database was examined for prescriptions for SGAs. Descriptive statistics were used to report data concerning prescribing patterns.

**RESULTS:** The number of unique PTSD patients increased dramatically from 8247 in 1999 to 28,309 in 2008. The percentage of PTSD patients prescribed an SGA increased steadily from 11.7% in 1999 to 31.9% in 2004, but then declined steadily to 18.5% by 2008. Prescribing patterns for individual SGAs showed variability over the study period, with the most striking examples being diminished use of olanzapine (approximately 50% of all SGA use in 1999–2000 versus approximately 5% of all SGA use in 2006–2008) and increased use of quetiapine (approximately 10–15% of all SGA use in 1999–2000 versus approximately 65–75% of all SGA use in 2003–2008). During the final years of the study period, patients who were prescribed quetiapine therapy were far more likely to receive high-dose (>100 mg/day) therapy as opposed to low-dose therapy.

**CONCLUSION:** SGAs were widely used in the treatment of veterans with PTSD, and quetiapine was by far the most frequently prescribed SGA. Given the metabolic concerns associated with the use of SGAs, guidelines for their appropriate use in PTSD may be warranted.

Presented at College of Psychiatric and Neurologic Pharmacists Annual Meeting, Tampa, FL, April 29, 2012.

### Pulmonary

#### 221E. Indacaterol 75 µg once daily improves health status in patients with moderate-to-severe COPD: responder analysis.

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Danny McBryan, M.D.<sup>6</sup>; (1)Dartmouth-Hitchcock Medical Center, Lebanon, NH; (2)Clinical Research of West Florida, Clearwater, FL; (3)Pulmonary Associates, Phoenix, AZ; (4)Novartis Pharmaceuticals Corporation, East Hanover, NJ; (5)Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, United Kingdom; (6)Novartis Pharma AG, Basel, Switzerland

**PURPOSE:** Patients with chronic obstructive pulmonary disease (COPD) experience impaired health status. Indacaterol is an inhaled, once-daily (od), long-acting  $\beta_2$ -agonist for treatment of COPD.

**METHODS:** Two identical randomized, double-blind, 12-week studies (S1 and S2), in moderate-to-severe COPD patients receiving indacaterol 75 µg od or placebo. Bronchodilator effects (trough FEV1 at Week 12) & health status using St George's Respiratory Questionnaire (SGRQ) were assessed. Changes of 4 units in SGRQ are considered minimal clinically important difference (MCID). Responders ( $\geq$  MCID) from all COPD studies with indacaterol 75 µg od versus placebo were analyzed for extent of SGRQ improvement (substantial health status improvement defined as SGRQ change of  $-8$  to  $-16$  units).

**RESULTS:** A total of 323 patients from S1 and 318 from S2 were randomized. Mean age: 64 and 61 years; post-albuterol FEV1 54% and 55% predicted, FEV1/FVC 52% and 53%. Mean baseline SGRQ scores: 48.4 and 51.3 (indacaterol) versus 49.7 and 50.5 (placebo). At Week 12, SGRQ score improved with indacaterol versus placebo in both studies; mean changes from baseline with indacaterol & placebo, respectively, were  $-5.8$  and  $-2.0$  (S1);  $-4.9$  and  $-0.9$  (S2). In responder analysis, an improvement in SGRQ of at least MCID was more frequent with indacaterol (203/410; 49.5%) versus placebo (618/1564; 39.5%). Higher percent of patients had substantial improvement ( $-8$  to  $-16$ ) with indacaterol (23.2%) versus placebo (14.5%). Expressed as percentage of patients with SGRQ response of at least  $-4$  (MCID), 46.8% (95/203) of responders on indacaterol had substantial SGRQ improvements ( $-8$  to  $-16$  units), versus 36.7% (227/618) placebo. The odds ratio (OR) for substantial SGRQ improvement of  $\geq -8$  favored indacaterol (OR: 1.52, 95% CI: 1.16, 1.99;  $p=0.0027$ ).

**CONCLUSION:** Indacaterol 75 µg od provided significant improvements in health status compared with placebo, with more patients achieving a clinically relevant improvement. Among indacaterol-treated patients with clinically relevant improvements, 46.8% had substantial ( $\geq 8$  unit) improvement in SGRQ.

Presented at The 2012 International Conference of the American Thoracic Society, San Francisco, CA, May 18–23, 2012.

#### 222E. Efficacy and safety of indacaterol 75 µg once daily in patients with moderate-to-severe COPD: pooled analysis of two phase III trials.

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**PURPOSE:** Indacaterol is a novel, once-daily (od), inhaled, long-acting  $\beta_2$ -agonist for treatment of chronic obstructive pulmonary disease (COPD). We analyzed pooled efficacy and safety data from two identically designed, randomized, double-blind, placebo-controlled, phase III trials in patients with moderate-to-severe COPD.

**METHODS:** Patients received indacaterol 75 µg od (n=322) or matching placebo (n=318) for 12 weeks. The primary efficacy variable was trough FEV1 (mean of values at 23 hour 10 minutes and 23 hours 45 minutes post dose), at Week 12. Key secondary efficacy variable was transition dyspnea index (TDI) total score, after 12 weeks. Additional efficacy data (rescue albuterol use, health-related quality of life [HRQoL; St George's Respiratory Questionnaire, SGRQ]) and safety were collected.

**RESULTS:** At baseline, mean age was 62.7 years with post-albuterol FEV1 54.0% predicted; 41.4% of patients were taking inhaled corticosteroids. Indacaterol 75 µg increased trough FEV1 at Week 12 by clinically relevant amounts ( $\geq 120$  ml;  $p < 0.001$  versus placebo). Indacaterol-treated patients had significantly ( $p < 0.001$ ) reduced use of rescue albuterol and decreased dyspnea versus placebo. In addition, SGRQ total score was significantly lower (better HRQoL) with indacaterol ( $p < 0.001$  versus placebo). The overall incidence of adverse events (AEs) was similar between indacaterol (46.9%) and placebo (43.9%). Serious AEs occurred in 2.5% and 4.1% of indacaterol and placebo patients, respectively, with two deaths (0.6%) in the placebo group. Notable serum potassium ( $< 3.0$  mmol/L) occurred in 0.3% of patients in both groups, while notable blood glucose ( $> 9.99$  mmol/L) was reported in 5.3% of indacaterol-treated and 7.8% of placebo-treated patients. There were no reports of QTc interval  $> 60$  milliseconds (Fridericia).

**CONCLUSION:** In this pooled analysis, indacaterol 75 µg od provided effective 24-hour bronchodilation, improved HRQoL, reduced use of rescue medication, and improved dyspnea versus placebo. Indacaterol had a safety profile similar to placebo in patients with moderate-to-severe COPD.

Poster presented at the International Conference of the American Thoracic Society, ATS 2012, May 18–23, 2012, San Francisco, USA.

**223E. Chronic obstructive pulmonary disease outcomes based on level of short-acting B2-agonist use.** Amir Sharafkhaneh, M.D., Ph.D.<sup>1</sup>, Nicola A. Hanania, M.D., M.S., FCCP, FRCPC, FACP<sup>2</sup>, Gene L. Colice, M.D.<sup>3</sup>, James D. Donahue, M.D.<sup>4</sup>, Aylin Riedel, Ph.D.<sup>5</sup>, Jonathan Kurlander, M.S.<sup>5</sup>, Pablo R. Altman, M.D., M.B.A.<sup>6</sup>, John Howard, Pharm.D.<sup>6</sup>, Joe Harper, Pharm.D.<sup>6</sup>; (1) Michael E. DeBakey VA Medical Center, Houston, TX; (2) Baylor College of Medicine, Houston, TX; (3) Washington Hospital Center, Washington, DC; (4) University of North Carolina School of Medicine, Chapel Hill, NC; (5) OptumInsight, Eden Prairie, MN; (6) Mylan Specialty L.P., Basking Ridge, NJ

**PURPOSE:** We determined a level of short-acting B2-agonist (SABA) use associated with increased acute exacerbations and healthcare cost.

**METHODS:** Retrospective analysis of two databases with linked medical and pharmacy data covering 37 million lives, similar to the US population. Each enrollee had at least two claims for chronic obstructive pulmonary disease (COPD) during January 1, 2008–March 31, 2010; and SABA use. Medical and pharmacy claims were used to calculate puffs and nebulization vials/day (90 µg and 2.5 mg albuterol, respectively or equivalent). COPD-related exacerbations included inpatient, emergency department, and urgent care events and new claims for systemic corticosteroids or antibiotics proximal to a COPD outpatient encounter. Descriptive and multivariate techniques examined the association between SABA use and outcomes. Sensitivity and specificity were examined by demographics, insurance type, and concomitant therapy.

**RESULTS:** There were 66,004 patients who met study criteria (mean [SD] age: 66.9 [10.3] years; 44% male; 56% commercial insurance, 44% Medicare). Of all, 20.5%, 56.6%, and 22.9% used nebulized SABA, metered-dose inhaler (MDI), or both, respectively. Incidence of exacerbations was significantly higher in patients using  $\geq 1.5$  vials or  $\geq 3$  puffs of SABA on average/day (2.5 exacerbations/year versus 1.9 for nebulized SABA and 1.7 versus 1.4 for MDI SABA;  $p < 0.05$  for both); these patients also had higher annual healthcare costs (\$19,459 versus \$11,862 and \$10,779 versus \$8555;  $p < 0.05$  for both).

**CONCLUSION:** SABA use  $\geq 1.5$  times/day ( $\geq 1.5$  vials of nebulization/day or  $\geq 3$  puffs of MDI/day) was associated with more exacerbations and higher costs. This translates to “The Rule of 3-2” (3 times in 2 days) to identify COPD patients needing treatment re-evaluation.

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ference, San Francisco, CA, May 18–23, 2012; the Eastern Allergy Conference, Palm Beach, FL, May 31–June 3, 2012.

## Substance Abuse/Toxicology

**224. ETapentadol abuse: the first 18 months.** Richard C. Dart, M.D., Ph.D.<sup>1</sup>, Edgar H. Adams, Sc.D.<sup>2</sup>, Becki B. Bucher-Bartelson, Ph.D.<sup>1</sup>, Gary M. Baker, Pharm.D.<sup>3</sup>, Janet K. Pitner, Pharm.D., M.B.A.<sup>3</sup>, Gary J. Vorsanger, Ph.D., M.D.<sup>3</sup>; (1) Rocky Mountain Poison and Drug Center, Denver, CO; (2) Covance Market Access, Gaithersburg, MD; (3) Janssen Scientific Affairs, LLC, Raritan, NJ

**PURPOSE:** Prescription opioid analgesics play an important role in the management of moderate to severe pain. An unintended consequence of these agents is the nonmedical use of prescription pain relievers. In 2008, nonmedical use of pain relievers among persons aged 12 years or older was second only to marijuana in the U.S. We describe the rates of abuse, misuse, and diversion of tapentadol immediate release (Nucynta<sup>®</sup>, CII), for the 18 months following launch in 2009.

**METHODS:** The RADARS<sup>®</sup> System measures rates of abuse, misuse and diversion throughout the U.S. Data from the Drug Diversion, Survey of Key Informants (SKIP), Poison Center, and Opioid Treatment Programs were analyzed to compare rates for tapentadol with other opioid analgesics from June 2009 through December 2010, utilizing both per 100,000 population (POP) and per 1000 Unique Recipients of Dispensed Drug (URDD) as denominators.

**RESULTS:** Based on data from the SKIP program from June 2009 to December 2010, non-medical use rates for tapentadol fluctuated between 0 and 0.572 per 1000 people who filled a prescription (URDD) and 0 and 0.015 per 100,000 population (POP), reflecting non-significant changes over time ( $p = 0.816$  and  $p = 0.867$ , respectively). Data from Poison Centers, Outpatient Treatment Programs, and Drug Diversion programs also showed similar non-significant trends in population and exposure rates (all  $p$ -values  $> 0.05$ ) during the observation period.

**CONCLUSION:** Since product launch, rates of abuse, misuse, and diversion of tapentadol have been low; however, continued monitoring of trends in the data are warranted. Published in Pain Med. 2012;13(2): 330–331, A270.

## Transplant/Immunology

**225. Contributions of the Orphan Drug Act: agents for solid organ transplantation.** Christopher R. Ensor, Pharm.D.<sup>1</sup>, Timothy R. Cote, M.D., M.P.H.<sup>2</sup>, Lili A. Barouch, M.D.<sup>3</sup>; (1) The Johns Hopkins Hospital, Baltimore, MD; (2) Keck Graduate Institute, Claremont, CA; (3) Johns Hopkins University, Baltimore, MD

**PURPOSE:** The Orphan Drug Act (ODA) of 1983 applies to the development of therapies for solid organ transplantations because are considered rare by definition ( $< 200,000$  patients per year). The ODA has worked impressively well to incentivize drug development in rare diseases and conditions, including solid organ transplantation (SOT). We sought to characterize the impact of the ODA on the development and advancement of agents for SOT.

**METHODS:** We used Food and Drug Administration data from the publically available Orphan Drug Product Designation Database to identify orphan designations and approvals for SOT therapies. We examined records from January 1, 1983 until December 31, 2011 and described temporal trends. We classified SOT therapies for peri- or post-transplant use. Peri-transplant agents were subdivided into (i) induction or rescue drugs, (ii) drugs for prevention of primary graft dysfunction, and (iii) preservation or procurement agents/solutions. Post-transplant agents were subdivided into (i) maintenance anti-rejection therapies, (ii) antivirals, or (iii) diagnostic agents. All statistical comparisons were made with Poisson (log-linear) regression and  $p < 0.05$  was considered statistically significant.

**RESULTS:** We found 45 designated products; 20 (44%) of which are fully marketed. Comparing the periods 1986–1990 to 2006–2010, designations and market approvals have progressively increased 5- and 8-fold, respectively. Year-by-year analysis of trends demonstrated a statistically significant increase in SOT designations ( $p=0.003$ ) and a strong trend toward statistical significance for increased market approvals ( $p=0.09$ ).

**CONCLUSIONS:** Transplant medicine is unique, and the ability to develop new therapies for SOT patients has been greatly magnified by the orphan designation process. Key approvals have been pivotal in making available drugs with new mechanisms of action that, in several cases, have revolutionized medical therapy for transplant patients.

**226E. Single center experience with prospectivemonitoring in renal transplantation.** Jennifer Trofe-Clark, Pharm.D., BCPS<sup>1</sup>, Simin Goral, M.D.<sup>2</sup>, Deirdre Sawinski, M.D.<sup>2</sup>, Melissa Bleicher, M.D.<sup>2</sup>, Matthew H. Levine, M.D.<sup>3</sup>, Peter L. Abt, M.D.<sup>3</sup>, Lauren Ende-Schwartz, M.D.<sup>4</sup>, Vivanna Vandeerlin, M.D., Ph.D.<sup>4</sup>, Roy D. Bloom, M.D.<sup>2</sup>; (1)Hospital of the University of Pennsylvania Pharmacy Services and Renal Division, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; (2)Renal Division, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; (3)Division of Transplant Surgery, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; (4)Department of Pathology and Laboratory Medicine, Hospital of the University of Pennsylvania, Philadelphia, PA

**PURPOSE:** Prospective screening for BK viremia (BKV) post renal transplant (RTR) may prevent BKV nephropathy (BKVN). We sought to: (i) Determine incidence and time to BKV with use of protocolized screening; (ii) Examine effect of screening on biopsy proven rejection and BKVN.

**METHODS:** In January 2008, we implemented quantitative BKV plasma screening for all RTR (including kidney-pancreas) patients at 3, 6, 12 months then yearly. Detectable BKV was  $\geq 2.6$  log copies/ml. Patients received induction with rabbit anti-thymocyte globulin (majority of patients), or basiliximab, and maintenance w/ tacrolimus, mycophenolate mofetil (MMF) or enteric coated mycophenolate sodium (ECMS), and steroids. MMF/ECMS was discontinued upon BKV detection, followed by tacrolimus dose decrease if BKV persisted. Biopsies were performed for graft dysfunction. BKVN was defined as light microscopy changes consistent w/ BKVN, and positive VP-1 capsid and SV40 immunostaining. Retrospective analysis was performed for patients transplanted Jan 1, 2008–Sept 31, 2010 who had  $\geq 1$  BKV results until Dec 31, 2010 and were HIV negative.

**RESULTS:** Ninety-three percent of 452 patients were screened with: 75%, 66%, 54%, 16% patients having data at 3, 6, 12 and 24 months respectively. Nine percent had  $\geq 1$  BKV values  $\geq 4.0$  log/copies/ml, (first detected most often at 3 months), which has been shown to be associated w/ BKVN. Of 111 pts transplanted 2005–2007 had biopsies performed during 3 years pre-screening period versus 111 pts transplanted during screening period. Despite immunosuppression reduction, there was no significant increase in rejection/total RTR patients in pre versus post screening (8% versus 11%,  $p=0.06$ ). BKV screening decreased BKVN/total RTR patients to 1% from 2% pre-period ( $p=0.37$ ). All five BKVN patients had BKV  $\geq 4.0$  log/copies/ml.

**CONCLUSION:** There is currently no effective treatment for BKVN. BKV screening and reduction of immunosuppression did not increase rejection rates and prevented BKVN on clinically indicated biopsies.

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**227. Multiple regression analysis of factors predicting mycophenolic acid free fraction in 91 adult organ transplant recipients.** Tony K. L. Kiang, B.Sc. Pharm., Ph.D., ACPR<sup>1</sup>, Karen O. Y. Ng, B.Sc. Pharm., ACPR<sup>1</sup>, Mary H. H. Ensom, Pharm.D., FASHP, FCCP, FCSHP, FCAHS<sup>2</sup>; (1)Faculty of Pharmaceutical Sciences, the University of British Columbia, Vancouver, BC, Canada; (2)The University of British Columbia, Children's & Women's Health Centre of British Columbia, Vancouver, BC, Canada

**PURPOSE:** Mycophenolic acid (MPA) is an anti-rejection drug used in various types of organ transplants. MPA is extensively bound to albumin (~97%) and free MPA is thought to be the primary immunosuppressive agent. Little is known of what contributes to the wide inter-individual variability in the observed MPA free fraction (f%) in humans. The purpose of this study was to determine, using multiple regression analysis, patient factors that predict f% in a large sample (n=91) of organ transplant recipients.

**METHODS:** Age, weight, height, total daily MPA dose, albumin, serum creatinine (SrCr), and f% were obtained from islet (n=16), kidney (n=28), and heart/lung (n=47) transplant recipients. Multiple linear regression analysis and Spearman Rank correlation were conducted using SigmaStat (version 3.5 for Windows). Significance was set a priori at  $p=0.05$ .

**RESULTS:** The pooled data can be described as (mean  $\pm$  SD): age (52  $\pm$  13 years), weight (72  $\pm$  15 kg), height (169  $\pm$  9 cm), total daily MPA dose (1632  $\pm$  667 mg), albumin (4.2  $\pm$  0.7 g/dl), SrCr (1.3  $\pm$  0.4 mg/dl), and f% (2.9  $\pm$  3.5%). Multiple regression generated the following equation:  $f\% = 1.865 + (0.0357 \times \text{age (years)}) + (0.0125 \times \text{weight (kg)}) - (0.0202 \times \text{height (cm)}) - (0.000323 \times \text{total daily dose (mg)}) + (0.0122 \times \text{albumin (g/L)}) + (0.0160 \times \text{SrCr } (\mu\text{mol/L}))$ , ( $r^2 = 0.06$ ), but none of the variables were significant predictors of MPA f% ( $p>0.05$ ). Spearman Rank correlation of each individual variable confirmed lack of significant correlation with f%.

**CONCLUSION:** To our knowledge, this is the first study attempting to describe factors predicting MPA f% in organ transplant recipients involving a large sample size. Our novel findings of lack of significant predictions warrant further investigations using additional patient factors.

**228E. Evaluation of outcomes following positive crossmatch renal transplantation despite failure to convert to negative crossmatch after desensitization.** Shree Patel, Pharm.D., Jamie Joseph, Pharm.D., Sanjeev Akkina, M.D., James Thielke, Pharm.D., Maya Campara, Pharm.D., Patricia West-Thielke, Pharm.D., Jose Oberholzer, M.D., Enrico Benedetti, M.D.; University of Illinois Hospital and Health Sciences System, Chicago, IL

**PURPOSE:** Desensitization allows successful transplantation of patients with a positive crossmatch (PXM) against their living donor. The purpose of this investigation was to evaluate outcomes following PXM renal transplantation despite failure to convert to negative crossmatch (NXM) after desensitization.

**METHODS:** UIH records were retrospectively reviewed to identify subjects that underwent desensitization for a PXM renal transplant between 1/1/00 and 11/1/11. Patients who failed to convert to NXM after desensitization were identified as the non-converted subgroup. Patients who converted to NXM were identified as the converted control group.

**RESULTS:** A total of 108 PXM patients were transplanted with a desensitization protocol during the study period. Forty-two patients failed to convert to NXM prior to transplant comprising the PXM group. Sixty-six patients successfully converted after desensitization comprising the converted group. Mean GFR at 1 year was 47 in the PXM group and 57 within the control group ( $p=0.04$ ). GFR at all other time points only differed significantly at discharge (58 versus 72,  $p=0.04$ ). The percentage of patients with GFR  $< 30$  ml/minute differed significantly at 1 year alone (23% versus 6%,  $p=0.04$ ). Absolute rejection rates were higher within the PXM group for each type of rejection and at each time point. These differences were not found to be statistically significant.

cant. Time to first rejection did not differ significantly between groups. No patient deaths occurred within the PXM and five within the converted group at 3 years ( $p=0.19$ ). Five graft failures occurred within the PXM versus two within the converted group at 3 years ( $p=0.06$ ).

**CONCLUSION:** Though the PXM group had inferior GFR and rejection data, this did not translate into patient or allograft mortality as rates of patient death or allograft failure were comparable between arms for the first 3 years after transplant.

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#### 229E. A pharmacokinetic comparison of a generic tacrolimus versus reference in subpopulations of kidney transplant recipients.

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**PURPOSE:** Tacrolimus pharmacokinetic (PK) differences may exist in transplant patient subpopulations. Generic tacrolimus formulations are widely used, but bioequivalence studies (BE) versus reference drug have only been performed in healthy volunteers.

**METHODS:** Prospective, two-center, open-label, randomized, two-period (14 days/period), two-sequence, crossover, steady-state PK study was performed to compare Sandoz generic tacrolimus (TS) versus Prograf® (TP) in stable renal transplant patients. PK parameters were compared (post-hoc analysis) according to gender, African American ethnicity, presence of diabetes, and concomitant steroids. Ratio of tacrolimus AUC<sub>0–12 hour</sub> and peak concentration (C<sub>max</sub>) with TS:TP was calculated using geometric mean (GM) of dose-normalized values at days 14 and 28.

**RESULTS:** Sixty-eight/71 patients provided evaluable PK data. Median time post-transplant was 3.5 years (range 0.6–15.3). Mean (SD) tacrolimus dose was 5.7 (4.2) mg/day. Overall, TS:TP ratios for AUC<sub>0–12</sub> was 1.02, 90% confidence intervals (CI) 97%, 108% and C<sub>max</sub> was 1.09, 90% CI 101%, 118%. The 90% CI for ratios of AUC<sub>0–12</sub> and C<sub>12</sub> were within 80–125% for all subpopulations, but 90% CI for ratios of C<sub>max</sub> in the two smallest subpopulations (females, African Americans) and non-diabetics exceeded FDA BE criteria (upper values were 1.27–1.28).

**CONCLUSION:** TS and TP subpopulation data was found to be BE by FDA AUC parameter. Future studies must be powered to identify if C<sub>max</sub> differences within subpopulations are genuine. These findings also apply to the branded generic Hecoria™ which has identical formulation to TS.

	AUC <sub>0–12</sub> ratio of GM/90% CI	C <sub>12</sub> ratio of GM/90% CI
Male (n=40)	1.02/0.96, 1.08	1.02/0.94, 1.09
Female (n=28)	1.01/0.91, 1.12	1.00/0.86, 1.14
Non-African American (n=44)	1.07/1.00, 1.14	1.07/0.98, 1.16
African American (n=24)	0.94/0.86, 1.04	0.92/0.82, 1.02
No diabetes (n=38)	1.04/0.97, 1.11	1.03/0.96, 1.11
Diabetes (n=30)	1.01/0.92, 1.10	1.00/0.88, 1.13
No steroids (n=40)	1.07/1.00, 1.15	1.06/0.97, 1.14
Steroids (n=28)	0.95/0.88, 1.04	0.97/0.86, 1.07

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#### 230E. Evaluation of medication education and adherence of patients being evaluated for kidney and/or pancreas transplantation.

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**PURPOSE:** (i) Assess prior experience with medication education, medication therapy management (MTM), and medication resources of pre-kidney and/or pancreas transplant patients; (ii) identify barriers to adherence; and (iii) evaluate patient perceptions regarding receiving pharmacist-provided MTM.

**METHODS:** Candidates for kidney and/or pancreas transplant were asked to participate in a verbal survey during initial pre-transplant evaluation (March–April 2012). The survey included open-ended, multiple choice, and likert-type questions addressing participants' experience with medication education, medication taking habits, and perceived barriers to medication adherence. Baseline demographics were collected, including criteria required for MTM eligibility. Participants completed a medication adherence assessment [Modified Morisky Scale (MMS)].

**RESULTS:** Twenty-five patients were surveyed, with a mean age of 48 (± 10) years. Fourteen (56%) were male, 17 (68%) Caucasian, and 10 (40%) with Medicare Part D. Patients took a median of 10 (range 4–24) medications and had 6 (range 2–12) chronic diseases, including 24 (96%) with end-stage renal disease, 24 (96%) with hypertension, and 13 (52%) with diabetes. MMS adherence scores were high in both knowledge and motivation. On a 4-item scale [a lot, some, a little, or none], 14 (56%) reported they knew "some" information about new prescription medication(s) when leaving the doctor's office and 16 (64%) reported knowing more about the medication(s) after leaving the pharmacy. No patient reported having had a pharmacist-provided MTM session, though 2 (8%) reported a previous nurse or doctor visit to specifically review medications. Nineteen (76%) thought it would be helpful to have a pharmacist appointment, and 56% indicated they would probably schedule one if given the opportunity. Sixty percent of patients reported remembering to take medications as their biggest adherence challenge.

**CONCLUSION:** Many pre-kidney and/or pancreas transplant patients are interested in pharmacist-provided MTM, though none have received it. Patients may benefit from MTM due to the complexity of regimens and the importance of adherence.

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#### 231. Four-year outcomes after corticosteroid withdrawal in kidney transplant patients: an analysis from the Mycophenolic Acid Observational Renal Transplant Registry.

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**PURPOSE:** To provide long-term data following post-transplant corticosteroid withdrawal (CSW) versus corticosteroid continuation (CSC).

**METHODS:** The Mycophenolic Acid Observational Renal Transplant (MORE) registry is a prospective, observational study of de novo adult kidney transplant patients receiving mycophenolic acid (MPA) according to local practice at 40 US centers. CSW was defined as steroid withdrawal by month 3 post-transplant.

**RESULTS:** Of the 872 tacrolimus-treated patients were analyzed (CSW 363, CSC 509). Groups were similar except for panel reactive antibodies < 30% (CSW 90%, CSC 77%;  $p<0.01$ ) and living donors (CSW 46%, CSC 41%;  $p=0.09$ ), rabbit ATG induction (CSW 62%, CSC 59%;  $p=0.02$ ) and alemtuzumab induction (CSW 24%, CSC 55%;  $p<0.01$ ). Tacrolimus trough levels were similar. Full recommended MPA dose (1.44 g EC-MPS, 2.0 g

MMF) was administered in fewer CSW versus CSC patients at all timepoints (all  $p < 0.01$ ). In the CSC group, more patients received the full MPA dose with EC-MPS versus MMF at months 1 ( $p = 0.05$ ), 3 ( $p = 0.03$ ), 6 ( $p = 0.03$ ) and 12 ( $p = 0.03$ ); there were no differences within the CSW group. Biopsy-proven acute rejection (BPAR) was similar (CSW 10%, CSC 14%;  $p = 0.12$ ), graft survival was higher in CSW patients (97% versus CSC 94%;  $p = 0.03$ ) and patient survival was similar (CSW 96%, CSC 95%;  $p = 0.65$ ). Final mean serum creatinine was similar (CSW 1.6 g/dl, CSC 1.5 g/dl;  $p = 0.38$ ). Neutropenia (CSW 17%, CSC 11%;  $p = 0.01$ ) and leukopenia (CSW 61%, CSC 30%;  $p < 0.01$ ) were more frequent following CSW, with a trend to fewer infections (25% versus CSC 31%;  $p = 0.06$ ).

**CONCLUSION:** Improved 4-year graft survival in CSW patients despite a similar rate of BPAR to CSC patients may be due to lower immunological risk and a trend to more living donors. CSW patients were more likely to receive lymphocyte-depleting induction, which may have accounted for the higher rate of hematological adverse events and lower use of full MPA dosing versus CSC patients.

**232. Impact of cytokine gene polymorphism on BK virus nephropathy in a large cohort of kidney transplant recipients.** *Don Vu, Pharm.D., Ph.D.*<sup>1</sup>, Prashant Sakharkar, Pharm.D., M.P.H.<sup>2</sup>, Tariq Shah, M.D.<sup>3</sup>, Robert Naraghi, M.D.<sup>3</sup>, Ian V. Hutchinson, Ph.D., D.Sc.<sup>4</sup>, David I. Min, Pharm.D.<sup>5</sup>; (1) National Institute of Transplantation and Western University of Health Sciences, College of Pharmacy, Los Angeles, CA; (2) Western University Health of Sciences, Pomona, CA; (3) National Institute of Transplantation and St. Vincent Medical Center, Los Angeles, CA; (4) USC School of Pharmacy, Los Angeles, CA; (5) Western University of Health Sciences, College of Pharmacy and National Institute of Transplantation, Los Angeles, CO

**PURPOSE:** BK virus nephropathy (BKVN) has emerged as an important cause of progressive graft dysfunction in renal transplantation, with incidence rates ranging from 1% to 10%. Several single nucleotide polymorphisms in the promoter of cytokines have been associated with parvovirus B19, hepatitis C virus, HIV-1/AIDS infection. Deregulated production of pro- or anti-inflammatory cytokines plays an important role in the disease progression. We studied the association of gene polymorphisms in the interleukin-10 gene (IL10; 1082 A>G, -592 A>C), interferon-gamma gene (IFNG; +874 A>T), and tumor necrosis factor-alpha gene (TNFA; -308 A>G) with BKVN, taking into account the role that these cytokines might play in the immune response against BK virus.

**METHODS:** The IL10, IFNG and TNFA genotypes were determined in 70 kidney allograft recipients with BKVN and 182 without BKVN. Distributions of genotypes were compared to the Hardy-Weinberg theoretical distribution chi-square test. Nongenetic and genetic characteristics were included in the multivariate risk model. A  $p$  value less than 0.05 was considered statistically significant.

**RESULTS:** BKVN developed at an average of 1.2 years post-transplantation (range from 38 days to 5 years). Analysis of the results showed that IFNG +874 A>T A allele ( $p = 0.019$ , OR = 1.76) and IL10 (-592 A/C) AC genotype ( $p = 0.004$ , OR = 2.4) were significantly associated with BKVN. On the other hand, IFNG 874 A>T AA and IL10 (-592 A/C) CC were protective (OR 0.11 and 0.41, respectively; both  $p < 0.05$ ). The allelic as well as genotypic frequencies of TNFA (-308 G>A) and IL10 (-1082 A>G) gene polymorphism did not significantly differ between BKVN and without BKVN group. Of the nongenetic factors, use of tacrolimus and older age were associated with increased risk for BKVN.

**CONCLUSION:** The results suggest that IFNG (+874 A>T) and IL10 (-592 A/C) gene polymorphisms have predictive values for the development of BKVN in renal allograft recipients.

**233. Intravenous immunoglobulin (IVIG) as rescue therapy for BK virus nephropathy.** *Don Vu, Pharm.D., Ph.D.*<sup>1</sup>, Tariq Shah, M.D.<sup>2</sup>, Robert Naraghi, M.D.<sup>2</sup>, Ian V. Hutchinson, Ph.D.<sup>3</sup>, David I. Min,

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**PURPOSE:** BK virus infection is clinically significant in renal transplant recipients, causing BKV-associated nephropathy (BKVN) leading to renal allograft dysfunction and the loss of the renal grafts. The usual management of BKVN involves reduction of immunosuppression, or the addition of leflunomide, quinolones and cidofovir, but the rate of graft loss remains high. Our aim was to assess the impact of IVIG in treating BKVN in renal transplant recipients.

**METHODS:** Between September 2009 to April 2011, a total of 43 renal allograft recipients who were treated with IVIG after diagnosis of BKVN. Upon diagnosis of BKVN by clinical symptoms with BK viremia (viral load > 500 copies/ml by PCR), patients were given anti-polyomavirus treatment consisting of reduction of immunosuppression and use of leflunomide therapy. Treatment with IVIG was given only to patients who did not respond to those therapies. Patients were treated with IVIG in a 0.5–1.0 g/kg regimen. Response to IVIG therapy was monitored by measuring the viral load, serum creatinine level and repeated allograft biopsy if needed clinically. Clearance of viremia (<500 copies/ml) was considered a positive response to IVIG treatment.

**RESULTS:** There was a significant drop in viral load seen one month after IVIG therapy. Mean peak BK load was 205,314 copies/ml compared to 697 copies/ml after 1 year follow up. Thirty three patients (84%) had a positive response in clearing viremia. The actuarial patient and graft survival rates after 12-months among the 43 patients receiving IVIG were 100% and 97.4%, respectively. No serious adverse events from IVIG therapy were observed in these patients. The average total amount of IVIG was 106.56 g per patient and the average cost per patient was \$7682.00.

**CONCLUSION:** IVIG appears to be safe and effective in the treatment of BKVN and preventing graft loss in BKVN patients

**234. Outcomes at 4 years after kidney transplantation in African-American kidney transplant patients in the era of modern immunosuppression: an analysis from the mycophenolic acid observational renal transplant registry.** *Lonnie Smith, Pharm.D.*<sup>1</sup>, Anne Wiland, Pharm.D., BCPS<sup>2</sup>, Ali Olyaei, Pharm.D.<sup>3</sup>; (1) University of Utah Hospitals and Clinics, Salt Lake City, UT; (2) Novartis Pharmaceuticals Corporation, East Hanover, NJ; (3) Oregon State University and Oregon Health and Science University, Portland, OR

**PURPOSE:** African-American (AA) kidney transplant patients are at increased immunological risk and show attenuated tacrolimus absorption, and thus may be more prone to rejection following mycophenolic acid (MPA) dose reductions. An analysis was undertaken to assess outcomes in tacrolimus-treated AA kidney transplant patients receiving MPA.

**METHODS:** The Mycophenolic Acid Observational Renal Transplant (MORE) registry is a prospective, observational study of de novo adult kidney transplant patients receiving MPA at 40 US centers.

**RESULTS:** The analysis included 218 AAs (149 enteric-coated mycophenolate sodium [EC-MPS], 69 mycophenolate mofetil [MMF]) and 686 non-AAs (467 EC-MPS, 219 MMF). Living donors were less frequent in AA recipients (24%) versus non-AAs (48%,  $p < 0.01$ ). AAs and non-AAs had similar mean tacrolimus trough levels throughout. More AAs versus non-AAs received steroids, but the mean steroid dose administered was similar. For AA patients, the full recommended MPA dose (1.44 g EC-MPS, 2.0 g MMF) was administered more frequently with EC-MPS than MMF at month 6 (56% versus 36%,  $p = 0.02$ ) and month 36 (47% versus 17%,  $p = 0.03$ ). Compared to non-AAs, AA patients experienced more frequent biopsy-proven acute rejection (BPAR) (19% versus 11%,  $p < 0.01$ ) with lower graft survival (89% versus

96%, log rank  $p < 0.01$  [Kaplan Meier] but patient survival was similar (96% versus 94%,  $p = 0.99$ ). There were no significant differences in efficacy with EC-MPS versus MMF in AAs or non-AAs. Diabetes (17% versus 11%,  $p = 0.02$ ) and cardiovascular events (11% versus 6%,  $p = 0.03$ ) were more frequent in AAs versus non-AAs, but bone-related events were less frequent (8% versus 14%,  $p = 0.02$ ).

**CONCLUSION:** Despite similar tacrolimus exposure and greater use of steroids, BPAR and graft loss occurred more frequently in AAs versus non-AAs at 4 years post-transplant. In AA patients, full MPA dose was maintained more frequently with EC-MPS than MMF at months 6 and 36 but more intensive immunosuppression may still be required.

**235. A 4-year analysis of immunosuppressive regimens and outcomes in expanded criteria donor kidney transplant recipients from the mycophenolic acid observational renal transplant registry.**

*Ali Olyaei, Pharm.D.<sup>1</sup>, V. Ram Peddi, M.D.<sup>2</sup>, Anne Wiland, Pharm.D., BCPS<sup>3</sup>, Kimi Ueda, Pharm.D.<sup>2</sup>, (1) Oregon State University and Oregon Health and Science University, Portland, OR; (2) California Pacific Medical Center, San Francisco, CA (3) Novartis Pharmaceuticals Corporation, East Hanover, NJ*

**PURPOSE:** To compare long-term immunosuppressive practices and outcomes in expanded criteria donor (ECD) or standard criteria donor (SCD) graft recipients.

**METHODS:** Mycophenolic Acid Observational Renal Transplant (MORE) is a prospective, observational registry of de novo kidney transplant recipients receiving mycophenolic acid (MPA) managed according to local practice. ECD was defined as donor  $\geq 60$  or 50–59 years with two of: hypertension, serum creatinine  $> 1.5$  mg/dl, or cerebrovascular accident death.

**RESULTS:** Of the 103 ECD (29 mycophenolate mofetil [MMF], 74 enteric-coated mycophenolate sodium [EC-MPS]) and 838 SCD (277 MMF, 561 EC-MPS) patients were analyzed. Mean donor age in the ECD and SCD groups was 61 versus 39 years, respectively ( $p < 0.01$ ); mean recipient age was 62 versus 50 years ( $p = 0.02$ ). Use of induction (100% versus 99%), tacrolimus (97% versus 95%) and corticosteroids (74% versus 74%) was similar. Full MPA dose (2.0 g MMF, 1.44 g EC-MPS) was less frequent in ECD versus SCD patients at months 3, 24 and 36 (all  $p < 0.03$ ). Four-year biopsy-proven acute rejection (BPAR) rates were similar for ECD versus SCD patients (11% versus 13%,  $p = 0.66$ ), as was graft survival (91% versus 94%,  $p = 0.12$ ), but patient survival was lower for ECD patients (85% versus 96%,  $p < 0.01$ ). BPAR and graft survival were similar in the ECD and SCD groups for MMF versus EC-MPS. Patient survival in the SCD group was lower with MMF (93% versus EC-MPS 97%,  $p = 0.01$ ). Mean (SD) serum creatinine was 1.9 (1.0) mg/dl versus 1.5 (1.3) mg/dl in ECD versus SCD patients ( $p = 0.05$ ). Cardiovascular events occurred in 15% ECD and 7% SCD patients ( $p = 0.01$ ). Infections in the ECD group were more frequent with MMF versus EC-MPS (45% versus 22%,  $p = 0.03$ ).

**CONCLUSION:** BPAR and graft survival were similar in recipients of ECD or SCD grafts at 4 years after kidney transplantation despite higher donor and recipient ages and less frequent maintenance of full MPA dose.

**236. A comparison of enteric-coated mycophenolate sodium and mycophenolate mofetil to 4 years after kidney transplantation: an analysis from the mycophenolic acid observational renal transplant registry.**

*Ali Olyaei, Pharm.D.<sup>1</sup>, Anne Wiland, Pharm.D., BCPS<sup>2</sup>, Lonnie Smith, Pharm.D.<sup>3</sup>, (1) Oregon State University and Oregon Health and Science University, Portland, OR; (2) Novartis Pharmaceuticals Corporation, East Hanover, NJ; (3) University of Utah Hospitals and Clinics, Salt Lake City, UT*

**PURPOSE:** Bioavailability of mycophenolic acid (MPA) is higher with concomitant tacrolimus than cyclosporine. This analysis was undertaken to compare MPA dosage and outcomes with enteric-coated mycophenolate sodium (EC-MPS) versus mycophenolate mofetil (MMF) in tacrolimus-treated kidney transplant recipients.

**METHODS:** The Mycophenolic Acid Observational Renal Transplant (MORE) registry is a prospective, observational study of de novo adult renal transplant patients receiving MPA, managed according to local practice at 40 US sites.

**RESULT:** Of the 904 patients (616 EC-MPS, 288 MMF) were followed for up to 4 years. Baseline characteristics were similar except for living donors (EC-MPS 39%, MMF 49%;  $p = 0.04$ ). More patients received the full recommended dose of MPA (1.44 g EC-MPS, 2.0 g MMF) with EC-MPS versus MMF at month 1 (79% versus 72%;  $p = 0.02$ ), month 3 (68% versus 57%;  $p < 0.01$ ) and month 6 (53% versus 44%;  $p = 0.03$ ) but proportions were similar thereafter. Mean MPA dose was higher in patients receiving EC-MPS versus MMF patients up to month 6 post-transplant. Efficacy to 4 years post-transplant was similar with EC-MPS versus MMF: biopsy-proven acute rejection 14% versus 10% ( $p = 0.20$ ), graft survival 93% versus 95% (log rank  $p = 0.52$ , Kaplan-Meier), and patient survival 96% versus 94% ( $p = 0.28$ ). Mean (SD) serum creatinine was 1.5 (1.1) mg/dl with EC-MPS and 1.7 (1.8) mg/dl with MMF ( $p = 0.25$ ). Adverse events were similar with EC-MPS or MMF. Gastrointestinal complications were reported in 73% of EC-MPS-treated patients versus 75% of MMF-treated patients ( $p = 0.57$ ).

**CONCLUSION:** More kidney transplant patients receiving EC-MPS were maintained on the full recommended MPA dose to month 6 post-transplant than MMF-treated patients, and mean MPA dose during the first six months was correspondingly higher with EC-MPS. Although there were fewer living donor recipients in the EC-MPS group, efficacy was similar with EC-MPS or MMF to 4 years. Safety profiles, including gastrointestinal complications, were similar with EC-MPS or MMF despite higher early MPA dosing with EC-MPS.

**237. Thymoglobulin versus simulect induction in hepatitis C positive kidney transplant recipients.**

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**PURPOSE:** The optimal agent to use for induction therapy in hepatitis C virus positive (HCV+) kidney transplant recipients is not known. We sought to investigate effects of induction therapy with thymoglobulin (THY) versus Basiliximab (BAS) in HCV+ kidney transplant recipients.

**METHODS:** HCV+ kidney transplant recipients between January 2008 and August 2011 were tracked prospectively. Comparisons were performed between patients who received induction therapy with THY versus BAS with Fisher's exact test or Student t-test for categorical and continuous variables, respectively.

**RESULTS:** Our analysis was performed in a total of 37 HCV+ kidney transplant recipients of whom 26 patients received induction therapy with THY and 11 received BAS. Baseline demographic characteristics such as age, ethnicity, panel reactive antibody levels and HCV-RNA were similar between the groups. After a mean follow-up of  $834 \pm 386$  days, graft survival was 73% versus 82% ( $p = 0.695$ ) and patient survival was 81% versus 91% ( $p = 0.646$ ) in the THY versus BAS group, respectively. There was one acute rejection episode in each group. The mean serum creatinine at the last follow-up was  $2.4 \pm 2.3$  mg/dl in the THY group versus  $1.8 \pm 1.2$  mg/dl in the BAS group. There were no significant differences between the two induction groups in the other clinical outcomes such as hospital length of stay, intensive unit admission, return to OR, blood transfusion, and bacterial infections. For viral infections, incidence of CMV infections was similar between the two groups. However, there were two cases of BK virus infections in the THY group versus none in the BAS group.

**CONCLUSIONS:** There were no significant differences in treatment outcomes with either THY or BAS induction in HCV+ kidney transplant recipients. Either agent can be used as an

induction therapy in appropriately selected HCV+ kidney transplant recipients.

**238. Incidence of invasive fungal infections following aerosolized amphotericin B lipid complex as sole prophylaxis in adult lung transplant recipients.** *Rachael E. Waterson, Pharm.D., Neha Patel, Pharm.D., BCPS, Richard Drew, Pharm.D., M.S., BCPS, FCCP; Duke University Hospital, Durham, NC*

**PURPOSE:** To determine the incidence of invasive fungal infections (IFIs) at 30 and 90 days post-operatively in adult lung transplant recipients receiving aerosolized amphotericin B lipid complex (aABLC) as the sole antifungal prophylaxis. Prophylaxis-limiting adverse events related to aABLC were also described.

**METHODS:** This was a retrospective, single-center cohort study conducted in patient's  $\geq 18$  years of age undergoing lung transplant at Duke University Hospital between 1/1/08 and 12/31/10 and receiving at least one dose of aABLC as the sole fungal prophylaxis. Retransplant within 90 days, receipt of concomitant systemic antifungals or alemtuzumab, active IFI at transplant, and those with incomplete medical records were excluded. Patient demographics, IFI criteria, antifungal use, and aABLC treatment descriptions were collected. Probable or definite IFI were determined using MSG/EORTC definitions.

**RESULTS:** Of the 243 subjects were evaluable. Most were Caucasian (86%) and male (64%), with a mean age of 56 years (range 18–78 years). Most received a bilateral-lung transplant (77.4%), most frequently due to idiopathic pulmonary fibrosis (~50%). Antifungal use for empiric or documented IFIs was common (35.8%). Probable or definite IFI at 30 and 90 days occurred in 29 (11.9%) and 44 (18.1%) patients, respectively. Of these, 34.8% and 46.7% were caused by *Candida* spp. and 24.3% and 20% were caused by *Aspergillus* spp., respectively. While aABLC was prematurely discontinued in 7 (2.9%) subjects, only one (0.4%) was due to intolerance.

**CONCLUSION:** Use of aABLC as sole prophylaxis was associated with rates of IFI in the early post-transplant period comparable to other strategies. Rates of invasive aspergillosis were low. Patients receiving aABLC were unlikely to experience intolerance leading to discontinuation of therapy.

**239. Efficacy and safety of 3 versus 6 months of low-dose valganciclovir for prevention of cytomegalovirus disease in moderate-risk (D+/R+ and D-/R+) renal transplant recipients receiving antilymphocyte antibody induction therapy.** *Steven Gabardi, Pharm.D.<sup>1</sup>, Rosemary Cross, Pharm.D.<sup>2</sup>, Kelly DePiero, Pharm.D.<sup>3</sup>, Travis B. Dick, Pharm.D., BCPS<sup>4</sup>, Angela Q. Maldonado, Pharm.D., BCPS<sup>5</sup>, Pamela R. Maxwell, Pharm.D., BCPS<sup>6</sup>, Joelle Nelson, Pharm.D.<sup>7</sup>, Kathleen Nguyen, Pharm.D.<sup>8</sup>, Jeong M. Park, M.S., Pharm.D.<sup>9</sup>, Eric M. Tichy, Pharm.D., BCPS<sup>10</sup>, Kimi Ueda, Pharm.D.<sup>11</sup>, Renee Weng, Pharm.D.<sup>12</sup>, Erin N. Newkirk, Pharm.D.<sup>13</sup>; (1) Department of Pharmacy & Renal Division, Brigham & Women's Hospital; Department of Medicine, Harvard Medical School, Boston, MA; (2) Piedmont Hospital, Atlanta, GA; (3) Lahey Clinic Medical Center, Burlington, MA; (4) Intermountain Medical Center, Murray, UT; (5) Sacred Heart Medical Center, Spokane, WA; (6) University Transplant Center, the University of Texas Health Science Center at San Antonio, San Antonio, TX; (7) University Health System, San Antonio, TX; (8) University of California Irvine Medical Center, Orange, CA; (9) University of Michigan, Ann Arbor, MI; (10) Yale-New Haven Hospital, New Haven, CT; (11) California Pacific Medical Center, San Francisco, CA; (12) UC-Irvine, Orange, CA; (13) Froedtert & the Medical College of Wisconsin, Milwaukee, WI*

**PURPOSE:** The cytomegalovirus (CMV) recipient-positive (D+/R+ or D-/R+) population represents the largest group of at-risk renal transplant recipients (RTR). Practice guidelines recommend valganciclovir (VGC) prophylaxis for 3–6 months in this population. This study compared the efficacy and safety of 3 versus 6 months of low-dose VGC prophylaxis in moderate risk RTR following rabbit antithymocyte globulin induction.

**METHODS:** This multicenter, retrospective analysis evaluated 723 adult RTR from 9/1/2005 to 10/31/2010. All received VGC 450 mg/day: Group 1 (n=426) for 3 months, Group 2 (n=297) for 6 months. All patients were initially maintained on tacrolimus, mycophenolate (MPA) and corticosteroids. The primary endpoint was CMV disease prevalence at 1 year. The rates of T-cell mediated rejection (TCMR), antibody-mediated rejection (AMR), graft loss, patient survival, opportunistic infections (OI), leukopenia and early VGC discontinuation (DC) were also assessed.

**RESULTS:** Patient demographics and transplant characteristics were comparable, with the exception of Group 1 being slightly younger, containing more African-Americans and less Caucasians. In terms of immunosuppression, there were more patients receiving early steroid-withdrawal in Group 2. Tacrolimus concentrations were somewhat higher in Group 2 at months 6, 9 and 12, but MPA daily doses were slightly lower at months 1 and 3.

12 month efficacy analysis	Group 1	Group 2	p-Value
CMV disease	19 (4.5%)	12 (4.0%)	0.86
TCMR	44 (10.3%)	38 (12.8%)	0.34
AMR	15 (3.5%)	9 (3.0%)	0.83
Graft loss	16 (3.8%)	9 (3.0%)	0.19
Patient survival	418 (98.1%)	291 (98.0%)	0.79
OI	86 (20.2%)	63 (21.2%)	0.78

The safety analysis revealed Group 2 to have significantly more patients develop leukopenia at post-op months 4 (p=0.005), 5 (p=0.04) and 6 (p=0.0001). The rate of early VGC DC due to myelosuppression was higher in Group 2 (p=0.006).

**CONCLUSION:** Both regimens provide similar efficacy in CMV prophylaxis, but the prolonged course was associated with more leukopenia. The short-course of VGC may also provide significant cost avoidance.

**240E. Incidence of suprathreshold tacrolimus troughs before and after implementation of an initial dosing protocol in orthotopic heart transplantation.** *Tracy M. Sparkes, Pharm.D., Tamara Claridge, Pharm.D., BCPS, Todd A. Miano, Pharm.D., BCPS, Erin H. Ticehurst, Pharm.D., Lee R. Goldberg, M.D., M.P.H., FACC; Hospital of the University of Pennsylvania, Philadelphia, PA*

**PURPOSE:** In July 2010, an initial tacrolimus dosing protocol was implemented in the heart transplant population at our institution. The objective of this study was to compare the incidence of suprathreshold tacrolimus troughs before and after the introduction of the initial tacrolimus dosing protocol and corresponding outcomes of acute kidney injury and early acute graft rejection.

**METHODS:** This retrospective study included 133 patients who underwent orthotopic heart transplantation between July 1, 2008 and July 31, 2011. Patients were excluded from this study if they received multi-organ transplantation, had undergone a previous organ transplant, received intravenous tacrolimus, were less than 18 years of age, or did not have tacrolimus trough levels reported. Acute kidney injury was evaluated using modified RIFLE criteria. Rejection was defined as a biopsy grade greater than 1R using the International Society for Heart and Lung Transplantation (ISHLT) standardized cardiac biopsy grading criteria.

**RESULTS:** Implementation of an initial dosing protocol resulted in a significant decrease in the incidence of suprathreshold tacrolimus trough levels in post-protocol patients (59.8% versus 35.3%, p=0.008). Fewer patients in the post-protocol group developed acute kidney injury during post-transplant week one (56.1% versus 39.2%, p=0.07) and post-transplant week two (34.1% versus 19.6%, p=0.08). Post-protocol patients took longer to achieve therapeutic tacrolimus trough levels (8  $\pm$  3 versus 5  $\pm$  3 days, p<0.01). There was no significant difference in the incidence of early acute graft rejection between groups (6.1% versus 2.0%, p=0.7).

**CONCLUSIONS:** Implementation of an initial tacrolimus dosing protocol was associated with a significant reduction in the inci-

dence of suprathreshold tacrolimus trough levels. A corresponding reduction in the incidence of acute kidney injury was likely the result of a less aggressive initial dosing approach. No difference was seen in rates of early acute graft rejection, and this initial dosing protocol remains the standard practice at the institution.

Presented at the Eastern States Conference for Pharmacy Residents and Preceptors, Hershey, PA, May 3, 2012.

**241E. Impact of optimization of antiviral therapy and removal of cytomegalovirus immune globulin on clinical outcomes in liver and combined liver/kidney transplant recipients.** Jennifer Jebrock, Pharm.D., BCPS<sup>1</sup>, Venessa Price, Pharm.D.<sup>1</sup>, Alexandra Centeno, Pharm.D.<sup>1</sup>, Lilian Abbo, M.D.<sup>2</sup>, Michele Morris, M.D.<sup>2</sup>, Andreas G. Tzakis, M.D.<sup>2</sup>; (1) Jackson Memorial Hospital, Miami, FL; (2) University of Miami Miller School of Medicine, Miami, FL

**PURPOSE:** The efficacy of cytomegalovirus immune globulin (CMVIG) prophylaxis in transplant recipients is poorly investigated and studies that demonstrated benefit were conducted before the current gold standard of ganciclovir (GCV) and valganciclovir (VGC) were widely available. Consensus guidelines remain unclear whether addition of CMVIG improves outcomes when appropriate antivirals are given. The purpose of this study was to demonstrate that CMV prophylaxis with optimized antiviral therapy is noninferior to combination antiviral therapy plus CMVIG in liver and liver/kidney recipients.

**METHODS:** A single center, retrospective analysis was conducted to assess outcomes of patients transplanted between 2/2008 and 9/2009. Patients were excluded if less than 18 years old, intestine transplants, or expired within 30 days of transplant. Pre protocol patients who were CMV seronegative (R-) received 3 months of antiviral prophylaxis plus CMVIG and seropositive recipients (R+) received 6 weeks of antiviral prophylaxis. Post protocol patients received 3 months of antiviral prophylaxis and no CMVIG with implementation of routine PCRs. Comparisons made using Fisher's exact test.

**RESULTS:** Analysis included 104 patients (55 pre versus 49 post). Patient demographics, induction, and immunosuppression were similar in both groups. The post group had more high risk (D+/R-) patients (13% versus 28%, p=0.065). There was no difference regarding intermediate (R+) or low risk (D-/R-) between groups. There was no significant difference in incidence of CMV disease (10.9% versus 12.2%, p=0.536). Of the 12 patients with proven CMV disease, more patients had received alemtuzumab for induction (23%, p=0.023) and 42% developed CMV after treatment of rejection (p=0.003). No difference was found between the agents used for treatment of rejection. One CMV-related mortality was identified in the pre protocol group.

**CONCLUSION:** No significant difference was found between pre and post protocol change in CMV-related outcomes. CMV prophylaxis with optimized antiviral therapy was found to be noninferior to combination CMVIG plus GCV/VGC.

Presented at the American Transplant Congress, Boston, MA, June 2-6, 2012.

**242. Prevention of cytomegalovirus disease in moderate-risk (D+/R+ and D-/R+) renal transplant recipients receiving basiliximab induction therapy: an efficacy and safety evaluation of 3 versus 6 months of low-dose valganciclovir.** Steven Gabardi, Pharm.D.<sup>1,2</sup>, Rosemary Cross, Pharm.D.<sup>3</sup>, Kelly DePiero, Pharm.D.<sup>4</sup>, Travis B. Dick, Pharm.D., BCPS<sup>5</sup>, Pamela R. Maxwell, Pharm.D., BCPS<sup>6</sup>, Joelle Nelson, Pharm.D.<sup>7</sup>, Erin N. Newkirk, Pharm.D.<sup>8</sup>, Kathleen Nguyen, Pharm.D.<sup>9</sup>, Jeong M. Park, M.S., Pharm.D.<sup>10</sup>, Eric M. Tichy, Pharm.D., BCPS<sup>11</sup>, Kimi Ueda, Pharm.D.<sup>12</sup>, Renee Weng, Pharm.D.<sup>13</sup>, Angela Q. Maldonado, Pharm.D., BCPS<sup>14</sup>;

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**PURPOSE:** Cytomegalovirus (CMV) recipient-positive (D+/R+ or D-/R+) patients represent the largest group of at-risk renal transplant recipients (RTR). Practice guidelines on CMV prophylaxis when patients receive basiliximab. This study compared the efficacy and safety of 3 versus 6 months of low-dose VGC prophylaxis in moderate-risk RTR following basiliximab induction.

**METHODS:** A multicenter, retrospective analysis of 268 adult RTR (9/1/2005-10/31/2010) receiving VGC 450 mg/day (dose adjusted for renal function): Group 1 (n=195) for 3 months, Group 2 (n=73) for 6 months. All patients received initial immunosuppression with tacrolimus, mycophenolate (MPA) and corticosteroids. The primary endpoint was CMV disease within 1-year. The rates of T-cell-mediated rejection (TCMR), antibody-mediated rejection (AMR), graft loss, patient survival, opportunistic infections (OI), leukopenia and early VGC discontinuation (DC) were assessed.

**RESULTS:** Patient demographics and transplant characteristics were comparable, with the exception of Group 1 containing more Hispanics and less Caucasians, as well as more deceased-donor transplants. There were more patients in Group 2 with a previous transplant. In terms of immunosuppression, more patients in Group 2 received early steroid withdrawal. Tacrolimus trough concentrations were similar between groups throughout the analysis, but MPA daily doses were slightly lower in Group 2 at month 6.

12 month efficacy analysis	Group 1	Group 2	p-Value
CMV disease	1 (0.5%)	2 (2.7%)	0.18
TCMR	18 (9.2%)	12 (16.4%)	0.13
AMR	1 (0.5%)	3 (4.1%)	0.06
Graft loss	9 (4.6%)	4 (5.5%)	0.76
Patient survival	191 (97.9%)	69 (94.5%)	0.67
OI	28 (14.4%)	11 (15.1%)	0.85

Group 2 had more patients develop leukopenia at post-op months 4 (p=0.008), 5 (p=0.0005) and 6 (p=0.003). The rate of early VGC DC due to myelosuppression was higher in Group 2 (p=0.001).

**CONCLUSION:** Both regimens provide similar CMV prophylaxis efficacy, but the prolonged course was associated with more leukopenia. The short-course of VGC may also provide significant cost avoidance.

**243. Effect of thymoglobulin on the development of BK virus viremia and viremia in renal transplant recipients: a case-control study.** Allison L. Mruk, Pharm.D.<sup>1</sup>, Yevgeniya Gokun, M.S.<sup>2</sup>, Thomas H. Waid, M.D.<sup>1</sup>, Carol Broughton, Pharm.D., BCPS, APRN<sup>1</sup>, Timothy M. Clifford,<sup>1</sup>; (1) University of Kentucky Chandler Medical Center, Lexington, KY; (2) University of Kentucky College of Pharmacy, Lexington, KY

**PURPOSE:** BK virus infection is an emerging complication in renal transplant recipients. Viremia or viremia can precede BK nephropathy, which can contribute to graft loss. Studies have described a relationship between immunosuppressive therapy and BK virus reactivation. The purpose of this study is to determine risk factors for the development of BK virus infection in renal transplant recipients over a 12 month period. We hypothesize that larger doses of thymoglobulin (>5 mg/kg) will increase the incidence of BK virus infection in renal transplant recipients.

**METHODS:** A retrospective, single center, unmatched case-control study. Patients included were > 18 years of age, received a renal transplant at our institution from 2007 to 2010, and received rabbit-derived thymoglobulin for induction therapy with frequent monitoring of BK virus available. Data collected included: maintenance immunosuppression and drug concentrations, time to BK virus detection, renal function measurements, biopsy results, and BK virus infection treatment.

**RESULTS:** Seventy seven met inclusion criteria for the study. Patients that received a high dose of thymoglobulin (>5 mg/kg) during induction therapy, had a 10% lower odds of developing BK virus infection compared to patients that received a low thymoglobulin dose (OR 0.90 95% 0.29–2.79). The incidence of BK nephropathy was four of 307 (1.3%) and zero progressed to graft loss over the study period. Treatment of BK virus infection was frequently not documented (67.6%); discontinuation of mycophenolate mofetil (20.5%); reduction in total immunosuppressive therapy (8.8%); and leflunomide treatment (5.8%).

**CONCLUSIONS:** Our study demonstrated no single risk factor for the development of BK virus viremia/viremia 12 months post renal transplantation. The incidence of BK virus was 11%, BK nephropathy was 1.3%, and graft loss due to BK nephropathy was 0%. Larger studies must be performed to determine if the total thymoglobulin dose for induction therapy is a risk factor for the development of BK virus infection.

## Women's Health

**244. Investigation of the HPV vaccine, Gardasil: are patients completing the series as recommended?** Lori Ernsthansen, Pharm.D., Brinda Dave, Pharm.D., Candidate, Christine Osborn, Pharm.D., Candidate, Amanda Palgut, Pharm.D., Candidate; The University of Findlay College of Pharmacy, Findlay, OH

**PURPOSE:** The quadrivalent HPV vaccine is recommended for person's age nine to 26 and should be given as a three dose series. Due to the number of injections and the high cost of the vaccine, many people may not complete the series as recommended. The primary objective of this retrospective chart review study is to determine if patients at the Wood County Health Department are being administered the complete vaccination series as recommended and the secondary objective is to identify common barriers to compliance.

**METHODS:** Data was gathered and formatted from the Impact SIIS database into a Microsoft<sup>®</sup> Excel spreadsheet to record series completion, demographics, and potential barriers. Medical records were analyzed for any patients who did not receive the full series.

**RESULTS:** Overall, only 13% of patients completed the Gardasil vaccine as recommended, compared to 32% of patients nationally. The most common barrier identified for not completing the series was pregnancy. Specific barriers were unable to be identified for most patients due to poor documentation in the patient chart.

**CONCLUSION:** The inability to identify barriers demonstrates the need for improvement in patient documentation and organization of patients' health records at this site. Additionally, a patient compliance program at the health department should be developed to improve HPV vaccination rates.

**245. Preliminary study of FMO3, MSRA, and AOX1 gene polymorphisms on pharmacokinetics of sulindac and its metabolites.** Kyungeun Lee, Pharm.D.<sup>1</sup>, Nara Lee, M.S.<sup>1</sup>, Sunny Park, B.S.<sup>1</sup>, Byungkoo Lee, Ph.D.<sup>1</sup>, Youngju Kim, M.D., Ph.D.<sup>2</sup>, Hyesun Gwak, Ph.D., Pharm.D.<sup>1</sup>; (1)Division of Life and Pharmaceutical Sciences, Ewha Womans University, Seoul, South Korea; (2)Department of Obstetrics and Gynecology, Ewha Womans University School of Medicine, Seoul, South Korea

**PURPOSE:** The pharmacokinetics of sulindac exhibits a wide inter-individual variability that may lead to poor predictability of treatment-related outcomes and side effects. This study aimed to

investigate the effects of polymorphisms of sulindac-metabolizing enzymes on the pharmacokinetics of sulindac and its two metabolites, sulfide and sulfone, in patients with preterm labors.

**METHODS:** Eleven single nucleotide polymorphisms (SNPs) of 3 genes, flavin-containing monooxygenase 3 (FMO3), methionine reductase A (MSRA), and aldehyde oxygenase 1 (AOX1), were genotyped, and plasma sulindac and its metabolite concentrations of 19 patients were measured at 0, 1.5, 4, and 10 hour after drug administration. The area under the curve from time 0 to the last sampling time point ( $AUC_{last}$ ) for sulindac, sulfide, and sulfone were obtained, and the ratios among sulindac and its metabolites were calculated. The production rate constant ( $k_p$ ) was calculated by the residual method.

**RESULTS:** The  $AUC_{last}$  ratio of sulfide to sulfone in patients with wild-type alleles or heterozygotes was less than half compared to those with variant homozygotes of FMO3 (rs909530). In contrast, patients with wild-type homozygotes or heterozygotes of the MSRA gene (rs9329221) resulted in an almost two-fold higher  $AUC_{last}$  ratio of sulfide to sulfone compared to those with variant-type homozygotes. In terms of sulfide production, all patients with variant-type homozygotes in the FMO3 gene (rs909530) were fast producers ( $k_p \geq 5$  per hour) whereas all patients with wild-type homozygotes or heterozygotes in the MSRA gene (rs9329221) were slow producers ( $k_p < 5$  per hour).

**CONCLUSION:** Differences of bioavailability ratios among sulindac and its metabolites are attributable to the genetic polymorphisms of FMO3 and MSRA in subjects with preterm labors. The results of this study could give some preliminary data to predict efficacies and side effects of sulindac for developing individualized treatment for patients with preterm labors.

## CLINICAL PHARMACY FORUM

### ADR/Drug Interactions

**246. Identification of serious iatrogenic OPIOID-related adverse events in hospitalized patients.** Michelle R. Huber, Pharm.D., Monica Hanson, Pharm.D., Bob Lobo, Pharm.D.; Vanderbilt University Medical Center, Nashville, TN

**PURPOSE:** This study was performed in order to document serious respiratory or central nervous system adverse events in patients receiving opioid analgesics in the hospital. Risk factors for adverse events were described in order to identify potential medication safety opportunities.

**METHODS:** A retrospective chart review of inpatients receiving naloxone for opioid reversal was conducted during a three month period in 2011. Patients were included if they experienced CNS or respiratory depression reversible with naloxone with adequate supporting documentation from medical or nursing notes. We excluded patients who were less than 18 years of age and patients who received naloxone for non-iatrogenic overdose indications.

**RESULTS:** There were 155 patients identified who received naloxone during the study period. After excluding those who received naloxone for reversal immediately following surgery, and non-iatrogenic overdose indications, there were 49 patients who met our inclusion criteria. Postoperative patients comprised 58% of the population who required naloxone for reversal. The ADE met Naranjo criteria for a probable or definite adverse drug reaction in 76% of cases; the remaining 24% were considered possible adverse drug reactions. Transfer to a higher level of care was required in 35% of cases and intubation in 8%. Sleep apnea was a risk factor in 24%, and renal dysfunction was a risk factor in 14% of those who experienced events related to morphine. Inadequate monitoring of level of sedation was noted in 54% of the patients who experienced events on PCA.

**CONCLUSIONS:** Serious opioid adverse events requiring naloxone administration were commonly identified through this systematic review. We identified several key safety improvement opportunities that hospitals should implement in order to reduce risk of harm in this population.

## Adult Medicine

**247. Hospitalist-pharmacist collaboration: a novel approach to improving patient care.** Jonathan D. Edwards, Pharm.D., Zia Hassan, M.D., Sudheer Kantharajpur, M.D., Akshai Janak, M.D., Samuel Myers, Pharm. D., Adam Sawyer, Pharm.D., Suzanne Morrow, Pharm.D., Ryan Novosad, Pharm.D., Jacqueline Runnels, Pharm.D., Christopher Newlin, Pharm. D.; Huntsville Hospital, Huntsville, AL

**PURPOSE:** To develop a collaborative practice between hospitalists and pharmacists by following the recommendations of the consensus statement published by the Society of Hospital Medicine (SHM) and the American Society of Health-System Pharmacists (ASHP).

**METHODS:** Between November 2011 and February 2012, the hospitalist-pharmacist collaboration developed six order sets, a collaborative practice, and a patient interaction program. Outcomes from these initiatives were collected to determine the impact a collaborative hospitalist-pharmacist practice had on patient safety and cost avoidance.

**RESULTS:** The following order sets were developed during the study period: diabetic ketoacidosis, acute alcohol withdrawal, hypoglycemia, nicotine replacement, admission, and contrast-induced nephropathy prophylaxis. In addition to the creation of order sets, a collaborative practice was developed that resulted in a total of 77 interventions during the study period. These interventions included IV to PO conversions, initiation of therapy, discontinuation of therapy, duration of therapy, and medication regimen adjustments. These interventions resulted in \$5602 of cost avoidance. A patient interaction program was also developed to increase interactions between patients and pharmacists that were admitted to the hospitalist service. This project resulted in a total of 79 interventions that included allergy clarification, allergy identification, and pain management assessment. These interventions resulted in \$4223 of cost avoidance. The cumulative impact of the hospitalist-pharmacist collaboration included the development of six order sets, 156 total interventions, and a total cost avoidance of \$9825 during the study period.

**CONCLUSIONS:** An interdisciplinary approach to health care has the potential to improve the quality, safety, and cost of patient care. Our study used the recommendations from the consensus statement published by SHM and ASHP to develop a successful hospitalist-pharmacist collaborative relationship. We found that when these ideas were introduced into practice, patient care was improved.

**248. Management of hyponatremia in the hospital: Interim results of a disease-based registry.** Joseph Dasta, M.Sc.<sup>1</sup>, Jun Choing, M. D.<sup>2</sup>, Sandra Chase, Pharm.D.<sup>3</sup>, Alpesh Amin, M.D.<sup>4</sup>; (1)The University of Texas College of Pharmacy, Austin, TX; (2) Loma Linda University, Loma Linda, CA; (3)Otsuka America Pharmaceuticals, ADA, MI; (4)UC Irvine College of Medicine, Irvine, CA

**PURPOSE:** Hyponatremia (HN), the leading electrolyte abnormality in hospitalized patients, is an independent predictor of increased mortality in patients with cirrhosis, heart failure (HF), neurologic disorders, and in general hospitalized patients. Since little is known about its current management, a registry was conducted to analyze HN therapies and characterize their relative efficacy.

**METHODS:** This is a multicenter, observational registry of adults with euvolemic (SIADH) and hypervolemic (cirrhosis, HF, and nephrotic syndrome). HN is defined as serum sodium concentration ( $[Na^+] \leq 130$  mmol/L, with overcorrection as  $> 12$  unit change in 24 hour. Target enrollment is 3500 patients in US and EU. After informed consent or waiver, medical records of eligible patients were abstracted and summarized using descriptive statistics.

**RESULTS:** A total of 1672 US patients were analyzed through April 2012. The mean entry and discharge  $[Na^+]$  were  $126.4 \pm 7.5$  and  $131.7 \pm 5.0$  mmol/L, respectively. HN etiology was HF (34%), SIADH (36%), cirrhosis (16%), and nephrotic syndrome

(3%). HN was the admitting diagnosis in 25%, and was chronic in 40%. A total of 41% remained hyponatremic at discharge, most commonly in patients receiving only fluid restriction (FR). Overall, 44% of patients received no treatment, and monotherapies of FR (29%), normal saline (NS) (21%), any pharmacologic therapy (5%), and hypertonic saline (1.3%). Combination therapy was initially prescribed in 14%. Overcorrection of  $[Na^+]$  developed in 2% overall; 29% receiving hypertonic saline only, 5% each receiving NS only, 4% on vaptans alone, 2% were untreated, and  $< 1\%$  receiving FR only.

**CONCLUSION:** Patients are often admitted with chronic HN and frequently have SIADH or HF. One-third of patients received no treatment for HN, with FR the most common intervention. Patients are frequently discharged with persistent HN. Overcorrection most commonly occurred in patients receiving hypertonic saline. These data suggest HN in hospitalized patients is suboptimally managed.

**249. Impact of clinical pharmacy services on the surgical care improvement project measures in a Community Hospital.** Estela M. Trimino, Pharm.D., BCPS, Marta Benitez, Pharm.D., Ann-Lori Perez, Pharm.D., John Lamarque, Pharm.D., BCPS; Mercy Hospital, Miami, FL

**PURPOSE:** To assess and evaluate the impact of clinical pharmacy services on increasing and maintaining compliance with the Centers of Medicare and Medicaid services (CMS) surgical care improvement project (SCIP) hospital quality initiatives.

**METHODS:** Two-thousand and eleven SCIP indicator baseline data was obtained and evaluated. Aspects where pharmacy services would provide direct impact were identified – appropriateness, duration, and timeliness of antibiotics, venous thromboembolism (VTE) prophylaxis, and beta-blocker administration within 24 hours. Preprinted order forms for surgical procedures, as well as a VTE preprinted order form were developed. Pre and post surgical procedure antibiotics and number of doses immediately following surgery were streamlined to comply with current recommendations. Alternative agents in patients with allergies were also included as to avoid delays in post-operative therapy. Electronic “pop-up” windows that included surgical end times were implemented at time of order entry to aid the pharmacist in complying with antibiotic discontinuation in less than 24 hours of the surgical end time. A daily SCIP list was provided to all pharmacists prior to surgery to aid in identification. Additionally, a computer generated core measure report, which included SCIP, and standardized times for prophylactic anticoagulation was implemented to prevent patient “fall outs.”

**RESULTS:** Venous thromboembolism prophylaxis improved from 94% at baseline to 99% in the first quarter of 2012, and compliance with VTE prophylaxis assessment was improved in all patients. Antibiotic discontinuation prior to 24 hours of surgical end time improved from 94% to 99% and timely administration of antibiotic prior to surgery increased from 96% to 99%.

**CONCLUSION:** Quality indicators in SCIP patients have maintained and improved since the implementation of various pharmacy driven initiatives, demonstrating the direct impact of clinical pharmacy services on improving patient outcomes.

## Ambulatory Care

**250. Pharmacist-physician collaboration for diabetes care: the diabetes initiative program.** Michelle Z. Farland, Pharm.D., BCPS, C.D.E.<sup>1</sup>, Jeremy L. Thomas, Pharm.D., C.D.E.<sup>2</sup>, Debbie C. Byrd, Pharm.D., BCPS<sup>1</sup>, M. Shawn McFarland, Pharm.D., BCPS, BC-ADM<sup>3</sup>, Andrea S. Franks, Pharm.D., BCPS<sup>1</sup>, Christa M. George, Pharm.D., BCPS, C.D.E.<sup>4</sup>, Alexander B. Guirguis, Pharm.D., BCPS<sup>1</sup>, Benjamin N. Gross, Pharm.D., BCPS, BCACP, BC-ADM, C.D.E.<sup>5</sup>, Katie J. Suda, Pharm.D., M.S.<sup>4</sup>; (1) University of Tennessee Health Science Center College of Pharmacy, Knoxville, TN; (2) University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR; (3) Alvin C. York Veterans Administration, Murfreesboro, TN; (4) University of Tennessee

Health Science Center College of Pharmacy, Memphis, TN; (5) University of Tennessee Health Science Center College of Pharmacy, Kingsport, TN

**PURPOSE:** This study assessed the impact of a statewide pharmacist-physician collaborative practice model to care for patients with type 2 diabetes mellitus (DM2) on disease-oriented endpoints.

**METHODS:** This was a prospective, quasi-experimental before and after study that enrolled patients from seven different primary care practice sites in Tennessee. Eligible patients were  $\geq 18$  years of age, diagnosed with DM2 with a life expectancy greater than 12 months and had either a glycosylated hemoglobin (A1c)  $> 7\%$ , or blood pressure above 130/80 mmHg, or low density lipoprotein (LDL) greater than 100 mg/dl. Care was provided to patients in a collaborative manner with involvement from both clinical pharmacists and physicians. Patients were followed prospectively for 12 months. Primary outcomes evaluated included: A1c, percentage of patients with A1c  $< 7\%$ , and percentage of patients with A1c  $> 9\%$ . Paired t-tests were used to assess continuous data and McNemar's test was used for categorical data. A p-value  $< 0.05$  was considered significant.

**RESULTS:** A total of 206 patients were enrolled in the study. At baseline, mean A1c was  $8.90 \pm 1.97\%$ . A significant difference was observed in post-intervention A1c (mean  $7.74 \pm 1.69\%$ ;  $p < 0.0001$ ). Patients achieving A1c  $< 7\%$  significantly increased following the intervention (pre-intervention 12.75% versus post-intervention 36.76%;  $p = 0.0002$ ). Patients with A1c  $> 9\%$  significantly decreased (pre-intervention 34.15% versus post-intervention 16.50%;  $p < 0.0001$ ). Total number of anti-hyperglycemia drugs remained stable (mean  $1.78 \pm 0.92$  pre-intervention versus  $1.72 \pm 0.85$  post-intervention;  $p = 0.9909$ ).

**CONCLUSION:** Implementation of a collaborative practice model between pharmacists and physicians improved DM2-related disease endpoints without increasing the total number of anti-hyperglycemic agents. This study adds to the existing literature supporting pharmacist involvement in the management of diabetes as very few multi-center, prospective studies have been reported.

**251. Pharmacists providing disease state self-management education in the patient centered medical home.** *Kira B. Harris, Pharm.D., BCPS, Cassie Boland, Pharm.D.; Wingate University School of Pharmacy, Wingate, NC*

**PURPOSE:** Patient-centered medical home (PCMH) models were created to improve the quality of patient care in the primary care setting. Multidisciplinary teams are one component to successfully implementing a patient-centered practice model. Pharmacists' services can be integrated into PCMH models to assist primary care practices in gaining PCMH recognition. The purpose of this poster is to describe integration of pharmacy services into primary care clinics to meet PCMH standards.

**METHODS:** Prior to PCMH application, two family medicine clinics sought to involve pharmacy services to meet disease state self-management education standards, a must pass PCMH standard. Pharmacy services had been established for 2 years in one clinic but were new in another clinic. A policy and procedure were developed for each clinic to guide referral to and patient management for pharmacy services. During patient visits, pharmacists provided disease state education and/or recommendations for management of the clinics' clinically important disease states: diabetes, hypertension and hyperlipidemia. Education included but was not limited to diet, exercise, glucometer training, injection technique, medication adherence, and treatment goals. In addition, medication therapy recommendations were provided to physicians as needed.

**RESULTS:** Both clinics were recognized as level III patient-centered medical homes. The pharmacists conducted an average of 2.26 and 1.6 patient visits per half-day in the established and new clinics, respectively. Diabetes was the most common visit type with 172 patient visits providing diabetes education and/or management. Hypertension and hyperlipidemia made up 63 and 52

patient visits, respectively, while polypharmacy made up only 16 patient visits.

**CONCLUSIONS:** Pharmacists can serve an important role in the PCMH model through provision of disease state self-management education and medication management.

**252. Evaluating a multi-disciplinary approach in a primary care setting to decrease hospital readmission rates and medication-related issues after hospital discharge.** *Radha S. Vanmali, Pharm.D.<sup>1</sup>, Shelley H. Otsuka, Pharm.D.<sup>1</sup>, Lache T. Wilkins, B.S.<sup>2</sup>, Kristin G. Christensen, M.D.<sup>2</sup>, Susan C. Day, M.D.<sup>2</sup>; (1) Philadelphia College of Pharmacy, Philadelphia, PA; (2) Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA*

**PURPOSE:** This quality-improvement study aimed to: (i) evaluate the clinical effectiveness of a multi-disciplinary transition of care model in a primary care setting, in combination with social workers and clinical pharmacists, and (ii) recognize the role of the clinical pharmacists in identifying and resolving health, medication, or social-related concerns in order to decrease preventable hospital readmissions

**METHODS:** Between October 1, 2011 to March 31, 2012, established patients of two general internal medicine resident clinics at The University of Pennsylvania Health System were seen in the post-acute care clinic (PACC) if their primary care provider was not available within 1-2 weeks of hospital discharge. First, the pharmacist conducted a medication reconciliation visit and communicated any concerns to the examining physician. Each medication issue was assigned a severity level: (i) minor (non-life threatening and unlikely to have adverse outcomes), (ii) moderate (non-life-threatening but could interfere with therapeutic goals), and (iii) severe (potentially life-threatening if left unaddressed). Patients' charts were reviewed to verify hospital readmission thirty days after discharge.

**RESULTS:** A total of 226 out of 371 patients showed for the PACC appointment. Of these, 84% of patients who met with a pharmacist had at least one medication-related issue identified. Furthermore, 26%, 51%, and 7% had a potential medication issue severity level of I, II, and III, respectively. Thirty day readmission rates for patients scheduled in PACC from October 2011 to March 2012 declined from 20% to 8%, respectively. The all-cause readmission rate for the health system from July 2011 to March 2012 was 25%.

**CONCLUSION:** Using a multi-disciplinary transitions-of-care model in a primary care setting, in combination with clinical pharmacists, may be an effective way to decrease preventable hospital readmission, improve patient safety, optimize medication use, and avoid medication errors.

**253. Role of the clinical pharmacist in the successful implementation of an electronic medical record in an interdisciplinary Diabetes Education and Research Center.** *Amy Henneman, Pharm.D., BCPS, Seena Haines, Pharm.D., FASHP, FAPhA, BCACP, BC-ADM, C.D.E.; Palm Beach Atlantic University, West Palm Beach, FL*

**PURPOSE:** The Diabetes Education and Research Center (DERC), is an interdisciplinary clinic, providing comprehensive family and community centered diabetes education and care for children and adults at risk for diabetes or its complications. Implementation of an electronic medical record (EMR) was pursued to enhance documentation, track interventions by students, residents, clinical staff, and for reimbursement. Prior to EMR implementation no electronic capturing of data occurred.

**METHODS:** The EMR transition necessitated a decrease in group educational classes and number of patients seen. This was corrected as providers adapted. Existing paper charts were scanned into the EMR. The pharmacist championed to ensure allergies and medication lists are accessible to the providers, accurate, and appropriate medication/allergy alerts were in place, as well as integration of a pharmacist template.

**RESULTS:** Implementation of the EMR in this innovative practice setting resulted in clearer documentation, facilitating better

communication amongst providers and consistent patient follow-up. A decrease in no-shows and increase in patients completing program components was demonstrated. Improved documentation and integrated billing processes led to an increase in revenue. Challenges for the pharmacist associated with implementation of the EMR include: timeliness of interaction documentation affecting provider communication, necessitating ongoing education, updated computer systems and additional workstations. Ensuring provider utilization of information entered from various disciplines has been challenging. Notes are not displayed unless the individual disciplines tab is selected, and tabs are not integrated or time stamped on the home screen. Establishing EMR access for multi-disciplinary rotation students has been challenging due to need for appropriate clearances through the remote desktop, which holds the EMR application.

**CONCLUSIONS:** Implementation of the EMR has resulted in improved clinic flow, patient follow-up, documentation, and revenue. The challenges of timeliness of provider documentation, provider utilization of interdisciplinary information, and EMR access for students are being addressed on an ongoing basis.

**254. Comparing change in hemoglobin A1C of patients in pharmacist managed telehealth clinic versus in-person clinic.** *Khyati Patel, Pharm.D.<sup>1</sup>, Danielle Alsip, Pharm.D.<sup>1</sup>, Roshani Raval, Pharm.D.<sup>1</sup>, Todd Lee, Pharm.D., Ph.D.<sup>2</sup>; (1) Edward Hines, Jr. VA Hospital, Hines, IL; (2) University of Illinois at Chicago-College of Pharmacy, Chicago, IL*

**PURPOSE:** The primary objective of the study was to assess the effectiveness of a telehealth program by comparing changes in HgbA1c over 6 ± 3 months of patients in a clinical pharmacist managed telehealth clinic versus in-person clinic. Secondary endpoints included change in HgbA1c over 12 ± 3 months, change in weight, enrollment into the MOVE! program, diabetes medication changes, compliance to clinic appointments, and adverse events related to diabetes medications. The study also evaluated patient responses to an ease of telehealth use survey.

**METHODS:** This was a retrospective chart review of patients receiving diabetes care by a clinical pharmacist via in-person and telehealth modalities from January 2010 to December 2011 at an outpatient clinic affiliated with the Edward Hines, Jr. VA Hospital. Patient data collected include clinic location, age, gender, comorbid diseases, diabetes management via other healthcare professionals, HgbA1c, weight, diabetes medications, status of enrollment into MOVE! program, and adverse events of diabetes medications at baseline ±2, 6 ± 3, and 12 ± 3 months. An ease of telehealth use survey consisting of 10 multiple choice questions was conducted to assess whether patients perceived any barriers to the telehealth use and believed it to be an appropriate method for diabetes management.

**RESULTS:** The in-person group had an average HgbA1c reduction of 1.1% at 6 months versus 0.88% reduction in the telehealth group,  $p=0.46$ . Secondary outcomes revealed no statistically significant difference between the two patient groups. Outcomes of the ease of telehealth use survey were in favor of the telehealth technology use.

**CONCLUSION:** Telehealth was found to be an equally effective method of health care delivery when compared to the traditional in-person method used in a clinical pharmacist run diabetes clinic. Telehealth technology opens opportunities for increasing access to care and decreasing healthcare costs.

**255. Challenges in implementing an interdisciplinary cardiometabolic risk reduction clinic.** *Cara Liday, Pharm.D., BCPS, C.D.E.*; Idaho State University, Pocatello, ID

**PURPOSE:** To determine the effectiveness and feasibility of a comprehensive clinic care model that utilizes a dietician/clinical lipid specialist, a pharmacist/certified diabetes educator, and a physician in improving cardiovascular risk factors associated with the metabolic syndrome through intensive lifestyle intervention.

**METHODS:** Patients with a diagnosis of metabolic syndrome, as outlined in the National Cholesterol Education Program (NCEP)

guidelines, were referred to the program by their primary providers. After determination of "readiness for change," participants were given in-house nutrition and behavior change education, medical nutrition therapy, diabetes education, pharmacotherapy, as well as community education classes. Patients chose bi-monthly individual or shared medical appointments over a period of 12 weeks. Blood pressure, weight, waist circumference, BMI, A1c, fasting blood glucose, fasting lipid panel, sub-maximal VO<sub>2</sub> treadmill testing for fitness level, and actual behavioral change were evaluated.

**RESULTS:** Forty-six participants were referred during a 12-month period, although only 13 completed the full program. One-third of participants attended only the initial appointment. Improvements were seen in most parameters in completers. There was a low referral rate, despite staff efforts in patient identification and marketing. Due to the high attrition rate, surveys were mailed to all enrolled. Positive feedback received about educators and program content. Reasons for discontinuation included cost, difficulty with intensity of lifestyle modifications, motivation, time, and psychosocial issues.

**CONCLUSION:** Although much data exists regarding the benefits of lifestyle modification and interdisciplinary approaches to managing cardiovascular risk, the implementation of such programs remains difficult. Reimbursement for these services is inadequate and patients are many times not willing to pay out of pocket. This population had a significant psychosocial component and as such, a behavioral counselor as a team member would be beneficial. Lastly, a physician or primary provider champion is a vital component to an interdisciplinary clinic.

**256. A reimbursement model through a University's self-insurance for ambulatory care clinical pharmacy services.** *Katy E. Trinkley, Pharm.D., Gina Moore, Pharm.D., M.B.A., Kavita V. Nair, Ph.D., Steven M. Smith, Pharm.D., M.P.H.*; Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Aurora, CO

**PURPOSE:** Reimbursement for clinical pharmacy services is often problematic and not always effective. Here we describe a novel reimbursement model and preliminary results stemming from a contract between a School of Pharmacy and the University's self-insurance administration to offer comprehensive medication reviews to the University self-insured population.

**METHODS:** A 1-year contract was signed, with optional renewal, that enabled the school to offset the salary of two ambulatory care clinical pharmacists, each at 0.5 FTE, hire administrative help, and cover other miscellaneous expenses. The services were marketed to both beneficiaries as well as providers through newsletters, mailings, and a website. On April 4, 2012, the clinical pharmacists began offering 30-minute appointments to beneficiaries and their adult dependents without a fee-for-service. The services were offered one or two half days each week, rotating among one of the five campuses within a 90 mile radius. Additionally, visits were conducted at varying locations on each campus to make it more convenient for beneficiaries.

**RESULTS:** Thus far, 52 comprehensive medication reviews of 402 medications have been performed, resulting in the clinical pharmacists making 128 interventions for an average of 2.46 interventions per comprehensive review. Interventions included 74 prescription medication-related problems and 116 over the counter medication-related problems. The medication-related problems consisted of 16 adverse drug events, six drug interactions, five untreated conditions, 69 medications without an appropriate indication, 35 inappropriate medications for an indication, four inappropriate dose regimens, 10 cost concerns, 18 adherence issues, and 23 needing additional education. There were two adverse drug events that were considered severe or life-threatening.

**CONCLUSION:** The service will continue to be offered to all beneficiaries with a goal of targeting high-risk patients based on medication claims data.

**257. Patient acceptance of STI screening services by pharmacists.**

*Sara J. Deppe, Pharm.D.<sup>1</sup>, Brooke Y. Patterson, Pharm.D.<sup>2</sup>, Mark T. Sawkin, Pharm.D.<sup>3</sup>, Chessa R. Nyberg, Pharm.D.<sup>4</sup>;* (1)University of Missouri-Kansas City School of Pharmacy, Kansas City, MO; (2)Janssen Services Inc., Kansas City, MO; (3)University of Missouri, Kansas City School of Pharmacy, Kansas City, MO; (4)University of Illinois at Chicago, Chicago, IL

**PURPOSE:** Sexually transmitted infections (STIs) remain one of the most common disease states in adults and adolescents. Various barriers, such as stigma and lack of access to care, prevent patients from obtaining the appropriate screening they need. This lack of screening in turn perpetuates transmission and delays treatment of STIs. Community-based pharmacists are readily available to the general public and are routinely ranked by Americans as one of the most trusted professions. With better access to pharmacists, patients may be more willing to undergo STI screening and treatment and thereby decrease transmission and long-term sequelae.

**METHODS:** To assess patient attitudes toward pharmacists as STI providers, patients who presented to an urban free health clinic seeking STI screening and testing were given a confidential survey. This survey was comprised of a series of questions relating to STI testing and the acceptability of a pharmacist as their provider.

**RESULTS:** From this survey, patients showed overwhelming acceptance of a pharmacist as their STI treatment provider (75.1%). The responsibilities they were comfortable with a pharmacist performing included running a urine screen (94%), performing a physical exam (78%), diagnosing and treating STIs (97.3%), and discussing STI test results (92.9%). Patients also approved of pharmacists working under a collaborative practice agreement with a physician (96.2%).

**CONCLUSION:** Acceptance by patients of a pharmacist-provider for STI screening may lead to adoption of STI screening clinics by community pharmacists. This would increase accessibility as well as identification of those infected with sexually transmitted infections ultimately leading to a decrease in the spread and long-term sequelae of untreated STIs.

**258. Implementing a medication management pilot to decrease polypharmacy within a medical home.** *Erin B. Neal, Pharm.D., BCPS, David F. Gregory, Pharm.D., BCPS, FACHE, Walt R. Woods, B.S. Pharm., MMHC; Vanderbilt University Medical Center, Nashville, TN*

**PURPOSE:** This pilot program was implemented within a medical home focusing on employees and their dependents who are insured by our institution with the goal of (i) decreasing polypharmacy and (ii) providing medication therapy management (MTM) for patients on > 12 medications.

**METHODS:** Patients within the medical home who were insured by our institution's health plan with > 12 medications documented on their medication list within the EMR (electronic medical record) who had an appointment scheduled with their primary care provider between March and April 2012 were identified. The pharmacist contacted these patients prior to their appointments either by phone or in person to provide MTM. Recommendations were communicated to the provider both in person and via the EMR.

**RESULTS:** Twelve patients met inclusion criteria and received the intervention. There was not a significant reduction in the number of medications following intervention (18 versus 17.2). The pharmacist documented 84 total interventions (seven per patient). The most common interventions included updating the medication list, counseling patient and providing drug information, and identifying and addressing non-adherence. Estimated cost savings to the health plan, based on the direct cost of medication, was \$950 per month, or \$79.10 per patient.

**CONCLUSION:** Based on this pilot program, it may be difficult to reduce the number of medications in this patient population; however, providing MTM for these patients can result in several interventions and can decrease medication costs. The lessons

learned from this pilot will be used to refine the implementation of MTM within the medical home at our institution.

**259E. Establishment of a pharmacist-run dofetilide initiation clinic.** *Sarah Land, Pharm.D.<sup>1</sup>, Jackie Roh, R.Ph., BCPS<sup>1</sup>, Sally Putt, Pharm.D., BCPS, C.P.P.<sup>2</sup>;* (1)Cone Health, Greensboro, NC; (2)LeBauer HeartCare, Greensboro, NC

**PURPOSE:** The FDA currently recommends a minimum hospital stay of 3 days for patients initiated on dofetilide (Tikosyn<sup>®</sup>). The purpose of this study is to determine if a pharmacist-driven dofetilide initiation clinic can decrease time from hospital admission to first dose through a preadmission clinic at an ambulatory cardiology practice.

**METHODS:** A pharmacist-driven dofetilide initiation protocol was developed to screen patients and address criteria that may prolong time to first dose of dofetilide upon hospital admission. Retrospective data collected from patients initiated on dofetilide from January 1st, 2011 to June 30th, 2011 was compared to prospective data collected from patients managed in the pharmacist-run dofetilide clinic from January 1st, 2012 to March 31st, 2012. The primary outcome of this study was time from hospital admission to first dose of dofetilide. The secondary outcome of this study was total length of hospital stay.

**RESULTS:** There were eight patients included in the retrospective group and seven patients in the prospective group. The median time from hospital admission to first dose of dofetilide was decreased by 4.4 hours (8.7 versus 4.3, 51% change) for patients seen in the dofetilide initiation clinic. Mean length of hospitalization was decreased by 1.2 days (4.3 versus 3.1, 28% change). It took on average 3 days longer (10 versus 13) from when a physician planned to initiate dofetilide until patients were admitted to the hospital for dofetilide loading.

**CONCLUSION:** The dofetilide initiation clinic decreased time to first dose, decreased length of hospitalization, and increased time from plan to start dofetilide until hospital admission. The new service was well received by patients and providers and will continue to be offered in the future.

Presented at the Southeastern Residency Conference, Athens, GA, April 26-27, 2012

**260. ACTION: an interdisciplinary approach to outpatient-based transitions of care.** *Zachariah M. Deyo, Pharm.D., BCPS, C.P.P.<sup>1</sup>, Mark Gwynne, D.O.<sup>2</sup>, Amy Prentice, M.S.W., P-LCSW<sup>2</sup>, Gretchen Tong, Pharm.D., C.P.P.<sup>2</sup>, Sam Weir, M.D.<sup>2</sup>;* (1)University of North Carolina Hospitals and Clinics, Chapel Hill, NC; (2)University of North Carolina Department of Family Medicine, Chapel Hill, NC

**PURPOSE:** To create an interdisciplinary team-based process of care through a post-hospitalization appointment set called complex-return-continuity (CRC). Primary outcomes include reduced rehospitalizations and modeling an effective interdisciplinary team that facilitates medication reconciliation, coordination of care, communication, and patient activation which are key principles of a Patient Centered Medical Home (PCMH).

**METHODS:** We followed the principles of the Model for Improvement by identifying an interdisciplinary team focused on reducing rehospitalizations. We used Plan, Do, Study, Act cycles to test changes with predefined metrics to ensure that change led to improvement. Initial process measures included detailed appointment cycle time, efficiency of CRC appointment use, patient and provider satisfaction.

**RESULTS:** Process improvements include successfully linking the CRC appointment with a pharmacist and a physician within our scheduling system, involving department scheduler and coordinating with the inpatient team. This led to 36 scheduled CRC appointments with a no-show rate of 22.2%. The readmission rate for no-show versus those attended was 27.3% versus 16.7% respectively. Average cycle time was 90.08 minutes for CRC versus 66.96 minutes for usual appointments however the majority of patients perceived the CRC appointment as the same duration as the usual appointment. Most patients and providers perceived

that patients had an improved understanding of their medications.

**CONCLUSION:** Using principles of quality improvement we demonstrated the feasibility of an innovative interdisciplinary appointment focused on transitions of care in an outpatient primary care practice. This included collaboration of physicians, pharmacists, care managers and their learners. CRC appointments demonstrated a positive experience for patients and clinicians, an improvement in patient's and physician understands of patient's medications, and a process for measuring efficiency of hospital follow-up and readmissions. Future opportunities exist in modeling effective PCMH principles of team-based care to learners, improving utilization metrics in readmission rates, clinical outcomes and appropriate medication use.

**261. Collaborative hypertension case management by clinical pharmacy specialists and registered nurses in a VA primary care clinic.** *Jessica O'Neill, Pharm.D.,* Tori Cunningham, Pharm.D., Emily Bartley, Pharm.D., Wyndy Wiitala, Ph.D.; VA Ann Arbor Healthcare System, Ann Arbor, MI

**PURPOSE:** This study evaluated a novel care model of collaborative case management with clinical pharmacy specialists (CPSs) and registered nurse (RN) case managers. The primary objective was to establish non-inferiority of CPS-directed RN case management of hypertension (HTN) versus the usual model of physician-directed RN case management in the Veterans Affairs Ann Arbor Healthcare System primary care clinic.

**METHODS:** Medical records between 9/20/2011 and 10/31/2011 were used to identify patients who attended RN hypertension case management appointments. The sample included 126 patients whose medical decision-making was directed by a CPS (n=63) or physician (n=63). The difference in systolic blood pressure (SBP) between index and the next consecutive visit was collected for each patient. The following variables were also collected: sex, smoking status, age, BMI, comorbidities, number of antihypertensive medications, home blood pressure cuff prescriptions, time between visits, and referrals provided at the visit.

**RESULTS:** Demographic data were similar between groups. Patients in both groups had significantly lower mean SBP at follow-up ( $135 \pm 13$  mmHg) compared to the initial visit ( $147 \pm 11$  mmHg). Patients receiving CPS-directed HTN case management had greater average decreases in SBP compared to those receiving physician-directed care ( $14 \pm 13$  versus  $10 \pm 11$  mmHg;  $p < 0.05$ ). After adjusting for the amount of time between visits, initial SBP, and smoking status, provider type was no longer significant ( $p = 0.177$ ). Patients with higher initial SBP had greater SBP reduction at the follow-up visit ( $p < 0.001$ ).

**CONCLUSION:** Collaborative HTN case management by clinical pharmacy specialists and RNs is a novel model of care, which was non-inferior to physician-directed RN case management. Clinically significant blood pressure reductions occurred in both the CPS- and physician-directed RN case management groups. Baseline SBP was a predictor of SBP change; this may be due to regression to the mean. This represents an expanded role for clinical pharmacy specialists in ambulatory care clinics.

**262. Patient education, lifestyle modification, and medication therapy management (MTM) with a diabetes focus in an underserved population within a primary care setting.** *Krystal K. C. Riccio, Pharm.D., BCACP,* Roseman University of Health Sciences, Henderson, NV

**PURPOSE:** Many chronic conditions can be improved with lifestyle modification and appropriate medication therapy; however, especially in underserved populations, patients lack the education necessary to make healthier choices. An Ambulatory Care pharmacist sought to establish a clinical service that would benefit an underserved community and provide a unique pharmacy student opportunity.

**METHODS:** The development of a referral based education and MTM clinic has been designed to tackle specific obstacles identified in the primary care setting, including patient's perceptions, physician's lack of time available to provide comprehensive edu-

cation, and limited affordable resources for patients to acquire disease, medication, and lifestyle specific education. This poster describes an interdisciplinary practice model including a primary care physician, nursing staff, schedulers, pharmacy students, and a clinical pharmacy faculty member. Patients are offered a one hour initial visit with patient history taking, vital sign and laboratory value assessment, education, and MTM services provided by an ambulatory care pharmacist and pharmacy students. Follow-up monitoring and return visits were recommended according to individual patient needs.

**RESULTS:** Chronic disease state education and MTM Clinic was established July 2011. Referrals from the primary care physician have been able to receive one hour of education regarding pathophysiology of chronic disease(s), appropriate medication use, rationale for specific medication use, individualized nutritional counseling, and self-monitoring reinforcement. Over 300 patients have been seen for initial visits and many have returned for follow-up visits within the last year. Interdisciplinary team and patients are pleased with the success of the program and the trends seen with patient health improvement.

**CONCLUSION:** Data collection is underway for evaluation of clinical pharmacist interventions in improving patient health and altering patient perceptions.

**263. Development and implementation of a pharmacist managed clinic for the titration of medications in chronic heart failure patients.** *Vicki L. Groo, Pharm.D.<sup>1</sup>,* Mayank Kansal, M.D.<sup>2</sup>, George T. Kondos, M.D.<sup>1</sup>; (1) University of Illinois at Chicago, Chicago, IL; (2) University of Illinois @ Chicago, Chicago, IL

**PURPOSE:** Published guidelines for the management of chronic heart failure (HF) recommend administration of ACE inhibitors and beta blockers (BB) to patients with an EF < 40%. In addition, Heart Failure Society of America recommends ACE inhibitors be titrated to doses used in clinical trials and BB be initiated at low doses and up-titrated at 2-week intervals. We previously reported that patients managed in a multi-disciplinary HF clinic are more likely than those managed in a general cardiology (GC) setting to receive guideline recommend therapies. Therefore we proposed that pharmacist/s specialized in HF management could be a valuable resource to GC for medication titration.

**METHODS:** A specialized clinic was developed for the HF pharmacist to take referrals from GC for systolic HF patients with the purpose of up-titrating ACE inhibitors and BB per guidelines. The clinic is offered ½ day weekly. Appointments are scheduled at 30 minute intervals. At each visit, the pharmacist reviews vitals, symptoms, educational needs, laboratory results and medication regimens. ACE inhibitor and BB are initiated and/or increased as tolerated. Prescriptions and the progress note are sent to the referring cardiologist for co-signature. Patients are seen at 2 week intervals with a cardiologist available for additional consultation as needed. Pharmacist services are billed via a hospital-based facility fee model at a level 3 or 4 technical fee, depending on visit complexity.

**RESULTS:** Since clinic implementation (July, 2011), 46 patients have been referred and 126 visits provided by the HF pharmacist. Clinic acceptance was high with seven of the 11 GC referring patients for pharmacist management. Within 1 month of clinic initiation, pharmacist availability needed to be increased from ½ day bi-weekly to weekly.

**CONCLUSION:** A pharmacist managed medication titration clinic is a mechanism to assist GC in their treatment of systolic heart failure patients with the ultimate goal of improving patient outcomes.

**264. Pharmacist-managed diabetes care in a medically underserved population.** *Jennifer L. Rosselli, Pharm.D.,* J. Christopher Lynch, Pharm.D.; Southern Illinois University Edwardsville School of Pharmacy, Edwardsville, IL

**PURPOSE:** This study evaluated the impact on clinical outcomes of patients receiving pharmacist-managed diabetes care in a Federally Qualified Health Center.

**METHODS:** This retrospective case series included all patients over the age of 18 years with diabetes meeting one of the following criteria during the year prior to referral: A1C greater than 9%, systolic blood pressure (SBP) greater than 140 mmHg, diastolic blood pressure (DBP) greater than 90 mmHg, hospital admission or emergency department visit for a diabetes-related complication. Patients participating in the pharmacy outreach program received disease state management, patient education, and medication management. The pharmacist provided clinical services under a standing order set agreement with collaborating physicians and had autonomy to initiate, modify, or discontinue drug therapy. The pharmacy outreach program was supported by a grant funded by the Health Resources and Services Administration (HRSA), with a significant portion of grant dollars being spent on purchasing medications for uninsured patients. Primary outcomes analyzed were A1C, blood pressure, and low-density lipoprotein cholesterol (LDL-c). Baseline and end point data were analyzed for patients who attended at least one session with a clinical pharmacist during a 28 month period. Outcomes were assessed using general descriptive statistics and paired t-test.

**RESULTS:** A total of 112 patients with a mean age of 48.7 years (standard deviation 11.5) met inclusion criteria and were included in the analysis (62.5% female). Of the primary outcomes targeted by the pharmacy outreach program, statistically significant reductions were realized for A1C, DBP, and LDL-c (1.1%, 2.4 mmHg, 12.7 mg/dl, respectively;  $p < 0.05$ ). There was a non-statistically significant reduction in SBP of 2.1 mmHg ( $p = 0.22$ ).

**CONCLUSION:** Patients with uncontrolled diabetes benefited from receiving pharmacist-delivered diabetes care. The significant improvements in A1C, blood pressure, and LDL-c support the role of a clinical pharmacist in a medically underserved population.

## Cardiovascular

**265. Integration of a pharmacist led active learning class into the cardiac rehabilitation program at a community hospital.** *Natalie Y. Paul, Pharm.D., BCPS*; Comprehensive Pharmacy Services, Inc, Chicago, IL

**PURPOSE:** To incorporate a pharmacist-led active learning medication class into a cardiac rehabilitation program.

**METHODS:** Monthly one-hour active learning classes given by a pharmacist are currently offered to patients attending cardiac rehabilitation. The drug classes reviewed include: beta-blockers, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, HMG-CoA reductase inhibitors, nitrates and antiplatelets. Class size is limited to six patients (not including caregivers) to allow adequate opportunity for participation. Basic mechanisms of action, common side effects, and usual titrations are discussed and dialogue amongst patients regarding experiences with the medications is encouraged. Patients are expected to bring their medications to the class as they complete a medication list in conjunction with the pharmacist. The session ends with general questions regarding adherence, alternatives to therapy for cost savings, and questions to follow up with their cardiologist. A short post-test to assess learning and an evaluation are given to the patient for feedback.

**RESULTS:** Four classes have been offered in the cardiac rehabilitation program. Attendance averages four patients/class (not including caregivers). Classes last for a total of 50 minutes with extra time for individual questions. Post-test results indicate an average of 80% of questions answered correctly. Suggestions for future classes include: how to reduce a patient's medication burden, attacking the cough and cold aisle with heart disease, and taking supplements with cardiac medications.

**CONCLUSION:** Incorporating a pharmacist into the curriculum of a cardiac rehabilitation program provides more detailed education on common cardiac medications. Future plans include the implementation of one-on-one pharmacist appointments to discuss more detailed medication-related issues and expanding the topics discussed.

**266. Reducing heart failure readmissions: a multidisciplinary approach.** *Brian Trevarrow, Pharm.D., BCPS<sup>1</sup>*, Elizabeth Purvis-Jeffrey, RN-BSN<sup>1</sup>, Paul P. Dobesh, Pharm.D., FCCP, BCPS<sup>2</sup>; (1)The Nebraska Medical Center, Omaha, NE; (2)University of Nebraska Medical Center, Omaha, NE

**PURPOSE:** Heart failure (HF) is a chronic disease that progressively decreases patients' ability of self-care, and is the most frequent reason for hospital readmissions. Each year 27% of patients with HF on Medicare are readmitted within 30 days with an unplanned hospitalization costing \$17.4 billion annually. Medicare has recently implemented a financial penalty for hospitals based on their 30-day HF readmission rates. Therefore, we sought to design a method for reducing these readmissions

**METHODS:** Processes in three areas were piloted and subsequently implemented across the institution. These steps included: early identification of HF patients upon admission; interdisciplinary education during the inpatient stay; interdisciplinary follow-up phone calls after discharge. Patients with HF were targeted for focused education from nursing, pharmacy and nutrition. Pharmacists directed education to patients and families on heart failure medications: ACE inhibitors, ARBs, beta blockers, diuretics, digoxin and vasodilators. Medication education focused on pharmacologic impact on disease pathophysiology, possible side effects, dosing, regimen adherence, drug interactions and special instructions. The educational efforts were initiated in January 2011. A retrospective analysis of readmissions in HF patients for 2010 was conducted, which represented the pre-education group. A prospective analysis of readmissions in HF patients was conducted in 2011, which represented patients exposed to the new education program.

**RESULTS:** There were 532 admissions for HF in 2010 (pre-education group) and 482 in 2011 (with education group). There were no major differences between the HF patients in each group. The rate of all-cause readmission for these HF patients was significantly reduced after implementation of the multidisciplinary program from 28% in 2010 to 20% in 2011 ( $p = 0.003$ ). The incidence of HF readmissions were also decreased (12% versus 5%;  $p < 0.001$ ).

**CONCLUSION:** A multidisciplinary team approach, with pharmacist involvement focused on medication education, was able to contribute to significant reductions in readmission in patients with HF.

**267. Ability of a clinical pharmacist to make drug therapy interventions using email in patients with advanced heart failure and ventricular-assist devices.** *Douglas L. Jennings, Pharm.D., BCPS, AQC-CV*, Jona Lekura, Pharm.D.; Henry Ford Hospital, Detroit, MI

**PURPOSE:** Inpatient clinical pharmacists are often required to provide coverage to multiple patient care teams and are often limited in their ability to interface directly with physicians when suggesting drug therapy recommendations. This project explores email as a potential medium for pharmacists to communicate interventions with prescribers.

**METHODS:** This retrospective descriptive analysis was conducted at an urban, academic teaching hospital where one clinical pharmacist is responsible for the daily pharmaceutical care for the inpatient advanced heart failure (AHF), cardiac intensive care unit (ICU), and cardiothoracic ICU teams. If the pharmacist identified a potential drug therapy problem and couldn't make direct face-to-face contact with the attending physician, the intervention was attempted via an email communication. Eligible patients for this project were admitted to the AHF team between December 1st, 2010 and July 31st, 2011 and had at least one attempted email intervention. Data collection included patient demographics, past medical history, and the suggested intervention from the clinical pharmacist. The primary outcome was the number of interventions accepted by the physicians during the study period, while the secondary endpoint was the time between the suggested intervention and the physician email response.

**RESULTS:** A total of 51 email interventions were attempted on 29 patients (mean age = 53, 24% caucasian, 59% male, 69% LVAD). Overall, 44 of the total 51 number of interventions were accepted (86.3%). The average physician time to a physician response email was 41 minutes. The most frequent type of interventions were starting therapy (33%) and changing dose, route or frequency (33%). The most common drug classes involved in email interventions were ACE inhibitors/angiotensin receptor blockers (15.7%), loop diuretics (9.8%), and antiplatelet agents (7.8%).

**CONCLUSIONS:** Clinical pharmacists with well-established physician relationships can effectively implement timely drug therapy recommendations using email communications in patients with advanced heart failure or ventricular assist devices.

**268. Evaluating the incidence of contrast induced nephropathy in patients undergoing heart catheterizations with proposed protocol for optimizing outcomes.** *R. Naseem Amarshi, M.S., Pharm.D.<sup>1</sup>, Victoria Miller, Pharm.D.<sup>2</sup>, Friej Gobal, M.D.<sup>1</sup>, Barry Uretsky, M.D.<sup>1</sup>;* (1) Central Arkansas Veterans Healthcare System, Little Rock, AR; (2) Central Arkansas Veterans Healthcare System, Little Rock, AR

**PURPOSE:** To evaluate current methods of hydration for prevention of contrast induced nephropathy (CIN) in patients undergoing heart catheterizations using radiopaque contrast media at Central Arkansas Veteran's Health Care System (CAVHS) and to develop a hydration protocol and CIN risk score based on the Mehran protocol.

**METHODS:** Medical charts for 100 inpatients at CAVHS between October 20, 2011 and January 28, 2012 were reviewed. Patients were evaluated for percentage risk of developing CIN based on the Mehran score, appropriateness of hydration based on the proposed hydration protocol, and the incidence of CIN. A hydration protocol and CIN risk analysis will be proposed for implementation into the Computerized Patient Records System (CPRS).

**RESULTS:** One hundred patients were evaluated according to the Mehran protocol. The calculated risk for CIN was as follows: 54 patients had a 7.5% risk, 32 patients had a 14% risk, nine patients had a 26.1% risk, and three patients had a 57.3% risk. Two patients were excluded from the study. Fifty-one patients received pre-catheterization hydration that was consistent with the proposed hydration protocol. One patient (2.2%) developed CIN during the specified time frame. There were 53 patients who did not have a serum creatinine drawn post-catheterization. Eleven patients did not receive any pre-catheterization hydration.

**CONCLUSION:** The incidence of CIN after undergoing a heart catheterization appears to be low at CAVHS. Also, documentation of the volume of contrast used occurred in 100% of the patients evaluated. Hydration for prevention of CIN in this patient population should be standardized. Implementation of a hydration protocol and CIN risk analysis based on the Mehran score will standardize fluid administration. Hopefully, this will also decrease the number of renal consults for patients undergoing heart catheterizations.

## Clinical Administration

**269. Pharmacist-directed rivaroxaban prescribing in patients undergoing elective hip/knee replacements in a rural, regional hospital in Ontario.** *Stephan Sadikian, B.Sc., Pharm.D.;* Grey Bruce Health Services, Owen Sound, ON, Canada

**PURPOSE:** To develop a process in which clinical pharmacists would communicate suitability of rivaroxaban thromboprophylaxis in patients undergoing elective hip/knee surgery.

**METHODS:** A procedure and a communication form were produced from analysis of inclusion and exclusion criteria from clinical trials as well as information from the drug monograph. Clinical pharmacists would review the patient's chart one day before their scheduled operation. Creatinine clearance would be calculated using Cockcroft-Gault, medications were assessed

and the communication form was completed giving clear direction to the orthopedic surgeon in regards to the suitability of rivaroxaban. This communication form listed criteria for absolute and relative contraindications. If a patient had any one absolute contraindication or two relative contraindications, the patient was deemed to not be a suitable candidate for rivaroxaban thromboprophylaxis. Otherwise, the surgeon was given the choice to order rivaroxaban.

**RESULTS:** The communication form was (and is) well received by the orthopedic surgeon. The clinical pharmacists would identify about one patient out of ten who would not be a candidate for rivaroxaban therapy. The involvement of the pharmacist improved trust in the proper and safe prescribing of a new oral thromboprophylactic agent. This level of trust as well as anecdotal evidence that there were no more than usual bleeding events, or venous thromboembolism, led the other three orthopedic surgeons to change their choice of thromboprophylaxis.

**CONCLUSION:** A process that involves clinical pharmacists as the central figure in directing orthopedic surgeons to prescribe a new oral thromboprophylactic agent for patients undergoing elective hip/knee replacement is beneficial. There is improved collaboration amongst surgeons and pharmacists. Anecdotally, there is no appreciable difference in bleeding or VTE events.

**270. Justifying the integration of a clinical pharmacist into a primary care team.** *Margaret L. Wallace, Pharm.D.<sup>1</sup>, Todd D. Sorensen, Pharm.D.<sup>2</sup>, Haley Holtan, Pharm.D.<sup>3</sup>;* (1) University of Minnesota, Minneapolis, MN; (2) University of Minnesota College of Pharmacy, Minneapolis, MN; (3) Hennepin County Medical Center, Minneapolis, MN

**PURPOSE:** To evaluate the sustainability of clinical pharmacy services in one primary care clinic within a large, integrated, county-based health system serving a diverse, low-income population.

**METHODS:** A PGY2 pharmacy resident established a clinical practice (0.5 FTE) in a primary care clinic that had not previously included a pharmacist. Nine months following initiation of services, the impact of the practice was evaluated from several perspectives as part of a proposal for permanent staffing. Elements of impact evaluated to justify sustainability of the pharmacy practice included fiscal measures (patient encounters, fee-for-service billing, and institutional cost savings opportunities), quality improvement initiatives (impact on disease specific quality measures), provider and patient satisfaction.

**RESULTS:** Pharmacy services demonstrated the potential to generate \$55,650 in revenue through fee-for-service billing. Reduction in emergency department (ED) and hospital visits through medication management services for uninsured patients (\$124,948), and reductions in overall health costs for patients enrolled in an Accountable Care pilot program (\$69,677) had the potential to produce \$194,625 in cost-savings for the organization. A redesigned approach to asthma care including a clinical pharmacist resulted in a 21.7% increase in patients receiving optimal asthma care, as defined by Minnesota Community Measures. Patient satisfaction surveys revealed a high level of satisfaction. Additionally, patients indicated that they were very likely (86%) or likely (14%) to suggest a visit with a clinical pharmacist to a friend. Medical providers and staff were likewise very supportive of continuing clinical pharmacy services in the clinic with 90% of staff indicating that presence of the clinical pharmacist has impacted the quality care in the clinic.

**CONCLUSION:** Integration of clinical pharmacy services resulted in improvements in quality and cost savings. Combined with revenue opportunities, data and experience suggest justification for a permanent clinical pharmacy position at this clinic.

**271. Justification of a therapeutic drug monitoring clinical pharmacist position.** *Pratish Patel, Pharm.D., David F. Gregory, Pharm.D., Bob Lobo, Pharm.D.;* Vanderbilt University Medical Center, Nashville, TN

**PURPOSE:** There is a growing consensus that higher vancomycin doses that are currently used to treat severe infections is leading to increased risk for nephrotoxicity. Our goal was to provide justification for a clinical pharmacist FTE in the area of therapeutic drug monitoring (TDM) to reduce the risk for vancomycin nephrotoxicity.

**METHODS:** In 2011 an increased incidence of vancomycin-associated nephrotoxicity was observed at our institution. As a result, we formed a multidisciplinary steering committee in order to discuss the problem and to identify potential solutions. The committee included representatives from pharmacy, infectious disease physicians, nursing, and hospital administration. Meetings were convened in order to discuss the literature as it relates to antibiotic nephrotoxicity and to review our processes for dosing and monitoring vancomycin and aminoglycosides. This led to recommendations to standardize several processes for dosing and monitoring, and to conduct a return on investment (ROI) analysis of a clinical pharmacist dedicated to therapeutic drug monitoring. The ROI required hiring a clinical pharmacist as a "temporary" position within the pharmacy budget, and quantifying their interventions to reduce risk factors for nephrotoxicity. The costs of adverse drug events were estimates based on current literature.

**RESULTS:** During the two month period of time used to estimate the ROI, the pharmacist documented 190 interventions. There were 143 interventions related to vancomycin and 42 for aminoglycosides. An estimated 21 adverse drug events were prevented. Estimated cost savings were \$48,737 and the cost of the FTE during the study period was \$24,583, yielding an estimated ROI of \$144,924 for the year. This data was shared with hospital administration and a permanent FTE was approved.

**CONCLUSIONS:** Concern about an increased incidence of vancomycin-associated nephrotoxicity led to an institutional strategy to reduce risk which included a proposal to hire a clinical pharmacist. Our ROI analysis justified this position.

**272. Justification of a clinical pharmacist position for inpatient anticoagulation.** Patricia B. Miller, Pharm.D., David F. Gregory, Pharm.D., Bob Lobo, Pharm.D.; Vanderbilt University Medical Center, Nashville, TN

**PURPOSE:** Anticoagulation is associated with a high risk for serious adverse drug events. The Joint Commission and other national healthcare quality related organizations recommend close pharmacy oversight and involvement with anticoagulation and implementation of a pharmacist managed anticoagulation service. Our goal was to provide justification for a clinical pharmacist FTE in the area of anticoagulation in order to reduce the risk for serious adverse drug events.

**METHODS:** The ROI required hiring a clinical pharmacist as a "temporary" position within the pharmacy budget, and quantifying their interventions to reduce risk factors for nephrotoxicity. The costs of adverse drug events were estimates based on current literature.

**RESULTS:** During the 90 day trial, the pharmacist made 145 interventions and prevented 30 serious adverse drug events. Most of the events were related to warfarin dosing and monitoring. Cost savings related to reduce adverse drug events were estimated at \$50,751 in the first 90 days and the cost of the position was \$35,863 during the same period yielding an estimated ROI of \$59,553 annually. This data was shared with hospital administration and a permanent FTE was approved.

**CONCLUSIONS:** We proposed an FTE for a clinical pharmacist to assist with the management of inpatient anticoagulation in order to reduce risk for adverse events. Our ROI analysis justified this position.

## Community Pharmacy Practice

**273. Establishing an accredited diabetes self management education program within a school of pharmacy.** Kayce Shealy, Pharm.D.; Presbyterian College School of Pharmacy, Clinton, SC

**PURPOSE:** The purpose of this poster is to describe the development of an accredited diabetes self-management education program within a school of pharmacy.

**METHODS:** In fall 2010, practice faculty involved with diabetes management began developing a diabetes self-management education program. Initially, the program served patients from a local free clinic to augment pharmacotherapy services that were delivered there. Accreditation was applied for and granted through the American Association of Diabetes Educators (AADE) in summer 2011. The program partnered with the local hospital system to take over its American Diabetes Association (ADA)-accredited program and establish a Diabetes Care Center beginning January 2012. The school of pharmacy is responsible for providing clinicians to see patients and deliver program content, while the hospital system is responsible for billing third party payers for services rendered. The new program consists of three separate tracks with four classes each, delivered over a 5 month period, and one free class offering.

**RESULTS:** The AADE/ADA diabetes self-management program's enrollment has grown since its inception. Five patients were initially referred from the free medical clinic to participate in the group education classes. Currently, the program has eight patients in track A and is actively enrolling patients in track B; approximately 20 have completed the program. Approximately 6 new patients are seen each week for an individual appointment and are referred from four primary care practices in the area. Two faculty members and a registered nurse see patients individually two days per week and deliver class content up to 3 days per month. Reimbursement data is not currently available. In the summer of 2014, the program is expected to begin accepting students for advanced pharmacy practice experiences.

**CONCLUSION:** Diabetes self management education programs within schools of pharmacy can be successful and will also offer opportunities for student experiences.

## Critical Care

**274 Pharmacist and provider perceptions of the clinical and financial impact of pharmacy services in the ICU.** Robert MacLaren, Pharm.D., R. Brett McQueen, MA, Jon Campbell, Ph.D.; Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Aurora, CO

**PURPOSE:** To comparatively evaluate the perceptions of pharmacists and providers regarding the clinical and financial outcomes of direct pharmacy services in the intensive care unit (ICU).

**METHODS:** Eighty packets, each containing one pharmacist questionnaire and two provider questionnaires, were distributed at two national meetings of critical care clinical pharmacists. Pharmacists were instructed to complete their questionnaire and ask two providers from the same ICU to complete the provider questionnaires. Questions were designed to solicit frequency, efficiency, and perceptions about the clinical and financial impact (10 point scale) of various pharmacy services, including patient care (eight functions), education (three functions), administration (three functions), and scholarship (four functions). Services were delineated as fundamental, desirable, and optimal.

**RESULTS:** Forty-one (51%) pharmacists and 47 (29%) providers returned completed questionnaires. Pharmacists had worked in the respective ICU for  $8.3 \pm 6.4$  years and devoted  $50 \pm 18.9\%$  of their effort to practice functions. In general, providers rated the clinical and financial impact of pharmacy services higher than pharmacists across all functions (e.g. clinical and financial outcomes of providing drug information were rated as  $7.9 \pm 2.6$  and  $5 \pm 3.9$  by pharmacists and  $9 \pm 1.5$  and  $7.2 \pm 3$  by providers, respectively;  $p=0.015$  and  $p=0.004$ , respectively). Fundamental services were provided statistically significantly more frequently and were rated more favorably than desirable or optimal services by all respondents. The efficiencies of providing the services without the pharmacist ranged between 40% and 70% and the median

willingness to pay for the pharmacist by providers was \$17,500 (IQR, \$0–78,750).

**CONCLUSION:** Pharmacists and providers believe most clinical pharmacy services are associated with beneficial clinical and financial outcomes with providers rating most services higher. Fundamental services are viewed more favorably than desirable or optimal services, possibly because they are provided more frequently or they are required for safe patient care. Considerable inefficiencies are perceived by providers if pharmacy services were to disappear.

## Education/Training

**275. Development of a clinical operating room surgical rotation.** *Michelle Holm, Pharm.D., R.Ph., John Rueter, R.Ph.; Mayo Clinic, Rochester, MN*

**PURPOSE:** A safety consensus document by The Anesthesia Patient Safety Foundation and practice guidelines published by the American Society of Health System Pharmacists (ASHP) recommend inclusion of a clinical pharmacist in the operating room (O.R.). Pharmacy surgical rotations at our institution previously focused only on training for postoperative care of surgical patients. The authors describe a specialty clerkship rotation that introduces students to the O.R. and some of the unique therapies there-in.

**METHODS:** Students spend their full rotation focused on intra-operative care of the surgical patient. Medication management, observation and topic research are major components of the rotation. Students are exposed to a high volume practice of approximately 340 surgical cases daily. The wide variety of specialties at our tertiary care facility maximizes opportunity and allows tailoring the rotation to the trainee's interest.

**RESULTS:** Students find that the once intimidating environment of the O.R. offers a new dimension to their experiences and education. Topics that may have only been briefly mentioned in their didactic training are now more thoroughly presented to the students. Based on the interest generated by the clerkship rotation, we plan to extend the opportunity to our pharmacy residents in the near future.

**CONCLUSION:** We are fortunate to be part of a large medical institution that encompasses a wide variety of surgeries coupled with unique, rare disease states. Interventions by clinical pharmacists are frequent in this arena. Student interaction with our O.R. pharmacy staff and preceptors offers experiences that are not available in other rotations at our institution.

**276. The impact of a pharmacist-run diabetes self-management program on patient self-management activation and healthy behavior in an underserved patient populatio.** *Laura Perry, Pharm.D., Tonya Dauterman, Pharm.D., Lori Ernsthausen, Pharm.D., Debra Parker, Pharm.D., Jenifer Kitchen, Pharm.D., Candidate, Thomas Kahle, Pharm.D., Candidate, Peter Samberg, Pharm.D., Candidate, Brett Christy, Pharm.D., Candidate; College of Pharmacy, the University of Findlay, Findlay, OH*

**PURPOSE:** The Transtheoretical Model stages of change have been used as outcome measures to predict self-care behavior change in a variety of medical conditions. The Patient Activation Measure (PAM) is a reliable and valid tool to assess stage of change through patient self-reported knowledge, skill, and confidence for self-management. Few studies have assessed patient activation in diabetes. The aims of this study were to investigate the impact of a pharmacist-run diabetes self-management education program on patient activation and healthy behavior towards glycemic control in an underserved patient population.

**METHODS:** The diabetes self-management program included five monthly pharmacist-run sessions, designed to meet the American Association of Diabetes Educators (AADE) standards and AADE7 Self-Care Behaviors framework. Each session included a didactic lecture and a break-out support group activity. Follow up support group activities were held at 6 and 12 months. The primary outcome was the PAM score. Secondary outcomes

included change in HbA1c, change in healthy behavior, and patient satisfaction. All outcome measures were collected at baseline, 6 and 12 months. This program was funded by the ACCP Ambulatory Care PRN Seed Grant Program.

**RESULTS:** A total of 21 patients were enrolled into the program. Upon enrollment, 46.7% of patients were at the highest level of activation, indicating they have made most of the necessary behavior changes, but may have difficulty maintaining behaviors over time or during times of stress. Most patients maintained or improved their level of activation at 6 and 12 months. Patients were highly satisfied with the program, but no significant change in HbA1c or healthy behaviors were observed.

**CONCLUSION:** Despite referral of all eligible patients, the program attracted those who were already heading toward self-management. The pharmacist-run diabetes self-management program was effective at maintaining patient activation, glycemic control, and healthy behaviors in motivated diabetic patients.

**277. Use of the minute paper as a large-classroom assessment technique in pharmacotherapy modules.** *Lamis Karaoui, Pharm.D., BCPS; Lebanese American University, Byblos, Lebanon*

**PURPOSE:** To describe the use of the minute paper as a class assessment technique in two pharmacotherapy modules, and to report the student reactions to the minute paper.

**METHODS:** The minute paper is used in the gastrointestinal and pulmonary pharmacotherapy modules, which are offered to second professional year pharmacy students and extend over 4 weeks. It consists of three key questions on the most important, most confusing and most interesting fact students learn after each lecture. There is a total 93 in the classroom, divided over two sections. At the beginning of the module, faculty explains the purpose of the minute paper and asks students in each section to work in groups of 2–3 to reinforce peer feedback. At the end of each lecture, faculty distributes the minute papers and gives students five minutes to generate one answer per question per group. Faculty collects minute papers, reviews and organizes questions, picks the common muddiest point and posts written answers online on BlackBoard prior to the next class hour. The faculty time spent for preparation is 2 hours on average. At the end of the module, students complete a 13-question survey related to the minute paper using a standard four-point Likert scale.

**RESULTS:** Thirty-one male and 62 female students took the survey. Fifteen students (16.18%) had a previous university degree. Students agreed that the minute paper was beneficial (100%), improved their understanding of difficult material (98.8%), and helped them prepare for their exams (96.6%). They were satisfied checking answers on BlackBoard (98.8%) and benefited from seeing other students' responses (91%). Students preferred using the minute paper in this (95.5%) and other pharmacotherapeutic module (98.8%).

**CONCLUSION:** The minute paper seems plausible as a large-classroom assessment technique. It is well-perceived by students. Faculty will utilize the obtained feedback to improve the course content and clarify the muddiest points in future classes.

## Emergency Medicine

**278. Pharmacists as members of the rapid response team.** *Christine M. Groth, Pharm.D., Nicole M. Acquisto, Pharm.D.; University of Rochester Medical Center, Rochester, NY*

**PURPOSE:** Rapid response teams (RRT) have been developed to provide early therapy to patients identified with risk factors for cardiopulmonary arrest. We sought to investigate the role a pharmacist could have as a member of the RRT.

**METHODS:** Two pharmacists trained in critical care and emergency medicine proposed a pilot program to the members of the RRT. The primary goal of the pilot program was to determine if a pharmacist as a member of the RRT could help to optimize pharmacotherapy and facilitate medication administration. To evaluate these goals, the responding RRT pharmacist collected patient demographics, medications administered, and any phar-

macotherapy recommendations. Additional information of interest was the time commitment for pharmacist involvement. The two pharmacists were added to the RRT alerts through the institution paging system and responded when in the hospital and available. During response, one pharmacist was at the bedside with the RRT for patient evaluation, consult, chart review, and to facilitate medication administration.

**RESULTS:** Between January and June 2012 the pharmacists responded to 29 RRT alerts. Cases were respiratory (27.6%) or cardiac (24%) related most often. A majority of patients (62%) required at least one medication during the RRT evaluation and a total of 36 medications were administered to these patients. The pharmacists on the RRT performed 44 pharmacotherapy related interventions in 18 patients. Specific interventions included medication facilitation (15), dose (13) or therapy (6) recommendations, and adding (6) or discontinuing (6) a medication. In nine patients that did not have a direct pharmacotherapy related intervention, chart review was performed. The pharmacists spent a median time of 15 minutes (IQR 16.25) for each RRT alert and a total of 562 minutes.

**CONCLUSION:** With a minimal time commitment, pharmacists can be valuable members of the RRT.

**279E. Evaluation of a pharmacist culture review process in an Emergency Department.** *Michaela M. Doss, Pharm.D., BCPS, Julie B. Giddens, Pharm.D., BCPS, Cara L. Phillips, Pharm.D., BCPS; OSF Saint Francis Medical Center, Peoria, IL*

**PURPOSE:** To evaluate a pharmacist directed culture review process in the Emergency Department (ED) at a large community teaching hospital in Central Illinois. The process focuses on patients who are discharged to home prior to final culture information being available. These cultures are followed to assess whether empiric therapy was appropriate based on the site of infection and organism isolated, the need for additional care or a change in therapy.

**METHODS:** A retrospective chart review was performed on cultures obtained in the ED on all non-admitted patients from August 1st–January 31st. Pharmacist interventions are stored in the electronic database. An Excel spreadsheet of intervention data was reviewed and analyzed.

**RESULTS:** Total number of cultures reviewed by pharmacist was 5323 of which 1625 were positive. Cultures were treated appropriately by physician 76.2% of the time (n=1245). Cultures most commonly requiring pharmacist intervention included urine at 36% and sexually transmitted infections (STI) at 32%. The majority of urine cultures (77/139) required pharmacist intervention due to drug-microorganism mismatch. *E. coli* resulted as most common urine microorganism requiring pharmacist intervention (33/77). Sulfamethoxazole/trimethoprim and levofloxacin were most commonly prescribed at 13/33 (39.4%) and 12/33 (36.4%), respectively, which required subsequent intervention due to non-susceptible *E. coli*.

**CONCLUSION:** Pharmacist intervention was required on 23.8% of positive cultures (n=390). Cost avoidance as a result of return ED visits prevented in patients with no PCP calculated at \$64,274.31. Urine cultures required the most pharmacist interventions due to drug-microorganism mismatches of *E. coli* against sulfamethoxazole/trimethoprim and levofloxacin. This suggests that current prescribing practices for empiric urinary tract infections in the ED may not be adequate for local sensitivities. Presented at Poster Presented at the Illinois Council of Health-System Pharmacists Spring Meeting, Bloomington, IL, March 24, 2012.

**280. Role of pharmacists in the Emergency Department: medication reconciliation on admission.** *Hani Abdelaziz, Pharm.D.<sup>1</sup>, Mitesh Patel, Pharm.D.<sup>2</sup>, Scott Price, Pharm.D.<sup>3</sup>, Jennifer Thomas, Pharm.D.<sup>2</sup>, Lea Eslava, Pharm.D.<sup>2</sup>, Kim Walsh, R.Ph., M.B.A.<sup>3</sup>, Mona Philips, R.Ph., M.A.S.<sup>2</sup>, Sandra Richardson, Pharm.D., C.C.P.<sup>4</sup>;* (1)Barnabas Health, Brick, NJ; (2)Barnabas Health, Belleville,

NJ; (3)Barnabas Health, Toms River, NJ; (4)Barnabas Health, Lakewood, NJ

**BACKGROUND:** Inadequate medication reconciliations are often cited as the cause of medication discrepancies seen in the Emergency Department (ED). Poorly conducted ED medication reconciliations increase the risk for adverse events and serious patient harm during the patients' hospitalizations due to inaccurate or incomplete admission orders. As medication experts, pharmacists have been trained in conducting patient interviews specific to drug therapy

**PURPOSE:** To identify the number and types of medication discrepancies missed in the ED which were identified through a pharmacist-conducted medication reconciliation process.

**METHODS:** Study was conducted over a 2 week period at Clara Maass Medical Center (CMMC). Patients who presented to the ED and were admitted to CMMC were reviewed and interviewed by a pharmacist from Monday to Friday, 8:00–15:00. Patients were excluded if unable to communicate (written or verbal) due to language barriers or physical disability. A caregiver present to speak for the patient was acceptable. ED triage sheets, nursing home records, and patient's self reported medication lists were reviewed before the interview. Pharmacist-conducted medication reconciliation interviews were conducted and documented on a standardized form. The forms were then compared with the ED medication reconciliation form and admission orders to identify discrepancies.

**RESULTS:** Forty-six patients were interviewed by a pharmacist. Seventy percent had at least one discrepancy identified after the pharmacy medication reconciliation interview. The average discrepancies per patient was 1.17. Omission was the most common discrepancy identified, which accounted for 74%. Omissions included home medications (which included legend drugs, over-the-counter (OTC) medications, herbals and vitamin supplements)

**CONCLUSION:** Pharmacist present in the ED identified multiple medication discrepancies which could have impacted patient's hospital stay. Continued pharmacist presence in the ED could help reduce medication discrepancies, prevent adverse events, and improve patient care.

## Endocrinology

**281. Identifying employees with undiagnosed diabetes for participation in a pharmacist-run worksite wellness program.** *Nicole D. Gillespie, Pharm.D., Thomas L. Lenz, Pharm.D., M.A., PAPHS, FACLM, Michael S. Monaghan, Pharm.D., M.A., PAPHS, FACLM; Creighton University School of Pharmacy and Health Professions, Omaha, NE*

**PURPOSE:** Undiagnosed diabetes is a prevalent and costly health condition for employers. The purpose of this project is to describe a procedure used to identify employees with undiagnosed diabetes and describe the process by which these employees are recruited to participate in a pharmacist-run worksite diabetes risk reduction program.

**METHODS:** Hemoglobin A1c (HbA1c) measurements were obtained for any employee participating in the company sponsored health risk assessment with a fasting glucose value of  $\geq 117$  mg/dl. Information regarding participation in the worksite diabetes risk reduction program was sent directly to any employee with a HbA1c  $\geq 5.7\%$ .

**RESULTS:** A fasting glucose  $\geq 117$  mg/dl was demonstrated in 87 of 1611 (5.4%) employees who participated in the health assessment. Of the 87 HbA1c measurements obtained, 27 employees were found to have undiagnosed pre-diabetes (HbA1c 5.7–6.4%) and 16 employees were found to have undiagnosed diabetes (HbA1c  $\geq 6.5\%$ ). Worksite diabetes risk reduction program information was confidentially mailed to any employee with a HbA1c level  $\geq 5.7\%$ . As a result of the letter, nine employees volunteered to participate in the program. The cost to run an additional HbA1c was \$9.00 per test. The employer spent \$783.00 to identify 16 previously undiagnosed employees with diabetes or \$48.94 per employee with undiagnosed diabetes.

**CONCLUSIONS:** Using a procedure to identify employees with undiagnosed diabetes and pre-diabetes and promoting participation in a diabetes risk reduction program may improve employee health and quality of life while also saving money. A fasting glucose  $\geq 117$  mg/dl and HbA1c of  $\geq 5.7\%$  proved to be successful in identifying and recruiting such employees to enroll in the pharmacist-run worksite program.

**282. Impact on outcomes of patients seen by ambulatory care clinical pharmacists for diabetes management in a large public health care system.** Margaret Y. Pio, Pharm.D., Marissa E. Quinones, Pharm.D., Diem H. Chow, Pharm.D., Jeffrey L. Hulstein, Pharm.D., Steven M. Boatright, Pharm.D., Elizabeth Moss, Pharm.D., Annie C. Mathew, Pharm.D.; Parkland, Dallas, TX

**PURPOSE:** To evaluate clinical outcomes and costs in patients seen by ambulatory care clinical pharmacy specialists (CPS) for diabetes management in a large urban county health care system. Seven ambulatory care CPS manage diabetes mellitus at their respective practice sites under a collaborative practice agreement. Outcomes and cost are evaluated annually to justify services offered.

**METHODS:** Patients seen by a CPS for diabetes management between January 1, 2009 and December 31, 2011 were included in the yearly analyses. Diabetes-related outcomes and costs, including hemoglobin A1c (HbA1c), blood pressure (BP), lipids, medications, and other standards of care measures, were assessed at the end of 2009, 2010, and 2011 for patients discharged from CPS services.

**RESULTS:** A total of 586 patients were included in the annual assessments. At each yearly assessment, patients demonstrated improvements in glycemic control with absolute decreases in HbA1c averaging 2.4% ( $p < 0.001$  for each year). Lowering of systolic BP, diastolic BP, total cholesterol, triglycerides, low density lipoprotein cholesterol, and non-high density lipoprotein cholesterol were also observed. Rates of achievements in various standards of care measures increased. Patients' medication adherence rates increased by at least 65%. Patients' average number of medications did not increase by more than 8.5%, while the cost of 30-day supply of medications increased by no more than 6.8%.

**CONCLUSIONS:** Annual assessments of the outcomes of patients seen by ambulatory care CPS for diabetes management demonstrated positive impact in HbA1c reduction, as well as other clinical outcomes including BP and lipids. Adherence to standards of care measures improved. CPS increased patient medication adherence while maintaining costs of medications for the health system. Through interventions such as medications changes, patient education, and drug therapy monitoring, ambulatory care CPS have positively impacted the patients referred for diabetes management on a consistent basis for three consecutive years.

**283. Lessons learned from clinical pharmacists' review of glucometer download reports in the primary care setting.** Craig D. Logemann, Pharm.D.<sup>1</sup>, Nicholas P. Lehman, Pharm.D.<sup>2</sup>, Carrie F. Koenigsfeld, Pharm.D.<sup>2</sup>, Ginelle A. Bryant, Pharm.D.<sup>2</sup>; (1) Iowa Health Physicians and Clinics, Des Moines, IA; (2) Iowa Health Physicians and Clinics and Drake University, Des Moines, IA

**PURPOSE:** The purpose of this study was to evaluate the incidence and types of diabetes-related medication changes completed by clinical pharmacists when reviewing glucometer download reports in a primary care setting.

**METHODS:** Data was collected from patient encounters involving a glucometer download by a clinical pharmacist during a seven month period (October 2011 through May 2012). Collected information included: type of diabetes, current diabetes treatments, and lessons learned from the glucometer review and type of diabetes medication intervention that occurred during the encounter. Each clinic had a collaborative practice agreement which allowed the pharmacist to adjust medications.

**RESULTS:** A total of 305 glucometer downloads were completed during the study period. The majority of patients had type 2 dia-

betes (91.5%). Medication adjustments were made during the visit of 118 of 305 patients (38.7%). Only 48 of the 305 (15.7%) of the reports were reviewed with the provider. The most common interventions were increasing insulin dose ( $n=60$ ) or decreasing insulin dose ( $n=16$ ). An oral medication was either added ( $n=15$ ) or removed ( $n=2$ ) during the visit. Medication interventions were based solely on review of glucometer data for 55 of 118 (46.6%) patients and unrelated to review of A1C testing.

**CONCLUSION:** Review of glucometer data by clinical pharmacists can assist with medication dosage titration, especially insulin-requiring patients. Many of the medication interventions occurred when A1C testing did not factor into the treatment decision. Analyzing glucometer reports can provide additional insight related to pattern management and glucose trends over time.

**284. Pharmacist-led diabetes collaborative drug therapy management program improves glycemic control in patients with uncontrolled T2DM treated with insulin.** Carrie McAdam-Marx, Ph.D., R.Ph.<sup>1</sup>, Brandon T. Jennings, Pharm.D.<sup>2</sup>, Arati Dahal, Ph.D.<sup>3</sup>, Karen Gunning, Pharm.D.<sup>4</sup>; (1) University of Utah College Pharmaco-therapy Outcomes Research Center, Salt Lake City, UT; (2) University of Utah College of Pharmacy, Salt Lake City, UT; (3) University of Utah Pharmaco-therapy Outcomes Research Center, Salt Lake City, UT; (4) Departments of Pharmaco-therapy & Family and Preventive Medicine, Salt Lake City, UT

**PURPOSE:** Describe a pharmacist-led, collaborative drug therapy management (CDTM) program. Identify clinical and economic outcomes in CDTM patients treated with insulin.

**METHODS:** Two University of Utah Community Clinics implemented a CDTM program in 2008 and 2009. Under a collaborative practice agreement, community clinic pharmacists manage drug therapy and provide medication and disease counseling to patients referred to CDTM by clinic physicians; most are referred for insulin management. To identify CDTM-related outcomes, we compared HbA1c, healthcare utilization, and cost changes after CDTM enrollment in patients with uncontrolled T2DM (HbA1c  $\geq 7.0\%$ ) treated with insulin in 2009–2010 to patients with uncontrolled T2DM treated with insulin under usual care at non-CDTM clinics. Change in HbA1c was identified at 6-months (–90 to 180 days) as were changes in utilization and costs 6-month pre-index to 6-months post-index date. Multivariate regression analyses were used to estimate adjusted changes in HbA1c and overall costs controlling for baseline HbA1c and other confounders.

**RESULTS:** A total of 95 DCCM patients (mean age 60.4 years; 59% female) and 46 comparison patients (mean age 61.2 years [ $p > 0.05$ ]; 48% female [ $p > 0.05$ ]) were included. Identification of comparison patients was challenging due to lower insulin use and lack of HbA1c data to assess outcomes. Baseline HbA1c was higher for CDTM (10.3%) than comparison patients (9.1%;  $p < 0.001$ ). CDTM patients had a 1.97% greater reduction in HbA1c, which remained significant after adjusting for confounders (coefficient: –1.31; 95% CI –1.76, –0.86). Comparison patients had a greater increase in sub-specialty clinic visits during the follow-up period than CDTM patients (0.5 versus –0.05 visit change;  $p = 0.01$ ); the adjusted difference in overall costs from pre- to post index date did not differ between groups.

**CONCLUSION:** This pharmacist-led CDTM program improved glycemic control without increasing overall costs in patients with uncontrolled T2DM treated with insulin in the community setting.

## Family Medicine

**285. Implementation of new FDA-mandated dose limitations with simvastatin in an outpatient family medicine clinic.** Ila M. Harris, Pharm.D.<sup>1</sup>, Ann M. Philbrick, Pharm.D.<sup>2</sup>, Christopher J. Fallert, M.D.<sup>1</sup>; (1) University of Minnesota Medical School, St. Paul, MN; (2) University of Minnesota College of Pharmacy, Minneapolis, MN

**PURPOSE:** Widespread and timely implementation of medication labeling changes is difficult to implement. In June 2011, the

FDA released recommendations and labeling changes regarding dosing, drug interactions, and contraindications with simvastatin.

**METHODS:** We developed and implemented a clinical pharmacist-managed protocol to apply the FDA-mandated changes for simvastatin. Patients taking simvastatin 80 mg, a contraindicated medication, or medication requiring simvastatin dose limitation were identified through the medication list in the clinic electronic health record (EHR). These patients were scheduled for an appointment with the clinical pharmacist. If patients saw their physician, the change was made following the pharmacist-written protocol. If patients did not follow up, letters were sent to the patients and prescriptions were faxed to their pharmacies. When clinical pharmacists saw patients, they were authorized to order a lipid profile and CK if necessary, decrease the dose of simvastatin, switch to another statin, and switch gemfibrozil to fenofibrate.

**RESULTS:** A total of 125 patients were identified. After 43 patients were excluded, 82 patients entered the study. Clinical pharmacists implemented the change in 51 of the patients (63%); physicians implemented the remainder. A total of 68 patients had follow up lipid profiles. Of these 68 patients, 52 (76%) were below their goal LDL at baseline. Following intervention and medication change, 52 (76%) was below their goal LDL. Fourteen patients did not have follow up lipid panels drawn. LDL was lower after intervention than at baseline in 27 patients (40%).

**CONCLUSION:** A protocol written and implemented by clinical pharmacists was successful in applying FDA-mandated changes regarding simvastatin dosing with no change in the percentage of patients below goal LDL. Currently, work is being done to obtain follow-up lipid panels in the 14 patients with incomplete follow-up and this will be presented in the final data. A pharmacist-managed protocol can be implemented for other labeling changes.

## Gastroenterology

**286. Immunization rates of inflammatory bowel disease patients receiving TNF- $\alpha$  inhibitor therapy.** *Bryan L. Love, Pharm.D., BCPS, Jackson Murphy, Pharm.D., Candidate, Justin Goette, Pharm.D., Candidate; South Carolina College of Pharmacy, Columbia, SC*

**PURPOSE:** Inflammatory bowel disease (IBD) patients are at increased risk of infection secondary to underlying disease and the immunosuppressive therapies used. Although evidence supports routine vaccination of IBD patients, many opportunities to vaccinate this vulnerable population are missed. The purpose of this research was to assess vaccination rates for IBD patients receiving tumor necrosis alpha (TNF- $\alpha$ ) therapy and compare the vaccination rates to rheumatoid arthritis (RA) patients receiving TNF- $\alpha$  therapy.

**METHODS:** All patients receiving at least one dose of TNF- $\alpha$  medication during a 44 month period were obtained using the pharmacy computer system and were randomly selected for study inclusion. Included subjects had a diagnosis of IBD or RA. Patients with multiple autoimmune diseases were excluded. Influenza, pneumococcal, hepatitis A, and hepatitis B vaccination rates were manually obtained from the patients' electronic medical records. Baseline patient characteristics were summarized using descriptive statistics with comparisons for each cohort. Differences in vaccination or screening between treatment cohorts were assessed using chi-square test (categorical measures) or t-tests (continuous measures) of independence. Statistical significance was determined at the 0.05 level.

**RESULTS:** A total of 48 patients were evaluated (24 IBD, 24 RA). Half of the IBD patients received at least 75% of annual influenza vaccinations during the study period, compared with 54% of RA patients ( $p=NS$ ). Pneumococcal vaccine was received in 75% and 79% of IBD and RA subjects, respectively ( $p=NS$ ). Hepatitis A vaccination occurred more frequently in IBD patients than RA patients; 37.5% versus 16.7%, respectively ( $p=0.193$ ). Similarly, hepatitis B vaccination was more common in IBD (58.3%) compared with RA (29.2%) patients ( $p=0.08$ ).

**CONCLUSION:** Rates of influenza and pneumococcal vaccinations were similar among IBD and RA patients. Although not statistically significant, IBD patients were more likely to receive hepatitis A and B vaccination than RA patients. Opportunities exist to improve vaccination rates in both IBD and RA patients.

## Geriatrics

**287E. An innovative collaborative practice for clinical pharmacists in an interdisciplinary, primary care based memory clinic in Ontario, Canada.** *Carlos Rojas-Fernandez, Pharm.D., Tejal Patel, Pharm.D., Linda Lee, M.D.; University Of Waterloo School of Pharmacy & Centre for Family Medicine, Kitchener, ON, Canada*

**BACKGROUND:** It is vital that patients with cognitive impairment are diagnosed and appropriately managed early. Optimising medications is an integral part of quality care and requires expertise in geriatric pharmacotherapy. Clinical pharmacists have successfully participated in interdisciplinary care for some time, yet little attention has been given to the role pharmacists could play within a memory clinic.

**PURPOSE:** To describe the role of clinical pharmacists in a primary care, interdisciplinary memory clinic in Ontario, Canada.

**METHODS:** Narrative description of a novel practice setting.

**RESULTS:** In 2006, the Centre for Family Medicine FHT established a memory clinic. The team consisted of a family physician, social worker, and two nurses. After about 6 months of operation a pharmacist was added to the team due to the complexity of the patient's medication regimens. Patients are assessed over a 2 hour period by the clinic team. Pharmacists assess and rectify: (i) anticholinergic load and/or load of drugs that can impair cognition and/or function, (ii) medication adherence and management skills, (iii) adverse drug events, (iv) vascular risk factor control; (v) provide patient education for new medication regimens and disease state education, (vi) ensure seamless care by communicating with community pharmacists, and (vii) conduct home visits as necessary. Pharmacotherapeutic plans are developed and implemented as appropriate, and the pharmacist is recognised as an integral part of the team.

**CONCLUSION:** The pharmacist's participation in this clinic has revealed an opportunity for productive collaboration, optimal use of resources, and the ability of pharmacists to manage pharmacotherapy in older patients with complex and high-risk regimens. Pharmacist participation in this clinic represents a novel opportunity to advance practice in primary care, interdisciplinary models. Additionally, certain aspects of our practice could be modified for other practice settings. Work is ongoing to further refine the role of the pharmacist in this setting.

Published in Rojas-Fernandez CH, Patel T, Lee L. A novel practice setting for pharmacists: Practicing in an interdisciplinary, family health team based memory clinic. *Canadian Pharmacists Journal* 2011; 144 (5): e42.

**288. Documentation of home-based primary care pharmacist interventions.** *Virginia Krause, Pharm., D., Bridget Kaufmann, Pharm., D., Kara Wong, Pharm., D.; (1) VA Puget Sound Health System, Seattle, WA*

**PURPOSE:** Home-Based Primary Care (HBPC) is a home-based interdisciplinary service provided to Veterans requiring complex chronic disease management through Veterans Affairs hospitals. The clinical pharmacist provides medication recommendations on a scheduled basis on a variety of disease states. The pharmacist is new to the HBPC team as of 2008, and there is limited definition for the scope and daily activities for this position. The purpose of this descriptive study is to provide a representation of the HBPC population and the scope of the clinical pharmacist in the interdisciplinary team approach to care by documenting and describing current HBPC pharmacist activities.

**METHODS:** Conducted an analysis using the computerized medical record of the HBPC pharmacist recommendations including regular medication reviews, individualized drug regimens, drug

information consultation, and drug monitoring. Patients were included if they were enrolled in HBPC from August 2009 to December 2010 and received a medication review during their enrollment. The data were used to describe the workload of the HBPC pharmacist, characterize the medication-related problems of the HBPC sample, and document the pharmacist's role in improving medication use (including percentage of accepted recommendations and the medication appropriateness index).

**RESULTS:** Interim analysis of the first 20% of the data collected shows the percentage of accepted recommendations is 83%. Further results are pending.

**CONCLUSIONS:** Pending

## HIV/AIDS

### 289E. SPIRIT study: switching to the single-tablet regimen (STR) of emtricitabine/rilpivirine/tenofovir DF from a ritonavir-boosted protease inhibitor and two nucleoside reverse transcriptase inhibitors maintains HIV suppression and improves serum lipids.

Frank Palella, M.D.<sup>1</sup>, Pablo Tebas, M.D.<sup>2</sup>, Peter Ruane, M.D.<sup>3</sup>, David Shambraw, M.D.<sup>4</sup>, Jason Flamm, M.D.<sup>5</sup>, Ramin Ebrahimi, M.S.<sup>6</sup>, Kirsten White, Ph.D.<sup>6</sup>, Hiba Graham, Pharm.D.<sup>6</sup>, Mark Bernstein, R.Ph., M.B.A.<sup>6</sup>, Jason T. Hindman, Pharm.D., M.B.A.<sup>6</sup>; (1)Northwestern University, Chicago, IL; (2)University of Pennsylvania, Philadelphia, PA; (3)Peter J. Ruane, M.D., Inc., Los Angeles, CA; (4)La Playa Medical Group and Clinical Research, San Diego, CA; (5)Kaiser Permanente, Sacramento, CA; (6)Gilead Sciences, Foster City, CA

**PURPOSE:** Antiretroviral regimen simplification improves both quality of life and long-term medication adherence while reducing risk of HIV virologic failure (VF) and long-term drug-related toxicities. FTC/RPV/TDF is a well-tolerated, once daily STR treatment option. This is the first study to evaluate the efficacy and safety of switching from a ritonavir-boosted (PI+RTV) based HAART to the STR FTC/RPV/TDF.

**METHODS:** This randomized, open-label, international, 48-week study evaluated the safety and efficacy of switching from PI+RTV regimens to the STR FTC/RPV/TDF in virologically-suppressed [HIV-1 RNA (VL)<50copies/ml], HIV-1 infected subjects. Subjects were randomized 2:1 to switch to the STR FTC/RPV/TDF or maintain their current PI+RTV based therapy. The primary endpoint was non-inferiority (12% margin) of the STR FTC/RPV/TDF relative to PI+RTV in maintaining VL < 50 copies/ml at Wk24 (Snapshot analysis). Changes in fasting lipids from baseline were evaluated.

**RESULTS:** Of the 476 subjects were randomized to the STR FTC/RPV/TDF (n=317) and PI+RTV (n=159). Baseline characteristics were similar. Switching to STR FTC/RPV/TDF was non-inferior to maintaining a PI+RTV regimen (93.7% versus 89.9%; 95% CI -1.6%, 9.1%) at Wk24 for VL < 50 copies/ml. Fewer subjects in the STR FTC/RPV/TDF arm than the PI+RTV arm had VF (0.9% versus 5.0%). Two subjects in the STR FTC/RPV/TDF arm had emergent resistance and one in the PI arm. Mean change in lipids from baseline at Wk24 for the STR FTC/RPV/TDF versus PI were TC -25 versus -1, LDL -16 versus 0, TG -53 versus 3 (mg/dl, p<0.0001), respectively. The mean Wholesale Acquisition Cost (WAC) for switching to FTC/RPV/TDF was 16% less at \$10,275 versus staying on a PI+RTV regimen \$12,272 for 24 weeks.

**CONCLUSIONS:** Switching to the STR FTC/RPV/TDF from a PI+RTV based regimen in virologically-suppressed, HIV-1-infected subjects maintained virologic suppression with low risk of VF, decreased pill burden, improved total cholesterol, LDL, triglycerides and was \$1,997 (16%) less per subject over 24 weeks in medication costs per WAC evaluation.

Presented at International AIDS Conference, Washington, D.C., July 2012.

**290. Implementation of clinical pharmacist-conducted rapid point-of-care HIV testing.** Elizabeth Sherman, Pharm.D., AAHIVE<sup>1</sup>, Shara Elrod, Pharm.D., BCACP<sup>1</sup>, Paula Eckardt, M.D.<sup>2</sup>; (1)Nova Southeastern University College of Pharmacy, Ft Lauderdale,

FL; (2)Memorial Healthcare Systems, South Broward Community Health Services, Miramar, FL

**PURPOSE:** To describe rapid point-of-care HIV counseling and testing services performed by an interdisciplinary team, including clinical pharmacists, in a healthcare setting.

**METHODS:** This rapid HIV testing project initially targeted African-Americans as a part of the Centers for Disease Control and Prevention African-American Testing Initiative, but was expanded in 2010 to include all populations increasing the likelihood of finding positive individuals in this urban area of high HIV prevalence as part of the Expanded Testing Initiative. Counseling and testing services were initially offered in the emergency department and mobile van in a single healthcare system, but were later expanded to the primary care clinics including an HIV clinic for more targeted testing of partners and caregivers of HIV-infected individuals. An interdisciplinary approach incorporated pharmacists as testers and counselors in the HIV clinic. After certified training at the County health department, pharmacists tested individuals using the following process: obtain consent, perform rapid point-of-care HIV fingerstick test, provide post-test counseling, obtain confirmatory specimens for reactive samples, and provide linkage to care for all confirmed HIV-infected individuals.

**RESULTS:** From January 2008 through May 2012, project staff performed 17,081 voluntary rapid HIV tests with health-system patients. Clinical pharmacists performed 165 of these tests over a 1-year time period (May 2011 through May 2012).

**CONCLUSION:** This project offers proof of principle that pharmacists effectively contribute to community health-system based HIV testing initiatives. Pharmacists are uniquely poised to promote HIV prevention yet little description of pharmacists performing HIV testing exists. This project was effective in reaching people at high risk of infection, identifying types of venues that would be important to target, and offering lessons to be used by other pharmacists in the design and implementation of HIV testing programs in healthcare settings.

## Infectious Diseases

**291. Nitrofurantoin: great for cystitis, but appropriate for everyone?** Andrea G. Centi, Pharm.D., BCPS, Rachel M. Chambers, Pharm.D., Henry Ford Hospital, Detroit, MI

**PURPOSE:** Nitrofurantoin is now a first line treatment for cystitis due to declining susceptibilities with trimethoprim-sulfamethoxazole and quinolones. However, nitrofurantoin has important considerations when prescribing: it is contraindicated in elderly patients, patients with creatinine clearance (CrCl) < 60 ml/minute, and patients pregnant at term or in labor. Nitrofurantoin is available in two solid oral formulations: nitrofurantoin mono/macrocrystals and nitrofurantoin macrocrystals, the latter being the drug on inpatient formulary. We evaluated if nitrofurantoin was prescribed appropriately to inpatients according to patient characteristics, institutional and package insert guidelines, and culture results.

**METHODS:** This was a retrospective cohort of inpatients receiving nitrofurantoin from July 2010 through September 2010. Data collected included: patient characteristics, infection type, microbiology, treatment regimen, and appropriateness. Analyses were descriptive in nature.

**RESULTS:** Fifty-four patients were included in the study sample. Median (IQR) age was 51 (31-66), 48 females (88.8%), median weight 78 kg (72-88), and median CrCl 76 ml/minute (44-91). Urinalysis was performed in 64.8% of patients. Only 65.7% of patients with a urinalysis had a positive result. Nitrofurantoin was appropriately prescribed in only 11.1% of patients. Problems identified: Inappropriate formulation (43.4%), impaired renal function (31.3%), prescribing in the elderly (29.1%), pregnancy (10.4%), and resistant organisms (6.2%).

**CONCLUSION:** Patients overwhelmingly were not prescribed nitrofurantoin appropriately due to inappropriate patient selection and formulation confusion. From this data, an automatic therapeutic substitution was created to change all nitrofurantoin orders

to nitrofurantoin macrocrystalline formulation. Pharmacy staff and physicians were educated on the substitution protocol and contraindications to nitrofurantoin through pharmacy staff meetings and newsletters. Future plans are to evaluate if this change in practice resulted in a decrease in inappropriate prescribing of nitrofurantoin.

**292. Evaluation of pharmacist managed vancomycin therapy compared to physician managed dosing in establishing timely and therapeutic vancomycin serum concentrations at a community hospital.** *Rachel Sussman, Pharm.D.<sup>1</sup>, Andras Farkas, Pharm.D.<sup>2</sup>, Andrea H. Lee, Pharm.D., Candidate<sup>3</sup>; (1) Nyack Hospital, Nyack, NY; (2) Optimum Dosing Strategies, Teaneck, NJ; (3) Touro College of Pharmacy, New York, NY*

**PURPOSE:** Vancomycin (VAN) remains a mainstay for the treatment of serious infections caused by gram-positive organisms. The purpose of this study was to assess if pharmacist managed therapy can produce timely therapeutic levels at least as effectively as physician managed dosing of VAN.

**METHODS:** A total of 100 patients were evaluated for baseline characteristics. Demographic, laboratory and VAN monitoring data were collected. Percentage of patients with initial, second, and third levels within subtherapeutic (<10 mg/l), therapeutic (10–20 mg/l) and supratherapeutic (> 20 mg/l) ranges were compared. Secondary end points included comparing initial mean  $\pm$  SD VAN concentrations, levels between 8 and 22 mg/l, percentage of patients never reaching concentrations of  $\geq$  10 mg/l, and time to reach the therapeutic range.

**RESULTS:** There were no statistically significant differences in baseline characteristics between the two groups evaluated. VAN levels within the therapeutic range for initial, second and third measurements were 77%, 71%, 74% for pharmacist managed therapy and 37%, 58%, 55% for the comparator. Initial mean  $\pm$  SD VAN levels were  $13.4 \pm 3.6$  and  $8.8 \pm 3.9$  mg/l ( $p < 0.05$ ), while levels between 8 and 22 mg/l were 88% and 63%, for the intervention and comparator groups, respectively. An additional 40% of patients never reached 10 mg/l in the physician group compared to the intervention group. Median  $\pm$  SD number of days to reach therapeutic range was  $1.9 \pm 0.9$  days for the intervention group versus  $2.5 \pm 2.7$  days for the comparator group ( $p < 0.05$ ).

**CONCLUSION:** Pharmacist managed VAN therapy resulted in both a greater percentage of therapeutic levels and a shorter time to reach therapeutic range. Consequently, the pharmacist managed VAN therapy appears to be at least as or more effective in achieving pre-specified laboratory endpoints when compared to physician dosing of VAN at our institution.

**293E. Integrating a clinical pharmacy specialist into an existing hepatitis C clinic.** *Bryan L. Love, Pharm.D., BCPS<sup>1</sup>, Helen Woods, R.Ph.<sup>2</sup>, Steedman A. Sarbah, M.D., M.B.A.<sup>2</sup>; (1) South Carolina College of Pharmacy, Columbia, SC; (2) Dorn Veterans Medical Center, Columbia, SC*

**PURPOSE:** The Department of Veterans Affairs (VA) is the largest single provider of HCV care in the US. In May 2011, new direct acting antiviral agents (DAA) were approved by the FDA. We anticipate increased numbers of veterans will seek care; thus, additional trained providers are needed to meet demand. Pharmacists with advanced training are in an ideal position to provide care for HCV patients receiving DAAs due to the complicated regimens, long duration of therapy, drug-drug interactions, and the need for close monitoring of adherence, adverse effects and laboratory values. The purpose of the presentation is to: (i) describe the process of integrating a clinical pharmacy specialist into an existing HCV practice, and (ii) describe clinical pharmacist activities of viral hepatitis management.

**METHODS:** All patients seen and evaluated by both physician and pharmacist for treatment from July 2011 through June 2012 were included. A scope of practice was developed and approved by the medical staff. The pharmacist was imbedded in the Hepatology clinic and had alternating office visits with a physician

provider. Patient encounters were tracked using an electronic medical record system.

**RESULTS:** A total of 45 patients were evaluated for treatment by the physician-pharmacist team and 34 received treatment with a DAA regimen during the 12 month period. The majority of patients initiating treatment were male (94%), African-American (55%), and the median age was 59 years. A total of 144 encounters were documented representing an average of 4.2 visits per patient. Clinical activities included patient education, drug-interaction management, adherence assessment, side effect management, and medication dosage adjustment.

**CONCLUSION:** A pharmacist trained in HCV management was successfully integrated into a HCV clinic within the VA and provided a variety of important clinical activities. Further analysis is required to correlate improved access to treatment outcomes.

Presented at the Liver Meeting of the American Association for the Study of Liver Diseases, Boston, MA, November 9–13, 2012.

**294. Comparison of two pharmacy practice models for pharmacokinetic management of vancomycin at an Academic Medical Center.** *Zhe Han, Pharm.D., Heath R. Jennings, Pharm.D., Natasha N. Pettit, Pharm.D., Emily Landon, M.D., Benjamin D. Brielmaier, Pharm.D.; University of Chicago Medicine, Chicago, IL*

**PURPOSE:** National pharmacy practice model (PPM) advancements include pharmacokinetic (PK) programs. The optimal PPM for vancomycin PK management is not known. This retrospective cohort review compared two progressive PK models at an academic medical center.

**METHODS:** New PK services were implemented in two phases as part of an institutional comprehensive PPM change. Phase 1 (May 2009–April 2010) included universal monitoring by pharmacists with recommendations made to prescribers (business hours, 7 days per week). Phase 2 (November 2010–October 2011) expanded coverage to 24/7 and provided optional pharmacist-managed consults. Consults included comprehensive medication therapy management and progress note documentation. All adult inpatients receiving intravenous vancomycin were retrospectively reviewed. Surgical prophylaxis, duration < 72 hours, and initiation prior to admission were excluded.

**RESULTS:** Patient characteristics and indications were similar in both phases. Phase 2 had greater proportion of courses with initial therapeutic trough concentrations (45.3% versus 27.1%,  $p = 0.02$ ), higher initial trough values (16.4 versus 10.5  $\mu\text{g/ml}$ ,  $p = 0.03$ ), greater proportion of therapeutic concentrations (77.3% versus 59.5%,  $p = 0.013$ ), and reduced hospital length of stay (12.0 versus 14.5 days,  $p = 0.02$ ). Both phases had similar time to therapeutic trough concentrations (4 versus 5 days,  $p = 0.76$ ), incidence of vancomycin-associated nephrotoxicity (8.8% versus 11.2%,  $p = 0.40$ ) and all-cause mortality (11.0% versus 11.1%,  $p = 0.98$ ). In phase 2, patients with consults had greater proportion of initial therapeutic trough concentrations (51.4% versus 39.4%,  $p = 0.30$ ), higher initial trough values (17.1 versus 13.5  $\mu\text{g/ml}$ ,  $p = 0.64$ ), and greater proportion of therapeutic concentrations (86.5% versus 65.8%,  $p = 0.02$ ).

**CONCLUSION:** Metamorphosis of PPM afforded expansion to 24/7 PK services with comprehensive pharmacist consults which improved vancomycin management. These results may help define optimal models as recommended by the Pharmacy Practice Model Initiative. Further study is needed to assess the impact of these models on patient outcomes and in other practice settings.

## Managed Care

**295E. Descriptive analysis of quality outcomes for Primary Care Clinical Pharmacy Service (PCCPS) interventions.** *Rachel M. F. Heilmann, Pharm.D., Stephanie Campbell, Pharm.D.; Kaiser Permanente Colorado, Denver, CO*

**PURPOSE:** To investigate alternative methods for capturing value of Primary Care Clinical Pharmacy Service (PCCPS) at Kaiser Permanente Colorado utilizing documented clinical out-

comes in the literature and applying them to PCCPS specialist's daily interventions.

**METHODS:** A Quality Committee was formed to explore novel ways to capture value associated with PCCPS daily interventions that included impact on quality based outcomes. The committee focused on three main intervention types: hypertension, hyperlipidemia, and osteoporosis. In 2010, 3891 patients were identified from an internal database and were matched to pre-designated goals for each disease state: blood pressure <140/90, LDL decreased by 40 mg/dl, or initiation of an anti-osteoporotic drug. Utilizing available peer-reviewed literature and reported costs for cardiovascular procedures, heart attacks, strokes, and fractures prevented, the economic impact was calculated for patients that met the respective disease state metric. Mortality reduction was also analyzed for hypertension.

**RESULTS:** PCCPS achieved blood pressure <140/90 in 3334 patients resulting in a predicted 125 cardiovascular events and eighty deaths avoided over 10 years and five strokes avoided per year. Sixty-five patients on statin therapy achieved  $\geq$  40 mg/dl LDL reduction resulting in a predicted two major cardiovascular or cerebrovascular events avoided per year. Anti-osteoporotic drugs were initiated in 492 patient's  $\geq$  65 years old status post-fracture resulting in a predicted fifty-six fractures avoided (six hips, thirty-six vertebral, fourteen non-vertebral). A \$919,000 annualized return on investment, defined as economic impact of event avoidance minus significant treatment costs of intervention, was calculated (\$593,000 hypertension, \$38,000 hyperlipidemia, \$288,000 osteoporosis).

**CONCLUSION:** Utilizing available literature and reported costs, PCCPS interventions can have a favorable quality outcome and economic impact on hypertension, hyperlipidemia, and osteoporosis.

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**296. Evaluation of clopidogrel, prasugrel and ticagrelor in the Department of Defense: applying cost-effectiveness analyses to formulary decisions.** *Olaitan Ojo, Pharm.D., M.B.A., BCPS<sup>1</sup>, Angela A. Allerman, Pharm.D., BCPS<sup>2</sup>, Bradley Clarkson, Pharm.D.<sup>2</sup>, Josh Devine, Pharm.D., BCPS<sup>2</sup>;* (1) University of Illinois at Chicago, Chicago, IL; (2) Department of Defense Pharmacoeconomic Center, Fort Sam Houston, TX

**PURPOSE:** To incorporate cost-effectiveness analysis (CEA) in formulary management recommendations for antiplatelets when used for secondary prevention of acute coronary syndrome (ACS).

**METHODS:** Clopidogrel in combination with aspirin has been the standard ACS treatment option. Prasugrel and ticagrelor are new antiplatelet agents with comparative clinical trial data with clopidogrel. The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee considered both clinical and cost-effectiveness when determining the antiplatelet agents' formulary placement. The clinical review noted prasugrel and ticagrelor are more effective than clopidogrel in reducing the composite endpoint of cardiovascular (CV) death, myocardial infarction (MI) and stroke. Compared to clopidogrel, prasugrel confers a higher bleeding risk than clopidogrel, while ticagrelor exhibits a similar bleeding risk. Two separate CE models were constructed for the antiplatelet cost analyses: prasugrel versus clopidogrel and ticagrelor versus clopidogrel. Analysis was based on direct comparisons of relevant ACS clinical trial data. The models compared the annual cost per CV event avoided (the composite of nonfatal MI, nonfatal stroke, and death from CV cause).

**RESULTS:** CEA results showed that prasugrel and ticagrelor provide reasonable clinical benefit for the increase in treatment cost, as shown by their incremental cost-effectiveness ratios (ICERs) of \$28,083 and \$58,358 per cardiovascular event avoided, respectively. For both analyses, variation in the relative rates of MI and CV death and corresponding costs had the greatest impact on the ICER.

**CONCLUSION:** Ticagrelor or prasugrel may be cost-effective options for ACS in place of clopidogrel. However, clopidogrel

remains the preferred antiplatelet agent in DoD, due to wider clinical utility than the newer agents, and the significant price reduction occurring with recent patent loss.

## Medication Safety

**297. The impact of insulin sliding scale standardization.** *Nora AlBanyan, R.Ph., Manal AL-Nemari, R.Ph., Osama Tabbara, R.Ph., BCNSP., Yahya Moustafa, R.Ph., M.Sc., Ihab AlMadhoun, Pharm.D.; King Fahad Medical City, Riyadh, Saudi Arabia*

**PURPOSE:** Standardization of subcutaneous Insulin sliding scale (ISS), since, Insulin is considered one of the top five "high alert" medications because errors in dosing and administration can result in severe adverse effects; Insulin is one of the drugs most likely to be involved in errors. Currently at KFMC, we have 19 different forms for (ISS), therefore, our plan: (i) evaluate current practice, (ii) standardize ISS through preprinted order, (iii) evaluate the impact after implementation of a Correctional ISS in preprinted order (PPO).

**METHODS:** Observational evaluations of sliding scale Insulin. A chart of 50 before and 50 patients after the PPO implementation were evaluated for episodes and management of hypo- and hyperglycemia.

**RESULTS:** Our evaluation on current ISS protocols showed significant failure to achieve euglycemia. Thirty-six percent (18) were on sliding scale insulin for more than 1 week without adding basal therapy. Guidelines for the use of Correctional Insulin Sliding Scale were created by an interdisciplinary team and implemented in non-intensive care units. In addition, a preprinted physician order sheet was developed which included the guidelines and an option for ordering one of four standardized insulin sliding scales. Three month after implementation the physician order form was used for 95% of orders. The number of prescribing errors found on chart review was reduced from 15% at baseline to 2% at three months. The number of hyperglycemia episodes 3 months after implementation decreased from 17% to 6%.

**CONCLUSION:** The preprinted order was readily accepted by hospital staff and was associated with decreased variability in ISS prescribing and decrease frequency of hyperglycemia.

**298. Structured safety rounds: an effective forum for discussion of medication safety issues.** *Salma Satchu, Pharm.D.<sup>1</sup>, Heather Kertland, Pharm.D.<sup>2</sup>, Clarence Chant, Pharm.D.<sup>3</sup>, Jill Garland, B.Sc. (Pharm.)<sup>1</sup>, Elaine Tom, B.Sc. (Pharm.)<sup>1</sup>;* (1) St. Michael's Hospital, Toronto, ON, Canada; (2) St. Michael's Hospital and Leslie Dan Faculty of Pharmacy, Toronto, ON, Canada; (3) St. Michael's Hospital and Li Ka Shing Knowledge Institute, Toronto, ON, Canada

**PURPOSE:** Pharmacists play a key role in the safe use of medications. In response to an identified need for sharing of and learning from medication incidents, a structured discussion forum called 'Safety Rounds' was initiated and evaluated.

**METHODS:** The pilot phase of Safety Rounds, open to all pharmacists, consisted of eight biweekly sessions facilitated by the Professional Practice Leader. Ground rules, with emphasis on the confidential and non-punitive nature of the forum, were established. Content of rounds included medication incidents from the pharmacists' practice and additional examples from corporately-shared critical incidents. Satisfaction with each of the Rounds was assessed using a written evaluation tool consisting of four Likert scale questions and three open-ended question.

**RESULTS:** Of the 27 errors discussed in the eight sessions, 85% were brought forward by staff pharmacists. Average attendance was 25 pharmacists/students per session (range 13-30). Majority of participants agreed or strongly agreed that Safety Rounds enhanced their awareness of safety issues (98%), felt comfortable sharing their ideas and opinions (93%), and would make changes to their practice as a result of Safety Rounds (88%). A number of practical process improvements were identified and implemented, including workflow changes, revisions to training and

orientation practices and creation of a new electronic tool for structured sign-over. Workgroups were struck to refine and implement these improvements and to formulate recommendations to improve the corporate computerized physician order entry platform.

**CONCLUSIONS:** The establishment of Safety Rounds was well-received by the pharmacists and have resulted in open discussion regarding medication safety issues and subsequent practice improvements. These rounds will be continued on a monthly basis given the success of the pilot.

**299. Thrombophlebitis associated with peripheral amiodarone infusions.** *May Achi, Pharm.D., BCPS, Janet Hudkins, R.N., ACNP, Nadim D. Nasir, M.D., FACC; The Methodist Hospital, Houston, TX*

**PURPOSE:** Like most IV medications, amiodarone can be administered via peripheral venous catheter or via a peripherally inserted central catheter (PICC). Thrombophlebitis is associated with a variety of IV medications of which IV amiodarone is a culprit. The primary purpose of this study was to evaluate the incidence of thrombophlebitis with IV amiodarone based on IV site.

**METHODS:** This was a prospective observational study involving patients receiving IV amiodarone via a PICC line or peripheral venous catheter. Eligible patients included patients > 18 years of age, receiving intravenous amiodarone and admitted to cardiovascular units. Patients were evaluated daily for phlebitis until IV amiodarone was converted to oral formulation or discontinued.

**RESULTS:** One hundred and thirty-nine patients completed the study, of which 33% (46) were peripheral venous catheter patients and 67% (93) were PICC line patients. Thrombophlebitis occurred in 13% of the peripheral venous catheter patients versus 1.1% of the PICC line patients ( $p=0.0054$ ). The median length of infusion in the peripheral venous catheter arm was 47.6 versus 63 hours in the PICC line arm. Forty-one percent in the peripheral venous catheter arm had other IV medication co-administered with amiodarone versus 75.3% in the PICC line arm. The median total dose in the peripheral venous catheter arm was 1680 versus 2910 mg in the PICC line arm.

**CONCLUSION:** This study associated that the incidence of thrombophlebitis is higher among patients who received IV amiodarone via peripheral venous catheter than patients who received the drug via a PICC line. Thrombophlebitis not only causes patient discomfort, but can increase complications (i.e. bacteremia), length of stay and hospital costs. Based on this study, we have recommended to our hospital medication outcome management subcommittee and pharmacy therapeutics committee that amiodarone infusions greater than 24 hour infusion would require a central line catheter such as a PICC line.

**300. Making "Smart Pumps" smarter: utilizing electronic medical administration record information to optimize dose error reduction software on large volume infusion devices.** *Amanda C. Chuk, Pharm.D., BCPS, Colin L. Skinner, M.B.A., Robert W. Maloney, Pharm.D., BCPS, Joyce A. Gawron, Pharm.D., BCPS, Mary Catherine Rawls, M.S., B.S.N., RN-BC, O.N.C.; Dartmouth-Hitchcock Medical Center, Lebanon, NH*

**PURPOSE:** Large volume infusion devices with dose error reduction systems ("smart pumps") and associated drug libraries can offer increased safety and continuous quality improvement opportunities related to the administration of intravenous medications. The work of an innovative multidisciplinary Pharmacy and Therapeutics (P&T) Drug Library Subcommittee involving pharmacists, nurses, and value measurement analysts is described and includes: drug library software initiation and deployment, dose error reduction systems (DERS) data review, and DERS optimization through incorporation of electronic medication administration record (eMAR) information.

**METHODS:** In October of 2008, smart pumps were introduced in an academic medical center with house-wide implementation by July of 2009. Continuous quality improvement review of the

pumps' DERS data began in August of 2009. In April of 2011, the institution transitioned to a comprehensive electronic health record. The P&T Drug Library Subcommittee incorporated the newly-available eMAR data into its regular DERS review for further drug library optimization.

**RESULTS:** While initial drug library parameters were based upon medication administration recommendations from resources such as the institution's standard concentration chart and tertiary drug information references, DERS limits within the drug library were able to be added and/or optimized based on medication use throughout the institution.

**CONCLUSION:** Utilizing eMAR information allowed further evaluation of drug library limits through comparison to actual clinical practice, thereby maximizing potential patient safety gained through DERS within a smart pump. A multidisciplinary committee was expanded to include value measurement analysts within the institution's department of Value Performance, Measurement, and Patient Safety. Pharmacist and nurse representatives worked with analysts to guide the collection and interpretation of eMAR and DERS data. Such involvement of data review experts as part of a P&T Drug Library Subcommittee and integration of information obtained from two systems (electronic health records and smart pumps) is an advantageous approach to ongoing drug library management.

**301. Pharmacist intervention for medication safety in elderly according to screening tool of older persons' potentially inappropriate prescriptions (STOPP) criteria.** *Chia-shan Tsai, M.S., Yeo Loo Chang, M.S., Wuan-jin Leu, M.S., You-Meei Lin, M.S., Hui-Ping Liu, M.Sc.; Department of Pharmacy, Taipei Medical University, Shuang Ho Hospital, New Taipei City, Taiwan*

**PURPOSE:** Inappropriate prescribing (IP) are an important cause of hospitalization. There is a high risk of potential IP in elderly because of several characteristics, such as ageing and subsequent polypharmacy. Thus the aim of this study is to evaluate potential IP among elderly and set up a list of selected criteria based on STOPP criteria and generate the corresponding recommendations by pharmacists in Shuang-Ho Hospital.

**METHODS:** A prospective study was conducted in Shuang-Ho Hospital between March 6 and April 24, 2012. All patients aged 65 years and over who admitted over three days were randomly recruited in this study. The prescriptions on the third day after admission were reviewed by pharmacists according to STOPP criteria. Then the pharmacists consulted with the physician and provided recommendations for the inappropriate prescription. The inappropriateness of each selected criterion and the acceptance of pharmacist's intervention were recorded.

**RESULTS:** Two hundred and ninety patients were included. The five criteria with highest inappropriateness were "Glibenclamide or chlorpropamide with type 2 diabetes mellitus" (50%), "Theophylline as monotherapy for chronic obstructive pulmonary disease (COPD)" (44%), "Use of aspirin and warfarin in combination without histamine H<sub>2</sub> receptor antagonist or proton pump inhibitor" (33%), "Tricyclic antidepressants with an opiate or calcium channel blocker" (29%) and "Non-cardioselective betablocker with COPD" (22%). The acceptance of pharmacist intervention was 80%. Finally, 13 criteria were selected and the corresponding recommendations were generated.

**CONCLUSION:** This study selected the criteria with high inappropriateness and acceptance of pharmacist intervention. They were provided for pharmacists to evaluate medication safety in elderly more efficiently. However, the selected criteria can not replace clinical judgment since it requires high-level clinical knowledge and experience. They can be implemented in more inpatients and need to be reassessed and updated on a routine basis.

**302E. Bridging the gap between FDA safety warnings and patients: are pharmacists the appropriate messengers?** *McKay Robinson, Pharm.D.<sup>1</sup>, Karen Gunning, Pharm.D.<sup>2</sup>, Karly Pippitt, M.D.<sup>3</sup>, Carrie McAdam-Marx, Ph.D., R.Ph.<sup>1</sup>, Brandon T. Jennings, Pharm.*

D.<sup>1</sup>; (1) University of Utah College of Pharmacy, Salt Lake City, UT; (2) University of Utah College of Pharmacy and School of Medicine, Salt Lake City, UT; (3) Department of Family & Preventive Medicine, University of Utah School of Medicine, Salt Lake City, UT

**PURPOSE:** This study evaluated acceptance of pharmacist interventions to address new simvastatin safety concerns. We hypothesize that safety warnings are not being effectively implemented into current practice due to the lack of a formalized process for patient identification and treatment re-evaluation. By identifying patients at risk and recommending alternatives, processes can be developed to decrease the number of patients exposed to potentially unsafe pharmacotherapy.

**METHODS:** This is a prospective, descriptive quality improvement project involving patients in a university-based ambulatory care clinic who were identified as being treated outside the newly revised simvastatin labeling. After identification and review, pharmacist recommendations were made to providers to promote adherence with the most recent safety guidelines. The acceptance rate of recommendations and resources necessary to provide pharmacist interventions were measured. Percentage of patients treated outside the current simvastatin labeling on the date the safety alert was released (baseline), upon initiation of the study (usual care without targeted interventions) and after completion of the study (usual care plus targeted interventions), and pharmacist and technician time necessary to complete the interventions was also measured.

**RESULTS:** Six months after the warnings' release, 48.1% of the 158 patients identified still had regimens that fell outside the revised simvastatin labeling. After the intervention, this decreased to 0.6%. Recommendations were accepted 92% of the time without modification and 7% of the time with modification. Total pharmacist time to conduct the interventions was 21.5 hours; with 3.9 hours of technician time spent contacting patients.

**CONCLUSIONS:** Targeted pharmacist interventions were effective in promoting adherence with this complex medication safety alert. A standardized, comprehensive approach to patient assessment, including use of evidence to support pharmacist recommendations, resulted in a high level of acceptance by prescribers. The template used in this evaluation can serve to jumpstart patient specific review processes on future medication safety alerts.

Presented at the American Pharmacists Association Annual Meeting, New Orleans, LA, March 9–12, 2012

**303. Can a culture of safety be enhanced in a department of pharmacy?** Heather Kertland, Pharm.D., Clarence Chant, Pharm.D., Salma Satchu, B.Sc. Pharm., Pharm.D., Jill Garland, B.Sc. (Pharm.), Elaine Tom, B.Sc. (Pharm.); St Michael's Hospital, Toronto, ON, Canada

**PURPOSE:** While pharmacists are key in ensuring the safe use of medications, the culture of safety within the Pharmacy department is not well described in the literature. We sought to assess the departmental safety culture and determine if an intervention that addressed an identified safety concern could improve the overall safety culture.

**METHODS:** An initial departmental safety culture assessment using the validated Hospital Survey on Patient Safety Culture survey was conducted. The findings of the survey were then used to establish the intervention: Safety Rounds an open communication forum to discuss medication incidents. These rounds were held twice monthly for four months, followed one month later by a repeat survey.

**RESULTS:** A total of 71% of eligible pharmacists completed the baseline survey. The overall safety culture was 46% positive and the dimensions of concern were: communication openness, feedback and communication about error and hospital handoffs and transitions. The post intervention survey was completed by 50% of eligible pharmacists. The overall safety culture did not change (43% positive) however there were substantial changes in the proportion of positive responses in several dimensions including: feedback and communication about errors (25–58%), communication openness (38–51%), organizational learning (56–71%), and

teamwork within the unit (71–88%). Dimensions that demonstrated a decrease in the proportion of positive responses were: hospital management support (72–56%), handoffs and transitions (14% to 5%), and teamwork across hospital units (45% to 34%).

**CONCLUSION:** The open communication forum, Safety Rounds, did not change the overall culture of safety but led to improvements in important dimensions and identified areas requiring further work.

**304. Making the case for early medication reconciliation by clinical pharmacists.** Rasha Z. Al Anany, Pharm.D.<sup>1</sup>, Hoda M. Badran, M. Sc. (Clinical, Pharmacy)<sup>2</sup>, Halima Y. Al Tamimi, B.Sc. (Pharm.)<sup>1</sup>, Maha M. El Hamid, B.Sc. (Pharm.)<sup>1</sup>, Imran F. Khudair, B.Sc. Pharm., M.B.A.<sup>1</sup>, Omer AlAbad, B.Sc. (Pharm.)<sup>1</sup>; (1) Hamad Medical Corporation, Doha, Qatar; (2) HMC, Doha, Qatar

**BACKGROUND:** In 2005, the Joint Commission required health care facilities to implement medication reconciliation processes in line with stated National Patient Safety Goals (NPSG). Inaccurate medication reconciliation may increase the potential for errors, which may be associated with preventable adverse drug events (ADEs). Pharmacist's involvements may play a pivotal role in preventing these errors.

**PURPOSE:** To highlight the impact of medication reconciliation conducted by clinical pharmacists in Hamad General Hospital (HGH) on reducing adverse drug events during admission and transfer by identifying different types of interventions.

**METHODS:** Clinical pharmacists' interventions, done through a medication reconciliation process in the first 24 hours of admission or transfer, in one adult general medical unit and a pediatric hematology and oncology unit, were collected over 1 month. For each patient, both inpatient and outpatient records were reviewed. Clinical pharmacists conducted interviews with the patient or caregiver to review their medications. The collected data were then compared with the current medication list prescribed after admission or transfer. All information was documented in a special medication reconciliation form.

**RESULTS:** For the 52 patients interviewed, the total number of medications reconciled was 263. Of these, 93 medications (35%) required the intervention of clinical pharmacists. Omission was the most common type of error, having been the reason for 26 interventions (27%), followed by wrong doses, which required 23 interventions (23%). Medications with no indication accounted for 14 interventions (15%). Drug classes with the highest number of discrepancies included antimicrobials (17%), vitamins (15%), analgesics (14%) and cardiovascular medications (13%).

**CONCLUSION:** The clinical pharmacist's medication reconciliation conducted in the first 24 hours of admission or transfer can reduce ADEs by substantially reducing the incidence of medication errors. This pharmacist involvement in medication reconciliation may have a great impact on the cost effectiveness and quality of healthcare.

## Neurology

**305. Alteplase cost containment initiative.** Erika Dittmar, Pharm.D., BCPS, Sylvia Marrero, Pharm.D.; Baptist Hospital of Miami, Miami, FL

**PURPOSE:** Alteplase is the only FDA approved drug for the treatment of acute ischemic stroke and improves long term neurological outcomes in this patient population. Due to high acquisition cost, pharmacy drug expenditure can be significantly impacted with its use. The purpose of this IRB reviewed study was to identify potential areas where alteplase use may be further optimized to reduce waste.

**METHODS:** A retrospective review of acute ischemic stroke patients that received intra-arterial and/or intravenous (IV) alteplase between May 2010 and May 2011 identified opportunities for a potential cost savings of ~ \$19,000. These opportunities

included using alteplase 2 mg vials in place of 50 mg vials in the interventional neurology suite and also for IV doses within 6 mg of a 50 mg dose to avoid opening a second vial. Utilizing the manufacturer replacement program when applicable provided further savings. Nurses, pharmacy staff, and physicians were educated about the implementation of cost containment initiatives. Cost savings data collection started October 2011.

**RESULTS:** Nine patients received intra-arterial alteplase and 2 mg vials were used instead of 50 mg vials for a cost savings of ~\$18,141. Three patients' total IV alteplase doses were within 6 mg of a 50 mg vial and the 2 mg vial was utilized instead of opening a second 50 mg vial. This resulted in a cost savings of ~\$6,366. Seven 50 mg alteplase vials met criteria and were replaced through the manufacturer replacement program for a cost savings of ~\$16,478. The total amount saved from October 2011-May 2012 was ~\$40,985.

**CONCLUSION:** Small initiatives and education can impact cost savings associated with alteplase.

## Oncology

### 306. Results of a pharmacy driven erythropoietin stimulating agent dispensing and monitoring program at a Community Hospital.

*Anay Moscu, Pharm.D., Maria C. Figueroa, Pharm.D., Jorge Garcia, Pharm.D.; Baptist Hospital of Miami, Miami, FL*

**PURPOSE:** Inappropriate use of erythropoietin stimulating agents (ESA) has led to an increase in thromboembolic events for all indications, also to, shortened overall survival and/or increased risk of tumor progression. Posing a significant increase in hospital expenditures from an economic perspective. The purpose of this study is to document the results of a pharmacy driven, ESA dispensing and monitoring program.

**METHODS:** A prospective interventional IRB reviewed study of patients receiving darbepoetin alpha, formulary ESA at Baptist Hospital, from December 2011 to May 2012. An MEC (medical executive committee) approved protocol based on predefined hemoglobin levels consistent with FDA label for darbepoetin was utilized. Patients were reviewed for indication, dose, and laboratory parameters. Doses were adjusted, dispensed, held per protocol or pharmacist recommendation. Interventions were documented in SENTRI-7, clinical pharmacy surveillance program. Primary objective is to assess the impact of pharmacist interventions, including the total number of doses held per protocol and dose adjusted per recommendation. Secondary endpoint is cost savings from prevention of adverse drug events and decrease in medication costs.

**RESULTS:** Total of 79 pharmacist interventions were completed during the study period. Overall 24 doses of darbepoetin were not administered based on predefined hemoglobin levels, per protocol. The remaining 55 interventions were dose adjustment recommendations, resulting in an estimated annual medication cost savings of \$34,314. Cost avoidance of \$20,800 was estimated due to the prevention of adverse drug events. Overall, there was 31.6% reduction in the prescribing of darbepoetin from previous years, which can be partially attributed to pharmacist involvement in ESA dispensing and monitoring.

**CONCLUSION:** Over use of ESAs has led to FDA changes, consisting of hemoglobin thresholds for ESA administration. Pharmacy driven program helps promote the appropriate use of ESAs and may potentially prevent adverse drug events. Also can provide cost savings by decreasing over utilization.

## Other

### 307. Pharmacist-directed hypertension and diabetes mellitus medication management in sleeve gastrectomy patients.

*Christopher M. Bland, Pharm.D., BCPS, Adam M. Tritzsch, M.D., David A. Bookstaver, Pharm.D., Lori B. Sweeney, M.D., Yong U. Choi, M.D.; Eisenhower Army Medical Center, Fort Gordon, GA*

**PURPOSE:** There are little published data on hypertension (HTN) and diabetes mellitus (DM) medication adjustments in

patients undergoing bariatric surgery and more specifically sleeve gastrectomy (SG). These patients are at risk for hypoglycemia and hypotension in the early postoperative period. This study sought to document the impact of a pharmacist-directed HTN and DM medication management program in patients undergoing SG.

**METHODS:** All patients undergoing SG at a single center who were on at least one HTN or DM medication from November 2010-November 2011 were concurrently assessed. Medications were reconciled via patient interview by the pharmacist on post-operative day one. Recommendations were approved by the bariatric surgeon and implemented immediately postoperatively. Patients were encouraged to document home blood pressure/glucose readings and bring to first postoperative visit to aid medication adjustments. Patients were seen 2 weeks postoperatively and followed-up as needed by phone until seen by their primary care physician by week 6. Preoperative and 2-week postoperative blood pressures were documented. Readmissions and emergency department visits for medication-related hypoglycemia/hypotension were documented.

**RESULTS:** Fifty patients (78% female) were evaluated. All recommendations were accepted including HTN medication discontinuation (n=46), DM medication discontinuation (n=21), HTN medication dosage decrease (n=13), and insulin dosage decrease (n=11). Patients required a mean decrease of 1 DM and HTN medication immediately postoperatively which persisted through week 6 (p<0.01). Postoperative 2-week mean systolic blood pressure readings were decreased significantly compared to preoperative readings (122 versus 132 mmHg, p<0.01). No patients were readmitted for medication-related hypoglycemia/hypotension.

**CONCLUSION:** A pharmacist-directed program in the SG patient requiring immediate postoperative HTN/DM medication decreases and frequent monitoring was both safe and effective. Perioperative and long-term management of HTN/DM medications represent an excellent opportunity for pharmacist intervention and research.

### 308. A pilot study assessing the impact of the presence of a clinical pharmacist and a pharmacy resident at the infectious diseases department of a Lebanese University Hospital.

*Lydia Rabbaa Khabbaz, Pharm.D., Ph.D.<sup>1</sup>, Latife Karam, Pharm.D.<sup>2</sup>, Carla Farhat, Pharm.D.<sup>1</sup>, Renee Azzi, Pharm.D.<sup>1</sup>, Dolla Karam Sarkis, Ph.D.<sup>1</sup>; (1)Faculty of Pharmacy, Saint-Joseph University, Beirut, Lebanon; (2)Faculty of pharmacy, Saint-joseph University and Hotel Dieu de France hospital, Beirut, Lebanon*

**PURPOSE:** Clinical pharmacy services are still in their early implementation stages in Lebanon. The objective of this study was to evaluate the impact of clinical pharmacist presence at the infectious diseases department of a Lebanese university hospital even for a short period of time daily and to evaluate the acceptance of pharmacist's interventions by prescribers.

**METHODS:** A 21-month prospective analysis was conducted, including 240 hospitalized patients in the infectious diseases department and 475 interventions performed by the pharmacist. The pharmacy resident and the clinical pharmacist were present in the department for 1-2 hour/day. A pharmaceutical care plan was established and used to document patients' problems and pharmacist's interventions. Main criteria analyzed were: types and frequencies of problems detected, types of pharmaceutical interventions performed, their acceptance by the prescribers and factors affecting the interventions and their acceptance.

**RESULTS:** Most patients (47%) were treated with 7-9 drugs concomitantly. The three most frequent problems detected were incorrect dosage, inappropriate administration modalities and no clear indication for the drug in the patient's file or drug duplication and the three most frequent interventions performed by the pharmacist were stop/start/substitute a drug, change drug dosage/drug daily distribution, change drug administration time. The acceptance was the highest for I.TIM (change drug administration time) with 87%, followed by I.ROU (change route of administration) 75% > I.HIS (complete/correct/perform medication history) 67% and I.ADM (change administration method or drug

form) 67% and the lowest for I.FOL (request a lab test/exam/clinical follow-up) with only 40%.

**CONCLUSION:** Even a short daily pharmacist presence is an added value in inpatient care at the infectious diseases department of Hôtel-Dieu de France university hospital. Areas of improvement are a better communication between the pharmacist and the prescribers and a longer presence of the clinical pharmacist in the Clinical Department.

**309. Lost in transition: the benefit of interdisciplinary home-based care following hospitalization.** *Eliza Z. Borzadek, R.N., Pharm.D., John T. Holmes, Pharm.D., Diana B. Krawtz, M.S.N., ARNP;* Departments of Family Medicine & Pharmacy Practice, Idaho State University, Pocatello, ID

**PURPOSE:** Idaho has the lowest national 30-day re-hospitalization rate for Medicare beneficiaries at 13.3%, which may be misleading due to limited access to care. A home-based Transition of Care (TOC) clinic was developed to provide safe and effective transitions from acute care to home by utilizing a unique interdisciplinary team of nurse practitioner, clinical pharmacist, and health professions students with electronic medical record (EMR) access in the home; drug-related problems (DRPs) were identified.

**METHODS:** An office-based interdisciplinary TOC clinic was developed in 2006 but evolved into a semi-weekly home-based service in 2011 due to high no-show rates and an inability to thoroughly identify and resolve DRPs. Enrollment criteria for the home-based TOC program included inpatient hospitalization > 48 hours, age  $\geq 65$  and one additional risk factor (e.g.  $\geq 2$  hospitalizations in the past 6 months,  $\geq 2$  chronic illnesses, polypharmacy,  $\geq 2$  medication changes, documented history of poor adherence). Services provided were assessment for DRPs, medication counseling and reconciliation, personal medication record development, clinical assessment, depression/dementia screening, fall risk assessment, and assistance with advanced directives. An interim retrospective EMR chart abstraction of documented hospital follow-up was performed to compare DRPs identified at TOC and provider office visits.

**RESULTS:** From October 17, 2011 to June 15, 2012, there were 55 home-based TOC encounters. Interim analysis identified 2.6 DRPs documented per TOC clinic encounter compared to 0.6 DRPs per provider office encounter ( $p=0.023$ ). The most common DRPs in TOC clinic were secondary to unintentional/intentional non-adherence, incomplete/inaccurate discharge instructions, therapy duplication, and provider-provider/provider-patient miscommunication. A 12-month analysis of identified and classified DRPs and 30-day re-hospitalization rates will be presented.

**CONCLUSION:** An interdisciplinary home-based TOC clinic is effective at identifying DRPs. Although cost-prohibitive in many areas, interdisciplinary home-visit TOC delivery should be further explored.

## Pain Management/Analgesia

**310. Pharmacist participation on an interdisciplinary team to improve pain scores and patient satisfaction at a community hospital.** *Melissa W. Guarino, Pharm.D.<sup>1</sup>, Rich Geisler, Pharm.D.<sup>2</sup>;* (1) D'Youville College School of Pharmacy, Buffalo, NY; (2) Mercy Hospital of Buffalo, Buffalo, NY

**PURPOSE:** The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) is a standardized, publicly reported survey of recently discharged patients' perspectives of their hospital care, including pain management. The Patient Protection and Affordable Care Act of 2010, includes HCAHPS as a measure to calculate hospital value-based incentive payments. The purpose of this study was to evaluate the use of an interdisciplinary team, which includes a pharmacist, to improve pain management and patient satisfaction scores.

**METHODS:** Beginning September 2011, interdisciplinary teams consisting of the unit clinical pharmacist and the unit nurse man-

ager conducted daily pain rounds on seven patient care areas of a 390-bed community, teaching hospital. Rounds were performed Monday through Friday on an average of eight patients per patient care area. Targeted patients were newly admitted patients, however previously seen patients were revisited at the discretion of the team. Recommendations were communicated to the patient's physician for approval and implementation.

**RESULTS:** During May 2012, pharmacists participated in 107 of 154 possible instances of pain rounds. Pharmacists documented 109 interventions as a result of pain rounds. Types of interventions included patient education on pain medications, adjusting pain medication doses or frequencies, and resuming chronic patient medications as per the home regimen. HCAHPS patient satisfaction scores related to pain management increased during the intervention period, with three patient care areas achieving goal results on at least 90% of surveys in April.

**CONCLUSIONS:** This study demonstrated that an interdisciplinary team, including a pharmacist, performing daily pain rounds on newly hospitalized patients, may help improve pain management and HCAHPS patient satisfaction scores.

## Pediatrics

**311. Assessing the medication ordering process: are we complying with our own medication policy?** *Nancy Simon, Pharm.D.<sup>1</sup>, Karen Pasternac, M.S.W., Pharm.D.<sup>2</sup>, Raul L. Pino, Pharm.D.<sup>3</sup>;* (1) Department of Pediatric Pharmacy, Jackson Memorial Hospital at the Holtz Center for Maternal & Child Health, Miami, FL; (2) Pharmacy Operations & Pediatrics, Jackson Health System, Miami, FL; (3) Pharmacy Services, Jackson Health System, North Medical Center, Miami, FL

**PURPOSE:** This study was conducted to measure physician compliance in adhering to defined policies and procedures when ordering medications through Computer Physician Order Entry (CPOE). Specifically, assessment of physician utilization of the specified calculator to compute appropriate dosing was performed.

**METHODS:** This is a retrospective review of orders obtained for patients less than 14 years old. A total of 1275 orders were reviewed during a 12 month period. Electronic medical records were utilized to identify essential data. The information was transcribed to a collection tool where documentation included: medication name, priority of order, and ordering practitioner with corresponding service.

**RESULTS:** The data revealed 51% compliance by pediatric physicians to the prescribing policy. Consequently, the pediatric medical staff was educated on the importance of abiding to the institution's policies and procedures. Compliance increased to an average of 90% monthly following presentation of results and extensive education. Several concerns were identified that will be targeted to improve the prescribing medication process. The policy will be updated to exempt vaccines from requiring calculation based dosing. Monthly performance improvement data will continue to be collected with an annual discussion on outcomes with pediatric medical staff. Pharmacists continue to educate physicians on adhering to the dose calculator for order entry. All these initiatives will ultimately improve patient medication safety.

**CONCLUSION:** Since changes were enacted, compliance has averaged 90% monthly. The medication policy will be reviewed yearly to reflect any change to improve patient safety.

**312E. Frequency and severity of errors related to neonatal and pediatric parenteral nutrition.** *Laura Broome, Pharm.D.<sup>1</sup>, Sadie J. Cox, Pharm.D., M.S., M.H.A.<sup>1</sup>, Catherine M. Crill, Pharm.D.<sup>2</sup>;* (1) Le Bonheur Children's Hospital, Memphis, TN; (2) The University of Tennessee Health Science Center, Memphis, TN

**PURPOSE:** Parenteral nutrition (PN) is a high risk medication with the potential to cause patient harm. Errors may occur during prescription, transcription, compounding, and administration. Since June 2009, our institution has implemented a number of changes including use of a weight-based PN order form, in-house

automated PN compounding with age/weight-based templates and institution-specific limits, and an electronic medical record and computerized physician order entry (CPOE). The purpose of this study was to evaluate the incidence, location, type, and severity of errors related to the PN process before and after changes in practice.

**METHODS:** This retrospective review evaluated all PN-associated errors submitted through the internal event reporting system over a 36-month period (July 2008 to July 2011). Data collected included location of the incident; step in the PN process, and error type and severity (defined by the National Coordinating Council for Medication Error Reporting and Prevention).

**RESULTS:** Ninety-four PN-associated errors were reported during the evaluation period. PN-associated errors, which were primarily administration-related errors, trended downward after implementation of weight-based PN order form and in-house automated compounding and increased after implementation of CPOE, primarily due to increased transcription-related errors. The majority of all errors were determined to be wrong rate and classified as severity categories C and D. None of the errors reported resulted in patient harm.

**CONCLUSIONS:** Implementation of automated compounding software and weight-based PN order forms and limits may potentially minimize PN-associated errors, while CPOE may increase PN-associated errors most likely due to the lack of an interface between CPOE and PN compounding software. By instituting various safeguards throughout the PN process, PN-associated errors may be less likely to cause patient harm. When evaluating PN practices within institutions, the vulnerability of the PN process due to the lack of an interface between CPOE and compounding software should not be underestimated.

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## Pharmacoeconomics/Outcomes

**313. Cost-effectiveness of pharmacist managed medication therapy adherence clinic (MTAC) on type 2 diabetes patients in a Tertiary Hospital in Malaysia.** Navin K. Loganadan, Kah Y. Lim, Noorulashikin Mohd Nur, Fudziah Ariffin; Department of Pharmacy, Hospital Kuala Lumpur, Kuala Lumpur, Malaysia

**PURPOSE:** This study was conducted: (i) To study the impact of pharmacist managed Medication Therapy Adherence Clinic (MTAC) on medication adherence and glycemic control of Type 2 Diabetes patients and (ii) To evaluate the cost-effectiveness of MTAC program.

**METHODS:** In this prospective cohort study, 43 Type 2 Diabetes patients who attended pharmacist MTAC clinic visits in Kuala Lumpur Hospital besides their routine physician visits between February 2008 to August 2009 were assigned to Intervention group while 42 others who attended physician visits only (Standard Care) as Control. The Intervention group received medication adherence assessment, advise on drug related problems, medication counseling and diabetes education by pharmacists while the Control group did not. HbA1c levels (%) and Morisky Scores were measured and compared at baseline and after 9 months follow-up period between both groups. Direct medical costs including doctor's cost, pharmacist's cost, nurse's cost, cost of medications and cost of laboratory tests were used for cost-effectiveness analysis (CEA).

**RESULTS:** Medication adherence of subjects in the Intervention (MTAC) group increased significantly from a Morisky score of 4.23 at baseline to 7.84 ( $p < 0.05$ ) compared to increase from 4.00 to 6.14 seen in Control at the end of follow-up. The HbA1c of subjects in the Intervention arm also reduced significantly ( $p < 0.05$ ) by 1.7% from 10.6% at baseline to 8.9% at the end of follow-up compared with a relatively smaller decrease of 0.6% from 10.7% at baseline to 10.1% achieved in Control ( $p > 0.05$ ). Average cost effectiveness ratio (ACER) for Intervention group

was RM446.01 per 1% reduction and RM1328.52 per 1% HbA1c reduction for Control.

**CONCLUSIONS:** Pharmacist managed MTAC Diabetes program helped Type 2 Diabetes patients achieve significantly better medication adherence and glycemic control besides being more cost-effective than Standard Care with greater savings in diabetes expenditure to the hospital.

**314. Pharmacist-centered hospital to home care transition initiative improves patient outcomes.** Kim C. Coley, Pharm.D.<sup>1</sup>, Rima A. Mohammad, Pharm.D.<sup>1</sup>, Jenny Kim, Pharm.D.<sup>2</sup>, Amy C. Donihi, Pharm.D.<sup>1</sup>, Patricia D. Kroboth, Ph.D.<sup>1</sup>; (1) University of Pittsburgh School of Pharmacy, Pittsburgh, PA; (2) Bernard J. Dunn School of Pharmacy, Shenandoah University, Winchester, VA

**PURPOSE:** To standardize and assess a transitions of care (TOC) model where the hospital pharmacist resolved medication discrepancies and medication-related problems in the inpatient and outpatient setting and reduced 30-day readmissions.

**METHODS:** This quality improvement project utilized a hospital pharmacist to conduct TOC activities with general medicine patients during their hospitalization and after discharge to home. The pharmacist's responsibilities included: (i) medication reconciliation on admission and discharge, (ii) assessment of medication access and adherence problems, (iii) medication education, and (iv) telephone follow-up within 72 hours of discharge. Tools were developed to standardize patient interactions, assess medication access/adherence problems, and document in the inpatient and outpatient medical records. Primary outcomes were medication discrepancies in the inpatient and outpatient settings, medication-related problems after discharge, and changes in H-CAHPS scores and 30-day readmission rates.

**RESULTS:** Of the 220 patients were included: mean age 58 years; 47% male; 53% Medicare; 5 median comorbid conditions; and 8 mean scheduled medications on admission. Pharmacists resolved a mean 3.6 medication discrepancies per patient on admission, with missing medications being most common (mean 1.5 per patient). Pharmacists reached 72% of patients after discharge and resolved a mean 1.7 medication-related problems per patient. H-CAHPS scores on new medication education and side effects improved significantly (22% to 75% and 27% to 75%, respectively) on this medicine unit when compared to before program initiation. Additionally, pharmacists identified a mean 7.8 medication discrepancies per patient when comparing the discharge medication list to the outpatient medical record. The most common outpatient discrepancy was missing medications (mean 3.7 per patient). Thirty-day readmissions were 11% for TOC patients compared to 24% for patients matched on age, sex, hospital service, and primary diagnosis.

**CONCLUSION:** This model that incorporates a hospital pharmacist conducting TOC activities is an effective approach to improve patient care and reduce 30-day readmissions.

**315. Improving patient outcomes and decreasing length of stay through pharmacist participation in case management rounds.** Ann-Lori Perez, Pharm.D., Estela M. Trimino, Pharm.D., BCPS, Michaela Christian, Pharm.D.; Mercy Hospital, Miami, FL

**PURPOSE:** This study demonstrates the impact of a pharmacist on collaborative multidisciplinary patient care rounds in a community hospital in an effort to help facilitate discharge and decrease length of stay (LOS).

**METHODS:** Patients located on the medical, surgical, and oncology floors who had been hospitalized for three or more days were targeted by financial class (Medicare, charity, and self-pay). A multidisciplinary team consisting of, but not limited to, physicians, pharmacy, nursing, and case management met daily to discuss patients' needs and intervene as necessary. Pharmacists reviewed profiles identifying opportunities in antimicrobial stewardship, drug regimen modification, IV to PO conversions, anti-coagulation management, renal dosing, and meeting core measure requirements. LOS data was analyzed pre and post pharmacist

participation. Additionally, a sub-analysis of interventions documented from February through May 31, 2012 was evaluated, and a cost savings analysis was performed.

**RESULTS:** Length of stay prior to multidisciplinary rounds was 5.48 days, and after 3.5 months of rounds with a pharmacist LOS decreased to 4.88 days. Interventions made by the pharmacists included 119 in antimicrobial stewardship, 196 in general drug regimen modifications, 123 IV to PO conversions, 25 in anticoagulation management, eight renal dose adjustments, and 42 interventions related to core measure requirements. Cost savings from pharmacy interventions was \$21,675. Additionally, opportunities for patient education, pain management, adverse drug reactions, and counseling on discharge were identified.

**CONCLUSION:** Length of stay was decreased by 0.6 days through pharmacist participation in rounds, and total cost savings from interventions made was \$21,675. This demonstrates that pharmacist involvement can help facilitate safe and timely discharge from the hospital.

### Pharmacogenomics/Pharmacogenetics

**316. Implementation of a multidisciplinary warfarin pharmacogenetics service at the University of Illinois Hospital & Health Sciences System (UI-Health).** *Edith A. Nutescu, Pharm.D.<sup>1</sup>, Larisa Cavallari, Pharm.D.<sup>1</sup>, William Galanter, M.D.<sup>2</sup>, Shrihari Kadkol, M.D., Ph.D.<sup>3</sup>, Carol Dodge, C.T., ASCP<sup>3</sup>, Thomas Stamos, M.D.<sup>4</sup>, Jerry Krishnan, M.D., Ph.D.<sup>5</sup>, Bryan Becker, M.D.<sup>6</sup>, Darabi Houshang, Ph.D.<sup>7</sup>, Joe G.N. Garcia, M.D., Ph.D.<sup>5</sup>;* (1) Department of Pharmacy Practice, University of Illinois at Chicago College of Pharmacy, Chicago, IL; (2) Department of Medicine, Section of General Internal Medicine, University of Illinois at Chicago, Chicago, IL; (3) Department of Pathology, Molecular Pathology, University of Illinois at Chicago, Chicago, IL; (4) Department of Medicine, Section of Cardiology, University of Illinois at Chicago, Chicago, IL; (5) University of Illinois at Chicago, Pulmonary, Critical Care, and Sleep Medicine, Chicago, IL; (6) Department of Medicine, Section of Nephrology, University of Illinois at Chicago, Chicago, IL; (7) Department of Mechanical and Industrial Engineering, University of Illinois at Chicago, Chicago, IL

**BACKGROUND:** Genotype-guided warfarin dosing has the potential to improve dosing accuracy, shorten the time to dose stabilization, allow for more informed dose titration, reduce the risk for bleeding, and help identify individuals who require more frequent monitoring. Despite guidelines from the Clinical Pharmacogenetics Implementation Consortium and inclusion of genotype-guided dosing recommendations in the warfarin product labeling, clinical implementation of warfarin pharmacogenetics has been lagging in practice. The nuances of considering both genetic and clinical factors for warfarin dose estimation requires a level of expertise to support clinical decision making that can be best provided via a specialized clinical pharmacogenetics service. Additional considerations in underrepresented minority patients (as in our population) also need to be factored in.

**PURPOSE:** To develop a coordinated, genotype-guided dosing and management approach and implement a clinical pharmacogenetics service for warfarin therapy.

**METHODS:** A multidisciplinary team consisting of experts from pharmacogenetics, anticoagulation, clinical pathology, systems engineering, information technology, bioinformatics, and hospital administration was formed to develop strategies for implementing a warfarin pharmacogenetic service. Service responsibilities include selecting genotyping methodology, validating genetic tests, building the information technology infrastructure to support genetic testing, coordinating provider education, providing consultative services, serving as an information resource to support clinical decision making, exploring methods to improve workflow, and examining use of ancestry-specific dosing models.

**RESULTS:** The development and implementation of a multidisciplinary clinical pharmacogenetics service for warfarin therapy will be described.

**CONCLUSION:** Given our diverse patient population, implementation of warfarin pharmacogenetics provides a unique opportunity

to examine the feasibility and optimize the delivery of genotype-guided medicine to underrepresented patient populations, with the ultimate goal of reducing health care disparities and improving patient outcomes. This UI-Health initiative to implement warfarin pharmacogenetics is among the first and is consistent with our commitment to providing personalized medicine and translating genetic information to optimal medication management.

### Pharmacokinetics/Pharmacodynamics/Drug Metabolism/Drug Delivery

**317. Improvement of vancomycin utilization in a community teaching hospital.** *Brenda Gitman, Pharm.D., Rani Patel, Pharm.D., Mini Varghese, Pharm.D., BCPS, Sonia D. Patel, Pharm.D., BCPS, Ashmi A. Philips, Pharm.D., Joseph Gugliotta, M.D.;* Hunterdon Medical Center, Flemington, NJ

**PURPOSE:** Pharmacokinetic parameters must be taken into consideration to optimize the utilization of agents such as vancomycin. Currently, at our institution, dosing and monitoring does not follow a standardized approach which may potentiate suboptimal outcomes. The objective of this study was to implement a pharmacist-driven pharmacokinetic service to improve the utilization of vancomycin.

**METHODS:** A three month prospective study was conducted at Hunterdon Medical Center. Quadramed Computerized Patient Record System (QCPR) was utilized to identify patients receiving at least one dose of vancomycin from January 2012 to March 2012. Patients were evaluated for appropriateness of initial dosing based on weight and renal function and pharmacokinetics were calculated for all subsequent doses. This dosing strategy was used to assess for therapeutic troughs and compare to retrospective data collected January 2011 to May 2011.

**RESULTS:** One hundred and seven patients in the Phase II portion of the study received at least one dose of vancomycin; of these forty-seven patients (43.9%) were able to attain a therapeutic trough as compared to the seventeen out of one hundred patients (17%) included in Phase I of the study ( $p=0.00010$ ). Improvements were seen when assessing the percentage of patients who were able to attain a therapeutic first trough in Phase I and II, 25% and 39.3%, respectively ( $p=0.0372$ ). In assessing composite number of troughs not drawn there were forty-seven patients who were not monitored with troughs in Phase I and thirty-five patients in Phase II who required troughs but did not have them drawn ( $p=0.1349$ ); one hundred and nineteen troughs were requested in Phase II. Forty-eight cost saving interventions were recommended and accepted, including dose increases/decreases, frequency increases/decreases, and discontinuation of the agent.

**CONCLUSION:** Improvement in vancomycin utilization was observed after the implementation of a pharmacist-driven pharmacokinetic service.

**318. Pharmacokinetic (PK) and pharmacodynamic effects of immediate release niacin.** *Sony Tuteja, Pharm.D., BCPS<sup>1</sup>, Gaurav Bajaj, Ph.D.<sup>2</sup>, Jeffrey S. Barrett, Ph.D.<sup>2</sup>, Richard L. Dunbar, M.D.<sup>1</sup>, Muredach P. Reilly, MBBCH<sup>1</sup>, Daniel J. Rader, M.D.<sup>1</sup>;* (1) University of Pennsylvania Perelman School of Medicine, Philadelphia, PA; (2) Division of Clinical Pharmacology, Children's Hospital of Philadelphia, Philadelphia, PA

**PURPOSE:** To characterize PK of niacin (Nia) and one of its metabolite nicotinuric acid (Nua) in subjects receiving 1 g of niacin in relationship to variation in both of its major pharmacodynamics effects: flushing and the anti-lipolytic response.

**METHODS:** A prospective, single-dose healthy volunteer study. Serial plasma samples were collected for non-esterified fatty acids (NEFA) and Nia/Nua determination. Flushing was assessed objectively by laser Doppler flowmetry. Nia/NUA concentrations were analyzed by HPLC/MS/MS. PK analysis was done using non-compartmental analysis using WinNonLin.

**RESULTS:** PK profiles of Nia/Nua were assessed in 59 subjects (51% male, 51% African-American (AA)). AA had a significantly higher Nia C<sub>max</sub>, AUC, and lower clearance (CL) than Cauca-

sian (Cau) subjects. AA had a lower Nua Cmax and AUC, but higher CL. Nia/Nua PK was not significantly different by sex, once adjusting for race and body weight. Nia/Nua PK was not different in subjects experiencing extreme flushing versus those experiencing mild flushing. PK was also not different in subjects having a greater NEFA suppression versus those with lesser NEFA suppression. However, Nia AUC was greater in subjects with a larger NEFA rebound.

**Table 1. Pharmacokinetics of niacin and NUA stratified by race:**

	Cau	AA	p-Value
Nia Cmax (ng/ml)	17,915 ± 6782	23,411 ± 8158	0.008
Nia AUC 0-inf (ng*hour/ml)	28,980 ± 11033	37,970 ± 12134	0.005
Nia CL <sub>F</sub> (ml/hour)	39,954 ± 15967	29,941 ± 12166	0.005
Nua Cmax (ng/ml)	3388 ± 657	2703 ± 763	0.001
Nua AUC 0-inf (ng*hour/ml)	8777 ± 2147	7615 ± 2259	0.04
Nua CL <sub>F</sub> (ml/hour)	121,207 ± 31472	143,834 ± 45177	0.04

**CONCLUSIONS:** Race differences exist in Nia/Nua PK. Nia/Nua PK was not correlated with flushing response to Nia or degree of NEFA suppression. Subjects with a greater NEFA rebound had significantly greater Nia exposure, suggesting a complex mechanism of action of the rebound effect seen with Nia therapy.

## Transplant/Immunology

**319. Cytomegalovirus (CMV) IgG quantification and risk of CMV disease in seropositive renal transplant recipients with seropositive donors.** Joelle Nelson, Pharm.D.; University Health System, San Antonio, TX

**BACKGROUND:** The benefit of antiviral prophylaxis in high-risk, cytomegalovirus (CMV) IgG donor-positive, recipient-negative (D+/R-) renal transplants is well established. Yet, guidelines recommending prophylaxis in moderate-risk, recipient-positive (R+) transplants are based on expert opinion. Our center further stratifies risk based on CMV IgG recipient quantification.

**PURPOSE:** To determine if incidence of CMV disease differs based on recipient IgG quantification.

**METHODS:** A single-center, retrospective review was performed on all renal transplants between 7/2006 and 6/2010 with 1 year follow-up. Patients were included if they were 18–75 years old with a D+/R low+ or D+/R+ seromatch; and were excluded if they received a multi-organ transplant or had HIV, HCV, or HBV co-infection. The primary outcome was incidence of documented CMV disease. Secondary outcomes included time to CMV disease, patient and graft survival, acute rejection, and infections.

**RESULTS:** Of 250 renal transplants performed, 107 met inclusion criteria. Demographics between groups were similar. The patient population had a median age of 55 (IQR 44–61) years. The majority of patients were D+/R low+ (n=78, 73%) and the remainder were D+/R+ (n=29, 27%). Rabbit antithymocyte globulin was used for induction in 24% and rejection in 7% of recipients. Most patients received valganciclovir 450 mg daily for prophylaxis (n=98, 92%); nine received acyclovir. Median duration of prophylaxis was 6 months. CMV disease rates were similar between D+/R low+ and D+/R+ groups (2.5% versus 0%, p=1). No significant difference was identified between serogroups regarding acute rejection, patient survival, or graft survival. D+/R low+ transplants had significantly greater infections than D+/R+ (22% versus 4%, p=0.02).

**CONCLUSION:** Incidence of CMV disease wasn't significantly different between serogroups. Quantification of recipient CMV IgG didn't significantly affect the incidence of acute rejection or patient and graft survival. However, D+/R low+ transplants had an increased rate of infections.

**320. Risk of CMV after r-ATG or IL2 antagonist induction and the impact of CMV-directed prophylaxis in low risk renal transplant recipients.** Teena Sam, Pharm.D., BCPS<sup>1</sup>, Elise Carlson, Pharm.D.<sup>2</sup>, Ian C. Doyle, Pharm.D., BCPS<sup>3</sup>, Steven Gabardi, Pharm.D., BCPS<sup>4,5</sup>, Karen L. Hardinger, Pharm.D., BCPS<sup>6</sup>, John Knorr, Pharm.D., BCPS<sup>7</sup>, Lisa M. McDevitt, Pharm.D., BCPS<sup>8</sup>, Kimi Ueda, Pharm.D., BCPS<sup>9</sup>, Eric Tichy, Pharm.D., BCPS<sup>1</sup>; (1) Yale-New Haven Hospital, New Haven, CT; (2) Sanford Health, Fargo, ND; (3) Pacific University Oregon School of Pharmacy, Hillsboro, OR; (4) Department of Pharmacy & Renal Division, Brigham & Women's Hospital, Harvard Medical School, Boston, MA; (5) Department of Medicine, Harvard Medical School, Boston, MA; (6) UMKC School of Pharmacy, Kansas City, MO; (7) Albert Einstein Medical Center, Philadelphia, PA; (8) Tufts Medical Center, Boston, MA; (9) California Pacific Medical Center, San Francisco, CA

**PURPOSE:** Rabbit antithymocyte globulin (r-ATG) induction is associated with an increased risk for CMV after transplant. Limited data exists for optimal antiviral prophylaxis strategies in low CMV risk (D-/R-) renal transplant recipients (RTRs) receiving r-ATG. Our objective was to compare risk of CMV disease associated with r-ATG versus IL2 antagonist (IL2) induction and the impact of CMV-directed prophylaxis on the incidence of CMV disease in D-/R- RTRs who received r-ATG induction.

**METHODS:** A multicenter, retrospective analysis evaluated adult D-/R- RTRs between 01/01/04 and 09/30/10 at a multicenter, retrospective analysis evaluated adult D-/R- RTRs between 01/01/04 and 09/30/2010. All patients received induction therapy with either r-ATG or IL2 plus maintenance immunosuppression with tacrolimus, mycophenolic acid, with or without steroids. Group A (n=118) received r-ATG induction without CMV-directed antiviral prophylaxis. Group B (n=41) received r-ATG induction with CMV-directed prophylaxis using valganciclovir. Group C (n=73) received IL2 induction without CMV-directed antiviral prophylaxis. The primary endpoint was CMV disease incidence and secondary endpoints included CMV viremia, acute rejection (AR), antibody mediated rejection (AMR) and other opportunistic infections (OIs) at 1 year post-transplant.

**RESULTS:** Differences in baseline characteristics included proportion of living donor transplants (24.4%, 60.2% versus 75.3%), rate of early steroid withdrawal (2.4%, 48.8% versus 19.2%), and mean duration of antiviral prophylaxis (5.1, 3.0 versus 3.5 months) in group A, B and C, respectively (p<0.05). There was no difference in rate of CMV disease (0.0%, 0.8% versus 1.4%) or rate of AR (14.6%, 14.4%, versus 19.2%) in groups A, B and C, respectively (p>0.05). Similarly, there were no significant differences in rate of AMR, BK or HSV infection.

**CONCLUSION:** Our study demonstrates that the incidence of CMV disease in D-/R- RTRs is rare, regardless of induction or antiviral prophylaxis strategy utilized. Non-CMV-directed prophylaxis may provide sufficient efficacy and potentially offer significant cost avoidance in this population.

**321. Modification of induction in kidney transplants with pre-transplant viral infection or chronic long term immunosuppression.**

Jennifer Deyo, Pharm.D.<sup>1</sup>, Robert Dupuis, Pharm.D., BCPS<sup>2</sup>, RuthAnn M. Lee, Pharm.D., C.P.P.<sup>2</sup>, Tomasz Kozlowski, M.D.<sup>3</sup>; (1) Department of Pharmacy, University of North Carolina Memorial Hospital, Chapel Hill, NC; (2) UNC Eshelman School of Pharmacy, Chapel Hill, NC; (3) Division of Abdominal Transplant, UNC Memorial Hospital, Chapel Hill, NC

**PURPOSE:** Standard induction in renal transplant at our center includes Alemtuzumab (CIH) or thymoglobulin (rATG) to facilitate rapid steroid (SD) withdrawal. Selected patients with higher infection risk or on long term immunosuppression (LTIS) prior to transplant receive basiliximab (BAS) induction. This was a retrospective review to examine acute cellular rejection (ACR) rate 1 year post transplant.

**METHODS:** Adult kidney transplants receive rATG or C1H, followed by tacrolimus (Tac) and mycophenolate (MPA); BAS Group: Tac, MPA and SD taper to prednisone 5–10 mg/day. RATG/C1H groups stop SD on POD 4. Data collected during the first year post transplant and analyzed based on induction therapy.

**RESULTS:** BAS induction (n=18) due to pre-transplant viral infection BKV n=1, HCV n=6, CMV n=1, PTLN n=1, long term immunosuppression n=15 or vasculitis, n=4. One year ACR rate was 50% with severity of Banff I; n=4 and II; n=6. ACR occurred at mean 44.7 and range 8–133 days. ACR occurred in four of 10 pts on LTIS and in five of 8 pts without LTIS. Mean Tac levels at 1 month were BAS:9.4 + 7.4, rATG 8.3 + 2.1 C1H:7.4 + 2.4 (p=0.038 BAS versus C1H). In rATG, (n=46) & C1H groups (n=121) ACR was 9% and 11%, occurring at 51 ± 62 and 221 ± 106 days (p=0.002) respectively with CMV reactivation 5% and 8.6%, BK reactivation 1.5% and 8%. BAS Group CMV reactivation 11% and BK reactivation 16.6%.

**CONCLUSION:** ACR rate of 50% following BAS induction within 1 year of renal transplant is higher than rATG or C1H. Based on these results, our institution has redesigned patient selection for BAS induction as well as modification to LTIS. Ongoing data collection will be used to assess efficacy/safety of rATG induction with pre-existing viral infection and those chronically immunosuppressed.

## Women's Health

**322 Implications on vaccine compliance rates in an obstetrics and gynecology outpatient clinic with the implementation of a pharmacist driven vaccination assessment: phase 2.** *Alicia B. Forinash, Pharm.D., BCPS, BCACP, Jamie M. Pitlick, Pharm.D., BCPS, Abigail M. Yancey, Pharm.D., BCPS; St. Louis College of Pharmacy, Saint Louis, MO*

**PURPOSE:** To determine if a pharmacist driven immunization assessment influences compliance with the CDC immunization recommendations for hepatitis A, hepatitis B, influenza, tetanus/diphtheria/pertussis (Tdap), human papillomavirus (HPV) and pneumococcal vaccines at a community teaching hospital obstetrics and gynecology (Ob/Gyn) clinic.

**METHODS:** Phase 1 of the study included a baseline retrospective chart review of patients seen in the clinic during a 4 week period in 2009. Phase 2 of the study included an identical chart review 15 months after initiation of a pharmacist driven screening assessment. Rates were compared to determine efficacy of the protocol at increasing immunization compliance. The chart reviews included baseline demographics and patient specific indications for the various vaccines. Compliance was defined as having an indication for the vaccine and receiving at this visit or previously within the appropriate time frame.

**RESULTS:** Overall compliance with the 2010 CDC immunization recommendations was low but significantly improved from 2009 (25.9% 2010 versus 6.7% 2009, p<0.001). Nearly all individual vaccines rates significantly improved in 2010 compared to 2009 (Table 1).

Vaccine	Ob/Gyn 2010 (n=182)	Ob/Gyn 2009 (n=102)	p-value
Influenza	37.1%	13.7%	<0.001
Pneumococcal	7.2%	0%	0.06
Hepatitis A	54.3%	10.5%	0.002
Hepatitis B	42%	14%	0.001
Tdap	17%	1.7%	<0.001
HPV	6.3%	1.7%	0.4

**CONCLUSION:** Compliance with the CDC immunization recommendations improved with implementation of a pharmacist driven assessment; however, rates are still low signifying a need for additional pharmacist intervention such as development of a collaborative practice agreement.

## RESIDENTS AND FELLOWS RESEARCH IN PROGRESS

### Adult Medicine

**323. Effect of treatment variation on outcomes in patients with *Clostridium difficile* associated diarrhea.** *Adam T. Brown, Pharm.D., Charles F. Seifert, Pharm.D., FCCP, BCPS; Texas Tech University Health Sciences Center School of Pharmacy, Lubbock, TX*

**PURPOSE:** New guidelines for the treatment of *Clostridium difficile* associated diarrhea (CDAD) in adults were published by the Infectious Disease Society of America (IDSA) in 2010, however there has been no literature evaluating the effectiveness of these guidelines. The purpose of this study is to examine the difference in clinical outcomes of CDAD patients treated according to the guidelines compared to patients that were not treated according to the guidelines.

**METHODS:** Using data retrospectively collected from University Medical Center's electronic records, we compared the complication rates (death, infection recurrence, toxic megacolon and surgery) of patients with CDAD to determine if following the IDSA Guidelines improves outcomes.

**RESULTS:** Only 51.7% of the patients' prescribers followed the 2010 IDSA CDAD guidelines. Patients whose prescribers followed the IDSA Guidelines experienced fewer complications than patients whose prescribers strayed from the guidelines (17.2% versus 56.3%, p<0.0001). This difference was mainly due to a reduction in mortality (5.4% versus 21.8%, p=0.0012) and infection recurrence (14% versus 35.6%, p=0.0007). Patients who presented with severe and complicated disease received guideline based therapy significantly less often than patients with mild disease (35.3% and 19.7% versus 81.2% respectively, p<0.0001). Patients infected with a NAP-1 strain exhibited more severe disease (SAPS II 22.5 versus 22, p=0.0003) and had higher mortality (22.9% versus 7.3%, p=0.0027) than those infected with a non-NAP-1 strain.

**CONCLUSION:** There was a significant reduction in complications from CDAD associated with treatment plans that were consistent with recommendations in the IDSA Guidelines.

### Ambulatory Care

**324. Diabetes medication management program: impact of pharmacists on management of oral hypoglycemic medications.** *Taniyah Dawson, Pharm.D., Paul Godley, Pharm.D., Tricia A. Tabor, Pharm.D., Kangho Suh, Pharm.D., Cunningham Megan, Pharm.D.; Scott and White Health Plan, Temple, TX*

**PURPOSE:** To determine how oral hypoglycemic medication management and patient self-management impact A1c control in a pharmacist managed population versus control group.

**METHODS:** This 2 year study consists of a prospective intervention group and a retrospective, matched control group. Patients were matched one-to-one based on A1c, age, gender, time of enrollment, and Charlson co-morbidity index. The intervention consists of monthly visits with the pharmacist, co-payment waivers for selected diabetes medications and supplies, assessment of medications and review of patient education. Patients in the control group receive standard medical care and do not receive the co-payment waiver. Outcomes include the change in A1c, number of oral medications, number of dosage titrations per patient, maximum dosage achieved for individual oral agents, number of new diabetes medications initiated in each patient, persistence based on refill patterns and test strip utilization.

**RESULTS:** A total of 138 patients (69 in each group) completed 2 years. The average number of oral hypoglycemic medications per patient at base line was found to be 2.13 in the intervention group and 1.75 in the control group. The change in the number of medications from baseline to endpoint was not significant (p=0.5). The intervention group received significantly more dosage titrations than the control group (86 versus 57, p<0.05). Initi-

ation of new oral hypoglycemic medication occurred more frequently in the intervention group (41 versus 30). Medication possession ratio improved in the intervention group and declined in the control group (+0.030 versus -0.093,  $p < 0.001$ ).

**CONCLUSION:** Patients managed by pharmacist experienced an improved A1c compared to control group. More aggressive dose titrations may partially explain changes in A1c. There was an improvement in adherence as measured by MPR in pts in the MMP group. Further data analysis will be conducted and presented.

### 325. Effect of a clinical pharmacist-managed service on blood pressure in an underserved population with resistant hypertension.

Andrea C. Basso, Pharm.D.<sup>1</sup>, Zachary A. Stacy, Pharm.D., BCPS<sup>2</sup>, Amie D. Brooks, Pharm.D., BCPS<sup>2</sup>; (1) St. Louis County Department of Health, Saint Louis, MO; (2) St. Louis College of Pharmacy, St. Louis, MO

**PURPOSE:** To determine if a clinical pharmacist-managed resistant hypertension service has an effect on blood pressure (BP) in an underserved population.

**METHODS:** This ongoing prospective, observational cohort study is evaluating patients enrolled in a pharmacist-managed resistant hypertension service with at least one post-enrollment encounter. BP is measured in clinic and at home (monitors provided). Patients enrolled in the service are followed at 2 week intervals alternating telephone and clinic encounters. The primary outcome is mean change in home systolic blood pressure (SBP). Secondary outcomes include change in home diastolic blood pressure (DBP), clinic BP, and BP from initial encounter to end of study. Last observation is carried forward.

**RESULTS:** Eight patients are included in this interim analysis over a mean duration of 54 + 24 days. Baseline characteristics (mean ± SD) include age 56 (+8) years, BMI 40 kg/m<sup>2</sup> (+8), clinic SBP 155 mmHg (+8), DBP 83 mmHg (+11), treatment including 4.25 (+1.2) anti-hypertensives, 87.5% African American, 12.5% Caucasian, 88% with diabetes mellitus, and 25% with chronic kidney disease. The primary outcome of change in home SBP was -13 mmHg (+18),  $p = 0.099$ . Change in clinic SBP was -9 mmHg (+15),  $p = 0.13$ . Clinic BP goal has been achieved in 12.5% of participants and home BP goal has been achieved in 28.6%. Change in initial clinic SBP to end of study home SBP was -25 mmHg (+15),  $p = 0.005$ .

**CONCLUSION:** A reduction in home SBP was observed in the pharmacist-managed service, but the change did not reach statistical significance. The study is ongoing and statistical power has not been met. Fifteen subjects are needed to meet power and it is fully anticipated that the project will be completed by the time of presentation.

## Cardiovascular

### 326. Evaluation of P2Y<sub>12</sub> adenosine diphosphate receptor antagonists in patients with acute coronary syndromes undergoing percutaneous coronary intervention.

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**PURPOSE:** Acute coronary syndrome (ACS) represents a life-threatening form of coronary artery disease and is caused by a rupture of an atherosclerotic plaque or thrombosis of the infarcted artery. Current guidelines highlight the role of dual antiplatelet therapy in those undergoing medical and invasive strategy, particularly percutaneous coronary intervention (PCI) to reduce the risk of ischemic complications. The objective of this study is to compare the clinical safety and efficacy of three P2Y<sub>12</sub> adenosine diphosphate receptor antagonists; clopidogrel, prasugrel and ticagrelor.

**METHODS:** A retrospective analysis was performed on information extracted from a computerized physician order entry system, medical charts and CathPCI registry in patients with ACS under-

going PCI. Thirty day efficacy endpoints included mortality, stent thrombosis and patient readmission. Safety endpoints included bleeds within 72 hours and 30-day bleeds.

**RESULTS:** A total of 102 patients were analyzed (50 in the clopidogrel arm, 36 in the prasugrel arm and 16 in the ticagrelor arm). The primary endpoints, mortality and stent thrombosis did not occur in any patient. Readmissions occurred in 8% (4/50) of patients receiving clopidogrel, 39% (14/36) of patients receiving prasugrel and 19% (3/16) in patients receiving ticagrelor ( $p = 0.328$ ). A bleeding event within 72 hours occurred in 2% (1/50) of patients receiving clopidogrel, 8.3% (3/36) of patients receiving prasugrel and none in ticagrelor. Thirty day bleeds occurred in 4% (2/50) of patients receiving clopidogrel, 2.8% (1/36) of patients receiving prasugrel and none for the ticagrelor arm.

**CONCLUSION:** Mortality and stent thrombosis were not observed in the patients analyzed. Prasugrel was associated with a numerically higher rate of readmission compared to clopidogrel and ticagrelor. More patients in the prasugrel group experienced bleeds within 72 hours compared to clopidogrel and ticagrelor. Thirty day bleeds occurred more frequently in patients receiving clopidogrel, followed by prasugrel and none in the ticagrelor arm.

### 327. Esmolol IV versus metoprolol IV for post-operative rate and rhythm control.

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**PURPOSE:** This study retrospectively evaluated the use of two beta blockers, esmolol IV and metoprolol IV, at two community hospitals on rate and rhythm control in the postoperative setting. The study aimed to (i) collect clinical safety and efficacy indicators, and (ii) explore the pharmaco-economic potential between both treatment options.

**METHODS:** Electronic medical records of 100 patients who received esmolol IV (N=50) or metoprolol IV (N=50) post-operatively at two community hospitals from October 31, 2010 to October 31, 2011 were reviewed. Indication for use, duration of therapy, hospital stay, APACHE II scores, and efficacy defined as a decrease in heart rate by  $\geq 15\%$  or conversion to normal sinus rhythm were documented for each patient.

**RESULTS:** Tachycardia was the primary indication in 76% of metoprolol IV patients whereas atrial fibrillation comprised 48% of reasons for use in the esmolol IV group. APACHE II scores were statistically higher for patients who received metoprolol IV compared to patients treated with esmolol IV (12.5 versus 9.94,  $p < 0.0001$ ). Esmolol IV patients had an average length of stay (LOS) of 23 days versus metoprolol IV patients, who had an average LOS of 7 days ( $p = 0.0081$ ). Patients who received esmolol IV had a statistically longer duration of use with 3.2 days compared to 1.7 days for those who received metoprolol IV ( $p = 0.01$ ). The overall efficacy of esmolol IV versus metoprolol IV was 72% and 76%, respectively, with no demonstrated statistical significance ( $p = 0.65$ ).

**CONCLUSION:** Prolonged esmolol IV therapy is costly and may not be necessary in all patients requiring rate and rhythm control post-operatively. Metoprolol IV may prove to be an alternative cost-saving rate and rhythm controlling agent in comparison to esmolol IV with similar efficacy and safety. Future prescribing practices favoring metoprolol IV may prove to be a cost effective strategy in patients who require rate or rhythm control in the post-operative setting.

## Education/Training

### 328. A comparison of educational interventions to enhance cultural competency in pharmacy students.

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**PURPOSE:** The purpose of this study was to compare three educational interventions to determine which will enhance cultural competency to the greatest extent in pharmacy students.

**METHODS:** Second year pharmacy students (108 total) were invited to take a pre-intervention self-assessment survey measuring cultural encounters, awareness, knowledge, skills, desire, and empathy on a Likert scale. The class was then divided into three equal groups. Each group received the same content, but using one of the following teaching strategies: a simulated patient activity (SP), written case scenarios (CS), or a formal lecture (FL). The self-assessment survey was repeated following the intervention. Mean change in scores for each question was compared within and among all three groups.

**RESULTS:** A total of 84 students completed both the pre and post survey (28 SP, 30 CS, 26 FL). There were no differences in age, sex, or ethnicity between groups. Comparing pre and post responses within the SP group, there were significant changes in the cultural skills questions on modifying one's approach ( $p=0.001$ ) and asking offending questions ( $p=0.033$ ) during cultural encounters, and also an increase in the desire to learn about different cultures ( $p=0.037$ ). Within the CS group, there was a significant change in cultural awareness regarding mastery of cultural competency ( $p=0.041$ ). Within the FL group, there were significant changes in the cultural skills questions on modifying one's approach ( $p=0.001$ ) and in the cultural empathy question about viewing the encounter from the patient's perspective ( $p=0.032$ ). Comparing between groups, the SP and FL groups improved significantly more than the CS group in response to the cultural skills question regarding modifying one's approach ( $p=0.008$ ).

**CONCLUSION:** There were significant changes within each group indicating that certain ideologies and behaviors may be enhanced based on the activity received; however, a one-hour practicum may not be sufficient to enhance cultural competency.

**329. Validity and reliability with educational testing in the pharmacy and medical literature.** *Matthew J. Hoover, Pharm.D.<sup>1</sup>, David M. Jacobs, Pharm.D.<sup>1</sup>, Rose Jung, Pharm.D., M.P.H., BCPS<sup>2</sup>, Michael J. Peeters, Pharm.D., MEd., BCPS<sup>2</sup>; (1)The University of Toledo Medical Center, Toledo, OH; (2)University of Toledo College of Pharmacy, Toledo, OH*

**PURPOSE:** Validity and reliability are crucial to educational testing. This investigation characterized these psychometric properties in pharmacy education journals, and compared these with medical education journals.

**METHODS:** Among medical and pharmacy education journals, 2009–2011 tables of content were reviewed and articles selected that used educational testing for students. Two reviewers independently assessed for presence of reliability (internal consistency, inter-rater) and validity (content, construct, and criterion) descriptions. As well, we reviewed for authors' awareness of psychometric properties in the discussion, and pilot testing use.

**RESULTS:** Forty-seven articles (15 pharmacy and 32 medicine) met inclusion criteria. The two reviewers had an agreement of 0.803 (Cohen's kappa), and reached consensus where disagreement. Our initial data suggested that content validity, criterion validity, construct validity, internal consistency and inter-rater reliability were not differently reported in the medical and pharmacy education literature ( $p=0.31$ ,  $p=0.08$ ,  $p=0.16$ ,  $p=0.78$  respectively;  $p=0.30$  by chi-square). We confirmed that medical education journals had higher 5-year journal impact factors (JIF) than pharmacy education journals (median 2.3 versus 1.3,  $p=0.0009$  by Mann-Whitney), but on regression, neither JIF nor type (medical, pharmacy) differed in reporting validity and reliability (OR = 0.463 for JIF [95% CI 0.10–2.09], OR = 1.01 for type [95% CI 0.18–5.82]). Of note, awareness by authors differed as well. More medical education authors discussed implications with psychometric aspects of educational testing than did pharmacy education authors (50% versus 13%,  $p=0.02$  by chi-square). We did not find any difference between journal types with use of pilot testing (13% medicine, 13% pharmacy;  $p=1.00$  by chi-square).

**CONCLUSION:** Our preliminary results suggest no statistically significant difference between medical and pharmacy literature with reporting validity and reliability in educational testing. Journal quality (by JIF) did not factor into reporting either. However, our review suggested that pharmacy education authors could demonstrate greater awareness of psychometric aspects of educational testing by improving article discussions.

## Family Medicine

**330. Albuterol-metered dose inhalers: evaluation of a free medication program.** *Susan K Idd, Pharm.D.<sup>1</sup>, Roberta M. Farrah, Pharm.D., BCPS<sup>2</sup>; (1)UPMC St. Margaret, Pittsburgh, PA; (2)University of Pittsburgh School of Pharmacy, Pittsburgh, PA*

**PURPOSE:** Albuterol is a commonly prescribed medication for respiratory conditions. Guidelines exist that outline albuterol usage criteria for chronic pulmonary conditions, but current guidelines do not support albuterol use for most acute pulmonary conditions. This evaluation was conducted to determine appropriateness of albuterol metered-dose inhaler use dispensed as part of a free medication program in the family health center setting and overuse per national guidelines.

**METHODS:** Albuterol metered-dose inhalers are inventoried and hard copy prescriptions should be generated for medications dispensed from the free medication program at three UPMC Family Health Centers. An evaluation was done for 2 years (1/09–12/11) of albuterol inhaler usage. Prescriptions for each inhaler were matched to the inventory record to determine if current documentation practice is sufficient. From these records, patient electronic health records were utilized to determine reason for prescribing, appropriate usage of medication per current guidelines, and multiplicity of medication per monthly period indicating possible inadequate disease control.

**RESULTS:** Out of 485 total albuterol prescriptions dispensed through the free medication program, there were 258 hard copies obtainable. Of the 258 hard copy prescriptions, 199 of those were prescribed for appropriate reasons including asthma, COPD, and wheezing. The inappropriate reasons allergic rhinitis, bronchitis, cough, pneumonia, respiratory abnormalities/reactive airway disease, shortness of breath, upper respiratory infection, refill known medication, and unknown accounted for 59 of the prescriptions. Overuse of more than one inhaler in a calendar month was discovered in 43 out of the 167 patients.

**CONCLUSION:** In the majority of cases, albuterol is being prescribed according to guidelines. Also, in the majority of cases, albuterol is not being overprescribed. However, there is room for educational intervention on use of albuterol in non-chronic conditions, prescribing process to limit lost orders, and patient education to ensure medication safety and economic stewardship of the free medication program.

**331. Impact of an academic interprofessional collaborative practice clinic on preventive care services.** *Joseph A. Zorek, Pharm.D.<sup>1</sup>, Eric J. MacLaughlin, Pharm.D.<sup>1</sup>, Anitra A. MacLaughlin, Pharm.D.<sup>1</sup>, David S. Fike, Ph.D.<sup>2</sup>, Rodney B. Young, M.D.<sup>3</sup>, Mohammed Samiuddin, M.D.<sup>3</sup>; (1)Texas Tech University Health Sciences Center School of Pharmacy, Amarillo, TX; (2)University of the Incarnate Word, San Antonio, TX; (3)Texas Tech University Health Sciences Center School of Medicine, Amarillo, TX*

**PURPOSE:** To determine if differences exist between patients who participate in annual wellness visit (AWV) clinics delivered by an interprofessional team versus those who do not on Medicare preventive care services (PCS). Secondary aims include patient perceptions of care and impact of the medication review process.

**METHODS:** In this prospective, randomized, case-controlled trial, patients aged 66–74 years will be randomly invited to the AWV clinic (intervention;  $n=50$ ) or undergo a chart review (control;  $n=100$ ). Demographic information and status of PCS will be collected. Intervention patients will undergo a medication review process, receive recommendations regarding PCS, complete a sat-

isfaction survey, and receive a follow-up call 1 month after their visit to assess final PCS status. Descriptive statistics will be used to characterize patients, assess adherence to recommendations, and evaluate patient satisfaction. Fisher's Exact will be used to compare final PCS between the intervention and control groups.

**RESULTS:** To date, six intervention and 12 control patients have been enrolled. No significant differences in demographics between groups were identified. The average number of medication issues/patient was 1 (range 0–3) with the most common being inappropriate medication, non-adherence, and drug interaction(s). PCS recommendations with > 50% adherence include pneumococcal vaccination (50% versus 0%;  $p=0.167$ ), Td/Tdap vaccinations (50% versus 0%;  $p=0.077$ ), mammography (67% versus 13%;  $p=0.152$ ), fecal occult blood (60% versus 0%;  $p=0.022$ ), and DEXA (60% versus 20%;  $p=0.524$ ) for intervention versus control groups, respectively. Patient satisfaction scores on all 13 measures evaluated were positive (median [mean] 5/5 [4.5/5]). Based on enrollment rate, the study is expected to be completed by December 2012.

**CONCLUSIONS:** Statistically significant differences in final PCS between intervention and control groups are expected as sample size increases. Coupled with addressing medication-related issues and positive patient satisfaction ratings, interprofessional AWW clinics hold promise as a mechanism to improve preventive care outcomes.

## Geriatrics

**332. Prevalence of and factors associated with therapeutic failure-related hospitalizations in the elderly.** *Roshni S. Patel, Pharm.D.<sup>1</sup>, Zachary A. Marcum, Pharm.D., BCPS<sup>2</sup>, Emily P. Peron, Pharm.D., BCPS<sup>2</sup>, Christine M. Ruby, Pharm.D., BCPS, FASCP<sup>3</sup>;* (1)University of Pittsburgh Medical Center Presbyterian/Shadyside, Pittsburgh, PA; (2)University of Pittsburgh, Pittsburgh, PA; (3)University of Pittsburgh School of Pharmacy, Pittsburgh, PA

**PURPOSE:** A therapeutic failure (TF) is defined as a failure to accomplish the goals of treatment attributable to inadequate therapy, a drug-drug interaction that results in a sub-therapeutic level for a drug, or medication non-adherence. There is limited literature focusing specifically on TF-related hospitalizations and the factors associated with these hospitalizations in older adults. Importantly, there is a validated and reliable instrument called the Therapeutic Failure Questionnaire (TFQ) that can be used to measure TFs. The purpose of this study was to evaluate the prevalence of and factors associated with TF-related hospitalizations in older adults in a University-based hospital setting.

**METHODS:** This investigation was a retrospective cohort study that included patients with a primary care physician from the University of Pittsburgh Medical Center (UPMC) Senior Care Institute admitted to any UPMC hospital between September 1, 2011 and December 1, 2011. Chart abstracts of inpatient and outpatient records of eligible patients were screened for a TF by using the TFQ. Covariate data were obtained and grouped into three categories: demographics, health status, and access to care. Descriptive statistics and bivariate analyses using Fisher's exact tests were conducted to assess the association between the covariates and the primary outcome (TF).

**RESULTS:** Of the 93 hospitalizations screened, 57 met inclusion criteria, and 18% (10/57) of hospitalizations were due to possible/probable TFs, involving 14 medications. All therapeutic failures were classified as preventable. On bivariate analyses, both congestive heart failure ( $p = 0.028$ ) and dependency for medication management ( $p = 0.036$ ) were significantly associated with TF occurrence. Omission of therapy was the most common cause for a preventable TF-related hospitalization.

**CONCLUSION:** Therapeutic failures are a potentially preventable cause of hospitalization in the elderly population and are commonly caused by omission of therapy.

## Health Services Research

**333 Evaluation of a telephonic medication therapy management service in a home health population: an operational pilot.** *Caitlin K. Frail, Pharm.D.<sup>1</sup>, Margie E. Snyder, Pharm.D., M.P.H.<sup>1</sup>, Heather A. Jaynes, R.N., M.S.<sup>1</sup>, Patrick Dunham, BSEE<sup>2</sup>, Julie Lewis, M.B.A.<sup>3</sup>, Jason M. Sutherland, Ph.D.<sup>4</sup>, Alan J. Zillich, Pharm.D.<sup>1</sup>;* (1)Purdue University College of Pharmacy, Indianapolis, IN; (2)HealthStat Rx, LLC, Smyrna, GA; (3)Amedisys, Inc., Baton Rouge, LA; (4)University of British Columbia, Centre for Health Services and Policy Research, Vancouver, BC, Canada

**PURPOSE:** To provide pilot data on intervention operations and patient outcomes for a larger, ongoing multi-site evaluation of the impact of a telephonic medication therapy management (MTM) service on 60-day hospitalizations and emergency department (ED) visits in a predominately Medicare home health population.

**METHODS:** Patients in three randomly selected, geographically diverse home health care centers were randomized to the intervention or usual care control. The MTM program consisted of the following: 1) initial phone call by a pharmacy technician to verify an active medication list, 2) pharmacist-completed medication therapy review by telephone, and 3) follow-up pharmacist phone calls at days 7 and 30. Patients also received a medication action plan and personal medication record. Pharmacists intervened with prescribers and patients/caregivers to resolve identified drug therapy problems.

**RESULTS:** Sixty eight (intervention  $n=32$ , control  $n=37$ ) of a targeted 84 patients were enrolled with no significant differences in baseline demographics. A smaller proportion of patients in the intervention group were hospitalized within 60 days compared to the control (12.5% versus 19%;  $p=0.53$ ); while 3.1% of intervention patients visited the ED compared to 19% of control patients ( $p=0.05$ ). Opportunities for improvement of the intervention operations included the need for additional home health clinician education about the MTM intervention, clinician discomfort with the informed consent process, the importance of timely data transfer from home health care centers to the MTM providers, and timely initiation of the medication therapy review.

**CONCLUSION:** Pilot testing of the MTM program provided lessons learned that informed implementation of the larger, ongoing study. Pilot findings suggest that this program may result in a reduction in hospitalization and ED utilization; however results of the ongoing study are pending.

## Hematology/Anticoagulation

**334. Evaluation of low molecular weight heparin versus heparin for inpatient treatment of venous thromboembolism.** *Sami Sakaan, Pharm.D.<sup>1</sup>, Joanna Q. Hudson, Pharm.D., BCPS, FASN, FCCP<sup>2</sup>, Angel Jones, Pharm.D., BCACP<sup>1</sup>, Justin B. Usery, Pharm.D., BCPS<sup>3</sup>;* (1)Methodist University Hospital, Memphis, TN; (2)University of Tennessee, Memphis, TN; (3)Methodist University Hospital and University of Tennessee, Memphis, TN

**PURPOSE:** Recent literature suggests that hemodynamically stable patients with venous thromboembolism (VTE) may not require hospitalization and can be treated strictly as outpatients with low-molecular weight heparin (LMWH). The purpose of this study was to evaluate the length of hospital stay in patients with VTE treated initially with intravenous unfractionated heparin (UFH) compared to subcutaneous LMWH. Adverse effects, incidence of heparin induced thrombocytopenia (HIT), total hospital charges, and 30 day hospital readmission rates for VTE or VTE-related events were also evaluated.

**METHODS:** Medical records of patients diagnosed with VTE on admission between 01/01/2007 and 08/15/2011 were reviewed. Inclusion criteria: age  $\geq 18$  years and requiring parenteral anticoagulation treatment. Exclusion criteria: thrombolytic therapy or thrombectomy surgery, ICU admission, end stage renal disease, previous diagnosis of HIT or history of heparin allergy, or treatment with fondaparinux.

**RESULTS:** Of the 250 patients included (n=132 for LMWH, n=118 for UFH), the mean length of stay was 6.2 days for the UFH group versus 4.5 days for the LMWH group (p=0.0003). Major bleeding during hospitalization occurred in 5 patients in the UFH group compared to two patients in the LMWH group (4.2% versus 1.5%, p=0.259). Thrombocytopenia was identified in three patients in the UFH group compared to one patient in the LMWH group. Total hospital charges were lower in the LMWH group compared to the UFH treated group (mean \$20,133 versus \$25,105, p=0.0198). Six patients who were initially treated with UFH were readmitted to the hospital within 30 days for VTE or VTE-related events versus two patients in the LMWH group (5% versus 1.5%, p=0.1537).

**CONCLUSION:** The initial use of subcutaneous LMWH in newly diagnosed patients with VTE may reduce the length of hospital stay and be cost-effective without compromising patient safety when compared to intravenous UFH.

**335. Evaluation of INR follow-up in warfarin-treated patients after antibiotic initiation in the Emergency Department.** Amy E. Willets, Pharm.D.<sup>1</sup>, Debra W. Kemp, Pharm.D., BCPS, BCACP<sup>2</sup>, Amy Clarke, Pharm.D., BCPS<sup>1</sup>, Mary H. Parker, Pharm.D., BCPS (AQ, Cardiology)<sup>1</sup>, Stephanie B. Hollowell, Pharm.D., BCPS<sup>1</sup>; (1)Durham VA Medical Center, Durham, NC; (2)Durham VA Medical Center, UNC Eshelman School of Pharmacy, Durham, NC

**PURPOSE:** The purpose of this study was to determine if warfarin-treated patients prescribed interacting antibiotic therapy at the Durham Veteran Affairs Medical Center (VAMC) emergency department (ED) had INR follow-up within 1 week of antibiotic initiation.

**METHODS:** A retrospective chart review of patients on warfarin therapy who were prescribed an antibiotic in the Durham VAMC ED and filled it at the Durham VAMC pharmacy from July 1, 2009 through June 30, 2011 was designed. The study population included patients on warfarin monitored in a Durham VAMC anticoagulation clinic who were prescribed an antibiotic identified to interact with warfarin (amoxicillin, amoxicillin-clavulanate, azithromycin, ciprofloxacin, clarithromycin, doxycycline, fluconazole, metronidazole, moxifloxacin, and trimethoprim-sulfamethoxazole) in the Durham VAMC ED.

**RESULTS:** Of the 85 patients included in our study, 40% had INR follow-up within 7 days of antibiotic initiation. Communication between the ED and anticoagulation providers regarding the drug interaction was documented in the medical record for 25.9% of evaluated patients. Five patients had minor bleeding events and three experienced a critical INR. No patients included in our study had a major bleeding event or required the administration of vitamin K.

**CONCLUSION:** Fewer than half of warfarin-treated patients prescribed an interacting antibiotic in the ED had INR follow-up completed within 7 days of antibiotic initiation. Communication alerting the anticoagulation providers occurred in only a quarter of evaluated patients. These results suggest the need for improved communication between providers to ensure appropriate INR monitoring in patients receiving antibiotics that may interfere with warfarin.

**336. The effect of changing from simvastatin to rosuvastatin on the international normalized ratio of patients taking warfarin.** Kristen E. Taseca, Pharm.D., Mary H. Parker, Pharm.D., BCPS (AQ, Cardiology), Debra W. Kemp, Pharm.D., BCACP, Stephanie B. Hollowell, Pharm.D., BCPS, Jennifer Whittington, Pharm.D.; Durham VA Medical Center, Durham, NC

**PURPOSE:** This study evaluated the effect of rosuvastatin on the INR of patients taking warfarin in patients who were previously taking simvastatin. The goal of this study is to develop a clinical practice guideline for management of this interaction in our medical facility's anticoagulation service.

**METHODS:** A retrospective chart review of patients taking warfarin who were switched from simvastatin to rosuvastatin during

January 1, 2010 to December 31, 2011 was conducted at the Durham VA Medical Center. This study included patients who maintained a stable INR defined as remaining within  $\pm 0.3$  of the recommended range for the past two clinic visits. Charts were reviewed to determine changes in INR values, warfarin dosage adjustments made within 2 months of their statin switch date and the incidence of any bleeding events.

**RESULTS:** Thirty-two patients were converted from simvastatin to rosuvastatin while taking warfarin during the designated study period. Comparison of mean INR pre- and post- statin switch revealed that no clinically significant change in INR occurred after conversion (2.39 to 2.37). In the 28% of patients who required dose modification, 67% required an increase in warfarin weekly dose to maintain INR goal. No major adverse events were noted.

**CONCLUSION:** Patients taking warfarin were safely converted from simvastatin to rosuvastatin without clinically significant impact on their INR. In our study population, we found variability in warfarin dose requirements associated with this therapy change. Further analysis is required to develop a practice guideline for our facility.

## HIV/AIDS

**337. Pharmacist impact on CKD screening of HIV-infected patients.** Khayla Payton, Pharm.D., E. Kelly Hester, Pharm.D., BCPS, AAHIVE, Anne M. Liles, Pharm.D., Kala Trotter, Pharm.D.; Harrison School of Pharmacy, Auburn University, Auburn, AL

**PURPOSE:** It is estimated that 30% of HIV-infected patients have evidence of proteinuria on urinalysis. As a result, practice guidelines recommend a urinalysis upon diagnosis of HIV and annually thereafter for high-risk patients to identify and appropriately manage CKD. In 2010, a chart review (n=101) was conducted at an HIV clinic in Montgomery, Alabama to determine compliance with practice guidelines for CKD screening in HIV-infected patients. Results indicated an 11% compliance rate. The primary objective of this study was to evaluate improvement in CKD screening at this clinic following a pharmacist intervention. Secondary objectives included percentage of patients with proteinuria and appropriate management.

**METHODS:** CKD screening reminders were placed in patient charts October 19–December 31, 2011. A retrospective chart review was performed in April 2012. Data collected included demographics, serum creatinine, urinalysis, highly active antiretroviral therapy (HAART), current medications, viral load, CD4 count, concomitant disease states (HTN, hepatitis C, diabetes), and blood pressure. Results: Of 118 patients reviewed, 58% had orders for urinalysis. Of those patients with a urinalysis, 40% had proteinuria (n=26). Of all patients reviewed, 25% had CKD and 88% had at least two risk factors for CKD. ACE-inhibitors were prescribed in only 46% of those with proteinuria. Of those patients reviewed with diabetes, 42% were not screened and 33% had proteinuria.

**CONCLUSION:** The chart reminders had a positive impact improving CKD screening frequency from 11% to 58%. The 40% incidence of proteinuria observed in this population is higher than previously published (30%) signaling the need for greater vigilance in this high risk population. Optimization of pharmacotherapy in the primary care of these patients is needed. This study prompted development of quality improvement measures implemented in the transition to an electronic medical record. Routine CKD screening and appropriate management is imperative to limit progression.

## Infectious Diseases

**338. Evaluation of the ATLAS scoring system in the prediction of clinical cure and recurrence of *Clostridium difficile* infection in a large Academic Hospital.** Shauna M. Jacobson, Pharm.D.<sup>1</sup>, Douglas Slain, Pharm.D., BCPS<sup>2</sup>; (1)West Virginia University

Healthcare, Morgantown, WV; (2) West Virginia University School of Pharmacy, Morgantown, WV

**PURPOSE:** CDI treatment has become challenging with the advent of hypervirulent strains and increased presence of potential CDI risk factors. Several risk factors have been associated with the occurrence of severe CDI or CDI recurrence. Risk and severity assessment tools have been developed to aid treatment decisions. Recently a scoring system known as ATLAS based on five characteristics (age, temperature, leukocytosis, albumin, and concomitant antibiotics) was tested retrospectively in two studies. ATLAS scores correlated with mortality and cure rates (inversely). Thirty day recurrence rates did not correlate statistically with ATLAS scores. Neither study assessed patients treated with metronidazole. The purpose of this study is to determine if ATLAS predicts cure and recurrence (< 90 days) in patients receiving metronidazole and/or vancomycin.

**METHODS:** This was an observational study conducted with adult patients with a positive *C. difficile* toxin-PCR 2-step test treated with metronidazole and/or vancomycin. Potential risk factors for severe CDI, decreased cure rates, or recurrence were recorded as were variables to calculate ATLAS scores. Cases were considered complicated if ileus, perforation, megacolon, colitis, colectomy, or hypotension was present.

**RESULTS:** A total of 245 patients met inclusion criteria for the study. Median ATLAS score was 5. ATLAS scores showed a significant inverse association with cure ( $p=0.009$ ), but not with recurrence ( $p=0.901$ ). The only ATLAS component to be independently associated with cure was concomitant use of antibiotics ( $p=0.022$ ). Longer courses of vancomycin were associated with more cures ( $p=0.0009$ ), but no difference in recurrence was found ( $p=0.170$ ). Complicated cases were less likely to be cured ( $p=0.027$ ). The only factors associated with recurrence were complicated CDI ( $p=0.002$ ) and antibiotics continued after CDI treatment ( $p=0.055$ ).

**CONCLUSION:** The ATLAS score appears to correlate well with cure rates in patients receiving vancomycin and/or metronidazole. The ATLAS score does not appear to be useful for predicting recurrence.

**339. Comparison of length of stay in two treatment severity criteria for *Clostridium difficile* infections.** Kyle A. Sobecki, B.S., M.S., Pharm.D., Patrick J. Gallegos, Pharm.D., BCPS, Bhavin K. Mistry, Pharm.D., BCPS; Akron General Medical Center, Akron, OH

**PURPOSE:** IDSA *C. difficile* (CDI) guidelines stratify severity based on expert opinion. IDSA cites Zar et al. as evidence of vancomycin superiority over metronidazole in severe disease. The goal of this study was to determine which criteria for stratifying CDI severity is a better predictor of health care utilization.

**METHODS:** This retrospective review included adults  $\geq 18$  with a positive test for CDI. Patients were excluded if they received > 4 doses of metronidazole or vancomycin and switched therapy, received combination metronidazole and vancomycin, or were prescribed other CDI medications. The primary outcome was the difference in length of stay (LOS) between the IDSA group compared to the Zar group in patients treated with metronidazole. Secondary outcomes examined vancomycin-treated patients, readmission rates, economic impact, and proportion prescribed appropriate therapy. Subgroup analysis excluded critical care patients.

**RESULTS:** Mild patients treated with metronidazole in the IDSA group had a LOS of 4.7 days, while severe patients had a LOS of 4.0 days ( $p=0.41$ ). Mild patients in the Zar group had a LOS of 4.4 days, while severe patients had a LOS of 4.1 days ( $p=0.74$ ). The absolute difference between groups was not significant. There were no differences between patients treated with vancomycin. There were nine readmissions; six were treated with metronidazole. LOS in non-critical floors were similar. Patients treated with metronidazole had a LOS of 4.1 days and cost \$5,801, while patients treated with vancomycin had a LOS of 5.9 days and cost \$8,348. Appropriate therapy occurred in < 60% of patients. There were 21 total deaths, 16 of which were treated with metronidazole. There was a higher death rate in patients stratified as severe and undertreated with metronidazole ( $p=0.11$ ).

**CONCLUSION:** There were no statistical differences between criteria groups. There was a higher death rate in severe patients treated with metronidazole. Less than 60% of patients received appropriate therapy.

**340. Evaluation of the treatment of candiduria in intensive care unit and non-intensive care units patients at an Academic Medical Center.** John Radosevich, Pharm.D., David E. Nix, Pharm.D., BCPS, Brian Erstad, Pharm.D., FASHP, FCCM, FCCP, BCPS; The University of Arizona College of Pharmacy, Tucson, AZ

**PURPOSE:** This study evaluated candiduria therapy in adult intensive care unit (ICU) and non-ICU patients at an academic medical center in order to define the epidemiology, management, and outcomes associated with candiduria in these patient populations.

**METHODS:** Medical records of patients with candiduria from July 2010 through June 2011 were reviewed in this retrospective, single center study. Patients were included if they were between the ages of 18 and 75 years, and were admitted for a minimum of 5 days. Laboratory data, urinary symptoms, risk factors for urinary and invasive candidiasis, treatment decisions, and patient outcomes were collected and evaluated.

**RESULTS:** One-hundred and thirty-two patients met inclusion criteria, 67 from intensive care units (ICU) and 65 from non-intensive care units (non-ICU). The mean age was just over 50 years, and the majority of patients were female in both groups. The mean APACHEII score for the ICU patients was  $24.9 \pm 8.1$ . Patients in the ICU were more likely to have risk factors for invasive candidiasis and candiduria compared to non-ICU patients. *Candida albicans* was the most frequently identified isolate, followed closely by *Candida glabrata*. Fluconazole was the most commonly used antifungal agent, followed by micafungin and voriconazole. Hospital length of stay did not vary significantly between the groups ( $p=0.0628$ ). All cause mortality was significantly higher in the ICU patients compared to the non-ICU patients (22.4% versus 3.1%,  $p=0.0012$ ).

**CONCLUSION:** Differences exist between ICU and non-ICU patients that develop candiduria with respect to risk factors, management, and outcomes. Antifungals were often used inappropriately (i.e. asymptomatic patients) in both patient cohorts. Especially concerning was the frequent use of micafungin and voriconazole since neither is recommended in the consensus treatment guidelines and both have very poor urinary penetration.

## Nephrology

**341. Predictors of vitamin D status among maintenance hemodialysis patients.** Magdalene M. Assimon, Pharm.D., M.S.<sup>1</sup>, Page V. Salenger, M.D.<sup>2</sup>, Darius L. Mason, Pharm.D., BCPS<sup>1</sup>; (1) Albany College of Pharmacy & Health Sciences, Albany, NY; (2) Rubin Dialysis Center, Clifton Park, NY

**PURPOSE:** Vitamin D deficiency has been associated with increased mortality in end-stage renal disease. Despite a high prevalence of hypovitaminosis D in the hemodialysis (HD) population, it remains unclear which patients are at increased risk. The objective of this study was to identify risk factors for vitamin D deficiency among maintenance HD patients.

**METHODS:** A cross-sectional study was conducted at Rubin Dialysis Centers in July 2009. Inclusion criteria were: age  $\geq 18$  years and availability of laboratory results to verify outcome status. Vitamin D deficiency was defined as a serum 25-hydroxyvitamin D (25[OH]D) level < 30 ng/ml. Due to the high proportion (>10%) of patients with 25[OH]D concentrations < 30 ng/ml, log-Poisson regression was utilized to determine factors independently associated with vitamin D deficiency.

**RESULTS:** One hundred-sixteen patients (59% male, 84% white, 57% diabetic etiology) with a mean  $\pm$  SD age =  $63.3 \pm 16.4$  years, HD vintage =  $3.3 \pm 2.9$  years and  $25[OH]D = 32.3 \pm 16.3$  ng/ml were included in this analysis. Overall, 53% of patients ( $n=62$ ) were vitamin D deficient and 35% ( $n=42$ ) were receiving ergocalciferol supplementation (mean weekly dose =  $41,071 \pm 15,442$  IU and

duration of therapy =  $9.05 \pm 6.14$  months). In multivariate analyses, lack of current ergocalciferol use (prevalence ratio [PR] = 1.60; 95% CI 1.07–2.41;  $p=0.0232$ ), BMI  $\geq 25$  kg/m<sup>2</sup> (PR = 1.57; 95% CI 1.02–2.40;  $p=0.0377$ ) and black race (PR = 1.59; 95% CI 1.21–2.11;  $p=0.0011$ ) were independently associated with vitamin D deficiency.

**CONCLUSION:** Suboptimal vitamin D status is prevalent among HD patients. BMI and race appear to be important predictors of vitamin D deficiency. Furthermore, these data suggest supplementation with ergocalciferol is effective for normalization of 25[OH] D levels in the HD population.

## Nutrition

**342. Evaluation of the efficacy of management for occluded enteral access.** Jenna M. Faircloth, Pharm.D., Joseph Ybarra, Pharm.D., Vanessa Kumpf, Pharm.D., Douglas Seidner, M.D.; Vanderbilt University Medical Center, Nashville, TN

**PURPOSE:** Occluded enteral access can compromise clinical outcomes by delaying enteral nutrition and medication administration. Immediate-release pancreatic enzymes mixed with sodium bicarbonate have demonstrated efficacy in restoring patency of feeding tubes. Due to the removal of these pancreatic enzyme formulations from the market in April 2010, a lack of evidence-based data exists for the management of occluded feeding tubes. The objective of this study is to compare the efficacy of enteric coated pancrelipase mixed with sodium bicarbonate and a declogging kit for management of occluded enteral access.

**METHODS:** A retrospective, observational, single-center study was conducted evaluating occlusion events in patients 18 years or older, receiving tube feeding, and with an occluded feeding tube managed with enteric coated pancrelipase mixed with sodium bicarbonate and/or the declogging kit. The study was performed from January 2012–March 2012. Data collection consists of extracting information from the electronic medical record and an interview with nursing staff. The primary outcome for this study includes efficacy of restoring patency using enteric coated pancrelipase crushed and mixed with sodium bicarbonate and a declogging kit for managing occluded feeding tubes. Efficacy is identified per nursing report or chart review.

**RESULTS:** A total of 76 occlusion events meeting inclusion criteria have been reviewed thus far. Patency was restored in 46.8% ( $n=47$ ) in declogging kit treatment group and 44.8% ( $n=29$ ) pancrelipase with sodium bicarbonate treatment group ( $p=0.91$ ). A trend toward a higher rate of efficacy for nasogastric tubes is present for the declogging kit compared to pancrelipase and sodium bicarbonate (pancrelipase 7/29 [38.8%] versus declogging kit 18/18 [50%],  $p=0.44$ ).

**CONCLUSIONS:** Delayed release, enteric coated pancrelipase crushed and mixed with sodium bicarbonate and a declogging kit are reasonable options for treatment of occluded enteral access. Analysis of additional patients is ongoing.

## Pulmonary

**343. Impact of interdisciplinary chronic obstructive pulmonary disease (COPD) management on patient quality of life.** James S. Wheeler, Pharm.D.<sup>1</sup>, Shaunta' M. Ray, Pharm.D., BCPS<sup>1</sup>, Andrea S. Franks, Pharm.D., BCPS<sup>1</sup>, Lucky C. Morton, LPN<sup>2</sup>, Amy B. Stevens, M.D.<sup>2</sup>; (1) University of Tennessee Health Science Center College of Pharmacy, Knoxville, TN; (2) University of Tennessee Graduate School of Medicine, Knoxville, TN

**PURPOSE:** To determine whether COPD disease state management, as part of an interdisciplinary pulmonary clinic, improves patient quality of life as measured by the COPD Assessment Test™ Score (CAT™ score).

**METHODS:** This is a prospective study of patients with COPD receiving interdisciplinary management through a focused pulmonary team within a family medicine residency clinic. The pulmonary team consists of an attending faculty physician, a pharmacy resident, a faculty pharmacist, and a nurse. Patients receive one-

on-one disease state education and knowledge assessment, inhaler instruction and evaluation, smoking cessation counseling and pharmacotherapy (if applicable), spirometry (if appropriate) and medication optimization. As part of symptom assessment, study subjects complete the CAT™ at the initial encounter and again at a follow up encounter at least 4 weeks following the initial assessment. The CAT™ measures the impact of COPD on a patient's health status with a score ranging from 0 to 40 ( $> 30$  = very high impact,  $> 20$  = high impact, 10–20 medium impact,  $< 10$  = low impact). Change in overall mean CAT™ score from initial visit to follow up assessment will be compared using Wilcoxon Signed Rank Test.

**RESULTS:** To date, nine patients have completed the initial CAT™ and three patients have completed a follow up CAT™. Mean age of patients in the initial group is 58 years with over half being female and current smokers with a pack-year history of 29. Mean CAT™ score at initial assessment is 20.

**CONCLUSION:** Based on the preliminary data, CAT™ scores improved. This improvement may be due to more appropriate medication use, close follow up and/or better understanding of COPD and its management. We expect to see similar results with the other seven patients and with future patients enrolled.

## STUDENT SUBMISSIONS

### ADR/Drug Interactions

**344. Variations in citalopram and escitalopram drug interaction inclusion and severity level classifications with drugs that can prolong the QTc interval among selected drug compendia.** Jeffery Alborn, Pharm.D., Candidate, Kevin Sullivan, Pharm.D., Candidate, Patricia R. Wigle, Pharm.D., Shauna Buring, Pharm.D., Jeff Guo, Ph.D.; JLW College of Pharmacy, Cincinnati, OH

**PURPOSE:** The purpose of this project was to evaluate selected drug-drug interactions with citalopram, escitalopram and agents capable of prolonging the QTc interval for disparities in inclusion and severity level classifications amongst and within various widely used drug compendia.

**METHODS:** At the JLW College of Pharmacy, faculty, preceptors and students have access to four online drug compendia: Micromedex, E-Facts & Comparisons, Lexicomp and Clinical Pharmacology. Twenty-four medications known to prolong the QTc interval were identified and evaluated for interaction with either citalopram or escitalopram. The inclusion-status of each drug interaction was noted, and if applicable, the drug pair's severity level classification was recorded as it appeared in the four drug databases.

**RESULTS:** Each database varied in the number of drug interactions included, ranging from 21/24 citalopram-QTc prolonging drug interactions in E-Facts & Comparisons to 24/24 interactions in both Lexicomp and Clinical Pharmacology. For the escitalopram-QTc prolonging drug pairs, 0/24 interactions were found in Micromedex as compared to 24/24 interactions found in Lexicomp, while E-Facts & Comparisons yielded 1/24 interactions to Clinical Pharmacology's 8/24 interactions. For those interactions included in the several drug databases, a degree of variability was seen in severity level classification, ranging from "major" or "severe," to "contraindicated" and "avoid."

**CONCLUSION:** Faced with variations in inclusion and classification of interaction severity when consulting popular drug compendia, the clinician's ability to render important therapeutic decisions may be compromised. It would therefore be wise for healthcare professionals to be aware of the criteria used to classify drug-drug interactions in their particular database-of-choice, and to avail themselves of two or more drug databases when formulating important clinical decisions.

**345. Variations in dabigatran, rivaroxaban and warfarin drug interaction inclusion and severity level classifications among selected drug compendia.** Kevin Sullivan, Pharm.D., Candidate, Jeff Alborn, Pharm.D., Candidate, Patricia R. Wigle, Pharm.D., Shauna

Buring, Pharm.D., Jeff Guo, Ph.D.; JLW College of Pharmacy, Cincinnati, OH

**PURPOSE:** This project sought to examine selected drug-drug interactions involving dabigatran, rivaroxaban and warfarin for both inclusion and variations in severity level classification among four commonly used online drug databases.

**METHODS:** The James L. Winkle College of Pharmacy provides its faculty and students with access to four online drug compendia: Micromedex, E-Facts & Comparisons, Lexicomp and Clinical Pharmacology. In this analysis, 56 medications known to interact with either dabigatran or rivaroxaban were identified. To determine whether these interactions were unique to dabigatran or rivaroxaban, warfarin was evaluated as a comparison agent. Each of the four databases was evaluated for the presence of these interactions while assessing severity level classifications for any disparities.

**RESULTS:** The databases documented differing numbers of interactions and varying severity level classifications. The number of documented dabigatran interactions in the databases ranged from 12/56 (21%) to 52/56 (93%). Similar ranges were seen with rivaroxaban and warfarin. Differences in severity level classification were difficult to assess due to these wide inclusion ranges.

**CONCLUSION:** Dabigatran and rivaroxaban are newer, oral anticoagulants with fewer drug interactions than warfarin. Nevertheless, a number of drug interactions are similar for all three agents. This evaluation demonstrated disparities both in interaction inclusion and in severity level classification. It is therefore recommended that a clinician consult two or more compendia when making therapeutic decisions with these important medications.

### Ambulatory Care

**346. Student College of Clinical Pharmacy (SCCP) members provide student driven diabetes education to behavioral health care case managers.** *Matthew C. Reale, Pharm.D., Candidate, Shannon Burchett, Pharm.D., Candidate, Tahani Mansour, Pharm.D., Candidate, David A. Shifrin, Pharm.D., Candidate, Mate M. Soric, Pharm.D., BCPS, Patrick J. Gallegos, Pharm.D., BCPS, Sara Dugan, Pharm.D., BCPP; Northeast Ohio Medical University (NEOUCOM), Rootstown, OH*

**PURPOSE:** The primary purpose of this study is to evaluate the effectiveness of a student led presentation concerning diabetes mellitus in mental health patients to improve patient care by case managers. The secondary outcome was to evaluate the case managers' response to student led diabetes mellitus educational session.

**METHODS:** The Northeast Ohio Medical University Student College of Clinical Pharmacy (SCCP) membership partnered with Community Support Service Incorporated to deliver an educational presentation regarding the risks of diabetes mellitus in mental health patients. Presentations were scheduled on multiple occasions in May of 2012 to accommodate differing case managers schedules. The case managers were given a voluntary and anonymous survey that was used to assess various items including, but not limited to; pertinence of presented materials, level of comfort with student presenters, application of covered skills, and overall satisfaction of the educational sessions and student presenters.

**RESULTS:** Descriptive statistics to be evaluated upon completion of the survey.

**CONCLUSION:** Pharmacy students have a great opportunity to educate local case managers on ways to improve care for mental health patients who are at an increased risk of acquiring diabetes mellitus. These educational sessions were designed to increase the case manager's awareness of risk factors and complications of diabetes in their patient population, thereby, allowing for improved patient care. By using the survey tool and collecting information, we can assess the overall impact that pharmacy students can have indirectly on patient care.

**347. Characteristics of patients referred for comprehensive cardiovascular management by a pharmacist.** *Joseph Van Tuyl, Pharm.D., Candidate, 2013, Toni Ripley, Pharm.D., R. Chris*

Rathbun, Pharm.D., BCPS; The University of Oklahoma College of Pharmacy, Oklahoma City, OK

**PURPOSE:** We hypothesize that patients referred to a clinical pharmacist for comprehensive outpatient management will be more complex than populations with advanced cardiovascular disease (CVD) described in the literature. A retrospective study will be conducted to examine the characteristics of patients referred to a pharmacist-managed cardiovascular clinic by a hospital-based, private cardiologist group. Characteristics of the referred population were then compared with characteristics of other advanced CVD populations (e.g. heart failure [HF]) in the literature.

**METHODS:** A pharmacist-managed cardiovascular clinic was initiated in a private cardiovascular clinic in January 2012 and is open to referral by cardiologists. All patients seen by the clinical pharmacist are entered into an Excel database (referring provider, referral authorizations, date of visit, patient characteristics, comorbidities, and medications); descriptive analysis on this database for patients seen January 1, 2012 through September 30, 2012 will be presented. A comparison with other populations with advanced CVD described in the literature will also be presented.

**RESULTS:** Forty-eight patients have been analyzed to date (January 1, 2012–May 31, 2012).

Patient characteristics	Pharmacist clinic (N=48)	Advanced CVD populations in literature (N=63176)*
Mean age, years (SD)	68.1 ( $\pm$ 11.1)	61–62
Male, No (%)	23 (48%)	28–42%
Hypertension, No (%)	42 (88%)	
HF, No (%)	40 (83%)	
Coronary artery disease (CAD), No (%)	32 (67%)	
HF plus CAD, No (%)	29 (60%)	
HF or CAD, No (%)	43 (90%)	
Mean medications per patient (SD)	15.7 ( $\pm$ 5.7)	7.4–10.4

\*Advanced CVD = HF, CAD, or multiple risk factors for CVD.

**CONCLUSIONS:** This preliminary analysis shows that patients referred by specialized cardiovascular providers have highly complex CVD and significant polypharmacy. The extent of polypharmacy is greater than reported in populations with advanced CVD. These data support inclusion of pharmacists in the management of patients with advanced CVD, even in addition to specialized care.

**348. A retrospective study evaluating hemoglobin A1C (HgbA1C) control in a pharmacist run diabetes clinic.** *Raynold V. Yin, B.S., Josephine A. Quach, B.S., Justin W. Bouw, Pharm.D., Rebecca A. Keel, Pharm.D.; California Northstate University College of Pharmacy, Rancho Cordova, CA*

**PURPOSE:** This retrospective study evaluates the impact of a pharmacist-managed diabetes program on lowering Hemoglobin A1C (HgbA1C) using a structured diabetes mellitus (DM) education class combined with individualized disease state management.

**METHODS:** This retrospective outcomes study focuses on the DM population in the Sacramento County Primary Care Clinic. Patients who were included in this study were referred to the DM clinic by their primary care physician (PCP). The clinic is comprised of two components: (i) a DM education class and (ii) a pharmacist-managed DM medication management program designed to help patients achieve individualized goals based on the ADA guidelines. Newly diagnosed patients with HgbA1C > 8% or established patients with HgbA1C > 9%, significant compliance issues, and/or signs and symptoms of DM complications are eligible for disease state management. The DM education class is a structured group-based intervention, providing basic information on disease state, and focusing on principles of self-management. Patients are followed in clinic until discharge, which occurs if the patient meets individualized glycemic goals, if

they no-show two appointments in a row, or at the PCP's request.

**RESULTS:** In progress, pending IRB approval.

**CONCLUSION:** As challenges and medication regimens for patients become more complicated it becomes increasingly vital for pharmacist to engage in patient education and medication management. Consequently this study attempts to illustrate the importance of utilizing pharmacists in the primary care setting when treating patients with DM, specifically exploring the effects of combining a structured group-based educational intervention with individualized clinical management.

**349. Implementation of a medication reconciliation service in a primary care clinic.** *Ashley N. Chasse, Pharm.D., Candidate, 2013, Becky L. Armor, Pharm.D., C.D.E.; University of Oklahoma College of Pharmacy, Oklahoma City, OK*

**PURPOSE:** To evaluate the potential role of pharmacists and student pharmacists in conducting medication reconciliation services in a primary care clinic. The requirement for health systems to conduct medication reconciliation provides both an educational and service opportunity for pharmacists. This service is part of an existing learning experience for students and residents designed to improve patient interview skills, identify medication discrepancies, identify and resolve drug related problems.

**METHODS:** Clinic staff identified recently discharged patients and contacted them to participate in a onetime medication reconciliation visit with a pharmacist. Patients were scheduled prior to the hospital follow-up visit with the physician. Medication discrepancies and recommendations for resolving drug related problems were communicated with the physician.

**RESULTS:** Thirty seven patients were seen between September 2011 and May 2012. Interventions were categorized into twelve actions that could be performed to prevent adverse drug events and unwanted outcomes. The most common interventions were non adherence/underuse (8), order lab (10) and identifying untreated medical problems (8). The most common actions taken were to discontinue a prescription (8), new prescription (6), order tests (8) and education (12). The types of lab tests that were ordered included blood pressure, blood glucose, thyroid levels, potassium and CBC.

**CONCLUSIONS:** Primary care based pharmacists and student pharmacists can identify and resolve drug related problems during the transition between hospital and home. At least one intervention was detected for each patient. Having access to medical records in outpatient and hospital databases and having the drug knowledge necessary to address interventions allowed us to evaluate the drug therapy needs of patients in this transition. Future plans include tracking outcomes of the service, particularly for reduced readmission rates.

## Cardiovascular

**350. Clinical study of effect of proton pump inhibitors on efficacy of clopidogrel in patients with acute coronary syndromes.** *Parag R. Patel, Jr, M.Pharm; Shri Sarvajani Pharmacy College, Mehsana, Mehsana, India*

**PURPOSE:** The objectives for this study were to evaluate the significance of this interaction on clinical efficacy of clopidogrel and also to make comparative assessment among different PPIs used with clopidogrel.

**METHODS:** Comparison of clopidogrel efficacy and rate of Major Adverse Cardiac Events (MACE) was carried out in patient with Acute Coronary Syndrome (ACS) treated at Life Care Hospital's Ahmedabad. Patients taking Clopidogrel with PPI (n=39) were compared against patients taking clopidogrel alone (n=36). They were observed for platelet aggregation function by light transmission aggregometry and incidence of MACE like rehospitalisation, reinfarction, restenosis, stroke and death. The results were compared for their significances using ANOVA and chi-square analysis.

**RESULTS:** Inhibition of platelet aggregation was found significantly reduced in patient taking concomitant PPI compared to patients taking clopidogrel alone (Mean% IPA  $16.04 \pm 1.99\%$  Versus  $23.79 \pm 1.83\%$ ,  $p < 0.05$ ). Mean% IPA was found significantly reduced in patient taking Omeprazole (13.68%) as compared to Pantoprazole (16.78%) and Rabeprazole (17.18%). Incidence of MACE was also found more in patient taking concomitant PPIs.

**CONCLUSION:** Concomitant use of PPIs led to inhibition of antiplatelet effect and clinical efficacy of Clopidogrel. Omeprazole is more prone to interact with clopidogrel compared to other PPIs. It could not be conclusively established whether this interaction could lead to increase in MACE.

**351. Beyond heart failure: comprehensive review to improve the care of heart failure (HF) patients by clinical pharmacist at the Portland Veterans Affairs Medical Center (PVAMC).** *Sarah J. Nigro, B.S., Abby E. Floeter, B.S., Harleen Singh, Pharm.D.; Oregon State University/Oregon Health Science University, College of Pharmacy, Portland, OR*

**BACKGROUND:** Heart failure (HF) patients present with multiple competing comorbidities which results in polypharmacy – leading to non-compliance, drug-drug and drug-disease interactions. A comprehensive drug therapy review is important to screen for response to therapy, drug interactions, or contraindications to medications.

**PURPOSE:** The purpose of this project is to improve quality of care for HF patients by providing a comprehensive review of medications and comorbidities.

**METHODS:** Medical records of patients managed by the pharmacist-run HF clinic over the past year were abstracted. Patients with only one clinic visit were excluded from the analysis. A chart audit form was developed to assess quality of care in five areas: laboratory monitoring, medication reconciliation, referrals to specialty clinics, recommendations to primary care providers (PCPs), and medication adjustments. All HF clinic notes between the present day and the date of first clinic visit were reviewed to quantify interventions. Data were analyzed using descriptive statistics.

**RESULTS:** In the past year, 41 patients were seen by the pharmacist. To date, electronic medical records of 35 patients were screened. Of those, three patients had only one clinic visit and were excluded from analysis, leaving 32 for further evaluation. A total of 51 recommendations were made to PCPs, of which 29 (57%) were acted on by the PCP resulting in therapy adjustments. Nineteen patients (59%) required updated laboratory values to assess comorbidities. Among these patients, 9 (47%) received therapy modifications to control comorbidities. Referrals were made when indicated. Fifteen patients (47%) received at least one referral and were subsequently scheduled with a specialty clinic. Medication reconciliation identified 38 drug-related problems which were all resolved with therapy adjustments.

**CONCLUSIONS:** The clinical pharmacist trained in HF management provided effective comprehensive care. Our results demonstrate the quality of care pharmacists provide to manage this challenging disease.

**352. Genitourinary hemorrhage associated with coadministration of dabigatran and amiodarone: a case report.** *Dante A. Gravino, III, Pharm.D., Candidate<sup>1</sup>, Kristina M. Kipp, Pharm.D.<sup>2</sup>, Amber E. King, Pharm.D.<sup>1</sup>, Dorota Szarlej, Pharm.D.<sup>2</sup>, Fred Rincon, M.D.<sup>3</sup>; (1) Thomas Jefferson University, Jefferson School of Pharmacy, Philadelphia, PA; (2) Department of Pharmacy, Thomas Jefferson University Hospital, Philadelphia, PA; (3) Division of Neurotrauma and Critical Care, Thomas Jefferson University Hospital, Philadelphia, PA*

**PURPOSE:** To describe a genitourinary hemorrhage associated with co-administration of amiodarone, a P-glycoprotein (P-gp) inhibitor, and dabigatran, a P-gp substrate, and to review the published literature on the topic. P-glycoprotein is a plasma membrane transport protein that functions as an efflux pump in the

gastrointestinal tract (GIT), kidneys, liver and brain. In the GIT, P-gp transports drugs from the cell membrane to the gut lumen. P-gp inhibition leads to increased plasma concentrations of P-gp substrates. We report a 76 year-old male who presented to the hospital in atrial fibrillation, with rapid ventricular response. Upon admission, a genitourinary hemorrhage was discovered. Current outpatient medications included amiodarone 400 mg TID for rhythm control and dabigatran 150 mg BID for stroke prevention. The patient's PTT, PT and INR were elevated upon admission. His CrCl was 59 ml/minute. Dabigatran was held and the patient received blood products, but not hemodialysis. Eventually the dabigatran was restarted and the patient was discharged home on dabigatran 150 mg BID and amiodarone 400 mg daily.

**METHODS:** We performed a MEDLINE search (1946–June 2012) using keywords dabigatran, amiodarone and p-glycoprotein.

**RESULTS:** We found no published case reports of interactions between amiodarone and dabigatran. Pharmacokinetics studies reported that P-gp inhibition of dabigatran by amiodarone leads to increases in AUC ranging from 12% to 60%. Currently the US package labeling does not recommend dose adjustments for concurrent use of dabigatran and amiodarone in patients with normal renal function. According to the European Medicines Agency, however, concomitant administration of dabigatran and amiodarone requires decreased dabigatran dosing when used for postoperative thromboprophylaxis.

**CONCLUSION:** This is among the first published case reports of a hemorrhage associated with co-administration of dabigatran and amiodarone in a patient with normal renal function. Caution and clinical judgment must be used when using these agents in combination.

**353. QT prolonging effects of intravenous haloperidol: does every patient need electrocardiogram monitoring?** *Christine E. Puschak, Pharm.D., Candidate, Jill A. Rebeck, Pharm.D., BCPS, FCCM, FCCP, Kathy M. Makkar, Pharm.D., BCPS; Lancaster General Health, Lancaster, PA*

**PURPOSE:** Recent warnings of QT prolongation and torsades de pointes with intravenous (IV) haloperidol suggest electrocardiogram (ECG) monitoring; however, it is debatable if necessary in every patient. The purpose was to evaluate patients who received IV haloperidol to determine the mean increase in QT interval from baseline and whether a dose correlation was present.

**METHODS:** An analysis of prospectively collected data was conducted on all patients who received IV haloperidol at our institution during four consecutive months. Patients were further included if continuous ECG monitoring occurred. The ECG recorded before the first dose of haloperidol represented the patient's baseline QT interval; subsequent results were obtained from daily rhythm strips and other ECGs during haloperidol administration. A QT interval greater than 470 ms was defined as prolonged.

**RESULTS:** A total of 64 patients were included (age  $71.5 \pm 18.6$  years) who received haloperidol for a median of 2 (1–3) days. Overall, the average QT interval increased from 464 to 488 ms after haloperidol initiation ( $p < 0.0001$ ). Of patients with a normal baseline QT interval, 55.3% developed a prolonged QT interval after haloperidol administration. The following risk factors did not demonstrate a significant effect on prolonging the QT interval: gender, age, hypothyroidism, diabetes, and hypertension, history of heart block, hypokalemia, hypomagnesemia, and bradycardia. Patients with a history of heart disease ( $p = 0.041$ ), history of arrhythmia ( $p = 0.015$ ), and use of concomitant QT prolonging medications ( $p = 0.024$ ) were more likely to develop QT prolongation. A prolonged QT interval was more common in patients who received a cumulative haloperidol dose greater than 5 mg compared to lower dosages (76.7% versus 52.9%,  $p = 0.048$ ).

**CONCLUSION:** At our institution, intravenous haloperidol administration was related to an increase in the QT interval. Patients who received a cumulative dose greater than 5 mg were more likely to develop a prolonged QT interval.

**354. Validation of a linear dosing nomogram for enoxaparin anti-Xa levels.** *Janna L. Currie, Pharm.D., MSCR, Candidate<sup>1</sup>, Jenna M. Huggins, Pharm.D., BCPS<sup>2</sup>, J. Erin Allender, Pharm.D., BCPS<sup>2</sup>, Oksana Barakat, Pharm.D., BCPS<sup>2</sup>; (1)Campbell University College of Pharmacy and Health Sciences, Cary, NC; (2)WakeMed Health and Hospitals, Raleigh, NC*

**PURPOSE:** Unlike heparin, enoxaparin is a low molecular weight heparin that does not require routine monitoring for safety and efficacy; however patient populations not prospectively studied in clinical trials may require anti-Xa level monitoring. These populations include: pregnant, cachectic, obese or pediatric patients, patients with significant burn injuries, recent trauma, renal failure, significant edema or coagulation factor disorders, and patients receiving therapeutic hypothermia. Although not well studied, proposed target peak anti-Xa levels for enoxaparin are as follows: prophylactic doses, 0.15–0.4 IU/ml; 1 mg/kg every 12 hour dosing, 0.5–1.0; 1.5 mg/kg every 24 hour dosing, 1.0–2.0. For adult patients not in the appropriate anti-Xa level target range, no dose adjustment guidelines have been established. Owing to the linear pharmacokinetics of enoxaparin, a dose adjustment nomogram was developed. This study sought to compare the percentage of patients achieving target anti-Xa ranges when the novel dosing nomogram was used versus non-nomogram based dose adjustment.

**METHODS:** Enoxaparin dosing nomogram-treated patients with anti-Xa levels obtained between May and September 2012 will be prospectively identified using a laboratory-generated report. In addition, patients with anti-Xa levels obtained between June 2011 and March 2012, prior to the implementation of the dosing nomogram, were retrospectively identified. Patients will be excluded if they are pregnant or less than 18 years of age. Patients in the prospective cohort will be excluded if the dose adjustment nomogram was not followed or if peak anti-Xa levels were not drawn appropriately (3–5 hours post-dose, at steady state). The following information will be collected for each patient: age, gender, height, weight, serum creatinine, indication for enoxaparin, enoxaparin dose(s), anti-Xa level result(s), and time elapsed from dose to anti-Xa level collection, and bleeding or thrombotic events during index hospitalization.

**RESULTS:** Pending. A chi-square test will be used to analyze the results for the primary endpoint.

**CONCLUSION:** Pending.

## Clinical Administration

**355. A retrospective comparison of venous thromboembolism prophylaxis compliance following implementation of computerized prescriber order entry.** *Russell L. Findlay, B.A., Benjamin Staley, Pharm.D., BCPS, Amy Rosenberg, Pharm.D., BCPS, Thomas Johns, Pharm.D., BCPS; Shands at the University of Florida, Gainesville, FL*

**PURPOSE:** The primary aim of the study is to evaluate the appropriateness of mechanical and pharmacologic venous thromboembolism (VTE) prophylaxis in hospitalized patients before and after the implementation of a computerized prescriber order entry (CPOE) system.

**METHODS:** Medical records of patients admitted before and after CPOE implementation were reviewed. The pre-CPOE group was comprised of a randomized sample of 50 patients (25 high risk and 25 moderate risk) admitted between April 1st, 2011 and May 1st, 2011. The post-CPOE group was comprised of a second randomized sample of 50 patients (25 high risk and 25 moderate risk) admitted between August 1st, 2011 and September 1st, 2011. Patients' demographics, medical histories, VTE risk factors, and VTE prophylaxis regimens were evaluated. Appropriateness of risk stratification and resulting pharmacologic and non-pharmacologic therapy selection upon admission were assessed. The following patients were excluded: less than 18 years of age, pregnancy, and length of stay less than 24 hours, and orthopedic surgery.

**RESULTS:** 30% of high risk and 76% of moderate risk patients in the pre-CPOE cohort were risk stratified appropriately. Forty-eight percent of high risk and 96% of moderate risk pre-CPOE patients received appropriate VTE prophylaxis. All data will be collected and analyzed before August 31st, 2012.

**CONCLUSION:** Initial evaluation has suggested that inappropriate risk assessment and regimen selection is prevalent in pre-CPOE paper-based order set processes. It is possible CPOE can mitigate these deficits. Conclusion is pending completion of data collection of post-CPOE group.

## Community Pharmacy Practice

**356. Improving prescription auxiliary labels to increase to increase patient understanding.** *Michelle Locke, B.S., Pharm.D., Candidate, Olayinka Shiyabola, Ph.D., Elizabeth Gripenrog, B.S., Pharm.D., Candidate, Jillian Helseth, B.S., Pharm.D., Candidate; South Dakota State University College of Pharmacy, Brookings, SD*

**PURPOSE:** To develop new, easy to understand prescription auxiliary labels. To compare the effectiveness of existing auxiliary labels to newly created ones to determine which label most clearly states its' purpose (and determine why). To compare the effectiveness of existing auxiliary labels to newly created ones by determining the relationship between ease of reading auxiliary labels and corresponding reading level.

**METHODS:** Adults from a minority background, who were able to understand English and did not have any hearing or vision loss, were the sample population. Existing and newly created auxiliary labels were showed to participants in a 10–15 minute interview and interpretations, level of understanding and literacy levels (using the REALM-R) were determined. The level of reading difficulty for all labels was determined using the Lexile Score, based on sentence length and word frequency. Data analysis included descriptive statistics and chi-square analysis for all quantitative data and inductive thematic analysis for all open-ended questions.

**RESULTS:** One hundred and twenty participants completed the study. Some existing auxiliary labels yielded Lexile scores above the sixth grade reading level while all the newly developed labels were third grade level and below. Newly developed labels were either the best understood or second best understood across the auxiliary labels. There was a statistically significant difference in participants interpretation of the 'take with food and milk' label based on level of education completed ( $\chi^2 = 20.857$ ,  $p=0.02$ ) and literacy level ( $\chi^2 = 26.785$ ,  $p=0.02$ ). All other auxiliary labels did not have significant associations with REALM scores.

**CONCLUSIONS:** Incorrect interpretations of auxiliary labels occur across populations. Simpler auxiliary labels with improved patient comprehension can be developed. Pharmacies must consider how to include and use existing manufacturer auxiliary labels that meet the acceptable criteria for patients' with low health literacy.

**357. Evaluation of vaccination rate against pertussis and promotional strategies for increasing awareness of vaccination implemented in community pharmacy practice.** *Anh T. Lam, Pharm.D., Candidate, 2013, Andre P. Lian, Pharm.D., Candidate, 2013, Nathan P. Lian, Pharm.D., Candidate, 2013, Elizabeth Sebranek Evans, Pharm.D., BCPS, CGP, Katherine Smith, Pharm. D., BCPS; Roseman University of Health Sciences College of Pharmacy, South Jordan, UT*

**PURPOSE:** Outbreaks of pertussis have gradually increased in infants, children, and adults due to lack of awareness about vaccinations against the disease and concern for causing autism. The rate of Tdap vaccinations is lingering well below targets of Healthy People 2020. According to the Centers for Disease Control and Prevention, 27,500 cases of pertussis were reported in the United States in 2010. Specifically in Utah, 11 cases were reported in April of 2012. Our study aims to identify the percentage of Utah community pharmacies offering Tdap, percentage of Tdap administered compared with other available vaccinations,

and strategies pharmacies use to promote awareness or adherence to immunization schedules.

**METHODS:** Surveys were distributed to more than 100 community pharmacies in the Salt Lake City area by fax and hand delivery by student pharmacists. Information requested included whether Tdap vaccines were offered, number of Tdap vaccines administered from May 2011 to May 2012, number of all vaccines administered from May 2011 to May 2012, and promotional strategies implemented regarding availability or importance of immunizations. Pharmacies reported number of administered vaccines from drug maintenance records. The inclusion criterion is provision of any type of immunizations including or excluding Tdap.

**RESULTS:** Of the community pharmacies receiving the survey, 47 pharmacies responded with the requested information but four were excluded from data analysis due to not meeting the inclusion criterion. All 43 pharmacies included in the data analysis offer influenza vaccinations while 47% offer Tdap. For promotional strategies, the most common method was outdoor posters with 77% of pharmacies using them to enhance awareness about immunizations. The least common method was telephone calls at 21%. Text messaging was not a form of promotion for any pharmacy. Results for percentage of Tdap administered compared to overall vaccinations are pending.

**CONCLUSION:** To be presented at the ACCP Annual Meeting.

## Critical Care

**358. *Candida glabrata* and *tropicalis* pneumonia in an immunocompetent patient.** *Grant McGuffey, Pharm.D., Candidate<sup>1</sup>, Denise Kelley, Pharm.D.<sup>1</sup>, Leslie A. Hamilton, Pharm.D., BCPS<sup>1</sup>, Michael R. Crain, M.D.<sup>2</sup>; (1) Auburn University, Auburn, AL; (2) Princeton Baptist Medical Center, Birmingham, AL*

**PURPOSE:** To describe the hospital course of an immunocompetent patient with necrotizing *Candida* pneumonia. While *Candida* species are common causes of invasive fungal infections, lower respiratory tract infections due to *Candida* are rare, especially in non-neutropenic patients. Mortality associated with invasive *Candida* can be high (47%) with limited evidence on optimal treatment. When *C. glabrata* is suspected, an echinocandin is preferred at least until susceptibility of isolate can be confirmed.

**METHODS:** We describe a 72 year old immunocompetent male admitted to our institution after a trip to Ecuador. He was admitted with sepsis and received empiric treatment for both histoplasmosis and tuberculosis.

**RESULTS:** This patient was discovered to have *Candida glabrata* and *tropicalis* pneumonia upon tissue biopsy and was treated successfully with micafungin.

**CONCLUSION:** : Though uncommon, *Candida* pneumonia should be suspected as part of the differential diagnosis of sepsis

**359. Potential adverse outcomes of succinylcholine used for rapid sequence intubation.** *Courtney Watts, Pharm.D., Candidate<sup>1</sup>, Erin Archibald, Pharm.D., Candidate<sup>1</sup>, Jennifer Felder, Pharm.D., Candidate<sup>2</sup>, Leslie A. Hamilton, Pharm.D., BCPS<sup>1</sup>, Michael R. Crain, M.D.<sup>3</sup>; (1) Auburn University, Auburn, AL; (2) Union University, Jackson, TN; (3) Princeton Baptist Medical Center, Birmingham, AL*

**PURPOSE:** Succinylcholine, a depolarizing neuromuscular blocker used during intubation, has a black box warning for use in pediatric patients due to the risk of rhabdomyolysis, hyperkalemia, ventricular arrhythmias, and cardiac arrest in patients with skeletal muscle myopathy, though it is very commonly used in adult patients. The purpose of this study was to outline potential adverse outcomes related to the use of succinylcholine for rapid sequence intubation in an adult patient.

**METHODS:** To describe the hospital course of a 58 year old patient admitted for the placement of a biventricular cardioverter defibrillator. During intubation for the procedure, the patient went into asystole and arrested. The patient received etomidate,

fentanyl, isoflurane, midazolam, and succinylcholine during rapid sequence intubation.

**RESULTS:** After the initial asystole, the patient developed hyperkalemia and rhabdomyolysis and ultimately expired after another cardiac arrest.

**CONCLUSION:** Though uncommon, succinylcholine is a potential cause of hyperkalemia, rhabdomyolysis, and cardiac arrest in susceptible patients.

**360. Evaluation of concurrent vancomycin and pentobarbital use and the achievement of therapeutic vancomycin trough concentrations in a Neurosciences Intensive Care Unit.** *Danielle N. Smidt, Pharm.D., Candidate, 2013*, Melissa C. Erin, Pharm.D., Candidate, 2013, Tyree H. Kiser, Pharm.D., BCPS; Skaggs School of Pharmacy & Pharmaceutical Sciences, University of Colorado, Aurora, CO

**PURPOSE:** Vancomycin is frequently utilized for empiric coverage or treatment of severe gram positive bacterial infections, while pentobarbital is indicated for barbiturate coma in the Neuro ICU. Pentobarbital is known to affect the metabolism of hepatically metabolized medications, but little is known about its effects on renal drug clearance. Anecdotal observations have shown that there is potential for reduced renal clearance and risk of supratherapeutic vancomycin drug exposure with concomitant administration. The purpose of this study was to evaluate a correlation between concurrent exposure of vancomycin and pentobarbital and risk of supra-therapeutic serum vancomycin trough concentrations.

**METHODS:** This retrospective case-control chart review study was approved by the Colorado Multiple Investigational Review Board. Adult patients receiving concomitant vancomycin and pentobarbital administration in the Neuro ICU at the University of Colorado Hospital between January 2000 and May 2012 were evaluated and compared to matched control patients receiving vancomycin without concomitant pentobarbital. Vancomycin and pentobarbital doses, frequency, duration and drug levels were evaluated between groups. The primary objective was evaluated by comparing the incidence of supratherapeutic vancomycin trough concentrations ( $> 20 \mu\text{g/ml}$ ) between groups. Additionally, vancomycin total daily dose and weight based dose were compared between groups. The Fisher Exact test and Mann Whitney U-test were used for categorical and continuous data analysis, respectively. A p value  $< 0.05$  was considered significant.

**RESULTS:** A total of 26 patients were evaluated; 13 in the pentobarbital plus vancomycin group and 13 in the vancomycin control group. All data has been collected and is in the process of being analyzed. Results are pending and will be available for the poster symposium at ACCP Annual Meeting in October 2012.

**CONCLUSION:** The results of this study will clarify if a therapeutic drug interaction exists between vancomycin and pentobarbital resulting in the requirement for lower vancomycin doses.

## Drug Information

**361. Analysis of online patient information resources for complementary and alternative medicine.** *Christopher Bui, Pharm.D., Bradi L. Frei, Pharm.D., BCPS, BCOP; The University of the Incarnate Word, Feik School of Pharmacy, San Antonio, TX*

**BACKGROUND:** Emerging technology gives patients access to many online resources about complementary and alternative medicine (CAM). Healthcare professionals often debate which online patient resource provides correct information and can be easily accessible.

**PURPOSE:** To analyze and compare online patient information resources to a healthcare professional information resource regarding CAM in order to establish a reliable patient information resource to recommend to patients.

**METHODS:** Six online patient information resources (NCCAM, NIH:ODS, MedlinePlus, Pharmacy Times, Wikipedia, and WebMD) were compared to one resource (Micromedex). Data were col-

lected from each electronic database on the following CAM therapies: fish oil, garlic, ginseng, soy, resveratrol, acupuncture, and tai chi. The evaluation of each resource was based on the correctness, clarity of content, ease of use, and the Flesch-Kincaid reading level.

**RESULTS:** The NCCAM resource contained all of the CAM and ranked the highest in the correctness of the information (8), clarity of content (9), ease of use (8) and had the lowest Flesch-Kincaid reading level (10.6). The Wikipedia resource did not contain all of CAM and obtained the lowest grade correctness of information (6), clarity of content (5), ease of use (4), and had the highest Flesch-Kincaid reading level (15.3).

**CONCLUSIONS:** NCCAM is the most accurate and easily navigated source for patient online CAM information. It should be recommended by healthcare professionals to patients.

**362. Comparison of drug information on Wikipedia: trade-name only versus generic drugs.** *Mollie Reidland, Pharm.D., Candidate, John A. Thompson, Pharm.D., Candidate; Southwestern Oklahoma State University College of Pharmacy, Weatherford, OK*

**PURPOSE:** Previous studies indicate that the drug information on Wikipedia is accurate but incomplete; however it remains a ubiquitous resource accessed by both healthcare providers and the lay public. The user-generated nature of Wikipedia articles presents possibility for bias. This study aims to determine if quantity or quality of drug information available on Wikipedia varies between drugs still under patent and drugs that have generic equivalents available.

**METHODS:** Drugs for comparison were chosen from the "Top 200 Drugs of 2010" published in Pharmacy Times, May 2011. Each corresponding Wikipedia article was downloaded as a PDF file and reviewed for length, accuracy, omission of major warnings, and number of revisions.

**RESULTS:** Pending project completion.

**CONCLUSION:** Pending project completion, highly likely to be complete before presentation, estimated end date 8/2012.

## Education/Training

**363. Factors predicting pharmacy student's interest in applying for pharmacy residency.** *Brian D. Chatterton, Pharm.D., Candidate, Spencer R. Crook, Pharm.D., Candidate, Elizabeth Sebranek Evans, Pharm.D., BCPS, CGP; Roseman University of Health Sciences, South Jordan, UT*

**PURPOSE:** Acceptance into a PGY1 residency program is becoming increasingly competitive. ASHP statistics from 2006 to 2010 show large increases in the number of applicants, and a disproportionately small increase in accredited PGY1 residency programs. We investigate what the predictive factors for seeking a PGY1 residency are in pharmacy students at Roseman University of Health Sciences. We hypothesize that as a student's education progresses, the student will be more likely to seek PGY1 training.

**METHODS:** We are surveying Roseman University pharmacy students during two consecutive academic years. We ask about their graduation year, paid internships, internship settings, career aspirations, and interest in applying for a PGY1 residency. Interest in applying for a pharmacy residency is compared for each characteristic. Surveys were electronically distributed to 512 students for the 2011–2012 school year (response rate = 231/512, 45.1%) and will be sent to 500 students during the 2012–2013 school year. Participation is voluntary and responses are anonymous.

**RESULTS:** The first round of surveys shows no statistically significant difference in residency aspirations between graduation classes. There is also no difference between students who are employed or unemployed as pharmacy interns. Students who work in hospital pharmacy were more likely to pursue a PGY1 residency than those who work in a community setting (RR = 2.23 [1.69–2.93]). Also, students who plan to pursue hospital careers were more likely than those who plan to work in retail to pursue residency (RR = 8.87 [4.89–16.08]). The second survey will be completed in Fall, 2012 in order to determine if there is a

significant difference from one academic year to the next in the classes graduating in 2013 and 2014.

**CONCLUSION:** To be presented at the 2012 ACCP Annual Meeting.

**364. A student-led "APPE Boot Camp": improving pharmacy student competency and confidence in pharmacotherapy knowledge.**

*Tiffany K. VanDervort, Pharm.D., 2013, Krista L. Donohoe, Pharm.D.; Virginia Commonwealth University, Richmond, VA*

**PURPOSE:** To implement and evaluate the effectiveness of student-led pharmacotherapy review sessions for third year pharmacy students in preparation for APPEs. In addition, to assess the effect of teaching a review session on students' confidence in leadership and public speaking roles.

**METHODS:** A needs assessment survey was administered to determine which pharmacotherapy topics should be reviewed by members of the Rho Chi Society. A pre-test and post-test consisting of five multiple choice questions based on the topic being reviewed was administered to students at three of the review sessions. Attendees also completed a subjective evaluation following each review session. Students who presented at the review sessions completed an evaluation of the effect of leading the review session on confidence measures such as public speaking and leadership skills.

**RESULTS:** Fifty-six students in the third year class (45%) responded to the needs assessment survey expressing interest in Infectious Diseases, Cardiology, and Endocrine review sessions. Twenty-three students attended the Infectious Diseases review session with an average pre-test score of 43% and post-test score of 89%. Forty-six students attended the Cardiology review session with an average pre-test score of 54% and post-test score of 85%. Seventeen students attended the Endocrine review session with an average pre-test score of 33% and post-test score of 79%. Based on evaluations (overall response rate: 85%), students found the review sessions to be well-organized and at an appropriate level. The activity was rated overall as good or excellent by 94% of respondents, and 96% reported feeling more prepared for APPEs after attending the review sessions. The student leaders who taught the review sessions reported feeling more confident in their leadership and public speaking abilities.

**CONCLUSION:** Student-led educational programs had a positive effect on the students who lead the program as well as the students participating in the program.

**365. Clinical efficacy of drug therapy used in acute renal failure patients.** *Ankit Dineshbhai Chaudhari, B. Pharm., M. Pharm., P. Sam Daniel, M. Pharm., Ph.D., Indermeet S. Anand, B. Pharm.D., M.Sc, Med., Ph.D, PDCR; Shri Sarvajanic Pharmacy College, Mehsana, Mehsana, Gujarat, India*

**PURPOSE:** To monitor the medication pattern and to assess the clinical outcomes related to antibiotic, antihypertensive and diuretic drug therapy in acute renal failure patients.

**METHODS:** An observational, single centric study of patients with acute renal failure was carried out at Upasana Kidney Hospital, Mehsana. Patients were enrolled as per predetermined criteria. Medical records were reviewed for generic name, dose, dosage form, route of administration prescribed to 105 inpatients related to antibiotic, antihypertensive and diuretic therapy. Clinical outcomes were documented using dialysis record, laboratory parameters.

**RESULTS:** Among 105 patients the mean age was  $49.69 \pm 16.21$  years (mean  $\pm$  SD), 71 (67.62%) were male and 34 (32.38%) were female. Nearly 1/5th of the patients required supportive therapy (diuresis and hemodialysis). Baseline total leucocyte count was  $10521 \pm 4429$  (mean  $\pm$  SD) per cmm and 3 days since the start of antibiotics was  $9106 \pm 4898$  (mean  $\pm$  SD) per cmm ( $p < 0.05$ ). SBP and DBP at baseline were  $141.25 \pm 22.12$  (mean  $\pm$  SD) mmHg and  $86.80 \pm 12.11$  (mean  $\pm$  SD) mmHg ( $p = 0.24$ ) and 24 hours after the antihypertensive treatment were  $138.58 \pm 19.36$  (mean  $\pm$  SD) mmHg and  $84.51 \pm 8.57$  (mean  $\pm$  SD) mmHg ( $p < 0.05$ ) respectively. Urine output at base-

line was  $580.00 \pm 351.83$  (mean  $\pm$  SD) ml and 3 days since the start of diuretics was  $927.500 \pm 352.98$  (mean  $\pm$  SD) ml ( $p < 0.05$ ). Serum creatinine ( $p = 0.13$ ) and potassium level ( $p = 0.60$ ) did not change significantly after start of diuretic therapy compared to baseline values.

**CONCLUSION:** Appropriate and early initiation of antibiotic therapy in infective illness is suggested to improve the outcome in acute renal failure. Incrementing antibiotics in combinations of mono and double antibiotic therapy were effective in decreasing the infection significantly while increasing mean duration of hospital stay. The differences observed between various antihypertensive and diuretic therapy combinations have not been effective in reducing blood pressure significantly.

**366. A study on potential role of pharmacists in home health drug related problem management in India.** *Ankit Dineshbhai Chaudhari, B. Pharm., M. Pharm., Parag R. Patel, B. Pharm., M. Pharm., Pankaj A. Leuva, B. Pharm., M. Pharm.; Shri Sarvajanic Pharmacy College, Mehsana, Mehsana, India*

**PURPOSE:** Provision of pharmaceutical care at home is more suitable environment, getting to know the patient and assessing the level of support required in medication use is an expanding role for pharmacist.

**METHODS:** To assess the scenario of medication use at home, a survey was designed to assess medicine literacy, medication knowledge and willingness of clients at home for receiving home care pharmaceutical services. A set of questions in local language was drafted to collect adult literacy in medicine using REALM-R. The medication knowledge assessment form was provided to 200 randomly selected subjects in rural community.

**RESULTS:** Among the 200 participants, 120 (60%) were males and 80 (40%) were females. The mean age of the respondents was 42.5 years. Forty-eight (24%) were illiterate, 92 (46%) were higher secondary. Medicine literacy assessed using REALM-R mean score was found to be 6.24 out of 11 words. In medication knowledge assessment mean number of medications per patient was 1.88. Among the basic medication knowledge, they were able to answer correctly at the average of 4.1. As many as 91.4% of the medications were stored in room temperature. Willingness to know more about medication usage amounted to mean score was found to be 8.82 out of 10.

**CONCLUSION:** From the data gathered it can be deduced that medication knowledge and adult medicine literacy among Indian population is less and needs pharmacist to take adequate measure to educate clients on medication use and one such way is through home pharmaceutical care. This also provides an opportunity for identify roles and rapport with patient for provision of effective care.

**367. The effectiveness of a systematic approach to the delivery of a drug literature evaluation course.** *Natalie J. Vogt, Pharm.D., Candidate, Pamela H. Koerner, B.S.Pharm., Pharm.D., BCPS, John R. Tomko, Pharm.D., BCPP, Holly C. Lassila, Dr.Ph., R.Ph.; Mylan School of Pharmacy, Duquesne University, Pittsburgh, PA*

**PURPOSE:** The purpose of this study was to determine the effectiveness of a systematic approach to delivery of a two-credit drug literature evaluation course and the students' ability to critically evaluate the literature.

**METHODS:** The course material was divided into topic sections which included study design, methodology, statistics, and analysis. The semester was grouped into blocks and a different topic was presented in each block. At the beginning of each block, students were provided with reflective exercises on the topics to be presented. Following the presentation of material and student submission of the exercise, the answers were discussed in class. Application sessions were also incorporated in which students were given the opportunity to review selected portions of contemporary drug literature articles that pertained to the previous topic discussion. In addition, the students were given one article at the beginning of the course to review and answer a number of evaluation questions. The students were then required to evaluate the

same article at the end of the course. The intent was to illustrate skill development. Finally, an independent article assessment, which was distributed to the students in a randomized manner, was the capstone assessment for the course. Students' knowledge, confidence, and skills were evaluated via a pre and post assessment.

**RESULTS:** Surveys were distributed to the 165 students enrolled in the Drug Literature Evaluation course at the beginning and end of the course. The surveys contained 11 likert questions and three open-ended questions. Data analysis is currently underway and will be completed in advance of the ACCP meeting.

**CONCLUSION:** To be presented following the completion of data analysis.

**368. Development of an eLearning tool to educate teens and adults about the dangers of medication misuse and abuse.** *Chelsea M. DuHaime, Pharm.D., Candidate, Nabila E. Newaz, Pharm.D., Candidate, Rana AlMandy, Pharm.D., Candidate, Joann K. Whang, Pharm.D., Candidate, Thao T. Tran, Pharm.D., Candidate, An M. Bui, Pharm.D., Candidate, Helen C. Pervanas, Pharm.D.; Massachusetts College of Pharmacy and Health Sciences, Manchester, NH*

**PURPOSE:** Prescription and over-the-counter (OTC) medication abuse is a growing epidemic in the adolescent and adult populations across the country. As a result, prescription related deaths have exceeded motor vehicle fatalities in New Hampshire (NH). Contributing factors include lack of education and increased accessibility. The purpose of the study was to create a learning tool to promote medication safety and educate the public about medication misuse and abuse.

**METHODS:** Six student pharmacists from the Massachusetts College of Pharmacy and Health Sciences (MCPHS) collaborated with the Community Alliance for Teen Safety (CATS) to create an eLearning tool addressing issues concerning prescription and OTC drug abuse. The student pharmacists developed scenarios that targeted both adolescent and adult populations and were integrated into a 30–60 minute self-paced interactive web-based program. Scenarios provide the online participant with a real-life situation specific to medication abuse. As the participant navigates through the scenario they are faced with challenges and must make choices to proceed. Once a choice has been made feedback is provided explaining the outcome of the choice. The participant also has the option to navigate back and make a different choice. At the conclusion of the program the participant is provided with a final summary and take-away message.

**RESULTS:** Four eLearning scenarios were developed: two that focused on topics relevant to adolescents and two for adults. Adolescent topics included: (i) abuse of prescription stimulants, and (ii) peer pressure to abuse/misuse prescription drugs. Adult topics included: (i) dextromethorphan abuse, and (ii) diversion, disposal and proper storage of medications. The program will be piloted in the NH Derry Middle School in the fall of 2012.

**CONCLUSION:** The eLearning scenarios will serve as an interactive tool for promoting medication safety as well as educating the community about the dangers of medication misuse and abuse.

**369. Advanced pharmacy practice students creating sustainability on short term medical mission trip.** *Jigna Patel, Pharm.D., Candidate, 2013, Ioana Jones, Pharm.D., Candidate, 2013; Palm Beach Atlantic University, West Palm Beach, FL*

**PURPOSE:** Medical missions, often consisting of teams from wealthier nations have become increasingly popular. However, many criticisms on their outcomes exist such as it being a short term fix. The need to reach remote areas of developing countries is undeniable. Due to this need, our group instead worked towards establishing long term sustainability of our clinics through creating educational tools for ourselves, the local missionary family, and villagers.

**METHODS:** Upon determination of the predominant disease states in Guatemala using the CDC, the group of seven rotation students created specific algorithms to address major health con-

cerns using product monographs and guidelines. These were then used to educate missionaries and accompanying athletic team on prevalent disease states and over the counter medications. In order to address sustainability we took detailed information on each patient and diseases they presented with in order to update the information for the missionaries.

**RESULTS:** Visiting four remote villages we were able to reach 382 patients, mostly woman and children. Although many patients required prescription medications for fungal and bacterial infections, a majority of the patients seen presented with back and body aches and pain, headaches, fever, and coughs which we treated using our algorithms. Missionaries and members of the athletic team were able to triage and treat appropriately. They were also able to educate villages on recommended non pharmacological measures to prevent communicable diseases and reduce occurrence of common disease states.

**CONCLUSION:** Many argue that untrained medical professionals are not well equipped to properly administer medications. We cannot refute that aide to these remote villages is necessary. Education is imperative to safe practices oversees for missionaries and other volunteers. By providing initial upfront education on common disease states and a point of contact with the Gregory School of Pharmacy will allow them to reach underserved areas with appropriate recommendations.

**370. Development of an innovative pharmacy experiential core curriculum system for the newly implemented 6-year (2 + 4) pharmacy educational system in Korea.** *Su Hyun Hong, B.S.<sup>1</sup>, Nayoung Han, M.S.<sup>1</sup>, Kyu-Hyuck Chung, Ph.D.<sup>2</sup>, Jeong-Hyun Yoon, Pharm.D.<sup>3</sup>, Dae Kyong Kim, Ph.D.<sup>4</sup>, Eun Sook Lee, Pharm.D.<sup>5</sup>, Jung Mi Oh, Pharm.D.<sup>1</sup>; (1) College of Pharmacy, Seoul National University, Seoul, South Korea; (2) College of Pharmacy, Sungkyunkwan University, Suwon, South Korea; (3) College of Pharmacy, Pusan National University, Pusan, South Korea; (4) College of Pharmacy, Chung-Ang University, Seoul, South Korea; (5) The Korean Society of Health-system Pharmacists, Seoul, South Korea*

**PURPOSE:** Implementing the "Pharmacy Education Reform" in Korea has extended the 4-year program to a 6-year (2 + 4) program. In the transition period, pharmacy schools face the challenge of the lack of a specific curriculum for pharmacy practice experiences. Thus, the goal was to establish a core curriculum for experiential education for pharmacy schools in Korea.

**METHODS:** Based on background research and meetings held within the Experience Education Committee of the Korean Association of Pharmacy Education, composed of faculties from schools of pharmacy, practicing pharmacists, and education experts, a core curriculum on experiential education that comprises more than 20% of curricular hours. Thereafter the core curriculum obtained consensus from experts at multiple public hearings and advisory committee meetings.

**RESULTS:** Core curriculum of experiential education consists of 960 hours of Introductory Pharmacy Practice Experience (IPPE) and 640 hours of Advanced Pharmacy Practice Experience (APPE) in various settings of pharmacy professions. IPPE will provide an introduction to the practice of pharmacy in the areas of 320 hours in community pharmacy, 480 hours in institutional pharmacy, 120 hours in pharmaceuticals industry, and 40 hours in administrative/regulatory agency under appropriate supervision of preceptors and as permitted by practice regulations. APPE will provide students the opportunity to focus on clinical aspects of pharmacy practice, involving direct patient care in a specific clinical area. Whilst working together with a faculty advisor in APPE courses, students may choose to participate in research projects that match their research and professional interests.

**CONCLUSION:** The core curriculum for pharmacy experiential education for the newly implemented 6-year (2 + 4) pharmacy educational system in Korea was developed to provide students with opportunities to experience active learning through exposure to actual pharmacy practice settings.

**371. Current status of public perception of pharmacists and strategies for improvement.** *Allen PerriAnn, Pharm.D., Candidate,*

Michael Chiou, Pharm.D., Candidate, Munteanu Jimmy, Pharm.D., Candidate, Cavalari Alex, Pharm.D., Candidate, Bett Caroline, Pharm.D., Candidate, Gorman John, Pharm.D., Candidate, Do Kristen, Pharm.D., Candidate, Hurley Thomas, Pharm.D., Candidate, Keel Rebecca, Pharm.D.; College of Pharmacy, California Northstate University, Rancho Cordova, CA

**BACKGROUND:** Patient trust is necessary as the practice of pharmacy continues to grow. Although pharmacists still remain one of the most trusted professionals, the expansion of their roles will serve to foster that trust and will ultimately increase their contribution to the healthcare field.

**PURPOSE:** To assess the public's perception, their trust of pharmacists, and shed light on how to increase that trust and achieve earned respect as vital members of the healthcare team.

**METHODS:** Research public opinion to gain an understanding of the public's perception of pharmacists. Findings were considered for relevance and compared to current strategies to improve that perception.

**RESULTS:** In general, public's perception of pharmacists was positive. Studies showed 73% of those polled rated pharmacists as honest and ethical, 66% felt that the services provided by a pharmacist were good or excellent, and 83% considered pharmacists to be health care professionals, similar to physicians and nurses. Negative perceptions include a study revealing 65% of patients perceived themselves as customers not patients. Only 27% felt a pharmacist should counsel when filling a prescription. Barriers, particularly fear, intimidation, and lack of awareness were cited reasons for this non-communication. Only 36% felt comfortable with a pharmacist's qualifications to give immunizations. There was statistically significant improvement in patients' perceptions of pharmacists' roles and abilities when educational intervention was employed. Current strategies to create a positive public image of pharmacists include American Pharmacist Month and other Year-Round Health Events.

**CONCLUSIONS:** Pharmacists enjoy a positive perception by the public; however, there is a dearth of public knowledge that can be remedied through educational intervention and breaking communication barriers. Current strategies should be reviewed for effectiveness regarding patient education and improving communication between pharmacist and patient.

**372. An educational technology student and faculty needs assessment.** *Stephen C. Austin, Pharm.D., Candidate,*

Dana Hammer, Ph.D., Thomas Hazlet, Dr.P.H., Stanley Weber, Pharm.D.; School of Pharmacy, University of Washington, Seattle, WA

**PURPOSE:** To determine the education technology needs of student pharmacists and faculty in one school of pharmacy.

**METHODS:** A mixed qualitative/quantitative survey will be administered to assess student pharmacists' and faculty interests and needs regarding education technology in a Pharm.D. program. Data will be collected from students through an internet-based tool in late September at the beginning of their fall quarter. Data will be collected from faculty using the same survey instrument but via focus groups during a faculty retreat that will occur in early September. Descriptive statistics of the quantitative data will be calculated using Microsoft Excel. Qualitative data will be assessed via content analysis. The project should be completed by early October.

**RESULTS:** Results will be compared across each academic year of student pharmacists (P1, P2, P3, P4), as well as student pharmacists versus faculty responses. Faculty responses will be compared across departments.

**CONCLUSION:** Results will be used to guide a student-faculty technology committee's decisions on implementing certain learning technologies in the Pharm.D. curriculum.

**373. Impact of graduation year on pharmacy residency matching rates.** *Shirin Madzhidova, Pharm.D., Candidate,*

Julian Rodriguez, Pharm.D., Candidate, Maumer Dzebo, Pharm.D., Candidate,

Antonia Zapantis, M.S., Pharm.D.; College of Pharmacy, Nova Southeastern University, Davie, FL

**PURPOSE:** The demand of post-graduate residency programs has grown dramatically in the last few years, while the growth of such programs is less dramatic. Program directors evaluate various factors when matching a candidate. The purpose of this study is to evaluate the impact of graduation year on pharmacy PGY1 and PGY2 residencies obtainment.

**METHODS:** National match service data from 2007 to 2012 was evaluated based on graduation year for both PGY1 and PGY2. Assessments were made independently by at least two authors. Match participants were compared to those that did not match on the basis of graduation year (match year versus previous years). Fisher's exact and Chi-square tests were used to assess differences for each of the 6 years and overall, as appropriate. *p* Values below 0.05 were considered statistically significant.

**RESULTS:** PGY1 match rates ranged from 61.2% to 71.1% between 2007 and 2012, while PGY2 rates ranged from 65.5% to 80.2% over the same time period. Applicants consistently match if they participated during their last professional year of pharmacy school (range 66.3% to 72.5% versus 37.5% to 56%; *p*=0.007 to *p*<0.0001). PGY2 results were less dramatic with rates of 68.4% to 77% versus 43.9% to 85%; *p*=0.0005-1.00.

**CONCLUSION:** The rates of matching increase significantly for PGY1 applicants applying the year of graduation. It seems current students are more desirable to programs than applicants who may have been out of school a year or more. However, for a PGY2 residency, the year of graduation has less of an impact indicating that the desire to match a candidate that has been in training continuously since graduation once the candidate has had residency training in a PGY1 program.

**374. Pharmacy resident research publication rates: a national and regional comparison.** *Rickey A. Evans, Pharm.D., Candidate<sup>1</sup>,*

April D. Miller, Pharm.D., BCPS<sup>2</sup>, P. Brandon Bookstaver, Pharm.D., BCPS, AQ-ID, AAHIVE<sup>1</sup>, Dana Stafkey-Mailey, Pharm.D., Ph.D.<sup>1</sup>, Elizabeth W. Blake, Pharm.D., BCPS<sup>1</sup>, Whitney Maxwell, Pharm.D., BCPS<sup>1</sup>, Vanessa Millisor, Pharm.D.<sup>3</sup>; (1) South Carolina College of Pharmacy-USC Campus, Columbia, SC; (2) Vidant Medical Center, Greenville, NC; (3) Pittsburgh Medical Center, Pittsburgh, PA

**PURPOSE:** Dissemination of research findings through presentation and publication is essential to the scholarship process. The publication rate of abstract presentations for biomedical practitioners is approximately 45%. Currently, the national publication rate of pharmacy resident abstracts is unknown. This study aimed to determine the publication rate of pharmacy resident projects from 2004 to 2007, compare publication rates of abstracts from regional and national pharmacy conferences, and assess characteristics of published abstracts.

**METHODS:** A stratified random sample of abstracts for residency years 2004-2007 was selected from the American College of Clinical Pharmacy Fall and Spring Meetings (national meeting) and the following regional residency conferences: Alcalde, Great Lakes, Eastern, Southeastern, Midwestern, and Western States. Based on an expected frequency of 15% and a 95% confidence interval, 127 national conference abstracts and 679 regional conference abstracts were assessed for publication using a standardized search strategy for Medline, International Pharmaceutical Abstracts, and Google Scholar.

**RESULTS:** The overall publication rate of abstracts presented at national and regional pharmacy meetings from 2004 to 2007 was 9.5%. The publication rate of abstracts presented at ACCP meetings was determined to be 15.7% while the publication rate from regional conferences was found to be only 8.4%. From abstracts that were published, 80.8% had pharmacy residents as first author, 20.8% had pharmacy residents as corresponding author, and 57.5% of the publications were authored by an interdisciplinary team. Most (93.1%) of the published abstracts were identified

as full research reports, with 56.2% published in peer-reviewed pharmacy journals. Approximately 89% of published abstracts were indexed in PubMed and the median time from abstract presentation to publication was 23 months.

**CONCLUSIONS:** Abstracts presented at national pharmacy meetings were associated with higher publication rates when compared to regional meetings. Future studies should be aimed at identifying the barriers to publication of pharmacy resident projects.

**375. Professional development opportunities through the ACCP network at Ernest Mario School of Pharmacy, Rutgers University.** *Esther Liu, Pharm.D., Candidate, 2013*<sup>1</sup>, Rolee Pathak, Pharm.D., BCPS<sup>2</sup>; (1) Ernest Mario School of Pharmacy, Rutgers University, Piscataway, NJ; (2) Englewood Hospital and Medical Center, Englewood, NJ

**PURPOSE:** Since the introduction of the ACCP student network in 2010, the Rutgers University ACCP network student leaders have established a chapter and have implemented various programs with the objective of helping pharmacy students sharpen their clinical and professional knowledge.

**METHODS:** This observational study was conducted from September 2011 to May 2012 among professional pharmacy students at Rutgers University. Event attendance was used to evaluate student interest in ACCP and its growth as a newly established pharmacy organization on campus. *CV/Interview workshop:* Collaborated with New Jersey Health System Pharmacists (NJSHP) "Lunch and learn" series: One-hour case presentations *Rotation Roundtable:* 6th year pharmacy students answer questions on how to prepare for advanced practice rotations *Rutgers Day Collaboration:* Collaboration with American Pharmacists Association-Association of Student Pharmacists (AphA-ASP)'s Operation Diabetes Committee *Shadowing opportunity:* Potential opportunity pairing pharmacy students with clinicians to observe different roles of clinical pharmacy

**RESULTS:** Student attendance at CV/ Interview workshop, Rotation Roundtable, Rutgers Day Collaboration were 28, 35, and 15, respectively. "Lunch and learn" participation was smaller (around 10 per event). About 45 students signed up to participate in the potential shadowing program.

**CONCLUSIONS:** The Rutgers network used attendance to gauge student interest. Trends show higher participation in general professional events rather than specific educational events possibly because the mini-lectures are a new concept to Rutgers students. Students attending "Lunch and learn" series were usually active ACCP members. As the organization grows, the number of regular members will hopefully also increase. To ensure development, innovative topic presentations should be introduced. Student network activities at Rutgers University will continue to provide opportunities for intellectual and professional growth.

## Endocrinology

**376. Evaluation of the relationship between circulating omentin concentrations and components of the metabolic syndrome in nondiabetic adults without cardiovascular disease.** *Anh Vu, B.A., Maha Sidhom, B.A., Brooke Bredbeck, B.S., Lisa Kosmiski, M.D., Christina Aquilante, Pharm.D.; Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Aurora, CO*

**PURPOSE:** Omentin is a beneficial cytokine that is secreted by visceral adipose tissue and works to enhance insulin-stimulated glucose uptake in adipocytes. Circulating omentin concentrations are decreased in patients with obesity, impaired glucose tolerance, and type 2 diabetes. However, little is known about circulating omentin concentrations in adults with the metabolic syndrome. The objective of this study was to evaluate the relationship between plasma omentin concentrations and components of the metabolic syndrome in nondiabetic adults without cardiovascular disease.

**METHODS:** Blood samples were obtained from nondiabetic adults (n=124), ages 30–60 years, without cardiovascular disease.

Subjects were classified as having the metabolic syndrome according to AHA/NHLBI criteria. Plasma omentin concentrations were analyzed by ELISA. Pearson's correlations were used to determine the relationship between plasma omentin concentrations and components of the metabolic syndrome and clinical variables. Independent t-tests and ANOVA were used for 2-group and 3-group comparisons, respectively.

**RESULTS:** The study population was 54.8% women, 71.7% non-black, age  $48 \pm 8$  years, BMI  $31.2 \pm 5$  kg/m<sup>2</sup>, and 65.3% with the metabolic syndrome. Plasma omentin concentrations were significantly correlated with waist circumference ( $r = -0.18$ ,  $p=0.046$ ) and systolic blood pressure ( $r = 0.21$ ,  $p=0.02$ ). Plasma omentin concentrations were not significantly different between subjects with versus without the metabolic syndrome ( $151.0 \pm 71.8$  versus  $157.0 \pm 78.6$  ng/ml,  $p=0.86$ ). However, plasma omentin concentrations were 25% higher in lean compared with obese subjects ( $180.9 \pm 59.5$  versus  $144.0 \pm 70.2$  ng/ml), although not statistically significant ( $p=0.24$ ).

**CONCLUSION:** Our findings are consistent with data showing decreased omentin concentrations in obese states. We also found that plasma omentin concentrations were positively correlated with systolic blood pressure, which suggests that omentin may play a role in hypertension. Additional studies are needed to clarify the relationship between circulating omentin concentrations and components of the metabolic syndrome and hypertension in humans.

**377. Study of the impact of anxiety and depression on weight loss medication adherence.** *Karen Lai, B.S.*<sup>1</sup>, William G. Haynes, M.D.<sup>2</sup>, Graziela Z. Kalil, Pharm.D.<sup>2</sup>; (1) University of Iowa College of Pharmacy, Iowa City, IA; (2) Lucille Carver College of Medicine, University of Iowa Roy, Iowa City, IA

**PURPOSE:** Obesity is associated with depression and anxiety. Medication adherence can impact and impose burden on health outcomes and costs. Studies have shown that depressed patients are less likely to take medications. Non-adherence to weight loss (WL) medication may negatively impact on outcomes, such as improvement of cardiovascular risk and quality of life. However, there are no published studies evaluating the influence of depression and anxiety and WL medication adherence.

**METHODS:** These are interim 3-month results from a 12-month double-blind, randomized, parallel-group controlled trial. Fifteen obese (BMI  $\geq 30$ ) subjects, 40–75 y.o., randomized to three active medications/placebos (BID or TID) in five different combination WL pharmacotherapy groups. Depression evaluated using Beck Depression Inventory II (BDI-II) and anxiety evaluated using the Beck Anxiety Inventory (BAI). Medication adherence was calculated using cumulative 3-month pill count, using the equation: (amount dispensed – pill count)/amount expected

**RESULTS:** The interim analyses shows WL data for n=15 (eight female): age  $53 \pm 7$  years; BMI  $36 \pm 4$ ; BAI score  $6.0 \pm 6.7$ ; BDI-II score  $6.9 \pm 7.7$ . At the 3-month follow-up, BMI, BAI and BDI-II scores decreased significantly to: BMI  $32 \pm 4$  ( $p<0.0001$ ); BAI  $4.0 \pm 6.0$  ( $p=0.032$ ); and BDI-II  $3.5 \pm 4.6$  ( $p=0.006$ ), respectively. Mean study medication adherence for all three medications was  $97 \pm 2\%$ . Mean adherence for the combined three medications was not associated with either depression ( $p=0.5536$ ) or anxiety scores ( $p=0.4972$ ). Interestingly, the TID agent adherence and changes in BAI scores show a correlation estimate of  $-0.49339$  ( $p=0.0632$ ).

**CONCLUSION:** At the 3-month period adherence with WL medications is very high. This may have adversely impacted our ability to detect an effect of anxiety or depression on adherence. Additionally, even within this short follow-up substantial reductions were seen in anxiety and depression. Future analyses will include more subjects followed over a longer period of time.

## Gastroenterology

**378. Evaluation of alvimopan utilization at a four-hospital healthcare system.** *Prachi J. Shah, Pharm.D., Candidate, Corrie Vasilopoulos, Pharm.D.; NorthShore University Health System, Evanston, IL*

**PURPOSE:** To assess the appropriate utilization of alvimopan after addition to formulary.

**METHODS:** All patients who received at least one dose of alvimopan between January 1, 2011 and December 31, 2011 at any of four hospitals within the NorthShore University Health System were identified. Twenty-five percent of these patients were randomly selected for evaluation. Data collected includes demographics, surgical procedure performed, and administration of preoperative dose, total number of postoperative doses administered, documented ileus during hospitalization, documented placement of nasogastric tube postoperatively, and appropriate discontinuation of therapy (defined as first documented bowel movement).

**RESULTS:** Two hundred and seventy-two patients received at least one dose of alvimopan over the 12-month evaluation period. Of these, 69 were randomly selected for evaluation. Ten out of 69 patients, receiving 72 doses, were administered alvimopan for non-bowel resection indications, demonstrating 14% of all doses given with inappropriate indication. Of patients administered alvimopan for appropriate indications, including open and laparoscopic bowel resection, 90 of 447 doses (20%) were administered after first documented bowel movement. In total, 162 out of 519 total doses (31%) were administered inappropriately. A preoperative dose was administered in 63 of 69 (91%) patients, with a mean of 7.5 total doses per patient. The mean time to discharge order written was 4.8 days.

**CONCLUSION:** This evaluation demonstrated that 69% of alvimopan use is appropriate, with opportunity to improve compliance related to indication for use, preoperative dosing administration, and appropriate discontinuation. Opportunities to reduce cost and improve appropriate utilization of alvimopan include development of alvimopan utilization guidelines and incorporation into surgical order sets. Additionally, multi-disciplinary education among nurses, physician assistants, anesthesiology, surgery, pharmacy and dieticians may prove beneficial.

## Geriatrics

**379. Student College of Clinical Pharmacy provides education about medications and fall risk for Akron area agency on aging care managers.** *Mary E. Fredrickson, Pharm.D., Candidate, Andrew Smith, Pharm.D., Candidate, Patrick Gallegos, Pharm.D., R.Ph., BCPS, Mate Soric, Pharm.D., BCPS, Susan Fosnight, R.Ph., CGP, BCPS; Northeast Ohio Medical University, Rootstown, OH*  
**PURPOSE:** The purpose of the study was to evaluate the efficacy of a Student College of Clinical Pharmacy presentation seeking to educate case managers on falls and their effects on the elderly population. The study also assessed the care managers' global response to the educational sessions.

**METHODS:** The Northeast Ohio Medical University Student College of Clinical Pharmacy organization prepared a short presentation as a community outreach project for the Akron Area Agency on Aging (AAoA) care managers to improve their understanding of the effect of falls in the geriatric population and prevention strategies. This presentation was delivered on multiple occasions in the spring and summer of 2012. Voluntary and confidential pre- and post-surveys were administered to the care managers. The surveys were used to assess various items including, but not limited to; pertinence, level of comfort, application of covered skills, and overall perception of educational sessions.

**RESULTS:** Descriptive statistics to be evaluated upon completion of the study.

**CONCLUSIONS:** To be determined upon completion of the study.

**380. The role of the pharmacist in geriatric care coordination: comparing the United States, the United Kingdom and Japan.** *Simone M. Austin, Pharm.D., Candidate, Annesha W. Lovett, Pharm.D., M.S., Ph.D.; Mercer University, Atlanta, GA*

**PURPOSE:** The purpose of this study was to review the literature published within the last decade related to the role of the pharmacist in geriatric care coordination in the United States, the United Kingdom, and Japan. This is important because pharmacists are playing an increasing role in health care provision. They are uniquely suited to mold their responsibilities around the changing needs of the growing geriatric population.

**METHODS:** An Internet search was conducted using the key words pharmacy, geriatric care coordination, seniors, elders, and older Americans. Information posted between January 2001 and December 2011 was reviewed.

**RESULTS:** The three main differences between the United States, the United Kingdom and Japan in regard to pharmacist provided geriatric care relate to (i) the provision of home care, (ii) the delivery of coordinated services, and (iii) the perceptions of the quality of geriatric care provided. The key driving forces for these differences were culture, financing and education.

**CONCLUSION:** Variations in the provision of geriatric care coordination exist between countries. Due to limited resources, the challenge is to provide care that is balanced in cost and quality. Geriatrics-trained pharmacists may have a number of responsibilities, such as reviewing a patient's medication regimen, suggesting changes, assessing patient ability to take the medications as intended, and coordinating care. Although studies show that geriatric related efforts in the U.K. and Japan far exceed the U.S., America's older persons can expect geriatric medicine to evolve into an area that provides greater recognition of senior issues and improved efforts to coordinate care. Many older persons have seen benefits from increased emphasis on home care and a multidisciplinary team approach to care coordination. Pharmacists are in a unique position to meet the needs of seniors and all three countries provide unique efforts to deliver better health care to this ever-increasing population.

## Health Services Research

**381. Assessment of health related quality of life in patient with POOR glycaemic control in Ahmedabad District: generic and disease specific measurement.** *Shah Dharak, M. Pharm.; Shri Sarvajani Pharmacy College, Mehsana, Gujarat, India, Ahmedabad, India*

**PURPOSE:** This study constitutes an initial attempt at elucidating the relationship between quality of life (QoL), health status and psychological distress in patients with diabetes mellitus (DM) in Ahmedabad district, based on the short form-36 (SF36) and PAID (problem area in diabetes) between two different groups of type 2 diabetes mellitus patients with glycaemic control: those with a glycosylated haemoglobin (HbA1c) level at or below 7.5% and those above 7.5%.

**METHODS:** The analysis of covariance was used to obtain the adjusted mean scores of the SF-36 scales while controlling for age and duration of type 2 diabetes mellitus. The regression analysis was used between PAID scores and patients characteristics.

**RESULTS:** Of the 115 patients with type 2 diabetes mellitus were analyzed. There were 53 women and 62 men and their mean HbA1c level was 8.35% (SD  $\pm$  1.79). When comparing the two groups with different HbA1c levels, the adjusted means of four scales of physical health component: Physical functioning, role physical, body pain and general health, general health and two scales of the mental health component: vitality and role emotional differed significantly between the two groups. Social function and mental health not significantly differed between two groups of patients. The emotional distress measured through PAID also differed significantly between the two groups.

**CONCLUSION:** Type 2 diabetes mellitus patients with poor glycaemic control had lower mean SF-36 scores in: physical functioning, role physical, body pain, general health, vitality and role emotional and the emotional distress measured through PAID had higher in poor glycaemic control patients.

**382. A novel approach to decreasing asthma exacerbation rates by holding a multidisciplinary education intervention in a Community Hospital setting.** *Linda Lam, Pharm.D., Candidate, 2013*, Nancy Le, Pharm.D., Candidate, 2013, Christina M. Madison, Pharm.D., BCACP; Roseman University of Health Sciences, Henderson, NV

**BACKGROUND:** An estimated 47,000 children in Nevada are living with chronic asthma. Unplanned physician visits, emergency department admissions, and hospital utilization are often due to inadequate symptomatic management and asthma control.

**PURPOSE:** The Asthma Kids Club program was developed by St. Rose Dominican Hospital certified health educators to address the increased asthma exacerbation rates among the pediatric population in Southern Nevada. Early intervention of asthma education should decrease hospital utilization and emergency room visits compared to individuals who did not participate in this intervention.

**METHODS:** The Asthma Kids Club intervention was initiated in summer 2011 on a quarterly basis and included pulmonary screening with a respiratory therapist, physician consultation, medication utilization review, and access to free recommended immunizations. Roseman University of Health Sciences student pharmacists under the supervision of a clinical pharmacist demonstrated appropriate inhaler and spacer technique, explained the benefits of rescue inhaler usage and peak flow monitoring. In addition, medication counseling and asthma/allergy trigger management were conducted during the creation of asthma action plan. Since its conception, a total of four Asthma Kids Club events have been conducted.

**RESULTS:** Of the 114 families have participated with 201 children attending at least one asthma event during year 2011–2012. Of these, 83 have no documented emergency room visits or hospitalizations due to asthma exacerbations or complications. This represents a decline for those families that have participated in this targeted intervention.

**CONCLUSION:** Working within a coordinated healthcare team is a cost effective way to assist the underserved in the community. The impact of a targeted multidisciplinary team approach to asthma education in a pediatric patient population is a viable option to maximize current therapy and improve overall health outcomes.

## Hematology/Anticoagulation

**383. Safety and efficacy of new anticoagulants for the prevention of venous thromboembolism after hip and knee arthroplasty.** *Brett Venker, Pharm.D., Candidate, 2013*<sup>1</sup>, Beejal Ruparelia, B.S., Pharm.D., Candidate, 2013<sup>2</sup>, Elizabeth D. Lee, B.A.<sup>3</sup>, Ryan Nunley, M.D.<sup>3</sup>, Brian F. Gage, M.D.<sup>3</sup>; (1) Washington University in Saint Louis and Saint Louis College of Pharmacy, Saint Louis, MO; (2) Washington University in Saint Louis, University of Michigan College of Pharmacy, Saint Louis, MO; (3) Washington University in Saint Louis, Saint Louis, MO

**CONTEXT:** After hip and knee arthroplasty, venous thromboembolism (VTE) is common and often severe. Dabigatran, apixaban, and rivaroxaban are new anticoagulants that show promise for VTE prevention in this population, and have been proposed to be both safer and more effective than traditional anticoagulants. Current guidelines prefer a low-molecular-weight heparin, such as enoxaparin.

**PURPOSE:** To perform a current review of the existing literature and determine which anticoagulant has the best safety and efficacy in hip and knee arthroplasty.

**DATA SOURCES:** We searched Pubmed, Medline (through Pubmed), Embase, and Clinicaltrials.gov to find randomized controlled trials of these anticoagulants.

**METHODS:** From 1070 potentially relevant trials, 14 met the inclusion criteria and were included in the final meta-analysis. Information on trial design and duration, drug regimen, dose, frequency, route and clinical outcomes, were extracted systematically. Outcomes were: major bleeding, the composite of major

and/or clinically relevant bleeding, and the composite of VTE and/or death.

**RESULTS:** Compared to enoxaparin, the relative risk (RR) of VTE/death varied significantly with the new anticoagulants. RR of VTE/death was lowest (0.55, 95% CI, 0.46–0.66  $p \leq 0.001$ ) for rivaroxaban (10 mg once daily) and highest (1.20, 95% CI, 0.99–1.44  $p=0.058$ ) for dabigatran (150 mg once daily). Apixaban (2.5 mg twice daily) had the lowest RR of major/clinically relevant bleeding (0.84, 95% CI, 0.70–1.01  $p=0.058$ ), while rivaroxaban had the highest (1.30, 95% CI, 1.03–1.64  $p=0.027$ ).

**CONCLUSIONS:** With the possible exception of apixaban, new anticoagulants that lower the risk of VTE, increase the risk of bleeding. Similarly, new anticoagulants that lower the risk of bleeding, raise the risk of VTE.

**384. Net stroke equivalents for antithrombotic therapy prescribed for atrial fibrillation.** *Megan Nicklaus, Pharm.D., Candidate*<sup>1</sup>, Gina Hyun, B.S.<sup>1</sup>, Juan Li, M.P.H.<sup>1</sup>, Ambar A. Andrade, M.D.<sup>2</sup>, Laura Challen, Pharm.D., BCPS, M.B.A.<sup>3</sup>, Brian F. Gage, M.D., M.Sc.<sup>1</sup>; (1) Washington University, St. Louis, MO; (2) Texas Heart Institute, Houston, TX; (3) St. Louis College of Pharmacy, St. Louis, MO

**PURPOSE:** To conduct a systematic review of antithrombotic therapy for atrial fibrillation.

**METHODS:** Data sources that were searched included Pubmed, EMBASE, MEDLINE, and Clinicaltrials.gov. We conducted a systematic analysis of phase three clinical trials using the keywords apixaban, dabigatran, rivaroxaban, and atrial fibrillation (MeSH) by two independent reviewers. Of 196 studies, the primary studies of RE-LY, ROCKET-AF, ARISTOTLE, AVERROES, ACTIVE-A, and ACTIVE-W were selected for our analysis. The antithrombotics used in these studies were evaluated by adjusting for the time in therapeutic range (TTR) for International Normalized Ratio (INR). The rates of stroke, intracranial hemorrhage, extracranial hemorrhage, and myocardial infarction were calculated from the relative risk of each event compared to warfarin. These adverse events were converted into stroke equivalents based on quality adjusted life years lost.

**RESULTS:** The optimal antithrombotic therapy depended on risk of stroke, as estimated by CHADS<sub>2</sub> score. For patients with a CHADS<sub>2</sub> score of 1, either apixaban or dabigatran had the lowest rates of stroke and stroke equivalents, while aspirin (with or without clopidogrel) had the highest rates. For CHADS<sub>2</sub> scores of two or more, dabigatran 150 mg bid had the lowest rates of stroke and stroke equivalents, but this treatment had the highest rates of myocardial infarction and relatively high rates of gastrointestinal hemorrhage. There was insufficient information to quantify the effect of the new anticoagulants in patients with a CHADS<sub>2</sub> score of 0. Although rivaroxaban had the advantage of once daily dosing, it was not the optimal therapy for any CHADS<sub>2</sub> score.

**CONCLUSION:** We recommend dabigatran or apixaban twice daily for stroke prophylaxis in patients with atrial fibrillation who have a CHADS<sub>2</sub> score of 1 and dabigatran 150 mg twice daily for patients with a higher CHADS<sub>2</sub> score.

## HIV/AIDS

**385. Baseline antiretroviral drug resistance and clinical outcomes in an urban HIV clinic in Charlotte, North Carolina.** *Feredalem Assefa, Pharm.D., Candidate*<sup>1</sup>, Olga M. Klibanov, Pharm.D.<sup>1</sup>, Christian R. Dolder, Pharm.D.<sup>1</sup>, Tagbo J. Ekwonu, M.D.<sup>2</sup>; (1) Wingate University School of Pharmacy, Wingate, NC; (2) Eastowne Family Physicians, Charlotte, NC

**PURPOSE:** To assess the prevalence of transmitted drug resistance mutations (TDRMs) in HIV-infected treatment-naïve patients in our clinic.

**METHODS:** The primary endpoint was the prevalence of TDRMs 2008–2011. Antiretroviral (ARV) drug susceptibility was retrospectively analyzed in treatment-naïve patients 2008–2011. Resistance was defined on the basis of the International AIDS

Society 2011 definition and the 2009 CDC surveillance mutation list. Secondary endpoints included TDRM rates in recently diagnosed patients (HIV diagnosis in the last 12 months), predictors of persistence with care (12 months of follow-up data available) in patients who were initiated on ARV versus 2008–2010, and virologic success (HIV-1 RNA < 50 copies/ml after 12 months of therapy). Descriptive statistics, Pearson's chi-square analysis, and logistic regression were used to analyze results.

**RESULTS:** Among 189 treatment-naïve patients who entered care 2008–2011 (69% male, 87% African American, median CD4 count 299 cells/mm<sup>3</sup>), 19 (10%) had > 1 TDRM. Year-to-year comparisons indicated a 0% TDRM rate in 2008, 12% in 2009, 8% in 2010, and 16% in 2011 (p=0.36). Among 137 recently diagnosed patients, TDRM rates were 0% in 2008, 13% in 2009, 10% in 2010, and 20% in 2011 (p=0.49). NNRTI resistance was most common (14/19; 74%), followed by NRTI (5/19; 26%); no PI TDRMs were noted. Of the 137 patients initiated on HAART; 103 (75%) demonstrated persistence in care and 81 (59%) achieved virologic success. Recent HIV diagnosis was the only factor significantly associated with persistence with care (OR 3.53; 95% CI 1.49–8.36; p=0.004) and with achieving HIV-1 RNA < 50 copies/ml (OR 3.78; 95% CI 1.68–8.53; p=0.001). Counseling by a HIV clinical pharmacist was not associated with persistence in care or virologic success.

**CONCLUSION:** The prevalence of TDRMs in our clinic mirrors national surveillance data (15–19%). Efforts must be focused on improving patient retention and virologic success rates in urban HIV clinics.

### 386. Correlation between the concentration of darunavir in PBMCs and plasma in the HIV-infected patients. *Daisuke Nagano*<sup>1</sup>, Takuya Araki<sup>1</sup>, Kunio Yanagisawa<sup>2</sup>, Masayuki Ogawa<sup>2</sup>, Toshimasa Hayashi<sup>2</sup>, Fumito Gouda<sup>3</sup>, Momoko Mawatari<sup>4</sup>, Hideki Uchiumi<sup>2</sup>, Yoshihisa Nojima<sup>2</sup>, Tomonori Nakamura<sup>1</sup>, Koujiro Yamamoto<sup>1</sup>;

(1)Department of Clinical Pharmacology, Graduate School of Medicine, Gunma University, Maebashi, Japan; (2)Department of Medicine and Clinical Science, Graduate School of Medicine, Gunma University, Maebashi, Japan; (3)National Hospital Organization Takasaki General Hospital, Takasaki, Japan; (4)Department of Hematology, National Hospital Organization Nishigunma National Hospital, Shibukawa, Japan

**PURPOSE:** In the treatment of HIV-1 infection, proper maintenance of the concentration of darunavir (DRV) in blood is considered to be essential to prevent the proliferation of drug-resistant viruses, and therapeutic drug monitoring of DRV is considered to be an important tool to obtain the expected clinical efficacy as an alternative to counting CD4<sup>+</sup> cells or viral load. Recently, the importance for the measurement of the concentrations of DRV in PBMCs, the site of action for DRV, has been focused and discussed. In this study, we assessed the correlation between the concentration of DRV in human PBMCs and its level in plasma.

**METHODS:** The whole blood was separated to PBMCs and plasma fractions using density gradient method. The concentration of DRV at trough was measured by HPLC-FLR method.

**RESULTS:** We measured the concentration of DRV in four HIV-infected patients (three male, one female). The mean concentration of DRV in PBMCs was 15.82 ng/10<sup>6</sup> cells (12.35–19.19) and that in plasma was 4630 ng/ml (2610–5820). We found twice difference of ratio of DRV concentration in PBMCs to that in plasma among the patients. All patients showed good response to anti-HIV therapy.

**CONCLUSION:** We found that PBMCs concentration was not predictable completely on the basis of the concentration of DRV in plasma, because PBMCs concentration vary largely in HIV infected patients. In this study, anti-HIV therapy with DRV for all patients showed good response. Some of the major weakness of sentinel site is small number of patients in this case. Further detail studies with larger volume of sample were required to clarify

the impact of the concentration of DRV in PBMCs on the clinical effects.

### 387. Assessing medication adherence in an HIV/AIDS patient population: one pill versus three pills as a once a day regimen. *Sarah J. Tennant, Pharm.D., candidate, 2013*<sup>1</sup>, Celeste R. Caulder, Pharm.D.<sup>1</sup>, P. Brandon Bookstaver, Pharm.D., BCPS, AQ-ID, AAHIVE<sup>2</sup>, Zaina Qureshi, M.P.H., Ph.D.<sup>1</sup>;

(1)South Carolina College of Pharmacy, Columbia, SC; (2)South Carolina College of Pharmacy-USC Campus, Columbia, SC

**PURPOSE:** Adherence to antiretroviral therapy (ART) is one of the strongest predictors of disease progression in HIV/AIDS patients. This study compared adherence rates of two once-daily dosing regimens with different number of pills per daily dosing in patients with HIV/AIDS. Secondary objectives are to measure viral load suppression and CD4 count achieved with these two regimens.

**METHODS:** Adult HIV-infected or AIDS patients with a documented clinic visit during the study period who filled medications through the state AIDS Drug Assistance Program were eligible for study inclusion. The regimens compared were efavirenz/emtricitabine/tenofovir (EFV/FTC/TDF) in combined one pill, once-daily dose and emtricitabine/tenofovir/atazanavir/ritonavir (FTC/TDF/ATV/r) in three pills, once-daily dose. Twenty-four consecutive months of HAART were evaluated. Data collected includes: computerized pharmacy refill records, patient self-reported missed doses at each medical visit, demographics, number of concomitant medications, and ART information including treatment naïve or experienced. Viral load and CD4 count values throughout the study period were also collected.

**RESULTS:** Study sample consisted of 198 patients with 99 patients in each treatment group. Sixty-five percent of patients in EFV/FTC/TDF group had > 90% adherence according to pharmacy refill records. Fifty-seven percent of patients in FTC/TDF/ATV/r group had > 90% adherence according to pharmacy refill records. Forty-eight patients with a detectable viral load at the beginning of the study were undetectable at the end of the study. Average increase in CD4 cells was 104.

**CONCLUSIONS:** HIV/AIDS patients were more adherent to one pill once a day versus three pills once a day. Virus was controlled on both ART regimens and immune response was appropriate. Pill burden and frequency continue to be important factors in designing ART regimens for individual patients.

## Infectious Diseases

### 388. An evaluation of the combination of daptomycin and rifampin against vancomycin-resistant *Enterococci* isolated from the bloodstream of neutropenic patients. *Christine Trezza, B.S.*<sup>1</sup>, Jack Brown, Pharm.D., M.S.<sup>1</sup>, Alan Forrest, Pharm.D.<sup>1</sup>, Pamela Kelchlin, B.S.<sup>1</sup>, Patricia N. Holden, B.S.<sup>1</sup>, Brian T. Tsuji, Pharm.D.<sup>2</sup>;

(1)School of Pharmacy and Pharmaceutical Sciences, University at Buffalo Buffalo, NY; (2)Laboratory for Antimicrobial Pharmacodynamics, University at Buffalo, State University of New York, Buffalo, NY

**PURPOSE:** Therapeutic options for vancomycin-resistant *Enterococci* (VRE) endovascular infections are limited. This fact, along with the high morbidity and mortality resulting from these infections are cause for grave concern. Our objective was to evaluate the activity of daptomycin in combination with rifampin against VRE using in vitro time-kill experiments.

**METHODS:** VRE isolates (n=8) from the bloodstream of neutropenic patients from the University of Rochester Medical Center treated with the combination of daptomycin and rifampin were utilized. Minimal inhibitory concentrations (MIC) were determined according to Clinical and Laboratory Standards Institute guidelines. Time-kill experiments were performed at a starting inoculum of approximately 10<sup>8</sup> colony-forming units (CFU)/ml over 48 hours using two VRE isolates. A 5 × 4 concentration array of daptomycin alone (0, 1, 4, 16, 64 mg/L) and in combination with rifampin (0, 0.5, 2, 8 mg/L) was evaluated. Serial sam-

ples were withdrawn and bacterial counts were determined at 0, 1, 2, 4, 8, 24, 26, 28, 32, and 48 hours.

**RESULTS:** All isolates were susceptible to daptomycin (MIC 0.5–2 mg/L). Daptomycin, at concentrations less than or equal to 4 mg/L, alone and in combination exhibited limited activity with less than 1 log reduction in CFU/ml at 48 hours. Conversely, rapid bactericidal activity was exhibited at 16 and 64 mg/L with log reductions in CFU/ml at 24/48 hours of 3.80/3.97 and 4.73/5.58 respectively. The addition of rifampin 0.5 and 2 mg/L to high concentrations of daptomycin (64 mg/L) provided an additional 2.36 and 2.46 log reduction in bacterial count at 48 hours, respectively. Interestingly, there was a trend toward decreased activity of daptomycin 16 and 64 mg/L when combined with high concentrations of rifampin (8 mg/L) with log reductions in CFU/ml at 24/48 hours of 2.67/3.00 and 5.20/6.18 respectively.

**CONCLUSIONS:** The combination of daptomycin and rifampin achieved bactericidal activity against a high bacterial density of VRE. These results are promising and support further exploration of this combination as a potential therapeutic option for VRE endovascular infections.

**389. Cost-effectiveness of fidaxomicin for the treatment of severe *Clostridium difficile* infection in hospitalized patients in North America.** *Quinn Bott, Pharm.D., Candidate, Libbi Rice, Pharm.D., Candidate, John Oh, Pharm.D., Candidate, Veejaye Sinha, Pharm.D., Candidate, Nohemie Boyer, Pharm.D., Candidate; Northeastern University, Boston, MA*

**PURPOSE:** Current guidelines for *C. difficile*-associated diarrhea (CDAD) recommend oral vancomycin as treatment for severe infection. A new macrocyclic antibiotic, fidaxomicin, boasts similar cure rates and lower rates of recurrence. The price of a course of fidaxomicin exceeds \$2800 while the price of oral vancomycin is near \$1200. This study examines the cost-effectiveness of fidaxomicin compared with vancomycin for the treatment of severe *Clostridium difficile* infection (CDI) in the inpatient setting.

**METHODS:** A decision analytic model was developed to project the costs associated with the number of days a patient spends as an inpatient after primary infection with *C. difficile*. Clinical data was extracted from Phase 3 clinical trials of fidaxomicin and supported by other trials identified by systematic literature review. Cost data were taken from available literature and adjusted to 2011 US dollars.

**RESULTS:** A base case analysis resulted in a cost of \$8370 per patient treated with vancomycin and \$10,469 per patient treated with fidaxomicin. Monte Carlo simulations resulted in fidaxomicin being dominated by vancomycin; treatment with vancomycin provided an incremental benefit of 93 hospital days averted per 100 patients with CDI and resulted in a cost savings of \$2900 per patient. Sensitivity analyses showed that fidaxomicin becomes the more cost-effective option if more than 25.7 days are spent in the hospital for relapse; otherwise vancomycin remains the less costly option. If the cure rate for vancomycin falls below 75.6%, fidaxomicin becomes the more economical option.

**CONCLUSION:** This cost-effectiveness analysis demonstrated that fidaxomicin costs an additional \$2100 per patient and results in a length of stay that is slightly greater than if the patient had been treated with vancomycin. Fidaxomicin may be a cost-effective treatment in patients who are older, have comorbidities, have secondary or hospital-acquired CDI, or are at high risk for relapse. Otherwise, vancomycin appears to be a preferable strategy.

**390. Evaluating the impact of tuberculosis reporting by pharmacies/pharmacists to the Nevada state health authority.** *Jintu John, Pharm.D., Candidate, 2013, Christina M. Madison, Pharm.D., BCACP; Roseman University of Health Sciences, Henderson, NV*

**PURPOSE:** Rates of tuberculosis (TB) in the past ten years has been steadily declining in the United States, but a similar trend has not been seen in the state of Nevada. There have been approximately 100 cases of active TB disease diagnosed in

Nevada annually for the past 5 years. Appropriate management of TB disease following initial diagnosis can prevent further transmission and development of multi drug resistant organism. The Center for Disease Control and Prevention (CDC) recommends that all persons with active TB disease be treated under Direct Observational Therapy (DOT), which may not be possible if treatment is initiated by a private provider.

**METHODS:** The Nevada Administrative Code 441A was updated to reflect the following change: Pharmacies/pharmacists dispensing two or more TB drugs (isoniazid, rifampin, ethambutol, or pyrazinamide) are required to report to the Nevada State Health Authority according to the update, effective January 1st, 2011. Pharmacy/pharmacist reporting active TB disease is another possible way to identify cases. The law requires all pharmacies to include their name, address, contact information, name of the reporting pharmacist, patient demographics, medications prescribed and prescriber information. Increasing rates of reporting can help to identify and manage TB disease appropriately.

**RESULTS:** Since the implantation of the law, a total of six cases in Nevada have been reported by pharmacies/pharmacist, which is greater than 5% of the total number of active cases reported annually.

**CONCLUSION:** Appropriate drug therapy is imperative for effective TB control. Reporting active TB cases to the Health Authority by pharmacy/pharmacist can facilitate additional follow up that may not be available at through a provider's office. This is an additional tool to identify unreported active TB disease. Early identification allows for appropriate contact investigation and decreases the spread of this highly contagious respiratory disease.

**391. Retrospective review of antibiotic prophylaxis in open lower extremity fractures.** *Derek N. Bremmer, Pharm.D., Candidate<sup>1</sup>, April D. Miller, Pharm.D., BCPS<sup>2</sup>, P. Brandon Bookstaver, Pharm.D., BCPS, AQ-ID, AAHIVE<sup>1</sup>, Mark Cairns, M.D., Candidate<sup>3</sup>, Kenneth T. Lindley, M.D.<sup>4</sup>, David E. Koon, Jr, M.D.<sup>3</sup>; (1)South Carolina College of Pharmacy-USC Campus, Columbia, SC; (2)Vidant Medical Center, Greenville, NC; (3)School of Medicine, University of South Carolina, Columbia, SC; (4)Palmetto Health Richland, Columbia, SC*

**PURPOSE:** Patients with open fractures receive antibiotics to reduce the risk of future infections based on the Eastern Association for the Surgery of Trauma (EAST) Guidelines. Although recommendations exist, there are currently limited data supporting the use and appropriate selection of antibiotics for osteomyelitis prophylaxis in open fractures. The purpose of this study is to evaluate guideline practices' impact on osteomyelitis rates.

**METHODS:** This observational, retrospective, single-center study included adults with lower extremity open fractures of the ankle, tibia, fibula, or femur from January 2009 to March 2011. Demographic data, Gustilo fracture grade, antibiotics used, timing of antibiotics, and development of osteomyelitis within a year of wound closure were recorded. The primary endpoint was the incidence of osteomyelitis following open fracture. Secondary endpoint comparisons include infection rates between fracture grades, relationship between time of antibiotic initiation and infection rates, and impact of prolonged prophylaxis after closure.

**RESULTS:** A total of 96 patients were included. Patients suffered from Gustilo grade fractures 1 (12.5%), 2 (54.2%), 3a (26%), 3b (2%), and 3c (1%). Almost all patients received cefazolin (96%). Of the 25 grade three fractures, 16 patients received Gram-negative coverage with gentamicin (13), aztreonam (3), piperacillin-tazobactam (1), or ceftriaxone (1). The average time from patient presentation to antibiotic administration was 6.2 hours. The rate of osteomyelitis was 9.3%, with all cases involving Gustilo grades 2 (6.2%) and 3 (3.1%) fractures. All of the grade 3 fracture patients with osteomyelitis received Gram-negative coverage along with cefazolin.

**CONCLUSIONS:** The rate of osteomyelitis was slightly higher than in other previously published studies with osteomyelitis rates

of 7% and 6.5%. These increased rates require further evaluation to help optimize open fracture antibiotic prophylaxis.

**392. The SAGA components GCN5 and ADA2 influence the activity of fluconazole against *Candida glabrata* independent of the PDR1 transcriptional pathway.** Sarah G. Whaley, Pharm.D., Katherine S. Barker, Ph.D., P. David Rogers, Pharm.D., Ph.D.; University of Tennessee College of Pharmacy, Memphis, TN

**PURPOSE:** *Candida glabrata* exhibits reduced susceptibility to azole antifungals. In an effort to identify strategies to improve the utility of the azoles against this fungal pathogen, we screened a library of *C. glabrata* transcription factor disruption mutants to identify transcriptional pathways that when inactivated impart fungicidal activity to the fungistatic agent fluconazole.

**METHODS:** Fluconazole minimum inhibitory concentrations (MICs) and minimum fungicidal concentrations (MFCs) were determined according to CLSI standard methods. Expression of *PDR1* and *CDR1* with and without fluconazole treatment was measured using relative qPCR.

**RESULTS:** Of the 217 mutants of *C. glabrata* tested, four consistently showed increased susceptibility to fluconazole. Strains disrupted for *PDR1*, *GAL11A*, *GCN5* and *ADA2* demonstrated decreased MIC at 24 and 48 hours in both RPMI and YPD media. Interestingly, strains disrupted for *GCN5* and *ADA2* also showed decreased MFC. Fluconazole treatment induced expression of both *CDR1* (an ABC transporter involved in azole resistance) and *PDR1* (a transcription factor that controls expression of ABC transporters) in the wild type strain. In strains disrupted for *GCN5* and *ADA2* this response was only modestly attenuated. Fluconazole was unable to induce *CDR1* expression in the strain disrupted for *GAL11A*.

**CONCLUSIONS:** The four genes identified in this screen are associated with azole resistance in other yeasts. Pdr1 is a transcription factor that controls expression of drug efflux pumps including Cdr1. Gal11, part of the Mediator complex, is involved in transcriptional regulation of many pathways and is required for induction of *PDR1* expression by fluconazole and other xenobiotics. Gcn5 and Ada2 are both part of the SAGA complex which is responsible for histone post-translational modification. The ability of fluconazole to exhibit fungicidal activity against the *GCN5* and *ADA2* disruptant strains suggest the SAGA complex or its target genes may represent potential targets for enhancing azole activity against *C. glabrata*.

**393. Challenges in implementing antimicrobial stewardship in the emergency department (ED): a systematic review.** Sandy P. Bonfin, Pharm.D., Candidate; Palm Beach Atlantic University, West Palm Beach, FL

**PURPOSE:** To investigate challenges encountered when antimicrobial stewardship programs are implemented in the emergency department and identify potential solutions to overcome these challenges.

**METHODS:** A literature search on PubMed, The International Pharmaceuticals Abstracts, Cochrane and OVID was conducted. The keywords typed were: "antimicrobial stewardship AND emergency department," or "antibiotic AND emergency department AND clinical pharmacist." Descriptive analysis was conducted to assess challenges encountered by various institutions when implementing antimicrobial stewardship programs in their ED. Documented potential solutions will be discussed.

**RESULTS:** The search led to fifteen articles and abstracts. Three articles and four abstracts were included in this review. Challenges that emerged included: complications to obtain the bacterial culture results, depending on the hospital information technology systems or barriers to follow-up effectively and in a timely manner with patients and/or their primary care physicians. ED pharmacists may also face time constraint especially for cultures requiring immediate review. Documented solutions included appointing a specific person (provider and/or ED pharmacist) to be contacted by the microbiology laboratory to facilitate and expedite the process, educating ER providers by developing clinical

pathways and simplified algorithms to assist them when the ED pharmacist is not present due to schedule or staffing issues, or creating a multidisciplinary Quality Initiative committee.

**CONCLUSION:** This literature review confirms that organizational barriers to implement antimicrobial stewardship programs in the ED exist. There is no denial; however, that antimicrobial stewardship is beneficial to the ED. Our analysis will give insight on how these challenges can be overcome, depending on the type and size of the hospital and the type of clinical pharmacy services offered.

**394. Clinical experience with tigecycline against gram-negative infections.** Chase B. Bishop, Dr.Pharm., Candidate<sup>1</sup>, Srivedi Sambhara, Dr.Pharm., Candidate<sup>1</sup>, Sara J. Dingwall, Pharm.D.<sup>1</sup>, NaaDeDe O. Badger-Plange, Pharm.D., BCPS<sup>2</sup>, S. Todd Parker, Pharm.D.<sup>2</sup>, Chad M. VanDenBerg, Pharm.D., BCCP<sup>1</sup>, Vanthida Huang, Pharm.D., BSPHM<sup>1</sup>; (1)Department of Pharmacy Practice, Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (2)Piedmont Hospital, Atlanta, GA

**PURPOSE:** In vitro studies have shown efficacy of tigecycline in the eradication of multidrug-resistant (MDR) gram-negative organisms including Extended-spectrum  $\beta$ -lactamases-producing (ESBL) and carbapenem-resistant *Enterobacteriaceae* (CRE). Unfortunately, there is a lack of clinical data supporting the use of tigecycline for serious infections caused by these organisms. Therefore, we sought out to evaluate the efficacy and prevalence of tigecycline for the treatment of MDR gram-negative infections in a private community hospital.

**METHODS:** We conducted a retrospective cohort study of patients who received tigecycline for gram-negative infections from January 1 to December 31, 2010 at Piedmont Hospital, Atlanta, GA. Clinical and microbiological characteristics of all patients who were treated with tigecycline for MDR gram-negative infections were reviewed. Patients who received less than 3 doses of tigecycline were excluded. All statistical analyses were performed using standard bivariate and multivariate techniques to determine the association of treatment success with mono versus combination therapy and causative microorganism.

**RESULTS:** Of the 131 patients evaluated, 54 (41.2%) received tigecycline for FDA-approved versus 77 (58.8%) non FDA-approved use ( $p > 0.05$ ). There was not statistically significant difference in clinical outcomes in susceptible versus ESBL/CRE pathogens groups. There were 30 (22.9%) patients who received monotherapy versus 101 (77.1%) of patients who received combination therapy which was statistically significant in monotherapy group ( $p < 0.05$ ).

**CONCLUSIONS:** Tigecycline has established in vitro activity against a wide array of gram-positive and gram-negative strains of bacteria. Our study supports the use of tigecycline monotherapy for severe infections caused by MDR gram-negative organisms. The role of tigecycline is warranted for further investigation.

**395. Use of antibiotic lock therapy in central line-associated bloodstream infections in cancer patients: a systematic review.**

Farah Kablaoui, Pharm.D., Candidate<sup>1</sup>, P. Brandon Bookstaver, Pharm.D., BCPS, AQ-ID, AAHIVE<sup>1</sup>, LeAnn B. Norris, Pharm.D., BCPS, BCOP<sup>1</sup>, Charlie L. Bennett, M.D., Ph.D., MPP<sup>1</sup>, Robert J. Sherertz, M.D.<sup>2</sup>; (1)South Carolina College of Pharmacy, Columbia, SC; (2)Wake Forest University School of Medicine, Winston-Salem, NC

**PURPOSE:** To assess the use of antibiotic lock therapy (ALT) in prevention of central line-associated bloodstream infections (CLABSI) in cancer patients and provide evidence-based recommendations.

**METHODS:** A comprehensive literature search was performed through Medline and Google Scholar using the search terms "antimicrobial lock solution," "antibiotic lock solution," "hematology and oncology," "cancer," and "central venous catheter." Article reference lists were also reviewed. Published data were considered appropriate if antibiotic lock solutions were used in a

prophylactic manner, study population included cancer patients, and lock therapy outcomes of interest were reported. Case reports and case series were acceptable. In vitro data and published literature omitting outcomes such as clinical effectiveness, dwell times and type of solution were excluded. Clinical effectiveness was recognized by the rate of infections per 1000 catheter days. Studies were reviewed independently by three seasoned investigators. All data were compiled and analyzed to provide evidence-based recommendations.

**RESULTS:** A total of 70 articles were identified through the search methodology and 24 of those were investigations in a cancer population. Following all exclusions, study investigators identified 11 published articles including: eight randomized controlled trials, one prospective open-label trial, one case report and one brief report. Solutions studied included: vancomycin (5), ethanol (2), minocycline/EDTA (2), ciprofloxacin (1) and amikacin (1). Other than minocycline, all antimicrobials were in combination with heparin. The mean percent reduction of using ALT versus the control was 43.7%. No severe adverse events were reported.

**CONCLUSION:** The use of antibiotic lock therapy in a prophylactic modality decreases the incidence of CLABSI in cancer patients. Clinicians may consider ALT as a prophylactic option for reducing CLABSI. Future trials should focus on prospective evaluation of clinical effectiveness of various lock solutions.

## Medication Safety

**396. Community pharmacists' perceptions and knowledge of medication disposal.** Lanette J. Sipple, Pharm.D., Candidate, 2013, Autumn L. Stewart, Pharm.D.; Duquesne University, Pittsburgh, PA

**PURPOSE:** Medication disposal is an emerging topic of concern due to potential ecological consequences, prescription drug abuse, and accidental ingestion and poisoning within homes. The primary objective of this study is to describe pharmacist knowledge and attitudes towards medication disposal and confidence in the ability to counsel patients on appropriate medication disposal.

**METHODS:** A 16-item survey was distributed via SurveyMonkey™ to practicing community pharmacists. Data were analyzed using descriptive and inferential statistics. Pearson's Test for Correlation was used to explore relationships between variables. Nominal variables were compared using Chi-squared test.

**RESULTS:** Surveys were sent to approximately 250 community pharmacists of which there were 132 complete, usable responses. 43.2% of respondents indicated they counsel on medication disposal 2–3 times per month with 73.5% indicating confidence in this ability. Seventy-eight of respondents identified pharmacists as a "good resource" for information on medication disposal, and 72% identified it as a professional responsibility. Self-reported knowledge of disposal guidelines and take back programs is low, with only 56.1% and 54.5% of pharmacists responding in agreement. In general, the number of years in practice did not correlate with knowledge of confidence. However, new practitioners (those practicing 5 years or less), were 40% less likely to view inappropriate disposal of medicine as a significant public health problem compared with experienced practitioners (Chi Square = 0.037).

**CONCLUSIONS:** Appropriate medication disposal is a topic of concern for pharmacists and the public. Despite recognizing appropriate medication disposal as a responsibility and area of expertise of pharmacists, knowledge of appropriate practices is relatively low. This may be related to the overall indifference towards the impact of inappropriate disposal on the environment and public health.

**397. Prevalence of statin-induced rhabdomyolysis in Asian populations.** Xu Cong Ruan, B.Sc. (Pharm.), Yu Heng Kwan, B.Sc. (Pharm.), Joanne Chang, Pharm.D.; National University of Singapore, Singapore, Singapore

**PURPOSE:** The incidence of simvastatin-induced rhabdomyolysis occurrences is high at FDA recommended dosing guidelines in

Asian populations. This study aims to evaluate the prevalence of statin-induced rhabdomyolysis in Asians in order to 1) review the safety profile of statin use and 2) compare dose-related rhabdomyolysis in both mono- and combination statin therapy.

**METHODS:** A total of 24, 333 patients prescribed with any statins were reviewed via medical record from 2008 to 2011 in a general hospital in Singapore. These hospitalized patients with clinically diagnosed rhabdomyolysis were identified through ICD-9 codes, excluding those with post-operational rhabdomyolysis, peak creatine kinase (CK) < 1000 IU/L or incomplete clinical records. Data collection parameters include patient demographics, pertinent labs (peak CK levels, lipids, liver and renal panels) and clinical symptoms of myopathy.

**RESULTS:** Ninety two patients (0.38%) were hospitalized for rhabdomyolysis at the FDA recommended simvastatin dosages (median dosage = 20 mg). Four patients underwent recurrent rhabdomyolysis hospitalizations prior to their statins being discontinued (average dose = 25 mg). Eighteen cases (0.07%) reported severe rhabdomyolysis (CK > 10,000 IU/L) with a median peak CK of 30,765 IU/L and median simvastatin dose of 20 mg. The remaining cases (10,000 ≤ CK < 1000) had a median peak CK of 2385 IU/L and median simvastatin dose of 10 mg. The average statin exposure duration before the onset of rhabdomyolysis was 625.7 ± 625.4 days. Eleven patients (0.05%) expired during hospitalization due to the combinatorial effect of rhabdomyolysis, infection and/or acute myocardial infarction.

**CONCLUSION:** Our finding suggests the dosage of statins should be lower compared to that recommended by the US to avoid serious adverse events related to rhabdomyolysis. Given the potential pharmacokinetic and pharmacodynamic sensitivity of Asian patients to higher statin related adverse events, it may warrant a more judicious approach to statin titration in these patients.

**398. Use of unsafe abbreviations in pharmacy literature.** Joseph Kohn, Pharm.D., Candidate, Duchess Domingo, Pharm.D., Candidate, Ruth Nyakundi, Pharm.D., Candidate, Kai Feng, Pharm.D., Candidate, Christopher Maceri, Pharm.D., Candidate, Antonia Zapantis, M.S., Pharm.D., Jennifer G. Steinberg, Pharm.D.; College of Pharmacy, Nova Southeastern University, Davie, FL

**PURPOSE:** The intention of this study is to determine whether the use of selected medication-related abbreviations has diminished in pharmacy literature in compliance with the Joint Commission's (TJC) "Do Not Use" abbreviations list issued in 2004. Use of these abbreviations has been deemed a preventable threat to patient safety.

**METHODS:** Three pharmacy journals were selected representing medication safety culture. Researchers measured the frequency of TJC prohibited abbreviations within each issue of each of the journals published during the years 1997 and 2011, 7 years prior and 7 years after the publication of the TJC "Do Not Use" abbreviations list. The abbreviations consisted of U, IU, QD, QOD, MgSO<sub>4</sub>, MS, trailing zeroes, and naked decimals. The frequency of prohibited abbreviations per article, per issue, and per journal, per year was compared between the 2 years for each journal and between journals. All articles regardless of type were included in the study. Advertisements were not evaluated, and abbreviations used in reporting of medication errors or representing context not in line with TJC guidelines were excluded. Additionally, current submission guidelines were evaluated for abbreviation considerations.

**RESULTS:** Preliminary analysis indicates there was an overall lower incidence of prohibited abbreviations in each of the three journals over the course of 2011 compared to those from 1997. Total incidence of these types of abbreviations was low, with QD, U, and trailing zeroes most often identified. Final analysis pending and will be presented. No current submission guidelines provide instruction regarding abbreviation use in this context.

**CONCLUSION:** Results suggest that there has been a decrease in the frequency of inappropriate abbreviations in journal articles since the introduction of TJC's "Do Not Use" abbreviations list.

Any use of these abbreviations may re-emphasize such unsafe behavior and should be discouraged.

**399. Evaluation of dabigatran prescribing practices at University of Illinois Medical Center.** *Joey Lam, Pharm.D., Candidate, 2013*<sup>1</sup>, Adam P. Bress, Pharm.D.<sup>2</sup>, Edith A. Nutescu, Pharm.D.<sup>1</sup>, Vicki L. Groo, Pharm.D.<sup>2</sup>; (1) College of Pharmacy, University of Illinois at Chicago, Chicago, IL; (2) University of Illinois at Chicago, Chicago, IL

**PURPOSE:** Dabigatran (D) is the first oral anticoagulant available as an alternative to warfarin in 58 years. It was approved in October 2010 with only one indication; the prevention of stroke or systemic thromboembolism for nonvalvular atrial fibrillation. Unlike warfarin, dosing is a fixed bid regimen based on renal function and does not require INR monitoring. The University of Illinois Medical Center (UIMC) clinical pharmacists proactively educated physicians, nurses, and pharmacists on proper use of D. Additional education was provided as new information became available, specifically reports of bleeding and an update to the package insert. The objective of this study is to evaluate the prescribing practices since regulatory approval of D at UIMC.

**METHODS:** Retrospective review of D prescriptions from 12/10/10 to 12/23/11. Demographics, past medical history, CrCl, concomitant anti-platelet therapy and PGP-inhibitors were evaluated. High risk for bleeding was defined as age > 75, CrCl ≤ 30 ml/minute, on concomitant PGP-inhibitors, and/or body weight < 60 kg.

**RESULTS:** Among the 92 D prescriptions, 60 were converted from warfarin and 32 were new to anticoagulation. The mean age was 66.1 ± 13.4 years, 63.0% were male, 58% Caucasian, 31% African American, 11% other. Forty-seven percent of patients were taking daily aspirin and 0 were on other anti-platelet therapy.

**Table 1. Prescribing trend.:**

	n (%)
Indication appropriate	92 (100.0)
CrCl > 30 ml/minute and on 150 mg BID (n=83)	77/83 (92.8)
CrCl ≤ 30 ml/minute and on 75 mg BID (n=9)	9/9 (100.0)

**Table 2. Bleeding risk.:**

	n (%)
Age > 75 years	25 (27.2)
CrCl ≤ 30 ml/minute	9 (9.8)
Body weight < 60 kg	4 (4.3)
PGP-inhibitors and CrCl > 30 ml/minute (n=83)	11/83 (13.3)
PGP-inhibitors and CrCl ≤ 30 ml/minute	0 (0)

**CONCLUSION:** These data suggest that patients of UIMC are prescribed and dosed on D appropriately without significant drug interactions. Proactive education to prescribers may have contributed to appropriate prescribing. The most common bleeding risk is age > 75.

**400. The medication REACH program.** *Laura M. Williams, B.S., Pharm.D., Candidate*<sup>1</sup>, Deborah Hauser, R.Ph., MHA<sup>2</sup>, Angelo De Luca,<sup>2</sup>; (1) Jefferson School of Pharmacy, Thomas Jefferson University, Philadelphia, PA; (2) Einstein Medical Center, Philadelphia, PA

**PURPOSE:** Data from the literature suggests that one out of every five patients discharged from a hospital setting will experience an adverse event, with 72% of these adverse events being medication-related. When patients transition from one setting to another, there is often a disconnect between hospitalists, primary care physicians, community pharmacists, patients and caregivers. This lack of communication can result in adverse events and increased hospital readmissions. The medication REACH program (Reconciliation, Education, Access, Counseling, Healthy patient at home) at Einstein Medical Center was implemented to address medication management issues at discharge in high-risk

patients with acute myocardial infarction, congestive heart failure and hypertension. The overall goal of this program was to prevent hospital readmissions through interventions made by clinical pharmacists.

**METHODS:** Of the 89 patients (17% with acute myocardial infarction, 48% with CHF, and 82% with hypertension) were randomized to receive traditional nurse-mediated or clinical pharmacist-mediated discharge counseling. Four clinical pharmacists were directly involved in performing medication reconciliation, providing patient-centered education, resolving issues related to medication access, and completing medication counseling "after care" calls. The purpose of the call was to review medication regimens, resolve any medication-related issues and reiterate the importance of medication adherence.

**RESULTS:** Patients in the intervention group were less likely than those in the control group to be readmitted to the hospital within 30-days post discharge (10.6% versus 23.8%, respectively). Despite these results, the difference was not statistically significant (p=0.085). A total of 59 medication management interventions were made by clinical pharmacists, with the most common being the initiation of a medication therapy (25%).

**CONCLUSION:** The medication REACH program demonstrates the importance of clinical pharmacists in the setting of care transitions. Implementing a program to address medication management issues at discharge decreased 30-day hospital readmission rates, although further research with larger samples is warranted.

**401. Tech-Check-Tech program.** *Hung Le, Pharm.D., Candidate, 2013*, Yakima Regional Medical & Cardiac Center, Yakima, WA

**PURPOSE:** To develop a Tech-Check-Tech (T-C-T) Program for the Yakima Regional Medical & Cardiac Center through an intensive technician training program which includes both didactic and practicum.

**METHODS:** Research, program planning and implementation (in progress as of 07/06/2012).

**RESULTS:** Pending on the Washington State Board of Pharmacy and institution's P&T Committee.

**CONCLUSION:** The T-C-T Program enhances medication safety and focuses more pharmacists' efforts on clinical services (at the same time).

## Nephrology

**402. Student-pharmacist based medication reconciliation to identify drug record discrepancies and medication-related problems in an outpatient hemodialysis unit.** *Desiree E. Kosmisky, Pharm.D., Candidate*<sup>1</sup>, Oriyomi R. Alimi, Pharm.D.<sup>1</sup>, Chelsea R. Fitzgerald, Pharm.D., Candidate<sup>1</sup>, Kajal S. Patel, Pharm.D., Candidate<sup>1</sup>, Melissa A. Ruminski, Pharm.D.<sup>1</sup>, Iris Hayes, L.S.W.<sup>2</sup>, Heather Lash, R.D.<sup>2</sup>, Filitsa Bender, M.D.<sup>2</sup>, Kevin Ho, M.D.<sup>2</sup>, Thomas D. Nolin, Pharm.D., Ph.D.<sup>1</sup>; (1) University of Pittsburgh, Pittsburgh, PA; (2) DCI Renal Services of Pittsburgh, Pittsburgh, PA

**PURPOSE:** Drug record discrepancies (DRDs) occur when the electronic medical record (EMR) medication list differs from the patient's actual drug regimen. DRDs occur frequently in hemodialysis patients and are associated with increased incidence of medication-related problems (MRPs). The purpose of this project was to evaluate the role of student pharmacists in medication reconciliation to identify DRDs and MRPs in outpatient hemodialysis patients.

**METHODS:** This pilot study was approved by the University of Pittsburgh Medical Center as a Quality Initiative project. It was performed in two phases, from Jan to Apr 2011, and then repeated from Mar to Apr 2012. Chronic hemodialysis patients at a single outpatient clinic were asked to participate by bringing in medications for review by student pharmacists. DRDs and MRPs were identified through patient interviews, medication reviews, EMR review, and conversations with clinic staff. Data are presented as median (range).

**RESULTS:** Twenty-four patients participated in phase 1, and of these, 16 participated in phase 2 follow-up. A total of 87 DRDs

were observed in 22/24 patients (2.5 [0–16]), and 38 MRPs were identified in 16/24 patients (1 [0–7]), compared with 80 DRDs in 14/16 patients (2 [0–16]) and 30 MRPs in 11/16 patients at follow-up (1.5 [0–5]). The most common DRDs observed during phases 1 and 2 were ‘no longer taking a drug listed in the EMR (39/87)’ and ‘taking a drug not listed in the EMR (37/80)’, respectively. The most common MRP in both phases related to nonadherence, with 10/38 and 15/30 MRPs pertaining to patients not taking 1 or more prescribed drugs during phase 1 and 2, respectively.

**CONCLUSION:** Student pharmacists successfully identified DRDs and MRPs in the majority of patients interviewed. These results suggest that students participating in medication reconciliation activities can play a positive role in the identification of DRDs and MRPs in outpatient hemodialysis patients.

**403. Clinical pharmacist driven anemia management team care with evidence-based algorithm in chronic kidney disease patients.** *Chae Hee Kwak, M.S.<sup>1</sup>, Da-Hae Jun, M.S.<sup>1</sup>, Nayoung Han, M.S.<sup>1</sup>, Soojung Ha, M.S.<sup>1</sup>, Eunhee Ji, Ph.D.<sup>1</sup>, Yon Su Kim, M.D., Ph.D.<sup>2</sup>, Kwon Wook Joo, M.D., Ph.D.<sup>2</sup>, Kook Hwan Oh, M.D., Ph.D.<sup>2</sup>, Dong Ki Kim, M.D., Ph.D.<sup>2</sup>, Hye-suk Lee, Ph.D.<sup>1</sup>, Jung Mi Oh<sup>1</sup>;* (1)College of Pharmacy, Seoul National University, Seoul, South Korea; (2)Seoul National University Hospital, Seoul, South Korea

**PURPOSE:** Anemia is the most common complications and still the leading cause of death as a cardiovascular risk factor among patients with chronic kidney disease (CKD). However, there was none algorithm based Korean clinical treatment guideline and insurance criteria. Thus, this study was to evaluate the current status of anemia management in CKD patient through multidisciplinary team care (MTC) and to develop the evidence based anemia management algorithm.

**METHODS:** Patients who were administrated at SNUH were included between October 2010 and September 2011. The primary outcome was the proportion of patients who achieved target Hb level (10–11 g/dl) between the MTC and non-MTC groups. The Secondary outcome was the proportion of patients who reached the target, ferritin, and transferrin saturation (Tsat) level. When developing CKD anemia management algorithm, we reviewed clinical practice guidelines, clinical trials, recent safety reports, and domestic national health insurance criteria.

**RESULTS:** A total of 131 patients were allocated to either usual care or the protocol. The difference of proportion of Hb values between the two-groups was not statistically significant. The percentage of patients below Hb target level decreased significantly during admission period ( $p < 0.01$ ), indicating an improvement of CKD anemia treatment by MTC. Furthermore, the percentage of patients who reached the target ferritin level increased from 34.8% to 42.9% in MTC group. Based on this assessment of current CKD anemia management, we developed the algorithm composed of four parts: (i) Anemia work-up, (ii) Iron-deficient anemia treatment, (iii) Erythropoietin-deficient anemia treatment, and (iv) Vitamin B12 or folate-deficient anemia treatment.

**CONCLUSION:** This is the first study to evaluate the effectiveness and potential of MTC involvement in CKD anemia treatment in Korea. In addition, evidence-based CKD anemia treatment algorithms for clinical pharmacists developed for future implementation and application may improve anemia management.

## Neurology

**404. Utility of serum cytokines as biomarkers for ischemic stroke in translational research.** *Abdelrahman Y. Fouda, B.Sc.<sup>1</sup>, Anna Kozak, M.S.<sup>2</sup>, Ahmed Alhusban, Pharm.D.<sup>1</sup>, Jeffrey Switzer, D.O.<sup>3</sup>, Susan C. Fagan, Pharm.D.<sup>4</sup>;* (1)University of Georgia, Augusta, GA; (2)College of Pharmacy and Veteran's Affairs Medical Center, University of Georgia, Augusta, GA; (3)Georgia Health

Sciences University, Augusta, GA; (4)Program in Clinical and Experimental Therapeutics, Norwood VA Medical Center Au, University of Georgia College of Pharmacy Charlie, Augusta, GA

**PURPOSE:** The inflammatory response plays an important role in the pathogenesis of ischemic stroke. Many clinical studies use serum as a surrogate measure of the inflammation process in the brain. In this investigation we aimed at comparing the levels of four major cytokines (IL-1 $\alpha$ , IL-6, IL-10 & TNF- $\alpha$ ) in the rat brain and serum after experimental ischemic stroke.

**METHODS:** 25 Wistar rats were subjected to either temporary (tMCAO, n=11) for 3 hours, permanent (pMCAO, n=11) middle cerebral artery occlusion, or sham (n=3) and the animals were euthanized at either 24 or 72 hours after the onset of ischemia. Brain tissue and serum were collected and the levels of cytokines were assayed using a multiplex array system (Bio-Plex 200). Cytokine levels in each hemisphere were compared to sham operated animals.

**RESULTS:** At 24 hours after tMCAO, inflammatory cytokines (IL-1 $\alpha$ , IL-6 & TNF- $\alpha$ ) were significantly increased in the ischemic brain hemisphere ( $p < 0.05$ ) as compared to shams. This increase subsided after 72 hours. In the serum, cytokine levels significantly increased only after 72 hours of both tMCAO & pMCAO ( $p < 0.05$ ). At 24 hours, the anti-inflammatory IL-10 was significantly higher in the contralesional versus stroked side. However, IL-10 increased significantly in the stroked hemispheres of both pMCAO and tMCAO groups 72 hours after MCAO ( $p < 0.05$ ). A similar pattern was observed in the serum.

**CONCLUSION:** Changes in inflammatory cytokines occur earlier in the brain than in the serum and are exaggerated when reperfusion occurs. Serum cytokines reflect both the inflammatory and anti-inflammatory response to focal cerebral ischemia. In order to more accurately assess brain inflammation, both inflammatory and anti-inflammatory cytokines should be quantified.

**405. Blood pressure variability and outcome in ischemic stroke patients.** *Jocelyn A. Owusu-Yaw, Pharm.D., Candidate, 2013<sup>1</sup>, Susan C. Fagan, Pharm.D.<sup>2</sup>, Jody L. Rocker, Pharm.D.<sup>3</sup>, Jeffrey Switzer, D.O.<sup>3</sup>, David Hess, M.D.<sup>3</sup>;* (1)University of Georgia College of Pharmacy, Augusta, GA; (2)Program in Clinical and Experimental Therapeutics, Norwood VA Medical Center Au, University of Georgia College of Pharmacy Charlie, Augusta, GA; (3)Georgia Health Sciences University, Augusta, GA

**PURPOSE:** In the acute stroke setting, high blood pressure variability has been associated with poor outcome. However, the relationship to antihypertensive medication is less clear. The American Stroke Association has no clear blood pressure target in the acute stroke setting. Blood pressure lowering medication is often reinstated 24 hours after the patient presents with an ischemic stroke. This study is aimed at examining the relationship between blood pressure variability over the first 3 days after stroke and patient disposition.

**METHODS:** This retrospective study included all patients admitted to the stroke service with ischemic stroke symptoms in the period of between January and June 2010. Blood pressures were recorded from the time of admission through the first 3 days of hospital stay. Patients were assigned good disposition based on a discharge home, or poor disposition based on discharge to an inpatient rehabilitation or nursing center.

**RESULTS:** Of the 82 patients enrolled, 28% had a poor disposition and 72% had a good disposition. The definition of high variability in systolic blood pressure (SBP) was a change of  $\geq 40$  mmHg within one day. In a preliminary review, it appears that the patients with low variability had a better chance of a good disposition. The average number of BP lowering medications for good and poor outcome patients was 1.87 and 1.92 respectively. Analysis is ongoing.

**CONCLUSION:** Low BP variability in the first 3 days of hospital admission for ischemic stroke appears to be associated with

good outcome. Further analysis is needed to determine the role of BP lowering medications and outcome.

**406. The effect of dexamethasone on glioblastoma-associated stromal cells.** *Amira Hosni-Ahmed, M.Sc.<sup>1</sup>, Ken Pitter, B.S.<sup>2</sup>, Eric Holland, M.D., Ph.D.<sup>2</sup>, Terreia Jones, Pharm.D.<sup>1</sup>*; (1) University of Tennessee, Memphis, TN; (2) Memorial Sloan-Kettering Cancer Center, New York, NY

**PURPOSE:** The corticosteroid dexamethasone has been used for decades in the management of brain tumor-associated edema. Corticosteroids can be associated with a plethora of side effects. Additionally, no equally effective agents exist for managing neurological symptoms. Furthermore, it hasn't been identified yet the effect of dexamethasone on glioma/stromal cells or how it shapes the course of the disease. We hypothesize that dexamethasone exerts its effect by modulating tumor-associated stromal cell function such as microglia.

**METHODS:** PDGF-driven gliomas were generated using RCAS/Ntva system. In vivo studies were conducted on mice treated with dexamethasone and/or ionizing radiation (IR). Gene expression studies were performed to assess the effect of dexamethasone on tumor cells and microglia using the Illumina mouse ref8 array. Finally, in vitro studies were conducted using glioma cultures to validate in vivo findings.

**RESULTS:** Immunohistochemical studies demonstrated that dexamethasone could alter the characteristics but not the percentage of iba-1 expression (microglia) in brain tumor tissue. Mice that have been pretreated with dexamethasone followed by IR had a significant shorter survival time compared to mice treated with IR only. Furthermore, microglia gene expression data showed a modulation of a few inflammatory cytokines that might contribute in tumor progression after dexamethasone treatment. Finally, in vitro studies suggested that dexamethasone might influence stem cell characteristics.

**CONCLUSION:** In summary, our data suggests that dexamethasone modulates the course of glioma possibly through a tumor-microenvironment interaction. Dexamethasone shortened the animal survival rate when combined with IR. Finally, this study shed the light on the clinical importance of dexamethasone's mechanism of action and hence the development of new therapies to manage neuro-symptoms.

## Oncology

**407. The role of procalcitonin in hematopoietic stem cell transplant: a systematic literature review.** *Rabia Jamali, Pharm.D., Candidate, 2013<sup>1</sup>, William O'Hara, Pharm.D., BCPS, BCOP<sup>2</sup>*; (1) Jefferson School of Pharmacy, Philadelphia, PA; (2) Thomas Jefferson University Hospital, Philadelphia, PA

**PURPOSE:** Hematopoietic stem cell transplant (HSCT) is an essential component in the therapy for numerous hematologic malignancies. Post-transplant infectious complications are a major concern and are often difficult to distinguish from other complications, particularly Graft versus Host Disease (GVHD). Therefore, a suitable differential diagnostic indicator is needed. Procalcitonin is an inflammatory marker that is elevated in the presence of infection. The purpose of this literature review was to gain a deeper understanding for the role of procalcitonin in distinguishing infection from other causes of fever in HSCT patients.

**METHODS:** A systematic review using PubMed and Ovid databases was performed to retrieve the most recent studies that evaluated procalcitonin values during infectious episodes in HSCT patients. Key terms such as *procalcitonin*, *hematopoietic stem cell transplant* and *infection* were used. Studies from peer-reviewed journals and clear monitoring parameters of procalcitonin before and after HSCT were included. Articles were critiqued on the design, patient population selection, methodology, results and conclusions.

**RESULTS:** The literature search identified five relevant studies that were eligible to be reviewed. Four articles were prospective and one article was a retrospective study. All articles affirmed that there was a correlation between procalcitonin and the incidence of bacterial or fungal infection. In the incidence of GVHD, the serum levels remained within normal limits. However, one study claimed the trend was not significant. The largest study with the least confounding variables concluded that there is indeed a significant importance of procalcitonin in HSCT patients, regardless of concomitant steroid therapy.

**CONCLUSION:** Procalcitonin has been shown to have a definite correlation with the incidence of infection in HSCT patients. Further investigation is needed in a large patient population to adequately confirm the link between procalcitonin and HSCT associated infectious complications.

**408. An analysis of current prescribing practices in a community hospital: Filgrastim used to prevent and treat febrile neutropenia, a potentially dangerous side effect of myelosuppressive chemotherapy.** *Arlene Cheng, Pharm.D., Candidate, 2013<sup>1</sup>, Shane Clemans, Pharm.D., Candidate, 2013<sup>1</sup>, Agnieszka Konecka, Pharm.D., M.B.A.<sup>2</sup>*; (1) St Johns University, Jamaica, NY; (2) Huntington Hospital NS LIJ Health System, Huntington, NY

**PURPOSE:** Currently, Huntington Hospital lacks a protocol for the use of filgrastim for prophylaxis and treatment of febrile neutropenia (FN) in patients receiving myelosuppressive chemotherapy. Therefore, the primary objective of this medication utilization evaluation was to assess current prescribing practice. The secondary objective was to utilize findings to make a recommendation for a drug protocol. [56]

**METHODS:** Patients who received filgrastim within the respective period (Feb-Apr 2012) were compiled using Horizon Meds Manager. Records were reviewed retrospectively and data, including prescribing specialty, patient's admission weight, day of the last chemotherapy, filgrastim dose/frequency/duration/indication, pre-treatment temperature, white blood count and neutrophil percent count, if available, was assembled using Microsoft Excel 2010. Using the data collected filgrastim daily dose of 5 µg/kg and absolute neutrophil count were calculated [68].

**RESULTS:** Records of eighteen patients were reviewed. The majority (73%) of the orders were written by hematologists/oncologists. Four patients were excluded because: outpatient order (n=1), FN induced by non-chemotherapeutics (n=2), inadvertent administration while on pegfilgrastim (n=1). Fourteen patients (78%) received filgrastim for neutropenia due to myelosuppressive chemotherapy. There was a 20% difference between the calculated dose and actual administered in four (29%) patients. Half of them received filgrastim 480 µg and for the other two the calculated dose of 397 µg was rounded off to a dose of 300 µg. The majority (92%) of patients received filgrastim 24-72 hours post-chemotherapy with the exception of one. [103]

**CONCLUSIONS:** These findings identified two areas of opportunity to optimize filgrastim dosing in the setting of myelotoxic chemotherapy. Rounding off the calculated dose/kg/day to the nearest vial size by institution-defined weight limits may optimize initial dose and prevent reductions in chemotherapy dose or delays in therapy. Inappropriate filgrastim administration in the context of chemotherapy completion may compromise clinical outcomes, thus hematology-oncology consult may be warranted. Further studies are needed to support these conclusions. [72]

## Other

**409. A validation study of the Malay version of Minnesota nicotine withdrawal scale.** *Ali Qais Blebil, M. Pharm.<sup>1</sup>, Mohamed Azmi Ahmad Hassali, Ph.D.<sup>1</sup>, Syed Azhar Syed Sulaiman, Pharm.D.<sup>1</sup>, Alfian M. Zin, Dipl.<sup>2</sup>, Juman Dujaili, M. Pharm.<sup>1</sup>*; (1) School of Pharmaceutical Science, Universiti Sains Malaysia, Bayan Lepas, Malaysia; (2) Quit smoking Clinic, Penang General Hospital, Gorge Town, Malaysia

**PURPOSE:** The present study aimed to translate and validate MNWS scale for practical clinical purposes among Malay speaking people.

**METHODS:** A cross sectional design was used to elaborate the study data. Adult smokers who attend the Quit Smoking Clinic in Penang General Hospital at Penang State, Malaysia were included in the study. The translation was done according to standard guidelines: Forward translation, back translation from Malay to English language, pretesting and cognitive interviewing, and preparing the final version of the Malay scale for the reliability and validity study. Eligible subjects were interviewed by expert counsellor with the use of structured questionnaire to overcome any non-response by those who had reading difficulties. The interview was performed at day 7 of subject's quit smoking date. Internal consistency and homogeneity was used to test reliability of the Malay version of MNWS. Furthermore factor analysis and concurrent validity was employed to validate the psychometric properties of the scale.

**RESULTS:** The Malay version of MNWS scale has excellent reliability with Cronbach's alpha of 0.91. The test-retest reliability for the scale were presented and an excellent reliability and stability of the translated scale with Spearman's Rank Correlation Coefficient,  $r = 0.876$  ( $p = 0.001$ ). In addition, There was a significant positive correlation between carbon monoxide level, FTND total score and number of cigarettes smoked per day with MNWS total score ( $r = 0.72$ ,  $r = 0.68$  and  $r = 0.68$ ,  $p = 0.001$ ; respectively). A principal components analysis with orthogonal rotation yielded a uni-dimentional model which includes all the items of MNWS.

**CONCLUSION:** The Malay version of MNWS is reliable and a valid measure for withdrawal symptoms as well as the smoking urge and it is applicable for clinical practice and research study.

#### 410. Evaluation of psychometric properties for translated-Malay version of the brief questionnaire on smoking urges. *Ali Qais Blebil*<sup>1</sup>, Mohamed Azmi Ahmad Hassali, Ph.D.<sup>1</sup>, Syed Azhar Syed Sulaiman, Pharm.D.<sup>1</sup>, Alifian M. Zin<sup>2</sup>, Juman Dujaili<sup>1</sup>; (1) School of Pharmaceutical Science, Universiti Sains Malaysia, Bayan Lepas, Malaysia; (2) Quit smoking Clinic, Penang General Hospital, Bayan Lepas, Malaysia

**PURPOSE:** Craving for smoking is often considered as an important concept in smoking addiction and the most prominent and bothersome symptom experienced during the abstinence attempt. This study tries to evaluate the Malay version of the Brief Questionnaire on Smoking Urges (QSU-Brief).

**METHODS:** A cross-sectional study design was adopted for the conduct of the study. The reliability and validity of Malay version for the questionnaire was evaluated based on the data collected from 133 participants. Cronbach's alpha coefficient was calculated to assess the reliability. In order to assess the validity of the scales, Factor analysis and concurrent validity was employed to validate the psychometric properties of the scales.

**RESULTS:** The Malay version of QSU-Brief scale has good reliability with Cronbach's alpha of 0.82. The test-retest reliability for the scale were presented an acceptable reliability and stability of the translated scale with spearman's rank correlation coefficient with  $r = 0.757$  ( $p < 0.001$ ). Furthermore, There was a significant positive correlation between carbon monoxide level, FTND total score and number of cigarettes smoked per day with MNWS total score ( $r = 0.63$ ,  $r = 0.58$  and  $r = 0.62$ ,  $p < 0.001$ ; respectively). Surprisingly, principal components analysis with orthogonal rotation yielded a uni-dimentional model which includes all the items of QSU-Brief.

**CONCLUSION:** the findings from the current validation study revealed that the Malay version of the QSU-Brief are reliable and valid measure for the smoking urges and ready for use in clinical practice and research study.

#### 411. A meta-analysis of the effects of interleukin-10 promoter gene polymorphisms on acute graft-versus-host disease susceptibility. *InHye Cho, B.S.*, YunKyoung Song, M.S., Bo Yoon Choi, B.S., Jung

Mi Oh, Pharm.D.; College of Pharmacy, Seoul National University, Seoul, South Korea

**PURPOSE:** The interleukin-10 (IL-10) is an important immunomodulatory cytokine that regulates the effect of other inflammatory mediators in many aspects of immune responses. IL-10 promoter gene polymorphic features have been documented to contribute to the susceptibility of acute graft-versus-host disease (aGVHD). However, results of previous studies are inconsistent and inconclusive. A meta-analysis was performed to evaluate the association between the IL-10 promoter gene polymorphisms in allogeneic hematopoietic stem cell transplantation (alloHSCT) patients and donors on the risk of aGVHD.

**METHODS:** Up to April 2012, databases including MEDLINE, EMBASE and Cochrane Library were searched to access the relevant genetic association studies. A total of 22 studies that referred IL-10 promoter gene polymorphisms on aGVHD susceptibility were identified. The effect of the IL-10 genetic polymorphisms on aGVHD risk (grades I-IV, II-IV, and III-IV) were estimated from odds ratios (OR) with 95% confidence intervals (CI) for the dominant genetic model and recessive model, respectively.

**RESULTS:** IL-10 -819 CC genotype was associated with the increased aGVHD risk when compared with CT+TT genotype (grade I-IV: OR, 2.722, 95% CI, 1.360-5.450; grade II-IV: OR, 2.130, 95% CI, 1.322-3.430). Furthermore, patients with IL-10 -592 C genotype had an increased risk of grade II-IV aGVHD (CC versus A: OR, 1.999, 95% CI, 1.230-3.250) and grade III-IV aGVHD (CC versus A: OR, 1.276, 95% CI, 1.067-1.526; C versus AA: OR, 1.419, 95% CI, 1.001-2.012; CC versus AA: OR, 1.534, 95% CI, 1.076-2.185; C versus A: OR, 1.180, 95% CI, 1.000-1.392). Patients who received grafts from donors with the IL-10 C allele experienced less frequent grade III-IV aGVHD (OR, 0.711, 95% CI, 0.508-0.996).

**CONCLUSION:** This meta-analysis suggests that the -819C/T and -592C/A polymorphisms of IL-10 gene could be a risk factor for aGVHD in allo-HSCT patients. Moreover, our meta-analysis confirms the linkage disequilibrium between two single nucleotide polymorphisms (SNPs) as identified in other previous studies.

#### 412. Mechanisms of the vascular protective effects of metformin: vascular contractility. *Paul Hansen, Jr, Pharm.D., Candidate*, Rajkumar Pyla, M.D., Ph.D., Islam Osman, M.S., Susan C. Fagan, Pharm.D., Lakshman Segar, Ph.D.; Department of Clinical and Experimental Therapeutics, College of Pharmacy, University of Georgia, Augusta, GA

**PURPOSE:** Metformin is the only oral anti-hyperglycemic drug that has been shown to reduce overall mortality, yet the full spectrum of its effects is not fully elucidated. This study was designed to assess the vasoprotective effects of metformin by evaluating its inhibition of vascular contractility in response to serotonin, which is released during vascular injury.

**METHODS:** The aortas from wistar rats (250-300 g) were denuded of endothelium using polyethylene tubing. The aortas were then cut into 2-mm rings, mounted onto a myograph, and placed in an oxygenated Krebs's buffer. After a two-hour equilibration period, samples were treated with 80 mmol/L potassium chloride to assess viability, and then exposed to 100  $\mu$ mol/L acetylcholine to confirm endothelial denudation. Subsequently, the effects of increasing concentrations of metformin (10-3 mmol/L) or 1 mmol/L AICAR (an AMP-kinase activator) on serotonin-induced smooth muscle contractility were determined.

**RESULTS:** At 3 mmol/L concentration, metformin treatment resulted in significant inhibition of serotonin-induced contraction ( $p < 0.05$ ). Metformin reduced both the sensitivity ( $EC_{50}$ ) and the maximal contractile response ( $E_{max}$ ) to serotonin. Notably, the inhibitory effect of 3 mmol/L metformin on the contractile response was similar to that observed with 1 mmol/L AICAR group. AICAR was used as a positive control since the effects of metformin are associated with AMP-kinase activation, as revealed by western blot analysis. Furthermore, the inhibitory effect of 3 mmol/L metformin on serotonin-induced contractility was sustained, even after the withdrawal of metformin from Krebs's buf-

fer and sequential washing. The persistent decrease in serotonin-induced contractility with 3 mmol/L metformin may be due to tissue accumulation. Metformin at 10  $\mu$ mol/L and 1 mmol/L concentrations did not significantly affect serotonin-induced contractility.

**CONCLUSION:** Metformin reduced serotonin-induced contraction, indicating it may have a stabilizing effect on vascular smooth muscle. This stabilizing effect could partially contribute to the reduction in mortality associated with metformin use.

**413. Effect of dasatinib on TGF $\beta$ -induced fibroblast-to-myofibroblast differentiation.** Robert Newsome, Pharm.D., Candidate<sup>1</sup>, Maha Abdalla, Pharm.D.<sup>1</sup>, Somanath P. R. Shenoy, Ph.D.<sup>2</sup>; (1)Program in Clinical and Experimental Therapeutics, College of Pharmacy, University of Georgia, Augusta, GA; (2)College of Pharmacy and Veteran's Affairs Medical Center, University of Georgia, Augusta, GA

**PURPOSE:** The purpose of this study is to determine the effect of dasatinib, a broad spectrum non-receptor tyrosine kinase inhibitor, on myofibroblast differentiation as a means to identify therapeutic targets for fibrosis-related health issues and drug development.

**METHODS:** After incubation to 70% confluence, mouse embryonic fibroblasts were treated with 4 ng/ml of transforming growth factor- $\beta$  (TGF $\beta$ ) in Dulbecco's modified eagle medium (DMEM) for 48 hours. At 48 hours, the fibroblasts were further treated with 4 ng/ml TGF $\beta$  and dasatinib at doses of 0, 10, 5, 2.5, and 1 nmol/L. At 72 hours, cells were lysed and subjected for Western-blot analysis of alpha smooth muscle actin ( $\alpha$ -SMA), phospho-Src, Src, phospho-ERK, and ERK. Current investigation in the lab is focused on identifying the role of Src and/or other tyrosine kinases in myofibroblast differentiation using genetically modified cells (Src, Yes and Fynn knockout [*SYF*<sup>-/-</sup>]/fibroblasts), plasmids encoding different variants of Src as well as specific inhibitors.

**RESULTS:** Our data indicate that dasatinib at doses suggested for cancer cells (100 nmol/L) results in substantial toxicity to mouse embryonic fibroblasts to the extent that molecular targets cannot be identified through Western Blot analysis. From a dose-response study, we identified that dasatinib at a dose of 1 nmol/L was optimal to decrease  $\alpha$ -SMA without significant toxicity.

**CONCLUSION:** Our study so far demonstrates that dasatinib inhibits TGF $\beta$ -induced fibroblast-to-myofibroblast differentiation at a dose several fold lower than that is used for cancer cells. While our study suggests that low-dose dasatinib can be re-purposed for the treatment of fibrotic diseases such as pulmonary fibrosis, future research in our lab will identify additional targets for therapeutic interventions.

## Pain Management/Analgesia

**414. Evaluation of prescribing practices in the treatment of pain and nausea associated with acute pancreatitis at a Tertiary Care Hospital.** Courtney Watts, Pharm.D., Candidate, Jeffrey B. Doss, Pharm.D., Candidate, Karen Marlowe, Pharm.D., BCPS, John Allen, Pharm.D., BCPS, Sarah A. Treadway, Pharm.D., BCPS; Auburn University Harrison School of Pharmacy, Mobile, AL

**PURPOSE:** Acute pancreatitis is associated with severe abdominal pain and nausea. The American College of Gastroenterology recommends treatment of pain with a parenteral opioid; however, data is lacking indicating the safety and efficacy of antiemetics. We evaluated the use of opioid and antiemetic medications and the effect on hospital length of stay.

**METHODS:** This was a retrospective chart review. Patients eligible for enrollment in the study had a primary diagnosis of acute pancreatitis (as determined by ICD9 code) and were admitted to the hospital between September 2008 and October 2011. Patients were excluded if they were < 18 years of age, admitted to the ICU, HIV positive, pregnant, or had necrotizing pancreatitis.

**RESULTS:** Forty two patients met inclusion criteria; 50% male (n=21) and 79% (n=33) African-American. The 48 hour Ranson

score for 86% of patients (n=36) was less than 6. The initial opiates most commonly prescribed included IV morphine for 71% (n=30) of patients and IV hydromorphone for 20% (n=8). Average length of stay for patients receiving morphine was 4.6 ( $\pm$  4.3) days compared to 2.6 ( $\pm$  1.1) days with hydromorphone (r = 0.018). Ninety percent of patients received ondansetron as the initial antiemetic. Average length of stay for patients who received ondansetron was 4  $\pm$  3.9 days compared to 3 ( $\pm$  1.15) days with promethazine (r = -0.0077).

**CONCLUSION:** For the treatment of acute pancreatitis, morphine was the most commonly used opiate, and ondansetron was the most commonly used antiemetic. Preliminary analyses indicate that there is almost negligible correlation between initial opioid prescribed, whether morphine or hydromorphone, and hospital length of stay for patients with acute pancreatitis. Similarly, there was negligible correlation between initial antiemetic prescribed, ondansetron or promethazine, and hospital length of stay. Data collection is ongoing.

## Pediatrics

**415. An evaluation of theoretical loading doses in pediatric patients receiving vancomycin.** Meghan M. Caylor, Pharm.D., Candidate, Kacy L. Mulligan, Pharm.D., Candidate, Kalen B. Manasco, Pharm.D., BCPS, AE-C; Georgia Health Sciences Children's Medical Center, Augusta, GA

**PURPOSE:** Based on the 2009 ASHP/IDSA/SIDP guidelines for vancomycin use and monitoring, evidence suggests that adult patients with serious MRSA infections should be considered for a loading dose (25–30 mg/kg per actual body weight). However, there is no current evidence regarding the use of loading doses in pediatric patients. Therefore, the purpose of this study is to predict the pharmacokinetics in pediatric patients at an academic medical center to assess if giving a loading dose of vancomycin at the initiation of therapy would correlate to therapeutic levels following the initial regimen prescribed, rather than necessitating a regimen adjustment later in therapy as is commonly the case.

**METHODS:** A retrospective chart review from January to December 2011 was conducted in pediatric patient's ages 1–17 who received vancomycin at the Georgia Health Sciences Children's Medical Center and had complete sets of levels (both peaks and troughs). We calculated patient-specific parameters based on the peak and trough levels, and then calculated how each patient's levels would have been affected by administration of various loading doses (20 mg/kg, 25 mg/kg, 30 mg/kg, and 35 mg/kg).

**RESULTS:** Data was collected in 63 patients within 77 separate admissions and yielded 90 complete sets of vancomycin levels.

**CONCLUSION:** Analysis is currently under way with results and conclusions still pending.

**416. Vancomycin susceptibility and clinical action: a retrospective pediatric cohort of MRSA infections with MIC equal to 2  $\mu$ g/ml.** Amber M. Bacak, Pharm.D., Candidate<sup>1</sup>, Cris Hogue, Pharm.D.<sup>2</sup>; (1)Texas A&M Health Science Center Rangel College of Pharmacy, Kingsville, TX; (2)Driscoll Children's Hospital (Complete Rx LTD.), Corpus Christi, TX

**PURPOSE:** The primary objective of this study is to examine antibiotic regimens, administered to pediatric patients with methicillin resistant *Staphylococcus aureus* (MRSA) infections, in comparison with current MRSA and vancomycin guidelines. Secondary objectives include examination of pharmacist interventions and the 2011 MRSA cure rate.

**METHODS:** This is a retrospective, 1 year cohort study reviewing pediatric patients at Driscoll Children's Hospital (DCH) with a MRSA infection that has a vancomycin minimum inhibitory concentration (MIC) equal to 2  $\mu$ g/ml. The following inclusion criteria were met for each patient:  $\leq$  18 years old at the time of infection, culture positive for MRSA, and vancomycin MIC equal

to 2 µg/ml. Patients were excluded if they did not receive at least one dose of systemic antibiotics at DCH.

**RESULTS:** The study began with 191 isolates with a vancomycin MIC equal to 2 µg/ml, which is 37% of total MRSA isolates seen at DCH in 2011. After application of the inclusion and exclusion criteria, 121 isolates remained (n=121). Data analysis is in progress and will be completed August 2012.

**CONCLUSIONS:** Conclusions will be available pending the completion of data analysis and will be presented at the American College of Clinical Pharmacy Annual Meeting.

**417. Antioxidant use in severely burned children: a literature review.** *Rajinder Kaur, B.S., Pharm.D., Candidate, 2013, Henna Shah, B.S., Pharm.D., Candidate, 2013; Jefferson School of Pharmacy, Philadelphia, PA*

**PURPOSE:** To review and assess the recent therapeutic trends of antioxidant therapy for severely burned children.

**METHODS:** A MEDLINE search was run using the following criteria: 'antioxidants\* AND burns AND children'. Material was gathered from original research articles and reviews published in peer-reviewed journals.

**RESULTS:** One of the hallmarks of severely burned patients is accelerated metabolism, which manifests itself in the form of nutritional deficiency. Primary treatment modalities include optimal nutritional support and fluid resuscitation. In particular, reductions in zinc, vitamin C, and α-Tocopherol (vitamin E) signify the presence of oxidative stress. Antioxidant supplementation has shown promising results in the treatment of these deficiencies. Antioxidant supplementation has been shown to reduce burn related mortality as well as the overall time to heal. Because of the disparities between the studies and due to a limited pediatric study population, the results could not be optimally compared. Nevertheless, a randomized, double blind, placebo controlled study revealed that supplementation of vitamin E, zinc, and vitamin C showed a statistically significant decrease in lipid peroxidation and time for wound healing. Additionally, antioxidants inhibit free radical formation and protect organs from free radical damage.

**CONCLUSION:** Supplementation through zinc, vitamin C, and vitamin E has been associated with better outcomes and decreased time to heal for wounds in children. Antioxidant treatment is a suitable and recommended treatment modality for severely burned children.

## Pharmacoeconomics/Outcomes

**418. Pharmaceutical quality and access in Nigeria: evaluation of the mobile authentication technology and stakeholder perceptions on quality and access.** *Chioma J. Ebenezer, B. Pharm., M.Sc., CPIPP; UCL School of Pharmacy, London, UK*

**PURPOSE:** The purposes of this research are to evaluate the Mobile Authentication Technology and to identify wider issues related to accessibility of good quality medicines, from the perspective of Nigerian stakeholders. This will inform policies relating to availability and use of medicines.

**METHODS:** The study is in two phases. The first phase involves quantitatively analysing metformin tablets (tagged Glucophage® and the cheapest available generic versions of metformin) randomly sampled from retail outlets in Lagos, Nigeria via Packaging analysis, Near Infra Red spectroscopy and High Performance Liquid Chromatography. The tagged Glucophage® samples were authenticated through Short Message Service (SMS). The responses obtained will be compared with results of the chemical analysis. The quality of the tagged Glucophage® samples will also be compared with the cheapest generic versions without the authentication tags. The second phase involves the use of semi-structured interview schedules for different groups of purposefully sampled stakeholders; consumers, medicine sellers (community pharmacists, Patent Medicine Vendors, traders) and Policy makers. Variables explored were adapted from the socio-technical framework. All quantitative data arising from

the study will be analysed using the SPSS statistical software while Framework analysis will be used to analyse qualitative data.

**RESULTS:** In total, 94 tagged Glucophage® samples (out of which 92 passed the SMS authentication while two could not be authenticated) and 88 generic metformin samples were obtained. Chemical analysis of all the samples is on-going. A total of 38 semi-structured interviews (eight community pharmacists, five patent medicine vendors, six traders, four policy makers and 15 consumers) were conducted. Qualitative analysis of the interviews is on-going.

**CONCLUSION:** This study will help to validate the Mobile Authentication Technology and explore issues related to accessibility of good quality medicines from an independent stand point. This will aid formulation of recommendations for its implementation and future expansion.

**419. Cost-effectiveness analysis of genotype-guided antiplatelet therapy in patients with acute coronary syndrome and planned percutaneous coronary intervention.** *Fang-Ju Lin, M.S., Vardhaman Patel, M.S., Olaitan Ojo, Pham.D., M.B.A., BCPS, Sapna Rao, M.S., Shengsheng Yu, Ph.D., Lin Zhan, M.S., Daniel R. Touchette, Pharm.D., M.A.; University of Illinois at Chicago, Chicago, IL*

**PURPOSE:** Prasugrel-based therapy is recommended over clopidogrel-based therapy in poor/intermediate CYP2C19 metabolizers with acute coronary syndrome (ACS) and planned percutaneous coronary intervention (PCI). CYP2C19 genetic test, therefore, can be utilized to guide antiplatelet therapy in ACS patients. The purpose of this study was to evaluate the cost-effectiveness of the genotype-guided treatment approach, as compared with prasugrel and generic clopidogrel treatment irrespective of genotype, in ACS/PCI patients from the US healthcare provider's perspective.

**METHODS:** A decision analytic model was developed to project the lifetime economic and humanistic burden associated with clinical outcomes (including myocardial infarction [MI], stroke and major bleeding) for the three strategies in ACS/PCI patients. Probabilities of outcomes were obtained from the TRITON-TIMI 38 trial comparing prasugrel and clopidogrel; costs (adjusted to 2011 US dollars), age-adjusted quality of life, and disutilities were identified through systematic literature review. Incremental cost-effectiveness ratio (ICER) was calculated for the treatment strategies, with quality-adjusted life years (QALYs) as the primary effectiveness outcome. One-way and probabilistic sensitivity analyses were performed to assess the robustness of the results.

**RESULTS:** Genotype-guided therapy was the most cost-effective strategy in the base-case analysis. Clopidogrel cost \$19,763 and provided 10.0308 QALYs versus prasugrel (\$22,886, 10.0353 QALYs) and genotype-guided therapy (\$20,104, 10.0517 QALYs). The incremental cost per QALY gained with genotype-guided therapy compared with clopidogrel was \$16,265. Prasugrel therapy was dominated by the genotype-guided strategy. Results were sensitive to the cost of prasugrel, cost of clopidogrel, and cost of MI. Acceptability curve showed that genotype-guided therapy had at least 77% likelihood of being more cost-effective than clopidogrel at willingness-to-pay (WTP) of \$100,000/QALY. In comparison with prasugrel, genotype-guided therapy was more cost-effective with > 80% certainty at all WTP thresholds.

**CONCLUSION:** Our modeling analyses suggest that genotype-guided therapy is a cost-effective strategy in patients with ACS undergoing PCI.

**420. Evaluating the cost-effectiveness of using boceprevir and telaprevir in the treatment of newly diagnosed Hepatitis C genotype 1 patients: A payer's perspective.** *Yash J. Jalundhwala, B.Pharm., M.S., Pankaj Patel, Pharm.D., M.S., Hedlund Nancy, B. Pharm., R. Ph., M.B.A., Cheng Wendy, B. Pharm., M.S., Manzoor Beenish, M. P.H., Patel Haridarshan, Pharm.D., Daniel Touchette, Pharm.D., M. A.; University of Illinois at Chicago, Chicago, IL*

**PURPOSE:** The addition of protease inhibitors, boceprevir or telaprevir, to pegylated interferon alpha and ribavirin (usual care)

results in an improved sustained virologic response (SVR) in newly diagnosed Genotype 1 Chronic Hepatitis C (HCV) patients. The objective of this study was to evaluate the cost-effectiveness of all currently recommended pharmacotherapies from a payer's perspective in this population.

**METHODS:** A Markov model was developed to simulate treatment effectiveness, costs and disease progression in a hypothetical cohort of newly diagnosed HCV patients. In addition to the usual care, triple therapies with usual care and boceprevir or telaprevir were considered. The model included the following outcomes: SVR, eventual disease progression to long-term adverse outcomes in those who did not achieve SVR or relapsed, and side effects. Probabilities, costs and utility values were determined from a review of the published literature. All costs were inflated to 2012 costs. Costs and quality adjusted life years were also discounted at standard rate of 5%. Sensitivity analyses were performed to assess model sensitivity and address uncertainty.

**RESULTS:** Boceprevir therapy resulted in lifetime costs and utilities of \$106,376 and 12.68 QALYs compared to \$92,440 and 12.66 QALYs for Telaprevir therapy and \$83,036 and 12.19 QALYs for usual care. The ICER was found to be \$47,173/QALY for boceprevir and \$19,878/QALY for telaprevir relative to usual care. The ICER was found to be \$642,485/QALY for boceprevir relative to telaprevir. The model was found to be most sensitive to variations in costs of initial drug therapy.

**CONCLUSION:** Results indicate that when possible, telaprevir should be the preferred therapy for the Genotype 1 HCV patients. In patients where telaprevir is not tolerated or cannot be given, boceprevir should be the next preferred therapy. Effective management of side-effects is important to reduce the impact on rate of achieving sustained virological response.

## Pharmacogenomics/Pharmacogenetics

**421. Lack of association between MRP2 C-24T variant and the pharmacokinetics of fexofenadine.** Jung-In Park, Ph.D., Candidate, Byung-Sung Kang, Ph.D., Candidate, Chang-Ik Choi, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Fexofenadine is a selective histamine H<sub>1</sub>-receptor antagonist and is used for the treatment of seasonal allergic rhinitis and chronic idiopathic urticaria. In a previous animal study showed that the biliary excretion of fexofenadine is mainly mediated by Mrp2, an efflux transporter, in mice. MRP2 C-24T single nucleotide polymorphism (SNP) is known to decrease the efflux activity and function. We investigated the effects of MRP2 C-24T variant on the pharmacokinetics of fexofenadine in healthy Korean volunteers.

**METHODS:** Twelve subjects were selected and they were divided into two different groups according to MRP2 C-24T genotype, MRP2 -24CC (CC type, n=8) and MRP2 -24TT (TT type, n=4). After overnight fasting, each subject received a single oral dose of 180 mg fexofenadine. Blood samples were collected up to 24 hour after drug intake, and the plasma concentrations of fexofenadine were determined by using LC-MS/MS system.

**RESULTS:** C<sub>max</sub> of fexofenadine in the TT type was slightly higher than that in the CC type (765.0 ± 396.5 versus 559.5 ± 246.3 ng/ml, respectively). However, this difference was not statistically significant. Other pharmacokinetic parameters of fexofenadine between two genotype groups were also not significantly different AUC<sub>inf</sub> of fexofenadine in the CC type and TT type was 3632.9 ± 1348.1 and 3933.2 ± 1388.5 ng/hour/ml, respectively.

**CONCLUSION:** MRP2 C-24T genetic variant is not likely to influence the pharmacokinetics of fexofenadine

**422. CYP450 genetic polymorphisms have no significant impact on the pharmacokinetics of cilostazol.** Byung-Sung Kang, Ph.D., Candidate, Hey-In Lee, M.S., Chang-Ik Choi, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Cilostazol, a cyclic nucleotide phosphodiesterase type III inhibitor, is primarily indicated for the treatment of intermittent claudication. The metabolic pathway of cilostazol is so complex and multiple CYP450 isozymes are involved, including CYP3A, CYP2C19, CYP2C8, CYP2D6, CYP1A2 and so on. It is considered that co-administration of CYP3A or CYP2C19 inhibitors with cilostazol causes an increase in plasma concentration of cilostazol. We investigated the effects of CYP2C19, CYP2D6 and CYP3A5 genetic polymorphisms on the pharmacokinetics of cilostazol.

**METHODS:** Thirty-three healthy volunteers were selected and they were as extensive metabolizers (EMs) or poor metabolizers (PMs) for each isozyme according to genotype. After overnight fasting, each subject received a single oral dose of 100 mg cilostazol. Blood samples were collected up to 48 hours after drug intake, and the plasma concentrations of cilostazol were determined by using a HPLC-UV analytical method.

**RESULTS:** Although relatively higher C<sub>max</sub> and AUC values and lower CL/F value were observed in CYP2C19/CYP3A5 PM/PM group compared to CYP2C19/CYP3A5 EM/EM group, these differences were not statistically significant. There were also no significant changes in the pharmacokinetic parameters of cilostazol between different CYP2C19/CYP2D6 or CYP2D6/CYP3A5 genotype groups.

**CONCLUSION:** Genetic polymorphisms in CYP2C19, CYP2D6 and CYP3A5 did not affect the biotransformation of cilostazol.

**423. Effects of CYP2D6\*10 and CYP2D6\*5 alleles on the pharmacokinetics of carvedilol in healthy Koreans.** Byung-Sung Kang, Ph.D., Candidate, Hye-In Lee, M.S., Chang-Ik Choi, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Carvedilol is a non-selective α- and β-adrenergic receptor blocking agent, which is indicated for the treatment of hypertension, chronic heart failure, and left ventricular dysfunction following myocardial infarction. CYP2D6 is the major enzyme that mediates the metabolism of carvedilol via 4'-hydroxylation and 5'-hydroxylation. Among over 100 alleles in CYP2D6 gene, CYP2D6\*2, \*5, \*10, and CYP2D6 gene duplication/multiplication (\*XN) are functionally important in Asians, including Koreans. We investigated the effects of CYP2D6\*10 and CYP2D6\*5 alleles on the pharmacokinetics of carvedilol.

**METHODS:** Thirty-four healthy subjects were selected and they were divided into three different groups according to CYP2D6 genotype, group1 (CYP2D6\*1/\*1, n=8), group2 (CYP2D6\*1/\*5 and CYP2D6\*1/\*10, n=15) and group3 (CYP2D6\*5/\*10 and CYP2D6\*10/\*10, n=11). After overnight fasting, each subject received a single oral dose of 25 mg carvedilol. Blood samples were collected up to 12 hour after drug intake, and the plasma concentrations of carvedilol were determined by using HPLC system with fluorescence detection.

**RESULTS:** AUC<sub>inf</sub> of carvedilol in group3 was 270.2 ± 110.4 ng hour/ml, that is 2.0- and 1.6-fold higher than that in group1 and group2 (137.9 ± 66.3 and 168.5 ± 70.2 ng hour/ml, respectively, p<0.01). C<sub>max</sub> of carvedilol in group3 (54.0 ± 24.0 ng/ml) was also 1.7- and 1.3-fold higher than that in group1 and group2 (32.0 ± 13.0 and 43.0 ± 20.5 ng/ml, respectively), but these differences were not statistically significant.

**CONCLUSION:** CYP2D6\*10 and CYP2D6\*5 alleles significantly affect the pharmacokinetics of carvedilol.

**424. No association between OCT2 C602T genetic variant and the pharmacokinetics of lamivudine.** Mi-Jung Kim, Ph.D., Candidate, Choon-Gon Jang, Ph.D., Seok-Yong Lee, Ph.D.; School of Pharmacy, Sungkyunkwan University, Suwon, South Korea

**PURPOSE:** Lamivudine is a nucleoside reverse transcriptase inhibitor (NRTI) that is used for the treatment of human immunodeficiency virus (HIV) and chronic hepatitis B. It is reported that the renal excretion of lamivudine is mostly mediated by OCT2, an influx transporter encoded by SLC22A2 gene. We

investigated the effects of OCT2 C602T variant on the pharmacokinetics of lamivudine.

**METHODS:** Nineteen healthy volunteers were selected and they were divided into two groups according to OCT2 C602T genotype, c.602CC (CC type, n=12) and c.602CT (CT type, n=7). Each subject received a single oral dose of 100 mg lamivudine. Blood samples were collected up to 24 hour after drug intake, and the concentrations of lamivudine in plasma samples were determined by using LC-MS/MS system.

**RESULTS:** No significant differences in the  $C_{max}$  and AUC values of lamivudine were observed between CC type and CT type.  $C_{max}$  of lamivudine in CC type and CT type was  $1150.0 \pm 191.4$  and  $1255.6 \pm 249.8$  ng/ml, respectively.  $AUC_{inf}$  of lamivudine in each genotype group was  $4429.4 \pm 427.5$  and  $4297.4 \pm 1047.9$  ng hour/ml, respectively. Oral clearance (CL/F) and elimination half-life ( $t_{1/2}$ ) of lamivudine were not also statistically significant between two genotype groups.

**CONCLUSION:** OCT2 C602T genetic variant did not affect the pharmacokinetics of lamivudine. Further study with the subjects homozygous for the T-allele will be needed.

**425. The effect of the CYP4F2 V433M polymorphism on maintenance warfarin dosing: a meta-analysis.** *Beejal Ruparelia, B.S., Pharm.D., Candidate, 2013<sup>1</sup>, Brett Venker, Pharm.D., Candidate, 2013<sup>2</sup>, Jeremy Lai, B.S.<sup>3</sup>, Brian F. Gage, M.D., M.Sc.<sup>3</sup>; (1)College of Pharmacy, University of Michigan, Washington University, Saint Louis, MO; (2)Saint Louis College of Pharmacy, Washington University, Saint Louis, MO; (3)Washington University, Saint Louis, MO*

**CONTEXT:** Although VKORC1 and CYP2C9 gene polymorphisms affect warfarin dosing they only account for one-third of inter-patient variability in therapeutic warfarin dose. CYP4F2 is a mitochondrial  $\omega$ -hydroxylase catalyzing the first step in the degradation of vitamin K1. Some studies have indicated that the CYP4F2 V433M polymorphism (rs2108622, C>T allele) increases warfarin dose, while others have not.

**PURPOSE:** To quantify the overall effect of the CYP4F2 V433M polymorphism on warfarin dose.

**DATA SOURCES:** We conducted a systematic search of published literature using Embase, Medline (through PubMed), and Google Scholar to identify relevant studies.

**METHODS:** We identified 139 studies and 21 met our inclusion criteria. From eligible studies, we extracted the sample size, minor T allele frequency, warfarin dose effect, percentage increase in warfarin dose per T allele, and adjusted  $R^2$  value. The primary outcome was increase in warfarin dose per T allele.

**RESULTS:** Effects in 13 studies have been corroborated by two independent reviewers and show a 5.6% (95% CI 3.5–7.6%) increase in mean weekly warfarin dose per T allele of the rs2108622 polymorphism, quantifying the significance of CYP4F2 genotype.

**LIMITATION:** The clinical significance of a 5.6% increase in warfarin dose was not assessed.

**CONCLUSION:** The presence of the CYP4F2 V433M polymorphism results in a statistically significant increase in warfarin dose. In reducing the activity of the CYP4F2 enzyme per T allele, more Vitamin K is available requiring a relatively higher warfarin dose to achieve therapeutic effect.

### Pharmacokinetics/Pharmacodynamics/ Drug Metabolism/Drug Delivery

**426. Management of drug interaction between posaconazole and sirolimus in allogeneic hematopoietic stem cell transplantation recipients.** *Eunah Cho, Pharm.D., Candidate; Western University of Health Sciences, Pomona, CA*

**PURPOSE:** Posaconazole (PSZ) is contraindicated when used concomitantly with sirolimus (SRL) because of a substantial increase in SRL plasma concentration. However, PSZ is clinically used for prophylaxis and treatment of fungal infections in HSCT recipients receiving SRL. Currently, there are no published evalu-

ations of the clinical management of PSZ and SRL interactions. The objective of this study is to determine safe drug management strategies of SRL with PSZ in patients undergoing HSCT.

**METHODS:** The medical records of 75 allogeneic HSCT recipients at City of Hope who received tacrolimus (TCL), SRL and PSZ concomitantly were reviewed retrospectively. Records spanned from January 1, 2008 to December 31, 2011. Data including baseline demographics, SRL levels, and SRL and PSZ doses were recorded for each patient for 28 days. Subgroup analysis was conducted of patients whose initial SRL dose was reduced by greater than 50% (Group 1, n=38) and those whose initial SRL dose was reduced by less than 50% (Group 2, n=37).

**RESULTS:** Concomitant administration of PSZ and SRL resulted in an increased SRL steady state Concentration/Dose [(ng/ml)/(mg/day)] ratio by a factor of 2.6, which occurred on a mean of 18 days after initiation of PSZ. SRL C/D ratio increased a maximum 3.82 fold (range: 1.75–5.9) during coadministration of PSZ and SRL. Mean maximum SRL trough level was 11 ng/ml in Group 2 and 9.15 ng/ml in Group 1 ( $p=0.013$ ). No patients in Group 1 had SRL levels exceeding 15 ng/ml, while nine patients (24%) in Group 2 had SRL levels that exceeded 15 ng/ml ( $p=0.004$ ).

**CONCLUSION:** Additional PSZ increases SRL C/D ratio by a factor of 2.6 in HSCT recipients. Also, Initial SRL dose reduction above 50% seems to be appropriate for safe drug management in patients receiving concomitant PSZ.

**427. Development and pharmacokinetic characterization of new delayed pulsatile-release ondansetron formulation.** *N. Rebecca Barwick, Pharm.D., Candidate<sup>1</sup>, Corey Fowler, Ph.D.<sup>2</sup>, Tong Lee, M.D.<sup>2</sup>, Steven Szabo, M.D., Ph.D.<sup>2</sup>, Ashwin Patkar, M.D.<sup>2</sup>, Melissa Hall, B.S.<sup>1</sup>, Wayne F. Beyer, Jr, Ph.D.<sup>3</sup>, Lan-Yan Yang, Ph.D.<sup>2</sup>, Shein Chow, Ph.D.<sup>2</sup>, Bruce Burnett, Ph.D.<sup>2</sup>, Brett Froeliger, Ph.D.<sup>2</sup>, O. Barry Mangum, Pharm.D., FCP<sup>2</sup>; (1)Campbell University, Buies Creek, NC; (2)Duke Clinical Research Unit, Durham, NC; (3)Duke Translational Research Institute, Durham, NC*

**PURPOSE:** Several monotherapy agents have failed to show consistent clinical efficacy against methamphetamine dependence. Preclinical studies have demonstrated that combining a dopamine agonist with the 5-HT3 antagonist, ondansetron, and reverses behavioral and neurobiological alterations in animal models of psychostimulant abuse. The main purpose of this study is to assess the PK profiles of the novel single oral dose delayed, pulsatile release ondansetron formulation (Ond-PR1), which will allow temporally-dependent double-dosing combination treatments under a single-dosing regimen.

**METHODS:** Two formulations of ondansetron (Ond-PR1 and Ond-PR2), which, when administered simultaneously with a dopamine agonist, result in the requisite drug peak separation. Six subjects received one 8 mg tablet of the new formulation of ondansetron after 10 hours of fasting, and then twelve blood draws were taken over a period of ten hours for PK analyses. The primary PK parameter of interest was the  $t_{max}$ . Therefore,  $t_{max}$  with in vitro dissolution time of 3–4 hour is expected to be 5–6 hour.

**RESULTS:** Ond-PR2 provided optimal pharmacokinetic delivery to achieve maximum dosing at 3.5 hours post peak MPh administration.  $T_{max}$ : Ond-1 (6.8), Ond-2 (5.9); AUC: Ond-1 (136.1), Ond-2 (191.2);  $C_{max}$ : Ond-1 (31.2), Ond-2 (36.5); Half-life: Ond-1 (9.7), Ond-2 (8.2). The results from this single dose pharmacokinetic study provide some insight into the necessary release pattern of ondansetron. Ond-PR2 provided optimal pharmacokinetic delivery to achieve the desired pharmacokinetic profile.

**CONCLUSIONS:** The results from this single dose pharmacokinetic study provided insight into the release pattern of ondansetron alone and in combination with methylphenidate to pursue further study in a phase II clinical research program.

**428. Flavonoid biotransformation: pharmacokinetic and pharmacodynamic effects of flavonoid glycosylation.** *Mark R. Rosenberg, B.A., Pharm.D., Candidate, 2013, Robert M. Riggs, B.S.*

Pharm., Ph.D.; McWhorter School of Pharmacy, Samford University, Birmingham, AL

**PURPOSE:** Flavonoids are a class of polyphenolic compounds found in nature, specifically in fruits, vegetables, nuts, tea, and wine. The diversity of metabolism among flavonoid compounds makes this a germane topic for pharmacy. The elucidation of metabolic pathways and corresponding activity of metabolites is crucial towards the rational incorporation of these compounds in therapy. One primary aim of this review is to use structure activity relationship information pertaining to flavonoids to obtain a more precise understanding of the activity and metabolism of flavonoids. The pharmacokinetic and pharmacodynamic effects of flavonoid in vivo glycosylation will be addressed.

**METHODS:** Information pertaining to flavonoid biotransformation will be gathered from PubMed, UK PubMed Central, and American Chemical Society databases. PubMed will be searched with structured MeSH search terms “flavonoids,” “biotransformation,” and “glycosylation.” Additionally, the tertiary reference Natural Medicines Comprehensive Database will be utilized.

**RESULTS:** Glycosylation generally decreases flavonoid lipophilicity, has variable effects on antioxidant activity, and variable effects on bioavailability. In vivo sites of glycosylation and deglycosylation were identified for specific flavonoid dietary supplements, and the corresponding implications on extent of absorption based on metabolic outcome were noted.

**CONCLUSION:** Flavonoids demonstrate a diversity of biotransformation routes which affect their bioavailability and subsequent clinical utility. This review article consolidated recent research into the pharmacokinetic and pharmacodynamic properties of various flavonoids. An expanded clinical utilization of flavonoids is predicated on further research into how the glycosylation of flavonoids affects function.

**429. Inter-individual variability of Tacrolimus clearance in the early post-kidney transplantation: a model based population pharmacokinetic-pharmacogenetic analysis using estimated Ka from dense sampling data.** *Soo Jung Ha, B.S.<sup>1</sup>, Hwi Yeol Yoon, Ph.D.<sup>1</sup>, Nayoung Han, M.S.<sup>1</sup>, Sang Il Min, M.D.<sup>2</sup>, Jongwon Ha, M.D.<sup>2</sup>, HyeSook Lee, M.S.<sup>3</sup>, Jung Mi Oh, Pharm.D.<sup>1</sup>;* (1) College of Pharmacy, Seoul National University, Seoul, South Korea; (2) Department of Surgery, Seoul National University Hospital, Seoul, South Korea; (3) Department of Pharmacy, Seoul National University Hospital, Seoul, South Korea, Seoul, South Korea

**PURPOSE:** This study was designed to estimate the population pharmacokinetics and pharmacogenetics of tacrolimus in adult kidney transplantation recipients using dense sampling data and to evaluate the influence of clinical covariates including hemoglobin, hematocrit, platelet, post-operative days, concomitant immunosuppressant, *CYP3A5* and *ABCB1* polymorphisms.

**METHODS:** We densely sampled at just before, 0.5, 1, 2, 4, 6, 12 hour after administration of tacrolimus during after 10–15 post-operative days and trough levels until 6 months after transplantation. Clinical and genetic data were included for 6 months as well to evaluate covariates for pharmacokinetics of tacrolimus. Model development was conducted using NONMEM version 6 and model validation was done with Bootstrap and Visual Prediction Check.

**RESULTS:** In model estimation, data of sixty-one Korean adult kidney transplant recipients taking tacrolimus were used for analysis. The estimated population mean values of clearance (CL/F) and volume of distribution (V/F) were 7.85 L/hour (RSE 56%) and 125 L (RSE 26%), respectively. Absorption rate was estimated to 4.8 per hour (RSE 9%) and the lag time was fixed to 15 minute. Concomitant steroid dose, post-operative days, hemoglobin, hematocrit and *CYP3A5* genotype were identified as the covariates of CL/F. Age was the only factor affecting V/F significantly.

**CONCLUSION:** Our study identified significant factors affecting variability of tacrolimus pharmacokinetics in Korean kidney transplant recipients using dense sampling. This model will help to predict ideal dosage of tacrolimus more properly and develop rational guidelines for individual drug therapy after kidney transplantation.

**430. CYP3A4 activity of paclitaxel and vinorelbine in microemulsions.** *Ville Tiihto, Pharm.D., Candidate, Youngil Chang, Pharm.D., Candidate, Adwoa Nornoo, Ph.D.;* Palm Beach Atlantic University, West Palm Beach, FL

**PURPOSE:** To determine the CYP3A4 enzyme activity of two anticancer agents, paclitaxel (PAC), vinorelbine (VIN) and two microemulsions.

**METHODS:** The effect of PAC, VIN and two microemulsions on CYP3A4 enzyme activity was measured using a cytochrome P450 luminescent assay (P450-Glo™ Assay). PAC and VIN were dissolved in CE (1:1 (w/w) cremophor EL: ethanol) and water respectively, and diluted with water to obtain concentrations from 100 µmol/L to 10 pmol/L. Test compounds were mixed with CYP3A4 enzyme and the luciferin derivative of the CYP3A4 substrate in 96 well plates, and incubated for 10 minutes at room temperature. NADPH solutions were added to initiate the enzyme reaction. After 10 minutes of incubation, luminescence detection reagents were added luminescence measured after 20 minutes using a SpectraMax M5 plate reader. The half maximal inhibitory concentration (IC<sub>50</sub>) of PAC, VIN, and the microemulsions without drug was determined.

**RESULTS:**

**Table 1. The half maximal inhibitory concentration (IC<sub>50</sub>) of test compounds:**

Test compound	IC <sub>50</sub>
PAC in CE	63 nmol/L
VIN	4.7 µmol/L
ME1*	2.0 × 10 <sup>-5***</sup>
ME2**	2.7 × 10 <sup>-6***</sup>
CE	7.2 × 10 <sup>-5***</sup>

\*ME1 (1:1:1 (w/w) span 80-LQ: propylene glycol: capmul).

\*\*ME2 (2:1 (w/w) brij 010-SS: propylene glycol).

\*\*\*Dilution factor at which luminescence was 50% of maximum values.

**CONCLUSION:** PAC in CE had a lower apparent IC<sub>50</sub> value compared to VIN against the CYP3A4 enzyme. ME1 and ME2 had inhibitory effects on CYP3A4 at compatible or more dilute conditions than CE. Both PAC in CE and CE had similar inhibitory patterns at corresponding dilutions (data not shown), which suggests the inhibitory effect of PAC in CE was attributed to the inhibitory effect of CE rather than PAC.

**431. Cytotoxicity of vinorelbine and resveratrol in a caco-2 cell line.** *Sandy P. Bonfin, Pharm.D., Candidate, Patricia Ngebo, Pharm.D., Candidate, Adwoa O. Nornoo, Ph.D.;* Palm Beach Atlantic University, West Palm Beach, FL

**PURPOSE:** To determine the cytotoxicity of the anticancer agent vinorelbine (VIN) in combination with the natural product resveratrol (RES).

**METHODS:** Caco-2 cells (10<sup>6</sup>) were seeded and cultured in essential media for 24 hour in 96-well plates. The cultured cells were then treated for 3, 24 and 48 hour with VIN, RES and VIN + RES. Control cultures were allowed to grow without any treatment. After the treatment period the cells were washed with fresh culture media. Cell proliferation inhibition was determined by a CellTiter 96® Aqueous Non-Radioactive Cell Proliferation Assay (MTS). Cytotoxicity was determined at a drug concentration range of 0.008–100 µg/ml and the optical density of the viable cells measured at a wavelength of 490 nm. Reduction in proliferation

tion by 50% ( $IC_{50}$ ) of inhibition and extent of inhibition was determined.

#### RESULTS:

**Table 1. Concentration of PAC and VIN for 50% inhibition ( $IC_{50}$ ) and extent of inhibition at the 24-hour incubation period.:**

Formulation	$IC_{50}$ ( $\mu\text{g/ml}$ )	Extent (%)
VIN	32	35.33
RES	40	13.91

**Table 2. Percent inhibition of VIN alone compared to VIN+RES combination at identical concentrations at the 24-hour incubation period.:**

Formulations	12.5 ( $\mu\text{g/ml}$ )	25 ( $\mu\text{g/ml}$ )	50 ( $\mu\text{g/ml}$ )
VIN	9.5	14.99	21.22
VIN + RES	13.85	15.62	15.63
Percent change compared to VIN alone	45%	4%	26%

**CONCLUSION:** VIN and RES exhibit cytotoxic effects on caco-2 cells. At low concentrations (12.5  $\mu\text{g/ml}$ ), RES increases the cytotoxic effect of VIN. Further experiments will be conducted to determine the cytotoxic effect of the VIN + RES combination in a breast cancer cell line, MDA.

## Psychiatry

**432. Evaluation of non-psychiatric and antipsychotic medication use in long-term inpatient psychiatric facility.** *Pauline Park, B.A., Hugh Franck, B.S., Jose Rey, Pharm.D., BCPP; College of Pharmacy, Nova Southeastern University, Fort Lauderdale, FL*

**PURPOSE:** Patients on antipsychotic medications typically experience many adverse drug reactions such as extrapyramidal symptoms (EPS), akathisia, and weight gain. Our purpose is to investigate whether second-generation antipsychotics require more management of ADRs with additional pharmacotherapy and to compare the total number of medications in a patient's regimen versus patients who are on first-generation antipsychotics. Second-generation antipsychotics are associated with the onset of co-morbid conditions such as diabetes mellitus whereas first-generation antipsychotics are mostly limited to EPS as an adverse event.

**METHODS:** De-identified patient profiles containing diagnostic and medication records will be obtained from the South Florida State Hospital in Pembroke Pines, FL. Patients, ages 18–70, who have been placed on antipsychotic medications for at least 1 year will be evaluated. Three groups will be studied: patients exclusively on first-generation antipsychotics, patients exclusively on second-generation antipsychotics, and patients on both first-generation and second-generation antipsychotics. The total number of medications from each patient profile will be counted and t-test and chi-square analyses will be performed.

**RESULTS:** Our results are a work in progress.

**CONCLUSION:** Our prediction is that patients who are on second-generation antipsychotics will require more medication for management of adverse drug events. The results of this study can help inform clinical decision-making regarding care of patients on antipsychotics in long-term inpatient psychiatric facilities.

**433. Investigating the factors influencing the prescription of antidepressants with no FDA approved indication in the United States between 2006 and 2009.** *Brandy L. Marriner, Pharm.D., MSCR, Candidate<sup>1</sup>, Tina Tseng, Ph.D., MSPH<sup>2</sup>, Wesley Rich, Ph.D.<sup>2</sup>, Ryan Hall, M.D.<sup>3</sup>; (1)Department of Clinical Research, College of Pharmacy and Health Sciences, Campbell University, Buies Creek, NC; (2)Department of Public Health, College of Pharmacy and Health Sciences, Campbell University, Buies*

*Creek, NC; (3)Department of Psychiatry, University of South Florida, Tampa, FL*

**PURPOSE:** Prescribing of antidepressants has increased over the past several years and was the third most prescribed therapeutic class in 2007. From 2006 to 2009, approximately 40% of antidepressants were prescribed without an FDA-approved indication. The pharmacological class of the antidepressants [selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI)], along with other previously identified factors seem to play a role in whether or not an antidepressant is prescribed for an FDA approved indication.

**METHODS:** This was a retrospective cross-sectional study of adults who received an antidepressant prescription between 2006 and 2009. The study utilizes the publicly available de-identified National Ambulatory Medical Care Survey database administered by the National Center for Health Statistics of the Centers for Disease Control and Prevention. Psychiatric and mental health visits were determined by a mental health diagnosis according to ICD-9CM codes 290–319; indication of depression listed, or use of antidepressants with an FDA approved indication for the prescription. A subset of the data, 4894 visits, were analyzed to examine all antidepressants prescribed without FDA approved indications or psychiatric diagnosis for the visit. Weighted Odds Ratios were utilized to determine the association of patient and provider characteristics influencing receiving an antidepressant with no FDA approved indication.

**RESULTS:** The SSRI and SNRI classes accounted for 67% of antidepressants received without FDA approved indications. Receiving an SSRI/SNRI with no FDA approved indication was significantly associated with being female [1.32 (1.09–1.59)], Caucasian [1.93 (1.25–1.98)] and seen by general practice physician [1.32 (1.09–1.59)]. Both chronic problems and progress visit were the most common reasons for visit.

**CONCLUSION:** SSRIs/SNRIs were the most commonly prescribed antidepressant classes without an FDA approved indication. Sex, race and physician were associated with the class of antidepressant given, however further investigation is needed to identify specific factors that may be important to reducing the prescription of antidepressants.

**434. A retrospective analysis of inpatient utilization of paliperidone palmitate.** *Mikayla Klug, Pharm.D., Candidate, 2014, April N. Smith, Pharm.D., BCPS; School of Pharmacy and Health Professions, Creighton University, Omaha, NE*

**PURPOSE:** This study evaluated pharmacoeconomic considerations, specifically drug cost and patient readmission rates, of the non-formulary agent paliperidone palmitate, within the Alegent Health system. Pharmacy reimbursement rates for paliperidone palmitate are better on an outpatient versus inpatient basis. Given the low reimbursement rates for inpatient psychiatric care and the high cost of paliperidone palmitate, the drug cost could be justified if patients who received the injection demonstrated a subsequent reduction in readmission.

**METHODS:** Thirty two patients have received at least one inpatient injection of paliperidone palmitate within the Alegent Health system from January 2010–April 2012. The electronic medical record was used to determine indication, dose, administration date, concurrent antipsychotics, length of stay (LOS), and time to readmission. Finance reports determined hospital cost and reimbursement for each inpatient stay and pharmacy cost of each paliperidone palmitate injection.

**RESULTS:** The readmission rates for the paliperidone palmitate patients versus all patients at our institution with a drug related group (DRG) of psychoses were as follows: within 30 days, 22% versus 12.5%; 60 days, 15% versus 15%; and 90 days, 25% versus 18%, respectively. The hospital experienced a net loss of roughly \$5,610 per stay for the patients studied and paliperidone palmitate constituted approximately 15.9% of total hospital cost per stay. The average LOS was 18 days.

**CONCLUSION:** In this limited patient population, it appears inpatient administration of paliperidone palmitate increased hos-

pital cost without significantly reducing readmission rates at 30, 60, or 90 days post-injection. If patients are due for their monthly maintenance dose while institutionalized, the injection should be deferred to outpatient if discharge is anticipated within 1 week since product labeling states maintenance injections can be given 7 days after the monthly due date and outpatient reimbursement for the drug is superior.

**435. Utilization of the Patient Health Questionnaire to monitor depression in a primary care setting.** *Josh Stanton, Pharm.D.<sup>1</sup>, Patricia R. Wagle, Pharm.D., BCPS<sup>2</sup>, Chris White, M.D., J.D.<sup>3</sup>; (1)Shrivers Pharmacy, New Lexington, OH; (2)University of Cincinnati, Cincinnati, OH; (3)UC College of Medicine, Cincinnati, OH*

**PURPOSE:** Depression is a very common disease, which affected up to 10% of the U.S. population. The Patient Health Questionnaire (PHQ-9) is an effective tool for screening, diagnosing and monitoring depression. The primary objective for this study was to determine how often practitioners in an outpatient family practice clinic use the PHQ-9 to monitor depression.

**METHODS:** A retrospective chart review was performed at the Wyoming Family Practice center, where the PHQ-9 is easily accessible and pre-loaded into the medical record. Inclusion criteria were patients 18 years of age or older, who had a diagnosis of depression, were prescribed antidepressant medication and had seen a clinic provider at least 2 times in the previous 18 months. Exclusion criteria were patients who did not meet the inclusion criteria and patients who had a psychiatric comorbidity that was monitored by other applicable scales.

**RESULTS:** A total of 106 patient medical records were evaluated. Data was collected on several parameters including patient gender, age, prescribed antidepressant medication and PHQ-9 assessments. A total of 27 patients (25%) had at least 1 PHQ-9 documented in the 18 month period evaluated. A PHQ-9 assessment was more frequently performed in patients between 21 and 30 years of age, female patients and those prescribed either duloxetine or venlafaxine.

**CONCLUSION:** Multiple studies have proven the PHQ-9 assessment is an effective tool for monitoring depression. Our study showed physicians in this setting are not effectively using the PHQ-9 to monitor depression and patient response to antidepressant medications. Focus groups will be formed to discuss barriers and resolutions to increased PHQ-9 utilization.

## Transplant/Immunology

**436. Efficacy of valganciclovir plus cytomegalovirus immune globulin for prevention of cytomegalovirus disease in high risk renal transplant recipients.** *Amanda N. Bitterman, Pharm., D., Candidate, 2013<sup>1</sup>, Angela Q. Maldonado, Pharm.D., BCPS<sup>1</sup>, Okechukwu N. Ojogho, M.D.<sup>2</sup>, Ruby Siegel, M.S.<sup>1</sup>, Douglas L. Weeks, Ph.D.<sup>1</sup>; (1)Washington State University, Spokane, WA; (2)Providence Sacred Heart Medical Center & Children's Hospital, Spokane, WA*

**PURPOSE:** High prevalence of cytomegalovirus (CMV) disease in the first year after transplantation leaves a critical need for understanding patient risk factors and pharmacotherapy involved to better identify effective prevention strategies in renal transplant recipients (RTR). This study compared efficacy of 6 months of low-dose valganciclovir (VGC) prophylaxis with the addition of CMV hyperimmune globulin (IVIG) versus VGC prophylaxis alone in prevention of CMV disease in high-risk CMV donor-positive/recipient-negative (D+/R-) RTR.

**METHODS:** A single center, retrospective analysis evaluated 86 adult RTR, who were CMV D+/R-, transplanted between 1/1/2000 and 12/31/2010. Group 1 (n=30) received CMV IVIG (150 mg/kg × 1 dose; followed by 100 mg/kg on weeks 2, 4, 6 and 8; and 50 mg/kg on weeks 12 and 16 post transplant) plus VGC 450 mg/day (dose adjusted for renal function) for 6 months. Group 2 (n=56) received only VGC 450 mg/day (dose adjusted for renal function) for 6 months. Induction therapy

included IL2-RA (n=27), rATG (n=56) or both (n=3) and all received initial maintenance immunosuppression with tacrolimus, mycophenolic acid and corticosteroids. The primary endpoint was development of CMV disease at 1 year. Crude prevalence was established with chi-square analysis; multivariable logistic regression was used to estimate odds ratios for binary outcomes.

**RESULTS:** Patient demographics and transplant characteristics were comparable between the two groups. The overall incidence of CMV disease in both groups was 24.4% (n=21) with a larger percentage occurring in males versus females (26.8% versus 20% respectively; p=0.485) and with VGC alone versus VGC plus CMV IVIG (28.6% versus 16.7% respectively; p=0.221, OR = 2.093, CI = 0.662-6.616).

**CONCLUSION:** In this small sample of RTR, the addition of CMV IVIG to low-dose VGC did not provide a significant benefit in the prevention of CMV disease in the first year post-renal transplant.

**437. Insomnia and relationship with immunosuppressant therapy after lung transplantation.** *Ashley K. Weber, Pharm.D., Candidate<sup>1</sup>, Krista M. Katers, Pharm.D.<sup>1</sup>, Kalyann A. Rohde, Pharm.D., Candidate<sup>1</sup>, Donald S. Hawes, R.N.<sup>2</sup>, Kelly L. Radford, R.N.<sup>2</sup>, Mary L. Francois, R.N., M.S.N.<sup>2</sup>, Zachary W. Schlei, Pharm.D., Candidate<sup>1</sup>, Mary S. Hayney, Pharm.D., M.P.H.<sup>1</sup>, John M. Dopp, Pharm.D., M.S.<sup>1</sup>; (1)School of Pharmacy, University of Wisconsin, Madison, WI; (2)University of Wisconsin Hospital and Clinics, Madison, WI*

**PURPOSE:** Lung transplant recipients are at high risk of developing sleep disorders such as sleep apnea and restless legs syndrome. Anecdotal evidence indicates that insomnia is also common in lung transplant recipients, yet its prevalence and features are poorly characterized. We sought to evaluate the prevalence of insomnia and the relationship with immunosuppressant medications following lung transplantation.

**METHODS:** To date we have enrolled 34 subjects who did not have sleep problems prior to transplant and who had undergone lung transplantation at least 6 weeks prior to study entry. Insomnia was assessed using the Insomnia Severity Index (ISI), and using separate questions about frequency of difficulty initiating and maintaining sleep, awakenings, and subjective sleep latency. Exposure to tacrolimus for each subject was assessed by plotting days since transplant on the x-axis and every tacrolimus serum concentration after transplant on the y-axis and calculating area-under-the-curve (AUC).

**RESULTS:** To date, 22 out of 34 subjects report subclinical insomnia or clinical insomnia using the ISI (65%). Mean ± SEM tacrolimus AUC was higher in patients reporting subthreshold or clinical insomnia (11422 ± 2095 ng days/ml) compared to those not reporting insomnia (7586 ± 2601 ng days/ml). Tacrolimus AUC increased in a stepwise-manner with reported frequency of difficulty initiating sleep. AUC was 7637 ± 1840 ng days/ml (never or rarely had difficulty initiating sleep), 8904 ± 3599 ng days/ml (sometimes had difficulty initiating sleep), and 14544 ± 3119 ng days/ml (often or almost always had difficulty initiating sleep). Subject enrollment is ongoing and statistical analyses will be performed on the subsequent larger sample size.

**CONCLUSIONS:** In our cohort, insomnia is common after lung transplantation, with prevalence greater than in the general population. Insomnia complaint is associated with greater exposure to tacrolimus. Future research should investigate the relationship between immunosuppressant therapy and development of sleep disorders.

**438. Evaluation of acute graft rejection rates 1-year post renal transplantation: results of a formulary change to a steroid-sparing thymoglobulin regimen in an academic medical center.** *Andrea N. Sikora, Pharm.D., Candidate<sup>1</sup>, Robert C. Newsome, Pharm.D., Candidate<sup>1</sup>, Todd Merchen, M.D.<sup>2</sup>, Donna Vasil, Pharm.D.<sup>2</sup>,*

Dianne May, Pharm.D., BCPS<sup>1</sup>; (1) University of Georgia College of Pharmacy, Athens, GA; (2) Georgia Health Sciences University, Augusta, GA

**PURPOSE:** This study evaluated the incidence of acute graft rejection at 1-year post-transplantation in first-time renal transplant recipients with panel reactive antibody (PRA) level < 20% who received an induction regimen of interleukin-2 (IL-2) antagonist (basiliximab or daclizumab) plus corticosteroids versus a steroid-sparing thymoglobulin induction regimen. The incidence of complications in those on steroid-sparing thymoglobulin regimen was also compared with those on an interleukin-2 antagonist plus steroid regimen.

**METHODS:** A retrospective chart review was conducted on all Georgia Health Sciences Health System patients who met criteria from May 2009–May 2011. These data were compared to a previous evaluation from May 2005–May 2007, when IL-2 antagonists plus steroids was the preferred formulary induction regimen for low-risk renal transplant patients. In addition to 1-year post transplant rejection rates, evaluated events included the incidence of new onset diabetes, cardiovascular adverse events, infection rates and type, percentage of patients remaining steroid-free, steroid-resistance acute graft rejection, malignancy, lymphoproliferative disorder, and delayed graft function. This study was reviewed and approved by the HAC at Georgia Health Sciences Health System.

**RESULTS:** A total of 150 renal transplant patients were evaluated. Data analysis of 1-year post-transplant rejection rates in the steroid-sparing thymoglobulin group and in the IL-2 plus steroid group is currently underway. Data analysis should be completed by late August.

**CONCLUSIONS:** Conclusions are pending.

**439. Evaluation of the use and policies for medical marijuana in heart and lung transplant recipients: a survey of United States transplant medical directors.** Kimberly D. Shipp, B.S., Pharm.D., Candidate<sup>1</sup>, Robert Lee Page, II, Pharm.D., MSPH, FCCP, FAHA, BCPS<sup>2</sup>, Karin Keller, F.N.P., R.N.<sup>3</sup>, JoAnn Lindenfeld, M.D.<sup>4</sup>; (1) Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Aurora, CO; (2) Denver School of Pharmacy, University of Colorado, Aurora, CO; (3) University of Colorado, Aurora, CO; (4) Health Sciences Center, University of Colorado, Aurora, CO

**PURPOSE:** Medical marijuana is currently legal in 17 states across the US with multiple indications such as nausea and vomiting, chronic pain, and cachexia. In heart and lung transplantation, standard policies do not exist regarding medical marijuana use. Transplant centers continue to struggle with this controversial issue. We surveyed 317 US Medical Heart and Lung Transplant Medical Directors regarding their center's policies surrounding both medically-prescribed and recreational marijuana use in this population.

**METHODS:** In this descriptive study, we obtained names of Medical Directors for US Heart and Lung Transplant Centers through the United Network of Organ Sharing (UNOS). Using the websites of professional medical organizations and Google, we obtained each Director's email address. A survey regarding medically-prescribed and recreational marijuana policies was developed, approved by the Colorado Multiple Institutional Review Board, and emailed through SurveyMokney. Descriptive statistics were used to determine overall percentages of responses.

**RESULTS:** A total of 81 Medical Directors responded (25% response rate) with a distribution of 68% and 32% managing heart and lung transplant, respectively. Medical marijuana was legal statewide in 32.1% of respondents. Medical marijuana was considered an absolute contraindication to transplantation in 31.2% centers while recreational marijuana was in 63%. A total of 10 centers allowed the use of medical marijuana within the inpatient setting; 18 centers allowed oral ingestion and three either oral ingestion or inhaled/smoked. Major indications for medical marijuana consisted of severe nausea, cancer, or severe pain. For those who prescribed medical marijuana, 92.6% (n=26) managed between zero and five patients annually. Over 60% of

respondents did not know if marijuana interacted with immunosuppressant medications.

**CONCLUSION:** Policies regarding the use of medically-prescribed and recreational marijuana vary among US transplant centers. These data suggest that UNOS should provide standardized policy suggestions so as to afford consistent patient care across stateliness.

## LATE BREAKERS

### Adult Medicine

**440. A hospital's effort to lower the readmission of patients with heart failure (help-hf): a pilot study.** Pamela M. Moye, Pharm.D., BCPS<sup>1</sup>, Paul Douglass, M.D.<sup>2</sup>, Phillip S. Owen, Pharm.D., BCPS<sup>1</sup>, Teresa Pounds, Pharm.D., BCNSP<sup>2</sup>; (1) Mercer University College of Pharmacy and Health Sciences, Atlanta, GA; (2) Atlanta Medical Center, Atlanta, GA

**PURPOSE:** This study was designed to evaluate if a pharmacist-lead education intervention program would aid in the decrease of hospital re-admissions in heart failure patients at an urban community teaching hospital.

**METHODS:** Patients were randomized into an intervention and control group. Those included in study were admitted to Atlanta Medical Center from August 1, 2011 to January 30, 2012 with a primary or secondary diagnosis of heart-failure as identified by the daily Evidenced Based Medicine report. The control group received standard of care. The intervention included one-on-one medication/disease management discharge counseling from a pharmacist, patients were given individualized information regarding their disease state, patients were called on days 14 and 28 post discharge.

**RESULTS:** Sixty patients (control n=38, intervention n=22) were included in the study. The 30 day readmission rates for the control group and intervention group was 21% and 9.5%, respectively. The baseline characteristics were similar between the groups which included: ejection fraction, length of hospital stay, and co-morbidities.

**CONCLUSION:** The patients in the intervention group 30 day readmission rates were approximately 50% less than the patients in the control group. This suggests that a pharmacist supported intervention program may aid in decreasing 30 day readmissions in patients with heart failure.

### Ambulatory Care

**441. Prescribing patterns for the outpatient treatment of constipation, irritable bowel syndrome-related constipation and opioid-induced constipation.** Katy E. Trinkley, Pharm.D.<sup>1</sup>, Bruce Sill, Pharm.D., M.S.<sup>2</sup>, Kyle Porter, M.A.S.<sup>3</sup>, Milap C. Nahata, Pharm.D., M.S.<sup>4</sup>; (1) Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado, Aurora, CO; (2) Takeda Pharmaceuticals International, Inc., Glastonbury, CT; (3) Center for Biostatistics, Ohio State University, Columbus, OH; (4) College of Pharmacy, Ohio State University, Columbus, OH

**PURPOSE:** To identify both the treatment patterns for constipation and the associations between treatment and other variables across age groups.

**METHODS:** This was a retrospective cross-sectional study on the trends in pharmacologic and nonpharmacologic constipation treatments across age groups utilizing data from the National Ambulatory Medical Care Survey (NAMCS), 2000–2009. Treatment patterns for constipation alone, IBS-C alone, and opioid-induced constipation were considered. Information collected for each visit included demographics, physician specialty, nonpharmacologic (i.e., diet, behavior changes) and pharmacologic constipation therapies, concurrent medications, comorbidities, and procedures. Statistical sampling weights were used to obtain estimates representative of the US population. Separate analyses were performed for each combination of age group and type of

constipation. Differences between time periods were tested by weighted logistic regression models and used to test for associations with treatments.

**RESULTS:** From 2000 through 2009, there were 89.6 million visits for constipation and IBS-C: 63.4 million for constipation alone, 28.2 million for IBS-C alone, and 3.7 million for opioid-induced constipation. For all visits, there was a decrease in combination therapy for persons < 18 years (from 29% to 16%,  $p < 0.05$ ) and an increase in medication monotherapy for all (from 15% to 23%,  $p < 0.01$ ). For constipation, there was an overall decrease in combination therapy (from 17% to 11%,  $p < 0.05$ ), an increase in medication monotherapy (from 21% to 29%,  $p < 0.05$ ) and age group differences in prescribing of specific medications. For IBS-C, there was a significant increase in tegaserod over time (from 6% to 27%,  $p < 0.05$ ). For opioid-induced constipation, there were no significant changes over time. Age, gender, race, ethnicity, payer source, physician specialty and region were all found to be associated with treatment choice.

**CONCLUSION:** Patterns in constipation treatment were significantly influenced by many factors. Overall changes in treatment over time included a decrease in combination therapy for persons age < 18 years and an increase in medication monotherapy for all.

**442. A retrospective chart review of the standard of asthma care in a primary care teaching clinic.** *Lindsay A. Sorge, Pharm.D.,* Christian R. Pereira, Pharm.D.; College of Pharmacy, University of Minnesota, Minneapolis, MN

**PURPOSE:** There is a national need to evaluate the current standard of practice in asthma. This project works to measure uniformity of practice, identify gaps in follow up and measure hospitalization rate for asthma exacerbations within a primary care teaching clinic.

**METHODS:** The project was completed by chart review of patients ( $n=231$ ) who received primary care at Smiley's Clinic. Inclusion criteria were as follows: seen in the past 5 years, have a diagnosis of 'asthma', have presented to clinic in the past 2 years, and were between the ages 5 and 50. Patients with a diagnosis of reactive airway disease were excluded.

**RESULTS:** In the electronic medical record 54.2% ( $n=125$ ) of patients had a level of severity of asthma documented in the problem list (i.e., Moderate Persistent Asthma) whereas, 45.8% ( $n=106$ ) of patients had "Asthma" as the diagnosis in the problem list. The average number of clinic visits per patient 2010–2011 increased with increased severity of asthma and was highest for patients without a known severity of asthma control. Twenty-nine percent ( $n=67$ ) of patients are exposed to tobacco smoke by secondhand smoke or active use. Twenty-four percent ( $n=54$ ) of patients did not have a new prescription for an albuterol inhaler in 2010 or 2011.

**CONCLUSION:** There was lack of uniformity in the prescribing of albuterol inhalers, spirometry and disease documentation within this practice. The lack of detail in asthma diagnosis within the problem list was related to increased patient hospitalization and increased albuterol inhaler prescriptions, which may serve as a marker for the need for increased attention to asthma management.

## Cardiovascular

**443. Effects on warfarin dosage requirements after anticoagulation therapy with dabigatran.** *Beth H. Brubaker, Pharm.D.,* Kristy Lucas, Pharm.D., Mike Broce, B.A.; School of Pharmacy, University of Charleston, Charleston, WV

**PURPOSE:** This study measured the difference between the weekly warfarin dosage requirements for patients who were previously treated with warfarin, then treated with dabigatran before resuming warfarin therapy.

**METHODS:** An existing quality assurance database of patients who had their anticoagulation therapy monitored at an outpatient anticoagulation clinic located in a cardiology and electrophysiology office was reviewed. Patients selected had been

previously treated with warfarin, and then treated with dabigatran before resuming warfarin therapy. Previous and current weekly warfarin dose requirements and previous and current INR values were collected and compared using a 2-tailed paired t-test for 11 patients.

**RESULTS:** The average weekly warfarin dosage requirements post-dabigatran was higher in eight of the 11 patients: previous dose ( $32.15 \pm 9$  mg/week), current dose ( $36.96 \pm 15.8$  mg/week) with a difference of  $-4.81 \pm 11.97$  ( $p=0.212$ ). The average INR was lower in five of the eight patients who required a higher weekly warfarin dose: previous INR ( $2.35 \pm 0.19$ ), current INR ( $2.26 \pm 0.32$ ) with a difference of  $0.09 \pm 0.34$  ( $p=0.404$ ).

**CONCLUSION:** The increase in weekly warfarin dosage requirements had no statistical significance when each patient was compared to him/herself pre-dabigatran and post-dabigatran. Multiple factors can influence the dosage requirements of warfarin and should be evaluated in determining any changes in the warfarin dose. The formation of a consortium with other anticoagulation clinics would allow for further evaluation of the findings in this study.

## Community Pharmacy Practice

**444. Impact of medicare part d on community pharmacy: a multi-region, multi-state survey.** *Shamima Khan, M.B.A., Ph.D.,* Western New England University, Springfield, MA

**PURPOSE:** A multi-region, multi-state survey was conducted to understand community pharmacists' experiences with Medicare Part D.

**METHODS:** A cross-sectional survey of pharmacists practicing in six different states (New York, New Jersey, Massachusetts, Maine, Pennsylvania and Maryland) was conducted between June and December 2011 using SurveyMonkey.com. Questions were asked in multiple categories: demographics, impact of Part D on community pharmacy and patients, and beliefs about ideal pharmacy practice and Part D plans. Pharmacists received three email blasts. Participation was voluntary and anonymous.

**RESULTS:** The overall adjusted response rates were 67% ( $272/407$ ) and 12% ( $272/2175$ ) with 407 emails tracked and 2175 emails opened, respectively. Most respondents (71%) were practicing in independent pharmacies and 41% were either owner or part-owner. Seventy percent of the respondents were male (average age 51 years) and 84% had over 15 years of work experience. The survey responses were as follows: 56% of respondents indicated that reimbursement was the most significant concern in reference to Part D. Thirty seven percent reported declining or below average financial performance since the initiation of Part D and intended to sell their businesses within 5 years. However, 71% reported a lack of potential buyers. Although 43% reported that addressing formulary and copayment issues consumed most of their time, only a quarter (25%) thought it was their responsibility to address copayment/ cost issues. From the patient perspective, 53% of the pharmacists reported that the most significant concern was formulary and copayment. However, pharmacists thought that almost half (47%) of the patients were satisfied or very satisfied with Part D.

**CONCLUSION:** Pharmacists who responded to this survey reported poor reimbursement as the most significant concern associated with Part D. Although pharmacists were spending most of their time addressing formulary and co-payment issues, most felt it was not their responsibility to address these issues.

## Education/Training

**445. Evaluation of a lecture on hospice care for Pharm.D. students.** *Cara L. McDermott, Pharm.D., M.S.,* Dana P. Hammer, R.Ph., Ph.D.; University of Washington School of Pharmacy, Seattle, WA

**PURPOSE:** Student opinions and questions about hospice care were sought to maximize the learning potential of a new lecture in a required third year pharmacotherapy series.

**METHODS:** An anonymous internet-based survey was created and sent to all third-year Pharm.D. students enrolled in the therapeutics course series prior to a new lecture on hospice. Students were asked their opinion of hospice as well as what related questions they had about the topic. Answers to these questions were addressed in the lecture, with post-lecture opinions collected via a second anonymous non-linked internet-based survey.

**RESULTS:** Thirty-nine students (49%) completed the pre-lecture survey. Favorable and unfavorable perceptions of hospice prior to lecture were 67% and 2% respectively, whereas 31% were unsure of their opinion of hospice. The most common questions about hospice related to: eligibility for and structure of hospice services, hospice day-to-day operations, and insurance coverage and costs of hospice care. Fourteen students (18%) completed the post-survey lecture; of those, 86% had a favorable opinion of hospice and 14% were unsure of their opinion. Post-lecture responders noted the most helpful portions of lecture as: explanation of the hospice benefit coverage, medications used in hospice, the pharmacist's role in hospice, local resources/organizations, and hospice philosophy/history.

**CONCLUSION:** Among responding students, explanation of hospice benefits and the structure of hospice were the most valued portion of the hospice lecture. A higher percentage of respondents had favorable opinions of hospice following lecture. Seeking student opinions prior to lecture better enabled the instructor to focus the content to meet the students' learning needs.

**446E. Impact of a student pharmacist driven medication history service.** Lynette R. Moser, Pharm.D.<sup>1</sup>, Justine S. Gortney, Pharm.D.<sup>1</sup>, Josh Raub, Pharm.D.<sup>2</sup>, Kim Claeys, Pharm.D.<sup>1</sup>; (1) Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, MI; (2) Detroit Receiving Hospital, University Health Center, Detroit, MI

**PURPOSE:** This study describes the changes to the medical record and interventions performed as a result of student pharmacist participation in obtaining and documenting medication histories.

**METHODS:** This report describes student documentation of changes made to the Electronic Medical Record (EMR) and interventions accepted as a result of medication histories completed as part of an Advanced Pharmacy Practice Experience. Adult patients (> 18 years of age) admitted within 72 hours and being followed by a pharmacy student were included. Exclusion criteria were the inability to speak English and admission directly from a nursing home. Medication histories were obtained by a student pharmacist through patient interviews and pharmacy contacts. Changes to the home medication list in EMR were evaluated. Interventions were performed following discussion with the preceptor based at the institution. Institutional Review Board approval was obtained.

**RESULTS:** A total of 216 medication histories were completed. The changes made to the home medication list were: 530 medications deleted, 626 medications added, and 692 instructions added or corrected, an average of 8.6 changes/patient. The average time the student pharmacist spent interviewing the patient and contacting the patient's pharmacy to obtain a medication history was approximately 17 ± 6 minutes. There were 76 interventions made to inpatient regimens.

**CONCLUSIONS:** This structured activity provides opportunity to enhance the student's role in providing direct patient care resulting in benefit to patients and institutions. Student roles can be structured based on the culture of care, pharmacy department and documentation standards of each institution. Presented at American Association of Colleges of Pharmacy, July 16, 2012.

## Emergency Medicine

**447. Outcomes associated with emergency department pharmacists' participation in antimicrobial stewardship.** Stephanie Z. Kujawski, Pharm.D., Bethany S. Delk, Pharm.D., BCPS; Mission Hospitals, Asheville, NC

**PURPOSE:** To assess outcomes and documentation associated with incorporation of emergency department pharmacists (EPHs) in the antimicrobial culture follow up process.

**METHODS:** Eligible patients were at least 18 years old and assessed by an ED physician (ED MD) in March 2010 or March 2012 with at least one subsequent positive culture addressed by an ED MD, mid-level practitioner (MLP), or EPH after discharge. Data on baseline characteristics, empiric antimicrobials, cultures, definitive therapy, documentation, and readmissions were used in this retrospective descriptive analysis.

**RESULTS:** Of the 160 cultures were included in this IRB-approved study. Eighty cultures comprised the EPH and non-EPH cohorts. Baseline characteristics were similar between the groups, with a mean age of 45.4 years and 70% female. The most prevalent culture type was urine (EPH 55% versus non-EPH 63.8%), followed by skin and soft tissue (EPH 32.5% versus non-EPH 22.5%). Other sources included urogenital, blood, throat, body fluid, stool, and sputum. Thirty-four percent of EPH versus 16.3% of non-EPH cultured organisms were resistant to prescribed empiric antimicrobials. Of those resistant cultures, 81.5% EPH versus 53.8% non-EPH were modified based on susceptibilities, with 100% of modifications in both cohorts appropriate for sensitivities; however, 14.2% in each cohort were not ideal based on renal function or drug interactions. Readmission rates to the ED or hospital within 96 hours were similar (EPH 18.8% versus non-EPH 16.3%), with the most common reason being wound care. Full documentation of follow up therapy occurred more frequently in the EPH group (97.5% versus 31.3%), with 31.3% of the non-EPH cohort not having any documentation.

**CONCLUSION:** EPH involvement in assessment of culture results and subsequent patient follow up was at least as effective as ED MD or MLP assessment with regards to propriety of definitive therapy and readmission rates. EPH documentation of therapy modifications was more reliable.

## Oncology

**448. Cancer adverse events associated with dipeptidyl peptidase 4 inhibitors: data mining of public FDA adverse event reporting system.** Xiaodong Feng, Ph.D., Pharm.D., Amie Cai, B.S., Kevin Dong, Pharm.D., Student, Nilesh Bhutada, Ph.D., John Inciardi, Pharm.D., D.Sci.; College of Pharmacy, California Northstate University, Rancho Cordova, CA

**PURPOSE:** Dipeptidyl peptidase 4 (DPP 4) is an important enzyme cleaving a variety of physiologically and pathophysiologically important peptides in the circulation, such as certain chemokines, mitogenic growth factors and incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). This study evaluated the risk of cancer adverse events associated with anti-diabetic drugs targeting at DPP 4.

**METHODS:** Using the FDA Adverse Event Reporting System (AERS) public database, the adverse events reports (AERs) associated with DPP IV inhibitors, such as sitagliptin, saxagliptin and linagliptin, were generated and evaluated. The AERs involving combination drugs were eliminated. Standardized pharmacovigilance tools were applied to detect the signal of cancer risk. Based on the AERs from 2007 to 2011, the reported cancer adverse events associated with DPP 4 inhibitors were analyzed. The most prevalent cancer signals were also identified.

**RESULTS:** Among 12618 AERs associated with sitagliptin from 2007 to 2011, there were 223 cases of cancer adverse events. There is a significant correlation between the cancer proportional reporting ratio and the time course ( $R^2 = 63.4\%$ ,  $p < 0.001$ ). Pancreatic cancer, leukemia, lung cancer, breast cancer and bladder cancer were the top five most prevalent cancers reported. Pancreatic cancers accounted for 22% of all combined cancer adverse events. The trend of cancer adverse events associated with saxagliptin from 2009 to 2011 was similar to that of sitagliptin. Currently there are not enough AERs on linagliptin approved by the FDA in 2011.

**CONCLUSION:** This study signals an increasing trend of cancer risk associated with DPP 4 inhibitors, such as sitagliptina and saxagliptin. Pancreatic cancer is the most prevalent cancer associated with DPP 4 inhibitors. Considering the limitation of AERS, such as under reporting, reporting bias and Webb-effect, this study signals the potential cancer risk associated with popular anti-diabetic drugs and provides goal for future randomized control studies.

## Pediatrics

**449. Modeling and simulation to predict the pharmacokinetics of intravenous cefazolin in children – a strategy to reduce the number of pediatric subjects in pharmacokinetic studies.** *Felix Siegel, Ph.D.*<sup>1</sup>, Christopher M. Rubino, Pharm.D., BCPS<sup>2</sup>, Rebecca A. Stolarick, B.S.<sup>1</sup>, Patricia A. Smith, B.S.<sup>1</sup>, Martin Unverdorben, M.D., Ph.D.<sup>1</sup>; (1) B. Braun Medical Inc., Allentown, PA; (2) Institute for Clinical Pharmacodynamics, Latham, NY

**PURPOSE:** In contrast to pharmacokinetic (PK) studies in healthy adults, PK studies in the pediatric population typically involve patients. For ethical reasons, the number of pediatric patients studied should be limited. Modeling and simulation techniques are useful in the design of pediatric PK studies.

**METHODS:** To predict PK exposure in children undergoing antibiotic perioperative prophylaxis with cefazolin, an allometric-based population PK model for cefazolin was created using NONMEM based upon data from 24 adults in a Phase 1 study. For the simulations, two cohorts of 3000 children each (10–12 and 13–17 years) were generated; each child was randomly assigned a representative weight based on their age using CDC growth charts. Using the allometric-based population PK model, cefazolin concentration-time profiles were generated and PK exposures were estimated for each simulated child. Power analyses were conducted using simulation results, consistent with a recent FDA publication (Wang Y, et al. *J Clin Pharmacol*. Epub 2011 Dec 12).

**RESULTS:** A two-compartment model with volumes and clearances scaled allometrically best described plasma cefazolin PK data with < 15% interindividual variability in PK. Model-based simulations indicated that single dose regimens of 1 g for children and adolescents ≤ 50 kg and 2 g for those > 50 kg would provide cefazolin exposures within the range observed in adults receiving a single dose of 2 g. Thirty minute infusions may be warranted to obtain peak cefazolin concentrations observed in adults. A sample size of seven subjects should provide sufficient power to determine cefazolin PK parameters if a clinical study should be requested in children aged 10–12 years.

**CONCLUSION:** Modeling and simulation is integral to the design of pediatric PK studies and in this exercise was used to identify appropriate cefazolin doses for perioperative prophylaxis in children and to estimate the required sample size for a potential study in children aged 10–12 years.

## Pharmacoeconomics/Outcomes

**450. Increasing medication core measures compliance utilizing unit-based clinical pharmacists.** *Lindsay I. Varga, Pharm.D., BCPS*, Elizabeth Marino Sabo, Pharm.D., BCPS, Jacqueline M.von Vital, Suzanne Y. Brown, Pharm.D.; Pennsylvania Hospital, Philadelphia, PA

**PURPOSE:** Core Measures (CM) are outcomes derived from a set of quality indicators defined by the Centers for Medicare and Medicaid Services. Compliance increases optimal patient outcomes, failure to comply results in decreased quality of care and decreased reimbursement. There are 12 medication-related measures. Our purpose was to utilize unit-based clinical pharmacists (UBCPs) to assess and document medication-related CM in patients admitted for acute myocardial infarction (AMI), community-acquired pneumonia (CAP), congestive heart failure (CHF), and stroke. Our goal was to sustain 100% medication-related compliance in the AMI group and attain 100% compliance in all other disease states post implementation of the UBCPs.

**METHODS:** The UBCPs prospectively reviewed charts for patients admitted with diagnoses corresponding to the CM disease states from April 2011-May 2012. Patients were identified via e-mail notification generated by our institution's performance improvement analyst, during patient care rounds, and through the pharmacy clinical surveillance program (Sentri 7<sup>®</sup>). Prescribers who did not order an indicated medication were notified. If a medication was not administered due to a contraindication, this was documented by the UBCPs in the medical record.

**RESULTS:** The UBCPs reviewed 2267 patients. Two hundred six recommendations were made for medication compliance and 161 contraindications were documented. Monthly compliance rates were compared both pre and post implementation of the UBCP intervention. In the pre-intervention period (January 2010 – March 2011), 100% compliance was achieved only in the AMI group and in none of the remaining disease states. In the post-intervention period, compliance rates were sustained at 100% for AMI for 12/13 months and increased to 100% for 12/13 months for CHF; 7/13 months for CAP, and 2/5 months for stroke.

**CONCLUSION:** Utilizing UBCPs to assess patients and intervene on medication-related CM successfully attained 100% compliance in CHF, CAP, and stroke, and sustained 100% compliance in AMI patients.

**451. Economic evaluation of the impact of medication errors.** *Jennifer Samp, Pharm.D.*<sup>1</sup>, Daniel R. Touchette, Pharm.D., M.A.<sup>1</sup>, Jacqueline S. Marinac, Pharm.D.<sup>2</sup>, Grace M. Kuo, Pharm.D., M.P.H., Ph.D.<sup>3</sup>; (1) University of Illinois, Chicago, IL; (2) ACCP Research Institute, Lenexa, KS; (3) UCSD, La Jolla, CA

**PURPOSE:** Medication errors (MEs), defined as 'any preventable event that may cause or lead to inappropriate medication use or patient harm,' have recently been highlighted as a top national priority in a report issued by the Institute of Medicine. However, little information is available on ME costs. This study will estimate the cost of MEs reported by clinical pharmacists from an insurer's perspective.

**METHODS:** Information on over 700 MEs was collected in a previous study, the "Medication Error Detection, Amelioration and Prevention (MEDAP)." Clinical pharmacists in the American College of Clinical Pharmacy (ACCP) Practice-Based Research Network documented MEs observed during a 14-consecutive day period. The rate of MEs, outcomes (number of errors resulting in temporary/ permanent patient harm, prolonged hospitalization, or life-sustaining therapy), and interventions (communication, medication changes, patient monitoring, and treatment referrals) were collected. A decision model was developed to estimate the economic impact of MEs. Event probabilities were derived from MEDAP data, and costs through reviews of the literature, hospital charge data, and Medicare & Medicaid reimbursement. One-way and Monte Carlo sensitivity analyses (SA) were used to explore uncertainty.

**RESULTS:** In the base-case, the expected cost of managing a ME was \$88.57 and a mean cost of \$13.40 for each patient seen by a clinical pharmacist, regardless of ME occurrence. In the Monte Carlo simulation, the mean cost per patient seen (SD) was \$13.51 (\$4.58) and \$89.35 (\$30.17) per patient with a ME. One-way SA revealed that changes in the probability of MEs causing hospitalization and the cost of hospitalization had the greatest variability on the outcome (\$7.63 to \$23.56 [probability of hospitalization], \$4.93 to \$20.63 [cost of hospitalization]).

**CONCLUSIONS:** MEs are costly to the healthcare system. Better understanding of their actual costs can be used to justify initiatives to reduce the risk and inefficiency associated with these errors.

## Infectious Diseases

**452. Adequacy of empiric coverage for Gram-negative bacteremias in an adult population.** *Branden Nemecek, Pharm.D.*, Nicole Bohm, Pharm.D., Juanmanuel Gomez, M.D.; Medical University of South Carolina, Charleston, SC

**PURPOSE:** This study reviewed Gram-negative bacteremias for appropriateness of antibiotic therapy at three points in time: (i) prior to Gram-stain results, (ii) after Gram-stain results, and (iii) after susceptibilities are posted. The study also examined if a single antibiotic was more likely to cover any Gram-negative bacteremia or if the addition of a second agent increased the probability of appropriate coverage.

**METHODS:** This retrospective cohort examined patients 18 years of age or older with blood cultures positive for Gram-negative bacteremia from April 1st, 2011 to September 30th 2011. Charts were reviewed for demographics, co-morbidities, cultures, antibiotic utilization, and in-hospital mortality. Antibiotics were identified as appropriate if the organism was susceptible.

**RESULTS:** Antibiotic therapy was appropriate for 53.8% of cultures prior to Gram-stain results, 94.6% of cultures after Gram-stain results, and 99.2% of cultures after susceptibilities were determined. The monotherapy analysis showed susceptibilities of 88.1% for piperacillin/tazobactam, 94.7% for cefepime and 97.7% for meropenem. Comparing these agents produced a statistically significant benefit for meropenem over piperacillin/tazobactam ( $p=0.0014$ ) and the benefit of cefepime over piperacillin/tazobactam was nearing significance ( $p=0.062$ ). There was no significant difference comparing cefepime and meropenem. Addition of a gentamicin to piperacillin/tazobactam showed a statistically significant increase in appropriate empiric therapy. A significant increase in coverage was not seen with other combinations.

**CONCLUSION:** Utilization of piperacillin/tazobactam will be further reviewed to determine if a change in recommendations for empiric antibiotics should be recommended. Gentamicin may be considered as additional therapy if piperacillin/tazobactam is selected for empiric coverage. Additional studies are needed to analyze the adverse events associated with gentamicin versus the benefit of the double coverage.

**453. Impact of antibiotic selection on risk-adjusted mortality in ICU patients requiring gram-negative therapy.** John S. Esterly, Pharm.D.<sup>1</sup>, Jean A. Patel, Pharm.D.<sup>2</sup>, Milena McLaughlin, Pharm.D.<sup>3</sup>, Curtis H. Weiss, M.D., M.S.<sup>4</sup>, Richard G. Wunderink, M.D.<sup>4</sup>, Kristin March, Pharm.D.<sup>2</sup>, Craig Cooper, Pharm.D.<sup>4</sup>, Erik Rachwalski, Pharm.D.<sup>4</sup>, Michael J. Postelnick, B. Pharm.<sup>4</sup>; (1)College of Pharmacy, Chicago State University, Chicago, IL; (2)Northwestern Memorial Hospital, Chicago, IL; (3)Chicago College of Pharmacy, Midwestern University, Downers Grove, IL; (4)Feinberg School of Medicine, Northwestern University, Chicago, IL

**PURPOSE:** Recent analysis of 2010 antibiogram data from our institution suggests equal activity of cefepime (Cef) and meropenem (Mer) against gram-negative (GN) bloodstream and respiratory pathogens with Cef and Mer both being more active than piperacillin/tazobactam (P/T). APACHE IV predicted mortality (A-IV) is a well validated model for predicting patient outcomes in the ICU. We sought to evaluate risk-adjusted mortality of patients admitted to the medical ICU (MICU) who required GN therapy using Cef, Mer, or P/T.

**METHODS:** Adult MICU patients were included who had A-IV prospectively calculated and received Cef, Mer, or P/T on ICU admission from November 2011 to March 2012. A-IV was used to predict mortality and ICU length of stay (LOS). All-cause hospital mortality and actual ICU LOS minus predicted ICU LOS were assessed based on selection of Cef, Mer, or P/T for GN coverage with multivariate analysis and standardized mortality ratios (SMR).

**RESULTS:** This study included 182 patients ( $n=24$  Cef,  $n=33$  Mer,  $n=125$  P/T) for analysis. A-IV was similar between groups [mean% (SD) for Cef 39 (28), Mer 34 (24), P/T 31 (29),  $p>0.05$  for all]. The SMR for Mer was 1.6 compared with 0.75 and 0.77 for Cef and P/T, respectively. Logistic regression controlling for A-IV, antibiotic choice, suspected respiratory source of infection, and gram-positive therapy revealed that use of Mer was associated with greater odds of death (OR 4.2, 95% CI 1.8-9.8). Cef or P/T was not predictive of mortality in this model. Risk-adjusted

ICU LOS was longer than predicted with Mer by 4 days (95% CI 1.6-6.5) and similar to predicted for Cef and P/T.

**CONCLUSION:** MICU patients given Mer had greater odds of death and longer than predicted ICU LOS compared with Cef or P/T, even when risk-adjusting for acuity of illness. Further study of this interesting phenomenon is warranted.

## Oncology

**454E. Technetium-99m Sulfur Colloid (TSC) as a phenotypic probe for predicting pharmacokinetics (PK) and palmar-plantar erythrodysesthesia (PPE) toxicity of PEGylated liposomal doxorubicin (PLD) in patients with recurrent epithelial ovarian cancer (EOC).** Hugh Giovinazzo, B.Sc., Pharm.D., Candidate<sup>1</sup>, Parag Kumar, Pharm.D.<sup>1</sup>, Arif Sheikh, M.D.<sup>2</sup>, Marija Ivanovic, Ph.D.<sup>2</sup>, Mark D. Walsh, Pharm.D.<sup>3</sup>, Whitney P. Caron, Pharm.D.<sup>1</sup>, Gina Song, Pharm.D.<sup>1</sup>, Ann B. Whitlow, R.T., CNMT<sup>4</sup>, Suzanne E. Newman, B.Sc.<sup>4</sup>, Nihl La-Beck, Pharm.D.<sup>5</sup>, Richard J. Kowalsky, Pharm.D.<sup>4</sup>, Beth A. Zamboni, M.S.<sup>6</sup>, Daniel L. Clarke-Pearson, M.D.<sup>7</sup>, Wendy R. Brewster, M.D.<sup>7</sup>, Linda Van Le, Victoria Lin Bae-Jump, M.D.<sup>4</sup>, Paola A. Gehrig, M.D., Ph.D.<sup>7</sup>, William C. Zamboni, M.D.<sup>1</sup>; (1)Division of Pharmacotherapy and Experimental Therapeutics School of Pharmacy, University of North Carolina, Chapel Hill, NC; (2)School of Medicine, University of North Carolina, Chapel Hill, NC; (3)Mount Auburn Hospital, Cambridge, MA; (4)University of North Carolina, Chapel Hill, NC; (5)Texas Tech University, Abilene, TX; (6)Carlow University, Pittsburgh, PA; (7)Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC

**PURPOSE:** There is significant variability in the PK and pharmacodynamics (PD) (efficacy and toxicity) of PLD. Clearance of PLD occurs primarily via cells of the mononuclear phagocyte system (MPS). Our aim is to evaluate TSC, which can be used for imaging areas of the MPS, as a phenotypic probe of MPS activity to predict PLD PK, PPE toxicity, and progression free survival (PFS) in women with EOC.

**METHODS:** TSC was administered at 10 mCi IVP  $\times$  1 (D-1, -7). Dynamic planar and SPECT/CT images of patients' hands were acquired. Blood samples were collected up to 60 minute after TSC. PLD was administered at 30 or 40 mg/m<sup>2</sup> IV  $\times$  1 alone or in combination with carboplatin IV at AUC = 5 (D1). PK samples were obtained from 0 to 672 hour post PLD. Encapsulated and released doxorubicin was measured in plasma. TSC and PLD clearance were calculated by non-compartmental analysis. PPE toxicity and PFS were assessed using standard methods.

**RESULTS:** Corresponding imaging and PK data were acquired for eight patients. There was a positive linear relationship between TSC clearance and encapsulated doxorubicin clearance ( $R^2 = 0.61$ ,  $p=0.02$ ) and a stronger relationship ( $R^2 = 0.81$ ,  $p=0.03$ ) in patients receiving PLD monotherapy. A positive relationship (Spearman's  $\rho=0.84$ ,  $p=0.006$ ) was found between PPE toxicity developed and estimated AUC of encapsulated doxorubicin in hands [(TSC AUC<sub>Hand</sub>)/(TSC AUC<sub>Blood</sub>)\*Encapsulated doxorubicin AUC<sub>Plasma</sub>]. An inverse linear relationship between PFS and TSC clearance was seen for all patients who progressed ( $n=4$ ) ( $R^2 = 0.46$ ), and was stronger in patients who received PLD alone ( $n=3$ ) ( $R^2 = 0.97$ ).

**CONCLUSIONS:** Results suggest TSC is a probe for MPS function and PLD PK and PD and may be used to individualize PLD therapy in patients with EOC. Our findings also suggest TSC may be able to predict the development of PPE and PFS in women with EOC.

**455. Impact of an evidence-based pharmacotherapy elective on performance during the fourth-professional year** Nathan Pinner, Pharm.D., BCPS<sup>1</sup>, Jessica Starr, Pharm.D., BCPS<sup>2</sup>; (1)Auburn University Harrison School of Pharmacy, Tuscaloosa, AL; (2) Auburn University Harrison School of Pharmacy, Birmingham, AL

**PURPOSE:** To evaluate the impact of an evidence-based pharmacotherapy (EBP) elective on performance during the fourth-professional year.

**METHODS:** We included students enrolled in the EBP course in the fall of 2009 and 2010 and matched them with students with similar GPAs not enrolled in the EBP course. Performance during the fourth-professional year was assessed based upon overall Advanced Pharmacy Practice Experience (APPE) grades and performance on a professional seminar presentation (a pass/fail course), journal clubs, and patient presentations. All included assessments were from full-time faculty preceptors.

**RESULTS:** Twenty-eight EBP students and 58 GPA-matched students were included in the analysis. The mean APPE grades were 89.8% and 90.1% for the EBP and matched groups, respectively ( $p=0.65$ ). The first attempt pass rate for the professional seminar was higher in the EBP students (96%) compared to the GPA-matched students (86%), but did not reach statistical significance ( $p=0.26$ ). The proportion of students achieving “highest distinction” on the seminar was also higher in the EBP compared to GPA-matched students (36% vs. 19%), but also failed to reach statistical significance ( $p=0.11$ ). Grades on journal clubs (90.7% vs. 90.2%) and patient presentations (89.8% vs. 89.5%) were similar between the EBP students and GPA-matched students, respectively.

**CONCLUSIONS:** Students participating in the EBP elective performed similarly to GPA-matched peers on APPE rotations with full-time faculty members, but were more likely to pass their professional seminar on the first attempt, and more likely to achieve a rating of “highest distinction”. The EBP course requires students to critically evaluate and present primary literature throughout the semester. This translated into better performance on the high-stakes professional seminar course.

#### Pharmacokinetics/Pharmacodynamics/ Drug Metabolism/Drug Delivery

**456. Comparison of serum cystatin c versus serum creatinine in predicting vancomycin trough levels in patients with reduced muscle mass** Douglas D. DeCarolis, Pharm.D.<sup>1</sup>, Joey Thorson, Pharm.D.<sup>2</sup>, Rebecca Marraffa, Pharm.D.<sup>3</sup>, Megan A. Clairmont, Pharm.D.<sup>4</sup>; (1)Minneapolis VA Medical Center, Minneapolis, MN; (2)

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**PURPOSE:** Initial vancomycin dose is often calculated from population-based pharmacokinetic parameters. The serum creatinine (S.Cr) is often utilized to estimate creatinine clearance (eCrCl) to calculate elimination. It is recognized that creatinine may be inaccurate in patients with reduced muscle mass. Cystatin C has recently been identified as a correlate to renal function with less reliance on muscle mass. Equations using cystatin C are available to estimate eGFR in lieu of S.Cr.

**METHODS:** Since November, 2008 the Minneapolis VA Medical Center Pharmacy pharmacokinetic service has obtained cystatin C levels to calculate dosing regimens for patients with significantly reduced muscle mass. S.Cr. is also collected. Vancomycin trough levels are obtained at steady-state conditions to confirm achievement of target concentrations. We retrospectively compared the accuracy of S.Cr. versus cystatin C in population-based pharmacokinetic equations to predict vancomycin trough concentrations. Each prediction was then compared versus the true vancomycin trough concentration for bias and precision. The study population consisted of patients with spinal cord injuries and/or a BMI <18.5.

**RESULTS:** Thirty-two patients met inclusion criteria. The mean error of predicting the true trough using cystatin C was  $-3.4 \mu\text{g/ml}$  (95% CI =  $-5.1$  to  $-1.7$ ) versus  $-8.0 \mu\text{g/ml}$  (95% CI =  $-10.6$  to  $-5.3$ ) using S.Cr. ( $p=0.001$ ). Both methods under predicted the true trough. Precision, measured by mean absolute error was  $4.6 \mu\text{g/ml}$  (95% CI =  $3.4$ - $5.9$ ) using cystatin C compared to  $8.9 \mu\text{g/ml}$  (95% CI =  $6.5$ - $11.3$ ) using S.Cr. ( $p=0.002$ ). The ability to predict within 50% of the true trough (P50) was 91% using Cystatin C versus 56% using S.Cr. ( $p=0.007$ ).

**CONCLUSION:** In this patient population, use of cystatin C to predict vancomycin elimination was superior to use of serum creatinine.

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